



GlaxoSmithKline

Do more, feel better, live longer

September 2010 Interim Update

Updates to information in our 2009 Corporate Responsibility report published in March 2010 have been inserted into the relevant sections of the report and are highlighted in blue boxes in a similar style to this text.

Our responsibility

2009 Report

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Corporate Responsibility Report 2009

17 September 2010

This is our Corporate Responsibility Report 2009. You have selected the full report. See the following page which outlines updates made to the report in September 2010.

Contents

0. Overview
1. Corporate responsibility at GSK
2. Contribution to global health
3. Access to medicines
4. Research practices
5. Ethical conduct
6. Supply chain
7. Environmental sustainability
8. Our people
9. Human rights
10. Public policy and patient advocacy
11. Our work with communities

Find out more about corporate responsibility at GlaxoSmithKline online: www.gsk.com/responsibility/

Corporate Responsibility Report 2009

September 2010 Interim Update

Updates to information in our 2009 Corporate Responsibility report which was published in March 2010 have been inserted into the relevant sections of the report and are outlined below:

Access to medicines

- [Formation of a unit](#) dedicated to expanding access to medicines for people living in Least Developed Countries (Page 56)
- GSK's ranking at the top of the [Access to Medicine Index](#) for the second successive time (Page 56)
- The [independent administration](#) of the Pool for Open Innovation against Neglected Tropical Diseases by Bio Ventures for Global Health (Page 77)
- GSK becoming one of the first manufacturers to sign an [Advance Market Commitment](#) agreement with GAVI (Page 82)
- The launch of a [US programme](#) to provide our adult vaccines free of charge to eligible, low income individuals (Page 92)
- Progress from ViiV Healthcare, including the award of the first grants from the [Positive Action for Children Fund](#), two new [partnerships](#) designed to improve the management of paediatric HIV worldwide, progress on [research into new HIV treatments](#), and the extension of its policy on [voluntary licences](#) (Pages 56, 62, 66, 70)

Other updates include

- [Our response](#) to H1N1 flu pandemic (Page 32)
- Launch of a new [Third Party Code of Conduct](#) for suppliers (Page 180)
- [US healthcare reform](#) and the US Patient Protection and Affordable Care Act (PPACA) (Page 311)
- Implementation of updated labelling for our [LABA-containing](#) products in accordance with the FDA's directions for all LABA-containing products, and the decision awaited from the FDA about future use of [Avandia](#) (Pages 140,142)

Corporate Responsibility Report 2009

Contents

You have downloaded the full Corporate Responsibility Report 2009.

Overview 3

Corporate responsibility at GSK 6

Message from the CEO	7
Our Corporate Responsibility Principles	9
Business case for corporate responsibility	11
Our key issues	12
Corporate responsibility governance	13
Audit and assurance	15
Risk management	17
Stakeholder engagement	19
Benchmarking	25
About our reporting	27
Corporate responsibility data summary	28

Contribution to global health 30

Responding to pandemic flu	32
Disease prevention	35
Disease awareness	41
Treating ill health	43
Research and development	45
Q&As	51

Access to medicines 53

Our approach	55
– Improving access in developing countries	58
– Our approach to intellectual property	60
A new approach to HIV	61
– More about ViiV Healthcare	63
– HIV/AIDS research	65
– Pricing of HIV/AIDS medicines	67
– Voluntary licensing	69
R&D for the developing world	70
– R&D for neglected tropical diseases	72
– Products and formulations for the developing world	74
– Proprietary knowledge pool	75
– Medicines for the developing world	77
– Vaccines for the developing world	79

Access to medicines cont...

Flexible pricing	81
– Least Developed Countries	83
– Middle-income countries	86
– Developed Countries	89
Partnerships and acquisitions	93
– Technology transfers and joint ventures	94
– Portfolio expansion	97
Advocacy and government relations	100
Case studies	102
Q&As	104

Research practices 109

Emerging technologies	110
– Cloning technology and stem cell research	111
– Genetic research	112
Animal research	113
Human tissue research	119
Maintaining confidentiality of research participants	120
Medical governance	121
Clinical research	123
– Planning and approval	124
– Informed consent	125
– Training and auditing	126
– Post-trial treatment	128
– Clinical trials in the developing world	129
– Clinical trials in children	130
Public disclosure of clinical research	131
Patient needs and R&D	135
Patient safety	136
– Patient safety governance framework	137
– Collecting and reporting safety data	138
– Performance	144
Working with healthcare professionals	146
Case studies	147
Q&As	148

Ethical conduct 149

Code of Conduct and business ethics	151
Interactions with healthcare professionals and marketing ethics	154
– Interactions with healthcare professionals	156
– Direct-to-consumer advertising	161
Training and awareness	164
– Leading by example	166
– Performance	167
Monitoring and compliance	168
Case studies	172
Assurance statement and response	175
Q&As	179

Supply chain 180

Responsibility and our supply chain	181
– Human rights clause	183
– Choosing suppliers	184
– Monitoring and engagement	185
– Supply chain performance	186
– Training and capacity building	188
– Supplier diversity	190
– Fair treatment of suppliers	192
Maintaining quality	193
Security of supply	195
Counterfeiting	196
Case studies	199
Q&As	200

Environmental sustainability 201

Sustainability at GSK	202
Managing environmental sustainability	204
– Plans and targets	206
– Integration with business principles	210
– Awareness and recognition	211
– Audits and compliance	213
Climate change and energy	215
– Propellants	217
– Facilities and processes	218
– Transport and travel	219
– Performance and plans	221

Environmental sustainability cont...

Materials	224
– Mass efficiency	226
– Input materials	228
– REACH	230
– Pharmaceuticals in the environment	231
– Packaging	233
Environmental performance	234
– Water	235
– Waste water	238
– Waste	240
– Emissions to air	244
– Land	247
– Supplier performance	248
Transparency	249
– Summary data	250
– Stakeholder engagement	252
– Assurance	253
– GSK response to assurance	255
Case studies	256
Q&As	260

Our people 261

Our values and behaviours	263
Inclusion and diversity	265
Developing our people	270
Leading people	272
Restructuring	273
Communication and consultation	274
Reward and recognition	278
Health and safety	279
– Health and safety management	280
– Hazard assessment and communication	282
– Safety programmes	284
– Health and wellbeing programmes	287
– Health and business continuity	289
– Training and awareness	290
– Performance	291
Case studies	297
Q&As	298

Human rights 300

Employees	302
Suppliers	303
Communities	304
Society	305
Activities in embargoed countries	306

Public policy and patient advocacy 307

Our approach to external affairs	308
Public policy activity in 2009	310
– Advocacy on healthcare reform	311
– Advocacy on healthcare and disease prevention	315
– Advocacy on research practices	319
– Advocacy on patient safety	322
– Advocacy on intellectual property	324
– Advocacy on pricing and competitiveness	326
Political contributions and lobbying expenditures	327
Patient advocacy	328
– Transparency	330
– Understanding patients	331
– Advocacy in 2009	333
Q&As	335

Our work with communities 336

Community investment	337
Employee involvement	339
Preventing disease	341
– Eliminating lymphatic filariasis	342
– Personal Hygiene And Sanitation Education (PHASE)	343
– Local programmes	345
– Responding to disasters around the world	347
Building community capacity	349
– Supporting healthcare in Least Developed Countries	350
– Combating HIV/AIDS – Positive Action	352
– Combating malaria – Africa Malaria Partnership	353
– Local programmes	354
Supporting science education	356

· Home · Responsibility · [Overview](#)

Corporate Responsibility Report 2009

Overview

Read about our approach below and follow links to find out more in our 2009 CR Report online. Download a pdf version of this overview [here](#).

Corporate responsibility at GSK

Being a responsible business means operating in a way that reflects our values, treating our stakeholders with respect and connecting our business decisions to society's healthcare needs.

Our business makes a valuable contribution to society. However, we know that the research and development, manufacture and sale of our medicines, vaccines and consumer products raise ethical issues, and we aim to be open and transparent about how we tackle them. We seek to minimise the negative impacts and maximise the benefits of our business, and our approach is guided by our Corporate Responsibility Principles.

Read more about our approach in [CR at GSK](#).

Contribution to global health

Our medicines, vaccines and consumer healthcare products can make a real difference to patients' lives.

We research new treatments that address the needs of patients and healthcare payers and make our products as widely available as possible. This is at the heart of what responsibility means for GSK and is central to our commercial success.

We make a contribution by:

- Investing in the research and development of new medicines and vaccines
- Treating ill health from diseases such as diabetes and cancer
- Preventing disease through our vaccines and our consumer healthcare products

Read more in [Contribution to global health](#)

Access to medicines

Tackling the healthcare crisis requires global partnership and GSK is committed to playing its full part. Increasing access to medicines is not just morally the right thing to do, it contributes to our success by building trust in our business and increasing revenues.

We invest in R&D for medicines and vaccines to meet patient needs around the world and make them more available and affordable through preferential pricing arrangements and voluntary licences. We are forming innovative partnerships to support research into neglected tropical diseases and to support strengthening healthcare infrastructure in the world's least developed countries.

Read more in [Access to medicines](#)

Research practices

Maintaining high ethical standards in R&D is key to ensuring the quality of our research, and maximising the

benefits and minimising the risks of our medicines and vaccines.

Patient safety is our priority and we monitor and swiftly report potential safety issues to regulators.

Our R&D policies are global and we apply the same high standards wherever we operate and in all areas, from animal research to the use of emerging technologies.

We have rigorous procedures and assurance processes to ensure clinical trials are conducted according to internationally recognised standards and that the welfare of participants is protected. We disclose the results of our clinical trials to advance medical science and inform prescribers and patients.

Read more in [Research practices](#)

Ethical conduct

We are committed to creating a strong ethical culture at GSK. We do this by developing strong policies, recruiting the right people and equipping them with tools to make ethical decisions.

All GSK employees and contractors must comply with our Code of Conduct, which sets out fundamental ethical standards, and follow the guidance and policies in our Employee Guide to Business Conduct. Our regional marketing codes ensure we demonstrate high ethical conduct when marketing our products to doctors, hospitals and governments.

We run regular training courses to emphasise key ethics and integrity messages.

Read more in [Ethical conduct](#)

Supply chain

Patients depend on an uninterrupted flow of high quality medicines. This makes maintaining high standards in our supply chain vital to meeting patients' needs.

We only work with suppliers that score above a minimum health, safety and environment standard and we monitor their performance. Our supplier contracts include human rights clauses.

We work to ensure the quality of the materials we buy and to stop counterfeiting of GSK products.

Read more in [Supply chain](#)

Environmental sustainability

We are increasing our efforts on environmental sustainability. We need to optimise efficiency and increase our use of renewable materials and energy. We have prioritised reducing our impact on climate change and lowering our water use.

We have set challenging targets to reduce the energy and climate change impact of our operations and transport by 20 per cent by 2010 and 45 per cent by 2015.

Increasing the efficiency with which we use materials is also a priority. By 2020, we aim to achieve a level five times our performance in 2005.

Read more in [Environmental sustainability](#)

Our people

We employ over 90,000 people in 114 countries across the world. Our goal is for GSK to be an employer of choice because of how we value and empower our people.

We place great emphasis not only on what we achieve but also on how we achieve it. All employees must demonstrate the company's values and behaviours in their daily work.

We are committed to creating an inclusive and diverse working environment and offer employees a variety of training and development opportunities. We communicate regularly with our workforce and consult with

employees and their representatives before taking any action that affects them.

Read more in [Our people](#)

Human rights

We work hard to protect human rights within our sphere of influence, which includes employees, suppliers, communities and society.

We are committed to upholding the UN Universal Declaration of Human Rights, the OECD Guidelines for Multi-National Enterprises and the core labour standards set out by the International Labour Organization. We are a signatory to the UN Global Compact, a voluntary global standard on human rights, labour, the environment and anti-corruption.

Read more in [Human rights](#)

Public policy and patient advocacy

Through our public policy activity we support legislation and policy that encourage scientific innovation and balance the interests of business with those of other stakeholders. We also work with patient groups and professional groups to help give their members a voice in the healthcare debate.

We aim to increase stakeholder trust in GSK by being transparent about our lobbying and public policy work. We publish our annual public policy activity on this website and report on our memberships of trade associations and US Federal and EU institutions lobbying expenditures. We also publish information on our work with patient groups, including details of the funding we provide. GSK does not make political contributions.

Read more in [Public policy and patient advocacy](#)

Our work with communities

We donate money, time, medicines and equipment to support communities around the world.

Our programmes are long term and focus on preventing disease, building the healthcare capacity of communities and promoting education. We encourage employees to actively support causes they care about and we run volunteering programmes to make it easier for them to get involved.

Read more in [Our work with communities](#)

› [Back to top](#)

› Home › Responsibility › [Corporate responsibility at GSK](#)

Corporate Responsibility Report 2009

Corporate responsibility at GSK

We believe that strong values are central to business success. We place great importance on what we achieve but also on how we achieve it.

Being a responsible business means operating in a way that reflects our values, treating our stakeholders with respect and connecting our business decisions to society's healthcare needs. We seek to minimise the negative impacts and maximise the benefits of our business. Our approach is guided by our [Corporate Responsibility Principles](#).

Read more about what responsible business means for GSK in the [message from our CEO](#), Andrew Witty, and in our [business case for corporate responsibility](#).

GSK makes a valuable contribution to society through the medicines, vaccines and consumer healthcare products we produce which improve people's lives. However, we know that the [research and development](#), [manufacture](#) and [sale of medicines and vaccines](#) raise ethical issues, and we aim to be open and transparent about how we tackle them. We seek to understand and respond to the views of our [stakeholders](#) on these subjects.

We have established [management processes](#) to help advance progress on our CR Principles, and ensure we identify and manage [responsibility and reputational risks](#) to our business.

Our mission and values



Do
more,
feel
better,
live longer

The Spirit of GSK is a framework that enables us to achieve our mission to 'Improve the quality of human life by enabling people to do more, feel better and live longer'. It includes our company values:

- Respect for people
- Patient focused
- Transparency
- Integrity

See [Our people](#) for more information.

› [Back to top](#)

Corporate Responsibility Report 2009

Message from the CEO

GSK is changing

Welcome to GSK's 2009 Corporate Responsibility Report which provides information on our activities during 2009.

Our ambition for GSK is to create a values-based business that our employees, investors and wider society can be proud of and can rely on. We want to run our business to the highest ethical standards, adapting and changing so we are more responsive to the needs of society.

Since I became CEO of GSK, we have been focusing on changing our business to improve our financial performance through diversifying our sales growth and improving returns from the investment we make in R&D. And we know that part of being a successful and sustainable business is fulfilling our social responsibilities, making our company more responsive, more flexible and more open to society's expectations.

We are making progress on many areas such as improving access to our medicines, enhancing research opportunities for neglected tropical diseases, raising the ethical standards for conducting our research and business activities, and being more open and transparent in the way we run our business. Making the changes needed to reach our ambitious energy and climate change targets is proving to be a challenge and we are stepping up our efforts to achieve these.

Access to medicines and encouraging R&D into neglected tropical diseases

We believe access to medicines is the defining issue for our industry and during 2009 we took some significant steps forward. We reduced the price of our patented medicines in the world's poorest countries to no more than 25 per cent of the UK price. The resulting increase in sales volumes suggests that more patients are now accessing these medicines. We are also reinvesting 20 per cent of the profits from selling medicines in these markets in projects that will strengthen healthcare infrastructure in Least Developed Countries.

In middle income countries we are developing a more flexible approach to pricing that better reflects the ability to pay. Pilot studies in 2009 showed promising improvements in access to our products, and our more flexible approach to pricing is being extended during 2010.

We also have a unique opportunity with our candidate malaria vaccine which is being developed in collaboration with the PATH Malaria Vaccine Initiative, the Bill & Melinda Gates Foundation and African research organisations. The vaccine is still in development, however we are already thinking about access. We want to set a price which is sustainable but which is also as low as possible. So in January 2010 I announced that we will set a price that covers our costs and makes a small return which we will reinvest in R&D for the next generation of malaria vaccines, or for other vaccines for diseases of the developing world.

Tackling the acute need for more medicines to treat neglected tropical diseases needs innovative approaches and partnerships. We have set out our open innovation agenda where we will launch more new collaborations to share our intellectual property and know-how, and create broad-based partnerships to give researchers access to our expertise, processes, facilities and infrastructure. For example, we are publishing information on more than 13,500 compounds which have shown activity against the malaria parasite. We will not seek any rights over these compounds if researchers discover a new treatment for malaria.

Another important aspect to open innovation is the open lab we are creating at our Tres Cantos R&D Campus dedicated to research for combating diseases of the developing world. At the open lab researchers from across the world, especially from developing countries, will be able to work with GSK on their projects,

accessing our expertise, know-how, processes and industrial scale. To help fund these external partnerships GSK has set up a not-for-profit foundation with an initial investment of £5 million.

Transparency

Our social responsibilities go beyond enhancing our R&D efforts and improving access to our medicines and vaccines. I believe that being open and transparent about how we do business will help us to build trust with our stakeholders.

We continue to publish the results of all our clinical studies on our Clinical Study Register and now include the names of the principal clinical investigators and the institutions where they work. We will also seek publication of the results of all clinical studies as full scientific papers in peer reviewed journals. We believe we are the only company to make this commitment. If, as is sometimes the case, a journal does not want to publish the paper, we will include additional information to help interpretation of the study results on our Clinical Study Register.

We are also publishing more information on our payments to healthcare professionals. In 2009 we started publishing the speaking and consulting fees paid to US healthcare professionals and plans are in place to extend this to other countries. We have also set new standards for funding medical education in the US to ensure that we support programmes that bring the greatest improvements to patient health.

Our commitment

At GSK, we have a real opportunity to make a difference to patients and to society. We know there is always more we can do and we are committed to making changes to our business to achieve this. I believe we have made good progress in 2009 and I am excited by the opportunities to evolve GSK's business. I look forward to updating you on our future progress.

Andrew Witty
Chief Executive Officer

› [Back to top](#)

Our Corporate Responsibility Principles

Our Corporate Responsibility Principles identify our key responsibility issues and provide guidance for employees on the standards to which GSK is committed:

Employment practices We will treat our employees with respect and dignity, encourage diversity and ensure fair treatment through all phases of employment. We will provide a safe and healthy working environment, support employees to perform to their full potential and take responsibility for the performance and reputation of the business. Read more about our [employment practices](#).

Human rights We are committed to upholding the UN Universal Declaration of Human Rights, the OECD guidelines for Multi-National Enterprises and the core labour standards set out by the International Labour Organization. We expect the same standards of our suppliers, contractors and business partners working on GSK's behalf. Read more about our approach to [human rights](#).

Access to medicines We will continue to research and develop medicines to treat diseases of the developing world. We will find sustainable ways to improve access to medicines for disadvantaged people, and will seek partnerships to support this activity. Read about our approach in [Access to medicines](#).

Leadership and advocacy We will establish our own challenging standards in corporate responsibility, appropriate to the complexities and specific needs of our business, building on external guidelines and experience. We will share best practice and seek to influence others, while remaining competitive in order to sustain our business. Read about our approach to [public policy and patient advocacy](#).

Community investment We will make a positive contribution to the communities in which we operate, and will invest in health and education programmes and partnerships that aim to bring sustainable improvements to under-served people in the developed and developing world. Read about [our work with communities](#).

Engagement with stakeholders We want to understand the concerns of those with an interest in corporate responsibility issues. We will engage with a range of stakeholders and will communicate openly about how we are addressing CR issues, in ways that aim to meet the needs of different groups while allowing us to pursue legitimate business goals. Read about our [stakeholder engagement](#).

Standards of ethical conduct We expect employees to meet high ethical standards in all aspects of our business, by conducting our activities with honesty and integrity, adhering to our CR principles, and complying with applicable laws and regulations. Read about [ethical conduct](#).

Research and innovation In undertaking our research and in innovating:

- We may explore and apply new technologies and will constructively engage stakeholders on any concerns that may arise.
- We will ensure that our products are subject to rigorous scientific evaluation and testing for safety, effectiveness and quality
- We will comply with or exceed all regulations and legal standards applicable to the research and development of our products

Read more about our [research practices](#).

Products and customers We will promote our products in line with high ethical, medical and scientific standards and will comply with all applicable laws and regulations. Read more about our [marketing ethics](#).

Caring for the environment We will operate in an environmentally responsible manner through systematic

management of our environmental impacts, measurement of our performance and setting challenging performance targets. We will improve the efficiency of all our activities to minimise material and energy use and waste generated. We aim to find opportunities to use renewable materials and to recycle our waste. Read more about [environmental sustainability](#).

> [Back to top](#)

› Home › Responsibility › Corporate responsibility at GSK

› [Business case for corporate responsibility](#)

Corporate Responsibility Report 2009

Business case for corporate responsibility

Demonstrating that our practices are responsible and ethical, benefits the business and improves our reputation in the following ways:

- Engenders greater trust in GSK products
- The ability to attract, retain and motivate talented people. This is becoming increasingly important as fewer young people in our major markets choose science-based careers
- Constructive engagement with stakeholders. This helps us to prevent avoidable conflict and identify innovative approaches that benefit GSK and wider society
- Greater access to markets and the ability to influence healthcare policy through improved relationships with regulators and healthcare payers. Helping governments to increase access to medicines and resolve healthcare challenges is particularly important
- Greater ability to anticipate and prepare for legislative changes and maintain a competitive advantage
- Helping to maintain support for the intellectual property system by finding innovative ways to increase access to medicines
- Reduced costs and more efficient use of resources through increased environmental efficiency

Our strategy

We are focused on delivering three strategic priorities to transform GSK into a company that delivers more growth, has less risk and an improved long-term financial performance. To be a successful and sustainable business we must also fulfil our social responsibilities. We are doing this by making our company more responsive, more flexible and more open.

Strategic priorities

- **Grow a diversified global business** - We are diversifying our business to create a more balanced product portfolio and move away from a reliance on traditional 'white pill/ western markets'. We are investing in key growth areas such as Emerging Markets, Japan, Vaccines and our Consumer Healthcare business.
- **Deliver more products of value** - We aim to sustain an industry-leading pipeline of products, ensuring that they demonstrate value for healthcare providers. Our R&D strategy is built around focusing on the best science, diversifying through externalisation of research, and improving the returns on investment.
- **Simplify the operating model** - GSK is a large and, by default, complex organisation. We are transforming our operational model to reduce complexities, improve efficiency and reduce costs.

For updates on our progress against these priorities and further measures to operate with responsibility and integrity, please visit our [Annual Report website](#)

› [Back to top](#)

› Home › Responsibility › Corporate responsibility at GSK › [Our key issues](#)

Corporate Responsibility Report 2009

Our key issues

Our CR reporting is focused on the most material (significant and relevant) issues for our business.

The following factors influence our materiality assessment:

- Our business [strategy](#)
- Our risk [management processes](#)
- [Stakeholder interest](#), including investor feedback
- Changes in our business and operations, for example the types of product we produce or the locations where we operate
- Existing and proposed legislation
- Public opinion and press coverage

We have identified the following responsibility issues as most material to GSK:

- The [contribution](#) our core business makes to health through research, development, manufacture and the sale of medicines and vaccines
- Increasing [access to medicines](#) in under-served communities
- Ethical standards in [research and development](#) and [sales and marketing](#)
- Our [environmental impact](#), particularly climate change

See [Corporate responsibility governance](#) and [Risk management](#) for more about our decision-making processes.

› [Back to top](#)

Corporate Responsibility Report 2009

Corporate responsibility governance

Our Corporate Responsibility Committee (CRC) of Non-Executive Directors provides high-level guidance on our approach to CR.

The CEO and members of the Corporate Executive Team (CET) are accountable for responsible management of the business and participate in CRC meetings.

During 2009 the Committee members were Sir Christopher Gent (Chair), Dr Stephanie Burns, Mr James Murdoch, Dr Daniel Podolsky, Sir Ian Prosser¹ and Mr Tom de Swaan¹.

The Committee meets three times a year to review our policies and progress on our CR Principles. The Committee reviews our performance against five of our CR Principles annually. These are access to medicines, standards of ethical conduct, research and innovation, employment practices and community investment. Other Principles are discussed at least once every two years. The Committee reports its findings to the Board.

Management of corporate responsibility



During 2009 the CRC reviewed GSK's activity in a number of areas, including:

- Pandemic 'flu, including access to vaccine and antiviral medicines in developing countries
- Access and pricing of medicines in developing countries
- R&D on diseases of the developing world and a patent pool
- Community partnerships and investment
- Humanitarian donations
- Sales and marketing practices including harmonisation of GSK Codes of Practice
- Disclosure of payments to healthcare professionals
- Communication of clinical trial results
- Use of animals in research
- Employment practices including diversity and inclusion
- Employee wellbeing

- Employee relations including consultation arrangements and employment litigation in the US
- Supply chain management
- Climate change, energy use reduction and manufacturing efficiency
- Data privacy
- Corruption prevention

The Committee also reviews and signs off the annual performance information published on this website and our annual [CR highlights document](#).

To augment our engagement with stakeholder opinion, in March 2009 Sophia Tickell was appointed as an independent external advisor to the Corporate Responsibility Committee. Sophia is the Director of the Pharma Futures Series, which aims to better align societal and shareholder value, and she chairs the International Advisory Group of the Medicines Transparency Alliance. Sophia has extensive experience of constructively challenging companies to increase their understanding of societal expectations and to develop strategies to meet them. She has gained this experience in her work as a journalist in Latin America, through her work in international development and her advocacy work at Oxfam and, most recently, in her role as Director at SustainAbility, the think tank and consultancy on sustainability issues. Sophia attends the meetings of the Corporate Responsibility Committee and advises the company in this capacity.

Corporate responsibility risks

Our Risk Oversight and Compliance Council (ROCC) coordinates the management of significant business risks. The ROCC also considers reputational and corporate responsibility risks. Read more about our [Risk management](#).

Management structure

CR covers a very diverse range of issues at GSK so we believe it should be managed within our business functions, where the relevant subject experts work. We have a cross-functional team made up of representatives from key business areas which oversees development, implementation and communication of policies, including any responsibility elements, across GSK. The members are senior managers with direct access to our Corporate Executive Team.

We have a small central CR team to coordinate policy development and reporting specifically with respect to CR, and to communicate with socially responsible investors and other stakeholders.

We have a Sustainability Council of senior executives from across the business, which meets via teleconference four times a year to oversee GSK's [environmental sustainability plans and progress](#).

Measuring performance

We have established [metrics and key performance indicators](#) to track our performance on responsibility issues.

1. In May 2009, Mr James Murdoch joined the Committee, Mr Tom de Swaan ceased to be a member of the Committee and Sir Ian Prosser retired from the Board.

› [Back to top](#)

Corporate Responsibility Report 2009

Audit and assurance

Many aspects of our responsibility performance are monitored through our internal and external assurance processes.

GSK's internal audit group has responsibility for independently assessing compliance with laws, regulations and company standards and the adequacy and effectiveness of the management over significant risk areas and reporting it to the Audit and Risk Committee. GSK employs approximately 150 full-time internal auditors. Audits range in duration from two weeks for simple activities where the scope is limited, to several months for an audit involving complex or highly technical processes. The audit teams may be supplemented by external experts with specific technical skills, or by the use of guest auditors from within the businesses.

Where issues or control deficiencies are identified, the audit team will recommend improvements. GSK managers develop corrective and preventative action plans to eliminate the causes of non-compliance and gaps in internal controls. Our Audit and Assurance department (see below) track these plans through to completion and report results to senior management and the Audit and Risk Committee.

Below we explain the improvements we have made to our internal audit processes and outline the external assurance processes for this report.

Strengthening internal audit and assurance

In 2009, we reviewed and strengthened our internal audit processes in line with industry best practice. An Audit and Assurance department was created to improve consistency and oversight across the business. Its objectives are to:

- Develop and manage the GSK Assurance Programme
- Align audit activity to key business risks
- Improve efficiency and effectiveness of internal audit activity

Previously many audit activities were managed within our business units. The new structure promotes greater independence of our audit activities and provides a holistic view of how risks are managed across the company. The direct reporting line to the Audit and Risk Committee helps ensure significant issues are escalated in a timely manner.

There are four internal audit groups:

- Environment, Health, Safety and Sustainability Internal Audit (EHSS IA)
- Group Internal Audit (GIA)
- Manufacturing Internal Audit (MIA)
- Research & Development Internal Audit (R&D IA)

Strategic Risk Evaluations

Our Strategic Risk Evaluation (SRE) approach is a new way of providing assurance and enabling effective risk management at GSK. SREs are conducted in partnership with our assurance teams and business units and aim to quantify risks and develop appropriate mitigation strategies. They can be launched quickly without having to schedule a routine audit process, and are therefore suitable for newly identified risks or in circumstances where an existing risk suddenly becomes more significant due to changes in our business strategy or the external environment.

Read more about assurance, internal audit and risk management in the Corporate governance section of our 2009 [Annual Report](#).

External assurance of the CR Report

The information we provide about environment, health and safety activities at GSK has been externally assured by SGS, an independent external assurer. The assurance process includes verification of key environment, health and safety data through site visits and telephone calls to EHS professionals and review of systems and processes for collecting, collating, analysing and interpreting the data. Read the [assurance statement](#) by SGS.

We assure one other section of the CR report every other year. This year Bureau Veritas has provided [assurance of the Ethical Conduct](#) section of this report. In our 2007 CR Report, information on access to medicines was externally assured. You can read how we responded to the recommendations made by the assurers in the Access to medicines section of our [2008 CR Report](#).

› [Back to top](#)

Corporate Responsibility Report 2009

Risk management

Non-financial and reputational risks are included in our core risk management processes.

Our Risk Oversight and Compliance Council (ROCC) coordinates the management of significant business risks. The ROCC meets regularly to review and assess significant risks and mitigation plans, providing oversight of internal controls to ensure compliance with applicable laws, regulations and internal GSK policies. It is chaired by GSK's Corporate Compliance Officer and includes several Corporate Executive Team (CET) members and heads of departments with internal control risk management, assurance, audit and compliance responsibilities.

We continued to strengthen our risk management processes in 2009 and relaunched our Risk Management and Legal Compliance policy. The new policy provides further clarity on the roles and responsibilities of people in our internal control framework. CET members are now formally responsible for establishing an appropriate risk management structure within their business unit to identify and mitigate significant risks.

Each business unit must review significant risks at least once a year and include identifying operational risks, legal compliance risks and risks to the achievement of strategic goals and objectives. This ensures that significant risks connected with changes in management direction and the external environment are identified. Business units and corporate functions are required to present annually to the ROCC and Audit and Risk Committee detailing risk management and compliance approach, provide a balanced assessment of the status of internal controls over key risks, and highlight any significant compliance issues.

We are also changing the way we allocate [audit resources](#) to ensure sufficient attention is paid to areas of highest risk.

Based on the most recent annual CET risk workshop the following most significant risks facing GSK:

- Risk that R&D will not deliver commercially successful products
- Patent infringement litigation
- Potential changes in intellectual property laws and regulations
- Weakness of intellectual property protection in certain countries
- Risk of substantial adverse outcome of litigation and government investigations
- Product liability litigation
- Anti-trust litigation
- Sales and marketing regulation
- Third party competition
- Governmental and payer controls
- Regulatory Controls
- Risk of interruption of product supply
- Risk of concentration of sales to wholesalers
- Global political and economic conditions
- Taxation and treasury
- Pandemic influenza
- Environmental liabilities
- Accounting standards
- Failure of third party providers
- Protection of electronic information and assets

- Alliances and acquisitions
- Attraction and retention
- Applying GSK's strategic priorities

The Risk Factors section of our [Annual Report](#) details the most significant risks to GSK.

Alliances and acquisitions - due diligence

We acquired several new businesses in 2009 in line with our strategic priority to grow a diversified global business. Growth of the business must not undermine our commitment to high quality, ethical, environmental and workplace standards and due diligence is integral to this.

Our due diligence processes are designed to identify any risks posed by new business acquisitions, including ethical, social or environmental risks. Due diligence is usually managed by the relevant manager from our Corporate Development department in conjunction with regional business development managers. Oversight is provided by the Head of Corporate Development or the Chief Strategy Officer. Depending on the nature of the deal, technical and scientific experts may also be involved. We are working to improve the skills of those involved in due diligence processes and share good practices across the business.

> [Back to top](#)

› Home › Responsibility › Corporate responsibility at GSK › Stakeholder engagement

Corporate Responsibility Report 2009

Stakeholder engagement

Stakeholder engagement and dialogue enables us to keep in touch with the views and opinions of the societies in which we operate.

It helps us identify important issues and shape our responses in the interest of our shareholders and wider society.

Regular engagement means we are better informed of emerging and current issues and changing societal expectations. It provides an opportunity for us to voice our approach to responsibility issues, obtain important feedback and build trust.

Most of this discussion takes place in the normal course of business. For example, our scientists regularly meet academics, researchers and other pharmaceutical companies through advisory boards and medical conferences.

Here we describe how we engage with our stakeholders, give examples of our engagement in 2009 by stakeholder group and provide information on how we are responding to the feedback we receive. You will find further examples of our engagement with stakeholders throughout this website.

We provided training this year to help managers in our markets to communicate with local stakeholders on our approach to responsible business and transparency.

Contact

We welcome your feedback on any of the information contained in this report. Please contact us at:

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› Back to top

› Home › Responsibility › Corporate responsibility at GSK › Stakeholder engagement
› [How we engage](#)

Corporate Responsibility Report 2009

How we engage

Healthcare professionals

We engage with healthcare professionals in many ways, including through our sales representatives and when running clinical trials. Read about our [research](#) and [ethics](#) policies governing relationships with healthcare professionals.

Patients

GSK researchers and scientists meet patients as part of our 'Focus on the Patient' initiative. This engagement influences our understanding of diseases and our research priorities. Read more about [Focus on the patient](#). We also support the work of [patient advocacy](#) groups and we conduct market research via third parties to understand patient needs.

Governments and regulators

We engage in debate on legislation and seek to influence policy decisions that affect GSK. We also engage with [governments](#) on responsibility-related issues.

Healthcare providers

We engage with healthcare providers through our [government affairs](#), marketing and access to medicines activities.

Investors

We meet regularly with investors and socially responsible investors. Read more about our [investor engagement](#) activities.

Employees

We seek feedback from our employees through [regular surveys](#). We also consult employees on changes that affect them and discuss business developments through regional and national consultation forums.

Local communities

Our interactions with local communities are managed by individual GSK sites. Read more about our [financial and practical support for communities](#).

Multilateral agencies

We engage with multilateral agencies through our [access](#) and [public health](#) initiatives.

Non-governmental organisations (NGOs)

We engage with international and local NGOs through our [access](#), education and [public health programmes](#) and as part of our [public policy](#) work.

We also engage regularly with animal welfare organisations. Read more about [animal research at GSK](#).

Scientific community and academic partnerships

It is important for GSK to be part of scientific debates and we are involved in a number of [academic collaborations](#).

Suppliers

We hold global and regional supplier review meetings where senior GSK managers address and interact with suppliers on key issues. Read more about our [engagement with suppliers](#).

Peer companies

We engage with peer companies through membership of pharmaceutical industry organisations, for example EFPIA, PhRMA, and IFPMA, and through collaboration on specific projects.

› [Back to top](#)

› Home › Responsibility › Corporate responsibility at GSK › Stakeholder engagement
› [Engagement with employees](#)

Corporate Responsibility Report 2009

Engagement with employees

It is important that our employees know about our commitment to corporate responsibility, understand their responsibilities and keep up-to-date with our progress.

Read about our approach to [embedding an ethical culture](#) at GSK.

We keep employees informed about corporate responsibility through our myGSK intranet site and Spirit, our internal quarterly magazine, which feature articles on responsibility issues. Read about how we engage with employees on [environmental issues](#).

In 2009 over 20 articles on responsibility issues were published in Spirit. These included articles on the launch of ViiV Healthcare and our new commitments to tackle HIV, GSK's approach to pandemic flu, our community investment programmes and a range of environmental initiatives. This year we published four editions of Spirit, distributing 29,500 copies of each edition internally. An online version of the magazine is available on the intranet, offering access to more employees.

We distributed our 2008 Corporate Responsibility Highlights with Spirit magazine and directly to the Corporate Executive Team and GSK Board, senior managers, site directors and all communications staff. News articles and icons on our intranet site were used to guide users directly to the CR Report.

Our shorter [CR Highlights document](#) directs people to this website. We are raising awareness of this online CR Report by publicising it on our website and the company intranet.

In 2009 we also ran our employee CR survey, which was sent to 10,000 randomly selected people across GSK. Over 2,000 employees from across the business took part and answered questions on a range of responsibility issues including their awareness of corporate responsibility and which issues they consider the most important.

- 77 per cent have heard of the term 'corporate responsibility'
- 69 per cent recognised that they themselves and other employees were accountable for one or more areas of corporate responsibility. Ethical business conduct, access to medicines and health and safety were the three areas identified by employees as most important
- These are also the areas that employees believe the company is doing most to address

This complements our regular [employee surveys](#) which track employee views on a wider range of issues.

› [Back to top](#)

› Home › Responsibility › Corporate responsibility at GSK › Stakeholder engagement

› [Engagement with investors](#)

Corporate Responsibility Report 2009

Engagement with investors

We have interactions with investors and socially responsible investment (SRI) analysts throughout the year on a wide variety of responsibility issues. SRI analysts also attended briefings on our consumer healthcare business and approach to emerging markets as part of our broader investor relations programme.

Investor questions and discussions

Some of the responsibility issues raised by investors in 2009 concerned:

- [Access to medicines](#)
- [Animal research](#)
- [Clinical trial results disclosure](#)
- [Clinical trials in the developing world](#)
- [Employment practices](#), including diversity, health and safety, employee consultation and talent attraction
- [Environmental issues](#) including climate change, nanotechnology, packaging, renewable raw materials, water management
- [Ethical conduct](#) including Codes of Conduct, anti-bribery and corruption, audit and internal controls
- Our [operations](#) in embargoed countries
- [Patient safety](#)
- [Political contributions](#)
- [Sales and marketing practices](#)
- [Stem cell research](#)
- [Supply chain](#) standards and human rights

We also disclose information on our greenhouse gas emissions through the Carbon Disclosure Project (CDP).

› [Back to top](#)

› Home › Responsibility › Corporate responsibility at GSK › Stakeholder engagement
› [Engagement with other stakeholders](#)

Corporate Responsibility Report 2009

Engagement with other stakeholders

Engagement on access to medicines

Engagement on issues relating to access to medicines during 2009 is described in the [Access to medicines](#) section of this report. This includes a [workshop](#) with experts on access to medicines to get feedback on our new initiatives in least developed countries.

GSK previously conducted three formal stakeholder discussions during 2007 to get feedback on our approach to different issues relating to access to medicines. More information on these discussions can be found in the Access to medicines section of our [2007 CR report](#).

Engagement on EHSS

Many of our sites engage with stakeholders locally through activities such as open days, newsletters and community projects. Read about our [Environment, Health and Safety Stakeholder Panel](#) in the UK which has provided independent feedback on company-wide performance since 2005.

Ipsos MORI survey

GSK participated in the Ipsos MORI survey which rates companies according to CR experts' and NGOs' perception of their CR performance. In 2009 two thirds of the 42 people surveyed thought that GSK took its responsibilities seriously. GSK was the fifth-highest rated company on this question (out of 24 companies).

› [Back to top](#)

Corporate Responsibility Report 2009

Benchmarking

GSK received the following ratings from benchmarking organisations and a number of awards relating to corporate responsibility:

Indexes

Organisation: Access to medicines index - Access to Medicines Foundation and Innovest Strategic Value Advisers

GSK was ranked top in the 2008 Access to Medicines Index, which rated companies on their performance according to eight criteria: management, influence, research and development, patenting, capacity, pricing, drug donations and philanthropy. Publication of the next Access to Medicines Index is expected mid-2010.

Organisation: Dow Jones Sustainability Index

Rating: GSK continued as a member of the Dow Jones Sustainability Index, which covers the top ten per cent of sustainable companies in each sector. GSK was awarded Bronze Class distinction in the 2009 survey published in 2010.



Organisation: FTSE4Good

Rating: GSK was included in the FTSE4Good Index which benchmarks companies on corporate responsibility parameters including environmental sustainability, stakeholder relationships, human rights, supply chain labour standards and business ethics.



Organisation: Business in the Community - CommunityMark

Rating: GSK was one of 21 companies and the only manufacturing company to be awarded the new CommunityMark in 2008, following independent assessment, for outstanding community investment. The Mark is endorsed by the UK government and voluntary sector leaders and was given for our work at local and national level in the UK as well as for our larger international programmes. Companies are awarded the Mark for a three year period and monitored to ensure continued commitment and excellence. GSK retained its CommunityMark in 2009.



- Scrip Corporate Social Responsibility Award, received for GSK's efforts to increase access to medicines in the developing world
- FIRST award for Responsible Capitalism, presented to Andrew Witty. The award honours business leaders who have consistently demonstrated social responsibility as an integral part of commercial success
- HealthRight International, Health and Human Rights Award presented to GSK for extraordinary leadership in the cause of health and human rights
- Management Today (UK) Most Admired Company awards. GSK was rated fifth overall and rated top for its 'ability to attract, develop and retain talent' and for 'financial soundness'. The assessment is made by industry peers

Reporting

Organisation: SustainAbility Global Reporters benchmark

Rating:

Our 2008 report scored 73 per cent, an improvement of seven per cent on the 2007 report and above the average of 54 per cent for the 11 pharmaceutical companies benchmarked by SustainAbility. Strengths identified included clear articulation of material issues and GSK impacts, alignment of responsibility activities with business strategy, and consideration of corporate responsibility in core management processes. Areas suggested for improvement included development of metrics and targets.

› [Back to top](#)

› Home › Responsibility › Corporate responsibility at GSK › [About our reporting](#)

Corporate Responsibility Report 2009

About our reporting

Our Corporate Responsibility Report reflects our commitment to be open and transparent about our business activities.

We report our CR activities and performance annually via this website. Read more about [how to use this website](#), where selected performance information can also be downloaded by building a [custom report](#).

This year we have made an [Overview](#) available on this site to help users understand the breadth of our activities and to find relevant information in the report. A [site map](#) and search function have also been added to help users locate specific areas of interest. Our [Corporate Responsibility Highlights](#) document is available in print and provides details of our performance in 2009 and encourages readers to find out more on this website.

Data

Data relate to worldwide operations for the calendar year 2009, except where stated.

Data in the [environment](#) and [health and safety](#) sections are independently assured by [SGS](#) and in the ethical conduct section by [Bureau Veritas](#).

More information on our approach to external assurance is provided in the [audit and assurance section](#).

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Reporting standards

We use external guidelines to inform our reporting where relevant. We do not base our report on the Global Reporting Initiative (GRI) guidelines but we have produced a [GRI index](#) to show which elements of the guidelines are covered in the report and to aid comparison with other company reports. We have also joined the UN Global Compact and have provided an [index](#) to show how we are reporting in line with Global Compact expectations.

› [Back to top](#)

Corporate Responsibility Report 2009

Corporate responsibility data summary

Metric	2005	2006	2007	2008	2009
Access to medicines					
Number of <i>Combivir</i> and <i>Epivir</i> tablets shipped (millions)	126.3	86.3	85.0	70.0	33.0
Number of generic ARVs supplied under licence from GSK (millions)	-	120	183	279	439
GSK <i>Combivir</i> not-for-profit price (\$ per day) ¹	0.65	0.65	0.54	0.54	0.54
Voluntary licences granted to generic manufacturers for GSK ARVs (cumulative total) ²	7	9	9	9	8
Value of products donated through GSK Patient Assistance Program in the US (£ millions, 2008-2007 at cost, 2006-2004 at wholesale price (WAC)) ³	255	200	45	56	80
Research and Development					
Expenditure on R&D (£ billions)	3.1	3.5	3.3	3.7	4.1
Number of trials published on the GSK Clinical Study Register (cumulative total)	2,125	2,760	3,089	3,273	3,687
Ethical conduct					
Number of employees completing certification to the GSK Code of Conduct	>12,000	>12,000	>14,000	>14,000	>14,000
Number of contacts through our ethics compliance channels ⁴	3644	5363	5265	3812	5445
Employment					
Women in management grades (%)	35	36	37	38	38
Ethnic diversity - people of colour (US, %)	19.6	19.8	20.1	20.5	20.4
Ethnic diversity - ethnic minorities (UK, %)	14.9	18.3	19.1	19.2	19.4
Reportable injury and illness rate (per 100,000 hours worked)	0.72	0.72	0.68	0.57	0.47
Environment					
Total climate change impact (thousand tonnes CO ₂ equivalent) ⁵	2,652	7,910	8,291	7,765	7,164
- Climate change impact from energy for operations and transport ⁶	1,966	2,223	2,226	2,234	2,166

- Climate change impact from patient use of inhalers ⁶		4,685	5,200	4,747	4,243
Energy from operations and transport (million gigajoules) ⁶	19.4	25.4	26.4	26.2	25.3
Water consumption (million cubic metres)	21.8	22.1	20.7	19.6	19.2
Wastewater chemical oxygen demand (COD) (thousand tonnes)	18.7	15.9	14.3	14.9	13.0
Non-hazardous waste disposed (thousand tonnes)	41.2	37.9	38.0	33.4	31.2
Hazardous waste disposed (thousand tonnes)	67.8	71.0	72.6	53.9	48.4
Volatile organic compound emissions (thousand tonnes)	5.2	4.2	4.3	3.7	3.1

Community investment

Total community investment expenditure (£ millions, 2008-2007 at cost, 2006-2004 at wholesale price (WAC)) ³	380	302	109	124	163
Value of humanitarian product donations, including albendazole (£ millions, 2008-2007 at cost, 2006-2004 at wholesale price (WAC)) ³	41	38	7	12	13
Number of albendazole tablets donated for prevention of lymphatic filariasis (millions)	136	155	150	266	425

1. Includes freight and delivery costs. The Médecins Sans Frontières pricing report lists the average cost of generic equivalents.

2. Only eight are currently in force. This reduction is due to one company which had been granted a voluntary licence ceasing to trade.

3. 2009, 2008 and restated 2007 figures reflect value at cost (average cost of goods) rather than wholesale acquisition price (WAC). This is the second year we have valued our donations this way and believe it is a more accurate reflection of the true cost to GSK and is therefore more transparent. 2005 to 2006 figures remain at WAC.

4. Includes contacts with line managers, compliance officers, our confidential Integrity Helplines or offsite post office box (in the US).

5. Climate change impact is calculated as CO₂ equivalent using the Greenhouse Gas Protocol developed by the World Resources Institute and the World Business Council for Sustainable Development. Each year we review the CO₂ factors and update the data for all years as appropriate.

6. Energy from transport and climate change impact of patient use of inhalers were not calculated prior to 2006.

› [Back to top](#)

» Home » Responsibility » [Contribution to global health](#)

Corporate Responsibility Report 2009

Contribution to global health

Our medicines, vaccines and consumer healthcare products can make a real difference to patients' lives.

We are committed to maximising our contribution to health by researching new treatments that address the needs of patients and healthcare payers and by making our products as widely available as possible. This is at the heart of what responsibility means for GSK and is central to our commercial success.

We make a contribution in four key areas:

- Preventing disease: GSK is a leading producer of vaccines used in developed and developing countries. We also prevent disease through our community investment and our over-the-counter products
- Disease awareness: we work with patient groups and run our own campaigns to raise awareness about disease
- Treating ill health: many of our products treat diseases that place a high burden on society
- Investing in R&D: our pipeline includes new medicines and vaccines that are needed in developing and developed countries. We are partnering with others to accelerate development of new treatments

We are [responding to pandemic flu](#) with products and partnerships to help treat and prevent it.

Our contribution will be limited if our products are not accessible and affordable. We are committed to increasing access to our medicines and vaccines in all countries. Read more in [access to medicines](#). We also support healthcare through our [community investment](#).

The cost of disease

Ill health is expensive for the individual and for society. It is often a result of poverty, but it is also an important cause of poverty.

For patients it can mean loss of quality of life, loss of earnings and shortened life expectancy. It can place a great burden on families – for instance the need to care for sick relatives can reduce attendance at school or work. For governments, employers and taxpayers it can mean increased healthcare costs and loss of workforce productivity.

In Africa and parts of Asia, AIDS has had a serious effect on social and economic development, undermining progress towards the Millennium Development Goals and poverty reduction efforts. The World Bank estimates that the deaths of working age adults from HIV/AIDS may subtract one per cent a year from GDP economic growth in some sub-Saharan African countries. In South Africa HIV/AIDS may depress GDP by as much as 17 per cent over the next decade¹. Malaria is estimated to cost African nations at least \$12 billion a year in lost economic output². The economic cost of TB-related deaths, including HIV co-infection, in sub-Saharan Africa is estimated at \$519 billion between 2006 and 2015³.

Read about our research into [diseases of the developing world](#) and our efforts to help people in these countries [access](#) essential medicines and vaccines.

According to the US government's Centers for Disease Control and Prevention (CDC), the costs of chronic disease in the US alone include⁴:

- \$174 billion a year in direct and indirect costs due to diabetes
- \$81 billion in annual medical care costs for arthritis, and total costs including medical care and lost productivity of almost \$128 billion
- \$448 billion projected cost for 2008 for heart disease and stroke

Read about how we are [working in partnership in the US to combat chronic disease](#) and the role of our [vaccines](#) in preventing disease.

1. www.who.int/trade/glossary/story051/en/index.html
2. [Rollback Malaria http://rbm.who.int/globaladvocacy/pr2007-11-29.html](http://rbm.who.int/globaladvocacy/pr2007-11-29.html)
3. <http://www.who.int/mediacentre/news/releases/2007/pr64/en/index.html>
4. www.cdc.gov/nccdphp/overview.htm

› [Back to top](#)

Corporate Responsibility Report 2009

Responding to pandemic flu

Updated September 2010

The World Health Organization (WHO) declared an outbreak of pandemic flu in June 2009.

GSK responded rapidly to meet the needs of governments and health authorities. Our response was made possible by our investment over more than a decade in the research, development and manufacturing capacity of flu vaccines and antiviral medicines.

Pandemics are highly unpredictable. Fortunately, in terms of population-level impacts, the H1N1 pandemic flu was not as serious as initially feared, although there was a greater impact in some groups including pregnant women, young people, and those with certain chronic health conditions. As a result of the relatively moderate nature of the pandemic, government and health authority demands for pandemic flu vaccines and antiviral medicines have fallen.

GSK recognises that governments needs and plans have evolved as understanding of the H1N1 pandemic has increased and is committed to working with them to find fair solutions for their GSK H1N1 vaccine supply. Additionally we are reviewing our pandemic response to identify how we can provide a more flexible offering in future pandemics, while minimising risk for our business.

H1N1 2009 pandemic update

On the 10 August 2010 the WHO Emergency Committee reassessed the epidemiological and virological situation for the H1N1 2009 pandemic. In its assessment the WHO Emergency Committee concluded that the levels and patterns of H1N1 transmission now being seen differ significantly from what was observed during the pandemic. Based on the recent observations, the evidence is strong that the recent flu pandemic patterns are transitioning towards seasonal patterns of flu.

Our products

We launched our pandemic response measures as soon as the WHO declared the H1N1 outbreak to be a pandemic - in accordance with their classification system.

GSK products available to governments to support the public health needs of protecting their population from pandemic flu include 2 H1N1 pandemic vaccines (*Pandemrix* and *Arepanrix*) and *Relenza*, a flu antiviral medicine.

To meet potential increased demand for these products we had invested approximately US\$2 billion in previous years to increase manufacturing at our existing sites and to establish new manufacturing lines.

We also accelerated production of antibiotics used to treat secondary bacterial infections associated with flu.

Vaccines

Immediately after receiving the H1N1 pandemic virus strain in early June 2009, we began the complex process of developing and manufacturing vaccines at our 2 manufacturing sites in Germany and Canada respectively to help protect the population. Both vaccines consist of the H1N1 flu antigen and the AS03 adjuvant. Once a person is vaccinated the antigen triggers an immune response to the H1N1 virus. The use of the AS03 adjuvant allowed less antigen to be used per dose of vaccine, enabling significantly more doses of vaccine to be produced in a limited period of time.¹

Full-scale vaccine production was started in July 2009, and our H1N1 vaccines *Pandemrix* (with antigen manufactured in Germany) and *Arepanrix* (a similar vaccine but with antigen manufactured in Canada) received their first approvals for use in September 2009 and October 2009 respectively. Since then we have supplied over 250 million H1N1 pandemic vaccine doses to more than 60 governments.

GSK is committed to the highest standards of patient safety and all the H1N1 vaccine safety data we receive from clinical trials and vaccination programme usage is continuously reviewed and evaluated for any signals of vaccine safety or quality issues. In addition to several years of extensive safety and efficacy testing of our candidate pandemic vaccines, including the AS03 adjuvant combined with the H5N1 (avian flu) antigen, our H1N1 pandemic flu vaccines were evaluated in 29 clinical trials involving over 16,000 subjects, including healthy adults, elderly people and children. Additionally there are several programs established to evaluate the safety of those vaccinated. For instance in the UK, we have completed and are analysing a post-licensure study to monitor the safety of the vaccine when used in a mass vaccination programme, working in collaboration with the Medicines and Healthcare Products Regulatory Agency (MHRA), the Department of Health and the General Practitioner Research Network (GPRN). Data from our own clinical trials as well as independent safety evaluations by several regulatory authorities, including the European Medicines Agency as 19 Aug 2010, have confirmed that the benefit-risk profile of pandemic H1N1 vaccines is positive.

1. Leroux-Roels et al. Antigen sparing and cross-reactive immunity with an adjuvanted rH5N1 prototype pandemic influenza vaccine: a randomised controlled trial. *Lancet* 2007; 370 (9587): 580–89

Relenza

Relenza (zanamivir) is an antiviral medicine licensed for the treatment and prevention of influenza.

There was unprecedented demand for *Relenza* following the H1N1 outbreak. We distributed existing supplies equitably, increased production at three existing manufacturing sites, and established a further two production lines. As a result, our annual production capacity for *Relenza* rose to 190 million treatment courses – more than three times our previous maximum output. To achieve this level of production, we introduced *Relenza Rotacaps*, an additional *Relenza* presentation that can be manufactured in large quantities. We worked hard to quickly obtain approval for *Relenza Rotacaps*, so we could reach full production capacity. GSK worked with regulatory authorities in EU to find an appropriate mechanism to allow Governments to purchase this product, where appropriate, pending local approval.

In total we supplied more than 50 million doses of *Relenza* to more than 70 governments.

In response to specific requests from physicians treating severely ill hospitalised patients with flu, we supplied an unlicensed formulation of an antiviral medicine in clinical development. These requests were typically for treating patients in whom licensed antiviral medicines were either ineffective or where an intravenous route of administration was required. Several clinicians subsequently wrote case reports of their experience using this unlicensed treatment however its efficacy and safety remain unproven and are yet to be evaluated in clinical trials.

Actiprotect

Actiprotect is a single-use, disposable respirator (face mask) with an antiviral coating that inactivates flu viruses. GSK continues to offer *Actiprotect* to governments that have identified the need for personal protective equipment as part of their preparations for a future pandemic.

Responding to the needs of pilgrims during the Hajj

Attending the Hajj is an once-in-a-lifetime pilgrimage for many Muslims. Every year millions of people journey to Mecca, Saudi Arabia, to worship together at the world's largest annual religious gathering.

The 2009 Hajj took place in late November, coinciding with the northern hemisphere flu season and a predicted surge in pandemic flu cases. This raised the risk that the H1N1 pandemic virus might spread rapidly among pilgrims, who worship, eat and sleep in close proximity, potentially endangering their health and that of their families and communities when they returned home.

Concerned about the possible spread of the virus the Saudi Arabian government announced in the summer of 2009 that all attendees must be vaccinated against H1N1 pandemic virus before arrival in Mecca.

GSK worked with contract-holding governments, mainly in Europe, to find a solution that ensured that this high-risk group was protected against H1N1 in due time. GSK immediately established a plan to ensure access to our vaccine in many of the countries of origin of Hajj pilgrims. We worked closely with relevant governments to obtain regulatory approval for the vaccine, while producing and shipping the required doses in a very short period of time. We also shipped a consignment of vaccine to Saudi Arabia, so that instead of turning non-vaccinated people away at the border they could offer the option of being immunised upon arrival.

Donations to the developing world

Many developing country governments have limited resources available to protect their populations against pandemics.

We strongly endorse the principles set out by the Bill & Melinda Gates Foundation to help guide global allocation of pandemic vaccines, and we support its message that the global community should take all steps necessary to protect all populations, including those without resources to protect themselves.

GSK is committed to facilitating access to *Relenza* and our pandemic flu vaccines in all countries. We operate a tiered-pricing policy for these products, and make *Relenza* available at a not-for-profit price to Least Developed Countries. Read about [our approach to improving access to medicines](#).

In November 2009 we signed an agreement with the WHO to donate 50 million doses of our H1N1 pandemic vaccine to developing nations. We also made available two million treatment courses of *Relenza* to donate to the WHO for use in developing countries should it be required. To further ensure product availability in developing countries, we allocated 20 per cent of H1N1 vaccine production capacity at our Canadian manufacturing site, and 10 per cent of *Relenza* production capacity, to developing countries.

Our total H1N1 vaccine donation, with shipments beginning in January 2010, currently stands at around 28 million doses to 18 different countries. We remain committed to working with the WHO to support developing countries in the event of a future pandemic.

Reflecting on lessons learned

Many governments, national health organisations and intergovernmental bodies are conducting reviews of the response to the H1N1 pandemic, and beginning to plan for future pandemics.

GSK too is reflecting on lessons learned. We are listening to feedback from governments and other partners and using their comments to adapt and improve our pandemic response offering.

> [Back to top](#)

Corporate Responsibility Report 2009

Disease prevention

Preventing disease improves health, avoids human suffering and can reduce the cost of managing preventable and chronic diseases.

Vaccines play a vital role in preventing serious disease and we are one of the world's largest [vaccines](#) producers. Growing our vaccines portfolio is a key element of our business strategy, and an area where we can make a very significant contribution to global health.

We also develop [over-the-counter products](#) which can help people to reduce their risk of ill health by stopping smoking, losing weight and maintaining good oral health.

Many of our community investment projects focus on disease prevention, including our support for the [Global Alliance to Eliminate Lymphatic Filariasis](#), and our [PHASE hand-washing programme](#).

Corporate Responsibility Report 2009

The role of vaccines

Vaccines play a major role in preventing and eliminating disease. Immunisation is acknowledged by the World Health Organization (WHO) as being 'among the most cost-effective of health investments'. It is estimated that at least three million deaths are prevented and 750,000 children are saved from disability due to vaccines every year¹.

This section describes our vaccine pipeline and portfolio, how we increase access to our vaccines and the use of our vaccines for pandemic flu, cervical cancer, rotavirus and polio.

Our vaccine portfolio and pipeline

We have over 30 vaccines approved for marketing. These address the medical needs of developing and developed countries and cover most of the leading causes of childhood mortality, as defined by the WHO. Our current vaccine portfolio provides protection against the following diseases:

- Cervical cancer
- Chickenpox
- Diphtheria
- Hepatitis A and B
- Influenza (seasonal and H1N1)
- Measles
- Meningitis
- Mumps
- Otitis media
- Pneumococcal disease
- Polio
- Rotavirus
- Rubella
- Tetanus
- Typhoid
- Whooping cough (pertussis)

Over 1,600 scientists work in vaccine research at GSK and our vaccine pipeline has been recognised as the largest in the industry², with over 20 potential new vaccines. Since 2005 we have successfully launched four new vaccines (against cervical cancer, pneumococcal disease, rotavirus and H1N1 pandemic flu), and have obtained approval in Europe for a pre-pandemic and pandemic H5N1 avian flu vaccine.

One-third of vaccines in our pipeline target diseases particularly prevalent in the developing world, including

all three WHO infectious disease priorities: HIV, malaria and tuberculosis. Read about our progress in these areas in the [Access to medicines](#) section.

Increasing access to vaccines

Vaccines are still under-used in many countries. It is estimated that the lives of over two million children could be saved each year if existing vaccines were made accessible to all who need them. This will require sustained financing and the development of innovative vaccination programmes.

We aim to increase the affordability of GSK vaccines in developing countries through our long-standing commitment to tiered pricing. Read more [about tiered pricing](#). Our vaccines are included in immunisation campaigns in 182 countries worldwide. We delivered 1.4 billion vaccine doses in 2009, of which nearly 1 billion were shipped for use in developing countries.

We contribute to achieving Millennium Development Goal 4 ('Reduce child mortality') by ensuring our vaccines are included in the Expanded Immunisation Programmes for the world's most vulnerable children. GSK is involved in a project to improve the infrastructure for childhood [immunisation programmes in India](#), where millions of mothers and children do not receive basic immunisations.

Under our strategy to increase access to vaccines in middle-income countries, we are piloting two projects in Egypt and Mexico to develop a network of new clinics where people can more easily obtain immunisations in their local communities.

We are also increasing our involvement in technology transfer, which helps emerging markets develop their research and manufacturing capabilities, while increasing access to these markets for GSK. In 2009 we launched a technology transfer collaboration in Brazil and joint venture in China. Read more about these [examples](#).

Pandemic flu (*Pandemrix*)

Read about our [preparations and response to the H1N1 pandemic](#), including our vaccine, *Pandemrix*.

Cervical cancer (*Cervarix*)

Most cervical cancers are now preventable with vaccination against the human papillomavirus (HPV) combined with cervical screening. GSK's vaccine against HPV, *Cervarix*, is now available in more than 105 countries around the world and we are committed to accelerating global access to the vaccine.

Since the launch of *Cervarix* in 2007, approximately ten million doses have been distributed worldwide. The vaccine has been selected for immunisation programmes in several countries, including national programmes in the Netherlands and the UK and regional programmes across Italy, Poland and Spain. For example:

- In the UK, *Cervarix* was chosen as the vaccine for the national immunisation programme (NIP), the largest human papillomavirus immunisation programme in the world to date. More than 1.4 million doses of the vaccine have been delivered across the UK since the NIP launch in September 2008
- Over 500,000 doses of *Cervarix* have been administered since the Netherlands' national immunisation programme, launched in 2009

In June 2009, the WHO granted prequalification for *Cervarix*. This means the vaccine can be purchased by UN agencies and the GAVI Alliance in partnership with developing countries.

GSK is participating in several HPV vaccination demonstration projects in developing countries to help them with implementation of their HPV vaccination programmes locally. This includes initiatives led by a non-profit organisation, PATH, in India and Uganda. We have donated more than 130,000 doses of *Cervarix* to these programmes. In 2009, preliminary results from the first year of the Uganda project demonstrated high vaccination coverage and indicates the feasibility of HPV vaccination in such resource-constrained areas.

We are also exploring the use of innovative public-private partnerships to increase the availability of *Cervarix* for traditionally under-served groups, and one option being explored is to partner with a major international non-governmental organisation. Through this partnership we will be able to use this organisation's distribution

networks to create sustainable expansion of access to our vaccine in developing countries, where most deaths from cervical cancer occur. Results from a pilot programme launched in South America in 2009 are encouraging, with underserved groups achieving greater access our vaccine.

Read more about [flexible pricing of Cervarix in the Philippines](#).

Rotavirus (*Rotarix*)

Rotavirus, a severe diarrhoeal illness, is the second biggest killer of children under five years of age. More than 500,000 children die and two million go to hospital each year because of it. More than 85 per cent of those deaths occur in low-income countries in Africa and Asia³.

In June 2009, the World Health Organization awarded global prequalification for *Rotarix*, our vaccine against rotavirus, following initial regional prequalification for Europe and the Americas in 2007. The move will accelerate access to the vaccine in Asia and Africa. The WHO's expert advisory group also recommended that rotavirus vaccination be included in all national immunisation programmes. In our commitment to make *Rotarix* available to infants around the world, we work in partnership, for example with non-profit organisations such as PATH, and are committed to finding ways to help prevent pricing from becoming a barrier to access in the developing world.

Haemophilus influenzae type b (*Hiberix*)

Haemophilus influenza type b (Hib) is an often severe and potentially deadly bacterial infection that can cause meningitis. In 2009, in response to a shortage of Hib vaccine in the US, GSK received accelerated approval from the US Food and Drug Administration (FDA) for our vaccine, *Hiberix*, as a booster dose in young children. At the time, *Hiberix* was already available in nearly 100 countries and we supplied the FDA with information about safety and efficacy. The approval enabled us to respond to a public health need and meant we could quickly make the vaccine available so children could complete the full schedule of Hib vaccinations.

1. Ehreth J. The Global Value of Vaccination. *Vaccine* (2003); 21 (7-8):596-600
2. GSK has received two awards recognising its vaccine pipeline: the SCRIP Awards in 2008 and the 2nd annual Vaccine Industry Excellence Awards in 2009
3. World Health Organisation *Wkly Epidemiol Rec* 2008; 83: 421-8

› [Back to top](#)

Corporate Responsibility Report 2009

Our other products

GSK produces over-the-counter medicines and other products that help people protect themselves against disease. This includes our consumer healthcare products for smoking cessation, weight loss and oral healthcare.

Smoking cessation

Smoking is a major public health problem, contributing to around five million premature deaths worldwide every year. Nicotine replacement therapies (NRT) can significantly increase a smoker's chance of stopping. GSK created the first over-the-counter NRT and we now market a range of nicotine replacement brands, including *NiQuitin CQ/NicoDerm*, *Commit lozenge* and *Nicorette*. They have helped more than 7.3 million people stop smoking since 1996.

In 2009, the World Health Organization added NRT gum to its core list of essential medicines. This is considered a reference on the minimum medicine needs for a basic health-care system and lists the most effective, safe and cost-effective medicines for priority conditions. The inclusion of NRT gum recognises the significant public health benefits of this class of medicines and their contribution to preventing serious diseases by helping people stop smoking.

We estimate that around 20 per cent of smokers currently have access to GSK NRT. We continue to launch our NRT products in new markets, including Argentina in 2009.

We recognise that poverty can be a major barrier to NRT purchase, especially in emerging markets. We offer smaller pack sizes which are one way to address this, for example we recently launched a pack in Brazil which contains only four lozenges which can be bought for the equivalent of approximately US\$2.

In the US, we supported a 2008 petition by the New York Commissioner of Health, asking the Food and Drug Administration (FDA) to allow over-the-counter NRT products to be sold more widely wherever cigarettes are sold and to permit the sale of smaller packs with fewer doses that would have much lower prices. We welcome the citizen petition, filed jointly by the Association for the Treatment of Tobacco Use and Dependence and the Society for Research on Nicotine and Tobacco in early 2010, which urges the FDA to adopt a more flexible regulatory approach to expand access and use of NRT products.

We support government anti-smoking initiatives in several countries. For example, we provide smoking cessation education and counselling support to help low-income smokers in Brazil. In the UK, we support the National Health Service's Stop Smoking Clinics, providing educational materials and online and telephone support for smokers. We also help train nurses and pharmacists as 'stop smoking' advisers.

We are committed to finding new ways to help smokers quit. In 2009, we reached an agreement with Nabi Biopharmaceuticals on NicVAX. NicVAX, which recently entered phase III trials, is in development for treatment of nicotine addiction and the prevention of smoking relapse once a smoker has quit.

Preventing obesity

Obesity is a major cause of ill health and disease such as diabetes. *alli*, our over-the-counter weight-loss treatment, helps people lose weight when combined with a low-fat, reduced calorie diet.

alli has been marketed in the US since 2007 and in Europe since March 2009. Since its launch in the US, 7.5 million starter packs have been sold, helping millions of people to lose weight. In Europe, approximately 2.5 million people have tried *alli* in its first year, further adding to the number of people who have been helped in their weight loss efforts.

Read a case study on how we ensure that *alli* is marketed responsibly.

Oral healthcare

Good oral health can help to prevent gum disease and tooth decay, and has other health benefits. Our oral healthcare products include toothpastes, mouth washes and denture cleaners.

Our facility in Weybridge, UK, which makes global brands *Aquafresh* and *Sensodyne*, is the largest oral healthcare research centre in Europe. Employees from the facility regularly visit oral healthcare conferences and publish articles in journals to promote the importance of using oral healthcare products such as ours.

We co-sponsor the Innovation in Oral Care Awards with the International Association for Dental Research and we run an award scheme that recognises innovative research into preventing mouth infections and improving oral healthcare diagnostics.

In 2009 we began to expand our [PHASE handwashing campaign to include a focus on oral healthcare](#).

We also launched a global campaign in 2009 on the importance of two-minute tooth brushing. We have worked with independent experts to demonstrate for the first time that brushing for two minutes can improve fluoride's ability to protect tooth enamel from early signs of decay. The educational programme includes expert outreach to dental professionals, and also direct-to-consumer communications, using this new information to encourage patient compliance with a good oral hygiene routine.

› [Back to top](#)

Corporate Responsibility Report 2009

Disease awareness

We help to raise awareness of health-related issues among healthcare professionals and the public through our work with patient groups and our own disease awareness campaigns.

These can take place to coincide with the launch of a new product or after it is on the market. Raising awareness about disease can have a positive impact on public health and can create commercial benefits for GSK.

In 2009, our disease awareness campaigns included:

Promoting coordination between Asian NGOs to promote vaccination

Non-governmental organisations (NGOs) play a vital role improving access to vaccines in the developing world and raising awareness about the importance of immunisation. However, they have many priorities to reconcile and often lack the resources to ensure their work gets the wide reach necessary to benefit other NGOs or organisations.

In February 2009, GSK collaborated with the Asian Development Bank and Save the Children to host a workshop on the role of immunisation in improving maternal, newborn and child health in Asia. Nearly 30 NGOs came together for the event in Manila, the Philippines, where they were joined by the Global Alliance for Vaccines and Immunisation (GAVI) and the United Nations Children's Fund (UNICEF).

Participants discussed the challenges they face in getting vaccines to the people who need them most, shared best practices, and developed innovative ways to collaborate.

Feedback from the attendees showed the event was a success and a number of NGOs subsequently established a regional network committed to greater advocacy on healthcare and childhood immunisations.

Raising awareness of dengue fever treatment

Few people know the correct treatment for dengue fever, a debilitating disease that is transmitted by mosquitoes in tropical and sub-tropical regions, especially for children. People often use fever-reducers such as aspirin which can exacerbate bleeding, a symptom of dengue fever. Paracetamol is the recommended effective symptomatic treatment for dengue fever. They also seek medical treatment late, which increases the risk of serious complications and death.

GSK is in a position to take the lead in raising global awareness among healthcare professionals and the public of the dengue fever threat as Panadol, GSK's over-the-counter paracetamol brand, has a strong presence in regions where dengue fever is prevalent, notably Asia, Africa, the Middle East and Central and South America. We initiated and sponsored a dengue fever public awareness campaign in high-risk areas including the Caribbean and South-East Asia. We have worked in collaboration with organisations such as UNICEF and the Pan America Health Organization. We also engage with locally respected campaign ambassadors.

The campaigns increase awareness through television, radio and PR activities as well as roadside banners and posters in hospitals, public health centres, pharmacies and drugstores. Local media have picked up on these activities, helping to raise awareness further. Health professionals are targeted by the campaigns and provided with information that can help in diagnosis and treatment. Free Panadol samples are distributed in hospitals.

A campaign run in Costa Rica during 2006 contributed to a 68 per cent reduction in dengue fever cases as reported by the Board of Health. In 2007, when the campaign did not run, the number of cases increased by

110 per cent. In 2008, GSK activated the campaign again in collaboration with the Board of Health. By the end of 2008, the 'I save lives' campaign contributed to a 72 per cent reduction in dengue cases. Similarly the Panadol campaign contributed to decreases in South-East Asian dengue cases especially in Indonesia, where the dengue fever fatality rate dropped by 40 per cent in 2008 over the previous year. The campaign ran in Indonesia during 2009 and will continue in 2010 with activities that raise awareness with the public and provide training to healthcare professionals.

Raising awareness about immunisation in the US

Vaccines are crucial for disease prevention, but they are only effective if people have access to them and choose to be immunised. Adult immunisation is cost effective and is a good public health policy, but many adults in the US are not immunised, even though vaccines to prevent potentially serious diseases are available to them.

As part of our US healthcare initiative, the '[triple solution](#)', GSK is raising awareness among adults in the US about the importance of immunisation, where they can get vaccinated and what to be vaccinated for.

We are also reaching out to parents via our '[More than Medicine](#)' blog, designed to increase the objectivity of the online debate on childhood immunisations. We invited mothers who blog to visit our vaccine filling and packaging plant in Marietta, PA and engage in a general dialogue on immunisation. There were no discussions on specific vaccines which is in line with FDA regulation.

Improving community awareness in partnership with the Washington Redskins

In 2009 we launched a new partnership with National Football League team the Washington Redskins to help its fans improve their health. The initiative targets childhood obesity, cardiovascular disease in women, and breast and prostate cancer. A number of awareness-raising events were held at Redskins games throughout the 2009 season, including a specially themed 'Think-Pink' match to recognise breast cancer awareness month and a series of health screening events for US army veterans and their families on Veterans Day. We also sponsored a new Redskins Youth Fitness Zone to help boys and girls aged 8-14 combat obesity. Read more about the [veterans screening event](#).

› [Back to top](#)

Corporate Responsibility Report 2009

Treating ill health

Our medicines, vaccines and consumer healthcare products help to treat and prevent serious disease.

GSK medicines target diseases of the developed and developing worlds in the following areas:

- Anti-bacterials (antibiotics) and anti-malarials: infections, malaria
- Anti-virals: HIV/AIDS, herpes, hepatitis B, influenza
- Cardiovascular: heart failure, hypertension, deep vein thrombosis
- Central nervous system: migraine, epilepsy, anxiety, depression, Parkinson's disease, smoking cessation, anaesthesia, analgesia, anti-emetics
- Dermatology: eczema, dermatitis, psoriasis
- Metabolic: diabetes, osteoporosis, obesity
- Oncology: breast, cervical, lung and ovarian cancer, non-Hodgkins lymphoma, leukaemia, idiopathic thrombocytopaenic purpura
- Respiratory and immuno-inflammation: asthma and chronic obstructive pulmonary disease, rhinitis, post-operative ileus
- Urogenital: prostatic hypertrophy, over-active bladder

Read more about our [vaccines](#) which prevent serious diseases.

Paracetamol

Paracetamol is widely used as a low-cost medicine for treating adult and child pain and fever, and is listed as one of the World Health Organization's essential medicines.

GSK produces ten billion tablets each year of our over-the-counter paracetamol product, *Panadol*, which is available in more than 80 countries. This includes low- and middle-income countries, where we provide more affordable low-cost single-dose packs.

Medical guidelines across the globe recommend paracetamol, the medicine in *Panadol*, as the first-line oral painkiller for chronic diseases such as osteoarthritis, due to its efficacy, safety profile and cost-effectiveness. It is also a first-choice treatment for other conditions such as headache, backache and children's fever. WHO guidance on supportive care for those infected with the H1N1 'swine flu' virus strain has highlighted paracetamol as the antipyretic (fever reducer) of choice for flu symptom management. Read more about our response to [pandemic flu](#).

Paracetamol is the recommended treatment for the symptoms of dengue fever, a debilitating and life-threatening disease that is transmitted by mosquitoes in tropical and sub-tropical regions. More than 2.5 billion people are at risk for infection – two-fifths of the world's population – in over 100 countries. Read about our [efforts to increase awareness of dengue fever and correct treatment](#).

Our products help to improve health in a number of ways:

Our anti-retrovirals (ARVs) such as *Combivir* help patients to control the effects of HIV infection for many years. We sell our ARVs to the Least Developed Countries and to countries in sub-Saharan Africa at not-for-profit prices. Read more about our [responsible pricing in the developing world](#).

Many diseases such as diabetes are progressive and if patients do not receive the right treatment they can suffer severe complications. For example, every day in the US diabetes is the cause of an estimated 225 lower limb amputations, up to 66 cases of blindness, and 117 people experiencing kidney failure. *Avandia*, our diabetes treatment, helps patients to control their blood sugar.

Many of our medicines such as those for asthma and diabetes help patients with chronic diseases live full and productive lives. GSK preventative treatments for asthma such as *Seretide/Advair* control the symptoms of asthma and prevent asthma attacks.

We produce antibiotics that treat respiratory tract and other infections. We donate antibiotics to help [relief efforts in disaster areas](#).

Read about how we are improving [access to medicines](#).

Prevention, Intervention, Innovation: the Triple Solution

Healthcare costs in the US are a concern for patients, healthcare payers and the pharmaceutical industry alike. The increase in prevalence of many chronic diseases such as asthma, diabetes and heart disease is a major contributing factor. In 2006, expenditures in the US on healthcare exceeded \$2 trillion. Additionally, absence from work due to ill health can be a significant cost that often goes unrecognised.

We have worked with the government, employers and others in the US to find new ways to address the problem of chronic diseases while reducing healthcare costs through:

- Prevention – addressing the causes of chronic diseases, such as obesity and smoking, poor diet and lack of exercise
- Intervention – properly managing chronic diseases to prevent complications, avoid hospitalisation costs and reduce time away from work
- Innovation – developing new treatments for costly unmet medical needs such as Alzheimer's disease and stroke

For example, we have helped more than 200 employers in the public and private sectors across the US to create health management programmes that remove barriers to healthcare access, reduce healthcare costs and improve health. These programmes:

- Encourage employers to provide preventative services such as health screenings to workers
- Develop disease management programmes which help employees control their symptoms and stick to their treatment regimens
- Establish comprehensive wellness initiatives for obesity and smoking, for which we have leading products

Our work on the triple solution is closely connected to our [public policy advocacy on healthcare reform](#). We have launched a [website](#) with information on our approach, which encourages Americans to get involved in the healthcare debate.

› [Back to top](#)

› Home › Responsibility › Contribution to global health › **Research and development**

Corporate Responsibility Report 2009

Research and development

Despite advances in healthcare there are still many diseases for which there is no cure or for which treatments could be improved. Continued research and innovation is essential if we are to address these unmet medical needs.

In 2009, we spent £3.95 billion on R&D. Over 78 per cent of this expenditure was in pharmaceutical R&D with the remainder in vaccine research.

Our investment in R&D into new medicines and vaccines is at the core of our business. We are seeking to develop new treatments that can help many different patient groups. These treatments need to provide value over currently available treatments – both to patients and to payer.

We focus our efforts on areas where there is greatest need and where advances in science offer the best opportunities to discover new medicines. We use [emerging technologies in our research](#). While our own research teams apply their insight and expertise, we also welcome new science and ideas from outside GSK. To access diverse knowledge, we [form alliances with academia, NGOs, biotechnology firms, and other pharmaceutical companies](#).

We are committed to transparency in our R&D process and publicly disclose the outcomes of our clinical studies. Read more about this in the [Research practices section](#).

This section outlines GSK's [research activities in 2009](#) and our collaborations, partnerships and funding to help [advance scientific understanding](#).

› [Back to top](#)

› Home › Responsibility › Contribution to global health › Research and development

› [Research activities in 2009](#)

Corporate Responsibility Report 2009

Research activities in 2009

We focus our research on therapy areas where recent advances in science mean there are likely to be greater opportunities for finding new treatments.

We have nearly 150 prescription medicines and vaccines in clinical development, over 30 of which are in phase III development or registration.

Our early-stage pharmaceutical research activities are currently focused on:

- Biopharmaceuticals
- Immuno-inflammatory diseases
- Infectious diseases
- Metabolic pathways
- Neurosciences
- Oncology
- Ophthalmology
- Respiratory diseases

Our late-stage [pipeline](#) includes products targeting a range of diseases including many forms of cancer, infections, respiratory diseases, autoimmune disorders, metabolic and cardiovascular disease and neurological diseases.

Our research efforts continue to be guided by advances in science and the needs of patients. In 2009 we established three new research units, including:

- Tempero Pharmaceuticals, tasked with discovering a greater understanding of signalling systems in inflammation and autoimmune diseases and the opportunities these offer for new medicines
- An Epigenetics Discovery Performance Unit that looks at the potential for new treatments based on modification of genetic signalling
- A Regenerative Medicines Discovery Performance Unit, to maximise the potential of [stem cell science](#)

GSK is committed to meeting the needs of patients wherever they live. In 2009, we launched a [new research unit](#) to help shape our product portfolio to better suit the needs of patients in GSK's Emerging Markets and Asia Pacific regions.

We also celebrated the second year of our R&D facility in China (see feature box below).

Entirely new compounds and vaccines constitute 80 per cent of the pipeline. For the past three years GSK has had more entirely new compounds, or new chemical entities, approved by the US Food and Drug Administration than any other company.

In 2009, 12 GSK products were approved, including:

- *Arzerra* (ofatumumab) for chronic lymphocytic leukemia

- *Pandemrix*, our [H1N1 pandemic flu vaccine](#)
- *Synflorix*, for streptococcus pneumoniae disease prophylaxis in infants and children
- *Votrient* (pazopanib) for the treatment of a advanced renal cell carcinoma

Prix Galien awarded for serious blood disorder treatment *Promacta*

We won the 2009 US Prix Galien 'best biotechnology product' award for *Promacta* (eltrombopag), our recently launched treatment for a serious blood disorder. The award recognises *Promacta*'s ability to treat thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenic purpura (ITP).

The Prix Galien award is one of the industry's highest accolades for pharmaceutical R&D. The award recognises the technical, scientific and clinical research skills necessary to develop innovative medicines which make a significant impact on improving patient care and addressing unmet need.

The treatment was also highlighted as one of the Top 10 Medical Innovations for 2010 at the Cleveland Clinic's 2009 Medical Innovations Summit.

We made 11 submissions for new products and product line extensions in 2009. Over the next 18 months, we have the potential to launch six brand new medicines and vaccines, including *Benlysta*, the first potential treatment for lupus in 50 years.

We also created a new leading specialist dermatology business through the acquisition of Stiefel Laboratories. The new business has projects in late-stage development across a wide variety of dermatological conditions such as acne, dermatoses and fungal infection.

Read more about our pipeline progress and product approvals in our [Annual Report](#).

R&D in China

Our Chinese R&D centre, opened in 2007, now has 280 employees and is housed in state-of-the-art facilities in Shanghai. The centre is investigating neurodegenerative disorders such as Alzheimer's disease, Parkinson's disease and multiple sclerosis.

The centre is already progressing an early pipeline from target validation to candidate selection. We intend to develop the centre into our lead facility for global discovery and development activities in neurodegenerative disorders. We are also building a comprehensive collection of compounds isolated from traditional Chinese medicinal sources. This effort is being carried out with Chinese academic institutions.

The costs of conducting research in China can be lower than in other markets. However, lower costs are not the primary reason for opening the facility. China offers a huge pool of scientific talent – our 2008 recruitment roadshow reached over 1,200 PhD graduates at ten top universities.

Our R&D in China is conducted to GSK's global quality and ethical standards. All our R&D policies and monitoring procedures are global and apply to our operations in China.

Read more about how we ensure [high ethical standards in all of our R&D activity](#).

› [Back to top](#)

› Home › Responsibility › Contribution to global health › Research and development
› [Contributing to scientific understanding](#)

Corporate Responsibility Report 2009

Contributing to scientific understanding

GSK has a large pool of scientists, but we recognise that we do not have a monopoly on research or on the best science.

We are committed to accelerating the discovery of new medicines and vaccines by collaborating with external partners and by being more open to sharing our scientific understanding. We now have 47 external partner collaborations underway to complement our 36 internal Discovery Performance Units.

We also fund basic medical research conducted outside GSK to increase understanding of the human body and the impact of disease. This is frequently the foundation for future advances in the diagnosis, treatment and prevention of disease.

Our R&D policies are global and we apply the same high standards wherever we operate. We only collaborate with organisations whose principles are aligned with those of GSK. For research that is conducted as part of a collaboration, we raise awareness of our policies at the beginning of the collaboration and include clauses in the collaboration agreement requiring compliance with our principles.

Read more about how we ensure high ethical standards in [our R&D activity](#).

Opening new dialogues

We are working in a spirit of greater collaboration, and as part of this we are looking at making new alliances.

- We are supporting research into neglected tropical diseases by opening up our Tres Cantos R&D site to external scientists and by establishing a knowledge pool allowing others to access our intellectual property to develop new treatments for the developing world. Read more about the [knowledge pool](#)
- In 2009 we announced, in alliance with the UK Government, the Wellcome Trust and the East of England Development Agency, the creation of a biotechnology science park located at GSK's R&D site at Stevenage in the UK. The project aims to create a hub for innovation in life sciences research. Companies located on the park will have shared access to specialist skills, equipment and expertise to simulate new innovation in drug development
- GSK is partnering with the Wellcome Trust in a joint £4.1 million investment to generate 'chemical probes' for 25 proteins involved in epigenetic signalling and to make them available to other researchers, without restriction. This public-private partnership is being led by the Structural Genomics Consortium, and involves the National Institutes of Health's Chemical Genomics Centre in Washington, US, and the University of Oxford. The initiative could offer a new model for future interactions between academia and industry

Collaborating to accelerate drug development

- In November 2009, GSK and Pfizer jointly launched ViiV Healthcare, a major new collaboration to accelerate development of vaccines and treatments for HIV/AIDS. Read more about [ViiV Healthcare](#).

GSK is involved in the Innovative Medicines Initiative (IMI), a €2 billion collaborative research programme founded by the European Commission and European pharmaceutical industry. The IMI brings together the large and small biopharmaceutical and healthcare companies, academia, regulators and patient groups with the aim of removing barriers to the discovery and development of new medicines. Results of collaborations will be widely shared so that the broader research community can benefit from the

knowledge gained. GSK is involved in 12 projects funded by the IMI that focus on diverse topics. GSK is the coordinator of the IMI project aimed at developing tools to accelerate drug discovery in Alzheimer's disease. GSK is also participating in research projects in a range of areas including oncology, infectious diseases, electronic health records, and pharmacokinetic modelling that will be funded under the second wave of IMI projects

- GSK has been working with the PATH Malaria Vaccine Initiative (MVI) since 2001 to develop the paediatric vaccine against malaria, RTS,S. In 2008 the partnership announced study results which showed that RTS,S provides both infants and young children with significant protection against malaria. Phase III studies started in May 2009 and will run in seven countries across Africa. Read more about [vaccines for the developing world](#)

New specialist unit to research and develop medicines for rare diseases

In February 2010, we announced the formation of a new standalone unit to research and develop medicines for rare diseases, defined in Europe as diseases that affect fewer than one in 2,000 people. ¹

Over 5,500 rare diseases have been identified¹, yet treatments are available for only about ten per cent of these conditions². Despite the rarity of each condition, the number of diseases means that between six and eight per cent of the population³ may be affected by a rare disease. Many are genetic in origin, start in childhood and cause lifelong debility and premature death.

The new unit will seek to build on existing capabilities and partnerships and establish further in-licensing opportunities. In 2009, GSK announced two collaborations with companies, Prosensa and JCR Pharmaceutica, involved in researching and developing medicines for rare diseases.

The alliance with Prosensa focuses on developing nucleic acid based therapeutics intended to treat specific, but different, subpopulations of patients suffering from Duchenne Muscular Dystrophy (DMD).

As part of the agreement with JCR Pharmaceuticals, a Japanese developer and manufacturer of bioactive products, GSK has obtained global rights to a number of enzyme replacement therapies that could, upon approval, be used to treat orphan diseases such as Hunter syndrome, Fabry disease and Gaucher disease.

The entry into this new therapeutic area forms part of GSK's strategy to deliver more products of value and improve returns in R&D through a focus on areas with a higher probability of success. The risk associated with product discovery and development in rare diseases is generally lower than other disease areas as disease definitions are very clear and clinical trials tend to be small with robust endpoints.

1. www.orpha.net; portal for rare diseases and orphan drugs
2. www.fda.gov; analysis of approved therapies (249 in the US since 1983) vs. known rare diseases
3. 'Rare Diseases: Understanding this Public Health Priority.' European Organisation for Rare Diseases, November 2005

Patient safety

- We are collaborating with others to improve the safe use of medicines by patients and our work includes co-chairing the Serious Adverse Event Consortium's (SAEC) scientific management committee. Read more about our work with the [SAEC](#) which aims to improve patient safety through genetic research
- Being the industry lead for the Innovative Medicines Initiative's patient safety project which aims to develop methodologies to enhance assessment of benefit-risk profile of new medicines
- We are a founding member of the UK's public private collaborations Stem Cells for Safer Medicines. This organisation is investigating the potential for human stem cells to screen potential new medicines for safety and toxicology

Read more about [patient safety](#) at GSK.

Academic collaborations

We invest in research capabilities at universities, fund leading-edge academic research projects and support science students. We provided support of more than £21 million through alliances with academic institutions in 2009.

Our support benefits academic institutions through increased funding, technology transfer and access to our research facilities and expertise. It contributes to better scientific understanding and capability in the countries where we operate. It benefits GSK by enabling us to tap into R&D expertise and activity outside the company and expands our potential recruitment pool of better trained scientists.

Our academic collaborations in 2009 included:

- A newly launched £2 million, two year project with the Wellcome Trust to develop an antibiotic to treat methicillin-resistant *Staphylococcus aureus* (MRSA). Financed through the Wellcome Trust seed funding initiative, the GSK-Wellcome Trust research programme will use GSK's knowledge of structure-activity relationships for this novel class of antibacterial molecules
- In partnership with academics from the universities of London, Exeter and King's College, securing £1.7 million of grants from the Engineering and Physical Sciences Research Council (EPSRC) to develop systems to deliver drugs across the blood brain barrier, which would allow better treatment of diseases affecting the brain such as epilepsy and schizophrenia
- Two awards totalling £1 million have been given by the Medical Research Council to GSK scientists at the Hammersmith Hospital Clinical Imaging Centre to provide three-year training programmes in radiochemistry for brain imaging and for research to develop new ways of modelling pharmacological interactions in the brain
- A partnership with geneticists from Duke University Medical Center, leading to the discovery of two new genes associated with chronic obstructive pulmonary disease (COPD), increasing understanding of the genetic risk factors of this respiratory disease
- A new partnership with the University of Washington which will apply new statistical methods to rapidly analyse large sets of genetic data and predict responses to new therapies by identifying genes that influence drug response
- A collaboration between University College London and our Academic Discovery Performance Unit (DPU) to develop a new treatment for amyloidosis, a rare and potentially fatal condition. The Academic DPU is a new initiative to combine the best academic thinking with GSK's industry expertise

› [Back to top](#)

Corporate Responsibility Report 2009

Q&As

Here we respond to questions raised by our stakeholders.

Is your goal to cure disease or to find treatments for ongoing, chronic use?

Ideally we want to cure disease. Our antibiotics help to treat diseases caused by bacterial infection and our anti-parasitic medicines help prevent and treat prevalent diseases such as lymphatic filariasis and malaria.

Unfortunately, there is no known cure for most diseases. Our medicines help reduce symptoms and may need to be taken for long periods. These medicines are still valuable because they may enable the patient to have a more normal lifestyle, for example remaining in work or looking after their family. In many cases we are continuing research to find a cure.

Ideally we want to prevent a disease from occurring in the first place, which is where vaccines have an important role.

What factors do you consider when prioritising your R&D efforts?

There are three main interrelated factors – science, patient need and the value a potential new medicine or therapy can add compared to any existing treatment options.

We assess scientific opportunities to determine how advances in scientific and disease understanding may lead to innovative new ways to treat or prevent disease. We have used the outcome of a recent systematic Therapy Area Review looking at the scientific understanding in 17 therapy areas to refocus our research effort. We continually evaluate the scientific information we obtain on our compounds to help us predict whether they can be developed into effective and well-tolerated medicines.

Assessing patient need is fundamental to R&D at GSK. This ranges from looking for medicines that will treat diseases for which there are no current effective treatments, to the development of medicines that improve on existing treatments in terms of safety, efficacy or ease of use.

Our assessment of potential new treatments also recognises factors such as: how our product will provide advantages over others that are available; how many patients could benefit from the new therapy; and the range of conditions it may be suitable for treating.

The better able we are to meet patient needs, the more likely it is that a product will be seen to provide value in the provision of healthcare. However, it is not always possible to achieve a return on investment, for example when developing treatments for diseases that are prevalent in the developing world. In some cases, where a return on investment is limited but patient need is high, we may seek ways to [share the costs and risks associated with drug development](#).

Are you researching drugs to treat serious diseases?

Our pipeline and product range includes products against most of the major causes of mortality and morbidity (disease).

Our product launches in 2009 included *Arzerra* (ofatumumab) for treatment of chronic lymphocytic leukemia, *Pandemrix*, our [H1N1 pandemic flu vaccine](#), *Synflorix* for Streptococcus pneumoniae disease prophylaxis in infants and children, and *Votrient* (pazopanib) for advanced renal cell carcinoma. Our top-selling products in 2009 treat asthma and chronic obstructive pulmonary disease, diabetes, herpes and influenza.

Our vaccines portfolio includes vaccines to prevent influenza, hepatitis, rotavirus and human papillomavirus infection which can cause cervical cancer. We also make vaccines to prevent many childhood illnesses such as measles and rubella.

How do you measure R&D productivity?

The ultimate measure of our productivity is the delivery of new medicines to meet patients' needs. In 2009 GSK received 12 product approvals and completed 11 new filings. In the last three years GSK has obtained more FDA approvals for NMEs and vaccines than any other company. This delivery is set against a continued goal of maintaining around 30 assets in our late-stage pipeline. However, given that research and development can take longer than ten years, we measure productivity in a number of ways during the R&D process, including:

- The number of compounds in our pipeline, and the emerging risks and benefits of these compounds
- Our success at progressing compounds in our pipeline through clinical trial phases I, II and III and to market registration
- The speed of progress through our pipeline, which is an indication of the efficiency of our R&D processes

Is it true that research productivity is falling in large pharmaceutical companies? How is GSK managing this?

Investment in pharmaceutical R&D has risen while the number of new medicines gaining regulatory approval has remained relatively constant or decreased. We believe there are many reasons for this, including:

- An increasing focus on R&D into chronic degenerative diseases such as Alzheimer's which are scientifically challenging, require longer clinical trials and have increased failure rates
- Significant investment by industry in new technologies which will help deliver innovative medicines in the longer term, for example systems biology tools, genome-wide association scans, new pre-clinical models and sophisticated imaging equipment
- More extensive requirements from regulators and healthcare payers, including the need to conduct larger clinical studies to evaluate the long-term outcome of treatment with a medicine, as well as higher hurdles for approval
- The effectiveness of existing treatments for some conditions, so that demonstrating improved safety or efficacy of a new treatment is increasingly difficult

Our approach is to focus on meeting patients' needs and increasing the effectiveness and efficiency of R&D. For example, we have 36 Discovery Performance Units (DPUs) within our established Centres of Excellence for Drug Discovery. DPUs are small groups of scientists focused on a specific disease or molecular pathway, and are structured to be as efficient as possible. These organisations combine the entrepreneurial approach of a small company with the resources and reach of a larger organisation.

We are committed to accelerating the discovery of new medicines and vaccines by collaborating with external partners and by being more open to sharing our scientific understanding. We now have 47 external partner collaborations underway to complement our 36 internal DPUs.

› [Back to top](#)

Corporate Responsibility Report 2009

Access to medicines

Providing access to healthcare is one of the world's most pressing social challenges.

Every year millions of the world's poorest people die from curable or preventable infectious diseases or suffer unnecessary ill health because they do not have access to basic healthcare services, including essential medicines. The cost of healthcare can also be a barrier to access for patients in the developed world, particularly in the US where many people do not have [healthcare insurance](#).

We want to increase access to our medicines and vaccines in all countries. Not only do we believe it is the right thing to do but it will contribute to our business success. By striving to meet society's healthcare needs we build trust in our business, which helps to safeguard our licence to operate in the long term.

The barriers to access

There are many complex factors that hamper access to medicines in developing countries. Many people living in poverty do not have access to enough food or clean water or to a functioning healthcare system. Adequate medicines for prevalent diseases may be lacking because of a range of issues including the limited prospect of a return on R&D investment for neglected diseases. Added to this there is no unified registration system for medicines which makes the registration process costly, complex and time consuming, and individual regulatory authorities do not have sufficient capacity to deal effectively with numerous and complex product registrations.

In many developing countries the distribution network for medicines is weak and there is a lack of basic infrastructure, hospitals, clinics and healthcare professionals. These barriers are often compounded by insufficient political will for action resulting in inadequate funding across all aspects of the healthcare system. In middle-income countries the health system may be more developed, but large differences in income levels can prevent many people accessing healthcare.

However, these problems must not be an excuse for inaction; rather they should indicate where action is most needed.

Breaking down the barriers

Despite significant progress over the last decade, for example in the fight against AIDS, we know there is more we can do to increase access. While the complexity of the access challenge means that we cannot address the issue by acting alone, we can prioritise areas where we will make the most difference through our core business activities, skills and resources. In particular this means initiatives to [improve affordability](#) and to conduct and encourage more investment in R&D for diseases of the developing world.

In a speech at Harvard Medical School in February 2009, GSK's CEO Andrew Witty outlined our access strategy and announced a number of new initiatives which are reported on in this CR Report. In January 2010 Andrew gave a speech at the Council on Foreign Relations (CFR) in New York in which he outlined progress achieved on the commitments contained in the Harvard speech and expanded on GSK's approach to breaking down the barriers to innovation and access to medicines in the developing world.

The CFR speech addressed four areas:

- Establishing an independent open lab for research on neglected tropical diseases
- Making publicly available the information on more than 13,500 compounds from our compound library. These were identified through screening for activity against the malaria parasite
- Launch of new collaborations to further share intellectual property and know-how and accelerate the

delivery of new medicines for neglected tropical diseases

- Creating a sustainable pricing model for our malaria candidate vaccine

Further information about each of these areas can be found in this section.

› [Back to top](#)

Corporate Responsibility Report 2009

Our approach

We are committed to playing our full part in improving access to medicines.

Abbas Hussain, President of GSK's Emerging Markets region, leads our access efforts for developing countries. These are discussed and reviewed by the Corporate Executive Team, GSK's most senior executive management team, and by the Corporate Responsibility Committee of the Board.

Access to medicines is a global problem that requires global commitment. But barriers to access vary significantly between individual countries, depending on poverty and income levels, coverage and quality of healthcare infrastructure and political commitment and resources allocated to healthcare. We tailor our approach and focus on where, as a research-based pharmaceutical company, we can make the most difference. On this page we explain our approach to increasing access in the Least Developed Countries, middle-income countries and the developed world.

Extending access in developing countries



Most countries suffer from inequalities in income distribution and access to healthcare. These inequalities are often particularly pronounced in developing countries. While both infectious diseases and non-communicable diseases are present in all sectors of society, the scale of their impact on the overall disease burden in different segments can vary, as illustrated above.

In the past, the research-based pharmaceutical industry tended to focus on the higher income sectors of society in developing countries which were able to afford healthcare provision. To achieve growth in our business and to extend access to medicines to less well off sectors of society we need to improve affordability of medicines and develop a product range which is suited to all sectors of society.

To achieve this we are:

- [pursuing a number of pricing strategies](#)
- [refocusing our R&D activities](#)
- seeking [innovative partnerships](#) to try and reach people who would otherwise not have access to our products

Examples of these strategies are covered in this report section.

Partnerships that combine the resources and expertise of companies, governments, international agencies, academic institutions, NGOs and communities play a key role in all areas of our approach. We know that through partnership we can achieve more for patients than we can alone.

What do we mean by developing countries?

Deciding how to classify countries when looking at access to medicines policies is an imperfect art rather than a science. The term 'developing country' is used very broadly and can include the world's poorest countries as well as some of the world's largest economies such as Brazil, China, India and Russia.

When formulating our pricing and other access policies we tend to use three groupings in which there are some overlaps – the UN's list of 49 Least Developed Countries (LDCs)¹; the countries of sub-Saharan Africa (SSA); and middle-income countries.

LDCs and the countries of sub-Saharan Africa are well defined and fairly stable. Other international organisations also refer to LDCs, including the WTO and, in particular, the Doha Declaration on the TRIPS Agreement and Public Health. Generally, the LDCs and the countries of SSA are also where either the ability to pay is least, or where the impact of the HIV/AIDS pandemic is most acutely felt.

For middle-income countries we normally use the World Bank² categories – lower-middle income and upper-middle income. There is some overlap between the World Bank middle-income countries and the LDC and SSA groupings. For example, Angola, Botswana, Cameroon, Gabon, Kiribati, Namibia, Nigeria and South Africa are all classed as middle-income by the World Bank.

GSK uses the term 'developing countries' to include LDCs, SSA and middle-income countries.

Other definitions of developing countries used by some organisations include all countries outside of the World Bank High Income classification² or all non-OECD countries³. We do not strictly adhere to the World Bank classifications as this would exclude Equatorial Guinea and many Caribbean Islands from our access policies. A further complication with the World Bank classifications is that they are revised annually and so basing policies on this ranking could lead to country eligibility changing from year to year. If we used the non-OECD countries definition this would rule out Mexico and may soon exclude countries such as Chile, Russia, Brazil, China, India, Indonesia and South Africa which are likely to become OECD members.

When we talk about middle-income countries we are normally referring to the World Bank classifications, but excluding those countries that are LDCs or in SSA and some high-income countries such as Equatorial Guinea and many Caribbean Islands.

Least Developed Countries (LDCs)

The challenge of increasing access to medicines is particularly acute in the world's poorest countries as defined by the UN¹. In these regions our approach includes:

- **Research** – we invest in R&D for new medicines and vaccines to prevent and treat neglected tropical diseases. We are encouraging innovation outside GSK through our [Knowledge Pool](#) and by opening up our [Tres Cantos research centre](#)
- **Pricing** – we cap the prices of our patented medicines in LDCs; offer not-for-profit prices for HIV/AIDS medicines; and adopt tiered pricing for our vaccines
- **Partnerships** – it is important that we work with others and we have a range of partnerships that extend the reach of our activities, for example we grant voluntary licences for generic versions of our anti-retrovirals and have signed an agreement with Aspen to expand our portfolio in sub-Saharan Africa
- **Healthcare infrastructure** – we are investing 20 per cent of our profits from medicines in LDCs back into projects that [strengthen healthcare infrastructure](#) in those countries
- **Community investment** – we donate money and expertise to support disease prevention and community healthcare. Our reinvestment of profits and community investment programmes are covered in detail in the [Community investment section](#) of this report

In July 2010 we announced the formation of a new operating unit dedicated to expanding access to medicines for people living in Least Developed Countries (LDCs).

The new Developing Countries and Market Access group will integrate all our existing business in LDCs into one business unit, which will provide a focus on strategic approaches to expand access to medicines for people living in these countries.

The unit is another important step to ensuring access to medicines is integral to the way we do business.

Access to Medicines Index

GSK was ranked top in the 2008 Access to Medicines Index, which rated companies on their performance according to eight criteria: management, influence, research and development, patenting, capacity, pricing, drug donations and philanthropy. Publication of the next Access to Medicines Index is expected in June 2010.

Update September 2010 (2 of 2)

GSK was ranked top in the Access to Medicine Index for the second successive time in June 2010. The Index is produced by the Access to Medicines Foundation and financial analysts RiskMetrics. It aims to supply pharmaceutical companies, investors, governments, non-governmental organisations and other stakeholders with independent, impartial and reliable information on pharmaceutical companies' efforts to improve global access to medicine.

In 2010, the Index assessed 20 R&D-based pharmaceutical companies, and seven generics companies, on their performance against seven criteria: management, influence, R&D, pricing, patenting, capability and philanthropy. GSK was ranked highest in six of the seven categories.

GSK welcomes the acknowledgment the ATM Index report gives GSK and industry efforts and we are pleased that the progress achieved in recent years has been recognised. Clearly, there is still more that can be done and we will consider the recommendations in the ATM Index carefully and continue to look for areas where we can make the biggest difference.

Middle-income countries

Middle-income countries (MICs), as defined by the World Bank², such as Brazil, China, Thailand and Indonesia have a large and affluent middle class, offering significant business opportunities for GSK. But many MICs also have large numbers of people living in extreme poverty and healthcare demands often outstrip available resources.

MICs represent increasingly important customers for our industry and also present significant access challenges. As we expand in these regions we believe our efforts will only be successful if they deliver greater access to medicines for low-income groups, not just the better off segments of society.

This includes making our medicines and vaccines more affordable, developing products that address each country's health needs and using the right channels to reach more people in need. Our approach includes:

- **Research** – we invest in R&D for new medicines and vaccines to prevent and treat neglected tropical diseases. We are encouraging innovation outside GSK through our Knowledge Pool and by opening up our Tres Cantos research centre
- **Pricing** – we are developing a flexible pricing strategy that aims to make medicines affordable for more segments of society
- **In-licensing, joint ventures and acquisitions** – we are expanding our portfolio in middle-income countries as well as transferring manufacturing and research expertise
- **Community investment** – we also support community programmes in a number of middle-income countries

Developed countries

Access to medicines is not only an issue for the developing world. Even in developed countries some patients cannot afford the medicines they need.

We are adopting a range of flexible pricing models that reflect our commitment to work with governments and other stakeholders to support efforts to deliver our medicines and vaccines to as many people as possible.

¹ [LDCs](#)

² [World Bank classification](#)

³ [OECD countries](#)

› [Back to top](#)

› Home › Responsibility › Access to medicines › Our approach
 › **Improving access in developing countries**

Corporate Responsibility Report 2009

Improving access in developing countries

Improving access to healthcare in developing countries (least developed and middle-income countries) requires a holistic approach embracing prevention and treatment and efforts to fundamentally strengthen health systems. All stakeholders need to contribute.

Pharmaceutical companies, including GSK, must make their medicines as **affordable as possible** to people in the world's poorest communities, in a sustainable manner. We must invest in **research into diseases of the developing world** because new prevention tools and treatments are urgently needed. We must also work with other stakeholders to seek innovative solutions to delivering our medicines and vaccines to the people who need them most.

Wealthy nations should continue to be generous in their development assistance and give more where they can. Welcome new funding is coming from the Global Fund to Fight AIDS, TB and Malaria, the Bill & Melinda Gates Foundation, PEPFAR (The US President's Emergency Plan for Aids Relief), UNITAID and others. However, funds are still inadequate and need to be more predictable and sustainable to fund research, strengthen health systems, purchase medicines and vaccines and support disease prevention. This is a point we stress in our advocacy efforts with the G8 and other developed countries.

Developing countries should show genuine political commitment to prioritising healthcare in national budgets, addressing stigma and improving affordability by removing import tariffs on medicines. Middle-income countries can support a tiered pricing approach, based partly on ability to pay, by not seeking the lowest prices that are offered to the world's poorest countries. It is only by making a return in better off countries that we are able to offer the lowest prices to the poorest countries. This is another key message in our advocacy efforts.

New commitments in 2009

In February 2009 our CEO Andrew Witty delivered a speech titled 'Big Pharma as a catalyst for change' in which he reaffirmed GSK's ongoing commitment to improving access to medicines. In particular he committed to expanding our efforts to improve health in the Least Developed Countries. In summary he announced that we are:

- Seeking more partnerships and opening the doors of our diseases of the developing world research centre in Tres Cantos, Spain
- Exploring a more flexible approach to intellectual property rights to stimulate research into medicines for the Least Developed Countries (LDCs) by creating a proprietary knowledge pool for neglected tropical diseases. We have placed approximately 80 patent families (over 500 granted patents and over 300 pending applications) in a pool to help others to develop new medicines for neglected diseases
- Reducing prices for our patented medicines in the LDCs so they are no higher than 25 per cent of the developed world price, as long as this covers the cost of goods. We made price reductions from April 2009 for 11 products across the LDCs with an average reduction of 45 per cent
- Looking at how we can move from being a supplier of drugs to being a partner in delivering healthcare. Working with partners such as NGOs, we will reinvest 20 per cent of the profit we make from selling medicines in LDCs to help strengthen healthcare infrastructure in these countries. Our sales in LDCs are relatively low so this profit is limited; initially this funding amounts to around £1-2 million a year.

In July 2009 we announced a number of new initiatives to tackle HIV/AIDS in the developing world. These included:

- A new Positive Action for Children Fund of £50 million over ten years to help prevent mother-to-child transmission of HIV and to support orphans and vulnerable children
- £10 million seed funding to support a public-private partnership into research and development of new HIV/AIDS medicines for children
- A new commitment to collaborate with other companies to develop fixed-dosed combinations of currently available HIV treatments
- Royalty-free voluntary licences for the manufacture of abacavir

In November 2009 we launched ViiV Healthcare, a new specialist company dedicated to the discovery and delivery of treatments for HIV. This is a collaboration between GSK and Pfizer. We believe that by combining resources and expertise we will accomplish more for the treatment of HIV globally than either company can achieve on its own. ViiV Healthcare will deliver on the HIV commitments announced in July.

Read more about our [new approach to HIV](#)

› [Back to top](#)

Corporate Responsibility Report 2009

Our approach to intellectual property

The role that intellectual property (IP) rights, such as patents, play in access to medicines continues to be the subject of discussion and contention. For products where a viable market opportunity exists, patents and other IP rights play a vital role in encouraging the innovation needed to develop new treatments for many of the most serious and life-threatening diseases. Without the limited period of exclusivity that patents provide, our multi-billion R&D investment would not be commercially viable. For diseases of the developing world where no commercial opportunity exists, and particularly for neglected tropical diseases, new approaches are required such as product development [public-private partnerships](#) such as the Medicines for Malaria Venture and the TB Alliance.

We believe that concerns about IP as a barrier to access in the developing world are sometimes overstated and risk diverting understanding and efforts away from the key access problems in the developing world: lack of healthcare infrastructure and resources. However, we continue to explore approaches to being more flexible with our IP, where we believe this can help tackle the healthcare crisis in developing countries. For example we grant [voluntary licences](#) to allow local companies to manufacture our HIV/AIDS medicines where they are needed most. We have also created a [Knowledge Pool](#) for neglected tropical diseases in Least Developed Countries which we hope will stimulate research into new treatments for these diseases.

It is vital that all countries provide an environment that encourages innovation through support for intellectual property (IP) rights, and avoid measures such as widespread compulsory licensing which can remove the incentives for innovation and investment in R&D. A more supportive environment for IP generally will encourage companies to be more flexible with their IP to stimulate research into treatments for neglected diseases.

For more about our position on [intellectual property \(IP\) rights](#).

› [Back to top](#)

Corporate Responsibility Report 2009

A new approach to HIV

Over 33 million people worldwide are living with HIV. Two-thirds of these, and over 90 per cent of all new infections among children, are in sub-Saharan Africa. Global efforts to tackle AIDS must be maintained and reinforced and new HIV treatments are urgently needed to counter problems such as drug resistance.

In April 2009, in partnership with Pfizer, we announced our plans to create a new specialist company solely focused on the research, development and commercialisation of HIV medicines. ViiV Healthcare was launched in November 2009.

We expect ViiV Healthcare to bring commercial benefits to GSK and Pfizer and reach more patients and accomplish more for the treatment of HIV than either company's businesses could have achieved alone. Improving access to HIV medicines for everyone will be a priority for the new business. The creation of the new company is an example of how we are developing **new partnerships and business models** that benefit global health.

ViiV Healthcare shares GSK's commitment to increase access to medicines. It will continue to offer HIV medicines at **not-for-profit prices** and facilitate new **voluntary licences** in the world's poorest countries.

Our long-standing **Positive Action** programme, established by GSK in 1992, focuses on prevention of HIV and tackling HIV-related stigma and discrimination. Positive Action will be at the core of ViiV Healthcare's partnership programmes, supporting local communities impacted by HIV/AIDS globally.

ViiV Healthcare has a core objective to address the lack of treatments and formulations for children living with HIV, a significant unmet medical need. It will manage our new commitments, announced in 2009, to improve research, development, and access to medicines for children in sub-Saharan Africa and to support healthcare for people living with HIV and AIDS. These are:

- A new Positive Action for Children Fund of £50 million over ten years to help prevent mother-to-child transmission of HIV and to support orphans and vulnerable children
- £10 million seed funding to support a public-private partnership into research and development of new HIV/AIDS medicines for children
- A new commitment to collaborate with other companies to develop fixed-dosed combinations of currently available HIV treatments
- Royalty-free voluntary licences for the manufacture of abacavir

Update September 2010

Positive Action for Children Fund: first grants awarded

In June 2010, ViiV Healthcare awarded the first grants from the Positive Action for Children Fund. The grants are worth £3.6 million and will be used to support 12 projects focused on preventing HIV transmission from mother-to-child and supporting young people with HIV in Africa and India.

New paediatric HIV partnerships announced

ViiV Healthcare has announced two new partnerships designed to improve the management of paediatric HIV worldwide.

The company has committed US\$2 million over two years to support the Elizabeth Glaser Pediatric AIDS Foundation, which works to increase early detection of HIV and improve access to lifesaving care and treatment for infants and children with HIV/AIDS in Africa.

In Asia, ViiV Healthcare will contribute US\$2 million to a two-year partnership with TREAT Asia, a Bangkok-based programme run by amfAR, The Foundation for AIDS Research. Its support will help to strengthen clinical research programmes and increase access to treatment for infants and children with HIV/AIDS.

Accelerating Access Initiative

The Accelerating Access Initiative (AAI) is a public-private partnership to accelerate access to care and treatment for HIV/AIDS. GSK was a founder member of the AAI, formed in May 2000. ViiV Healthcare has now assumed GSK's membership of the AAI. The AAI is a partnership between UNAIDS, the WHO, the World Bank, UNICEF and UNFPA, and eight research-based pharmaceutical companies - Abbott Laboratories, Boehringer Ingelheim, Bristol-Myers Squibb, Gilead Sciences, Johnson & Johnson, Merck and Co Inc, Roche and ViiV Healthcare.

The objectives of the AAI are to:

- Accelerate sustained access and increase use of appropriate, good quality interventions for the prevention/treatment of HIV/AIDS
- Ensure that care and treatment reach significantly greater numbers of people in need, through new alliances involving committed governments, private industry, the UN, development assistance agencies, non-governmental organisations and people living with HIV/AIDS

Although impossible to quantify directly, the efforts of the AAI companies and their partners have made a significant contribution to the increase in the number of people receiving anti-retrovirals in low- and middle-income countries. According to the latest data from UNAIDS more than four million people had access to HIV treatment at the end of 2008, a ten-fold increase in five years¹.

¹ [UNAIDS global AIDS epidemic factsheet](#)

› [Back to top](#)

› Home › Responsibility › Access to medicines › A new approach to HIV
› [More about ViiV Healthcare](#)

Corporate Responsibility Report 2009

More about ViiV Healthcare

ViiV Healthcare will invest in research and development of innovative HIV treatments and formulations that improve adherence to treatment and help tackle drug resistance. The company will invest in R&D for HIV medicines conducted by GSK and Pfizer and will have exclusive rights of first negotiation in relation to any new HIV-related medicine developed by either company. GSK will continue R&D relating to HIV vaccines.

Facts about the new company

- Broad portfolio of ten marketed products
- Industry-leading pipeline with seven innovative potential medicines
- 19 per cent share of the worldwide HIV market
- Equity split of 85 per cent GSK and 15 per cent Pfizer

ViiV Healthcare's pipeline includes seven innovative and targeted medicines, including five compounds in phase II development. Including early stage research projects, altogether ViiV Healthcare has 17 molecules to develop as possible new HIV treatments and ViiV Healthcare will continue to invest in early-stage research and discovery of HIV medicines.

As well as its own R&D, ViiV Healthcare will form strategic partnerships and licensing arrangements with other organisations.

The company's portfolio of ten marketed products including *Combivir*, *Kivexa* and *Selzentry/Celsentri*, which generated sales of around £1.5 billion in 2009, will provide financial stability and support its investment in R&D.

UNITAID patent pool for HIV/AIDS medicines

During 2009 UNITAID continued its work to develop a patent pool for HIV/AIDS medicines¹. We share UNITAID's commitment to meeting the unmet medical needs relating to HIV. Both GSK and ViiV have held a number of meetings with UNITAID, and ViiV Healthcare remains in discussion with UNITAID on the details of its proposal.

GSK participated in UNITAID's event at the World Health Assembly in May 2009 and met with UNITAID in July and September. Also in September, GSK met with the consultancy that UNITAID has appointed to develop an implementation plan and business models for the pool. In November ViiV Healthcare met again with UNITAID and its consultancy.

In December 2009 UNITAID published its implementation plan for the pool and will be developing the legal framework for the pool during 2010. ViiV Healthcare is working actively with UNITAID in this process. In the meantime, ViiV Healthcare will continue to seek ways to expand access to its products through its widespread licensing approach, not-for-profit and preferential pricing, and the intensified focus on R&D for paediatric anti-retrovirals (ARVs).

ViiV Healthcare will lead on discussions with UNITAID as its proposals develop and any key developments will be communicated by [ViiV Healthcare](#).

¹ [UNITAID - The Medicines Patent Pool Initiative](#)

› [Back to top](#)

Corporate Responsibility Report 2009

HIV/AIDS research

On behalf of ViiV Healthcare, GSK is committed to the development of new molecules that target unmet medical needs in HIV. The treatment of children with HIV/AIDS remains a significant unmet medical need and there is a pressing need for new medicines to tackle problems such as drug resistance, complex treatment regimens, and side effects associated with current treatments.

As ViiV Healthcare was only launched in November 2009, HIV performance on R&D, pricing and licensing are written as though GSK managed the HIV business for the full year.

Treatment of children with HIV/AIDS

We have developed scored tablets and corresponding paediatric dosing schedules which enable our anti-retrovirals (ARVs) to be broken into two smaller doses and administered to children weighing 14 kg or more. This makes it easier for children to be treated with tablets, rather than liquid formulations. Tablets are often easier to store and distribute, and also less complicated to administer than the liquid formulations currently available – particularly when two or three medicines are combined in one pill and as children get older and need to take larger volumes of the liquid formulations. WHO and UNICEF have stated that access to a tablet form of ARVs could improve treatment options for children who are able to swallow tablets.

Our scored tablets for *Epivir*, *Combivir* and *Ziagen* have now been approved in Europe and the US. These scored tablets are also approved and pending approval in many developing countries. A child weighing 20 kg can now take half a tablet of *Combivir* in the morning and the second half in the evening in combination with another ARV, instead of requiring 8 ml of *Epivir* solution twice a day plus 12 ml of *Retrovir* solution three times daily.

GSK has provided support for many of the key clinical studies that have informed the current WHO Prevention of Mother-to-Child Transmission (PMTCT) and Paediatric Treatment guidelines, and continues to do so for a number of key collaborative trials. We have committed to support five currently active paediatric treatment studies in resource-poor countries to determine the best ways to implement and expand access to HIV/AIDS treatment.

In addition we are also currently supporting ten clinical trials evaluating strategies for PMTCT in resource-poor countries, where breast-feeding is often unavoidable, and addressing the impact of PMTCT regimens on future health and treatment options for both the mother and infant.

Research into new HIV treatments

Integrase inhibitors represent an important new class of compounds for the treatment of HIV, and it is increasingly clear that second-generation integrase inhibitors will be needed to address issues such as drug resistance and dosing complexity. Together with our partners at Shionogi, we have two second-generation integrase inhibitors in phase II of clinical development. Our lead candidate (S/GSK1349572) has demonstrated high potency with low doses and an increased ability to treat strains of HIV resistant to currently available integrase inhibitors.

Update September 2010

The collaboration with Shionogi generated promising results in 2010, with phase IIb clinical trials indicating that its novel once-daily, unboosted investigational HIV integrase inhibitor (S/GSK1349572) – the only one in development worldwide – has potent antiviral activity and could provide an important therapy for patients living with HIV.

Shionogi-ViiV presented trial results and findings at the XVIII International AIDS Conference in Vienna, Austria, in July 2010. The treatment will now enter phase III clinical trials.

In February 2009 we announced a licence agreement with Idenix Pharmaceuticals Inc. granting GSK exclusive worldwide rights to IDX899. This is a novel non-nucleoside reverse transcriptase inhibitor (NNRTI) in phase II clinical development being developed by Idenix for the treatment of HIV/AIDS. New NNRTIs are needed to address the increasing prevalence of viral resistance and side effects associated with this drug class. To date, IDX899 has demonstrated high potency with low doses, a high barrier to drug resistance, favourable risk/benefit profile and the convenience of once-a-day administration. GSK has progressed IDX899 (now GSK2248761) further in phase 1/2a clinical trials in which this agent has been shown to have limited drug interaction potential and to be well tolerated in up to 14 days of treatment. Phase 2b studies are anticipated to begin in mid-2010 to evaluate GSK2248761 in both treatment-naive and treatment-experienced patient populations.

HIV Collaborative Research Trials

Through our International HIV Collaborative Research Trials (CRT) Programme for resource-poor settings, we are supporting clinical trials that are sponsored by external organisations such as the WHO, the UK's Medical Research Council and the US National Institutes of Health (NIH). These CRTs focus predominantly on public health-related issues in the developing world, such as prevention of mother-to-child HIV transmission, paediatric and adult treatment strategies, when to start treatment, and HIV-TB co-infection. GSK donates study anti-retrovirals and/or financial support, and also provides scientific input throughout the life of the study.

At the end of 2009, 22 trials were underway and a further two are planned involving approximately 23,300 patients. Nineteen of these trials are conducted at sites in Africa. Five of these are paediatric studies, one of which will provide the first significant clinical data in the resource-poor setting on the efficacy, safety and pharmacokinetics of the GSK NRTI scored tablets.

We have committed to HIV CRT studies in:

African countries	Asia and Latin America countries
South Africa	India
Uganda	Thailand
Zimbabwe	Cambodia
Kenya	Vietnam
Botswana	Brazil
Zambia	Haiti
Tanzania	Peru
Malawi	Argentina

> [Back to top](#)

› Home › Responsibility › Access to medicines › A new approach to HIV
 › Pricing of HIV/AIDS medicines

Corporate Responsibility Report 2009

Pricing of HIV/AIDS medicines

In the Least Developed Countries and sub-Saharan Africa GSK has offered its HIV/AIDS medicines at not-for-profit (nfp) prices since 2001. ViiV Healthcare will maintain this commitment, and will include the additional products in its portfolio.

In middle-income countries, ViiV Healthcare will explore a range of pricing solutions that balance its commercial objectives with the need to increase access to medicines for those who cannot afford to pay in these markets.

As ViiV Healthcare was only launched in November 2009, HIV performance on R&D, pricing and licensing is reported as though GSK managed the HIV business for the full year.

Not-for-profit (nfp) prices for ARVs – key facts

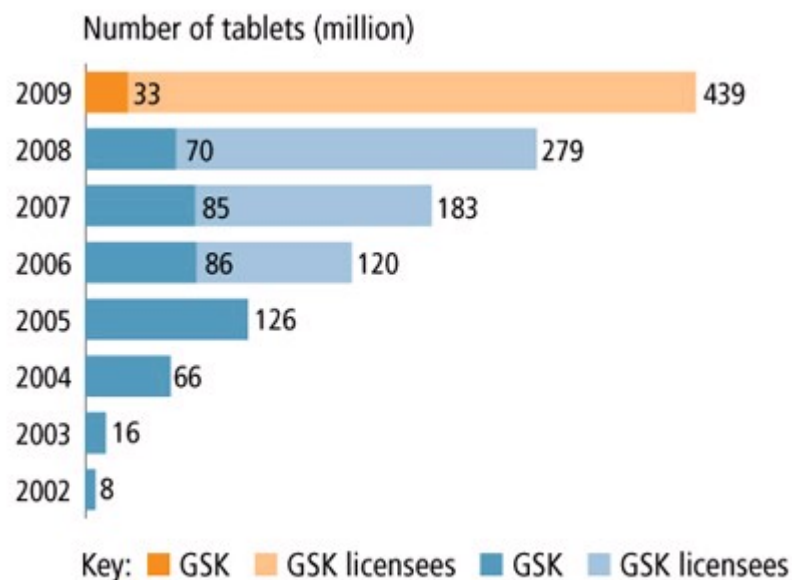
- Not-for-profit prices apply to all our anti-retrovirals
- GSK has offered preferential pricing for our anti-retrovirals since 1997 and formal nfp pricing since 2001
- Our nfp prices are sustainable – we do not make a profit on them, but we do cover our costs. This means that we can sustain supply of these high-quality products for as long as they are needed
- Nfp prices are available to all the Least Developed Countries and sub-Saharan Africa – a total of 64 countries
- In addition, PEPFAR projects and eligible Global Fund projects bring this number up to over 80 countries
- Eligible customers include public sector customers and nfp organisations as well as private employers in sub-Saharan Africa providing treatment to uninsured staff
- *Combivir*, our leading combination ARV, is available at \$0.54 a day
- Our nfp prices include insurance and freight costs, unlike the prices quoted by most generic companies. They are applicable to orders of any size and are not dependent on large order quantities

Least Developed Countries

Not-for-profit prices

In February 2008 we reduced our not for profit (nfp) prices for our ARVs for the fifth time since 1997. *Combivir*, our leading ARV, now sells at \$197 per patient per year in the Least Developed Countries compared to \$730 in 2001. This is clearly an improvement in affordability but it is important to recognise that for people living on less than \$1 a day in communities with inadequate healthcare systems, no price is affordable without significant additional resources directed towards healthcare.

In 2009 we shipped 11.7 million tablets of nfp *Combivir* and 21.0 million tablets of nfp *Epivir* to the developing world, compared with 11.4 million and 58.6 million respectively in 2008. The decline in supply of our own ARVs is more than outweighed by a growth in volumes from our licensees. In 2009 our licensees supplied over 439 million tablets of their versions of *Epivir* and *Combivir* to African countries. These figures do not include syrup and capsule formulations. They are therefore conservative in giving an estimate of the ARV treatments shipped at preferential prices by GSK and GSK licensees.



This includes preferentially priced tablets supplied by GSK and tablets supplied by our licensees

During 2009 GSK supplied ARVs at nfp prices to 23 countries, compared with 37 in 2008. This reflects countries moving away from supply by GSK to supply from licensees. ViiV Healthcare will continue to look for new customers for our nfp ARVs in these countries and regularly review our nfp prices. However, it may well be that our licensees are able to produce first-line ARVs at lower costs and will continue to increase their share of the business.

Patients receiving treatment

It is difficult to estimate the number of patients treated as a result of our preferential pricing agreements, since we do not control healthcare provision. However, UNAIDS estimates that more than four million people in the developing world had access to ARVs by the end of 2008, a ten-fold increase over five years.

A report from the [Accelerating Access Initiative](#) (AAI) suggests that by December 2007, around 900,000 patients in developing countries were receiving at least one ARV treatment supplied by the nine R&D-based pharmaceutical companies in the AAI. In the two years since December 2005, the total number of patients in developing countries receiving treatment from the AAI companies had increased by 45 per cent. In addition to the increase in Africa, the number of patients being treated with at least one ARV supplied by the AAI companies in Asia doubled between 2005 and 2008.

Middle-income countries

Preferential pricing for HIV/AIDS medicines

We negotiate preferential pricing arrangements for HIV/AIDS medicines with middle-income countries on a case-by-case basis. Prices are lower than those paid by developed countries, but not as low as the nfp prices paid by the Least Developed Countries. This is done bilaterally through dialogue with governments. We believe this approach is appropriate because the burden of disease and the resources available to address that burden vary significantly from country to country, and within countries. These arrangements combine a viable and sustainable commercial return for GSK with improved affordability for the healthcare systems concerned. This will be a key focus for ViiV Healthcare in 2010.

› [Back to top](#)

Corporate Responsibility Report 2009

Voluntary licensing

As ViiV Healthcare was only launched in November 2009, HIV performance on R&D, pricing and licensing are reported on as though GSK managed the HIV business for the full year.

Voluntary licences, when patent holders allow a third party company to manufacture and sell versions of their products, can help to increase the availability of HIV medicines and contribute to better security of supply. Some people assume that generics are always cheaper than branded products and are seen by many as a solution to the access crisis in the developing world. Pharmaceutical companies are under increasing pressure to grant licences during the lifespan of a patent.

However, generics are not always cheaper and the success of a voluntary licence will depend on the right licensees being chosen. This is particularly true for the treatment of a chronic disease such as HIV/AIDS, where the sustainable supply of good quality anti-retrovirals (ARVs) is essential.

GSK is prepared to grant royalty free voluntary licences covering sub-Saharan Africa for all our ARVs to appropriate third parties. The licences allow our licensees to combine our ARVs with those from other companies that they have rights to. We granted the first voluntary licence (VL) for ARVs in 2001 and have now negotiated eight licensing agreements for our ARVs in sub-Saharan Africa.

In July 2009 we agreed a royalty free voluntary licence to enable Aspen to produce our ARV abacavir. We have written to all our existing licensees offering to add abacavir to their licences. As of February 2010 six licences have been amended to include abacavir. Also in July we extended all our existing licences to cover all of sub-Saharan Africa (previously some were only regional) and made all the licences royalty free.

Since August 2007 we have allowed Apotex, a Canadian company, to manufacture a generic fixed-dose combination ARV, containing two molecules over which GSK has patent rights, for the treatment of HIV/AIDS in Rwanda. This consent was granted under Canada's Access to Medicines Regime which reflects the WTO '31f' agreement. This enables governments to authorise the production of certain patented medicines for export. GSK agreed to waive royalties on the basis that Apotex's triple combination generic ARV will be supplied on a not-for-profit basis.

Our licensees supplied 439 million tablets of their versions of *Epivir* and *Combivir* to Africa in 2009. This represents nearly 60 per cent growth over 2008. We welcome this trend as it gives customers in sub-Saharan Africa greater choice, improves affordability and contributes to better security of supply.

Update September 2010

ViiV Healthcare has extended its policy on voluntary licences. It will now consider requests from all genuine partners, on a case by case basis, to grant royalty free voluntary licences for its entire current and future anti-retroviral portfolio to generics companies in the 69 countries where 80% of all people with HIV live. This includes all Least Developed Countries, all low income countries and all of sub-Saharan Africa.

ViiV Healthcare collaborators Shire Pharmaceuticals and Shionogi have both agreed to waive their rights to royalty payments for these countries in order to improve access for these products.

Compulsory licences

Compulsory licences are issued by governments and involve intellectual property rights being taken away from the rights holder. Compulsory licences are one of the flexibilities in the World Trade Organization's

TRIPS agreement on intellectual property which can be used to address public health concerns. However, widespread use of compulsory licences will undermine the [intellectual property framework](#) and be counter-productive in the long term. R&D into new treatments, especially where commercial markets exist such as for HIV/AIDS, depends on protection of intellectual property. For more on compulsory licensing see our [public policy position](#).

› [Back to top](#)

Corporate Responsibility Report 2009

R&D for the developing world

We aim to make a major contribution to health in developing countries by researching and developing affordable new vaccines and treatments.

These are urgently needed. For some diseases disproportionately affecting developing countries there are no effective prevention methods or treatments, largely because normal market incentives for innovation do not exist. In other cases, treatments have become less effective due to drug resistance, which is more of a concern in developing countries where there is a greater burden of infectious diseases. Sometimes treatments are not suitable for these settings because they are difficult to administer in areas with poor healthcare infrastructure or they are expensive to produce. For example, a medicine that requires refrigeration would not be suitable for use in areas without fridges for storage.

We have a long-standing commitment to develop new treatments and vaccines for diseases specifically affecting developing countries. In addition we increasingly aim to make all GSK medicines and vaccines more suitable for use in the developing world.

Our R&D portfolio for diseases of the developing world includes projects for 12 diseases of particular relevance to developing countries: bacterial meningitis, chlamydia, Chagas disease, dengue fever, hepatitis E, HIV/AIDS, human African trypanosomiasis, leishmaniasis, malaria, pandemic flu, pneumococcal disease and TB. GSK is one of the few companies researching new vaccines and treatments for all three of the World Health Organization's priority infectious diseases, HIV/AIDS, malaria and TB.

The challenge of improving healthcare in the developing world is enormous and far too complex to be addressed by any one group or organisation alone. Given the scale of the task this means finding new ways for industry, academia, NGOs and governments to work together. We are pursuing what we call an open innovation approach which has three elements:

- Establishing an independent open lab for research on neglected tropical diseases
- Making publicly available the 13,500 compounds from our library, shown to have efficacy against the malaria parasite
- Launch of new collaborations to further share intellectual property and know-how to accelerate the delivery of new medicines for neglected tropical diseases

Each of these is explained in more detail in the following sections.

Our research units

We have a dedicated R&D group focused on diseases of the developing world and fully integrated into our pharmaceutical R&D organisation. This group includes scientists based in the UK and US, and at our developing world drug discovery centre at [Tres Cantos](#) in Spain. The group prioritises projects based on their socio-economic and public health benefits rather than on commercial returns. A similar group is active in our vaccines organisation in Belgium.

To complement our group at Tres Cantos working on neglected tropical diseases (NTD), we launched a new R&D unit in 2009 that is focused on developing products and formulations for other diseases that affect people in the developing world. This unit champions the needs of patients in the developing world across GSK's R&D operations. The unit will focus on products in late-stage clinical development and facilitate their final development and registration in developing countries. Additionally, it is working with our strategic external partners to deliver on our objective of developing a product portfolio more suited for the disease burden suffered by patients in developing countries.

GSK scientists working on treatment projects for DDW make access to medicines a priority right from the start of the R&D process. When researching a new DDW treatment we emphasise factors such as:

- Heat and humidity resistance – the product must be able to survive in a hot climate where refrigeration facilities may not be available
- Ease of use – it must be easy to use in settings where there are limited healthcare facilities. For example, once-a-day tablets that can be taken at home are preferable to an injectable medicine that must be administered in a hospital or clinic
- Affordability – price is one of the most important factors. We look for molecules and formulations that are straightforward to manufacture and therefore inexpensive to produce

¹ Tufts Center for the Study of Drug Development

² Pharmaceutical Industry Profile 2008, Washington DC, PhRMA March 2008

› [Back to top](#)

› Home › Responsibility › Access to medicines › R&D for the developing world
› **R&D for neglected tropical diseases**

Corporate Responsibility Report 2009

R&D for neglected tropical diseases

Our research centre in Tres Cantos, Spain has worked to develop new treatments to combat diseases of the developing world since it was established in 2001. From the start of this initiative, we have worked closely in public-private partnerships, with groups including the Medicines for Malaria Venture (MMV) and the Global Alliance for TB drug Development (TB Alliance). There are more than 100 scientists working at the centre, and many of these posts are partly funded by our partners.

Despite this level of collaboration, we believe that research into diseases that disproportionately affect the developing world is still too fragmented. To stimulate further research in this area, we are opening up our facility at Tres Cantos to new ways of working, known as the open lab. Our vision is for the Tres Cantos facility to become a global centre of excellence that stimulates research and collaboration.

We want to form new collaborations and bring new partners to the facility. We seek shared investment and participation from governments, NGOs, businesses and other groups.

Open lab: inviting scientists into GSK

We have launched the open lab at Tres Cantos as one way in which we can share our expertise and seek to stimulate open innovation in drug discovery into diseases of the developing world. The open lab will create up to 60 spaces at Tres Cantos for scientists from around the globe. GSK will not initiate the projects, but we encourage universities, not-for-profit partnerships and other research institutes come to us with their own proposals and to set out how they think GSK can help them.

The projects will be collaborations between the scientists' home laboratory and GSK at Tres Cantos. Visiting researchers will have access to our facilities, scientists and know-how. All projects will have clear objectives and the shared aim of discovering new medicines for diseases of the developing world.

To meet the needs of the external researchers we are expanding our facilities at Tres Cantos and establishing a not-for-profit foundation with an initial investment of £5 million. The funding will be used to support visiting scientists and their research projects.

Sharing research information

As part of our commitment to open innovation drug discovery for diseases of the developing world, in January 2010 we committed to making widely and freely available research information that could help identify potential new treatments against malaria.

In 2009 GSK screened two million chemicals from its compound library looking for potential efficacy against the deadliest form of the malaria parasite, *P. falciparum*. It took five people working in a special bio hazard unit 12 months to screen the two million compounds because it had to be done by hand, given the dangers of working with the malaria parasite. Normally a screening can be automated and takes 8-10 weeks.

We have committed to making public the 'hits' from this screening – more than 13,500 compounds – including their chemical structures and related data. Having this type of data is the first step on the road to developing new medicines. We believe that we are the first company to make such comprehensive data available.

By making this information publicly available, GSK hopes that many other scientists will review this information and analyse the data faster than we could on our own. Hopefully, this will lead to additional research that could help drive the discovery of new medicines. We would also encourage other groups,

including academics and pharmaceutical companies, to make their own compounds and related information publicly available.

This is essentially an example of 'open source' being applied to drug discovery. We know that data increases in value when connected with other data and that the more eyes looking at a problem, the more potential solutions may arise.

Speaking at the time of the announcement, Timothy Wells, Chief Scientific Officer of the Medicines for Malaria Venture, said: "GSK's new initiatives have the potential to dramatically alter the way the world approaches research and development for neglected diseases.

"Providing access to this level of information sees GSK set what I would hope to be a new trend that could revolutionise the urgent search for new medicines to tackle malaria. By sharing data, we start to build up a public database of knowledge that should be as powerful as the human genome databases."

Public-private partnerships

Biomedical R&D is a costly, risky and time-consuming activity. For diseases which disproportionately affect the developing world, but where a market exists in developed countries such as HIV/AIDS, we will accept all the R&D costs and risks involved on the expectation that there will be a market in wealthy countries where we will make a return on our R&D investment.

For other diseases of the developing world, where no such return on investment can be expected, we have to pursue new ways of working. One solution is the public-private partnership (PPP) model, in which businesses and the public sector work together. PPPs make this work commercially viable by sharing the risks and costs involved.

In a PPP companies such as GSK provide the R&D, technology, manufacturing and distribution expertise. Academic institutions may also provide research and disease area knowledge. Public sector partners, governments and organisations such as the Bill & Melinda Gates Foundation help fund the development and delivery costs and ensure that medicines and vaccines get to the people who need them. Funds are usually channelled through organisations such as the Medicines for Malaria Venture (MMV) which also help to coordinate global R&D activity. PPPs are becoming increasingly important and they have transformed the landscape for the development of medicines and vaccines for diseases of the developing world. We now have the most promising pipelines for malaria and TB the world has ever seen.

PPPs can work in many different ways. For example, some of our partnerships are centred on our dedicated diseases of the developing world discovery centre at Tres Cantos and our global vaccines business headquartered in Belgium. GSK provides the facilities for medicinal drug discovery and meets all the running costs. Around half of the scientific posts at Tres Cantos are subsidised by our partner organisations, MMV, the Global Alliance for TB Drug Development and the Drugs for Neglected Diseases initiative.

As compounds move into clinical development, GSK provides the clinical, regulatory and manufacturing expertise and resources through our global R&D and supply network. Partners help fund the cost of running clinical trials and address issues of access and distribution.

This reduces the costs of development and gets new products to patients faster. Research programmes are overseen by joint steering committees with representatives from GSK and our partners. Under the terms of our agreements, all new treatments resulting from PPPs are made available to disease-endemic countries at affordable prices.

› [Back to top](#)

› Home › Responsibility › Access to medicines › R&D for the developing world
› [Products and formulations for the developing world](#)

Corporate Responsibility Report 2009

Products and formulations for the developing world

In 2009 we established a new research unit to help ensure that our product portfolio is better suited to the needs of patients in developing countries in GSK's Emerging Markets and Asia Pacific regions.

The new unit will champion the needs of developing countries among all R&D teams at GSK. It will:

- Seek to develop a product portfolio suited to these countries, complementing the work of other teams focusing on medicines suitable for Europe and North America
- Seek products in late-stage clinical development and facilitate their development and registration in developing countries
- Forge partnerships with companies that want to develop their products for developing countries, but may not have the necessary experience or resources. We will develop and register their medicines providing GSK's local marketing, regulatory and clinical expertise and infrastructure. This will make a wider range of products available in developing countries. We will pay our commercial partners royalties on the revenue generated from sales
- Apply its development capabilities to GSK's branded generic pipeline, working with our partner companies to create combinations of branded generics and enhanced formulations to meet the needs of developing countries
- Support pipeline projects with the potential to benefit patients in developing countries, and ensure that research teams take account of different regional needs. Examples could include: simpler, lower cost analogues of our medicines; registration of the lower doses required in some countries; and taking on projects that meet specific regional medical needs and commercial opportunities

The new research unit is part of our broader strategy to focus on developing countries, which includes [partnerships to expand our branded generics portfolio](#).

In its first year of operation, the new R&D team made a number of achievements in helping to make our product portfolio better suited to the needs of patients in developing countries:

- In 2009 GSK signed a deal with Amgen to make denosumab, its osteoporosis medicine, available in developing countries. We will work with Amgen to complete the necessary clinical studies that will allow registration outside of Europe and the US. We also partnered with Gilead to make tenofivir, their medicine for hepatitis B, available in China
- In partnership with the Indian company Dr Reddy's, two new branded generics for developing countries were moved into development for the treatment of cardiovascular disease
- The unit started four late-stage projects which focus on developing country medical problems in respiratory disease, urology, dermatology and hepatitis B. For the four projects, we worked closely with the regions and countries to make sure we understood the local needs. The trials were focused specifically to meet these needs, rather than the more traditional way where we adapt trials which have been conducted to meet US or EU regulatory requirements. In the coming year we will spend time in each major market to better understand the medical needs, healthcare priorities and government relations in those countries

› [Back to top](#)

› Home › Responsibility › Access to medicines › R&D for the developing world
› **Proprietary knowledge pool**

Corporate Responsibility Report 2009

Proprietary knowledge pool

Being more flexible with our intellectual property and encouraging other pharmaceutical companies to do the same could stimulate research and help to speed up development of medicines for neglected tropical diseases (NTDs).

In March 2009 we created a [neglected tropical disease pool](#) to stimulate research into medicines for 16 NTDs (also known as diseases of the developing world). Our pool is focused on the 16 NTDs defined by the US Food and Drug Administration (FDA) as this provided a credible third-party list, which includes most of those diseases we believe to be a priority. The Act of Congress which included this list has allowed for more diseases to be added as deemed appropriate. We will review our list if the FDA adds new diseases.

To initiate the pool we published details of over 800 GSK patents and patent applications for small molecule pharmaceuticals which we have identified as being potentially useful for the treatment of the 16 NTDs.

Since then we have had discussions with three groups of stakeholders. In discussions with the scientific and research community who could potentially benefit from the pool, we learnt that they appreciated us making the patent information public. However, what would really help them was access to our know-how and experience. They want to ask us what we have tried already and what the results were, about what worked and what did not, and about how we overcame particular challenges. We have therefore committed to making this knowledge and experience, as it relates to the 16 NTDs, available to the pool. As the pool goes far beyond patents we now refer to it as a 'proprietary knowledge pool'.

We will allow products developed under the pooled patents and intellectual property to be sold in Least Developed Countries on a royalty free basis and will discuss the terms for sale in other countries with those involved.

In January 2010 we signed agreements with two organisations to give them access to information in the pool. These were with the Emory University Institute for Drug Discovery and with iThemba Pharmaceuticals, a company based in South Africa and working on TB, with financial help from the South African government.

The second group of stakeholders is other companies which could contribute assets to the pool. In July 2009, the US biotechnology group Alnylam became the first company other than GSK to contribute some of its patents to the pool. We have had constructive discussions with a number of other companies which were keen to see greater independence of the pool.

Our goal has always been to create an independent NTD pool, rather than a GSK pool. To this end, potential administrators of the pool were the third group of stakeholders we talked to. In January 2010 we announced that Bio Ventures for Global Health (BVGH) will take over administration of the pool. We are hopeful that this will lead to more companies joining the pool in due course.

The impact of the pool will increase if pharmaceutical and biotechnology companies, universities and other stakeholders contribute.

Update September 2010

The pool is now known as the Pool for Open Innovation against Neglected Tropical Diseases (POINT), and is administered by Bio Ventures for Global Health (BVGH). To date, there are more than 2,300 patents in the pool.

In May 2010, the Massachusetts Institute of Technology (MIT) became the first academic institution to

contribute intellectual property to the pool, followed by the first government agency, South Africa's Technology Innovation Agency (TIA). TIA intends to use intellectual property from the pool to enhance the South African biotechnology sector, and improve the quality of life for people affected by neglected tropical diseases. Initially, the Agency will focus on developing new medicines for tuberculosis and malaria.

In August, the Medicines for Malaria Venture (MMV) became the first product development partnership to join the pool. MMV's contribution of patents to the Pool, resulting from its research for new anti-malarials, is an important milestone from an organization that plays a major role in leading the development of new treatments for this disease.

For more information about the pool, visit the [BVGH website](#).

Neglected tropical diseases targeted by the pool (FDA list)

- Blinding trachoma
- Buruli ulcer
- Cholera
- Dengue/dengue haemorrhagic fever
- Fascioliasis
- Human African trypanosomiasis (sleeping sickness)
- Leishmaniasis
- Leprosy
- Lymphatic filariasis (elephantiasis)
- Malaria
- Onchocerciasis (river blindness)
- Dracunculiasis, guinea worm disease
- Schistosomiasis (bilharzia)
- Soil transmitted helminthiasis (intestinal worm infection)
- Tuberculosis
- Yaws

› [Back to top](#)

› Home › Responsibility › Access to medicines › R&D for the developing world
› Medicines for the developing world

Corporate Responsibility Report 2009

Medicines for the developing world

Malaria

Our work on malaria treatments includes tafenoquine and pyridone GSK932121.

Tafenoquine

We are developing tafenoquine, a potential new treatment for the radical cure of *P vivax* malaria, in partnership with the Medicines for Malaria Venture (MMV). As well as causing an acute infection of red blood cells, *P vivax* causes a dormant infection of liver cells from which malaria can reoccur. A radical cure completely eliminates the malaria parasites from the body, including the dormant liver stages. Tafenoquine offers the potential for a one- to-two day treatment course, significantly shorter than primaquine, the current standard of care. Tafenoquine, like primaquine, belongs to a class of drugs that is known to cause acute haemolytic anaemia in some subjects with inherited glucose-6-phosphate dehydrogenase (G6PD) deficiency. G6PD deficiency is common in areas where malaria is prevalent. An initial clinical study is focusing on further understanding the safety of tafenoquine in subjects with G6PD deficiency. The study began in 2009 and interim results are expected in 2010.

Dr Timothy Wells, Chief Scientific Officer at the Medicines for Malaria Venture has commented: “Tafenoquine is a novel inclusion for MMV’s portfolio. Given its activity against the liver stages of malaria, it is an essential part of the fight against *P vivax* infections. As the malaria elimination agenda moves forwards we need an increasing array of tools against the parasite.”

Pyridone GSK932121

Pyridones are a new class of compounds with the potential to be highly effective against drug-sensitive and drug-resistant strains of *P. falciparum* and *P. vivax* malaria. We are developing pyridone GSK932121 in partnership with MMV and entered ‘first time in human’ clinical trials early in 2009. In addition a back-up effort is ongoing to identify a pyridone compound if issues with the lead GSK932121 prevent further development.

Tuberculosis

Our tuberculosis medicines research is conducted in partnership with the Global Alliance for TB Drug Development (TB Alliance). A strong alliance has been forged that has increased the number of TB drug discovery projects in our portfolio.

In our lead TB project on mycobacterium gyrase inhibitors we hope to progress a candidate in the preclinical phase. We are also researching biomarkers that could help predict at an early stage how TB patients are responding to treatment. This could significantly speed up TB research as currently the effectiveness of a new TB drug cannot be determined until 18-24 months after completion of treatment.

Visceral leishmaniasis (VL)

Sitamaquine is our oral, once-a-day candidate treatment for visceral leishmaniasis (VL, kala azar), a potentially fatal parasitic disease spread by sand flies.

Data from two phase II proof-of-concept studies in Kenya and India are encouraging overall. After a 28-day course, 85 per cent of patients remained cured at six months^{1,2}. Sitamaquine was generally well tolerated by patients in these studies. However, there were some concerns regarding renal adverse events seen in a few subjects, some of which appear to be treatment related.

Interpretation of these data is complicated, in particular because VL itself is associated with renal impairment³. Before proceeding to phase III trials, we set up a phase IIb study in India³ to compare the safety and tolerability of a 21-day course of sitamaquine with that of intravenous amphotericin B, which is the current standard of care in India.

Results showed comparable efficacy to previous studies, despite the shorter course, and sitamaquine was very much better tolerated than amphotericin. A small number of patients had mild, reversible renal side effects.

We are currently in discussions with potential partners with a view to progressing development. We are also targeting VL through our partnership with the Drugs for Neglected Diseases Initiative (see below).

Other neglected diseases

We are strengthening our partnership for a collaborative research effort into other neglected diseases. In March 2008, we announced a collaborative research effort with the not-for-profit organisation Drugs for Neglected Diseases initiative (DNDi), targeting neglected tropical diseases. Research focused on compounds that may have activity against other neglected diseases, including visceral leishmaniasis, human African trypanosomiasis (sleeping sickness) and Chagas disease.

Over the last few years this collaboration has worked on identifying and developing compounds from existing GSK programmes as well as leveraging the expertise of GSK researchers at our Tres Cantos facility along with leading academic centres such as the London School of Hygiene & Tropical Medicine.

The collaboration was originally formed to specifically address unmet patient needs as current treatments for these diseases that have significant drawbacks, such as difficulty of administration, severe side effects, length of treatment, cost, and emerging parasitic resistance.

¹ Wasunna M, Rashid JR, Mbui J et al. A Phase II dose-increasing study of sitamaquine for the treatment of visceral leishmaniasis in Kenya. *Am J. Trop. Med. Hyg.* 73(5):2005:871-876

² Jha TK, Sundar S, Thakur CP et al. A Phase II dose-ranging study of sitamaquine for the treatment of visceral leishmaniasis in India. *Am J. Trop. Med. Hyg.* 73(6):2005:1005-1011

³ Prasad LS, Sen S, Ganguly. Renal involvement in kala-azar. *Indian J. Med Res* 1992 Jan;95:43-46 - Dutra M, Martinelli R, de Carvalho EM et al. Renal involvement in visceral leishmaniasis. *Am. J. Kidney Dis.* 1985: (6); 22-27

› [Back to top](#)

› Home › Responsibility › Access to medicines › R&D for the developing world
› **Vaccines for the developing world**

Corporate Responsibility Report 2009

Vaccines for the developing world

Malaria

We have been working on a malaria vaccine for more than two decades and have invested more than \$300 million of our own resources to date. We are currently developing a candidate malaria vaccine, RTS,S, in partnership with the PATH Malaria Vaccine Initiative (MVI), which has contributed more than \$200 million.

Our candidate vaccine, called RTS,S, is the first malaria vaccine candidate to demonstrate significant efficacy during early development to warrant phase III testing. Recent phase II studies showed that RTS,S reduced clinical episodes of malaria by 53 per cent over an eight-month period. In addition, RTS,S was shown to have promising safety and tolerability profile when used alongside the World Health Organization's (WHO) standard infant vaccines.

RTS,S is the first vaccine designed primarily for Africa and, if effective, it will be the first successful vaccine against a human parasite. Notably, RTS,S is also the first vaccine whose development has been spearheaded by an extended team of researchers and organisations spanning the globe, including GSK, MVI, the Bill & Melinda Gates Foundation, and scientists from across Europe, North America and Africa.

In 2009 GSK and its partners launched a large-scale phase III efficacy trial of RTS,S in seven countries in Africa. The trial, which is expected to involve up to 16,000 children, is on schedule, with almost 7,500 children enrolled by the end of January 2010. Christian Loucq, MVI Director, commented on the significance of the trial results by saying: "We are closer than ever before to developing a malaria vaccine for children in Africa." GSK's Joe Cohen, co-inventor of RTS,S and Vice President of R&D, Vaccines for Emerging Diseases and HIV, commented: "The phase III trial is a huge undertaking that depends on effective coordination among researchers, regulators, families and communities. Everyone involved has invested significant energy and resources to pave the way for what could become the world's first malaria vaccine."

Under current plans, the RTS,S vaccine candidate would be submitted to regulatory authorities in 2012 based on efficacy in children between five and 17 months of age. Additional safety and immunogenicity data from the infant population will be submitted soon afterwards, followed by efficacy data for infants, once available. Depending on the final clinical profile of the vaccine and timetable of the regulatory process, the first vaccine introduction could take place over the next three to five years. Read more in the [malaria vaccine case study](#).

Tuberculosis

M72 is our TB candidate vaccine being developed with the Aeras Global TB Vaccine Foundation. Early results are positive, suggesting that the vaccine is safe and produces a strong immune reaction in adults in TB endemic regions and in HIV positive adults on highly active anti-retroviral therapy (when several anti-retrovirals are taken in combination). Phase II trials are now planned for adolescents and infants in TB-endemic regions.

HIV/AIDS

We have been involved in AIDS vaccine research for over two decades. We are now pursuing three separate vaccine strategies. A successful AIDS vaccine might combine several of these approaches:

- Recombinant measles vector – the measles vaccine is one of the most powerful, providing life-long protection against the disease. We are working with the Pasteur Institute in Paris and other partners to develop an AIDS vaccine by fusing genes from the HIV virus onto a measles vaccine

- F4co, our own candidate vaccine, advanced into phase I/II trials in HIV-infected subjects in 2009 and these are ongoing
- An extramural collaborative discovery R&D programme that aims to identify an HIV envelope-based protein vaccine capable of producing broadly neutralising antibodies against HIV infection
- In addition, we continue to collaborate with the international AIDS Vaccine Initiative (IAVI)

Pneumococcal disease

Pneumococcal disease is a major global health issue. Each year, *Streptococcus pneumoniae* infections are estimated to kill one million children under five years of age worldwide. There are more than 90 distinct strains (serotypes) of pneumococcus but only 10-15 cause the vast majority of invasive disease in young children.

In January 2009, the European Medicines Agency's Committee for Medicinal Products for Human Use issued a positive opinion and recommended approval of GSK's paediatric pneumococcal candidate vaccine *Synflorix*. The paediatric vaccine is proposed to be indicated for active immunisation against invasive pneumococcal disease and middle ear infections (acute otitis media) caused by *S.pneumoniae* in infants and children from six weeks up to two years. We obtained European Marketing Authorisation for *Synflorix* in March 2009.

In November we received prequalification for the potentially life-saving vaccine from the World Health Organization. Prequalification is a service provided by the WHO to facilitate access to medicines in less affluent countries and allows UN agencies to purchase vaccines on behalf of developing countries. It will accelerate global access to *Synflorix*.

We have also signed an agreement with the Global Alliance for Vaccines and Immunization to accelerate the availability of funding for pneumococcal vaccination through the pilot Advance Market Commitment (AMC) mechanism. AMCs are a new approach to public health funding designed to stimulate the development and manufacture of vaccines for developing countries. Donors commit money to guarantee the price of vaccines once they have been developed, thus creating the potential for a viable future market.

Update September 2010

In March 2010, GSK became one of the first manufacturers to sign an Advance Market Commitment agreement (see above) with GAVI. Since then, we have committed to supply up to 300 million doses of *Synflorix* over ten years, with the potential to prevent the deaths of millions of children in the world's poorest countries.

The agreement is financed by GAVI, five donor countries – Canada, Italy, Norway, Russia and the United Kingdom – and the Bill & Melinda Gates Foundation. This guaranteed long-term order will enable us to invest in development and manufacturing capacity for the vaccine, and to significantly reduce the cost of each dose to around 10% of the purchase price in developed countries.

Children in Africa will begin receiving *Synflorix* vaccinations later in 2010.

› [Back to top](#)

› Home › Responsibility › Access to medicines › **Flexible pricing**

Corporate Responsibility Report 2009

Flexible pricing

Pricing is one factor that impacts on access to medicines and vaccines.

We are adopting a range of flexible pricing models that reflect our commitment to work with governments and other stakeholders to deliver our medicines and vaccines to as many needy people as possible.

In the Least Developed Countries (LDCs) we offer substantially reduced pricing for patented medicines. In these countries and beyond in sub-Saharan Africa we offer not-for-profit prices for HIV/AIDS medicines. We offer tiered pricing for GSK vaccines worldwide.

Many of the poorer communities within middle-income countries also need assistance. However, our ability to offer not-for-profit or highly preferential prices in the world's poorest countries is only sustainable if we can continue to make an adequate return on our medicines and vaccines in better off markets. Many middle-income countries are also growing commercial markets for GSK and represent an important source of future business for our industry. We are exploring a range of pricing approaches that balance our commercial objectives with the need to increase access to medicines for those who cannot afford to pay in these markets. These include: flexible, tiered and preferential pricing models; tailored products; and local sourcing and manufacturing arrangements.

Even in developed countries, some patients lack access to medicines. This is a particular problem for uninsured patients in the US. We seek to price medicines fairly in these countries and at a level that reflects their value to patients and payers. Our US Patient Assistance Programs and discount savings cards provide access to GSK medicines for uninsured patients at no or minimal cost. We also offer discount cards in Lithuania and Ukraine.

Vaccines – our tiered pricing model

Vaccines make a significant [contribution to public health](#), helping to prevent many potentially fatal infectious diseases. Immunisation is acknowledged by the World Health Organization (WHO) as being 'among the most cost-effective of health investments'.

For over 20 years we have made our vaccine portfolio available at preferential prices to developing countries, including LDCs, using a tiered pricing system. Prices are linked to gross national incomes as defined by the World Bank, as well as the size of an order and the length of a particular supply contract. By selling our vaccines in large volumes through longer-term contracts we are able to significantly reduce the price of each individual dose. For the developing world, prices can be as little as a tenth of those for developed countries. This model works for vaccines because the demand is relatively predictable, because centralised bulk procurement by groups such as UNICEF, GAVI and PAHO is possible.

We work with these multinational organisations to provide appropriate and affordable vaccines for developing countries. Tiered pricing applies across our vaccine range from our basic polio vaccines to our specially developed combination vaccines that target several diseases.

In addition to tiered pricing, we are looking for innovative ways to increase access to vaccines in poorer countries. One option being pursued for *Cervarix*, our vaccine against human papillomavirus, is to partner with a major international non-governmental organisation to leverage its distribution network to create sustainable expansion of access to our vaccine in the developing world, where most cervical cancer deaths occur. Results from a pilot programme launched in South America in 2009 are encouraging.

Our malaria vaccine

We hope that our malaria vaccine will be ready to file with regulatory authorities in 2012 for young African children aged five to 17 months. So far GSK has invested \$300 million in R&D for this vaccine and our partner, PATH Malaria Vaccine Initiative (MVI), has invested a further \$200 million. The dilemma we face is that, unlike virtually every other vaccine, there is no wealthy market for this vaccine, so tiered pricing is not appropriate.

In a speech at the Council on Foreign Relations in January 2010, GSK's CEO Andrew Witty laid out the principles we will pursue when setting a responsible price for this vaccine.

First, we must set a price that is sustainable, which covers our costs and allows for investment in high quality manufacture and continued investment in follow on R&D.

Secondly, we do not want to price in a way that will discourage others from continuing to invest in R&D in this area. We believe, therefore, that it would not be helpful to launch the first vaccine at a not-for-profit price as it could create an expectation that all following products would have to be similarly priced. This could be a major disincentive to investment for some organisations.

We will therefore set a price which covers our costs and makes a small return. We will reinvest this return in R&D for second generation malaria vaccines or for other vaccines for diseases of the developing world.

Vaccine production is very sensitive to economies of scale, so until we have a better idea of our own cost structure and of the likely demand for the vaccine we will not be able to provide guidance on what the actual price will be.

In addition to the price commitment, GSK has pledged to donate at least 12.5 million doses of vaccine to the PATH Malaria Vaccine Initiative.

› [Back to top](#)

Corporate Responsibility Report 2009

Least developed countries

Approach

Performance

Early in 2009 we announced a new commitment to reduce our prices for patented medicines in the Least Developed Countries (LDCs). GSK-patented products in these countries will now cost less than 25 per cent of their price in the UK, while ensuring we cover our manufacturing costs so this offer is sustainable. This will be the maximum price – where possible we will reduce our prices further.

This commitment applies to all products where GSK is the sole supplier in that market. It did not initially apply to off-patent products where generic alternatives are available, since generic companies can typically provide even lower prices. However, feedback from local physicians indicated a need for lower-priced antibiotics given the high incidence of infectious diseases. We therefore reduced the prices of two antibiotics in January 2010 in East Africa, and will look to extending this to other LDCs during 2010.

In many LDCs the healthcare crisis is dominated by the social and economic impacts of HIV/AIDS, TB and malaria. We provide our anti-retrovirals (ARVs) to treat HIV/AIDS at not-for-profit (nfp) prices to public sector customers and not-for-profit organisations in 64 countries - all the Least Developed Countries and all of sub-Saharan Africa (see feature box below). [Voluntary licences](#) also help to increase access to ARVs in these countries.

Read more about [extending our product portfolio in the developing world](#).

Preventing product diversion

Product diversion, where not-for-profit medicines are illegally shipped back for sale in better off countries, denies treatment to patients in poorer countries. Our anti-diversion measures include specially designed access packs for most of our ARVs, and red rather than white tablets for *Epivir* and *Combivir*.

We only enter into voluntary licences when we know the manufacturer can ensure product diversion will not occur.

¹ [As defined by the UN](#)

› Home › Responsibility › Access to medicines › Flexible pricing
 › **Least developed countries - Performance**

Corporate Responsibility Report 2009

Least developed countries

Approach

Performance

Vaccines

In 2009, of the 1.4 billion vaccine doses we shipped, one billion went to developing countries, including least developed and middle-income countries.

Price reductions on patented medicines

From April 2009 we reduced prices in the Least Developed Countries (LDCs) for 11 GSK patented brands (110 individual product lines and formulations) in the countries where they are registered. Prices were reduced by an average of 45 per cent and apply to the following brands: *Seretide* (asthma, chronic obstructive pulmonary disease - COPD), *Avamys* (rhinitis), *Flixotide* (asthma), *Malarone* (malaria), *Avodart* (benign prostatic hypertrophy), *Avandia* (type-2 diabetes), *Avandamet* (type-2 diabetes), *Fraxiparine* (anaesthetic), *Ultiva* (anti-coagulant), *Arixtra* (venousthromboembolism - VTE) and *Zeffix* (hepatitis B).

There was a risk that products would be diverted from LDC markets to better off countries in East Africa and areas of West Africa because they shared supply chains and lack stringent border controls. We therefore introduced price reductions in some non-LDC markets to reduce the risk that products would be diverted to these markets, thereby reducing their availability in the LDCs.

We know that these products may not meet the priority health needs of the general population in LDCs, but we have started by reducing the price of products where there is a lack of competition and we are the only supplier. We will be introducing policies to improve the affordability of all our products in the developing world in 2010. We work in collaboration at all levels of the distribution network to ensure that our price reductions are passed on to the patients and not lost in the intermediate mark-up and margins. Through the work of our specialist R&D units and our acquisitions and strategic alliances we will continue to develop a product portfolio more suited for patients in developing countries.

We were able to implement the price reductions in most markets in April 2009. However, reductions have taken longer to implement in a few countries because we needed to obtain government authorisation. All reductions were in place by October 2009 in LDCs where we had existing product licences.

Sales volumes after price decreases

We have seen significant increases in sales volumes for the majority of products following the price decreases. For example, sales have often doubled, and in some instances they are eight times higher when comparing sales at the higher prices in the first three months of 2009 with sales in the last three months of 2009.

Where significant volume increases have not been achieved, the reasons seem clear. For example, *Fraxiparine* (anaesthetic) and *Ultiva* (anti-coagulant) are both speciality products that are used in hospitals rather than by the community and the patient population is smaller than for products used in the community.

In Francophone countries the name of our anti-malarial *Malarone* was changed to *Malanil* for regulatory reasons at the same time as the reduced price was introduced. In this instance we saw sales volumes decline. We were advised by pharmacists that this was because some customers thought the apparently new product was a counterfeit, given that it was introduced very quickly with a low price and a different trade name. This raised concerns about the quality of the product. We are working to inform customers of the

name change and to support their use of *Malanil* at the discounted price.

Ensuring patients benefit

In most instances we believe the price decreases are being passed on to patients. However in some countries where there is less control by the governments on mark-ups, early indications suggested that middlemen were taking advantage of the price reduction and not passing it on to the patient. We have been working with governments and the media to ensure patients are aware of and benefit from the reductions and we are beginning to see sales volumes increasing in those countries. We have also received feedback from some physicians indicating that more patients are using these medicines and that patient compliance with the prescribed dose has improved in some cases.

Reductions on off-patent products

Following the positive uptake of our patented products at their reduced prices, further feedback from local physicians indicated a need for lower priced antibiotics given the high incidence of infectious diseases. We have thus started to reduce prices of *Augmentin* and *Zinnat* by between 30 and 40 per cent from January 2010 in East Africa and will look to extending this to other LDCs during 2010.

Read about our [not for profit pricing of ARVs](#)

› [Back to top](#)

Corporate Responsibility Report 2009

Middle-income countries

Approach

Performance

Middle-income countries¹ (MICs), such as Brazil, China, Thailand, India and Indonesia are more economically developed than the world's poorest countries, and often have a large and affluent middle class. However, many middle-income countries also have large numbers of people living in extreme poverty and healthcare demands often outstrip available resources. These challenges are made worse by an increasing incidence of chronic diseases such as asthma and diabetes.

We want to do more to improve affordability and increase the number of people that have access to GSK medicines and vaccines. We also recognise that these markets offer important commercial opportunities. For example, a report by accounting firm, PriceWaterhouseCoopers¹, has suggested that Brazil, China, India, Indonesia, Mexico, Russia and Turkey could account for 20 per cent of the global pharmaceutical market by 2020. Growing our business in MICs is a key element of our overall strategy.

In the past, the majority of our revenue in MICs has come from private sector healthcare providers. To achieve growth we need to go beyond the high income sector, and increase access for patients at lower income levels.

However, the MICs are diverse in terms of economic status, demography and healthcare infrastructure which can vary significantly. Taking a single pricing approach would be difficult, inappropriate and inequitable. We are therefore extending our flexible pricing strategy for MICs to improve the affordability of our medicines and increase access for patients with lower income levels, while remaining profitable for GSK. This is challenging and the work is at an early stage.

Our approach also includes long-established practices such as [voluntary licences](#), tiered pricing for vaccines and preferential pricing for HIV/AIDS medicines. We are also [forming commercial partnerships](#) which give more patients access to medicines by bringing products to countries for the first time.

Improving access to medicines in middle-income countries – the challenges

- Low government healthcare spend relative to gross domestic product (GDP). This can be as low as one per cent of GDP compared with an average of nine per cent in the EU and over 15 per cent in the US
- Poor healthcare infrastructure, including hospitals, clinics, doctors and nurses
- A high level of income inequality within countries, which can complicate pricing considerations
- The affordability of medicines and vaccines
- Taxes and mark-ups on medicines and vaccines
- Stigma and discrimination associated with certain diseases
- Use of traditional medicines
- Remote rural populations

¹ [World Bank classification](#)

² [Pharma 2020: The vision](#)

› Home › Responsibility › Access to medicines › Flexible pricing

› Middle-income countries - Performance

Corporate Responsibility Report 2009

Middle-income countries

Approach

Performance

Established practices

Tiered pricing for vaccines

Our vaccines are available to 18 GAVI-eligible middle-income countries (MICs), including Indonesia, Sri Lanka and Cuba, at highly discounted prices. In 2009, of the 1.4 billion vaccine doses we shipped, one billion went to developing countries, including least developed and middle-income countries.

Many of our vaccines are included in government vaccination programmes in middle-income countries. For example, *Rotarix*, our rotavirus vaccine, is now included in government vaccination programmes for newborn babies in Brazil, El Salvador, Mexico, Panama and Venezuela. In 2009 we supplied over 25 million doses of this vaccine; the vast majority went to developing countries.

Preferential pricing for HIV/AIDS medicines

We negotiate preferential pricing arrangements for HIV/AIDS medicines in middle-income countries on a case-by-case basis. Prices are lower than those paid by developed countries, but not as low as the not-for-profit (nfp) prices paid by the Least Developed Countries (LDCs). We believe this approach is appropriate because the burden of disease and the resources available to address that burden vary significantly from country to country, and within countries. These arrangements combine a viable and sustainable commercial return for GSK with improved affordability for the healthcare systems concerned. Read more about [our approach to HIV/AIDS](#).

Extending our flexible pricing strategy

Our strategy is to grow our business in middle-income countries (MICs) by increasing the volume of products we sell and, in doing so, increasing the number of patients that receive them. To achieve this, we need to be more flexible on the prices we charge for our medicines.

With supportive systems in place, price reductions can have a big impact on the volume of products we sell and significantly increase access for patients, as our experience in the Philippines demonstrates (see feature box below).

Our pricing strategy will encourage our local operating companies to take a more proactive approach to pricing. This includes:

- Optimising our prices so that they reflect the markets' ability to pay, with poorer countries paying less for medicines than better off countries
- Introducing differential pricing structures within markets to reach new sectors of the population. This will include doing business with public sector organisations in markets where we previously only dealt with the private sector
- Working closely with MIC health authorities and payers to agree innovative pricing programmes and other support that help improve patient access to our medicines
- Closely monitoring our prices compared to local competition
- Ensuring that reductions in selling prices are passed on to patients where appropriate

Healthcare systems and pricing regulations vary widely between countries, so our strategy will be tailored in

each market to reflect local healthcare needs and commercial objectives.

Improvements in manufacturing, including local sourcing and manufacturing arrangements, can bring significant cost reductions so our commercial teams will collaborate with our manufacturing teams from an early stage. Our experiences in one market can help to inform our strategy in another, so we will develop forums for regional and country teams to share information and best practices.

We also need to work closely with other groups in the distribution chain to ensure our price reductions benefit patients rather than just increasing profit for middlemen. To do this we will seek opportunities to work with relevant partners such as the Medicines Transparency Alliance (MeTA).

Pricing is a complex and multi-dimensional issue. Factors such as new product introductions and the reaction of competitors to our price changes can also have an impact on GSK's ability to improve access to our own medicines. For example, however much we seek to evolve our business model, there will always be companies with a lower cost base which will be able to supply at lower prices than GSK. Also, our price reductions may lead to competitors reducing their prices which will improve affordability and benefit patients, but may mean that our own sales volumes stagnate or even fall.

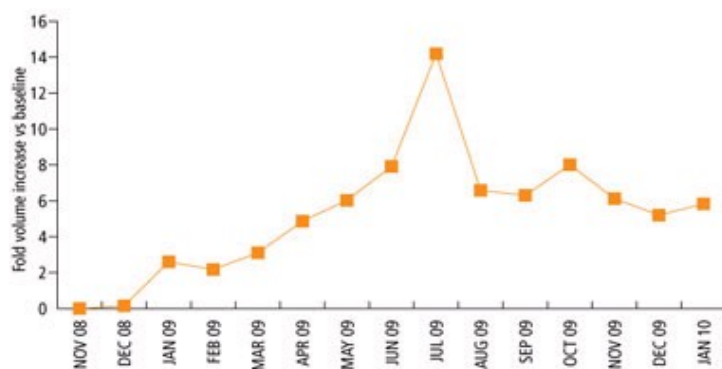
There are also commercial risks. For example, products sold at lower prices may be diverted to better off groups within that country or even to other countries. It is also possible that better off countries may seek the same price reductions even though their ability to pay is greater. Price reductions could start a price war with local generics companies resulting in a spiralling down of prices to a point where we cannot make a profit and the business in that market becomes unsustainable.

Taking these many factors into account, we will continue to review the prices of our medicines for private and public purchasers in each country to ensure that we are competitive, profitable and our medicines are available to the widest number of people who can reasonably afford them.

Cervarix price reductions

GSK is committed to ensuring pricing is not a barrier to access in the developing world and has reduced prices for *Cervarix* in the Philippines, Vietnam, Indonesia and South Africa. With supportive systems in place, price reductions can have a big impact on the volume of products we sell and significantly increase access for patients. For example, after reducing the price of *Cervarix* by 60 per cent in the Philippines monthly sales of the vaccine increased significantly, settling at around six times the volume of vaccines sold before the price reduction was introduced.

Change in *Cervarix* volume sales after price reduction



GSK has a long track record of tiered pricing for vaccines available in government-led programmes, where we charge reduced prices in countries with lower levels of income. The reduction of the price for *Cervarix* in a number of countries is a further demonstration of our commitment to increasing [access to our vaccines](#). Most recently, in March 2010, we reduced the price of *Cervarix* in Nigeria by 50 per cent.

» Back to top

Corporate Responsibility Report 2009

Developed countries

Approach

Performance

Access to medicines is not only an issue for the developing world. Even in developed countries some patients cannot afford the medicines they need.

This is a particular problem in the US where many people do not have health insurance and there is [limited public health provision](#).

We aim to price our medicines fairly in all markets. We have also developed Patient Assistance Programs (PAPs) and discount savings cards in the US and we have introduced discount cards in some middle-income countries.

Pricing new products

Prices for newly approved medicines are determined on a country-by-country basis. In some countries, prices are negotiated directly with governments or other payers, for example sickness funds and private health insurers. In others, manufacturers are free to set their own prices subject to other kinds of government controls.

We seek to ensure that the price of our new products reflects:

- Their clinical value to patients in terms of improved therapy, better safety and fewer side effects
- Providing value to payers
- The high risks associated with R&D
- The need for a fair return on investment

National price regulation is often a balancing act between managing public healthcare budgets, enabling patient access and rewarding innovation to ensure continued investment in R&D. We sell our medicines to wholesalers and pharmacies, not directly to patients. These intermediaries often add their own price mark-ups to pharmaceutical products, and in addition duties and tariffs may be imposed on imported products. This affects the price paid by the end customer, for example national health services, hospitals and patients

Our approach in Europe

Most countries in Europe require demonstration of the value of a new medicine, for example clinical effectiveness or cost-effectiveness, before reaching a decision on reimbursement by the government. Given the context in Europe of state-funded healthcare systems and wider budgetary constraints, in some cases innovative approaches to price setting may be needed to support patient access to medicines.

Wherever possible we want to demonstrate the full value of our medicines through evidence-based data at the time of introducing a new medicine. For most products, this should allow a fair price to be set which reflects a medicine's proven value, one that is affordable to customers and is sustainable for GSK. However, balancing these requirements can be challenging and complex, for example in cases where a level of uncertainty exists in relation to a new medicine. This uncertainty may be over aspects of evidence provided at launch or the expected financial impact of a new medicine.

GSK is exploring with regulators and policy makers innovative ways of balancing fair reward for its medicines with maintaining efficient and fast patient access. We are working with governments in a spirit of partnership and in order to help manage risk and uncertainty. GSK is already engaging in innovative pricing programmes

in [several countries](#).

Discount cards in other countries

GSK has introduced discount cards in Lithuania and Ukraine to enable low-income patients with chronic diseases such as asthma to obtain prescription medicines at a discount price.

Programmes in the US

Our Patient Assistance Programs (PAPs) and discount savings cards provide prescription medicines to uninsured patients in the US for free or at minimal cost. GSK operates several programmes, including *Commitment to Access*, which covers cancer treatments, and *Bridges to Access*, which covers other medicines for outpatients. In 2009, we introduced a self-enrolment system to our *Bridges to Access* programme so that patients can now apply using a simple, one-page application as well as by telephone with the help of an advocate.

[GSK Access](#) provides extra help for low-income senior and disabled patients enrolled in Medicare Part D. This programme provides free medicines for eligible patients who have spent \$600 or more on prescription medicines during the current year, and who meet income requirements based on the Federal Poverty Level. The Federal Poverty level is about \$11,000 for a single person, \$14,500 for a couple and \$22,000 for a family of four.

We are a member of *Together Rx Access*, an industry programme which gives uninsured US citizens 25 to 40 per cent discounts on medicines from GSK and seven other pharmaceutical companies. The programme is open to people who earn up to four times the Federal Poverty Level. Nearly two million Americans are enrolled in *Together Rx Access*.

We are also working with governments and employers in the US to find new ways to [address the problem of chronic diseases while reducing healthcare costs](#).

Update September 2010

In the US, we have launched a programme to provide our adult vaccines free of charge to eligible, low income individuals who do not have insurance coverage for vaccines.

The US government's Vaccines for Children programme provides vaccines for young people under the age of 18, regardless of their ability to pay. However, a similar reimbursement system does not exist for adults and immunization rates among adult Americans are low.

The GSK Vaccines Access Program will enable eligible adults to receive our FDA-approved vaccines for Hepatitis A, Hepatitis B, tetanus, diphtheria and pertussis. Eligible women aged 19 to 25 will also be able to receive our cervical cancer vaccine.

› [Back to top](#)

Corporate Responsibility Report 2009

Developed countries

Approach

Performance

Pricing in Europe

We are exploring flexible approaches to pricing, for example:

France

When launching *Requip XR* (extended release), results of trials were not available to show that the extended release form of the product achieved better results than the existing normal release form of *Requip*. GSK France agreed with the French health authorities to launch *Requip XR* at a lower price than the existing version, so that price would not be a barrier to access for patients. In 2009 we submitted additional study data demonstrating that *Requip XR* was superior. Based on the new clinical data, the French authorities agreed to increase the price. This flexible approach is a positive example and model for France and other countries.

Italy

The Italian Pharmaceuticals Agency has agreed a risk-sharing arrangement with GSK for the breast cancer medicine *Tyverb*. Under the agreement, the Italian state covers the cost of an initial 12-week treatment cycle. If the patient responds positively, the treatment continues at the state's expense. If the patient does not respond, the cost of the initial treatment cycle is covered by GSK.

United Kingdom

On initial review, the National Institute for Health and Clinical Excellence (NICE) ruled that *Tyverb* did not meet its required cost-effectiveness threshold. To address this, GSK offers a patient access programme for patients who are able to receive *Tyverb* in combination with capecitabine. Under the programme GSK covers the cost of *Tyverb* for the first 12 weeks of treatment, and the National Health Service pays for treatment beyond 12 weeks for those patients who continue to benefit.

NICE has now introduced supplementary guidelines for assessing medicines used at the end of a patient's life and has considered *Tyverb* in the light of these more flexible criteria. Despite these changes, to date NICE does not consider that *Tyverb* meets its required cost-effectiveness threshold. The appraisal of *Tyverb* is ongoing and we continue our discussions with NICE. In the meantime, a number of local health authorities have signed up for the GSK patient access programme in order that they can provide the product to suitable patients at a reasonable cost.

In the 2009 Pharmaceutical Price Regulation Scheme agreement, which regulates industry profits in the UK, the government, in partnership with industry, introduced new measures to promote flexible pricing arrangements. The agreement recognises that the use for which a medicine is initially launched may not fully reflect its longer-term value to patients in the NHS. It therefore allows a company to propose an initial price for a medicine that reflects value at launch, while retaining the freedom to increase or decrease this original list price either as further evidence or as new uses for the medicine emerge and change the effective value the medicine offers to NHS patients.

Discount cards in other countries

Lithuania

Our Orange Card programme gives senior citizens and the disabled a discount of up to 60 per cent on the

patient co-payment on all GSK prescription medicines. So far more than 86,000 patients have applied for an Orange Card and over 550 pharmacies (40 per cent of the pharmacies in Lithuania) are registered to participate. In 2009 the total discount given was £694,000.

Ukraine

Our Orange Card programme gives significant discounts to all asthma and chronic obstructive pulmonary disease patients who need financial support for purchasing *Seretide*, our inhaled treatment for asthma and chronic obstructive pulmonary disease. In 2009 more than 41,000 patients had Orange Cards and 237 pharmacies were registered to participate in the programme. In 2009 the total discount given on *Seretide* was £2 million.

Programmes in the US

In 2009 466,000 patients received GSK medicines worth over £80 million through our US programmes.

The value of our medicines is calculated using an average cost of goods rather than the wholesale acquisition cost (WAC). This approach to valuing medicines more accurately reflects the true cost to GSK and is therefore more transparent. We believe we were the first pharmaceutical company to adopt this practice.

This year almost 6,000 patients received over 13,800 30-day prescriptions of GSK medicines through the *Together Rx Access* programme, giving patients discounts of more than \$700,000. Since its inception in 2002, *Together Rx Access* has given over two million patients savings totalling \$97 million across a wide range of products.

› [Back to top](#)

Corporate Responsibility Report 2009

Partnerships and acquisitions

We are developing innovative partnerships that tackle some of the barriers to access to medicines in developing countries and are tailored to local healthcare needs.

Our approach includes:

- Joint ventures and technology transfer arrangements that help developing countries develop their research and manufacturing capabilities, while increasing access to these markets for GSK
- Voluntary licences that enable generics companies to manufacture low cost anti-retrovirals for treatment of HIV in Africa
- Expanding our product portfolio and pipeline in developing countries through new alliances, acquisitions and partnerships

A key barrier to access in developing countries is lack of healthcare infrastructure, both physical and human. Although we are not a health service provider, we want to work with others to improve healthcare infrastructure. We have committed to reinvest 20 per cent of our profits from medicines sold in Least Developed Countries back into projects that widen access to essential medicines and strengthen the healthcare infrastructure in those countries. Read about our [progress so far](#).

› Home › Responsibility › Access to medicines › Partnerships and acquisitions
› **Technology transfers and joint ventures**

Corporate Responsibility Report 2009

Technology transfers and joint ventures

We are pursuing joint ventures and technology transfer agreements in developing countries. These agreements benefit GSK by giving us access to new markets and benefit developing countries by expanding the supply of essential medicines and vaccines and supporting the development of local research and manufacturing capabilities.

We have shared our resources, knowledge and expertise with developing countries through joint ventures and technology transfer agreements for many years. Below we feature two significant examples from 2009.

Vaccines are a suitable candidate for technological transfer because of their importance to public health and because they are used across the whole population and needed in constant supply. It is also important to have local production capacity to be able to respond quickly to an epidemic. We have developed a network of 13 vaccine production sites in 12 countries worldwide which are a mixture of our own operations, joint ventures and collaborations.

Partnerships are developed on a local basis to meet the healthcare needs of the country involved. But not all developing countries are suitable for investment or technology transfer agreements. Factors include: economic and political stability; market size and potential; availability of skilled workers; a supportive regulatory environment (including enforcement of appropriate quality, safety and efficacy criteria) and intellectual property framework; availability of natural resources; and an adequate system to deliver the vaccine after production.

Most importantly, strong political will is needed to prioritise immunisation in health budgets, to promote partnerships to enable vaccine R&D, and to support programmes to vaccinate the population.

Local manufacturing can help to make medicines more affordable, but this is not always the case. The lowest manufacturing costs are achieved by concentrating production in large factories, so it can be more efficient to scale up existing facilities rather than create new sites.

Brazil

We have been partnering with Brazil's Oswaldo Cruz Foundation (Fiocruz) since 1985 to manufacture vaccines for public health priorities in Brazil including polio, Haemophilus influenzae type b (Hib), measles, mumps, rubella, rotavirus and most recently pneumococcal disease.

Our local manufacturing and technology transfer deal has generated sales for GSK vaccines while helping Brazil develop its research and manufacturing capabilities. It has also helped us to develop a positive relationship with the Brazilian government, an increasingly important customer for GSK.

We extended our partnership with Fiocruz this year, launching a joint R&D initiative to develop a vaccine for dengue fever. Scientists from GSK and Fiocruz will work across facilities in Brazil and Belgium on the new partnership which will enhance Brazilian R&D capacity.

GSK will also provide Fiocruz with access to the technology behind its *Synflorix* vaccine which protects against life-threatening infections such as pneumonia, meningitis and bacteraemia. We will supply *Synflorix* to Fiocruz until the technology transfer is completed. The Brazilian government will incorporate the vaccine into its national immunisation programme.

Our technology transfer agreement for our *Rotarix* vaccine which protects against rotavirus, a cause of gastroenteritis, continued this year. Since 2007 GSK (via Fiocruz) has been the sole supplier of 50 million

doses of rotavirus vaccine in Brazil. The vaccine was included in the National Programme of Immunizations in March 2006 and on 17 December 2007 the technology transfer between GSK Biologicals and Fiocruz/MoH was agreed. From 2012 Fiocruz will produce *Rotarix* for the Brazilian domestic market and manufacture *Rotarix* for GSK under contract for export.

The deal has benefited both GSK and Fiocruz and is helping to ensure that around 17 million babies in Brazil will be protected by GSK's *Rotarix* over five years. Several vaccine impact studies have been conducted with the following results:

- In Brazil, compared to the pre-vaccination period of 1998-2005, hospitalisation due to gastroenteritis decreased in 2007, by 31.3 per cent in children ≤ 5 years. A greater reduction of 48.2 per cent was observed among children aged less than 1 year¹
- In Recife, in the northern territory of Brazil, a case-control study showed that *Rotarix* provided a high and statistically significant protection of 77-85 per cent against severe diarrhoea and hospitalisations due to rotavirus gastroenteritis in the first year of life¹
- In São Paulo, the largest city in Brazil, a study showed a 29 per cent of reduction in hospitalisations due to all causes of gastroenteritis among children ≤ 5 years in 2007, compared with the pre-vaccine introduction period. Gastroenteritis due to rotavirus decreased by 59 per cent in 2007 compared with the pre-vaccine introduction period¹
- In São Paulo, according to data from the State Health Secretariat, there was a reduction in the proportion of cases of gastroenteritis caused by rotavirus from 88 per cent in 2004 to one per cent in 2008¹
- According to a mathematical model, the rotavirus vaccination programme in Brazil was estimated to prevent approximately 1.7 million (54 per cent) of rotavirus gastroenteritis cases and 703 (75 per cent) of rotavirus-associated deaths during a period of five years⁵

China

We have announced a new joint venture with Shenzhen Neptunus Interlong Bio-Technique Co. Ltd (Shenzhen Neptunus) focused on developing and manufacturing influenza vaccines for the Chinese market. This will include vaccines for seasonal, pre-pandemic and pandemic influenza.

The joint venture will benefit from both companies' expertise in vaccine development. GSK will provide access to its adjuvant system which helps to improve efficiency and optimise production by increasing the number of vaccine doses that can be produced using a smaller amount of antigen. Shenzhen Neptunus will provide local manufacturing capacity and R&D expertise.

In China we agreed to form a long-term joint venture with biotech company Walvax, to develop and manufacture paediatric vaccines (including *Priorix*, our measles, mumps and rubella vaccine) for use in the country. GSK will transfer the necessary technology so the joint venture can manufacture the vaccines locally over time. GSK is investing nearly £30 million in the collaboration.

We have also granted a voluntary licence to Simcere, a Chinese manufacturer, granting it the right to manufacture and sell zanamivir (*Relenza*) containing products in China, and to sell in a number of other countries including all 49 of the Least Developed Countries. Zanamivir is an anti-viral which can help treat influenza, and the voluntary licence was driven by a specific concern to help ensure sufficient supplies in the event of a global flu pandemic.

For further background on our position on voluntary licensing and technology transfer generally, please visit the public policy area of our website.⁶

¹ Lanzieri, T. et al, Data on file. Poster presented at WSPID, November 2009 Buenos Aires (Argentina)

² Correia, JB et al. J. Infect. Dis. (1 February) 2010:201

³ Safadi, MA et al Data on file. Poster presented at ESPID, June 2009, Brussels, Belgium

⁴ [Sao Paulo State Health Secretariat](#)

⁵ Coelho de Suarez ,P et al Rev Panam Salud Publica/Pan Am J Public Health 23(4), 2008

⁶[GSK Public policies](#)

› [Back to top](#)

Corporate Responsibility Report 2009

Portfolio expansion

Approach

Performance

Some of our growth in developing countries is being achieved through making our current product range more affordable. However, we believe that significant growth will come from expanding our product portfolio to make it more suited to the needs of patients in developing countries. As well as developing new products through our own R&D operations, we are achieving this through strategic alliances and acquisition of pharmaceutical companies.

Together, these deals are providing GSK with access to a renewable, high-quality and competitively priced pipeline of branded pharmaceuticals products that complements our existing portfolio of products, and will help increase access in low- and middle-income markets.

For example, our licensing collaboration established in 2008 with South Africa-based pharmaceuticals company Aspen is giving us access to a product portfolio of over 1,200 products which we can licence for sale in developing countries.

Our focus on quality and our secure supply chain mean these collaborations will provide a reliable and high-quality choice for patients in many countries.

› [Back to top](#)

› Home › Responsibility › Access to medicines › Partnerships and acquisitions
› Portfolio expansion - Performance

Corporate Responsibility Report 2009

Portfolio expansion

Approach

Performance

Alliances

Some of our growth in developing countries is being achieved through strategic alliances and acquisition of pharmaceutical companies. This allows us to broaden our product portfolio and provide medicines of value to more patients in these countries.

Our licensing collaborations with both Aspen, based in South Africa, and Dr Reddy's in India are giving us access to a portfolio of low cost, quality branded products across therapeutic areas such as cardiovascular, central nervous system, diabetes, gastroenterology and oncology. We can license these products for sale in GSK's Emerging Markets and Asia-Pacific regions. Regulatory applications have been filed for 35 molecules (more than 80 products) across the regions during 2009. The first set of products will be on sale from 2010.

We entered into a new collaboration this year with Aspen to combine our commercial activities in sub-Saharan Africa. The agreement builds on our previous alliance with Aspen, one of Africa's leading healthcare companies. Under the terms of the agreement, GSK and Aspen will collaborate on the commercialisation of their current and future product portfolios in sub-Saharan Africa (excluding South Africa). The vast majority of combined current sales in this region (approximately £65 million in 2008) are attributable to GSK.

The collaboration will build a broader and more diverse portfolio for these countries, with Aspen's extensive pipeline of new products expected to benefit from greater leverage through GSK's existing commercial infrastructure. It will help us provide more medicines of value to more patients in this region and overcome some of the access challenges. The agreement does not cover South Africa, where Aspen has extensive commercial capability. We will transfer marketing and distribution rights to Aspen for GSK's pharmaceutical products in this country.

As part of the overall deal GSK acquired a 16 per cent shareholding in Aspen, which has since been increased to 19 per cent, demonstrating GSK's commitment to investing in the sub-continent.

In December 2009 we entered into an agreement with Gilead to develop and launch its hepatitis B treatment *Viread* in China. The agreement builds on GSK's strong heritage in hepatitis B and provides an important addition to our current portfolio in one of our key markets. Together with Gilead, we are committed to increasing access to this medicine for more patients in Asia, bringing new ways to address the burden of chronic hepatitis B where it is most needed.

Also in December 2009, GSK reached an agreement to take a 100 per cent stake in the Algerian pharmaceutical manufacturing and distribution group, Laboratoire Pharmaceutique Algerien (LPA), to accelerate sales growth and further extend its pharmaceutical portfolio in Algeria.

GSK has collaborated with LPA, one of the leading pharmaceutical distribution companies in Algeria, for over 18 years. In taking full ownership of the LPA group, GSK acquires 12 branded generic pharmaceutical products in the analgesic, cough and cold and dermatology areas, as well as a manufacturing facility and distribution warehouse in Boudouaou, Algeria.

This agreement with LPA will enable us to increase access to high quality healthcare products for people in Algeria through local manufacture, an expanded portfolio of branded generics and greater distribution capability.

LPA will continue to operate as a separate entity and will focus on branded generics and distribution. GSK

Algeria will continue to focus on GSK's patented brands and vaccines.

Acquisitions

Acquisitions in 2009 included:

- Bristol-Myers Squibb Pakistan (Private) Ltd (BMSP), which has a portfolio of over 30 well-established pharmaceutical brands, many of which occupy leading market positions in key therapeutic disease areas in Pakistan. The BMSP portfolio includes antibiotics, vitamins and dermatology and will also provide new opportunities for GSK in cardiovascular and oncology
- Bristol-Myers Squibb's branded generics business in Lebanon, Jordan, Syria, Libya and Yemen, which comprises a portfolio of 13 branded pharmaceuticals
- UCB South Africa's marketed product portfolio in territories in Africa, the Middle East, Asia Pacific and Latin America. As a result of the agreement, GSK will acquire several leading pharmaceutical brands in a number of disease areas. These include *Keppra* for the treatment of epilepsy and *Xyzal* and *Zyrtec* for the treatment of allergic rhinitis.

› [Back to top](#)

Corporate Responsibility Report 2009

Advocacy and government relations

We lobby governments and policy makers to advocate a sustainable approach to [improving access to healthcare](#). Such an approach must support innovation which is critical to improving access in the longer term.

In 2009 we also responded to a report by the UN Special Rapporteur on Human Rights, on the Right to Health, see below.

Advocacy

In 2009 our advocacy work in this area included:

- Urging the G8 to continue making healthcare in the developing world a major agenda item
- Supporting the development of a pilot Advance Market Commitment for a pneumococcal vaccine
- Engaging in the work of the WHO's Intergovernmental Working Group (IGWG) on Public Health, Innovation and Intellectual Property and the Expert Working Group looking at financing
- Working with the UK Government on global health issues and in the development of the Department for International Development's (DFID's) Medicines Transparency Alliance (MeTA) and the review of its Good Practice Framework for pharmaceutical companies
- Discussing IP, innovation and funding with NGOs, foundations and other stakeholders
- Attending WHO Executive Board Meetings and the World Health Assembly
- Contributing to the design of an Affordable Medicines Facility for Malaria
- Playing a leading role in major global health initiatives. For example GSK sits on the Boards of the GAVI Alliance and participates in the Roll Back Malaria Board meetings
- Participating in Board meetings of the Global Fund to Fight AIDS, TB and Malaria and supporting the development of its Quality Assurance standards
- Engaging in the negotiations on the WTO Doha Round to seek sustainable pro-innovation outcomes
- Addressing HIV/AIDS in the EU and neighbouring countries through the European Commission's Bremen Process
- Engaging with the Intergovernmental Meeting on Pandemic Influenza Preparedness
- Contributed to a report prepared by Paul Hunt, the former UN Special Rapporteur on the Right to Health. The report is on GSK's approach to access to medicines. A number of senior executives, including our former CEO, Dr JP Garnier, and our Chairman Sir Christopher Gent, were interviewed

[Read more about our malaria advocacy.](#)

Stakeholder feedback

In November 2009 we held a stakeholder workshop with experts on access to medicines to get feedback on our new initiatives in Least Developed Countries. You can read a report on the workshop findings [here](#).

Government relations

GSK aims to support and work constructively with governments in their efforts to strengthen and develop sustainable healthcare systems across the globe. Read examples of our [activities in this area](#)

Engaging on the human right to health

In May 2009, the former UN Special Rapporteur on the Right to Health, Paul Hunt, [published a review](#) of GSK's policies and practices on access to medicines following a series of in-depth interviews with our senior management. As well as identifying good practices and obstacles to improving access, his report makes a series of recommendations for how GSK, and the pharmaceutical industry more broadly, can support people's right to health. We welcome the Special Rapporteur's constructive engagement with GSK and the recognition in the report of GSK's industry-leading position on improving access to medicines.

We agree with many of the report's recommendations for the pharmaceutical industry. However, we do not agree with the report's suggestion that our access to medicines programmes are mandated by international legal norms, whether relating to human rights or other areas. Given the lack of legal obligation on companies relating to the right to health it is not clear to us how the recommendation of the report to establish a human rights ombudsman could operate in practice.

We are committed to playing our part in tackling the global healthcare challenge. The global community must also provide political will, a significant mobilisation of additional resources and a spirit of partnership if we are to see achievement of the right of everyone to the enjoyment of the highest attainable standard of health across the developing world. We will continue with our efforts, improving our initiatives by applying lessons learned and looking for opportunities to do more. We welcome the Special Rapporteur's constructive engagement with GSK and provided a [response](#) to it when it was presented to the UN Human Rights Council in Geneva in June 2009.

› [Back to top](#)

Corporate Responsibility Report 2009

Case studies

The trials of malaria vaccine development – RTS,S moves into phase III

An effective vaccine will be critical to tackling malaria, alongside prevention efforts such as the use of bed nets and effective anti-malarial medicines. However, developing a vaccine is a complex scientific challenge and no vaccine has yet been registered.

RTS,S is the world's most clinically advanced malaria vaccine candidate. It is the first vaccine designed primarily for use in Africa, where malaria kills more than 800,000 people every year, the majority of them children under the age of five. RTS,S is the result of a groundbreaking partnership, begun in 2001, between leading African, European and US research institutions, the PATH Malaria Vaccine Initiative (MVI) and GSK Biologicals, with support from the Bill & Melinda Gates Foundation.

A phase III efficacy trial of RTS,S is underway in seven African countries: Burkina Faso, Gabon, Kenya, Malawi, Mozambique and Tanzania. This is the largest malaria vaccine trial to be undertaken and is expected to involve up to 16,000 children and infants under the age of five (the groups most vulnerable to malaria). More than 7,500 children had been vaccinated by the beginning of 2010 – the majority between five and 17 months old. We are currently enrolling the second age group, infants from six to 12 weeks of age, who will receive the vaccine as part of their regular schedule of immunisations.

By conducting the trial in seven different countries across sub-Saharan Africa, researchers will be able to evaluate the vaccine's efficacy in a variety of settings with diverse patterns of malaria transmission. For example, some trial sites are located in areas where there is a year-round threat of malaria, while others experience only seasonal transmission.

If current trials are successful, RTS,S could be submitted for regulatory review for children between five and 17 months of age as early as 2012. GSK has invested more than \$300 million to date and expects to invest at least another \$100-\$150 million before completion. MVI has contributed more than \$200 million to the project so far.

Technology transfer for vaccines – a local solution?

GSK has been partnering with Brazil's Oswaldo Cruz Foundation (Fiocruz) since 1985 to manufacture vaccines for public health priorities including polio, Haemophilus influenzae type b (Hib), measles, mumps, rubella, rotavirus and, most recently, pneumococcal disease.

This local manufacturing and technology transfer deal has generated sales for GSK vaccines, while helping Brazil advance its research and manufacturing capabilities. It has helped us to develop a positive relationship with the Brazilian government, an increasingly important customer for GSK.

Technology transfer has been successful in Brazil due to favourable economic, legal, regulatory, scientific and market conditions and the existence of the right partner. Fiocruz has the capacity to receive a technology transfer and shares our vision for how the partnership should work in practice.

GSK is committed to partnering with governments and others to help meet the world's vaccination needs in a sustainable manner. Technology transfer is one of many options that we consider for increasing availability of vaccines in the developing world. However, we do not believe that it is a universal solution.

Technology transfer agreements will only succeed in countries with the right business and scientific environment and suitable local partners. Conducive conditions include: skilled workers to carry out R&D and high tech manufacturing; a supportive regulatory environment; strong political will and commitment; intellectual property protection; a predictable commercial environment and significant investment availability

by the partner receiving the technology. Unfortunately, in many developing countries these conditions do not yet exist.

The evolution of our proprietary knowledge pool

Being more flexible with our intellectual property and encouraging other pharmaceutical companies to do the same could stimulate research and help to speed development of medicines for neglected tropical diseases (NTDs). In February 2009 we announced that we would create an NTD patent pool and in March we published details of over 800 GSK patents and patent applications for small molecule pharmaceuticals which we have identified as potentially useful for the treatment of 16 neglected tropical diseases. Products developed using information from the pool can be sold in Least Developed Countries on a royalty free basis.

In 2009 we held discussions with three groups of stakeholders which helped us to shape our thinking on the pool: the scientific and research community, potential contributors to the pool, and potential administrators of the pool.

In discussions with the scientific and research community, we learnt that they appreciated us making patent information public. However, what they really need is access to our know-how and experience. They want to ask us what we have tried already and what the results were, about what worked and what did not, and about how we overcame particular challenges. We have therefore committed to making this knowledge and experience, as it relates to the 16 NTDs, available to the pool. To reflect this, we now refer to the pool as a 'proprietary knowledge pool'.

In January 2010 we signed agreements giving two organisations access to information in the pool. These are the Emory University Institute for Drug Discovery and iThemba Pharmaceuticals, a company based in South Africa and working on TB, with financial help from the South African government.

To date, one other company, the US biotechnology group Alnylam, has contributed some of its patents to the pool. We held constructive discussions with a number of other companies which could contribute assets to the pool. They told us they would like to see greater independence of the pool. Our goal has always been to create an independent NTD pool and in January 2010 we announced that Bio Ventures for Global Health (BVGH) will take over administration of the pool. We are hopeful that this will lead to more companies joining in due course.

We will continue to work with BVGH, Alnylam and other stakeholders to develop the operating model for the pool so that it can achieve its ultimate objective of stimulating and facilitating more R&D into neglected tropical diseases.

› [Back to top](#)

Corporate Responsibility Report 2009

Q&As

Here we respond to questions raised by our stakeholders

Aren't your access programmes just a drop in the ocean, given the scale of the healthcare crisis in the developing world?

The global healthcare crisis is extensive and complex, and the programmes of any single organisation are insufficient on their own. Political will and the effective investment of extra resources are required to support healthcare development and build infrastructure. GSK and the wider pharmaceutical industry do not have the mandate, expertise or resources to address the problem alone. Without a global partnership to address the issues, the efforts of any individual stakeholder will be inadequate. Primary responsibility for dealing with the crisis lies with governments, which can call on international agencies and NGOs for support. GSK is committed to playing a full part in partnerships with these organisations and is seeking to act as a catalyst to encourage all stakeholders to find new ways to make a contribution.

We focus our access programmes on specific areas where we think we can make a real difference. For example, we research and develop medicines and vaccines that are particularly needed in developing countries, and make them available at lower prices through preferential pricing arrangements and voluntary licences. We are also working to identify other ways that we can contribute towards improved healthcare through seeking out new partnerships, expanding our pricing policies, being more flexible with our intellectual property and by investing in healthcare infrastructure.

Why are your medicines so expensive? Wouldn't the most responsible thing you could do be to cut the price of your medicines?

Improving affordability of our medicines is important and we are taking steps to do more in this area. Poverty, income levels and public healthcare resources vary hugely between countries and we aim to tailor our pricing to meet the needs of individual countries.

We recognise the importance of pricing our medicines fairly in developed countries to meet patient needs and help relieve the burden on public healthcare budgets. We have to price our products in these richer countries at a level that enables us to make enough profit so that GSK remains an attractive prospect for investors and so that we can continue to invest in R&D and discover the medicines and vaccines that will bring benefits to society in the future.

We would not be able to offer not-for-profit or highly preferential prices in the world's Least Developed Countries (as defined by the UN) if we did not generate a reasonable return in developed countries. In middle-income countries, where there is often a large, wealthy middle class, as well as poor communities, we are exploring pricing models that enable us to responsibly seek commercial opportunities in wealthier segments of society while seeking to increase access to medicines for those who cannot afford to pay in these countries.

However, affordability is not the most significant barrier to access in developing countries. As Kevin de Cock said, when Head of HIV/AIDS at the WHO, "If you work in these countries it is very obvious, very quickly, that the elephant in the room is not the current price of drugs. The real obstacle is the fragility of the health systems, particularly in Africa." Therefore, unless action is taken to address the underlying problems of poverty and healthcare infrastructure, reducing prices alone will not solve the problem.

Why doesn't GSK extend its not-for-profit prices to middle-income countries?

We offer our greatest discounts to the countries where the need is greatest and resources are most limited. It is widely accepted that, in terms of support for improving healthcare services, these are the Least Developed Countries (LDCs) (as defined by the UN) and sub-Saharan Africa, which includes some middle-

income countries.

Other middle-income countries are not eligible for the not-for-profit prices offered to LDCs and sub-Saharan Africa.

Many middle-income countries represent growth opportunities for GSK and are an important source of future business for our industry. We are exploring a range of pricing solutions that balance our commercial objectives with the need to increase access to medicines for those who cannot afford to pay in these markets. These include:

- Optimising our prices so that they reflect the markets' ability to pay, with poorer countries paying less for medicines than better off countries
- Introducing differential pricing structures within markets to reach new sectors of the population. This will include doing business with public sector and civil society organisations in markets where we previously only dealt with the private sector
- Working closely with MIC health authorities and payers to agree innovative pricing schemes and other support that help improve patient access to our medicines
- Closely monitoring our prices compared to local competition
- Ensuring that reductions in selling prices are passed on to customers where appropriate

Why are so few people with HIV/AIDS receiving treatment in the developing world?

There has been important progress in this area and now over four million people in the developing world are receiving treatment with life-saving anti-retrovirals. This has led to a decline in deaths caused by AIDS despite an increase in the number of people living with HIV. However, there is much more to do. The core issue is that many people in developing countries do not have access to effective healthcare services and are therefore unable to access medicines. Due to poverty, many clinics and patients are unable to pay for even the cheapest basic generic medicines. ViiV Healthcare will bring renewed focus on addressing these challenges.

The access issue is complex and multifaceted. Pricing of medicines is important, but we believe there are many other more significant barriers. Other factors that play a part are inadequate healthcare resources, lack of clinics and hospitals, poor distribution networks, low numbers of trained healthcare providers, high levels of patient illiteracy, significant stigma and discrimination, and a lack of political will and inadequate prioritisation of health in government budgets. This is why in 2009 we announced that 20 per cent of the profits we make from selling medicines in Least Developed Countries will be reinvested into projects that strengthen infrastructure and widen access.

Why don't you just donate your AIDS products to the world's poorest?

In common with many other stakeholders, including Oxfam and the WHO, we do not believe that donations of ARVs offer a solution to the AIDS pandemic or for healthcare problems in the developing world more generally. This is a widespread crisis and one which requires a long-term commitment to treatment. This commitment cannot be assured through donations. As WHO Director General Margaret Chan has said: "Health systems are the tap root for better health. All the donated drugs in the world won't do any good without an infrastructure for their delivery."

In some limited circumstances donations may be appropriate, for example, in disease elimination efforts such as the Global Alliance to Eliminate Lymphatic Filariasis. We have in the past donated ARVs to support UNICEF Prevention of Mother-to-Child Transmission programmes, and we continue to support collaborative clinical trials to assess the appropriate use of ARVs in resource-poor settings.

Why don't you allow middle-income countries to buy your ARVs from generic manufacturers?

We have granted eight voluntary licences for our ARVs to African generics companies. Under these arrangements they can supply a number of middle-income countries in Africa. Middle-income countries are generally more economically developed than the Least Developed Countries and often have a large and affluent middle class. These countries also have large numbers of people living in extreme poverty and healthcare demands often outstrip available resources. We recognise that many middle-income countries need assistance. However, we believe a different approach is needed from the one we take in the world's poorest countries and we continued to refine our approach during 2009.

Our offer to supply products at not-for-profit prices in the world's poorest countries is only sustainable if we

can continue to make an adequate return on them in wealthier markets. Many middle-income countries are also growing commercial markets for GSK and represent an important source of future business for our industry. Our response in these markets must therefore be one that balances our commercial objectives with our global commitment to work with governments and other stakeholders to ensure that our medicines and vaccines reach as many as possible of those who need them.

We believe governments in middle-income countries can improve access by increasing investment in disease prevention and healthcare; eliminating taxation and tariffs on medicines; and creating an environment which allows a strong private healthcare sector to co-exist with public healthcare provision. We are working with governments to find creative ways to meet these goals.

Why don't pharmaceutical companies work together to increase access to medicines?

We recognise that companies can do more together than they can alone and we are seeking out new partnerships. For example, together with Pfizer we launched ViiV Healthcare in 2009, a specialist company solely focused on the research, development and commercialisation of HIV medicines. ViiV Healthcare has a core objective to address the lack of treatments and formulations for children living with HIV, a significant unmet medical need.

We are encouraging other companies to join our knowledge pool for neglected tropical diseases in which we have placed approximately 80 patent families (over 500 granted patents and over 300 pending applications) to help others to develop new medicines for neglected diseases.

We also aim to attract new partners, including other businesses, to our Tres Cantos diseases of the developing world research centre in Spain with the aim that the facility becomes a centre of excellence, stimulating research and collaboration that is open to a wide range of stakeholders rather than just one company.

› [Back to top](#)

› Home › Responsibility › **Research practices**

Corporate Responsibility Report 2009

Research practices

We are committed to focusing on the patient in everything that we do. Our R&D pipeline is central to our ability to meet patients' needs.

High ethical standards in R&D are key to protecting participants in our clinical research, ensuring the quality of our research, and maximising the benefits and minimising the risks of our medicines and vaccines. High ethical standards are also essential for us to obtain regulatory approval for new medicines, and for patients and doctors to put their trust in our research programmes and products.

As part of our strategy to grow a diversified global business and deliver more products of value, we are expanding our presence in emerging markets, buying new businesses and collaborating with more organisations. Our R&D policies are global and we apply the same high standards wherever we operate including contract organisations which conduct research on our behalf. We only collaborate with organisations whose principles are aligned with those of GSK. For research that is conducted as part of a collaboration, we raise awareness of our policies at the beginning of the collaboration and include clauses in the collaboration agreement requiring compliance with our principles. Research collaborations are typically overseen by a Joint Steering Committee (JSC) made up of senior staff from GSK and our collaborator.

We continuously evaluate the risks and benefits of our medicines at every stage, from initial research through to clinical trials and then after a new product is approved for sale.

We are committed to being open about the results of our clinical research and use a number of reporting channels so that those who evaluate the efficacy and safety of our medicines or use our medicines can make informed decisions on their use. To further increase transparency, we have committed to publishing the research payments we make to healthcare professionals, starting in the US and followed by GSK's Europe and Asia Pacific, Japan and Emerging Markets (APJEM) regions.

As part of our commitment to understand patient needs and to develop better medicines we have a programme of activities where we invite patients to discuss their conditions with our research teams.

We recognise that biomedical research can raise ethical concerns, including those relating to:

- The use of emerging technologies such as cloning and the use of stem cells
- Animal research
- Clinical research
- The storage and use of human tissue
- The protection of personal information about research participants
- We participate in discussions on research practices and we regularly [engage with academic scientists, regulators, policy makers and other stakeholders](#) on related issues.

› [Back to top](#)

› Home › Responsibility › Research practices › [Emerging technologies](#)

Corporate Responsibility Report 2009

Emerging technologies

Research capabilities are expanding through the development of technologies related to areas of research such as stem cell and genetic research.

These emerging technologies are helping to expand the boundaries of scientific understanding. They hold out hope for new ways to treat serious diseases as well as better ways to evaluate the risks and benefits of the medicines we develop. For example, advances in genetic research are beginning to enable identification of patients who are more likely to experience certain side effects from a medicine.

We use emerging technologies in our research and we are involved in [collaborative research on these technologies](#).

We recognise that research using emerging technologies can give rise to ethical concerns.

Here we outline our involvement and approach to:

- The use of [cloning technologies](#)
- The use of [stem cells](#)
- [Genetic research](#)
- Use of [transgenic animals](#)

› [Back to top](#)

› Home › Responsibility › Research practices › Emerging technologies
› [Cloning technology and stem cell research](#)

Corporate Responsibility Report 2009

Cloning technology and stem cell research

Cloning technologies

GSK uses cloning technologies to replicate molecules and cells for research. These technologies have provided better ways to evaluate compounds, enabling greater insight into the risks and benefits of potential medicines and helping to create better medicines for patients. This technology is a fundamental component of medicine discovery and development.

GSK does not clone animals. We do not use cloning technologies with the intention of reproducing entire human beings and we do not see a medical or research case for doing so.

Read our [position statement on cloning technologies and stem cell research](#).

Stem cell research

We recognise the importance of being clear about our [approach to stem cell research](#) and the standards we apply in this area of research. Our [position statement on cloning technologies and stem cell research](#) sets out the standards we apply when using stem cells, including embryonic and foetal stem cells.

In 2008 we began a five-year collaboration with the Harvard Stem Cell Institute (HSCI). This includes a \$25 million investment to support research at Harvard University and a number of affiliated hospitals in the areas of neuroscience, heart disease, cancer, diabetes, musculoskeletal diseases and obesity. The collaboration is overseen by a joint steering committee made up of HSCI and GSK scientists and managers.

We are also a founding member of the Stem Cells for Safer Medicine (SCSM) initiative in the UK. SCSM aims to develop a bank of human cell lines to be used in early medicine discovery. This will provide early identification and elimination of potential toxicity issues before clinical testing. A number of public sector organisations are contributing to the initiative, including the Department of Health, the Department for Innovation, Universities and Skills, the Scottish Government, the Medical Research Council and the Biotechnology and Biological Sciences Research Council.

In 2009 SCSM awarded a grant of £160,000 to enable research teams to investigate the generation of cardiac cells from pluripotent stem cells. The funding aims to advance scientific understanding of how medicines affect the heart, to find ways to avoid chronic cardiac side effects or long term damage. The funding follows a previous award made by the SCSM to support research into the generation of liver cells from pluripotent stem cells, to be applied to early medicine research and screening.

Read more about how we are [collaborating in research on emerging technologies](#).

› [Back to top](#)

Corporate Responsibility Report 2009

Genetic research

Genetic variation underpins many aspects of human health, such as why some people get certain diseases while others do not, at what age diseases develop and how fast they progress. In the last four years, more genes have been identified for common human diseases than in the cumulative history of genetics research. Diseases for which genetic risk factors have been identified include asthma, Alzheimer's, diabetes, heart disease (including coronary heart disease), hypertension, obesity and several types of cancer including prostate, breast and lung, and a number of autoimmune disorders. GSK researchers have led or contributed substantially to several of these findings. These discoveries, and others to come, offer promise for the development of innovative new medicines.

Individual differences in genes also affect how people respond to medicines. Differences in genes can explain why some patients experience adverse responses to certain medicines while others have no such effects; why some individuals require greater doses of medicines than others to achieve the same level of efficacy; and why some groups of individuals respond well to treatment while others do not.

It has recently been reported that genetic variations affect how patients respond to a variety of medicines, including lipid-lowering agents, antimicrobials, anti-inflammatories and treatments for hepatitis C or HIV/AIDS. GSK scientists are using emerging genetic information to study how medicines can be differentiated to suit groups of patients with different genetic characteristics.

Successful genetic research requires close collaboration between organisations with different areas of expertise. We are engaged in a number of research projects involving academic partners, regulatory agencies and other pharmaceutical companies. These collaborations enable use of new technologies and facilitate sharing of research data with the larger scientific community. For example we are co-sponsors of the [Serious Adverse Events Consortium \(SAEC\)](#) collaboration which aims to improve patient safety through genetic research. We share research data through the dbGaP, a US National Institute of Health database which contains the results of studies exploring the association between specific genes and various medical conditions that have a genetic component such as high blood pressure and obesity.

We recognise that people have concerns about some of the applications and standards of genetic research. We aim to address these concerns by being transparent about how and why we conduct genetic research. Any genetic analysis undertaken as part of GSK clinical trials is only done after seeking and obtaining informed consent from the participant. This procedure includes providing information on the purpose and scope of the research and who has access to the genetic research data.

We believe that the pharmaceutical industry shares responsibility with governments for helping to identify and develop policy on genetic research. We refer to guidance from national and international groups to inform our genetic research activities such as the European Medicines Evaluation Agency, the US Food and Drug Administration and the Council for International Organisations of Medical Sciences.

Read about our [policy and standards for the collection, use and storage of human tissue for research we support or conduct ourselves](#).

Corporate Responsibility Report 2009

Animal research

Approach

Performance & plans

Animal studies remain a small but vital part of our research. In many cases, they are the only method that can demonstrate the effects of a potential new medicine in a living body before it is used in humans. In addition, research in animals can provide vital information about the causes of diseases and how diseases may develop.

Safety regulations require us to test all new medicines on animals before they are tested in clinical trials. Some vaccines have to be tested on animals each time a new batch is produced, but for our most recent vaccines, *Cervarix*, *Rotarix* and *Synflorix*, we have developed alternative approaches that have been accepted by EU regulators.

When animals are necessary for our research, we are committed to acting ethically, providing for the animals' health and wellbeing and practising good animal welfare.

During 2009 we undertook a comprehensive review of our policy on the care and ethical use of animals. This confirmed that the principles contained in the policy are appropriate. The review also identified a number of areas that would be enhanced by clarification and strengthening, so based on the review we are making the following changes:

- Prohibiting animal studies using great apes to support our principle of using the lowest phylogenetic order of animal
- Extending the prohibition of animal testing for cosmetic products to include medicinal products intended for cosmetic use. We do not believe it is appropriate to use animals to test products to enable their use as cosmetics, even when the products are classified as medicines or medical devices for regulatory purposes
- Allowing the testing of non-medicinal products or ingredients only where this is expressly required by a national regulatory authority in order to make a health benefit claim. This is because in rare instances a regulator can require safety or efficacy testing of non-medicinal products
- Specifying that the core principles of the policy will be part of the contracts for all types of animal research undertaken by third parties on our behalf, including contract, sponsored or supported research.

Our approach

Ultimately GSK would like to see the important benefits of research being achieved and applied to humans without the need for animals in research. We do not believe this can be achieved in the foreseeable future. Our goal is to use animals only when scientifically necessary, use as few as scientifically feasible and to minimise pain and distress.

GSK has animal research laboratories in Europe, Asia and the US. Some animal research is conducted by external contractors on our behalf, representing around nine per cent of our total animal use.

Almost all the animals used by GSK are rodents, mainly rats and mice. We also use rabbits, dogs, non-human primates, fish, ferrets, chickens, pigs, cats, sheep and goats; together these account for just over two per cent of the number of animals used and are listed in order of magnitude of use.

GSK remains committed to the 3Rs and to ensuring high standards of animal welfare in all animal studies

carried out by us or on our behalf. Our senior management reviews our strategy for working with animals on an annual basis.

The 3Rs

The 3Rs set out key principles for improving animal welfare in biomedical research:

- Replacing research using animals with non-animal alternatives or species of the lowest possible order (phylogenetically)
- Reducing the number of animals used in experiments and still obtaining the same information as in a larger study
- Refining techniques to minimise pain and distress and maximise the welfare of animals

In 2009 we launched the cross functional Animal Quality Council which provides governance and oversight in maintaining high quality standards and effective application of the 3Rs in all GSK animal testing. We also appointed a Worldwide Head, Animal Research Responsibility to develop and embed a co-ordinated 3Rs strategy across all GSK's business units and ensure quantifiable progress against the goals of this strategy.

Our scientists always try to devise experiments that do not require any animals. When that is not possible, the researchers work to design an experiment to obtain the necessary information from the smallest number of animals possible, with the least effect on each animal.

All proposed animal research must undergo an ethical review before it can go ahead which assesses study design and incorporation of the 3Rs. Ethical reviews are conducted by an independent committee based at the site or in the country where the research will take place. Ethical review committees include at least one veterinarian, at least one scientist and at least one person without a scientific background. They may also include specialists in laboratory animal science.

We also continue to discuss the latest 3Rs developments with regulators to help ensure that regulatory-required animal testing follows these approaches.

We encourage a 3Rs culture at GSK through:

- Regular training for staff involved in the care and use of animals
- Raising awareness and encouraging best practice by communicating advances in 3Rs across GSK's medicine discovery and development teams
- Recognising employees who have made outstanding advances in implementing the 3Rs through our Animal Welfare Awards
- [Read more](#) about recent GSK advances in replacing, reducing and refining animal use.

Non-human primates

Our studies involving animals must use the lowest possible phylogenetic order of animal appropriate for the research study. We therefore use non-human primates only if no species of lower neurophysiological sensitivity is appropriate. Occasionally, non-human primates may be the only animals where the anatomy and/or physiology of a disease is similar to that in humans.

Sometimes only human and non-human primates will be affected by, or respond to, a potential medicine or vaccine; for instance, a new medicine may be based on a molecule produced by primates, including humans, and could be destroyed by the immune systems of other species. The two most common non-human primates species used in research are macaques and marmosets. Less than half a per cent of the animals we use are non-human primates.

We have voluntarily committed to no longer carry out research on great apes. This means we no longer use the common chimpanzee, which has been used in biomedical research for over three decades. The other great apes are not used in biomedical research.

Read more in our position statements on the use of [non-human primates](#) and [great apes](#) in research.

Transgenic (genetically modified) animals

Genetically modified animals, also known as transgenic animals, have been genetically adapted by scientists to create new characteristics. Most transgenic animals (over 95 per cent) used in biomedical research are mice. Transgenic strains of animals are developed to answer specific compound or disease-related questions as part of the medicine discovery process. For example, transgenic mice that model Alzheimer's disease have been fundamental in biological research, new compound development and target validation. The use of such transgenic models in mice can sometimes replace the need for studies in higher order animals.

GSK worldwide standards

While recognising there are differences in country-specific regulations, GSK achieves worldwide standards by using [core principles](#) for the ethical care, welfare and treatment of laboratory animals. These principles establish our basis for animal work conducted by or on-behalf of GSK.

All GSK facilities and external laboratories conducting research on our behalf must follow all legal and regulatory requirements. In the UK these regulations are the responsibility of the Home Office. In Europe, animal research comes under Directive 86/609/EEC, and in the US it is covered by the Animal Welfare Act and Animal Welfare Regulations.

AAALACi accreditation

Our goal is to have all our animal facilities accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALACi), a private, nonprofit organisation that promotes the humane treatment of animals in science through voluntary accreditation and assessment programmes. To achieve AAALACi accreditation, an organisation must go through a rigorous assessment by the association which reviews facilities, workers and animal care. To maintain accreditation, updates and on-site reviews are required every three years. These site visits are conducted by members of the AAALACi Council and other trained professional staff.

Our accredited facilities cover 92 per cent of the animals housed in GSK laboratories. These accredited facilities are in Belgium, Canada, Croatia, Italy, Spain, the UK and the US. We are working to extend this accreditation to animal facilities we have in France, Hungary and two further small facilities in the US, all of which have either just completed refurbishment or are recent acquisitions. We also conduct animal research in small facilities in China which may be temporary. Due to the time and resources needed to achieve AAALAC accreditation we are not seeking this until we are sure of either staying in this facility or moving to an alternative. In the meantime we are confident that the standards within these units are similar to those of our other facilities.

Communicating our approach

Some people hold strong views on animal research and testing. We believe it is important to explain the need for animal research and testing and to be transparent about what we do.

We engage regularly with animal welfare experts and our investors, as well as contributing to the public debate. Many of our laboratories host visits from schools, colleges, animal welfare organisations and others. For example, in 2009 we hosted an investor visit to our Stevenage Laboratory Animal Science Facility. Our scientists also go to schools to talk with pupils about the role of animals in pharmaceutical research.

Protest

We accept the right of lawful protest against animal research as a part of a free society, but condemn the use of violence and intimidation by some who are opposed to animal use.

› [Back to top](#)

Corporate Responsibility Report 2009

Animal research

Approach**Performance & plans**

The 3Rs

In 2009 we reviewed animal research at GSK to assess the types of studies performed and the numbers of animals involved. The review assessed the contribution of each animal testing process to the development of new medicines. The results of the review provide a baseline against which future use of animals will be measured.

We are reviewing the size of animal enclosures in our locations around the world to ensure all our sites are aligned with best practice principles in animal housing and welfare. We have completed a review for the housing of dogs using external experts. The implementation of this review will result in more consistent practices in the husbandry for dogs. In 2010 we will conduct a review of housing for non-human primates with external experts in non-human primate behaviour.

Collaboration on approaches to the 3Rs

We collaborate with others to promote use of the 3Rs. For example:

- We share information on methods used to collect blood from animals with the UK National Centre for the 3Rs (NC3Rs). These methods form the basis of the NC3R's blood sampling website. This UK site is used by many laboratory staff to choose the most appropriate technique for the humane and efficient sampling of blood
- We have been working on a protocol with US Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and European Centre for the Validation of Alternative Methods (ECVAM) to develop an *in vitro* assay to identify severe eye irritants. The method is being evaluated by our company for hazard identification of pharmaceutical process chemicals in occupational toxicology

Progress in the 3Rs

Recent examples of GSK advances in replacing, reducing and refining animal use are outlined below.

- We have been working to decrease the number of animals needed for vaccine batch testing. For example, we do not use animals in our batch test process in the regulatory submission for Cervarix, our vaccine against the human papillomavirus. This means that for many markets new batches of Cervarix will not need to be tested in animals. Similarly, in Europe we use laboratory based tests that do not involve animals for batch testing for our rotavirus vaccine Rotarix, and Synflorix our vaccine against pneumococcal disease
- We have developed a transgenic mouse model that mimics an accelerated form of Alzheimer's disease. This has allowed us to replace primates as a primary model for this disease. Fundamental biological research, target validation and compound optimisation have been carried out using this mouse model, facilitating greater understanding of the disease and the potential for future therapies
- We have implemented a non-invasive method to monitor heart function by continuously monitoring the ECG in dogs or non-human primates. This technique uses an external apparatus which can be attached to the animal without surgery and can record information continuously in non-restrained animals. This new approach eliminates the need for restraint and requires fewer animals by allowing the measurements to be incorporated into existing studies, thereby eliminating the need for additional separate studies

- A team from GSK Spain was awarded the Harlan Prize at the recent National Congress of the Spanish Society for Laboratory Animal Science (SECAL) for the Best Scientific Communication. The team's poster was entitled 'Humane Endpoints for efficacy studies in Mouse models of malaria'. This work is a major contribution to the 3Rs because it specifically refines an endpoint to a protocol without reducing the value of the scientific information.

Animal Welfare Award

Our internal Animal Welfare Award recognises work that is demonstrably above and beyond the high standards of care, experimental design and implementation expected in GSK from all employees involved in animal experimentation.

To receive the award, the contribution should have tangible benefits in terms of one or more of the 3Rs and should make a difference to how animal experimentation is conducted at GSK or how animals are routinely cared for.

A recent recipient of our internal Animal Welfare Award was a team in the UK which implemented blood-spot technology in preclinical toxicokinetic (TK) studies. Using this technology meant researchers needed significantly smaller volumes of blood, which therefore meant fewer animals were needed for TK studies.

In 2009 the team won the Refinement award at the National Centre for the 3Rs competition at the House of Lords. The award included prize money which we donated to a local charity

Number of animals

In 2009 the number of animals used in our laboratories was almost 20 per cent lower than in 1994; R&D activity has increased significantly in the same period.

We estimate that the proportion of animals used for GSK research conducted by external contractors was 8.4 per cent in 2009, compared with 6.2 per cent in 2008.

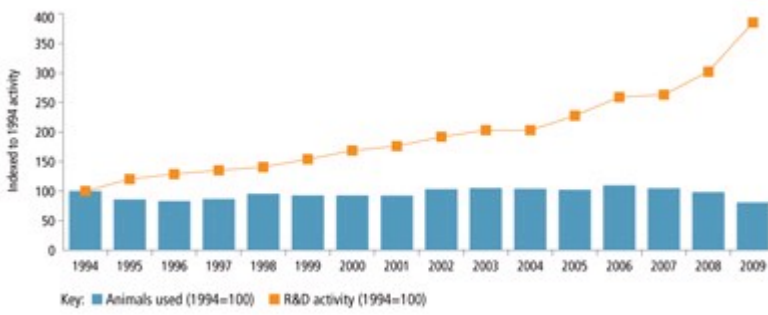
The total number of animals used within our own laboratories and by contractors on our behalf continues to decline. This is due to various factors including changing research priorities, fewer batches of vaccine requiring testing on animals before their release and continued focus on 3Rs initiatives.

Animals used by GSK in 2009 (per cent)*

Mice	72.8
Rats	19.6
Guinea pigs	6.5
Other rodents	0.1
Rabbits	0.4
Others	0.6

* This does not include animals used by external contractors on our behalf. Of the animals used by external contractors on our behalf in 2009, 91 per cent were rodents and rabbits.

Change in R&D activity compared to change in number of animals used by GSK#



These data do not include animal research conducted by external contractors on our behalf. R&D activity combines our R&D budget and our vaccine sales, the two main drivers of animal use.

› [Back to top](#)

› Home › Responsibility › Research practices › [Human tissue research](#)

Corporate Responsibility Report 2009

Human tissue research

Research using human tissue or human biological samples is fundamental to the discovery, development and safety monitoring of GSK medicines and vaccines.

It is vital that this research is conducted in a manner that respects the rights of research participants and meets legal and ethical obligations.

The UK Human Tissue Act 2004 made it a legal requirement to gain appropriate consent or ethical approval for the collection, use and storage of human tissue in the UK. This was introduced in 2004 following events at Alder Hey Hospital and Bristol Royal Infirmary, where human tissue was taken, used and stored without consent.

Our global policy is to apply the principle of needing appropriate consent or ethical approval for research conducted, sponsored, supported or funded by GSK. This ensures that ethical requirements are applied for research using human biological samples, wherever it takes place.

In 2009 the UK Human Tissue Authority inspected our Harlow and Stevenage research sites to assess whether GSK meets the standards necessary to hold a tissue storage licence. The routine inspection included an assessment of the premises, GSK policy and processes and internal governance framework, and the capabilities of the lead researcher.

The inspection concluded that GSK has achieved good standards, complies well with the Act and is suitable to be licensed for the storage of tissue for research.

› [Back to top](#)

- › Home › Responsibility › Research practices
- › **Maintaining the confidentiality of research participants**

Corporate Responsibility Report 2009

Maintaining the confidentiality of research participants

It is vital that medical information collected during research is protected to maintain the confidentiality of participants. We have rigorous procedures to control the use of research data.

We use a variety of procedures to protect the confidentiality of research participants' data, including data coding, data encryption and restricted access to research databases.

Third parties handling research data on our behalf are required to comply with relevant data protection legislation and standards.

We only collect information about individuals that is relevant to the research study. This includes medical information such as health status, medical conditions (including, on occasions, genetic data), treatment of conditions and ethnic origin. This means that, in the vast majority of instances, we do not collect or store information that can directly identify individuals such as initials, names, addresses or personal ID numbers. Information that can identify individuals is only used in very specific instances required by law and regulations such as safety monitoring and pharmacovigilance.

We retain medical research data using the minimum amount of identifying information and only for the duration reasonably necessary to meet regulatory, legal or research needs.

- › [Back to top](#)

Corporate Responsibility Report 2009

Medical governance

GSK is committed to the highest standards of ethical medical practice.

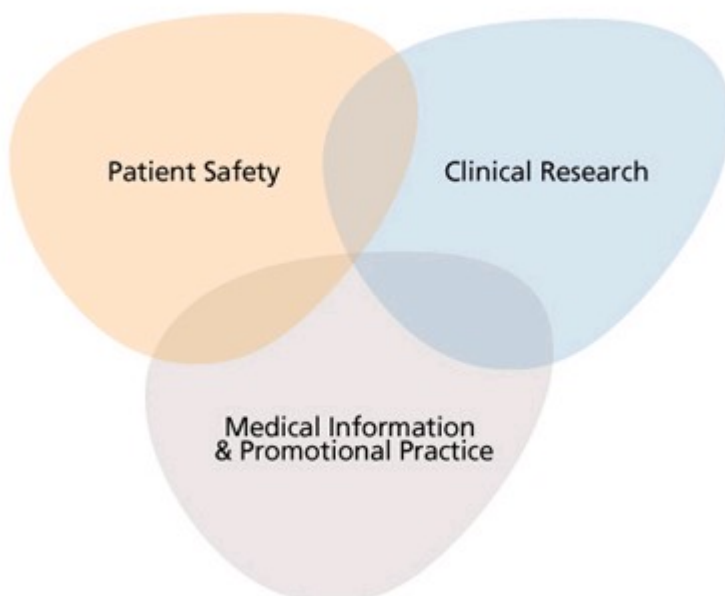
Medical governance at GSK is the system of principles, policies and accountabilities that ensures we apply generally recognised principles of good medical science, medical integrity, ethics and standards to the development and marketing of our products.

Medical governance includes a system for the management of human safety information and provides a framework to embed the following principles:

- Patient safety is the fundamental operating principle for GSK ahead of commercial or other interests
- Our clinical research is conducted in an objective, scientific and ethical manner which protects and informs participants
- Promotional practices and the information we provide on our products is ethical, accurate, evidence-based and balanced so that our medicines are used appropriately to benefit and minimise the risks for patients

Medical governance also ensures that any safety, ethical or compliance issues identified with our clinical research, marketed products, medical information or promotional practices are dealt with quickly and effectively and, where possible, that steps are taken to correct the root cause of the issue.

Medical governance across GSK encompasses the principles, policies and accountabilities of three areas:



We have a framework for medical governance across all our businesses and our Chief Medical Officer (the most senior physician at GSK) has responsibility and authority for establishing an effective medical governance system. Our Corporate Executive Team members are responsible for the performance of, and compliance with, this system within their areas of responsibility.

Our Medical Governance Executive Committee sets direction and establishes policy for medical governance,

subject to approval from the Corporate Executive Team. It also ensures that our medical governance systems are operating effectively. Regional medical directors together with their regional presidents and the country/territory medical directors ensure our policies and systems for medical governance are understood and complied with in the countries for which they have responsibility.

Read about our [patient safety governance framework](#).

Plans for 2010

Maintaining high standards of ethical medical practice requires continual commitment to improving our processes and to ensuring all GSK staff and collaborators are aware of our principles. In 2010 we will strengthen our medical governance framework by harmonising practices across GSK and raising awareness of the principles of medical governance among our employees.

This will ensure that everyone involved in medical governance, including those in medical, scientific and commercial roles, understand the framework, its principles and their individual responsibilities for safety reporting, medical integrity and high ethical standards. The initiative will particularly target employees involved in managing human safety information, conducting and disclosing the results of human subject research, and ensuring medical information on our products is accurate and balanced.

› [Back to top](#)

Corporate Responsibility Report 2009

Clinical research

We conduct clinical trials to assess the potential for a compound to become a new medicine or, once a medicine has been approved for marketing, to further evaluate the effect of the medicine for the approved use, to assess other potential uses, or to obtain additional safety data.

We have rigorous procedures and assurance processes to ensure clinical trials of our medicines are conducted according to the Good Clinical Practice (GCP) guidelines developed by the International Conference on Harmonisation (ICH) and the principles contained in the World Medical Association Declaration of Helsinki on the 'Ethical Principles for Medical Research Involving Human Subjects (2008)'. GSK-sponsored clinical trials are conducted to the same ethical standards irrespective of whether they take place in developed or developing countries. Contract research organisations conducting studies on our behalf are required to apply GSK's standards.

The effect of a potential medicine will often be compared against currently available medicines or, in some cases, an inactive substance, a placebo. The ethics of conducting placebo-controlled trials are sometimes questioned because one patient group receives a placebo which will not provide active treatment. Placebo-controlled trials are carried out only where there are compelling and scientifically sound methodological reasons, where the risks are minimised and reasonable in relation to the knowledge gains, and where patients who receive placebo are not subject to any additional risk of serious or irreversible harm.

Successful clinical trial programmes usually have three or four phases, and safety is evaluated throughout the [clinical trials process](#).

The safety of those who participate in our clinical trials is of paramount importance. GSK works with ethics committees and investigators to achieve an [informed consent process](#) that informs volunteers about the study and its risks and benefits.

All GSK employees involved in conducting trials receive [training](#) on regulatory requirements and GSK policies. Trials may be audited by our internal audit department and by external regulators, based on risks associated with the trial. Risk factors include the complexity of the study, the patient population, the location of the study, previous audit history and any unusual findings during the conduct of the study.

› Home › Responsibility › Research practices › Clinical research › **Planning and approval**

Corporate Responsibility Report 2009

Planning and approval

A protocol is developed for each clinical trial. This sets out the purpose of the research and explains how the trial will be conducted and the results analysed, including details of the dosage and duration of treatment and the number of participants required. The protocol defines the measurements that will be used to evaluate the safety and efficacy of the medicine, and appropriate procedures should participants wish to withdraw from the study.

All protocols are reviewed by an independent ethical review committee of lay people, medical professionals and scientists. These committees also review and approve the information to be provided in the informed consent process. Ethics committees have the power to reject or stop a clinical trial. Trial protocols may also be reviewed by government regulatory agencies.

› [Back to top](#)

Corporate Responsibility Report 2009

Informed consent

Informed consent means that a potential clinical trial participant voluntarily confirms their willingness to participate after being informed about the study and its risks and benefits. Informed consent for a clinical trial involves more than just reading and signing a consent form. This is part of a wider process for communicating essential information about the trial, including risks and benefits, and answering any questions.

The informed consent information is written and communicated in a non-technical style so that a lay person can understand it. It includes a summary of the clinical trial (including its purpose, the treatment procedures and schedule, potential risks and benefits, alternatives to participation and provisions for data protection) and explains participants' rights (including voluntary participation and the right to end participation). We continually seek to improve the informed consent in response to feedback received and actively seek input from patient groups.

A written document alone may not ensure that someone understands what participation means. Therefore, the research team discusses with the person the trial's purpose, procedures, risks and potential benefits, and the participant's rights. If the person decides to participate, the team will continue to update them on any new information that may affect whether they want to continue in the trial, such as potential new side effects. Before, during and even after the trial, the person is given opportunities to ask questions and raise concerns. Thus, informed consent is an ongoing and interactive process.

There may be special cases where obtaining someone's informed consent is not possible, for instance if they are below the age of legal consent. In these circumstances, consent is sought from someone who is allowed to provide it under local laws and regulations. If someone cannot read but is able to speak and understand the local language, an impartial witness is present during the informed consent process to confirm in writing that the information in the form was accurately explained and that the potential participant was able to ask questions and gave consent voluntarily.

› [Back to top](#)

Corporate Responsibility Report 2009

Training and auditing

Approach

Performance

Training for clinical trials

All employees involved in designing, conducting, recording and reporting GSK-sponsored clinical research studies are trained in the Good Clinical Practice (GCP) guidelines developed by the International Conference on Harmonisation (ICH). Employees must have completed the required training before undertaking these roles.

We keep detailed training records which are routinely requested by regulatory authorities when undertaking an inspection of GSK clinical research trials.

We work with regulators and other organisations to continually improve the quality and compliance of clinical trials. This includes training for clinical researchers who conduct clinical trials on behalf of GSK and other sponsors. For example, we are supporting [training of clinical researchers in India](#).

Auditing for clinical trials

Our risk management and compliance framework includes independent audit and assessment of the conduct of clinical trials. The scope of audits and assessments include GSK systems and processes, as well as external clinical research organisations and investigators conducting clinical research on our behalf.

Trials are selected for audit and assessment based on risk. Risk factors include the complexity of the study, the patient population, the location of the study, previous audit history and any unusual findings during the conduct of the study.

Audit results are reported quarterly to the R&D Compliance Board, and annually to the Risk Oversight and Compliance Council and the Audit Committee of GSK's Board of Directors. Read more about these in the corporate governance section of our [Annual Report](#).

Any concerns or issues identified are fully investigated and appropriate corrective action taken. For GSK staff, corrective actions may include development of new training programmes or retraining for the individuals concerned. In more severe cases, where clear breaches of policy have occurred, appropriate disciplinary action will be taken, up to and including dismissal.

For external investigators, GSK may retrain the investigator or stop working with the investigator. Where significant non-compliance is identified at an investigative site, trial data will be reported to regulators both including and excluding that site, and a rationale provided for exclusion.

Regulatory authorities also carry out inspections of GSK and the investigators we use to conduct clinical trials.

› [Back to top](#)

› Home › Responsibility › Research practices › Clinical research
› **Training and auditing - Performance**

Corporate Responsibility Report 2009

Training and auditing - Performance

Approach

Performance

Training for clinical trials

In 2009 there were 100,331 training activities related to Good Clinical Practice (GCP). Each 'training activity' represents a successful completion of an e-learning module or instructor-led course related to GCP by one of our employees or contractors.

Auditing for clinical trials

In 2009 we conducted 209 audits and assessments. These included:

- 169 investigator sites conducting GSK-sponsored trials. This represents approximately five per cent of investigator sites participating in pivotal clinical trials
- Two GSK systems and processes
- 32 clinical research organisations carrying out clinical trials on GSK's behalf
- Six GSK local operating companies involved in clinical research activities.

In addition, 14 investigations were conducted in response to suspected irregularities at investigator sites.

Any concerns or issues identified are fully investigated and appropriate corrective action is taken.

Inspections of investigators, clinical research organisations, independent ethics committees/Institutional Review Boards and sponsors of clinical trials are also carried out by regulatory authorities to ensure the safety of trial participants, the quality of data and that trials are conducted according to Good Clinical Practice. During 2009 there were more than 75 such inspections of GSK and investigators used by GSK to conduct clinical trials.

› [Back to top](#)

Corporate Responsibility Report 2009

Post-trial treatment

We recognise that continued treatment of clinical trial participants with nationally licensed medicines at the end of a trial is often required for the continued care of patients. In general, we are not responsible for the funding of nationally licensed medicines after a trial, because this is the responsibility of governments and other providers as part of national healthcare systems.

However, before beginning trials in diseases or conditions that will continue after the completion of the trial, we must be assured that the healthcare system is able to provide, and will take responsibility for, the continued care of patients. In exceptional circumstances nationally licensed medicines may be funded by GSK after the trial so that they can be made available to trial participants who derived a measurable medical benefit. We will continue to fund the medicine until it is funded through the normal healthcare infrastructure or until the patient no longer derives a medical benefit.

There may be circumstances in which there is a compelling medical rationale for patients to continue to receive a GSK investigational medicine after the clinical trial. In this case, post-trial treatment may be provided through a further clinical trial as part of expanded access programmes which enable appropriate oversight and reporting of adverse events. In these circumstances, GSK will fund the investigational medicine for as long as the patient benefits from it or until the compound is approved and licensed in that country.

Read more in our public policy on [Clinical trials in the developing world](#).

› [Back to top](#)

› Home › Responsibility › Research practices › Clinical research
› [Clinical trials in the developing world](#)

Corporate Responsibility Report 2009

Clinical trials in the developing world

All GSK clinical trials, wherever they are carried out, are conducted to the same high standard.

GSK does not conduct clinical trials in countries when we know at the outset that there is no intent to pursue registration and make the product available for use in that country.

Additional steps may be needed to ensure that trials in some of the Least Developed Countries are conducted according to the Good Clinical Practice (GCP) guidelines. For example, matching the objectives of informed consent to local culture may be necessary, for instance by involving local leaders and/or family members.

GSK provides training to ensure healthcare professionals have the necessary skills and knowledge to conduct clinical trials on our behalf. As well as benefiting GSK, enhancing the skills of healthcare professionals in this way brings lasting benefits to communities.

Read more about [post-trial treatment](#).

Read our position statement on [clinical trials in the developing world](#).

› [Back to top](#)

Corporate Responsibility Report 2009

Clinical trials in children

Children have a number of important physiological differences from adults which means they can respond differently to medicines and experience different side effects. Clinical trials in children are vital to develop safe and effective medicines for children, and to address the recognised lack of medicines approved for children.

Conducting clinical trials in children carries practical and ethical challenges. For example recruitment for clinical trials in children can be particularly difficult and there are fewer speciality centres in paediatric research compared to those for adults. Extra steps will often need to be taken in seeking the [informed consent](#) of parents as well as the assent of children to agree to participate.

Children in care

Very occasionally, it may be necessary to recruit children in care to clinical trials. For example many children with HIV/AIDS have lost both their parents to the disease and may be in care.

Trials involving children in care present further ethical concerns because without parental protection these children may be more vulnerable. We take additional steps to ensure high ethical standards are followed.

Approval must be obtained from our Chief Medical Officer or delegated GSK physician before children in care can be recruited for a GSK clinical trial. The Institutional Review Board or Ethics Committee overseeing the trial must also give explicit approval for the inclusion of these children.

In 2009 we revised our standard operating procedure and guidelines to implement these requirements for all phases of clinical trials. These requirements supplement any local or regional ethical and legal requirements.

› [Back to top](#)

Corporate Responsibility Report 2009

Public disclosure of clinical research

Approach

Performance and plans

Pharmaceutical companies are legally required to disclose relevant data from clinical trials to the appropriate regulatory authorities when seeking approval for a new medicine.

After approval, sponsors have a continuing obligation to provide regulatory authorities with updated safety information from clinical trials. Read more about [patient safety](#).

Safety and efficacy information is provided to doctors through prescribing information which is approved by regulators.

Public disclosure of our research is fundamental to advancing medical science and informing prescribers and patients about scientific findings relating to our medicines. We are committed to ensuring our studies are made publicly available irrespective of whether the results are perceived to be positive or negative for our medicines.

Our Clinical Study Register

Our [Clinical Study Register](#) website was launched in 2004 and serves as a resource for researchers, medical professionals and the public to use alongside locally approved prescribing information and publications in the scientific literature. Initially the site included summaries of results of clinical studies of compounds that subsequently became marketed medicines.

In 2008 we launched a new [Clinical Study Register](#) in place of the old site. This register now also includes protocol summaries for ongoing studies as well as result summaries for completed studies. It also has enhanced searching capabilities. Our latest figures show that the site is receiving over 14,000 visitors a month.

Since 2004 we have included summaries of the results of clinical studies of compounds that subsequently became marketed medicines. From January 2009 we expanded the register to include:

- Summaries of results of observational research (studies of medicines used in normal medical practice) and meta-analyses (which combine and analyse the results from two or more previously conducted studies) that evaluate our medicines
- Summaries of results from studies of all terminated medicines (compounds that are no longer being developed). This will help to inform the scientific community about non-productive areas of research and to reduce unnecessary exposure of study participants to similar compounds in clinical trials
- The names of principal investigators who participate in our clinical research

The information contained on our Clinical Study Register and other online databases is designed to supplement publications in scientific journals, which undergo independent peer review and provide context and interpretation of research data. When studies are not published in journals (for example if they are not perceived to be of sufficient interest to the journal's readers) we have committed to providing context and interpretation of results on our register to help users interpret the data.

Read a case study on how our register is helping to improve access to [clinical trials information](#).

Read our [position statement on disclosure of clinical trial information](#).

Read about our principles for [working with healthcare professionals](#).

› [Back to top](#)

Corporate Responsibility Report 2009

Public disclosure of clinical research

Approach

Performance and plans

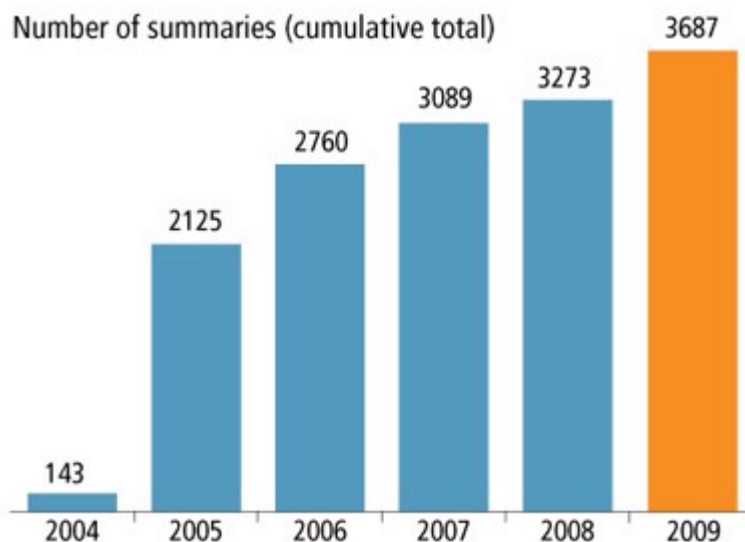
At the end of 2009 there were protocol summaries of all actively recruiting GSK clinical trials of medicines on the GSK Clinical Study Register, 186 in total.

There were 3,687 clinical trial results summaries on our [Clinical Study Register](#). This includes results summaries for observational studies and meta-analyses.

Our objective is to disclose trial results summaries for all new medicinal products on our register at the time of first approval or within 12 months of terminating development of a medicine. Our target is to disclose the results of all trials completed after a product is approved for marketing within one year of trial completion. All studies due for posting during 2009 have been placed on the register. Less than two per cent of studies were not posted by our target timelines. Additionally, during 2009 we identified a small number of studies that had not been posted in previous years and these studies have also been placed on the register during 2009.

We have also committed to seeking publication of the results of all clinical studies as full scientific papers in peer reviewed journals. We believe we are the only company to make this commitment. If the paper is not published we will include additional information to support interpretation of study results on our Clinical Study Register.

Number of results summaries of GSK clinical trials on the GSK Clinical Study Register (cumulative total)



Making transparency fundamental to research

In 2009 we took steps to ensure that all employees involved in R&D at GSK consider public disclosure an integral part of research – as important, for example, as informed consent.

We launched extensive training and awareness programmes and developed tools and support processes to ensure we meet our commitments to expand disclosure of research results. For example, as part of our commitment to ensuring clinical research is published as manuscripts in peer reviewed journals where

possible, we developed training to help our researchers identify appropriate scientific journals and develop manuscripts.

› [Back to top](#)

Corporate Responsibility Report 2009

Patient needs and R&D

Our Focus on the Patient programme helps our R&D employees understand patient needs and inspires them to do more to help improve the lives of patients.

We invite patients to meet GSK scientists, researchers and marketers to help us understand patient needs and develop better medicines. This also shows GSK employees the difference their work can make to people's lives.

In 2009 we held 17 seminars where patients visited GSK sites to help our R&D employees understand the realities of living with an illness. The seminars included discussions on kidney cancer, type 1 diabetes, human papillomavirus/cervical cancer, chronic obstructive pulmonary disease, asthma, allergic rhinitis, insomnia, motor neurone disease, osteoarthritis, atherosclerosis, HIV, schizophrenia and epilepsy. In total the seminars were attended by 3,447 GSK employees and patient representatives.

We are working to improve patients' experience of the clinical trials informed consent process. We have reviewed and simplified our informed consent forms to make the language clearer and easier to understand and will continue to make improvements based on [feedback from our advisory boards](#) which include patient representatives.

To inform our employees about the patients they are helping through their work in R&D, regular monthly bulletins highlight key medicines in our pipeline and how they will meet the needs of patients. This helps to motivate employees by reminding them about the importance of their work.

In 2009 we conducted four feedback surveys to measure effectiveness of the Focus on the Patient programme. Almost all responses indicated that the seminars provided attendees with a good understanding of the impact the disease had on patients' lives and raised their awareness of GSK's efforts to develop treatments for these diseases.

› Home › Responsibility › Research practices › [Patient safety](#)

Corporate Responsibility Report 2009

Patient safety

Ensuring the safety of our medicines and medical devices is critically important for the health and wellbeing of patients and the success of our business.

All medicines have potential risks as well as benefits, although not everyone who takes a medicine will experience side effects. It is important that we identify, evaluate and minimise safety concerns to ensure that the overall benefits of a medicine outweigh any risks.

We strive to serve patient interest by promptly detecting potential safety issues with our products and communicating with regulators so that appropriate decisions can be made and actions taken.

Product safety is assessed in clinical trials before a product can be approved for marketing. Adverse events (potential safety issues or side effects) may only be detected after approval when a product is being used by large numbers of patients. We have policies and a governance framework in place to help us detect and act on any adverse events. We have a dedicated team of scientists and healthcare professionals across the world which monitors and communicates safety issues to regulatory authorities.

We are also investing in genetic research to help predict how individual patients respond to a medicine. In the future this will help healthcare providers prescribe safer and more effective medicines.

Read about our [patient safety governance framework](#) and how we [collect and report safety data](#).

› [Back to top](#)

Corporate Responsibility Report 2009

Patient safety governance framework

We have a Global Safety Board (GSB) which makes decisions on product safety issues. The board is chaired by the Chief Medical Officer and composed of senior physicians and scientists. Its role is to:

- Oversee the safety of all investigational and marketed medicines and vaccines
- Approve the first administration of investigational medicines to humans
- Define the conditions for use of medicines and vaccines that minimise risks. This includes any special safety monitoring and doses and durations of treatments that are considered safe
- Approve the progression of investigational medicines into pivotal trials (these are trials which provide the primary data on which regulatory approval is based)
- Assess any issues related to patient safety that arise during product development or marketing

Three central departments are responsible for recording, investigating and evaluating adverse events and reporting them to the relevant regulatory authorities, for example the US Food and Drug Administration (FDA) or the European Medicines Evaluation Agency (EMA):

- Global Clinical Safety and Pharmacovigilance team (GCSP), part of GSK Research & Development, responsible for the safety evaluation of all our pharmaceuticals and devices
- GSK Biologicals Clinical Safety and Pharmacovigilance department, part of our vaccines business, responsible for the safety evaluation of GSK vaccines
- Consumer Healthcare Product Safety group, part of our Consumer Healthcare business, responsible for the safety evaluation of consumer healthcare products

We require that all GSK staff immediately report any issues relating to the safety or quality of our medicines. Read more about our expectations in our [Code of Conduct](#).

Read about our [medical governance](#).

Benefit-risk management

We assess the balance between the benefits and risks of a particular medicine throughout its life cycle – from early development, during clinical trials, and once the product is on the market.

We evaluate and document all available safety information to build a detailed benefit-risk profile of each product. We use this information to develop a benefit-risk management plan, which identifies ways to improve a product's benefits and minimise risks. We review and update plans regularly during clinical development and for a period after a product is approved for marketing.

Corporate Responsibility Report 2009

Collecting and reporting safety data

We receive information on adverse events (possible side effects) from several sources, including:

- Unsolicited reports from health professionals and patients
- Post-marketing trials or observational studies
- Investigators who submit clinical study reports
- Regulatory authorities
- Medical and scientific literature
- Newspapers and other media

Each GSK employee is required to report any adverse event they become aware of. All adverse events reported to GSK are recorded on our global safety database and clinical trial database and are investigated by our clinical and pharmacovigilance teams. We report potential safety issues to regulatory authorities on a regular basis.

Each country manager is responsible for ensuring the collection of safety information and reporting this to the relevant central safety department and to the local regulatory authority. During 2009, as part of our 2009 [Management Certification process](#), over 14,000 managers confirmed their compliance with our policy on Adverse Event Reporting which specifies that each GSK employee is responsible for reporting any adverse event they become aware of during the conduct of their work. We have added an Adverse Event Reporting button to the front page of myGSK, our intranet site, to make reporting of adverse events easier for employees.

Regulators in some countries are also publishing information on adverse events on the internet. For example, data for products marketed in the UK are available via the Medicines and Healthcare products Regulatory Agency. Some safety data are also available in Canada, while in the US the Food and Drug Administration (FDA) has made the information in its database more accessible to the public by publishing a quarterly report of potential safety issues that it is investigating further.

In 2009 we initiated a new cardiovascular outcome study involving our diabetes product *Avandia* as required by the FDA. Read more on [questions raised about the safety of Avandia](#).

In December 2008 there was a combined FDA Advisory Committee review of respiratory products containing long-acting beta2 agonists and in February 2010 the FDA proposed label changes. Read more on [questions about the safety of our products containing long-acting beta2 agonists](#).

Read about [our medical governance](#).

Read our [position statement on pharmacovigilance](#).

Responding to adverse events

Adverse events can affect the benefit-risk profile of a product and corrective actions may be needed to minimise the risk. This can include carrying out further clinical trials, modifying the prescribing information, communications to physicians and other healthcare providers or establishing specific methods to minimise risk, for example highlighting a warning in the prescribing information. Some products are subject to limited distribution programmes, for prescription by specialist doctors only. In

certain cases it may be appropriate to stop a clinical trial or withdraw a product from the market. Our global labelling committees review and approve the prescribing information for our medicinal products and ensure this is updated when appropriate.

› [Back to top](#)

› Home › Responsibility › Research practices › Patient safety › Collecting and reporting safety data
 › [Responding to questions about Avandia](#)

Corporate Responsibility Report 2009

Responding to questions about *Avandia*

Avandia is a treatment for type 2 diabetes. In 2007 a meta-analysis published in the New England Journal of Medicine¹ and GSK's own meta-analysis² (submitted to the FDA and other regulators in 2006) were at the centre of a debate about whether *Avandia* may be associated with an increased risk of myocardial infarction and death from cardiovascular causes.

Following an FDA Advisory Committee meeting, the FDA approved updated prescribing information for *Avandia*, including new text in the existing boxed (highlighted) warning, in November 2007. This updated prescribing information with summarised data from an FDA meta-analysis of myocardial ischemic events that suggested a risk associated with *Avandia*, and from three long-term clinical trials³ comparing *Avandia* against both placebo and other oral anti-diabetes medicines that did not confirm or exclude the risk. This revised prescribing information included that 'in their entirety, the available data on the risk of myocardial ischemia are inconclusive'.

Research involving *Avandia* has continued, including the cardiovascular outcome study called RECORD, a large, prospective, randomised, controlled study that was initiated in 2001. This clinical trial was designed to compare cardiovascular outcomes of patients on *Avandia* added to metformin or sulfonylurea to those on metformin and sulfonylurea. The results of RECORD were published in June 2009. The study showed that the combined endpoint of cardiovascular hospitalisation or cardiovascular death (which includes heart attack, congestive heart failure and stroke) was not statistically different between the two groups after an average of 5.5 years of therapy.⁴

In 2009, we initiated a new cardiovascular outcome study involving *Avandia*, called TIDE.

All medicines, *Avandia* included, carry risks as well as benefits. Because type 2 diabetes is chronic, progressive and a life-threatening disease, and because physicians often need to prescribe two or three medicines to help their patients maintain their blood sugar levels, having an array of treatment options is important. GSK believes it is important that *Avandia* is available to support effective treatment of type 2 diabetes in appropriate patients. [GSK has responded to a US Senate Committee on Finance report on *Avandia*, published in February 2010.](#)

1. S. Nissen & K. Wolski, Effect of Rosiglitazone on the Risk of Myocardial Infarction and Death from Cardiovascular Causes, N. Engl. J. Med. 2007; 356: 2457-71
2. A. Cobitz, et al, A retrospective evaluation of congestive heart failure and myocardial ischemia events in 14237 patients with type 2 diabetes mellitus enrolled in 42 short-term, double-blind, randomized clinical studies with rosiglitazone, Pharmacoepidemiology and Drug Safety, 2008; 17: 769–781
3. i) P. Home, et al, Rosiglitazone Evaluated for Cardiovascular Outcomes – An Interim Analysis, N. Engl. J. Med. 2007; 357: 28-38; ii) S. Kahn, et al, Glycemic Durability of Rosiglitazone, Metformin, or Glyburide Monotherapy, N. Engl. J. Med. 2006; 355: 2427-43; iii) The DREAM (Diabetes REduction Assessment with ramipril and rosiglitazone Medication) Trial Investigators, Effect of rosiglitazone on the frequency of diabetes in patients with impaired glucose tolerance or impaired fasting glucose: a randomised controlled trial, Lancet, 2006; 368: 1096-105.]
4. P. Home, et al, Rosiglitazone Evaluated for Cardiovascular Outcomes in oral agent combination therapy for type 2 diabetes (RECORD): a multicentre, randomised, open-label trial, Lancet, 2009, 373: 2125-2135.

Update September 2010

In July 2010, a joint advisory committee to the US Food and Drug Administration (FDA) voted to allow

Avandia to remain on the market. Committee members voted for recommendations ranging from making no changes to the current label, to revising the label with additional warnings and restrictions, to withdrawal from the U.S. market. The joint committee's recommendations will be considered by the FDA in making its final decision about future use of *Avandia*. At the request of the FDA, GSK has suspended enrollment of new patients into the Thiazolidinedione Intervention with Vitamin D Evaluation (TIDE) clinical trial pending FDA review of recommendations from the committee.

Avandia is one of the most extensively researched diabetes medicines and has been studied in more than 50,000 patients. We believe that when used in accordance with labeling, *Avandia* is a safe and effective treatment option for type 2 diabetes.

Please see the [Avandia Resource Centre](#) for the latest information on *Avandia*.

› [Back to top](#)

› Home › Responsibility › Research practices › Patient safety › Collecting and reporting safety data
› [Questions about the safety of our products containing long acting beta2 agonists](#)

Corporate Responsibility Report 2009

Responding to questions about the safety of our products containing long acting beta2 agonists

Long-acting beta2 agonists, known as LABAs, are daily controller medicines that relieve and help prevent airway constriction. Airway constriction is one of the two main components of asthma. LABAs do not treat the other main component of asthma – inflammation. This can be treated by another type of daily controller medicine called an inhaled corticosteroid (ICS). LABAs, including GSK's product *Serevent*, should not be used alone in the treatment of persistent asthma. Leading treatment guidelines recommend that LABAs be used for appropriate patients with asthma only in combination with an ICS.

GSK makes two products containing the LABA salmeterol. *Seretide/Advair* is a combination of salmeterol and the ICS fluticasone, while *Serevent* contains salmeterol alone.

In December 2008 a combined Advisory Committee to the US Food and Drug Administration reviewed the benefit-risk profile of medicines containing LABAs in children and adults with asthma. This review included all LABA-containing products indicated for use in treating asthma, not just GSK's products, and addressed lingering concerns that LABAs may increase the risk of asthma-related death, as current product labels prominently warn. The Advisory Committee makes recommendations to the FDA, which then makes the final decision on any actions required.

For *Seretide/Advair*, the Committee unanimously voted that the benefits of *Seretide/Advair* outweigh the risks for patients 18 years and older. The Committee also voted in favour of a positive benefit-risk profile in younger patients, although the individual votes were mixed. For *Serevent*, the Committee found that the benefits do not outweigh the risks for the treatment of asthma. Concerns were expressed about the potential for *Serevent* to be used alone in the treatment of asthma, contrary to the current prescribing information, in a way that would make the benefit-risk profile unfavourable. In contrast, *Seretide/Advair* is a combination therapy of a LABA and an ICS, so combination use is assured.

Although GSK acknowledges concerns that use of *Serevent* without an ICS is not in the best interests of asthma patients, we favour the option of allowing dual therapy using separate inhalers. Use of separate inhalers is an important treatment option for asthma patients who need an alternative ICS to fluticasone (the ICS contained in *Seretide/Advair*), or the flexibility of ICS doses beyond those available in a combination product. It is also important for asthma patients who receive more favourable reimbursement for separate inhalers.

GSK believes that with appropriate labelling and proactive communication of the risks of using a LABA alone, the potential for misuse of *Serevent* as monotherapy can be acceptably reduced so that dual therapy using separate inhalers remains available for asthma patients who need it.

In September 2008, before the Advisory Committee meeting, GSK submitted a proposed label change to the FDA for *Serevent* to clarify that use in asthma patients must be in combination with ICS, in line with prescribing information in all countries in which *Serevent* is marketed.

In February 2010 the FDA proposed label changes for LABAs and requested plans for communicating use to healthcare providers updated information about LABA safety. GSK is working with the FDA on appropriate labelling and communications to protect the interests of patients who suffer with asthma.

Update September 2010

In June 2010, after constructive discussions with the FDA following the Agency's initial proposals in

February 2010, GSK implemented updated labeling for its LABA-containing products in accordance with the FDA's directions for all LABA-containing products. The updated labeling includes strengthened risk information and recommendations intended to promote safe use. Consistent with GSK's position, the FDA allowed *Serevent* (the single active ingredient inhaler containing only salmeterol) to retain its indication for use in treating asthma, provided that use without an inhaled corticosteroid is now contraindicated. The FDA is also requiring further clinical research; potential approaches were explored at a March 2010 Advisory Committee meeting and consultations with FDA about appropriate trial design are ongoing. The FDA is also requiring a risk evaluation and management strategy which includes an updated medication guide for use by patients and a forthcoming communications plan for educating prescribers about the strengthened risk information and recommendations intended to promote safe use.

› [Back to top](#)

Corporate Responsibility Report 2009

Performance

We have continued to improve our patient safety systems, safety databases and monitoring processes. Examples from 2009 include:

- Implementing the first components of SafetyWorks, a semi-automated software tool developed by GSK to enable rapid review of safety information from different sources. In 2009 the SafetyWorks programme received the 2009 BIO IT award and was awarded first prize at the International Society of Pharmacology Annual Meeting
- Expanding the capabilities and number of users of the Molecular Clinical Safety Programme, a tool that optimises the safety of medicines before testing in humans by integrating chemistry with pre-clinical and human safety data
- Developing H1N1 pandemic planning, including specific actions our Global Clinical Safety and Pharmacovigilance team will take to ensure evaluation and reporting of the safety of our products if the pandemic escalates. We submitted the plan to key regulatory agencies
- Developing automated causality assessment for drug-induced liver injury in clinical trials to speed up and improve liver safety assessments

Working with others

We work with government officials, industry partners and policymakers in efforts to build an enhanced safety system. For example GSK is the industry lead in the patient safety project of PROTECT, the European Commission's public-private partnership, the Innovative Medicines Initiative, which aims to develop methodologies to enhance the assessment of the benefit-risk profile of new medicines.

We participate in the US Food and Drug Administration's (FDA) Critical Path Initiative which aims to improve the process for evaluating the safety and efficacy of new medicines. We are a member of the Initiative's Predictive Safety Testing Consortium that brings together pharmaceutical companies to share and validate their safety testing methods under the guidance of the FDA and the European Medicines Evaluation Agency (EMA).

We are a member of the executive and scientific oversight committees of the Cardiac Safety Research Consortium, which uses the principles of the Critical Path Initiative and focuses on improving evaluation of cardiac safety during the development of new medicines.

GSK is a key partner among the US Food and Drug Administration, other pharmaceutical companies and academia in the US to explore the development of a new system for the detection of adverse events and benefits of medicines using large healthcare system databases.

Read about our [collaborative research on emerging technologies](#).

Serious Adverse Events Consortium

In 2007 we co-founded the Serious Adverse Events Consortium (SAEC), a collaboration involving more than 20 partners which is working to improve patient safety by identifying genetic variants that predict adverse events. GSK scientists co-chair the SAEC scientific management committee and have a seat on the board of directors.

SAEC's initial research has focused on two reactions which are considered serious enough to discontinue

medication: drug-induced liver injury and drug-induced serious skin rashes (Stevens-Johnson Syndrome and toxic epidermal necrolysis).

In 2009 SAEC released data from these studies, just 16 months after the launch of the consortium. GSK contributed patient samples and scientific expertise to the studies.

› [Back to top](#)

› Home › Responsibility › Research practices › [Working with healthcare professionals](#)

Corporate Responsibility Report 2009

Working with healthcare professionals

Our policies governing interactions between GSK R&D staff and healthcare practitioners require that:

- All clinical trial investigators must be selected solely on their qualifications to conduct good quality clinical research. Their history of using or not using GSK products must not be taken into account when deciding whether to include or exclude them in a particular trial
- Payments to practitioners are governed by contracts and any compensation reflects fair market value for the work performed and the services provided
- No payments are offered or made to influence their judgement on whether to enrol or maintain a participant in a clinical study
- Gifts to healthcare professionals involved in research projects for GSK are not permitted

We have also committed to disclose research payments made to healthcare professionals and their institutions. This will start with payments made to US healthcare professionals and institutions for research studies that begin on or after 1 January 2010. The first disclosure will be made in the first quarter of 2011 and will capture payments for all phases of medicine discovery and development, including clinical trials. We will then extend disclosure of payments to healthcare professionals and their institutions outside the US.

We are also publishing [speaking and consulting fees paid to US healthcare professionals](#).

Read more about our policies and monitoring systems that govern our [relationships with healthcare professionals](#).

› [Back to top](#)

› Home › Responsibility › Research practices › **Case studies**

Corporate Responsibility Report 2009

Case studies

Raising the standard of clinical research in India

By the year 2020, around 70 per cent of all cancer cases will occur in the developing world. One-fifth of these – about 2 million cases each year – will be in India¹.

INDOX was created in 2006 as a partnership between the University of Oxford, eight Indian cancer centres and GSK to develop new and better treatments for cancer. The partnership focuses on addressing cancer treatment needs specific to India and enables GSK to access expertise for conducting Phase I, II and III oncology trials.

INDOX provides infrastructure support for research, fellowships for scientists and clinicians in India and training courses to promote leading research practices. It also enables scientists and clinicians in India to visit Oxford to learn more about specific cancer types or research techniques.

INDOX is conducting phase I, II and III trials in all common cancers but particularly those which are more prevalent in India. The partnership aims to raise the standard of trial management in the Indian centres to match the best in the world.

In 2009 we extended our funding for INDOX. In total, GSK has committed £1.2 million to support INDOX.

¹ <http://www.indox.org.uk/>

GSK investigators meet in Thailand

In 2009 we launched the GSK Investigator Club. This brought together more than 40 senior doctors involved in GSK research projects in Asia/Thailand to network and share best research practices. The event was designed to communicate our disclosure policy, reinforce our commitment to innovative research and to inform them of regulatory developments.

Attendees learned about new tools to detect medicine safety issues and discussed ways to improve the quality of research data, sharing personal experiences. Dr Yuppadee Javroongrit, Head of the Thai Food and Drug Administration, described plans to inspect trial sites in Thailand from October.

The GSK Asia Pacific Medical Director spoke about medicine development and new ways to bring molecules to market as well as the importance of transparency and disclosure of research protocols and results.

› [Back to top](#)

Corporate Responsibility Report 2009

Q&As

Here we respond to questions raised by our stakeholders

How can you be sure that the risks for healthy volunteers who take experimental medicines for the first time are minimised?

Before a clinical trial can take place, a new compound must undergo a series of stringent laboratory tests. These tests involve the use of animals and human tissue to predict the effects of an investigational medicine in the human body, including any potential side effects. On the basis of the predictions we establish dosing levels with a sufficient margin of safety and/or appropriate monitoring procedures.

The 'pre-clinical' data from laboratory tests, and our proposal for the design of each 'first time in human' clinical trial, are reviewed by a GSK committee, known as the Global Safety Board, of experienced senior physicians and other experts who are independent of the project team. Regulatory authorities and independent ethics committees must approve the trial before it can go ahead.

Clinical trials are designed to minimise risk. For example, we initially give volunteers a very low dose of the investigational medicine and increase dosing gradually, carefully sequenced among subgroups, to be cautious in our approach. Trials of an investigational medicine being tested in humans for the first time are conducted in clinical units with rapid access to hospital emergency care.

All clinical trial volunteers are provided with information about the study, including potential risks, and have the opportunity to discuss these risks with researchers before deciding whether to participate. This is known as informed consent.

You are entering more research collaborations. How will you ensure that the organisations you partner with meet your research and animal welfare standards?

We recognise that working in collaboration with other organisations brings certain risks. We are developing routine safeguards to ensure our partners work according to the same core principles as GSK, including those that govern our use of animals in research. These checks will be applied when we are evaluating whether to enter into collaboration, and subsequently on an ongoing basis within the framework established to govern a collaboration, typically a Joint Steering Committee. GSK's willingness to enter or continue a collaboration depends on having adequate assurance of a shared commitment to core principles.

GSK has opened an R&D facility in China. Will this affect your research standards? Is it a cost reduction exercise?

We have opened a new R&D facility in China which is focusing on R&D into neurodegenerative disorders, for which better therapies are desperately needed: Alzheimer's disease, Parkinson's disease and multiple sclerosis.

The costs of conducting research in China are currently relatively lower than those in other markets. However, lower costs are not the reason behind the decision to set up this new facility. The new centre enables us to benefit from accessing the vast talent pool and knowledge in life sciences in China, and to increase focus and depth in important disease areas.

Our R&D in China is conducted in accordance with GSK's global quality and ethical standards. All R&D policies and monitoring procedures apply to our operations in China. We have committed significant regional and local resource to ensuring our operations in China comply with both Chinese government requirements and GSK's global standards.

» Home » Responsibility » **Ethical conduct**

Corporate Responsibility Report 2009

Ethical conduct

We are committed to creating a strong ethical culture at GSK.

We do this by developing strong policies, recruiting the right people and equipping them with the information they need to make ethical decisions. Putting patients first is the core principle of being an ethical pharmaceutical company. Profit without principle is short lived.

Failure to uphold high standards of ethical conduct carries significant business risk:

- Erosion of trust in GSK and our products including among regulators, doctors and patients
- Fines and litigation resulting in serious financial or legal consequences
- Damage to GSK's reputation

Our [Code of Conduct](#) sets out fundamental standards for all employees. It is supported by the [Employee Guide to Business Conduct](#) which helps employees make ethical decisions and emphasises GSK's key values:

- Show respect for people
- Be patient focused
- Commit to transparency
- Always demonstrate the highest integrity in your conduct

We stress our commitment to performance with integrity. This means that all employees must understand our values and what we stand for as well as the policies and procedures that underpin our approach.

Our internal compliance systems are designed to identify and address breaches of our codes. We fully investigate suspected breaches and take appropriate disciplinary action, including dismissal where appropriate.

GSK is expanding its presence in emerging markets and we acquired a number of new businesses during 2009. Ethical risks are also reviewed as part of our due diligence process for acquisitions. We take steps to inform employees in newly acquired businesses about our values and ethical practices.

Ethical compass

Our Employee Guide to Business Conduct includes an 'ethical compass' that helps employees deal with ethical issues that are difficult to resolve. When faced with such a situation, we encourage our people to ask themselves these questions:

- Is it legal and ethical?
- Is it consistent with GSK policy and the Code of Conduct?
- Is it consistent with GSK's Mission and Spirit?
- Can I explain it to my family and friends?
- Would I be comfortable if it appeared in a newspaper?

We encourage employees to seek additional guidance and to keep asking questions until they are certain that they are making the right choice.

The contents of this page have been externally assured by [Bureau Veritas](#) March 2010.

› Home › Responsibility › Ethical conduct › [Code of conduct and business ethics](#)

Corporate Responsibility Report 2009

Code of Conduct and business ethics

Code of Conduct

The GSK Code of Conduct applies to our employees and contractors. Its key requirements include:

- Conduct business with honesty and integrity and in a professional manner that protects GSK's good public image and reputation
- Build relationships with customers, vendors, suppliers and fellow employees based on trust and treat each of these individuals with respect and dignity when conducting business
- Become familiar with and comply with legal requirements and GSK policy and procedures
- Avoid any activities that could involve or lead to involvement in any unlawful practice or harm to GSK's reputation or image
- Avoid actual or potential conflicts of interest with GSK, or the appearance thereof, in all transactions

[Read the full Code of Conduct.](#)

Employee Guide to Business Conduct

Our Employee [Guide to Business Conduct](#) builds on the Code and explains what employees must do to meet its requirements. It contains policies and guidance to ensure that we operate within the letter and spirit of the law and maintain high standards of ethical business behaviour. The guide emphasises the importance of good ethical conduct for ensuring continued business growth and success in improving the quality of human life, and includes real life scenarios.

In 2009 we published a new edition of the Employee Guide which helps employees understand how each of our policies is aligned with our values.

Sample questions from our Employee Guide to Business Conduct

Question: It is recommended to me that I use a particular agent in a foreign country because he has a reputation as the person who gets things done. The agent, who operates out of a hotel room and has no staff, tells me he can guarantee us substantial reductions in our tax rates and customs duties, and that all we have to do is pay his fee, in advance, in cash. This seems too good to be true. Is there a problem with this?

Answer: Anything like this should be a strong signal that you need to investigate further and conduct due diligence. The status of the agent, his guarantee of results without explaining what he will do, and his request for advance cash payment are all red flags. Under the US Foreign Corrupt Practices Act and similar laws you could be held responsible for what this agent does, such as using your cash to pay bribes, even if you do not know exactly what he is doing. These laws prohibit bribes for any improper purpose, including reduction of taxes and customs fees.

Question: A vendor offers to sell a GSK product manager a mailing list of 10,000 names of individuals who are being treated for depression. Are there any concerns with the purchase of such a list?

Answer: Yes. Many countries, including the US and those in the EU, have established strict laws protecting healthcare information that identifies an individual. Written authorisation by each individual is usually required for GSK to receive this information.

Anti-competitive behaviour policy

We are committed to free and open competition. We succeed as a company because of the high quality and competitiveness of our products and the talent and commitment of our employees. Corrupt and anti-competitive behaviour undermines fair competition, inhibits economic development and is bad for economies, business and people.

Our policy on anti-competitive behaviour covers issues such as mergers, abuse of monopoly powers, resale price maintenance, predatory pricing and other restrictive agreements and practices. It sets out the standards of behaviour we expect from our employees and agents.

In 2009 our Consumer Healthcare legal department developed training materials designed to help relevant employees better understand the principles of competition law and GSK's commitment to free and open competition in the marketplace. All retail sales representatives are required to take the training annually, and anyone dealing with pricing is required to take competition law training.

Preventing bribery and corruption policy

In October 2009 we updated our policy on preventing bribery and corruption. The policy now also applies to GSK interactions with government officials and to third parties working on our behalf.

The revised policy:

- Strengthens rules regarding payments for third-party services
- Explains permissible activities
- Prohibits political contributions
- Clarifies our position on the prohibition of facilitation payments

Training on the new policy is being rolled out across the business and train-the-trainer workshops have provided guidance on roll-out for over 40 countries to date.

Applying our policies in practice

We want to do business with companies which meet high ethical standards, in all countries where we operate. We will not pursue business opportunities that could undermine our integrity and reputation.

During 2009 we were looking to engage a local contract manufacturing company in one of our markets. In this country, supplying products through a partnership with a local company could enable us to secure long-term supply agreements for the government sector.

The local company we identified was confident of being awarded such long-term supply agreements. However, when we enquired about their cost of goods they were initially hesitant to share that information with us. Following further enquiries, the company revealed that the reason for the higher cost of goods than would normally be expected was that the local company needed to make payments to certain government officials to secure the contracts.

This breaches our anti-corruption policy and we immediately terminated discussions with that company.

An example of corruption prevention training

During 2009, we piloted our new anti-corruption training in Egypt, Mexico, Panama, Russia, the United Arab Emirates and Venezuela. The training uses scenarios to help employees understand what constitutes corrupt behaviour and how they should respond if they encounter it during their work. For example:

Scenario:

GSK is negotiating with government officials about a possible tender for a GSK vaccine. During the course of conversations, one official innocently mentions that the minister's wife has a particular interest in a well-known medical charity. He then asks GSK's representative whether the company would be interested in making a donation.

Questions:

- What issues does this incident raise?
- How would you respond to the question?

Correct response:

There is a serious risk that any contribution to the named charity would be seen as providing a benefit to the official in order to procure favourable treatment on the tender. This is prohibited by law, and by GSK's Policy 007.

Bribery does not have to take the form of a direct payment. It could also be a personal favour, a promise to pay in future, or an indirect payment such as that described above.

In this scenario, GSK's representative should advise the official that the company operates a Global Community Partnerships programme at the corporate level, which decides about GSK's charitable work and donations that the company makes.

The contents of this page have been externally assured by [Bureau Veritas](#) March 2010.

› [Back to top](#)

› Home › Responsibility › Ethical conduct
› [Interactions with healthcare professionals and marketing ethics](#)

Corporate Responsibility Report 2009

Interactions with healthcare professionals and marketing ethics

We market our prescription medicines and vaccines to healthcare professionals, hospitals and governments.

In some countries, such as the US, we also advertise medicines [directly to consumers](#). Our specialist sales representatives meet regularly with doctors and pharmacists to inform them about our medicines and their approved uses.

We believe that sales representatives play an important role in providing up-to-date information to doctors on our products and their benefits and risks to patients. However, we recognise that the marketing of pharmaceutical products raises some challenging issues.

In particular, some people are concerned that marketing by pharmaceutical companies exerts undue influence on doctors, that sales representatives do not always give doctors full information about potential side-effects, or that promotion of unapproved uses of medicines may be occurring. Our global marketing code forbids these practices and other unethical conduct. We provide regular [training](#) for sales teams and monitor [compliance](#).

Marketing Codes of Practice

The sale and promotion of pharmaceutical products is highly regulated by governments and medical agencies. In addition, our revised global code on promotional activities and interactions with [healthcare professionals](#) and regional marketing codes set consistent standards for our employees and agents. They commit us to promotional practices that are ethical, responsible, principled and patient-centred. They prohibit kickbacks, bribery or other inducements to doctors, and any promotion for unapproved uses of our medicines.

Our regional codes reflect differences in market structures, national healthcare systems and regulations. They are at least as stringent as our global code, and may be more restrictive.

GSK supports efforts to strengthen marketing standards across the pharmaceutical industry. This benefits us by creating a 'level playing field' in the countries in which we operate and helps to improve the reputation of the pharmaceutical industry as a whole.

Our Marketing Codes of Practice in summary

- Information – information can only be provided on approved uses for a medicine. It must be based on valid scientific evidence and must be accurate, balanced, fair, objective, unambiguous and up to date
- Items for healthcare professionals – these must either be educational, assist patients in the administration of their treatment or management of their condition, or reflect local customs in accordance with local laws, regulations and industry codes. Items cannot be given as an inducement to prescribe any of our medicines or to medical professionals retained as consultants to GSK
- Hospitality for meetings – GSK must not host meetings at venues that could reasonably be perceived as lavish or extravagant for a business meeting. It must be the programme, not the venue or hospitality on offer, that attracts delegates to attend. GSK will not invite delegates' guests to accompany them or pay the guest's costs.
- Grants – decisions about grants for medical education are reviewed by qualified medical or scientific

personnel. GSK will never use grants, donations or charitable contributions as an inducement to or reward for the prescription of products.

The contents of this page have been externally assured by [Bureau Veritas](#) March 2010.

[Back to top](#)

› Home › Responsibility › Ethical conduct › Marketing ethics

› [Interactions with healthcare professionals](#)

Corporate Responsibility Report 2009

Interactions with healthcare professionals

Approach

Performance & plans

Doctors and other healthcare professionals (HCPs) are valuable partners for GSK, providing us with scientific and medical expertise and insights into patient care.

GSK makes payments to healthcare professionals in the following circumstances:

- Medical education programmes – we provide funding so physicians, pharmacists, nurses and other healthcare professionals can attend education courses and conferences in therapeutic areas relevant to GSK. We do not consider this to be part of our marketing and our policies state that the content of the education programme must not be influenced by GSK and the provider must be independently approved
- Sponsoring speakers – we provide funding for healthcare professionals to attend conferences to present their research results or to speak on healthcare issues. Speakers must be transparent about GSK's support for their attendance
- Speaker and advisory services – we pay healthcare professionals to speak at meetings about disease and therapy areas relevant to GSK. We also engage with healthcare professionals to learn more about unmet medical needs and developments in science and treatments. This helps us to understand current and future markets for our products. This engagement may take the form of convening advisory panels or conducting broader market research

These services are valuable to GSK and we believe it is appropriate that we pay HCPs for their time and expertise, and help them develop their knowledge by supporting attendance at educational events and conferences. However, it is in our interest that the external consultants we work with do not receive excessive funding from GSK. Their work for the company should not detract significantly from the time they spend with patients or conducting research. This could reduce their professional credibility and their value to GSK as independently sources of current medical expertise. Payments to HCPs must be reasonable and be of fair market value. Payments must take into account the individual's speciality area and level of expertise, and the amount of time he or she spends working for GSK.

Read how we engage with [healthcare professionals who conduct medical research](#) on our behalf.

Regional practices

Our policies and processes governing relationships with HCPs vary by region to comply with local laws and industry practices. They meet or exceed relevant industry organisation codes, including those from: the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), the Pharmaceutical Research and Manufacturers of America (PhRMA), and the European Federation of Pharmaceutical Industries and Associations (EFPIA).

United States

In addition to the requirements of our global code, in the US our policies and practices also include:

- A limit on payments to HCPs, with speaker and advisory fees restricted to a maximum of \$100,000 a year for an individual physician from 2010. In 2009 the cap was \$150,000. Most of our US healthcare professional consultants receive total fees of less than \$10,000 per year
- A state reporting system for payments to HCPs, in line with legislative requirements in several US states
- A requirement that GSK grants to healthcare-related groups, including [patient advocacy groups](#) and

physician associations, cannot exceed 25 per cent of the group's annual income

- A speaker evaluation process for HCPs sponsored by GSK. Our regional medical scientists evaluate high-frequency speakers, and provide feedback to them on their effectiveness and compliance with the GSK Speaker Programmes policy. In 2009 over 500 speaker evaluations of this type were conducted
- All questions from doctors on off-label uses for our products must be referred to our medical information department. The number and type of referrals made by individual sales representatives are monitored to help ensure that representatives are not promoting off-label uses

Our US sales and marketing practices are fully aligned to the requirements of the US PhRMA code on interactions with healthcare professionals. In some cases our US policies exceed the PhRMA code requirements.

Europe

In Europe we updated our code of practice on interactions with HCPs in line with a new Code of Promotion published by the European Federation of Pharmaceutical Industries and Associations. Our code now specifies that:

- **Use of consultants** – GSK employees responsible for selecting consultants must have the expertise and authority to evaluate whether the consultant is suitable to meet the identified business need and is of real value to GSK. The consultant is required to declare the consultancy arrangements when speaking publicly on a related issue
- **Samples** – Product samples are to be given only in limited numbers and for a limited time, by reference to local standards, so HCPs can familiarise themselves with a new product. This replaces previous limits that were less restrictive and did not specify a quantity or timeframe
- **Grants and donations** – Our procedure on grants and financial donations to health organisations states that we must not be involved in how a grant or donation is used and must receive no service in return. In addition, grants and donations:
 - May only be given to a health organisation in response to an unsolicited request and only for the purposes of healthcare or research
 - Must not be offered or given on the understanding that the recipient will prescribe or recommend our products
 - Must be documented and published externally. To meet this requirement the amount of the grant and the recipient will be published on GSK's website from 2010
 - Grants and donations to individual HCPs for their personal benefit are not permitted
- **Phase IV clinical studies** – These are studies conducted after a medicine for a use that has been approved for marketing. We clarified the principles behind these studies, clearly setting out the terms for GSK and collaborative studies:
 - Studies must not be commissioned as an inducement to prescribe, supply or recommend medicines. They must have a clear scientific and/or educational purpose
 - There must be a contract with the institution undertaking the research
 - The trial protocol must be reviewed and approved by an ethics committee
 - GSK R&D or medical personnel must approve and supervise studies
 - Study results will be distributed to investigators and in line with our publications policy

Asia Pacific, Japan and Emerging Markets regions – 2009 code update and newly acquired companies

The Promotion and Marketing Code was reviewed and revised in 2009 and is effective from 2010. There were no substantive changes in principle, however in addition to our global policy the revised code includes the following:

- **HCP fees** – each country must set an annual maximum limit (cap) for the fees that can be paid to an individual HCP within their country.

- **Grants or donations** – may only be provided in response to requests from HCPs or institutions as long as they are not provided or offered in exchange for prescribing medicines or for a commitment to continue prescribing medicines. Grants or donations should be given to institutions, associations or hospitals, rather than to individual HCPs.

GSK must be assured there is a valid purpose for any grant or donation but should not get involved in the details of how they are implemented and must receive no service in return. In future, GSK will aim to obtain written permission from relevant institutions / associations / HCPs (as part of their agreements with GSK) for the annual disclosure of details of any grants and donations, including the value and purpose. Summary level data will be published in 2010

- **Samples** – the revised code continues to require oversight of the distribution of product samples. Samples must not be provided as an inducement to prescribe. Additional clarity has been included to specify that any samples provided to HCPs must be of a limited number (for example, x samples per year) and for a limited period of time (for example, up until x years after product launch in that country). The maximum number of samples per HCP and the maximum time will be set by national codes or else must be defined in a local Standard Operating Procedure.

As an example, GSK Australia updated its approach to strengthen controls on product sample distribution. Sales representatives no longer distribute samples directly to healthcare professionals. Instead, orders are taken by our representatives and samples are delivered direct to surgeries from our central warehouse. This gives us better oversight of the number of samples given to each HCP, improves security and supports our aim to achieve the highest levels of professional standards.

- **Market research** – market research is the collection and analysis of information. The collection methods must be unbiased and non-promotional, however the subsequent use of the statistics or information may be promotional. The two phases must therefore be kept distinct. Local guidance must be available for the development of market research materials, which must not contravene this code. Where there is doubt, the materials must be reviewed by the medical department to ensure that the research process does not constitute promotion or a clinical study. Market research studies must be clearly identified as such to potential participants.

Beyond our code, GSK works diligently to reinforce our values and policies with our newly acquired businesses as part of the integration process. For example, on completion of the acquisition of UCB Taiwan in March 2009, the integration phase focused on the training of UCB's employees on GSK's policies and procedures. The majority of these new employees were sales and marketing staff.

GSK acquired BMS's business in Egypt, Pakistan and Saudi Arabia. All staff, including management and sales and marketing teams, received training and compliance awareness sessions on promotion and marketing codes, the GSK Code of Conduct, and adverse event reporting.

Acquisition of Stiefel Laboratories

GSK completed the acquisition of Stiefel in July 2009, creating a unique dermatology business within GSK and making GSK a leading global dermatology company. The acquisition involved the integration of the Stiefel operations across all GSK business units. During integration GSK's local operating companies delivered training covering GSK's Code of Conduct and key corporate policies, including those on pharmacovigilance and promotion and marketing codes.

The contents of this page have been externally assured by [Bureau Veritas](#) March 2010.

› [Back to top](#)

› Home › Responsibility › Ethical conduct › Marketing ethics

› Interactions with healthcare professionals

Corporate Responsibility Report 2009

Interactions with healthcare professionals

Approach

Performance & plans

Global

Our global code on promotional activities was revised and extended to include interactions with healthcare professionals in November 2009. It brings together existing policies and sets standards for promotional activities and interactions with healthcare professionals that all GSK employees must follow. The revised code:

- Specifies how and when GSK can hire HCP consultants and support their attendance at medical congresses, and where we can conduct meetings with them
- Contains guidelines specifying the types of gifts that GSK can offer HCPs
- Applies to third-party companies that advertise or promote the prescription, supply, sale, administration and distribution of GSK products

The revised code represents a common baseline for GSK's sales and marketing practices and defines how GSK interacts with healthcare professionals globally. It does not replace any regional or country-level codes, which may be more detailed and restrictive.

Payments to HCPs for speaking and advisory services

Payments to HCPs globally must be reasonable and be of fair market value. In the US, fair market value is a regulatory requirement and is mandated under the new PhRMA code. However, the process for calculating fair market value has not been specified by US regulators.

GSK commissioned a consultant in 2009 to help us calculate the fair market value of payments to HCPs and ensure we meet best practice standards in the US. This was done by calculating hourly rates for different specialisms using information from several national wage surveys. As a result of this research we now have a standard schedule of fees for HCPs. This has reduced the need for us to negotiate with HCPs about fees, made payments more consistent across the business, and simplified the process for approving and auditing payments. Fees vary according to an HCP's speciality, and whether the HCP is a local, regional or national speaker.

In 2009 we continued to develop a system for disclosing the fees we pay to HCPs. This is a challenge because payments are managed locally and not reported centrally within GSK. For disclosure, each HCP must be uniquely identified and all expenditures must be captured for reporting. In 2009 we began to disclose payments in the US (see below). We will report aggregate HCP fees in GSK's Europe and the Emerging Markets and Asia Pacific/Japan regions in 2010.

United States

Continuing medical education grants

GSK funds continuing medical education because it provides HCPs with the latest information on disease prevention, diagnosis and management. It contributes to higher quality decision-making and better patient health outcomes.

In 2009, we announced new standards on funding continuing medical education for HCPs, to ensure programmes result in improved patient health. From 2010, GSK will fund only independent medical education

programmes that are clearly designed to close gaps in patient care. We have decided to restrict our funding to academic medical centres and affiliated teaching and patient care institutions, as well as national-level professional medical associations. This means we will no longer fund medical education programmes offered by commercial providers. The change means we will award fewer grants, but the total amount we spend on grants will not be affected.

Payments to healthcare practitioners

In February 2009 we began to publish quarterly reports of all the educational grants and donations we make to HCPs in the US. We post news of all approved grants on www.us-gsk.com.

In December 2009 we began to publish payments made to HCPs for speaking and advisory services. The initial publication covered payments made from April to June 2009. Future reports will be published quarterly and will show cumulative, year-to-date total payments by calendar year.

In GSK's Europe, Emerging Markets, and Asia Pacific/Japan regions we will publish summary level data for the second half of 2009 relating to HCP payments.

Other activities

We simplified and updated our US Commercial Practice Policies (CPPs), which support our marketing code. These are now fully aligned to our values. The language used has been simplified to make it easier for employees to understand what the policies mean in practice.

In 2008, we worked with the US pharmaceutical industry association, PhRMA, to develop changes to its Code on Interactions with Healthcare Professionals. GSK certified compliance to the code during the first quarter of 2009 and it will guide the sale and marketing of GSK pharmaceutical products in the US. We have aligned our own codes with the PhRMA code.

Europe

In Europe we [updated our code of practice on interactions with HCPs](#) during 2008, in line with a new Code of Promotion published by the European Federation of Pharmaceutical Industries and Associations. During 2008 and 2009, European country codes were updated to reflect changes to the European code.

GSK's Emerging Markets and Asia Pacific regions

During 2009 we undertook a routine review and update of our promotion and marketing code for GSK's Emerging Markets and Asia Pacific regions (formerly called International). The revised code will be implemented in 2010. Substantive changes were not required.

GSK continues to focus internally on educating all levels of management on the importance of ethical decision making. For example, at a management meeting in the Russian business we covered approaches for ensuring compliance and tools for making ethical decisions, and the monitoring and appropriate reporting of unethical cases.

The contents of this page have been externally assured by [Bureau Veritas](#) March 2010.

› [Back to top](#)

Corporate Responsibility Report 2009

Direct-to-consumer advertising

Approach

Performance

In the US it is legal to advertise prescription medicines to consumers through television and print advertisements. This is known as direct-to-consumer (DTC) advertising.

New Zealand, Bangladesh and South Korea also allow limited DTC advertising and some other markets allow limited advertising for select vaccines. DTC advertising of prescription medicines is not permitted in other markets.

Promoting the use of prescription medicines directly to consumers can raise concerns. Critics believe that it encourages people to request unnecessary treatment, adding to the burden on healthcare systems.

We believe that responsible pharmaceutical advertising is a useful source of health information for patients. It helps to increase knowledge of conditions and educates patients about treatment options. In countries such as the US where DTC advertising is common industry practice, we would be at a competitive disadvantage if we did not promote our products in this way.

Patients must still consult with their physicians about their condition, the appropriateness of a prescription medicine and obtain his or her consent before receiving such medicines.

Prescription medicines in the US

Our DTC communications policy is based on the PhRMA Guiding Principles: Direct to Consumer Advertisements About Prescription Medicines.

We have a detailed approval process for DTC advertising, which includes review by legal, regulatory and medical specialists as appropriate. We have trained US marketing employees on our DTC policy.

New DTC television advertisements are submitted to the US Food and Drug Administration (FDA) for review and comment prior to broadcast.

Members of the public and healthcare professionals can send comments or complaints on DTC advertising to PhRMA's Office of Accountability, which reports the comments and the responses of the companies to the FDA.

We fund disease-awareness campaigns which are designed to increase understanding of a specific disease but are not linked to the promotion of GSK products. These are also governed by our DTC policy. Our disease-awareness campaigns include television and print advertisements, and direct mail. They do not mention specific GSK products, but make people aware that treatments are available for their condition and encourage them to see their doctor.

Campaign materials are branded to indicate that they have been produced by GSK.

Our principles for DTC advertising in the US

Our policy requires that DTC advertising should:

- Dedicate an appropriate amount of time to educating healthcare professionals prior to initiating DTC promotion for a new medicine or new therapeutic indication for an approved medicine

- Be designed to educate the public about the medicine and the condition for which it is prescribed
- Be accurate and supported by evidence
- Include information on the risks and benefits of treatments
- Provide information on other treatment options such as diet and lifestyle changes, where these are referenced in the prescribing information for a product
- Only be targeted at an audience at least 80 per cent of whom are adults

Over-the-counter medicines and consumer healthcare products

Our advertising for over-the-counter medicines, oral healthcare and nutritional products is governed by national regulations or codes of practice for advertising. Our over-the-counter medicines are also promoted to pharmacists, doctors and dentists by our sales teams.

We belong to the Consumer Healthcare Products Association in the US and comply with its Code of Advertising Practices for Non-prescription Medicines.

GSK Consumer Healthcare advertising is reviewed by copy review committees in our larger markets, or by medical and legal personnel in our smaller markets, before publication to ensure it meets our standards.

Advertising to children

Our guidelines for advertising to children prohibit advertising designed to appeal to, or targeted at, children below the legally mandated minimum age. For example, to comply with our guidelines in the UK we do not buy advertising space in children's media and we do not supply vending machines to primary schools.

Sports star sponsorship is important to brands such as *Lucozade Sport*. Our guidelines state that only people who set an appropriate example should be used for sponsorship, and they should have an appeal that is not solely to children below the age of 13.

The contents of this page have been externally assured by [Bureau Veritas](#) March 2010.

› [Back to top](#)

Corporate Responsibility Report 2009

Direct-to-consumer advertising

[Approach](#)[Performance](#)

In 2009, our US Pharmaceuticals business received three ‘notices of violation’ from the FDA’s Division of Drug Marketing, Advertising and Communications (DDMAC). In each case we immediately stopped all advertisements that were still running and retrained our marketing staff where required.

The first, in February 2009, related to a television advertisement for our product *Avodart*. DDMAC felt it presented a misleading suggestion of superiority to other drug therapies and overstated *Avodart*’s efficacy. The advertisement aired from March to September 2008 and was no longer in use at the time the letter was received. We took the additional precaution of discontinuing many *Avodart* promotional materials and revised our marketing plan for the drug.

In March 2009, DDMAC wrote to GSK regarding an online banner advertisement for *Treximet*. The FDA felt that the banner gave insufficient prominence to safety information and disclaimer text. We responded by creating and applying improved standards on the presentation of safety information in all future GSK banner advertisements.

Also in March 2009, GSK was one of 14 companies approached by DDMAC regarding paid online search listings (known as sponsored links). The FDA felt that in our sponsored links for *Avandia*, *Avandamet*, *Avandaryl*, *Avodart*, *Coreg* and *Tykerb* the product indications were described too briefly and that product names were too prominent. We have now created and applied standards on sponsored links that prohibit the use of both brand name and intended use within the same link. We also prohibited sponsored links for products that carry a boxed warning, indicating a risk of serious side-effects.

Two of GSK’s commercial partners received similar letters regarding brands that we promote together. In each case GSK corresponded with the FDA and we believe we have complied with its requests.

We take the directions provided to us by the FDA very seriously and are developing new standard operating procedures that will help to ensure that FDA requirements are reflected in all our future advertising.

We received one comment in 2009 from the PhRMA Office of Accountability relating to a television advertisement regarding a product that GSK co-promotes. The comment was addressed with a letter from our co-promotion partner to PhRMA.

The contents of this page have been externally assured by [Bureau Veritas](#) March 2010.

› [Back to top](#)

Corporate Responsibility Report 2009

Training and awareness

Training and awareness programmes help employees understand the importance of ethical conduct and to apply our policies in practice.

Before hiring new recruits we carry out extensive pre-employment checks to ensure they share GSK's values. This includes asking questions on ethics and integrity during interviews. GSK's values are to:

- Be patient focused
- Show respect for people
- Commit to transparency
- Always demonstrate the highest integrity in your conduct.

We expect all employees to live up to the GSK values and this is reinforced through our re-launched Employee Guide to Business Conduct and by senior leaders during meetings and employee broadcasts. Regular training courses also emphasise key ethics and integrity messages. For example:

- GSK has an unwavering commitment to conducting business with integrity and in full compliance with the law
- Every GSK employee is personally and professionally responsible for helping GSK maintain its organisational integrity and good reputation
- Profits without principles are short lived
- When faced with difficult ethical situations, reference the ethical decision-making model:
 - Is it legal?
 - Is it consistent with company policy?
 - Is it consistent with GSK values and Code of Conduct?
 - Can I explain it to my family and friends?
 - Would I be comfortable if it were printed in the newspaper?

Our Corporate Ethics & Compliance intranet contains links to all company policies, ethics and compliance training for new recruits, an ethical decision-making model, an ethics quiz, contact details for compliance officers and the free phone numbers for our global confidential reporting line, and US Integrity Helpline. Employees can also get advice and guidance from their manager, human resources and legal departments, and their local compliance officers and champions. Read more about [reporting channels for ethical issues](#).

New employees in the UK and the US complete induction training on our [Code of Conduct](#), which is available on our intranet. We also train new general managers and site directors on their compliance responsibilities, as well as wider monitoring and compliance arrangements at GSK. Our annual [management certification programme](#) requires managers to confirm that they comply with our ethics policies. Managers can access three e-Learning modules on ethical leadership on the company intranet.

Specialised training is provided for employees working in R&D, manufacturing and sales and marketing, where there are additional regulatory requirements. Training for employees working in sales and marketing includes:

- Induction training and testing on our marketing code of practice

- Detailed training for sales representatives on the medicines they promote and the diseases they are designed to treat
- Regular refresher courses held at least once a year
- Regular management updates through our Risk Management and Compliance Boards in Europe, our Emerging Markets and Asia Pacific regions and in the US on the types of unethical conduct detected and disciplinary actions taken

We provide extra training and guidance for employees committing minor breaches to prevent them committing more serious breaches in future.

Ethics training in practice

Ethics training helps employees make the right decisions and apply our policies in practice. We run ethical decision-making training for employees and leaders that explores ethical dilemmas they may face in their work and provides guidance to help them understand the appropriate response. This is one example of an ethical dilemma:

You are attending a family dinner party. Your uncle, who is very interested in your career, asks you about your current work. He is particularly interested in the progress of the phase III clinical trials of a drug with which you have considerable involvement.

Which sections of GSK's Code of Conduct (POL-GSK-001) will help you to make a decision on how to act in this situation?

Should you:

- (a) Share only a summary of the latest trial results and information with your uncle without giving specifics
 - (b) Only share the information which places GSK in a positive light
 - (c) Invite your uncle to visit the GSK website with you to see what interesting pipeline information is published there, and discuss the public information with him
- The only acceptable answer is (c).

The contents of this page have been externally assured by [Bureau Veritas](#) March 2010.

› [Back to top](#)

Corporate Responsibility Report 2009

Leading by example

Our senior managers are expected to lead by example by complying with company policies and by supporting their staff to do the same.

This is reinforced annually by a formal 'Management certification on business ethics' in which managers confirm their understanding and compliance with the company policies contained in the [Employee Guide to Business Conduct](#). The programme covers over 14,000 managers worldwide.

Management certification promotes awareness of GSK's ethical standards and company policies. It emphasises the important role managers play in embedding an ethical culture and ensuring that all employees understand and apply our policies. This is the full certification statement:

- I understand that GSK is committed to the principle of performance with integrity, and in particular, to ensuring that its activities comply with all applicable laws
- I have received a copy of or have access to the GSK Code of Conduct (POL-GSK-001), Standards of Conduct (STD-GSK-001) and other GSK corporate policies through the Corporate Policy Index page accessible on the Corporate Ethics & Compliance Community
- I have read and understand The Employee Guide to Business Conduct, accessible on the Corporate Ethics & Compliance Community
- I have complied with applicable laws, regulations, and GSK corporate and local policies and procedures
- I understand my responsibility to promptly report any actual or suspected violations of the law, regulations, or GSK corporate and local policies and procedures
- I have reported all actual or potential compliance issues of which I am aware concerning legal requirements or company policies

The following statements are also applicable to supervisors with personnel management responsibility:

- All people under my supervision have received copies of or have access to the GSK Code of Conduct and other applicable GSK policies and have been informed of their responsibilities
- I have put in place appropriate measures to ensure that the people under my supervision comply with applicable laws, regulations, and GSK corporate and local policies and procedures while working on behalf of GSK
- All new hire employees under my supervision have completed or are scheduled to complete the GSK Corporate Ethics & Compliance new hire training programme at GSK Induction or through the Corporate Ethics & Compliance Community

I have read, understood and shall comply fully with the policies and procedures specified in the learning activity.

For Belgium, France and Germany, the Management Certification wording is adjusted to comply with local laws.

The contents of this page have been externally assured by [Bureau Veritas](#) March 2010.

› Home › Responsibility › Ethical conduct › **Training and awareness**

Corporate Responsibility Report 2009

Training and awareness performance

Global

Training and awareness activity in 2009 included:

- Globally, all sales and marketing staff are required to undertake annual refresher training on our promotion and marketing codes
- As an example of the extent of training undertaken during 2009, in the US 8,148 employees and contractors completed compliance refresher training. Training for new employees was completed by 1,025 people. We launched a redesigned training curriculum for new US Pharmaceuticals field sales employees which integrates training on ethical commercial practices with sales training, rather than providing stand-alone modules. We also added an ethics section to our employee manual of commercial policies to help employees make the right decisions during commercial interactions
- Over 14,000 managers completed our self-certification process
- We raised awareness of our Global Confidential Reporting Line for reporting possible breaches of our policies through an extensive poster campaign and awareness programmes on our intranet. Our Confidential Reporting phone line is now available in 70 countries and more than 25 languages. In 2009, we enhanced access to reporting by introducing an internet-based reporting facility

The contents of this page have been externally assured by [Bureau Veritas](#) March 2010.

› [Back to top](#)

Corporate Responsibility Report 2009

Monitoring and compliance

Approach

Performance and plans

All managers must ensure compliance with company policies in their areas of responsibility. They are overseen by and can seek advice from our Corporate Ethics and Compliance department, which promotes effective compliance programmes, addresses compliance issues, and reports problems and progress to senior management and the Board.

We have a dedicated compliance officer for each of our business units – R&D, Manufacturing, Vaccines, Pharmaceuticals Europe, Pharmaceuticals Emerging Markets, Pharmaceuticals Asia Pacific and Japan, Consumer Healthcare, Corporate, US Pharmaceuticals – and additional compliance representatives in some markets. Compliance officers are senior managers with direct access to the leadership teams of GSK functions. They are a source of expertise for anyone with a question on ethics or GSK policies. Our Corporate Compliance Officer reports directly to the CEO.

We also have full-time compliance directors in the Commonwealth of Independent States (CIS; includes Russia), Latin America, Middle East and North Africa, Asia Pacific and China, to provide additional support to our senior management teams in these large and diverse regions. Existing partial roles will be expanded to full-time roles for sub-Saharan Africa and South Asia (includes India) in 2010.

We review our ethics and compliance strategy every two years, and twice a year the GSK Audit Committee of the Board assesses our progress towards meeting our strategy review objectives.

Risk management

Our [Risk Oversight and Compliance Council](#) (ROCC), which includes several Corporate Executive Team (CET) members, oversees risk management and internal control activities. The ROCC is supported by GSK's Corporate Assurance department and Corporate Ethics & Compliance department. GSK's Corporate Compliance Officer, who chairs the ROCC, regularly reports on significant risks to the CET and the Audit Committee of the Board.

For more information on risk management see the corporate governance section of our [Annual Report](#).

Monitoring for sales and marketing

Sales representatives are supervised by their managers, who regularly monitor educational events, visits to doctors and expenses. We use a risk-based approach to determine the frequency of our checks on different districts and individual sales representatives.

In the US, sales representatives who receive enquiries from physicians about off-label uses of GSK products must notify our medical information department, which responds to the inquiry via a medical information letter. Sales representatives must not solicit off-label questions from physicians. Frequent medical information letter requests by a sales representative can indicate that the employee is prompting questions and promoting off-label uses of GSK products. We monitor requests for medical information letters. Our internal audit department regularly audits our sales and marketing practices globally.

Monitoring of payments to healthcare professionals and organisations

We are developing a global system to monitor and report on payments to healthcare professionals (HCPs). Currently, payments are recorded and monitored in different ways in different countries. For example, in the US we have introduced a state reporting system for expenditure with HCPs, in line with legislation in several

US states. In Japan, payments to individual HCPs and medical institutions are monitored on a quarterly basis and the results are reported to promotion compliance officers and our internal audit department.

Reporting channels

Employees are encouraged to seek help on ethical issues and to report any concerns or suspected cases of misconduct. They can do this through their line manager, the Corporate Ethics & Compliance department, a compliance officer or compliance champion, GSK's human resources and legal departments, or through our global confidential reporting line or the US Integrity Helpline. The global confidential reporting line is available globally and in over 25 languages. It can be used for reporting any concerns employees may have relating to compliance with our policies and the Code of Conduct. In 2009 this global reporting mechanism was further strengthened by the addition of an internet reporting option. Our US Integrity Helpline provides advice to callers from both within and outside the company, as well as being a reporting channel. In the US, employees can also report concerns through an offsite post office box or via email.

Reporting channels are promoted through the [Employee Guide to Business Conduct](#), on the GSK intranet and during training. We also raise awareness about the Global Confidential Reporting Line through the company intranet.

Addressing misconduct

Our Corporate Ethics & Compliance department monitors and tracks allegations and suspected legal, ethical or policy infractions. It ensures that all such allegations are appropriately investigated. Disciplinary action, up to and including dismissal and reporting to the relevant external authorities, is taken where necessary. Serious violations of our policies are reported to the Audit Committee of the Board.

The contents of this page have been externally assured by [Bureau Veritas](#) March 2010.

[Back to top](#)

› Home › Responsibility › Ethical conduct › **Monitoring and compliance**

Corporate Responsibility Report 2009

Monitoring and compliance

Approach

Performance and plans

In 2009 there were 5,445 contacts made through our ethics compliance channels. These included enquiries and requests for information or guidance as well as allegations of misconduct made via line managers, compliance officers, our confidential Integrity Helplines and offsite post office box (in the US).

Addressing misconduct

In 2009:

- 972 employees were disciplined for policy violations
- Of these, 246 were dismissed or agreed to leave the company voluntarily (known as separations)
- Other disciplinary actions included 726 documented warnings
- The 972 disciplinary actions included 178 cases of employees breaching sales and marketing codes
- These 178 cases resulted in 26 dismissals or separations from the company. All the other 152 cases resulted in documented warnings

In addition to appropriate discipline, employees staying with the company received retraining and increased monitoring. In some cases retraining is also extended to an employee's colleagues to prevent them making similar mistakes.

The main types of violations this year included:

- Marketing and promotional activities
- Good manufacturing/good distribution practices
- Falsification of documents
- Violation of company car policies and procedures
- Travel and expenses claims
- Code of Conduct issues

Developing our approach to compliance and risk management

In 2009 we continued to develop a more sophisticated compliance programme and took steps to embed an ethical culture at GSK. Read about [our risk management and compliance processes](#).

Specifically, we are expanding our risk management capabilities and developing an audit plan to better assess the effectiveness of company controls and oversight by our compliance officers. We have also established a Global Privacy Office to enhance protection of the personal information that we hold on employees and others.

The Audit Committee of the Board reviews progress on meeting our assurance plans throughout the year. Assurance plans include risk management, ethics, compliance and audit activities which, when completed, demonstrate an effective internal control framework to GSK management and the Board of Directors.

Monitoring compliance with our suppliers

In 2009 our US Pharmaceuticals compliance, procurement and legal departments launched a project to improve monitoring of the ethics and compliance performance of our suppliers involved in sales and

marketing. In the US, suppliers and agents engaging in activities that may be subject to GSK's Commercial Practice Policies are now contractually required to read and certify compliance with our ethics policies before initiating any services for GSK. To simplify this process, we established a web-based system to communicate relevant policies to suppliers and update them as necessary.

Read more about [GSK's supply chain](#).

The contents of this page have been externally assured by [Bureau Veritas](#) March 2010.

› [Back to top](#)

Corporate Responsibility Report 2009

Case studies

Exercising good judgment, not just following the rules

We work hard to raise awareness of our approach to ethical conduct and to help employees live our values. For example, the following text is an extract from a recent article by our North America compliance officer which appeared in our High Road Newsletter for employees in North America. This article describes GSK's expectations that employees will exercise good judgement and not just follow the rules.

Many of the unwritten rules that we follow are based on our principles and judgement. The US policy on Acceptable Use of IT Resources states, 'GSK IT Resources are to be used in a professional manner only, and must not be used to engage in offensive or inappropriate behaviour', but the policy does not try to list every website that could be considered offensive. The presumption is the principle behind the policy makes those types of sites self-evident.

Under Andrew Witty's leadership, all of us are being expected to rely less on rules and more on values and principles. This changed approach may make some people uncomfortable. Rules can make people feel safe, as if they know exactly what they can and cannot do. But acting on principles and using good judgement is actually much 'safer' when you think about it because there simply cannot be a rule for everything. If you apply sound, ethical judgement to an unfamiliar situation – one without a specific rule – you are likely both to make the right decision and to be confident about the decision that you make.

Our policies list the boundaries of behavior, but ethics and good judgment should be your guiding operational force within those boundaries.

*Now don't get me wrong: policies and rules will always be an important framework of our business. We are too highly regulated for them not to be. As such, it is essential that you know, understand and follow our policies – empowerment does **not** mean 'anything goes'. It is equally essential, however, for you to understand the principles behind our policies, so that you can make sound decisions when there is not a specific policy or rule in place.*

When you are faced with a decision, consider how your actions will align to the CPPs' Guiding Principles:

- *Never provide money or anything else of value to a healthcare professional (HCP) or organisation for past or future decisions to purchase, prescribe, or recommend GSK products.*
- *Keep product promotion truthful and balanced, on-label and consistent with FDA-approved package insert – and never overstate the benefits or understate the risks of our products.*
- *Develop relationships with HCPs intended to benefit patients and to enhance the practice of medicine. Focus interactions on informing HCPs about products and providing scientific and educational information.*
- *In your interactions with consumers, patients, and patient advocacy or consumer groups, reflect GSK's commitment to honesty and integrity, and focus on the best interests of the patient and protect patient privacy.*

If you focus on the underlying principle, it will help you identify whether or not there may be issues with the activity you are considering, and help assure that you keep the purpose and intent of our policies central in guiding your decisions.

If you still are unsure of how to act, you should never hesitate to use the tools and resources available to help you make the right decision. If you have questions about the compliance of

Suitability for GSK's approved speaker list

As well as ensuring that our employees comply with our policies, it is vital that people working on our behalf meet the highest ethical standards. We make our requirements clear to people speaking on GSK's behalf and we monitor their performance.

In 2009, GSK removed two physicians from our approved speaker list. They had not used the slides provided and approved by GSK because they had inserted some of their own slides in an attempt to inject humour into their programmes. Many attendees found these slides to be offensive. GSK's President of North American Pharmaceuticals sent a letter of apology to all of the attendees at the events.

Responsible marketing for our weight loss treatment

Nearly two-thirds of US adults, and around half the adult population in Europe, are either clinically obese or seriously overweight. This is causing a dramatic increase in life-threatening medical conditions such as heart disease and diabetes, and adding strain to national healthcare systems. But even a small amount of weight loss can greatly reduce the risk of developing associated medical problems.

GSK's over-the-counter weight loss product, *alli* (orlistat 60 mg), helps overweight adults lose weight by preventing about 25 per cent of dietary fat from being absorbed in the gut¹. It helps people lose 50 per cent more weight than diet and exercise alone². *alli* was launched in the US in June 2007 and since then we have sold over 7.5 million starter packs. In January 2009 the European Commission granted a non-prescription licence for the product. *alli* was launched in 29 countries across Europe, with approximately 2.5 million people trying the product during its first year.

It is vital that *alli* is marketed responsibly so that it is used in the right way and only by those who need it. We educate physicians, dieticians and pharmacists to ensure *alli* is sold appropriately and patients receive the right information about the treatment. Our marketing emphasises that using *alli* requires lifestyle changes, including exercise and a low-fat diet, to produce the right results without unwanted side effects. The safety and efficacy profile of orlistat is well documented and has been established through data from more than 100 clinical studies³.

We set up the website www.myalli.com to provide further support for *alli* users. It enables people to set targets, track their weight loss and post success stories. It includes an 'am I ready for *alli*?' quiz, which asks potential users to confirm their commitment to moderating their diet, taking exercise and reading the label carefully. The site also includes '*alli* circles', an online moderated forum where users can share experiences and help each other stay focused on their weight loss targets. The forum gives us valuable feedback from patients on the effectiveness of the product, and we monitor the site for reports of adverse effects which are then reported to the FDA, and for inappropriate content. Similar sites exist throughout Europe.

In 2009, we donated \$50,000 to Dress for Success (DFS) in the US as part of our on-going partnership with this international non-profit organisation that provides business clothing and career support for disadvantaged women. We encourage *alli* users to volunteer for DFS and to donate clothing that becomes too big for them as they lose weight. DFS received more than 38,000 pieces of clothing from *alli* users in the first year alone and continues to share the clothing that *alli* users donate.

¹ Anderson J. Orlistat for the management of overweight individuals and obesity: a review of potential for the 60-mg, over-the-counter dosage. *Expert Opin Pharmacother*. 2007;8 (11):1733-1742.

² *alli* Summary of Product Characteristics (SPC)

³ Jacob S, Togerson J. Orlistat treatment beneficial in both primary care and tertiary settings. *obesity reviews*. 2005;6(s1):166.

The contents of this page have been externally assured by Bureau Veritas March 2010.

› [Back to top](#)

Corporate Responsibility Report 2009

Assurance statement and response

Commentary and Assurance

Bureau Veritas' Independent Assurance Statement

To: The Stakeholders of GSK

Background

A recommendation from the previous assurance exercise (of Access to Medicines) was to extend the assurance to other prominent material issues over which external review would benefit GSK and its stakeholders.

Ethical Conduct is a key area in relation to trust and reputation and Bureau Veritas UK Limited (Bureau Veritas) has been engaged to provide external assurance of the Ethical Conduct Section in GSK's 2009 Corporate Responsibility (CR) Report.

Roles and Responsibilities

The content of the CR Report is the sole responsibility of GSK. Bureau Veritas' aim is to provide reassurance to stakeholders on the accuracy, reliability and objectivity of the information and express an independent, balanced opinion as per the scope of assurance.

Objectives and Scope of Assurance

The objectives were to:

- Review GSK's approach to ethical conduct across its global operations and how it identifies related risks and emerging issues
- Review how GSK manages ethical conduct issues through examination of its governance structures, supporting policies and related management and implementation systems
- Check the accuracy of associated information, statements and performance metrics and data for the reporting period 1 January to 31 December 2009

Methodology

To conduct the assurance we undertook the following:

- Interviews with four senior managers at GSK's UK and US offices to build an understanding of the ethical conduct strategy, the formulation of policies, and the identification and management of risks
- Interviews with eight regional and divisional managers at GSK's UK and US offices to assess the implementation of ethical conduct policies and commitments and the robustness and effectiveness of internal management systems
- Verification of performance data and factual information through interviews, document review and data sampling, and interrogation of databases
- A country visit to GSK's Philadelphia and Research Triangle Park offices in the US to evaluate the implementation of Ethical Conduct policies and adherence to related standards. The US was chosen because it has the largest sales force. In addition, the PhRMA Code was updated in January 2009 in relation to its requirements when interacting with healthcare professionals (HCPs)
- We undertook a materiality review by conducting a media analysis, peer review and internet research for references to GSK in relation to its ethical conduct during the reporting period. We reviewed GSK's stakeholder engagement activities, which took the form of a survey on HCPs perception of sales representatives for *Avandia*, *Lovaza* and *Coreg* products. Bureau Veritas did not undertake any direct stakeholder engagement except with GSK staff

- We did not interview any GSK sales team field operatives or external HCPs

Opinion

Accuracy and reliability

Based on our work, it is our opinion that the ethical conduct section in GSK's 2009 CR Report:

- Provides a fair summary of GSK's related performance and activities
- Contains factual information, performance metrics and data trends that can be considered to be accurate and reliable

GSK's approach

Ethical conduct is a key part of GSK's strategic priority to build trust with society and there is a strong culture of this throughout the organisation. This is demonstrated at the highest level by its role in influencing policy for industry-wide improvements, for example in its work with the US trade organisation PhRMA. Ethical conduct is well embedded through the organisation, in turn demonstrated by company values and principles that are implemented through a sound governance structure, policies, procedures, ethical decision-making tools, audit and monitoring processes, and training and awareness programmes.

Report content and materiality

GSK strives to be a leader in ethical conduct and this is reflected in the content of the CR Report, which clearly communicates the key challenges and demonstrates an understanding of the material issues, although these are not always identified in a complete and systematic way. The report includes details of how issues are managed and presents performance data in areas such as misconduct and training. Transparency is further demonstrated by the publication of payments to HCPs in the US and plans to extend this disclosure globally. Bureau Veritas also considers the report to be balanced by inclusion of 'bad news' stories such as the violations received in relation to Direct to Consumer (DTC) advertising.

GSK's leadership approach to ethical conduct and associated reporting could be further improved by addressing the priority recommendations outlined below.

Observations and Recommendations

Increasing transparency and managing risk

Observation: GSK has a good understanding of its key risks in relation to ethical conduct which include: off-label promotion; acquisition of new companies and due diligence; increased outsourcing, for example in emerging markets; and internal change management issues.

Recommendation: GSK's CR Report should contain greater detail and more substantive information on management and performance in these key risk areas. GSK should consider how to demonstrate and communicate to stakeholders that these issues are being managed and what best practice performance in these areas would look like. GSK should examine the applicability of improved monitoring processes, quantifiable targets and key performance indicators (KPIs) in these key risk areas.

GSK Response: In 2009, GSK continued to strengthen our risk management processes and completed a risk identification and prioritisation review to identify the most significant risks. We are actively developing and implementing enhanced risk management plans to address these risks. Substantial progress will be made in 2010 to develop, operate and measure best practices in relation to risk management, monitoring and compliance processes.

Emerging issues – US healthcare reform

Observation: A key issue for the pharmaceutical sector is healthcare reforms in the US and other industry-wide changes such as increased government tendering of pharmaceutical products (as opposed to purchase directly by HCPs).

Recommendation: GSK should continue to ensure that it maintains consistency in its lobbying positions and public policy statements. It should monitor and communicate any impacts of the US healthcare reforms and changes in government tendering practices on its ethical conduct and, in particular, its sales and marketing

activities.

GSK Response: GSK will continue to maintain consistency between our public policy statements and the positions we advocate with governments and regulatory agencies. Our [public policy positions](#) are published in this report. Through our Legal Operations and Government Affairs departments, we actively monitor new legislation and changes in government positions as they relate to effects on GSK's business and practices.

Internal process improvements

Observation: GSK operates in over 100 countries and so its operations are spread over a number of different cultures, including emerging markets. Managing ethical conduct on this scale and to this diversity creates particular challenges. GSK has responded to this by simplifying and developing consistent operating policies and minimum standards across the organisation. There have been a number of updated policies in 2009 and alignment of data systems continues to develop.

Recommendation: GSK should ensure that it monitors and reviews the effectiveness of any new/updated policies across the organisation. In relation to data, GSK should continue to look for opportunities to further automate collection processes and for these to be documented and consistent, enabling performance trends to be provided where available.

GSK Response: GSK routinely reviews the effectiveness of its policies including new and updated policies. As recommended we will continue to work to improve our monitoring and reporting processes to continuously upgrade our efficiency and effectiveness. Ethical conduct improvements and supporting processes are also subject to the simplification strategy that is moving forward in all core business areas of GSK. Information analysis and reporting are key to the overall assurance programme we are managing. Further detailed recommendations from Bureau Veritas have been provided to the management of GSK in a separate internal management report.

Assurance standards used

Bureau Veritas used a range of standards and guidelines to undertake this assurance exercise. These included the International Standard on Assurance Engagements 3000 (ISAE3000) and the criteria within the Global Reporting Initiative (GRI) on balance, comparability, accuracy, timeliness and reliability.

This opinion has been formed on the basis of, and is subject to, the inherent limitations outlined below in this independent assurance statement. The assurance work was planned and carried out to provide reasonable, rather than absolute, assurance and we believe it provides a reasonable basis for our conclusions.

Limitations and Exclusions

Excluded from the scope of our work is information relating to:

- Activities outside the defined reporting period
- Company position statements (including any expression of opinion, belief, aspiration, expectation, aim or future intention provided by GSK)
- Financial data which is taken from GSK's Annual Report and Accounts, audited by an external financial auditor

This independent statement should not be relied upon to detect all errors, omissions or misstatements that may exist within the report.

Statement by Bureau Veritas of Independence, Impartiality and Competence

Bureau Veritas is an independent professional services company that specialises in quality, environmental, health, safety and social accountability with over 180 years' history in providing independent assurance services, and an annual turnover in 2008 of €2.55 billion.

Our assurance team does not have any involvement in any other Bureau Veritas projects with GSK and there is no conflict between the other services provided by Bureau Veritas and that of our assurance team.

Bureau Veritas has implemented a Code of Ethics across its business which is intended to ensure that all our staff maintain high ethical standards in their day-to-day business activities.

Competence: Our assurance team has extensive experience in conducting assurance over environmental, social, ethical and health and safety information, systems and processes.



> [Back to top](#)

› Home › Responsibility › Ethical conduct › Q&As

Corporate Responsibility Report 2009

Q&As

Here we respond to questions raised by our stakeholders.

Can one company on its own establish high standards of ethical conduct, or is an industry approach required?

We set our own high standards of ethical conduct which we hope will establish a benchmark by which all companies are judged. We also work with other companies through trade associations to develop high ethical standards. We believe that it is in the best interest of patients if the pharmaceutical industry adopts common high standards of ethical conduct. This will also help to improve trust in the industry among all our stakeholders.

A lot of GSK employees were dismissed for unethical conduct. Are your policies working?

In 2009, 246 employees were dismissed or agreed to leave the company voluntarily as a result of policy violations. Unethical conduct occurs in all companies. We believe these figures demonstrate the effectiveness of our monitoring and compliance programmes.

Furthering our ethical culture, recruiting the right people, providing the right training and tools, improving our checks and encouraging people to speak up enable us to identify and address unethical conduct in a consistent and responsive manner.

Is GSK unduly influencing doctors?

We take several approaches to protect against inappropriate influence of doctors, including regional marketing codes of practice, regular training and monitoring. Our policies apply to all employees and agents and commit us to promotional practices that are ethical, responsible, principled and patient centred. They prohibit kickbacks, bribery or other inducements to doctors and any promotion for unapproved uses of our medicines. Our sales force is regularly trained and supervised by managers who monitor educational events, visits to doctors and expenses.

In 2009 we commissioned a consultant to help us calculate the fair market value of payments to healthcare professionals (HCPs). This makes payments more consistent across the business. In the US, we limit payments to HCPs who advise us to \$100,000 a year and most receive fees of less than \$10,000 a year. We are developing a system to disclose HCP fees and began to report payments in the US in 2009. We will report payments in other markets from 2010.

How do you prevent off-label promotion?

All GSK employees dealing with healthcare professionals undergo extensive training and monitoring. They are instructed that only full and accurate information may be provided on approved uses for a medicine. It must be based on valid scientific evidence, and must be accurate, balanced, fair, objective, unambiguous and up to date.

Questions from doctors on off-label uses for our products must be referred to our medical information department. In the US, additional processes are in place for monitoring these referrals to help us ensure that representatives are not promoting off-label uses. We now monitor both the volume of letters responding to questions and the types of referrals made by our individual representatives, for example the number of referrals relating to a particular product or a particular off-label use.

Additionally, our internal audit department audits our sales and marketing practices globally using a risk-based approach.

Corporate Responsibility Report 2009

Supply chain

We want to source from companies that maintain high standards for quality, labour and the environment.

Inadequate environment, health and safety (EHS) and human rights standards are an indicator of poor management. This can impact on quality, compromise patient safety and impede continuity of supply of essential medicines. Association with poorly performing suppliers could also damage our reputation.

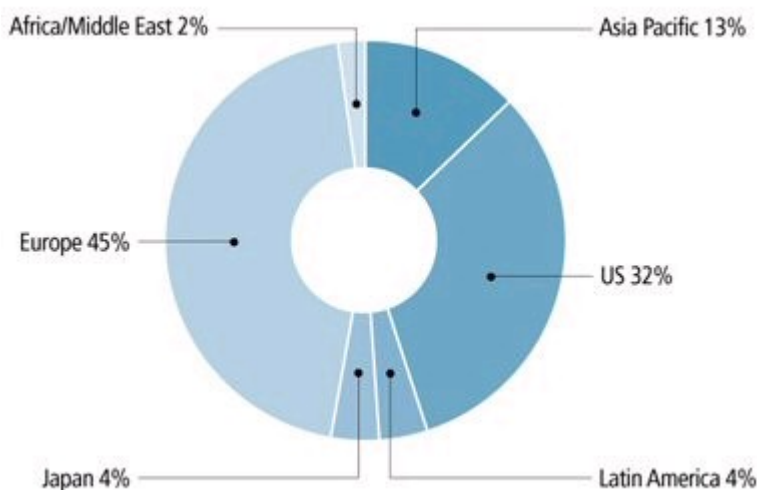
Suppliers that are critical to our supply chain must meet our minimum standard before we will work with them and we conduct detailed assessments of new and existing critical suppliers to monitor their performance on EHS and human rights issues.

We are also beginning to measure the [environment, health and safety impacts of our manufacturing suppliers](#).

Counterfeit drugs can pose a serious threat to patients. We build anti-counterfeiting features into our products and packaging and we take steps to prevent criminals from making and distributing fake GSK products.

Our supply chain

Number of suppliers: 95,000
Spend: £10 billion



In 2009 GSK made purchases from over 95,000 suppliers around the globe. Our supply chain is complex: it ranges from strategic relationships with suppliers that manufacture active pharmaceutical ingredients, intermediates, raw materials and packaging for GSK medicines to contracts for goods and services such as office equipment, cleaning and security.

Corporate Responsibility Report 2009

Responsibility and our supply chain

Our approach to ensuring high EHS and human rights standards among our global suppliers includes:

- Pre-audit assessments of potential suppliers to gather information and to help evaluation
- Inclusion of a human rights clause in supplier contracts and full environment, health and safety (EHS) requirements in contracts for critical suppliers
- Review of EHS and human rights in routine supplier engagements
- EHS audits of potential and existing suppliers
- Agreed improvement programmes with suppliers
- Regular progress monitoring and advice

Update September 2010

In April 2010 we launched a new [Third Party Code of Conduct](#) for suppliers that sets out our expectations relating to:

- Ethical conduct
- Labour practices and human rights
- Environment, health and safety
- Management systems
- Interactions with GSK employees.

The Code is based on the Pharmaceutical Supply Chain Initiative's (PSCI) Pharmaceutical Industry Principles for Responsible Supply Chain Management.

While this approach supports our programme to establish secure supply we continue to look for other opportunities to help raise awareness and implementation of our standards. In 2009, we conducted [training and awareness sessions](#) to help suppliers understand our expectations and strengthen their EHS management systems. We are also collaborating with other companies in the Pharmaceutical Supply Chain Initiative (PSCI) to help promote EHS and human rights standards.

Supplier contracts

Our supplier contracts contain EHS requirements based on our [global EHS standards](#) and [human rights clauses](#) based on the International Labour Organization conventions and the UN's Universal Declaration of Human Rights. Companies must agree to our EHS and human rights requirements before they can be included as a supplier.

Risk-based approach

Our supply chain is large and complex so we use a risk-based approach to target our engagement and monitoring efforts. We focus on 'critical suppliers' that represent approximately 30 per cent of our supplier spend, and are mostly based in Europe, North America and Asia.

Critical suppliers include contract manufacturers and suppliers that are pivotal to our business. We consider the following factors when defining critical suppliers who may present a high risk to GSK:

- Relevance to the supply of essential medicines
- Threats to continuity of supply
- The value of affected products to GSK
- Regulatory compliance and requirements
- Hazards associated with manufacturing processes and materials
- Environmental impacts

We develop long-term relationships with critical suppliers and conduct regular monitoring to support the uninterrupted supply of high quality materials and services to GSK.

Training for GSK procurement teams

We train all new procurement employees in our standards and requirements for EHS and [human rights](#). This emphasises their role in promoting compliance with the standards. Key procurement employees, including procurement managers, receive ongoing training on these topics.

Industry collaboration

By working with others, we recognise that we can achieve more to improve EHS and human rights standards than we can alone, particularly in developing countries. That is why we are collaborating with other companies in the Pharmaceutical Supply Chain Initiative (PSCI).

The PSCI has developed the Principles for Responsible Supply Chain Management to provide guidance for suppliers on the standards that the pharmaceutical industry expects. These align closely with GSK's EHS and human rights standards.

GSK is working with other PSCI members to identify further opportunities for collaboration. These include projects to improve communication and evaluation of a wider base of potential suppliers and to improve suppliers' understanding of the importance of EHS and human rights standards.

Environmental sustainability

We are adding environmental sustainability topics to the questionnaires we use to assess potential new suppliers. In 2010 we will start to introduce sustainability requirements for existing critical suppliers and will use supplier review meetings to encourage these companies to improve their sustainability performance.

Read more about our efforts to improve the [sustainability performance of our suppliers](#).

> [Back to top](#)

Corporate Responsibility Report 2009

Human rights clause

Our supplier contracts contain a human rights clause (below) which is based on the International Labour Organization's conventions and the UN's Universal Declaration of Human Rights.

We may amend the exact wording of the clause during negotiations with suppliers or during translation to suit local law. These changes will not reduce the contractual impact or intent of the clause.

The GSK standard contract clause for Ethical Standards and Human Rights

Unless otherwise required or prohibited by law, the Supplier warrants, to the best of its knowledge, that in relation to the supply of goods or services under the terms of this Agreement:

1. It does not employ engage or otherwise use any child labour in circumstances such that the tasks performed by any such child labour could reasonably be foreseen to cause either physical or emotional impairment to the development of such child;
2. It does not use forced labour in any form (prison, indentured, bonded or otherwise) and its employees are not required to lodge papers or deposits on starting work;
3. It provides a safe and healthy workplace, presenting no immediate hazards to its employees. Any housing provided by the Supplier to its employees is safe for habitation. The Supplier provides access to clean water, food, and emergency healthcare to its employees in the event of accidents or incidents at the Supplier's workplace;
4. It does not discriminate against any employees on any ground (including race, religion, disability or gender);
5. It does not engage in or support the use of corporal punishment, mental, physical, sexual or verbal abuse and does not use cruel or abusive disciplinary practices in the workplace;
6. It pays each employee at least the minimum wage, or a fair representation of the prevailing industry wage (whichever is the higher) and provides each employee with all legally mandated benefits;
7. It complies with the laws on working hours and employment rights in the countries in which it operates;
8. It is respectful of its employees' right to join and form independent trade unions and freedom of association;
9. The Supplier agrees that it is responsible for controlling its own supply chain and that it shall encourage compliance with ethical standards and human rights by any subsequent supplier of goods and services that are used by the Supplier when performing its obligations under this Agreement.

The Supplier shall ensure that it has ethical and human rights policies and an appropriate complaints procedure to deal with any breaches of such policies.

GSK reserves the right upon reasonable notice (unless inspection is for cause, in which case no notice shall be necessary) to enter upon the Supplier's premises to monitor compliance by the Supplier of the warranties set out in the clause above and the Supplier shall, subject to compliance with law, furnish GSK with any relevant documents requested by GSK in relation thereto. This sub-section will only be required where there is no general right of audit elsewhere within the Agreement.

› [Back to top](#)

› Home › Responsibility › Supply chain › Responsibility and our supply chain
› [Training and capacity building](#)

Corporate Responsibility Report 2009

Choosing suppliers

We conduct a detailed assessment of critical suppliers as part of our supplier assessment process.

Critical suppliers include contract manufacturers and suppliers that supply products that are pivotal to GSK. We use questionnaires, pre-audit assessments and environment, health and safety (EHS) audits to assess their performance on health and safety, environmental and human rights issues.

Environment, health and safety

We assess potential new critical suppliers against [our EHS standards](#). They must achieve a minimum audit score of 50 per cent against the standards if they are to join our supply chain. The minimum score provides assurance that suppliers are managing basic EHS risks, reducing the likelihood of significant incidents that could harm people or the environment, or disrupt the supply of essential medicines.

Following an audit, most suppliers that have not met our requirements implement plans to improve their EHS performance. In many cases we help suppliers to improve by identifying the steps they need to take to improve their EHS management and advising them on expert consultancies that can provide additional support. We also expect our existing suppliers to make improvements and we monitor their progress through reviews and follow-up visits.

In 2009, we increased our use of pre-audit assessments of potential new suppliers in emerging economies, in response to a large number of companies in those countries failing to meet our minimum standard in full EHS audits. Pre-audit assessments focus on key issues and enable us to identify suppliers that are more likely to meet our standards if subjected to a full audit, as well as suppliers that, though unlikely to initially meet our standards, have the capabilities to improve. Suppliers that are unlikely to meet our standards are given feedback so that they can make the necessary improvements.

Human rights

Our audits also include questions which help us identify potential breaches of the human rights clause included in supplier contracts. Suppliers are asked for information on policies and practices relating to:

- Age limits for employees
- Discrimination against employees and the local population
- Prevention of abuse of individuals
- Wages, benefits and working hours (whether they meet the legal minimum)
- Rights for workers to organise and recognition of worker organisations

These questions do not contribute to the EHS audit score, but may be a reason not to progress business with a supplier and may result in GSK escalating the finding to appropriate authorities.

[Read about our audit programme which ensures compliance with quality standards.](#)

› [Back to top](#)

› Home › Responsibility › Supply chain › Responsibility and our supply chain
› [Monitoring and engagement](#)

Corporate Responsibility Report 2009

Monitoring and engagement

Once a supplier has been selected, we monitor performance against our standards through routine interactions including reviews and follow-up visits by GSK staff responsible for procurement, quality and EHS. We consider EHS and human rights issues in these interactions.

We hold global and regional supplier review meetings where senior GSK managers interact with suppliers on key issues. We provide contract manufacturers with information on the EHS risks associated with the GSK materials they are producing or handling. Our supplier booklet 'How to Work with GSK, a Production Supplier Guide' reiterates GSK's expectation for suppliers to operate to the highest ethical standards, act responsibly and comply with the law and industry guidelines.

We conduct regular EHS and loss prevention audits of critical suppliers in our supply chain. We focus on higher-risk suppliers. Supplier facilities are evaluated against [our EHS standards](#) and must achieve a score of at least 50 per cent against these standards to demonstrate acceptable performance and to continue to supply GSK. Suppliers develop improvement plans based on the audit findings and we follow up to monitor progress against these plans.

We provide feedback to suppliers if we identify any issues through the [questions relating to human rights](#). We require corrective action if the issues present a potential breach of the [human rights clause](#) included in supplier contracts.

Suppliers of promotional materials

Many of the promotional materials for our Indian business are sourced from within India in an industry with a higher risk of the use of child labour.

We conduct unannounced spot checks for these suppliers, often during the night. These focus on maintaining quality standards but are also used to check that suppliers are not using child labour. The spot checks are conducted by GSK procurement and regional sales staff.

We have used the findings from the programme in India to strengthen our promotional supplier qualification process in other regions. We are conducting more detailed inspections of assembly sites and have added extra checks in regions where child labour is more common.

› [Back to top](#)

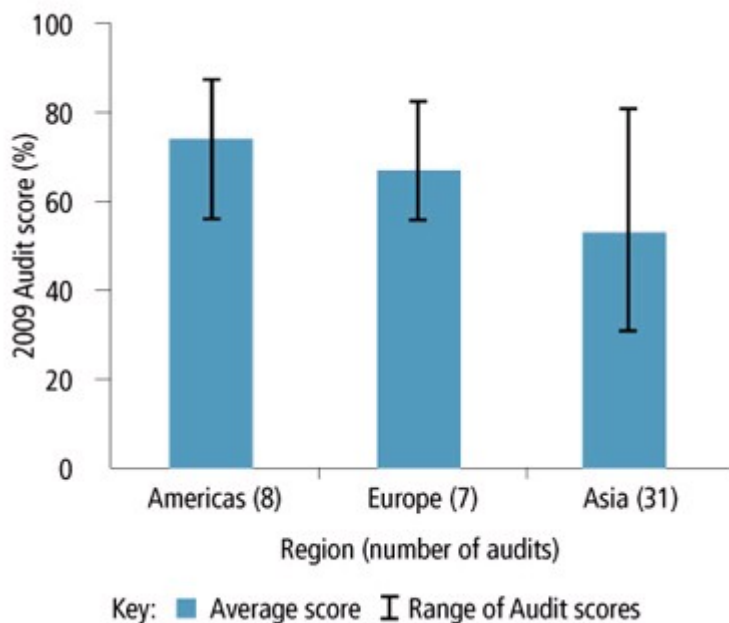
Corporate Responsibility Report 2009

Supply chain performance

In 2009 we conducted 46 supplier audits. The average audit score against GSK EHS standards was 59 per cent; the highest score achieved was 87 per cent and lowest was 32 per cent.

We are helping to raise standards by engaging with potential new suppliers. Fifteen suppliers that initially failed to meet our requirements have now achieved minimum EHS criteria following our engagement efforts.

2009 EHS audit scores of key suppliers



Americas = North America and South America regions

The higher average scores in North America and Europe, in contrast to the lower average scores in Asia, are largely related to the maturity of EHS management systems and the supporting legislative framework and its enforcement in these regions. The broad range of scores in the Asia region reflects the higher-performing suppliers where there has been long-term intervention from GSK. The lower scores relate to suppliers where we have undertaken initial audits and found significant deficiencies in EHS management and risk control.

In 2009 ten potential suppliers failed to meet our minimum requirements. Through pre-audit assessments we identified a further eight potential suppliers that were unlikely to meet minimum requirements.

The most significant audit findings in 2009 were similar to those found in 2008 and occurred mainly in developing countries. They included:

- No infrastructure for fire protection and poor emergency response capabilities
- Absence of fundamental risk controls for process safety
- Poor control of exposure to hazardous substances

- Poor waste management and environmental controls
- Frequent regulatory findings

No significant issues were identified relating to the human rights questions we ask during audits.

Based on an analysis of audit findings, we continue to develop [information to assist suppliers](#) in understanding GSK EHS requirements and to help them to have a better understanding of the most common significant issues and how they can improve their EHS management systems.

Number and types of audits in 2009

	Americas*	Europe	Asia	Africa	Total
Type of supplier					
Primary (raw materials, intermediates and active pharmaceutical ingredients)	3	11	34	0	48
Pharmaceutical (formulations)	7	2	1	0	10
Consumer healthcare (excipients, actives, raw materials)	1	0	11	0	12
Type of engagement					
Audit	8	7	31	0	46
Review	3	6	15	0	24
Average audit score (per cent)	74	67	54	-	59

* Americas = North America and South America regions

Number of suppliers audited between 2002 and 2009

	Total number visits	Americas*	Europe	Asia	Africa	Cumulative Total number visits
2002	9	0	8	1	0	9
2003	18	0	12	6	0	27
2004	29	3	9	17	0	56
2005	40	7	8	23	2	96
2006	32	0	13	18	1	128
2007	55	10	8	37	0	183
2008	53	6	18	28	1	236
2009	70	11	13	46	0	306

* Americas = North America and South America regions

Suppliers of promotional materials

In 2009 we increased spot checks of suppliers of promotional materials. We conducted a total of 16 announced and unannounced spot checks and found no evidence of child labour and no violations of other contract terms.

› [Back to top](#)

› Home › Responsibility › Supply chain › Responsibility and our supply chain
› **Training and capacity building**

Corporate Responsibility Report 2009

Training and capacity building

Communication and training

We use our experience of auditing in developing countries to identify opportunities to improve supplier understanding of good EHS management.

In 2009 we held a workshop in China attended by 18 companies. The workshop raised awareness of the most common significant issues that we find during audits, including fire protection and emergency response, process safety and environmental controls.

Initial feedback from attendees was very encouraging and we are reviewing the potential to hold similar workshops in the future.

We are also encouraging suppliers to use external consultants to help improve their systems. We have identified a list of preferred consultants and we participate in meetings with the supplier and their consultant to ensure they understand our requirements.

Highly Protected Risk status

In 2009, we continued a pilot project for a strategic supplier to achieve Highly Protected Risk (HPR) status. To achieve HPR status, a 'best in class' insurance industry designation, companies must adopt an engineering approach to minimising property and supply chain risks. Our plan is to extend this to other strategic suppliers, starting in 2010.

Building EHS management capacity at key suppliers

At our larger suppliers that have a number of facilities, we are engaging with senior management to encourage them to develop their own EHS governance systems. This will help to improve EHS performance and will enable companies to develop EHS management strategies that align with our own. Previously we have largely worked with managers at site level. We are focusing on the suppliers where we have the most influence – mostly companies that have long-standing relationships with us and derive a large amount of business from GSK.

We trialled this strategic approach with a company based in India that provides GSK with a range of essential ingredients from multiple sites. Using workshops and improvement tools we helped the supplier to develop a three- to five-year improvement plan which includes measures to strengthen their internal audit procedures and their system for managing corrective actions. The plan also includes steps to improve communication with GSK and to develop performance improvement goals in line with our own.

The trial was a success, benefiting both the supplier and GSK. The supplier now has an improved understanding of our expectations and the project helped to strengthen our working relationship and provide the foundation to support future investment. Increasing ownership of EHS management also helped to improve engagement and motivation among the supplier's employees.

The project has given us increased confidence in the supplier's management of EHS and loss prevention. As the supplier implements its improvement plan, this will enable us to rely less on site visits and to move to a system of verification of the supplier's EHS management systems.

We will expand this approach to more key suppliers in 2010.

Corporate Responsibility Report 2009

Supplier diversity

Small companies and those owned by women or minority groups are often under-represented in the supply chains of large companies.

In response, the US government and many large companies require their suppliers to source from diverse companies. GSK developed a supplier diversity programme to identify, develop and position diverse businesses to support the commercial ambitions of GSK while contributing to its social responsibility to improve the economies in the global communities we serve. We recognise the value diverse businesses have in diverse communities and therefore are committed to provide opportunities that will prepare them for sustainability beyond GSK. In 2009 our commitment resulted in 21 per cent of our US Pharma and Consumer Healthcare discretionary spend with small and diverse businesses.

We work to increase the diversity of our supply chain by providing opportunities for small and diverse businesses to provide us with goods and services, we are enabling these suppliers to sustain their businesses, create jobs and boost their local economies. Moreover, our business also benefits. Beyond complying with regulations, supplier diversity also encourages innovation and exposes us to new perspectives and fresh ideas.

In addition to identifying new business opportunities with diverse suppliers, we work to build their capabilities so they can expand their business and compete for global contracts with GSK and other multinational companies. Our diverse supply base must meet GSK's standards of quality and service. Read a [case study](#) on how we helped a diverse supplier to meet the quality standards needed to do business with GSK.

As we implement our business strategy to simplify our operating model, we are rationalising our supply base and selecting fewer suppliers. We are taking steps to ensure diverse suppliers benefit from these opportunities. For example, in 2009 we included a number of diverse suppliers in a bid for our temporary staffing contract. The contract was awarded to a minority supplier with global capacity.

US programme

In the US, we have a dedicated team working to create opportunities for diverse suppliers to work with GSK and to channel our procurement spend to companies owned by women, minorities, veterans and disabled veterans. The team collaborates with a Procurement Supplier Diversity Advocacy team to help ensure diverse supplier inclusion throughout GSK by proactively developing supplier diversity goals and developing ways to engage business partners.

The supplier diversity team's activities include:

- Participating in national and local diversity councils
- Mentoring high-potential diverse suppliers and providing improvement grants to help them expand their business with GSK and other corporations. Read more in our [case study](#)
- Sponsoring diverse business leaders to attend executive programmes at the Tuck School of Business and Kellogg School of Management
- Sponsoring and attending outreach and networking conferences. For example, in 2009 senior employees from GSK legal and our supplier diversity team participated in the American Bar Association's National Summit on Diversity and GSK was a major sponsor of the Diversity Alliance for Science fair
- Hosting workshops to enable diverse suppliers to understand our business requirements

- Organising matchmaking forums to give diverse suppliers an opportunity to meet key senior executives and buyers within GSK. In 2009, we hosted forums to identify and develop diverse suppliers of engineering, facilities, R&D and marketing services

As part of the Adopt a Neighbourhood for Development initiative, our procurement and community relations teams work with local communities in Durham, North Carolina, and Philadelphia, Pennsylvania. These areas are historically deprived and are often overlooked by companies when choosing where to locate their businesses. GSK provides an annual grant to help communities to develop and become more attractive as business locations.

Outside the US

GSK's dedicated supplier diversity team is based in the US, but all procurement employees worldwide are responsible for supporting diverse suppliers where possible. In 2009 supplier diversity goals became part of performance evaluations for procurement employees globally. When a US diverse supplier has the capabilities to provide goods and services globally, the team works with procurement in other regions to enable the supplier to compete for contracts outside the US.

We are a sponsor of the Global Link Programme as part of our role on the International Advisory Board of the US National Minority Supplier Development Council. The programme helps diverse suppliers develop partnerships with local businesses around the world, explore activities outside their core business, share risks and opportunities and access new innovative technology. GSK is a member of the new UK Minority Supplier Development Council. The council forms a link between corporations and certified minority business enterprises, with the aim of increasing procurement and business development opportunities.

Recognition

In 2009 our supplier diversity efforts were recognised through a Corporate IMPACT Award from the Carolinas Minority Supplier Development Council. We were also nominated for the National Minority Supplier Development Council's Corporation of the Year.

Testimonials

'Our association with GSK has positively impacted every aspect of our operations. GSK's impact is felt beyond the walls of our business, as we have shared our gains with the local minority business council and began mentoring peers and developing businesses.'

Worldwide Labels & Packaging, Memphis, Tennessee

'The GSK Mentoring Program was the catalyst to provide my company with a different mindset on how we solve issues, improve efficiencies and obtain any goal we set for ourselves.'

Aten Solutions, Cary, North Carolina

> [Back to top](#)

› Home › Responsibility › Supply chain › Responsibility and our supply chain
› **Fair treatment of suppliers**

Corporate Responsibility Report 2009

Fair treatment of suppliers

It is important that we foster relationships with our suppliers which are characterised by mutual trust and respect.

GSK has established procurement policies and processes requiring high standards of ethical conduct and integrity. Our [general terms and conditions](#) are published on our website. In 2010 we plan to implement a Third Party Code of Conduct reinforcing the principles and values GSK expects from its business partners. By adopting the code, suppliers will strengthen mutual trust and respect with GSK.

Fair bidding

GSK supports impartiality in all phases of the procurement cycle. Our global electronic bid system ensures all suppliers are treated fairly and equally. The vast majority of suppliers providing goods and services to GSK are registered on the system. Companies invited to bid on products and services sourced by GSK all receive the same information at the same time, to ensure a fair and ethical bidding process. In 2009 we managed over 9,500 bids and negotiations in over 50 countries through the system. For highly competitive goods and services the system is even more transparent, as we allow suppliers to see where their bids rank against their competition.

Monitoring concerns

GSK employees, suppliers and other third parties can report concerns through our confidential reporting lines. Callers can remain anonymous and the line includes technology to prevent caller identification. They are provided with a case reference number which enables them to call back and receive feedback on the status of their report.

GSK's UK Confidential Reporting Line is 0808 100 5689 (access code 47500); the US Integrity Helpline is 1-866-GSK-ETHICS (1-866-475-3844).

Payment to suppliers

In 2008 GSK changed its standard payment terms to a minimum of 60 days from receipt of invoice. This step has been taken as part of a corporate programme to reduce working capital. Sixty-day payment terms bring GSK more in line with the practice in other industries and are faster than the terms set by some other companies. GSK Procurement is reviewing payment terms with all suppliers to revise them in line with this corporate initiative.

› [Back to top](#)

› Home › Responsibility › Supply chain › **Maintaining quality**

Corporate Responsibility Report 2009

Maintaining quality

Maintaining the quality of the products we make and the materials we buy is essential to the safety of patients and the success of our business.

We conduct quality assessments for all suppliers of ingredients and packaging materials used in all of our products. We agree specifications for our ingredients and packaging materials with our suppliers and apply a set of global auditing standards for each type of ingredient and packaging material that we buy.

We use a risk-based approach to determine the frequency of audits. In 2009 we conducted 885 quality audits of our ingredient and packaging material suppliers, compared to 558 in 2008 and 776 in 2007.

On receipt at GSK sites, samples are taken and testing is performed according to a testing protocol. All samples are tested for identity. Every batch is also tested against our quality specification.

Examples of additional measures in place to maintain quality in our supply chain and prevent contamination include the use of dedicated transport, use of tamper-evident seals and the use of sophisticated analytical tools to check the authenticity of the materials we receive.

Our quality teams

In 2009 we established regional and country teams so that our quality managers have a greater understanding of local culture and language and to ensure our standards, training and reporting are applied consistently. We also developed a global database for quality information, which was previously held at site level.

Helping suppliers to meet our quality standards

We conduct quality assessments of all potential suppliers. This enables us to identify companies that meet our required standards as well as those we can work with to make the necessary improvements.

For example, in 2009 one of our suppliers in Asia had an inspection by a European regulatory agency which had five major findings. GSK worked closely with the supplier to help it to better understand the expectations of the European Regulator. GSK Quality department staff visited the company three times in six months to educate the supplier and to continually assess progress against the improvement plan. A re-inspection took place in November 2009 which confirmed the supplier had successfully addressed these findings.

Working with others to improve quality

Through Rx-360, an industry consortium, we are working to set global standards for auditing materials suppliers. This will make it easier for suppliers to understand the expectations of the industry, rather than every company having their own standards. The long-term goal is to move towards a shared audit model for lower-risk suppliers, where suppliers used by a number of companies would be audited once rather than multiple times and the results shared between the purchasing companies.

The consortium aims to agree the common standards during 2010.

Quality statement



Quality is at the heart of all activities that support the discovery, supply and marketing of products to our patients and customers. Quality is critical to building trust with society and, therefore, to our future business success.
Andrew Witty, Chief Executive Officer

› [Back to top](#)

› Home › Responsibility › Supply chain › **Security of supply**

Corporate Responsibility Report 2009

Security of supply

Ensuring a continuous supply of high-quality medicines is essential to the patients who depend on our products, as well as to the success of our business.

It is vital that security of supply is not compromised at any stage of the distribution chain. We prepare for major incidents that may disrupt supply, ranging from large-scale theft of products to natural and man-made disasters near a facility.

GSK's Global Manufacturing & Supply business implements contingency plans for 'medically critical' products. We define products as 'medically critical' if they are life-saving or those where if they were not available to patients, there is likelihood of serious detriment to health and there is no known alternative. These plans are defined on a product-by-product basis and may include holding sufficient stocks of products or active pharmaceutical ingredients.

We work with all critical suppliers to encourage them to implement their own contingency plans. In high-risk countries we will set up joint ventures to ensure that we maintain control over the distribution chain. We have two global contracts for suppliers that deliver goods across borders between GSK manufacturing sites and GSK distribution centres. We conduct regular high-level operational reviews of these suppliers, which include security elements. We also include security requirements in contracts with road and air freight carriers that move goods from our distribution centres to the market.

Read about the measures we are taking to [protect our employees in the event of a pandemic flu outbreak](#) to ensure the supply of critical medicines is not disrupted.

› [Back to top](#)

Corporate Responsibility Report 2009

Counterfeiting

Approach

Performance

According to the World Health Organization (WHO), less than one per cent of pharmaceutical products sold in developed countries are counterfeit, but in the developing world this figure may be higher than 10 per cent, and up to 30 per cent in some countries.

Counterfeit drugs come in many variations, and may contain:

- None of the legitimate active ingredient
- The active ingredient in reduced or sub-therapeutic amounts
- A completely different and/or inappropriate active ingredient
- Impurities such as unapproved colourants or micro-organisms
- Packaging that falsifies the product description or expiry date

The vast majority of counterfeit drugs are not subject to quality control, hygiene standards, testing of ingredients and monitoring of product specifications or equipment. Counterfeiting is a threat to public health, potentially causing harm to patients and even death.

We add anti-counterfeiting features to our product packaging. These include holograms, security seals and complex background patterns that are difficult to photocopy or scan, as well as a wide variety of covert identifiers which are added using print technologies and sophisticated markers. These help us to identify counterfeits and gather evidence against offenders. Our Packing Design Technology and Security team in the UK carries out forensic examinations of suspected counterfeit GSK products.

GSK country managers are required to identify products that are most likely to be counterfeited and to develop training for sales representatives. Our sales representatives worldwide play an important role in helping to discover counterfeit products, as they have constant contact and detailed knowledge of the markets and outlets where counterfeit products are likely to be sold.

Our Corporate Security department investigates every potential case of counterfeiting. It uses internal and external investigators to collect evidence for criminal prosecutions by the authorities or civil enforcement proceedings by our legal department.

As well as removing fake products from the market, one of our primary aims is to trace the products back to source, to shut down the manufacturers and their partners (for example the packaging printers and distributors).

We provide training for regulatory authorities, such as the State Food and Drug Administration (SFDA) in China, law enforcement agencies and customs officers in many parts of the world.

GSK works closely with the wider pharmaceutical industry to investigate cases of counterfeiting and we also raise awareness with governments internationally, pressing for stricter laws and more severe penalties. GSK is a founding member of the Pharmaceutical Security Institute (PSI), which coordinates information collection and investigations within the industry internationally.

The PSI is influential in helping to shape anti-counterfeiting policy among national governments and international organisations. Together with the PSI, GSK is a major contributor to the WHO's internationally

represented anti-counterfeiting working groups.

› [Back to top](#)

Corporate Responsibility Report 2009

Counterfeiting

Approach

Performance

In 2009 there were 259 reported cases of counterfeiting of GSK products.

These resulted in 94 raids by the Authorities, during which 129 suspected counterfeiters were arrested. Of the 94 raids, 59 took place at criminal manufacturing facilities and 35 at wholesale/distribution outlets. The 59 factories represent criminal operations that were capable of mass production of counterfeit medicines and other healthcare products. The raids on these facilities undoubtedly prevented huge amounts of counterfeit product from entering legitimate markets around the world.

Anti-counterfeiting in practice

In 2009, we conducted a number of successful anti-counterfeiting operations focusing on China, which is the primary source of counterfeit products for the Chinese domestic market and international markets:

A GSK Corporate Security undercover operation led to the arrest and successful prosecution of three counterfeiters in China and the seizure of 60,000 counterfeit Seroxat tablets. The tablets had been counterfeited by a major licensed pharmaceutical company in the north of China.

As a result of a long-term undercover operation, Chinese prosecutors in Guangzhou City have charged six defendants involved in the manufacturing, distribution and illegal export of counterfeit Panadol from China to Taiwan. The investigation culminated in a raid by Chinese police on a factory and two warehouses in Guangzhou City, Guangdong Province. The Taiwanese authorities have also arrested the person coordinating the illicit distribution network in Taiwan.

As the result of a GSK operation, Chinese authorities raided a factory in Shenzhen, Guangdong Province and seized 75,000 counterfeit *Zinnat* tablets, 49,600 cartons, 60,000 *Zinnat* leaflets and 12 rolls of counterfeit *Zinnat* blister pack foil. The counterfeiting machinery was seized and three counterfeiters arrested. The medicine was being produced for African and Middle Eastern markets.

Anti-counterfeiting

	Number of reported cases of counterfeit	Number of raids	Number of arrests
2009	259	94	129
2008	289	94	84
2007	429	71	127
2006	248	57	94
2005	334	47	31

› [Back to top](#)

› Home › Responsibility › Supply chain › **Case studies**

Corporate Responsibility Report 2009

Case studies

Mentoring diverse suppliers in the US

Callis Construction Services (CCS) is a minority-owned contracting company in Durham, North Carolina. The company's President, Jesse Callis, took part in our diverse supplier mentoring programme, beginning in 2004, which helps suppliers form partnerships with GSK and other large corporations.

As part of the programme, we assessed CCS's business processes and identified issues preventing the company becoming a GSK preferred supplier. Concerns ranged from management accessibility to the ability to scale up its supply to the needs of GSK. The company implemented improvements based on our recommendations which enabled it to become a preferred supplier and win business worth around \$2.8 million.

The success of this partnership enabled CCS to contribute to its local community. It paid for two employees to attend a local university and Mr Callis developed a training programme with Durham Technical College which prepares minority construction workers for management positions on major projects in the area.

When asked about his relationship with GSK, Mr Callis said, 'GSK has been a wonderful mentor. They are a real leader in their commitment and actions to help diverse minority suppliers. In my case, they provided assistance that has led to a very significant growth of my business. This in turn has provided jobs for others in the Durham and surrounding area ensuring that monies paid by GSK stay in the local communities. This is a win for everyone involved.'

Improving supplier performance in developing countries

With a large number of potential raw material suppliers in China failing to meet our minimum EHS criteria, we took action to improve standards.

In 2009 we increased our use of pre-audit assessments to determine which potential new suppliers have the capability and commitment to improve. Using the results of these assessments we facilitated meetings between a supplier and expert consultants to identify and implement pragmatic improvement plans.

For example, GSK approached a Chinese pharmaceutical manufacturing company in 2004 to assess whether it could provide key ingredients needed to manufacture asthma medicines. An initial audit identified multiple deficiencies against our EHS standards, including poor approaches to fire prevention and protection and significant gaps in the design and safe operation of process equipment.

The supplier agreed to work with GSK and employ the services of expert consultants to make the necessary improvements. This involved the commitment of its senior management team, which regularly met with GSK as we monitored progress. A re-audit in 2009 demonstrated that the company now meets our minimum standards and has put in place management systems to provide the foundation for further improvements. The supplier is now manufacturing trial quantities of materials and we are assessing the possibility of establishing a long-term supply contract. We are pleased to note that the supplier has introduced EHS and loss prevention improvements into the design, construction and operation of a new site it recently built.

We are now using this approach regularly in China and India.

› [Back to top](#)

› Home › Responsibility › Supply chain › **Q&As**

Corporate Responsibility Report 2009

Q&As

Here we respond to questions raised by our stakeholders.

What are you doing to raise standards in your supply chain?

We have long-term relationships with our critical suppliers and we offer them training and support to help them raise standards. Our monitoring process is a key part of raising awareness of our expectations and identifying areas where suppliers need to improve. We work with our suppliers to help them make the necessary changes identified.

Are there human rights risks in your supply chain?

GSK's supply chain is large and complex, and like all similar supply chains, contains a risk of human rights violations. These risks vary considerably, based on the type of supplier and the goods or service we are sourcing. Our manufacturing and R&D suppliers employ skilled workers so there is a lower risk of human rights violations. Our EHS audits help to provide assurance that good working conditions are in place at these supplier facilities. There are considerably higher human rights risks in suppliers that employ low-skilled workers, for example promotional goods suppliers. We conduct spot checks of these suppliers in India.

Our supplier selection process aims to ensure we only enter relationships with suppliers that respect human rights. We also include clauses in contracts with all suppliers which specify that upholding human rights is a condition of doing business with GSK.

What are you doing in your supply chain to plan for a flu pandemic?

We have implemented a contingency plan to ensure our operations, and the supply of medically critical products, are not compromised by a flu pandemic. We are now encouraging our critical suppliers to implement their own contingency plans.

You are outsourcing more manufacturing. Will this mean you have less control over your products, increasing risk for patients?

The manufacture of all our medicines and vaccines is closely controlled and subject to the same quality standards, regardless of whether we produce them ourselves or outsource the process to contract manufacturers. Before outsourcing any stage of the manufacturing process, we confirm that the contractor can carry out the required processes to our high standards. All contract manufacturers must also be approved by relevant regulatory authorities, and are subject to inspection by GSK and regulators.

› [Back to top](#)

› Home › Responsibility › [Environmental sustainability](#)

Corporate Responsibility Report 2009

Environmental sustainability

We are stepping up our efforts to become more sustainable, under the oversight of a new Sustainability Council of senior executives. [Our vision](#) is ultimately to transform how we do business, following the principles of industrial ecology, optimising the efficiency of our processes and increasing our use of renewable materials and energy. We recognise that this will be a challenging journey with many hard decisions.

Since 2007 we have been implementing a [climate change programme](#) with ambitious targets for our emissions and energy use in operations and transport. We are aiming for a 20 per cent reduction per unit of sales by 2010 and a cut of 45 per cent by 2015 (from 2006 levels). In 2009 emissions and energy consumption per unit of sales fell by five per cent and six per cent respectively. These reductions follow two years of limited progress, so we need an outstanding performance in 2010 to meet our interim 20 per cent target. It is unlikely we will achieve this target, however we are committed to achieving the 2015 target and are looking for further incentives that will engage and motivate staff and operations to achieve the necessary leap forward.

Increasing the [efficiency with which we use materials](#) is a priority. In 2009 we increased the target of 2.0 per cent (introduced in 2005), to a target of 2.5 per cent efficiency by 2015 for new products moving from R&D to manufacturing after 2010. For the first time, we also set a mass efficiency target for our manufacturing sites to achieve additional improvements raising mass efficiency to three per cent after they take over processes from R&D. Our long-term aspiration is to achieve five per cent efficiency by 2020 – five times the typical level in the pharmaceutical industry which will reduce input materials and waste by 80 per cent. The average mass efficiency since 2005 stands at 2.8 per cent for our late-phase development compounds, compared to our target of 2.0 per cent by the end of 2010.

We understand that sustainability requires a holistic view of everything that we do, especially the optimal use of all resources. Water is a particularly important natural resource, and we recognise that businesses can play a positive role in managing it more sustainably. We endorsed the United Nations CEO Water Mandate in 2009. [Water consumption](#) in 2009 fell by more than five per cent (per unit of sales), which exceeds our target. We now want to go beyond saving water in our operations to engage with a range of water issues that are relevant to a healthcare business such as water borne diseases.

[Transparency](#) is a key element in our sustainability strategy and this report plays an important part in being open about our aims and performance. However, we want to do more to report on the performance of individual operations and we are putting a system in place to do this. Data in this section are assured by SGS United Kingdom, an independent assurance provider. Read their assurance statement [here](#).

[Management of environmental sustainability](#) is driven by plans supporting our three environmental sustainability strategic priorities:

- Embed environment, health and safety fundamentals in the business
- Embrace environmental sustainability
- Maintain open and transparent external relations

In 2010 we will update the environment plan, broadening it into a Plan for Sustainability with new, more challenging targets to 2020. We recognise we need to do a better job of integrating the environmental with the social and economic opportunities in order to create truly sustainable solutions, and will address these concerns in the updated plan.

› [Back to top](#)

Corporate Responsibility Report 2009

Sustainability at GSK

Environmental sustainability is an important component of GSK's activities. We need to use resources more efficiently; this will be good for our business and will contribute to addressing the many challenges facing the world.

The Copenhagen Climate Summit in December 2009 placed [climate change](#) firmly at the top of the sustainability agenda. Water has gained almost equal prominence, and GSK joined the [CEO Water Mandate](#) in 2009, but sustainability means that all resources must be conserved. We need to optimise resource consumption and eliminate waste by finding beneficial uses for all by-products. Social and economic aspects of sustainability are also critical – they are covered in other sections of this report. We need to integrate environmental activity with social and economic aspects to fully develop sustainability in the business.

A vision of transformation

Our vision for sustainability is to transform how we do business to align ourselves with the natural cycle, in which we use renewable resources and convert wastes to by-products that become inputs to other processes. This approach to 'industrial ecology' requires that we optimise the efficiency of our processes, increase our use of renewable materials and energy, and eliminate waste streams, converting them to useful by-products

[Our sustainability strategy developed in 2001](#) is to:

- Embed the environmental fundamentals to eliminate adverse impacts
- Embrace sustainability to use resources responsibly
- Provide transparency to inform stakeholders of our actions

GSK has been on a path to sustainability since the formation of the company in 2000, while the legacy companies were working on these issues before that. In the early years the emphasis was on improving the immediate impacts of our operations – creating a management framework with policies, standards and targets to improve our use of energy and other resources and reduce emissions. Now we are broadening our focus, looking at how to transform the way we operate to become more sustainable.

The operational objective is to become more efficient in all our facilities and processes with the ultimate aim of changing waste into by-products. Process outputs that are currently regarded as waste must become by-products that are reused either by GSK or other businesses.

This may mean a fundamental reappraisal of our sourcing and manufacturing processes. It is possible that adopting a different approach to sourcing renewable raw materials and manufacturing pharmaceuticals more efficiently could significantly reduce the energy, water and materials required, at the same time as improving quality and safety and saving money. Ultimately it may mean using renewable material as well as renewable energy – material derived from organic matter rather than petroleum. We also need to work towards 'closed loop' systems, as we are beginning to do in our Consumer Healthcare business with 100 per cent recycled plastic bottles.

Developments in 2009

In 2009 we created a Sustainability Council to direct our efforts in this area. Demonstrating the seriousness with which we are taking this challenge, the Council consists of senior managers from across the business. Individual businesses are also developing or already pursuing their own specific sustainability strategies.

This year we also introduced the [CEO's Sustainability Award](#) to recognise innovations by GSK teams that

have created real benefits for society, the environment and our business. The award replaces the Environment Health and Safety Excellence Award, reflecting the greater focus on sustainability rather than the narrower EHS agenda.

Feedback

We engage formally with stakeholders through the External [Stakeholder Panel](#) but we are always eager to hear views on our plans and progress. You can contact us about all corporate responsibility matters through csr.contact@gsk.com.

› [Back to top](#)

Corporate Responsibility Report 2009

Managing environmental sustainability

We revised our approach to managing sustainability and environmental issues in 2009 as part of our drive to widen the focus of GSK's efforts to address environmental sustainability more broadly.

Having focused on improving our immediate impacts such as energy and waste, we are now aiming to transform the way we operate in a more holistic way to become more sustainable.

Management of health and safety has been transferred to the Human Resources function and GSK now has two Centres of Excellence – covering [health, safety and performance](#); and sustainability and environment. Environment, Health and Safety directors moved from the central organisation to become embedded in the businesses, supporting the integration of sustainability in our operations. Further developing the business focus, business units are developing [sustainability strategies](#) specific to their businesses that we need to coordinate to ensure we pursue an integrated approach.

Governance

The focus on sustainability is supported by a new Sustainability Council of senior executives from across the business. The council oversees GSK's sustainability plans and progress and meets via teleconference four times a year. It has reviewed plans for several key aspects of sustainability at GSK and submitted them for endorsement by the Corporate Executive Team (CET).

Overall responsibility for sustainability and environment rests with the CET. The Chief of Staff has management responsibility while operational responsibility lies with the business heads and the Vice President, Sustainability and Environment.

Board subcommittees have oversight respectively of risk and compliance, audit, and corporate responsibility. These committees regularly review performance and progress.

Vision and strategy

GSK's [environment, health, safety and sustainability \(EHSS\) vision](#) is to achieve sustainable competitive business advantage and environmental sustainability through leadership and excellence.

[Our strategy](#) is to begin by embedding the environmental fundamentals such as energy management and waste reduction to eliminate adverse impacts from our operations. The second stage is to embrace sustainability in all of our businesses, developing a culture of product stewardship and sustainable resource use. The strategy also requires transparency, making sure we inform stakeholders of our actions and our results.

The GSK EHSS Policy

Our EHSS policy defines our aspiration to global leadership and excellence. It outlines the broad scope of our plans and how they will be achieved. This revised policy was approved by the CET in 2008:

We will be leaders in EHSS performance, protecting the environment and the communities in which we work and enabling healthy motivated employees to be fully engaged with our success. We will maintain a culture of continuous improvement.

EHS fundamentals, risk and impacts

We will embed EHS fundamentals into the fabric of the business by implementing management systems,

EHS governance and risk management practices to address risks and impacts from our facilities, processes, contract research and manufacturing organisations, and suppliers.

Sustainability

We will integrate sustainability principles into all aspects of our healthcare business by working with our stakeholders, operating within environmentally sustainable limits, lowering our ecological footprint, enhancing social equity and addressing future issues.

Open EHSS communication

We will be open and transparent with all stakeholders about our efforts to address our EHSS responsibilities and our EHSS performance.

The Corporate Executive Team (CET) will ensure risks are tracked until mitigated and that communication of the more significant risks is escalated within the business management structure, as commensurate with the risks and impacts involved. The CET will ensure effective management and involvement of staff with clearly assigned accountability and responsibility.

Management systems

We manage sustainability, environment and occupational health and safety issues using a management system aligned with recognised international standards such as ISO 14001 and OHSAS 18001.

Our management system is based on a structured framework building on the vision and policies and supported by standards, guidance materials, tools, training, recognition and audits that help the businesses to manage these issues.

[Targets](#) have been set for five-year periods, originally to 2005 and then 2010. We are currently developing targets to 2015 and new metrics to reflect the revised focus on environmental sustainability rather than narrower environment impacts.

› [Back to top](#)

Corporate Responsibility Report 2009

Plans and targets

Approach

Performance & plans

The GSK sustainability and environment strategy is implemented through a Plan for Excellence with Group-wide goals to improve our performance. We work with the [External Stakeholder Panel](#) to define the plan and to review our performance.

The plan supports the three strategic priorities:

- Embed environment, health and safety fundamentals in the business
- Embrace environmental sustainability
- Maintain open and transparent external relations

Individual plans are in place for the key elements of each strategic priority, as shown in the chart.

Sustainability and environment, health safety and performance strategic framework 2006-15

Strategic priorities	Plans
Embed EHS fundamentals in the business	Provide governance Use management systems Include EHS in business processes Engage internal stakeholders Support EHS
Embrace sustainability	Develop a sustainability culture Adopt a product stewardship approach Promote resource efficiency Utilise sustainable operations Develop health and performance sustainability
Maintain transparent external relations	Provide transparent reporting Engage external stakeholders Work through partnerships

Initially the plan covered the period 2000–2010. A mid-term review extended the period to 2015 and we are currently preparing to extend the plan for the period 2010 to 2020.

The revision will be named Plan for Sustainability, reflecting an increased focus on sustainability. We plan to introduce new kinds of metrics related to sustainability impacts as well as direct environmental performance. These will include measures of the extent to which we are building sustainability into our decision-making and day-to-day operations, as well as operational measures such as carbon reduction and resource efficiency. Identification of appropriate metrics will be informed by stakeholders' views on the environmental sustainability priorities for GSK.

GSK's businesses are developing sustainability strategies relevant to their business strategies and operations.

Consumer Healthcare has adopted a strategy to embed sustainability in business plans and brands, including making it part of the new product development process. Packaging is a key issue for Consumer Healthcare, but the sustainability strategy goes beyond packaging to address the whole supply chain. It also addresses water and energy consumption and developing formulations that minimise all environmental impacts. Targets align with Group targets.

Targets

We believe it is important to set and achieve targets because lower resource consumption and less emissions and waste benefit the environment and GSK. The Plan for Excellence includes Group-wide targets to improve environmental (and health and safety) performance. The targets are based on site-specific, practical improvement plans and forecasts from all manufacturing operations.

We compare proposals for company targets put forward by operations with benchmarking information. Environment, health and safety professionals and management teams throughout the business closely review them and agree the final target numbers.

We are [on track to meet seven of our nine targets](#) but recognise that some will be difficult to meet within the time we have set ourselves. We explain progress to the targets in the discussions on the individual performance sections.

› [Back to top](#)

Corporate Responsibility Report 2009

Plans and targets

Approach	Performance & plans	
Targets and progress 2009		
	Group Target	Progress in 2009
Energy for operations and transport	20% reduction per unit of sales from 2006 baseline by 2010	Reduced 6% per £ sales. Cumulative 6% since 2006 ¹
Climate change impact from energy for operations and transport ¹	20% reduction per unit of sales from 2006 baseline by 2010	Reduced 5% per £ sales. ¹ Cumulative 5% since 2006
Mass efficiency of new processes	2% average for transferred products for the period 2005-2010	Average mass efficiency of 2.8% achieved by 2009
Water	2% annual reduction from 2006 baseline per unit of sales	Reduced 5% per £ sales. Cumulative 15% since 2006
Wastewater (chemical oxygen demand)	3% annual reduction from 2006 baseline per unit of sales	Reduced 15% per £ sales. Cumulative 20% since 2006
Solid waste disposed	1% annual reduction from 2006 baseline per unit of sales	Reduced 9% per £ sales. Cumulative 19% since 2006
Ozone depletion ²	100% elimination of CFCs from processes and equipment by 2010	Eliminated 97%
Air emissions (volatile organic emissions)	2% annual reduction from 2006 baseline per unit of sales	Reduced 19% per £ sales. Cumulative 27% since 2006
EHS audit scores	Average: 82% by 2010 Minimum: 70% by 2010	Average 81% Minimum 67% ²

Note: figures per unit sales are calculated at constant exchange rates (CER)

1. Figures for energy and climate change were relatively unchanged between 2006 and 2008, so the progress achieved was in 2009

2. The numbers reflect 19 sites with scored Corporate audits in 2009

We made progress against all targets in 2009. In some cases we have already exceeded our target for the end of 2010. In others, especially energy, we are not on track to meet the 2010 target. Energy consumption per £ sales fell by six per cent and greenhouse gas emissions fell by five per cent as earlier investments started to pay off. However, the cumulative reductions are only six per cent for energy and five per cent for greenhouse gas emissions, compared to the target of 20 per cent to the end of 2010. We clearly need to step up our performance.

Average mass efficiency of transferred products increased once again and we have exceeded the average two per cent target to 2010.

We exceeded other targets, especially for wastewater and emissions to air but these measures can be sensitive to changes in the business, especially in manufacturing, so future progress will not necessarily follow the same trend. Our environmental audit scores are moving in the right direction against our 2010 targets.



› [Back to top](#)

› Home › Responsibility › Environmental sustainability › Managing environmental sustainability
› **Integration with business principles**

Corporate Responsibility Report 2009

Integration with business principles

To achieve improved performance, sustainability and environmental management should be integrated in the businesses rather than being an add-on. We have developed processes and programmes to help scientists, engineers and managers to support our sustainability and environment goals as part of their everyday activity.

The Milestone Aligned Process helps scientists identify and address sustainability and environmental issues during new product development and supply activities. It ensures that:

- Scientists understand environment, health, safety and sustainability principles and impacts and how to manage them through a product's life cycle
- New products and processes are developed that do not harm people, property or the environment
- Opportunities are identified, such as process efficiencies and elimination of waste that reduce EHSS impacts and improve product development and supply

Procurement and acquisitions

GSK procurement activities support our sustainability and environmental goals in these areas:

- Sourcing renewable and recycled materials where appropriate
- Choosing safe and energy-efficient equipment
- Managing sustainability and environmental risks in our supply chain

Our capital project technical review process is designed to ensure that we consider sustainability, environment and loss prevention in the design of new facilities and processes. By identifying sustainability and environmental issues early in a project, we can engineer facilities and processes that are efficient and safe for the environment while still being cost effective.

Our due diligence process for acquiring and divesting businesses ensures that sustainability and environmental issues are considered in contract negotiations and that adequate management systems are in place. We work with acquired companies to develop action plans to align their sustainability and environmental practices with GSK's.

Emergency response and crisis management

The discovery, development and manufacture of pharmaceutical and consumer products involve the use of hazardous materials and processes. All sites incorporate emergency response and crisis management programmes in their management plans. These programmes ensure that accidents are effectively managed when they occur and that any impact on our business, the local community and the environment is minimised. Each site conducts an annual review of its internal emergency response programmes and technical capabilities and develops plans to address any areas needing improvement.

› [Back to top](#)

› Home › Responsibility › Environmental sustainability › Managing environmental sustainability
› **Awareness and recognition**

Corporate Responsibility Report 2009

Awareness and recognition

We recognise a responsibility to make the GSK community aware of environmental sustainability issues and to engage people at all levels of the organisation so they take sustainability into account in their work and decision-making.

We offer training and orientation to the business leaders so they understand the issues and how best to respond. In 2009 we launched new training packages and an EHS Training Connect intranet site. Specific sustainability and environmental training is managed by individual sites and is relevant to job roles. Sustainability and environment professionals receive induction training and undertake regular updates to ensure they are aware of the latest technical information in their fields, but we still need to continue to upgrade the level of competence in our site environmental staff.

The company's global internal communications include regular messages about environmental sustainability issues. In 2009 this included features in global employee publications, a regular calendar of internal news releases about environment sustainability issues, and an intranet site containing regularly updated material on GSK's climate change and energy reduction initiatives.

The CEO's Sustainability Award programme (see below), launched in 2009, gives the highest level of recognition to employees who have furthered GSK's environmental sustainability agenda.

Awareness

We raise employee awareness of sustainability and environment through the intranet, regular internal publications and events. However, this has been passive communication and we need to develop more interactive communications to engage employees.

Several areas of the GSK intranet support sustainability and environment, including the main site known as myEHSS. This is the way news about sustainability and environmental programmes (and health and safety) is shared within the Group. It is the source of supporting materials for the EHSS Framework, such as the policy, standards and guidelines, and for training materials and other documents. We also use it to collect data for measuring performance and reporting results.

In 2009 we launched a climate change microsite called Climate Change, GSK and You. The site explains the importance of climate change, why everyone needs to act, what GSK is doing and what individuals can do. It includes items reporting action to cut carbon dioxide emissions across the business, and celebrates successes. In 2009 this included GSK being named to the Carbon Disclosure Projects' Global 500 Carbon Disclosure Leadership Index, and being awarded certification for the Carbon Trust Standard in the UK.

Publications are available electronically and in print. We publish articles on sustainability and environment in Spirit, our internal magazine, and brief news stories on internal web pages.

Many of our sites celebrate Earthweek to raise awareness of environmental issues and to encourage integrating environmental concerns into the GSK culture. Earthweek encourages employees to think about their impact on the environment.

Sustainability awards

The CEO's Sustainability Award programme recognises GSK teams for innovation that creates benefits for society, the environment and our business – creativity that achieves a genuine step change towards sustainability. We publicise the innovative practices that win awards on a dedicated intranet site.

Any team in GSK may be considered for this award, except from the Sustainability and Environment Centre of Excellence, which administers the scheme. An internal review committee agrees a shortlist and winners are chosen by a panel that includes experts from academia, government and public interest groups. Each winner receives a trophy and selects a charity to receive a donation from GSK.

Awards can be given in three categories:

- Environmental Sustainability – for creative and adventurous thinking that reduces the total impact of our business on the environment and builds trust with the communities where we work
- Health & Safety Sustainability – for innovative ideas that create measurable improvements to employee performance due to health and safety initiatives
- Sustainable Science & Technology – for scientific and engineering breakthroughs of any size or scale that change things for good, leave a lasting legacy and feed and support continued innovation

In 2009 there were 81 entries from 25 countries. Honours went to 11 projects from Belgium, India, the UK and the US. A special honour, the Vanguard award, went to a team from R&D in Stevenage, UK, for their project on continuous manufacturing of active pharmaceutical ingredients. This six-year project overcame significant technical hurdles to develop a more efficient process, with less waste, lower emissions of volatile organic compounds (VOCs) and lower costs.

Read about the winning [sustainability and environment projects](#) here.

› [Back to top](#)

› Home › Responsibility › Environmental sustainability › Managing environmental sustainability
› [Audits and compliance](#)

Corporate Responsibility Report 2009

Audits and compliance

Approach

Performance

In 2009 we regularly audited our operations, contract manufacturers and key suppliers to assess systems to manage risks and impacts, compliance with legislation and performance against our environment, health, safety and sustainability standards. Audits also assess whether appropriate management systems are in place to improve performance and maintain compliance. Our internal auditors are certified as lead auditors against the ISO 14001 and OHSAS 18001 standards.

In 2009 GSK created an Audit and Assurance function and the Environment, Health, Safety and Sustainability (EHSS) audit team was integrated in this new group. This provides an independent audit and assurance function, separate from the EHSS management organisation that will examine areas it considers to be high level risks to the business.

The GSK Audit and Assurance function developed a standardised and simplified audit process for the Group, which will be used to audit management of environmental risk. The new integrated process will be launched in 2010 and will provide a greater focus on thematic risks across the Group. Audit strategies will be further developed in 2010 to achieve greater coverage of sustainability and environmental impacts. This will require operations to develop stronger self audits to address the areas that may no longer be included in the new audit approach.

All GSK manufacturing and R&D sites were audited at least once every four years. The actual frequency was determined by the level of risk and impacts and a site's performance at managing those risks. In 2009 we audited 38 sites, including ten follow-up audits. See [Performance](#) for details.

See the [Supply chain section](#) for more on supplier audits.

Certification

In 2009 we reviewed the programme to certify all manufacturing sites to international standards ISO 14001 and OHSAS 18001. The businesses concluded that certification does not equally benefit all sites and that they should concentrate on those that need to make the most significant improvement. These sites will be identified based on their performance in internal audits and will be required to achieve certification. All sites are required to have robust self audit systems in place and are encouraged to have them certified but this is no longer a formal requirement.

› [Back to top](#)

› Home › Responsibility › Environmental sustainability › Managing environmental sustainability
› Audits & compliance performance

Corporate Responsibility Report 2009

Audits and compliance

Approach

Performance

In 2009 we conducted 28 audits at GSK facilities covering implementation of our EHS standards and conducted audit follow-up reviews at a further ten facilities. Of the 19 scored audits, the average performance score was 81 per cent compared with 78 per cent in 2008, but this improvement may reflect the quality of the sites selected. The lowest score we consider to be acceptable is 50 per cent. No site scored below this level, with the lowest score at 67 per cent in 2009.

Three sites achieved 'leadership' scores above 90 per cent (two in 2008), while a further eight achieved scores of at least 80 per cent (11 in 2008). High audit scores indicate good management systems and control of risks.

There were no critical findings that indicate lack of proper management of risks with potentially serious consequences concerning the environment. The best performance on environmental issues related to waste management systems and sites were generally weakest on environmental risk assessment processes.

The sustained improvement in audit performance reflects the emphasis on ensuring robust and effective management systems are in use across all our operations, regardless of formal certification.

In Pharmaceuticals and Consumer Healthcare, 30 of our 77 manufacturing sites are now certified to both the ISO 14001 and OHSAS 18001 standards (a further three are certified to ISO 14001 only). Three sites were newly certified in 2009. One Consumer Healthcare R&D site is certified to both standards, while one GSK vaccines site and one Pharmaceuticals R&D site are certified to ISO 14001. The certified sites are in Argentina, Australia, Brazil, China, Egypt, France, Germany, India, Italy, Japan, Kenya, Mexico, Panama, Philippines, Poland, Romania, Saudi Arabia, Singapore, Spain, the US and the UK.

Compliance

We remain vigilant to stay in full compliance with all environmental laws and regulations but incurred two environmental fines in 2009:

- \$4,500 from the New Jersey Department of Environmental Protection for failure to clearly mark two containers of hazardous waste and failure to list the date of use on the drums
- €580 in Romania for discharging polluted wastewater above permitted limits

› Back to top

Corporate Responsibility Report 2009

Climate change and energy

It is widely acknowledged that human activity, primarily burning fossil fuels to produce energy, is contributing to climate change.

The Intergovernmental Panel on Climate Change (IPCC), the world’s leading climate authority, has stated that urgent action is needed to mitigate and adapt to the effects of climate change, including rising sea levels and more frequent extreme weather events such as droughts, floods and hurricanes. The world’s governments met under the auspices of the United Nations in Copenhagen in December 2009 to try and agree a new approach to curbing climate change.

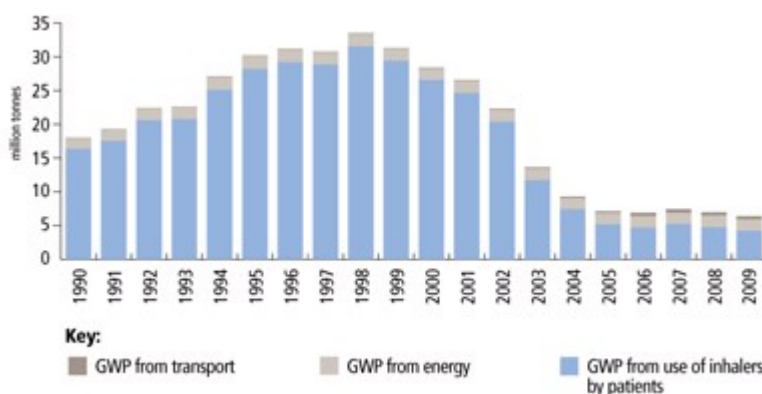
The main output from this meeting was the Copenhagen Accord – an agreement reached between the US, China, India, Brazil and South Africa. No specific targets were agreed, but the accord recognises the goal to limit global greenhouse gas emissions to ensure that the increase in global temperatures is kept below two degrees Celsius. It also includes commitments for developed countries to provide funding for developing countries to help them mitigate the effects of climate change and establishes some principles of international governance. The accord is intended to form the basis of a new agreement to replace Kyoto and the UN is anxious for a new legally binding treaty as soon as possible. GSK supports the need for an international treaty with legally binding targets because this will help us to plan for the future.

We want to be part of the solution and are committed to reducing our impact. However, finding the best approach is challenging. As well as benefiting the environment, taking action on climate change helps us cut costs, improves our reputation with stakeholders and helps us prepare for future legislation on emissions.

Our climate change programme

Our biggest direct climate impact comes from propellants used in inhalers for diseases such as asthma. We have [reduced this impact](#) by replacing CFC gases and continue to research ways to minimise greenhouse gases released by these products. Our emissions began to fall in 1998 as a result of the phase-out, having increased since 1990.

Global warming potential from energy, transport and inhaler use



We launched a new climate change programme for our own operations in 2007. This includes a commitment to reduce our climate change impact (CO2 equivalent emissions) and energy use in operations and transport by 20 per cent per unit of sales by 2010 and by 45 per cent by 2015 (from 2006 levels).

These challenging targets represent a step-change in our ambitions, replacing our previous improvement target for energy of one per cent per year and reflecting the increasing recognition of our responsibility to

address our climate change emissions.

We plan to achieve our new targets by:

- Making our buildings and equipment more energy efficient
- Installing onsite renewable technologies such as wind turbines and photovoltaic panels
- Buying electricity produced from renewable sources
- Reducing the climate impact of travel and transport by switching from air to sea freight and by transporting more per load to reduce the number of journeys needed

Energy reduction has been identified as a key objective for the business. As a result, energy consumption is now included in the key business metrics, and in 2009 the remuneration of senior managers in manufacturing was linked to the achievement of energy-reduction targets. This resulted in an eight per cent absolute reduction in energy usage in 2009, demonstrating the effectiveness of appropriate incentives. We have also created a central fund to help finance energy-saving projects, which has so far helped to avoid 96,000 tonnes of greenhouse gas emissions. We estimate that we have saved over £18 million since 2006 through energy reduction projects.

[Raising awareness](#) among staff is important for achieving our targets and in 2009 we launched a climate change intranet microsite. It publicises activity and progress, making people more aware of the issues and what they can do. This general awareness-raising supports site-specific activity.

Recognition

In 2009 GSK was commended for its approach to climate change disclosure by the Carbon Disclosure Project, an independent not-for-profit organisation which represents 475 institutional investors. In the UK we were awarded The Carbon Trust Standard, recognising that our UK operations have effective climate change and energy reduction systems in place, and we hope to be able to achieve global certification to the Carbon Trust Standard in 2010.

¹ Based on a constant exchange rate to avoid distortions caused by currency swings

> [Back to top](#)

Corporate Responsibility Report 2009

Propellants

The majority of our climate impact comes from propellants used in inhalers for asthma and chronic obstructive pulmonary disease. These products contain either hydrofluoroalkanes (HFAs) or chlorofluorocarbons (CFCs) which are potent greenhouse gases. CFCs also deplete the ozone layer.

We are committed to phasing out CFCs by the end of 2010 and are researching ways to minimise HFAs released by the remaining products. We have introduced dry powder inhalers, which do not use a propellant, but they are unsuitable for some patients and some treatments. In 2009, 54 per cent of inhalers sold included propellants. We continue to seek ways of minimising release of propellants which contribute to climate change.

› [Back to top](#)

› Home › Responsibility › Environmental sustainability › Climate change and energy

› **Facilities and processes**

Corporate Responsibility Report 2009

Facilities and processes

Our climate change programme commits GSK to reduce the climate change impact and energy use of our operations and transport by 20 per cent by 2010 and 45 per cent by 2015, compared with 2006 levels. This target is expressed as emissions (CO₂ equivalent) and energy per unit of sales based on a constant exchange rate so that comparisons are not distorted by exchange rate fluctuations. We plan to develop absolute energy and greenhouse gas emissions targets for 2020.

We aim to achieve these targets in our facilities and processes by becoming more energy-efficient and using more renewable energy. (See [here](#) for transport).

We created a central fund in 2007 to help finance energy-saving investments and more than 800 potential projects were identified. In 2009, we completed nearly 300 projects with potential savings of more than 165,000 MWh and nearly 56,000 tonnes of emissions. This follows 171 projects completed in 2008, with expected annual savings of more than 153,000 MWh (550,800 GJ) of energy and more than 40,000 tonnes of greenhouse gas emissions.

We have two main priorities for reducing emissions and energy use:

Combined heat and power (CHP)

CHP simultaneously generates usable heat and power, usually as electricity, in a single process. The heat produced is recovered to provide steam, hot water or even cooling, achieving overall efficiencies in excess of 70 per cent at the point of use compared to less than 50 per cent from conventional power plants

Heating ventilation and cooling (HVAC)

HVAC is responsible for more than 50 per cent of the operational energy that we consume. This equipment is essential to maintain the correct environmental conditions within our production areas but we aim to identify opportunities to reduce the energy required

Renewable energy will also help us reduce emissions. During 2009 solar photovoltaic panels have been installed at two sites in Belgium and the US. These systems are expected to generate around 350 MWh of electricity and are estimated to save around 106 tonnes of CO₂ equivalent emissions during 2010. Solar water heating systems have also been installed in Belgium, Mexico and Australia.

Emissions trading

In 2009, 13 GSK sites participated in the European Union Emissions Trading Scheme. Collectively these sites emitted below their specified CO₂ allowances, generating a surplus of carbon credits. Proceeds from the sale of carbon credits are invested in energy-saving projects.

Several of our UK sites participate in the UK government's voluntary Climate Change Agreement programme which provides companies with energy tax rebates if they meet agreed energy-efficiency targets. In 2009 GSK reported its compliance with these agreements and all participating GSK sites were found to comply with their Climate Change Agreements.

› [Back to top](#)

Corporate Responsibility Report 2009

Transport and travel

We estimate that transport of our products, the sales fleet and employees' business air travel accounted for 488,000 tonnes of CO₂ in 2009, compared with 490,000 tonnes in 2008. This was 22 per cent of our total climate change impact excluding propellants.

Our CO₂ emissions from transport and travel arise in roughly equal proportions from business air travel, our sales fleet and transport of products from manufacturing plants to distributors.

Our plans for reducing the impact of product transport include:

- Consolidating freight shipments
- Reducing the number of shipping points
- Making more use of round tripping (managing inbound freight trucks so they do not return empty)
- Switching from air to sea transport where possible

Travel

We have 'green travel plans' at a number of sites to encourage employees to reduce the environmental impact of their travel to work. For example, at GSK House in Brentford, UK, reserved parking spaces are given to car-sharers and drivers of fuel-efficient cars. We provide changing rooms and showers for cyclists, as well as discounts for bicycle equipment and repairs. See [case study](#). At our Philadelphia office the cost of public transport is subsidised.

Global Travel Services in the UK reports quarterly airline mileage and is encouraging the use of rail over air within Europe. The use of rail increased by 33 per cent in 2009 and we are amending the self-booking tool to encourage further progress. Travellers can request to have their CO₂ calculated and noted on the itinerary.

In 2009 the GSK Leadership Forum, which brings together approximately 1,000 senior executives, was a virtual event. Instead of travelling to a single location the participants met through video conferencing, which also enabled six times as many people to join in. We estimate this avoided 10,000 long-haul flights, saving 7,600 tonnes of emissions.

Transport

Measured by weight, more than three-quarters of shipments are by sea, with only 23 per cent by air. But approximately 80 per cent of all shipments are currently sent by air and we are aiming to reduce the use of air freight.

Global Manufacturing & Supply distributes more than four billion packs to over 160 markets around the world and has developed an Air to Ocean programme. Transport modelling identifies preferable routes, based on a trade-off between freight cost, distribution time and inventory investment. Switching to sea freight can make a big difference to emissions and costs – transporting one metric tonne from London to São Paulo by air freight generates 5,400 kilograms of CO₂, but by sea it is only 95 kilograms.

Since the programme was introduced, over 130 GSK transport routes have been switched to ocean freight, saving more than 28,000 tonnes of emissions. In 2009 alone over 12,000 tonnes of savings were achieved through changes in transport. However, while ocean freight increased slightly, air freight also increased due to an increased volume of business. This came from a number of new business arrangements that required movement of large volumes of product and increased sales of some existing products in developing countries, including shipments of pandemic flu vaccine.

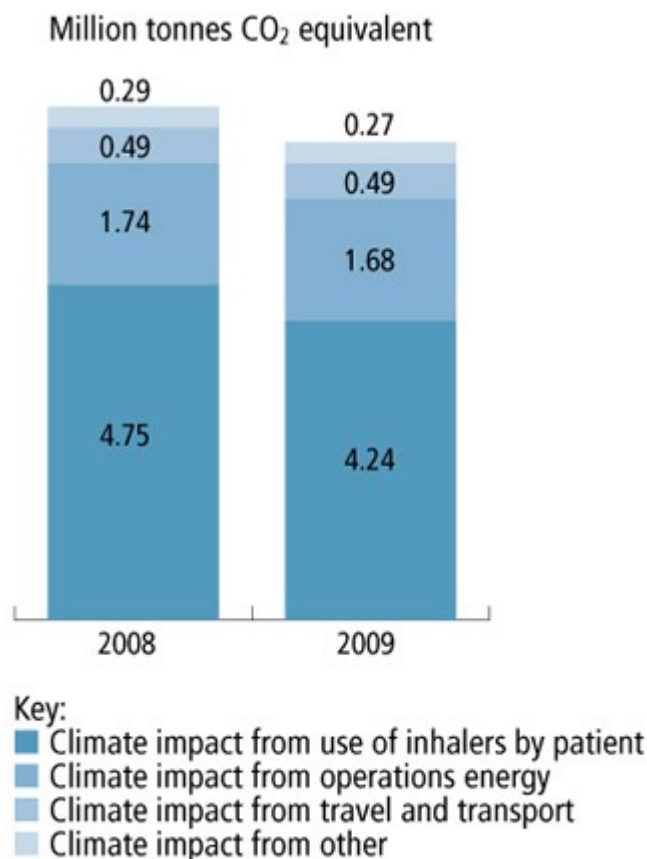
In 2010 we will focus on partnering between Global Distribution and GSK's strategic logistics service providers as a way of developing a longer-term strategy to reduce our carbon footprint further. Freight management initiatives have been identified that will drive network efficiencies through consolidation of supplies.

> [Back to top](#)

Corporate Responsibility Report 2009

Performance and plans

GSK's carbon footprint



'Other' includes greenhouse gases released from cooling systems, during the production of inhaler products, from wastewater treatment and other processes

Total energy and emissions

In 2009 our carbon footprint was equivalent to 6.7 million tonnes of CO₂ compared to 7.3 million tonnes in 2008. The majority of our emissions come from the use of inhalers by patients with respiratory disease. Eliminating production of CFC inhalers, partly offset by a simultaneous increase in the use of HFA, meant that our climate change emissions from patient use of inhalers fell by 11 per cent to 4.2 million metric tonnes of CO₂.

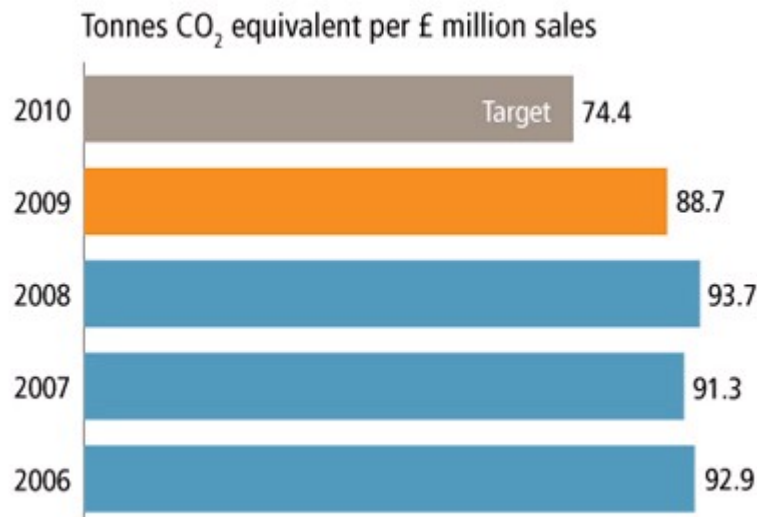
Excluding the manufacture and use of inhalers, our carbon footprint from operations energy and transport reduced slightly from 2.23 million tonnes of CO₂ in 2008 to 2.17 million tonnes in 2009. This mainly reflects lower emissions of greenhouse gases from pharmaceutical manufacturing – down from 0.97 million tonnes in 2008 to 0.91 million tonnes in 2009.

Energy use from operations and transport, which caused these CO₂ emissions, decreased 3.4 per cent in 2009 to 25.3 million gigajoules (26.2 million gigajoules in 2008).

Sales-related data

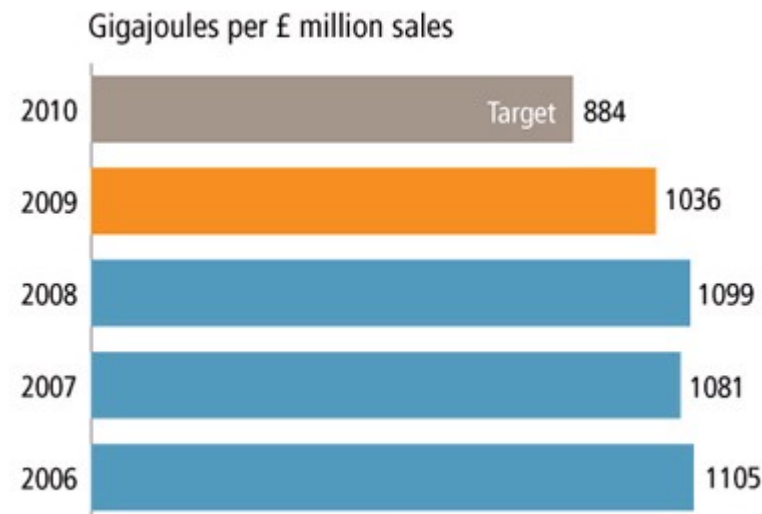
Our targets are based on emissions and energy consumption in operations and transport per million £ sales. In 2009, these normalised emissions decreased by 5.4 per cent from the previous year. Energy use per million £ sales fell by 5.8 per cent to 1036 gigajoules per million £ sales. Cumulatively we have cut normalised emissions by 4.6 per cent and energy use by 6.3 per cent since 2006,

Climate change impact from operations energy and transport



Sales adjusted at constant exchange rates

Energy use for operations and transport



Sales adjusted at constant exchange rates

Explanation for trends

Since peaking in 1998, total emissions fell as we removed CFCs from inhalers, but levelled out from 2005 when climate change targets were under discussion. We then set aggressive targets in 2007 to reduce energy use and related climate change emissions by 20 per cent per unit of sales by the end of 2010. Progress towards targets for the first two years was limited, but it accelerated in 2009 due to the implementation of energy reduction programmes in manufacturing and R&D. While we may not achieve the 2010 target, we remain committed to the 2015 target of a 45 per cent improvement.

Progress in 2009 is due to incentives in manufacturing and R&D for reductions that rewarded performance and encouraged everyone to participate. This resulted in investment in many small projects to improve heating, ventilation and air conditioning (HVAC), steam generation and other energy uses. We have achieved significant efficiency improvements at several facilities which are high energy users.

Total energy consumption in R&D and pharmaceutical manufacturing fell by about eight per cent due to incentives, offsetting an increase in Biologicals due to higher vaccine production. But while total energy use in Biologicals was 11 per cent higher than in 2008, this must be set against a 30 per cent increase in sales, representing an improvement in energy intensity.

Elsewhere, some sites managed to reduce energy use despite production increases. A manufacturing site in Scotland won the Global Manufacturing Energy Reduction Challenge for reducing energy use by over ten per cent while production volume increased. This was achieved through energy efficiency projects such as optimising solvent recovery and by raising employees' awareness of energy wastage. The result was a saving of over 12,000 tonnes CO₂ and estimated savings of £2 million per year.

Plans

In 2010 we will develop a new plan that will identify further mitigation and strategies to reduce our climate change impact, aligning with global efforts to curb climate change. We will also undertake work to identify ways that we can respond to changing disease patterns due to climate change.

As inhalers represent roughly two-thirds of our climate impact, this will be a major focus. We want to minimise use of HFA propellants and aspire ultimately to phase them out.

In our own operations we will plan to optimise the number of facilities and make the remaining facilities more energy efficient, further reducing the climate impact by using more efficient processes, more renewable materials and renewable energy to power our operations. We will reinforce our efforts by engaging with employees, encouraging them to adopt energy-saving practices including alternative commuting, virtual conferences and phone meetings.

Switching to combined heat and power (CHP), which we are just beginning to do, will reduce the overall climate change impact. CHP is more efficient, resulting in lower emissions than the equivalent electricity imported from power stations. However, consumption of electricity generated at our facilities rather than imported from a power station means losses in generation and transmission will be eliminated. Our large vaccines manufacturing sites in Belgium are among the first to install CHP equipment. See [case study](#)

We will also work with suppliers to understand the embedded carbon in our supply chain and to encourage suppliers to improve energy efficiency and their use of renewable energy.



> [Back to top](#)

Corporate Responsibility Report 2009

Materials

We aim to use materials efficiently and safely, minimising waste and avoiding harm to humans or the environment.

We need to take the environment into account across the entire life cycle of our products, beginning with process design, continuing through manufacturing to use by patients and eventual disposal. We also need to routinely evaluate the environmental footprint of our processes to explore ways to minimise their impacts. For instance, our R&D and manufacturing operations regularly assess the environmental footprint of different chemical processes using a web-based tool known as Fast Life cycle Assessment for Synthetic Chemistry (FLASC). This enables us to identify the most sustainable processes and the materials with smaller environmental footprint.

Using materials more sustainably requires changing business processes to consume fewer resources and generate less waste, removing hazardous substances where possible and eliminating waste that is persistent, toxic or bioaccumulative.

Some of our wastes such as used solvents can be reused in our processes or as a raw material for another industry, achieving what is known as a 'cradle to cradle' approach. For instance, our sites that manufacture active pharmaceutical ingredients recover some solvents for reuse. Our pilot plants also send solvents such as ethyl acetate and ethanol for external recovery and reuse. We are evaluating the feasibility of using methanol after it is used for cleaning in windshield wiper solutions.

We aim to increase the efficiency with which we convert raw materials to finished products, aspiring to achieve a level five times our performance in 2005 by 2020. In 2009 we introduced new targets for research and development and introduced a [mass efficiency target](#) for manufacturing for the first time.

Water is a valuable natural resource, and we recognise that businesses can play a positive role in managing it more sustainably. GSK endorsed the [United Nations CEO Water Mandate in 2009](#).

Potential hazards

Pharmaceutical processes use potentially hazardous [input materials](#). We eliminate substances of concern (persistent, bioaccumulative and toxic) where possible.

We use genetically modified micro-organisms in research and development of new medicines but do not produce products that contain viable organisms. We are actively investigating opportunities to use nanomaterials but we currently have no nanomaterial products on the market

The EU's [Registration, Evaluation, Authorisation and Restriction of Chemicals \(REACH\)](#) legislation requires registration of certain materials. We have engaged with suppliers and adapted procurement programmes to ensure compliance and will ensure that we meet the November 2010 registration deadline.

Some active pharmaceutical ingredients may enter the environment when excreted by patients. Current evidence suggests that this does not pose a risk to people or the environment, but we continue to conduct tests and risk assessments to evaluate the potential effects. Read more [here](#).

Packaging

We work to reduce the environmental impact of [packaging](#) as well as products and materials. In 2009 we developed an integrated company-wide strategy to drive towards more sustainable packaging covering the Consumer Healthcare, Pharmaceuticals and Biologicals businesses. This is particularly important in the Consumer Healthcare business, which already uses recycled plastic for *Ribena* bottles. The consumer

business in India reduced the amount of packaging which also reduced waste. See [case study](#). Consumer Healthcare adopted a sustainability strategy in 2009 which includes plans to significantly reduce packaging impacts. However, we recognise that we have many more opportunities both in the Consumer Healthcare business and in the Pharmaceuticals business to reduce the amount of packaging that we currently use.

› [Back to top](#)

Corporate Responsibility Report 2009

Mass efficiency

Approach

Performance

We encourage innovation in the manufacturing process to increase the efficiency with which we convert raw materials to finished products – known as mass efficiency. This helps to reduce the resources we use, the waste we generate and the cost of production. It requires innovation in the way we discover and manufacture products.

Historically, the industry has used more than 100 tonnes of material for every tonne of active pharmaceutical ingredient (API) produced. Pharmaceutical processes are often complex, usually requiring large amounts of solvents and other raw materials. It can take several processes to obtain the right purity of pharmaceutical, and we want to finalise the processes quickly to avoid delaying drug approval and production.

We originally set a target in 2005 for R&D to double the average mass efficiency of processes for new products. This would achieve two per cent mass efficiency instead of the typical one per cent. In 2009 we increased the target, aiming for an additional 25 per cent increase in efficiency by 2015 for new products launched after 2010, taking the mass efficiency target to 2.5 per cent. One project at a UK site increased output by over ten per cent while saving solvents and water. See [case study](#)

In 2009 we also set a mass efficiency target of three per cent for our manufacturing sites to achieve by 2015 for products launched between 2007 and 2012. Our long-term aspiration is to achieve five per cent efficiency by 2020.

As well as improving individual process efficiency, the targets are designed to improve our overall environmental footprint because they:

- Give more weight to efficiency gains in products with larger production volumes
- Include efficiency rates across the product life cycle, including for final formulations such as tablet production
- Include efficiency rates at contract manufacturers for pre-production ingredients

Process design

Effective process design is essential to minimise environmental impacts. It determines which chemicals and processes are used in manufacturing as well as the impacts from production waste. The Sustainability and Environment Centre of Excellence works with process development teams to incorporate sustainability and EHS considerations into process design and materials sourcing, and to identify potential sustainability and EHS risks in manufacturing.

› [Back to top](#)

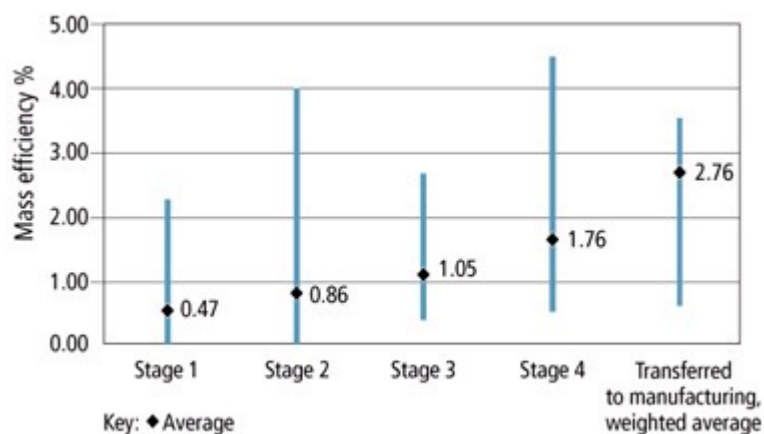
Corporate Responsibility Report 2009

Mass efficiency

Approach

Performance

Mass efficiency (average 2005-9)



The chart shows the range of mass efficiency and the average for each process stage while the manufacturing process is being developed in R&D. It demonstrates that we improve mass efficiency as compounds move through development stages. In the early stages many processes achieve less than one per cent mass efficiency. By the last stage when the process is transferred from R&D to manufacturing they average 2.76 per cent mass efficiency.

Improvements in mass efficiency translate into economic as well as environmental benefits. For instance, as development compounds progress from early stages into the last stage, the estimated cost of raw materials has fallen by 80 per cent, since fewer different materials and less of them are needed to produce the same amount of active pharmaceutical ingredient.

› [Back to top](#)

Corporate Responsibility Report 2009

Input materials

Some materials used in pharmaceutical processes raise concerns because of their potential impact on people or the environment. They include certain chemicals as well as genetically modified micro-organisms (GMMs) and nanomaterials.

Materials of concern

Materials of concern are chemicals where scientific evidence shows probable serious long-term effects to humans or the environment and for which there is existing or potential future legislation that may restrict their use. These compounds include substances that persist in the environment, accumulate in animals and plants or are toxic to life; carcinogens, mutagens, reproductive toxins, substances known to cause asthma, endocrine-disrupting chemicals and ozone-depleting substances.

Our operational sustainability team works with our process development teams to develop strategies to eliminate or substitute the use of these materials. We continuously examine the use of materials of concern across all phases of development to determine which substances are being used and identify how they can be replaced during development. For instance, as a result of this process, aluminium trichloride and chloroform were eliminated from the process to manufacture a novel antibiotic. In addition, dichloromethane, lithium and dioxane were eliminated in the process of a key intermediate. These projects received CEO's Sustainability Awards in 2009.

In 2009 we used 26 metric tonnes of materials of concern (down from 56 tonnes in 2008). Five solvents accounted for about 90 per cent of this volume. Most of the solvent waste from this production was destroyed by incineration, although some was recycled. For instance, during development campaigns in 2009 our pilot plants have recovered and reused in the same processes acetonitrile, toluene and isopropyl acetate. There are plans to do the same in 2010 for other development processes with a goal to eliminate these compounds from use.

Genetically modified micro-organisms

We use GMM in the research and development of new therapeutic agents and in the manufacture of certain medical products such as vaccines. They help us to identify the genetic targets and causes of disease and to develop new antibiotics and drugs for conditions such as heart disease, diabetes and depression. We use a number of different GMM, predominantly harmless organisms such as disabled strains of the bacterium *E.coli* and eukaryotic cells in culture. We also manufacture a number of products that are derived from GMM, such as hepatitis B vaccine.

We do not produce or plan to produce any products that are, or contain, viable genetically modified micro-organisms.

GSK is committed to ensuring that we control the risks to our employees and the environment when we use GMM technology to develop and manufacture products. All our work with GMM is assessed and controlled applying best practices across all our facilities. It follows our Environment, Health, Safety and Sustainability standards to ensure any risks of handling GMM are minimised. Our standards meet or exceed the requirements of local, national and international regulations.

Any work with GMM is subject to a risk assessment to identify appropriate controls, including safe conditions of use, storage, disposal and emergency management procedures to minimise contact between GMM, humans and the environment.

We manage the use of GMM through bodies such as site Institutional Biosafety Committees or Genetic

Modification Safety Committees in line with national and local regulations.

We require that GMM are inactive in waste streams to ensure safety to human health and the environment. We evaluate the risks associated with the GMM that we use and employ processes that are effective in inactivating waste streams.

We do not routinely undertake research and development involving the cultivation of genetically modified plant species.

Nanomaterials

Nanotechnology uses materials that are on an atomic or molecular scale. It may in future offer many benefits to patients and could be used to develop new medicines and oral healthcare products.

GSK is actively investigating a number of opportunities that use nanomaterials in our Research & Development programmes. However, we currently have no products on the market that contain deliberately engineered nanomaterials.

In 2009 we developed a [public position paper on the use of nanomaterials](#).

› [Back to top](#)

› Home › Responsibility › Environmental sustainability › Materials › **REACH**

Corporate Responsibility Report 2009

REACH

In 2009 we started in earnest to implement the requirements of the EU's Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) legislation. This involved:

- Incorporating REACH compliance activities into our procurement programmes and training staff involved in purchasing chemicals
- Identifying GSK's use of chemicals and ensuring that our suppliers include this in their REACH registrations
- Adopting 'lead registrant' status and developing data necessary to prepare registration dossiers for two high-volume substances requiring registration by November 2010
- Registering new substances we manufacture or import in volumes greater than one tonne per year

Read about our position on [REACH](#).

REACH plans

From 2010 REACH will be fully embedded in R&D and procurement operations. This approach will help us ensure that we meet our November 2010 registration deadline for substances that we import or manufacture in volumes more than 1,000 tonnes a year and will continue to register any new substances originating from our R&D pipeline. We will continue to engage with suppliers to ensure that they meet their 2010 registration obligations.

We will begin working to ensure that we meet the new EU requirements to notify classification and labelling information for any hazardous substances we place on the market or import to a central inventory maintained by the European Chemicals Agency.

Global harmonisation

- Updated our GSK Safety Data Sheet (SDS) format to allow production of GHS-compliant SDSs in 2010
- Reclassified over 1,000 substances to meet the EU GHS implementation deadline of November 2010
- Developed e-learning and posters to facilitate employee training on new hazard warning symbols and labels introduced as part of GHS
- Identified new software to allow printing of GHS labels at GSK manufacturing sites

During 2010 we will continue with staff awareness training on the new GHS label elements and will submit our EU GHS classification and labelling information to the EU Chemicals Agency inventory. By the end of 2010 we plan to have all GSK substance safety data sheets available from our intranet site in the new GHS format.

› [Back to top](#)

› Home › Responsibility › Environmental sustainability › Materials

› **Pharmaceuticals in the environment**

Corporate Responsibility Report 2009

Pharmaceuticals in the environment

A portion of active pharmaceutical ingredients (APIs), the substances that make medicines work, are eventually excreted by humans and enter the environment. Wastewater treatment removes most pharmaceutical residues but small concentrations do end up in rivers or in the sea, and very low concentrations of some pharmaceuticals are occasionally found in drinking water. In countries where wastewater is not treated, higher concentrations may enter the environment.

We continue to conduct tests and risk assessments to evaluate the potential effects of our pharmaceutical products on the environment. As in previous years, these results indicate that our products do not appear to pose a risk for humans or the environment based on current risk assessment methodologies and information, but it is important to continue monitoring the issue.

We conduct retrospective analysis of environmental data to refine our testing methodology and assessment models. We recently revised our material testing strategies to include chronic testing (to determine the impact of our products on the environment over the long term) and mode of action analysis (to identify the most sensitive species), to meet new regulatory guidelines and to improve our understanding of possible environmental effects.

We are committed to transparency about the data we collect and make environmental data publicly available. Assessments and environmental data for individual APIs are provided in online Safety Data Sheets. Data are also available on the Swedish Doctors Prescribing Guide (see below). We publish the results of our risk assessments in scientific journals.

We continue to monitor the latest scientific studies and findings to improve our risk assessment methodology. In addition, we conduct and contribute to environmental research in this area. We published a scientific paper assessing the potential impacts on human health from environmental exposures for 44 APIs included in GSK's pharmaceutical products portfolio. This was published in February in the Journal of Regulatory Toxicology and Pharmacology (see box). We also continue to identify and study emerging issues related to the presence of extremely low levels of pharmaceuticals and other household products in the environment.

Although the main source of pharmaceuticals in the environment is patients excreting medicines, GSK has established limits for active pharmaceutical ingredients in wastewater from our manufacturing sites. Based on our studies, we have established maximum levels at which APIs are not expected to adversely impact the environment. We assess process waste concentrations against these levels and treat the wastewater if required to ensure that the safe levels are achieved.

Read our public position statement about [pharmaceuticals in the environment](#)

Industry collaboration

We work with other pharmaceutical companies, universities and research groups on pharmaceuticals in the environment. We also collaborate on joint projects with industry groups and sponsor academic studies to advance scientific understanding of risks.

For example, we submit environmental data on our products as part of the Swedish classification system for pharmaceuticals, a collaboration between the Swedish Pharmaceutical Association and the Swedish government. This is a voluntary transparency initiative making information about environmental risks available to the public, doctors and scientists.

We participate in technical working groups on pharmaceuticals in the environment. We continually engage

with regulatory scientists from the US Environmental Protection Agency, the US Food and Drug Administration and the UK Environment Agency.

› Home › Responsibility › Environmental sustainability › Materials › **Packaging**

Corporate Responsibility Report 2009

Packaging

We are working to reduce the environmental impact of packaging for our pharmaceutical and consumer healthcare products. We recognise that we have substantial opportunities to improve our packaging profile.

Our 'green packaging guide' provides guidance for evaluating and selecting packaging. It allows designers and managers to benchmark new and existing packaging designs using five metrics:

- Manufacturing impacts
- Mass of the material
- Biodegradability
- PVC content
- Resource depletion of petrochemical feedstocks

In 2009 we developed a company-wide strategy to drive towards more sustainable packaging, covering the Consumer Healthcare, Pharmaceuticals and Biologicals businesses. This strategy has set GSK's Sustainable Packaging Principles through the '7 Rs':

Reduce – the mass of materials, complexity and the life cycle footprint of packaging

Remove – materials with sustainability or EHS issues (for example, PVC, phthalates)

Reuse – increase the use of recycled materials in packaging

Recycle – design for recyclability

Renew – increase the use of materials and energy from renewable sources

Reward – make sound packaging decisions that account for cost and the needs of patients, customers and consumers

Respect – utilise responsible supplier selection

GSK's Consumer Healthcare (CH) business adopted a sustainability strategy in 2009 which includes an objective to measure and reduce packaging environmental impacts throughout the product life cycle. This will include identifying ways to support post-consumer recovery and recycling of GSK consumer packaging.

The business will work on reducing packaging weight, improving recyclability, increasing recycled content and using more materials from sustainable sources. CH will set up a system for collecting and reporting packaging data and will set improvement targets in 2010.

One example of reducing the impact of our packaging is the use of 100 per cent recycled plastic for our *Ribena* bottles, achieved despite the challenge of sourcing sufficient quantities of recycled plastic.

› [Back to top](#)

› Home › Responsibility › Environmental sustainability › [Environmental performance](#)

Corporate Responsibility Report 2009

Environmental performance

We have been working to reduce the direct environmental impacts of our operations for many years and continue reducing our water use, waste generation and emissions.

GSK has more than 90 manufacturing facilities, more than 20 research laboratories, numerous offices and warehouses and a large fleet of vehicles. They use substantial volumes of water and solvents as well as other substances which can result in damaging emissions and hazardous waste. (See [Climate change and energy](#) for coverage of energy and greenhouse gas emissions.)

We aim to create a culture where environmental considerations are part of everyday business decisions. Initially, this focused on effectively managing resource use and emissions, and while we continue to work on improving in these areas we are now adopting a broader approach. Our goal is to transform our environmental impacts by thinking more broadly about sustainability. For example, we may be able to change our production and business processes to avoid waste at source rather than simply treating the waste and emissions that arise.

In 2009 we focused particularly on water use and underlined our commitment by signing the [UN CEO Water Mandate](#).

› [Back to top](#)

Corporate Responsibility Report 2009

Water

Approach

Performance & plans

Fresh water is a finite and vulnerable resource, essential to sustaining life, development and the environment. The increasing demands on water sources, together with the effects of climate change, mean that many areas are now water-stressed. By 2025, it is estimated that a third of the world's population will suffer severe and chronic water shortages due to the impacts of climate change, population growth and increased affluence. This will result in environmental damage, political conflict and many deaths from water-related diseases.

We are committed to continuous improvement in these areas. Improving our water use benefits GSK by increasing our water security, improving our manufacturing efficiency and strengthening our reputation and relationships with stakeholders.

GSK requires access to clean water mostly for manufacturing (for processes, products, cooling and cleaning) as well as for R&D and general site uses such as drinking, food services and sanitation. We aim to use water sustainably, and seek to minimise any negative environmental or social impacts. Our overall target is to reduce water consumption by two per cent per annum per unit of sales from 2006-2010. We will consider site-specific targets for facilities in water-stressed regions.

Using clean water is important for public health, and we operate the philanthropic Personal Hygiene and Sanitation Education (PHASE) programme, a [simple hand-washing programme](#) teaching children how to reduce the spread of infection.

UN Water Mandate

GSK endorsed the United Nations CEO Water Mandate in 2009 and this is our first communication on progress. This demonstrates our recognition that water is a valuable natural resource, and that businesses can play a positive role in managing it. By endorsing the mandate, we pledge to:

- Improve our water sustainability in direct operations and our supply chain
- Work with other organisations and governments to encourage sustainable policy and practices
- Engage with our sites' local communities in providing education and support on water and sanitation
- Be accurate and transparent in our reporting of water-related issues

In the short term we will understand and measure how we and our suppliers use water in our factories, and how to make our use more sustainable. In the longer term we will integrate the water strategy into our overall strategy and develop a metric that measures water sustainability. As well as assessing the direct water footprint of GSK's and suppliers' operations we will focus on developing ideas about water neutrality.

Water-related risks vary widely by location and it is important to focus efforts on areas which are water-scarce. In 2009 GSK used the World Business Council for Sustainable Development's (WBCSD's) Water Tool to identify which of our sites are in areas likely to suffer from water shortages. This tool identified five sites in areas of concern in India, Pakistan, South Africa, Kenya and Nigeria. Seven other sites in Algeria, Morocco, Pakistan and Singapore are in areas considered at moderate risk of water shortages.

At these sites we have investigated water consumption in more detail and identified water-related risks, based on the availability of water, the effects of extreme weather events, and the social and regulatory environments in which they operate. The sites then developed risk-mitigation strategies. At one of our sites in

Australia, which is a slightly less water-stressed area, we have implemented measures such as rainwater capture for gardens and for cooling, waterless urinals, and using waste water for flushing toilets. In 2010 we will evaluate these strategies and monitor their implementation.

Supply chain and watershed management

Through the CEO Water Mandate, we have pledged to encourage and support suppliers in reporting their water use and improving their sustainability practices. In 2009 we collected water use from 17 suppliers of API – see the [supplier performance section](#). We have also pledged to help protect and manage the watersheds in which we operate.

Engagement with governments and other organisations

Some of our sites in water stressed areas routinely engage with their local communities and government authorities about water, however GSK has not yet joined any water advocacy organisations. Our integrated strategy will guide our engagement with these organisations.

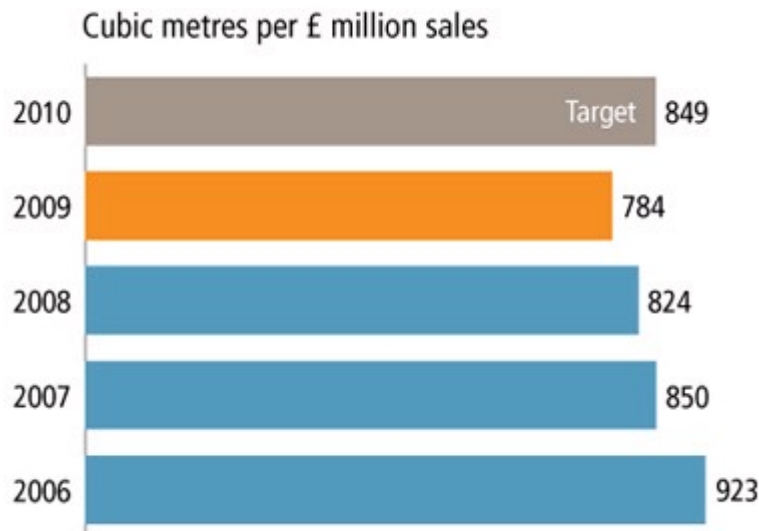
› [Back to top](#)

Water

Approach

Performance & plans

Water consumption



In 2009 GSK's worldwide water use totalled 19.2 billion litres. That is the equivalent of almost 150,000 UK households. We saved almost 480 million litres of water compared with 2008, despite significant increased use in Biologicals because of increased vaccine production.

Explanation for trend

Progress was due to continued conservation, especially in water-stressed areas such as Singapore and India. However, even in areas with less water stress we have implemented ideas to save water such as at a GSK site in Spain. Here, following suggestions from staff, a fountain was replaced with a planted area with native drought resistant bushes and trees that require only natural watering. Consumption also fell because of lower production in some water-intensive processes.

Water consumption per unit of sales was 4.8 per cent lower than in 2008, exceeding our two per cent target. Pharmaceutical manufacturing water use fell by nearly six per cent. Cumulatively, water use per unit of sales has fallen by 15 per cent since 2006, ahead of the two per cent annual reduction target. However, we will continue to look at water use and the impact of this, particularly in our sites in water stressed areas.



SGS verified

› [Back to top](#)

Corporate Responsibility Report 2009

Wastewater

Approach

Performance

Most GSK sites discharge their wastewater to municipal treatment facilities. Some locations have on-site wastewater treatment systems and some are permitted to discharge wastewater direct to the sea. The quality of the wastewater discharged is measured using the chemical oxygen demand (COD) – a measure of the oxygen required to chemically oxidise the compounds in the water. Lower CODs correspond to cleaner water.

For 2006-2010, GSK's target is a three per cent reduction in COD levels per year per unit of sales. As the vast majority of COD comes from the manufacturing of active pharmaceutical ingredients, 'domestic use' (for example from washrooms and canteens) is only included when measurements cannot be separated, and waste water is not measured at sites that do not have discharge permits that require monitoring.

› [Back to top](#)

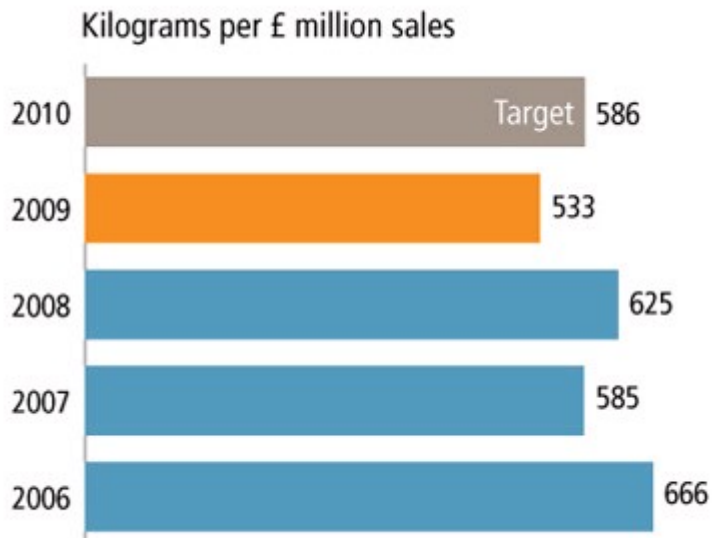
Corporate Responsibility Report 2009

Wastewater

Approach

Performance

Chemical oxygen demand of wastewater



We generated 9.7 billion litres of wastewater in 2009, 8.8 per cent lower than 2008 and more than 18 per cent below the 2006 baseline.

In 2009 the chemical oxygen demand (COD) of wastewater also fell 12 per cent. COD per million £ sales fell 15 per cent, reaching a cumulative 20 per cent from the 2006 baseline. This puts us ahead of the target to decrease three per cent per year. However, in some years water pollution goes up depending on the products made during the year, so fluctuations in the business mean we may miss targets.

Explanation for trend

The quality of wastewater discharged is closely related to the types and amount of materials produced in the manufacture of our active pharmaceutical ingredients and consumer products. The significant decrease this year is due to three factors: lower production of some water-intensive processes in the manufacture of active pharmaceutical ingredients; a newly commissioned wastewater treatment plant at a toothpaste factory in the UK; and a reverse osmosis system installed in a pharmaceutical ingredient manufacturing plant in India.

The changes in levels of wastewater pollution from year to year are due to changes in production in addition to continued improvements in wastewater treatment and waste minimisation. Our work to improve manufacturing efficiency should continue to decrease wastewater pollution in the future.



SGS verified

› [Back to top](#)

Corporate Responsibility Report 2009

Waste

Approach

Performance & plans

Our production, research and sales activities all produce waste:

- Production – hazardous wastes such as solvents and other chemicals
- R&D and quality control laboratories – small amounts of chemicals including products and intermediates, as well as broken glassware and plastics
- Offices – paper and other standard commercial waste
- Building renovations produce non-routine waste such as obsolete equipment, office furniture and structural materials

A significant proportion of our waste is classified as hazardous, mainly because it contains solvents and chemicals used to manufacture active pharmaceutical ingredients. Most non-hazardous waste is general material such as office waste paper, kitchen waste and non-hazardous substances used in manufacturing.

We aim to eliminate waste where we can, reduce it if we cannot eliminate it, reuse materials if possible, recycle other waste and dispose of any remaining material sensitively. This hierarchy also applies to solvents. Our first choice is to reuse or recycle them. Some used solvent is recovered and purified on site and reused in the original manufacturing process and some is sold to commercial reprocessing companies. When reuse or recycling is not possible, solvents are mostly incinerated and the energy recovered wherever possible. Regulations vary widely around the world but by working to this hierarchy we aim to manage waste in a way that meets or exceeds regulatory requirements.

We require disposal contractors to comply with our requirements and local regulations. Sites audit their waste contractors or hire consultants to carry out the audits.

Our target is to reduce non-hazardous waste disposed per unit of sales by one per cent per annum, which will give us a reduction of four per cent by the end of 2010. We have not set a target for reduction of hazardous waste, but are aiming to [improve material efficiency](#), which will reduce the volume of hazardous waste.

In addition to production changes to reduce waste volumes, some sites are aggressively working to recycle as much waste as possible and minimise disposal, eliminating waste sent to landfill. A team in one of our Consumer Healthcare manufacturing sites in India succeeded in reducing waste as well as water and energy use by reducing the amount of packaging. See [case study](#).

› [Back to top](#)

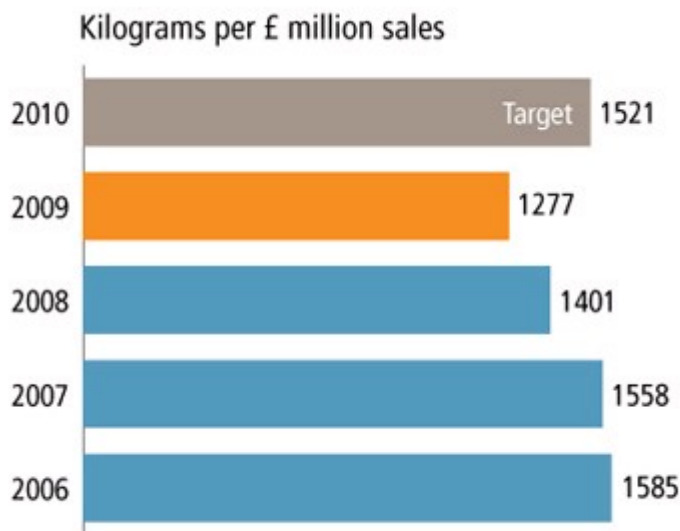
Corporate Responsibility Report 2009

Waste

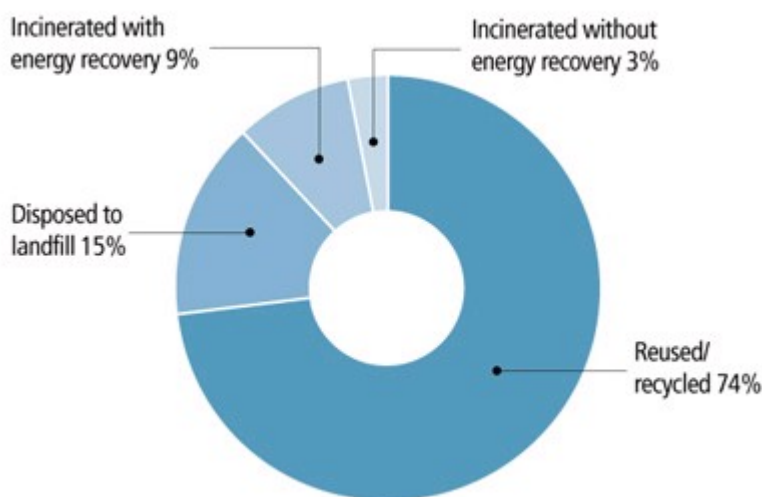
Approach | **Performance & plans**

Non-hazardous waste

Non-hazardous waste disposed



Destination of non-hazardous waste 2009



These data do not include non-routine waste such as construction and demolition rubble and similar material not related to day-to-day operations

In 2009 the amount of non-hazardous waste disposed fell by 6.6 per cent and was 17.7 per cent lower than the 2006 baseline at 31,197 tonnes. Waste per million £ sales was 8.9 per cent lower in the year and more

than 19.4 per cent down on 2006. This is beyond our one per cent per year improvement target but we still need to do more and plan to set more aggressive targets in future.

Our target is specific to non-hazardous waste disposed, but we also measure total non-hazardous waste generated, which includes waste that is recycled. In 2009 we generated 117,800 tonnes of non-hazardous waste, slightly higher than the previous year. Of this, 73.5 per cent was recycled and 26.5 per cent was disposed of via landfill or incineration, both figures showing improvements on 2008.

Explanation for trend

The decrease in non-hazardous waste disposed partly reflects continuing efforts to manage and recycle waste, especially in the pharmaceutical and consumer manufacturing operations. It is also due in part to decreased production of some pharmaceutical products but this is balanced by increasing waste in the vaccines business as it continues to grow.

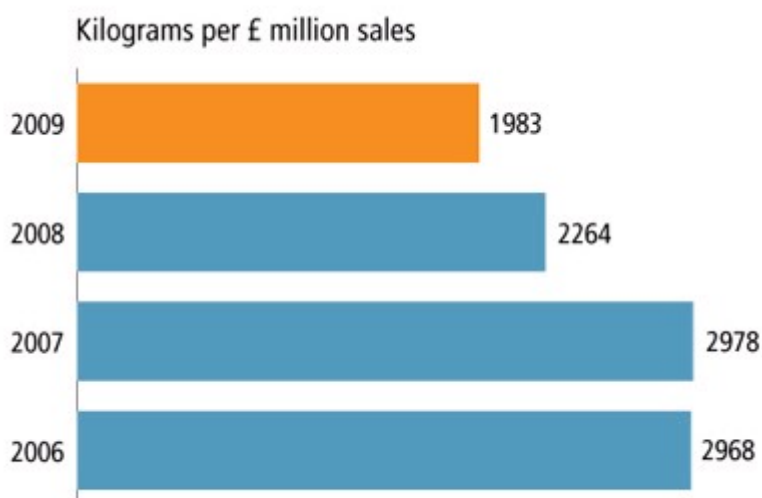
The impact of H1N1 (swine flu) vaccine production resulted in a 15 per cent increase in waste generated at Biologicals sites, including 1,325 tonnes at one site due to eggs used in vaccine production. This site accounted for nearly 12 per cent of all our non-hazardous waste disposed in 2009.

We continue to look for ways to reduce waste by recycling more and finding ways to use less raw material. Our focus on making our manufacturing processes more efficient will also reduce the amount of waste disposed.

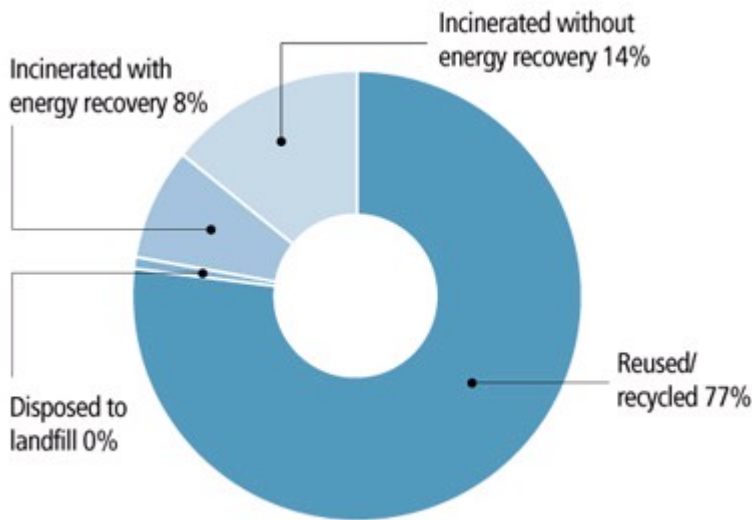


Hazardous waste

Hazardous waste disposed



Destination of hazardous waste 2009



In 2009 we generated 214,500 tonnes of hazardous waste, down from 237,000 in 2008. Less than one per cent of this waste went to landfill and 77 per cent was recycled – a similar proportion to 2008.

Hazardous waste disposed was 48,400 tonnes, 10.2 per cent lower than in 2008. Waste disposed per million £ sales fell by 12.4 per cent and was 33.2 per cent below the 2006 level.

Explanation for trend

The decrease in hazardous waste disposed is due to continued efforts to manage and recycle it, especially solvents. It is also due in part to decreased production of some products that used significant quantities of solvent.

The amount disposed is related to the types and quantities of products made and the amount of solvent used by factories that manufacture active pharmaceutical ingredients. Solvent waste is 90 per cent of hazardous waste generated. The five largest sites that manufacture active pharmaceutical ingredients together account for over 86 per cent of the solvent waste disposed.

We do not have a target for reducing hazardous waste disposed. Instead we focus our attention on improving manufacturing efficiency because efficiency improvements mean less material is used in the manufacturing process and therefore less waste is generated. For example a team in R&D developed a continuous manufacturing pilot plant that could significantly reduce the amount of solvent waste. See [case study](#).



› Back to top

Corporate Responsibility Report 2009

Emissions to air

Approach**Performance & plans**

The main emissions from GSK sites ([apart from greenhouse gases](#)) are gases that damage the ozone layer and volatile organic compounds (VOCs) that cause low-level pollution.

Ozone depletion

Ozone-depleting substances (ODSs) damage the ozone layer in the upper atmosphere, exposing people to radiation that can cause skin cancer and other health problems.

Industrial use of ODSs – mainly chlorofluorocarbons (CFCs), hydrochlorofluorocarbons (HCFCs) and halons – was common before their negative effects were understood. We used CFCs as the propellant gas in most of our metered dose inhalers. The gas is released when patients use the inhalers and a small amount escapes during production. We stopped manufacturing CFC inhalers in all GSK sites and our two contract manufacturing sites in 2009. We were unable to obtain information on the quantity of CFCs in inhalers manufactured by the two contract manufacturers so these data are not included in this report [Read more here](#).

We also use ODSs in some cooling systems and for other ancillary uses at GSK facilities. They are only released in the event of a leak or during maintenance but we have switched to using hydrofluorocarbons (HFCs), ammonia and hydrocarbons. We aim to eliminate CFCs and HCFCs from cooling systems and aim to remove larger pieces of equipment from service before the end of 2010.

Volatile organic compounds

Volatile organic compounds (VOCs) react with nitrogen oxides in the presence of sunlight, creating ozone in the lower atmosphere. This results in smog which is a factor in human respiratory illness.

We emit VOCs to the atmosphere mainly from solvents used in the manufacture of our active pharmaceutical ingredients and in R&D pilot plants. Our target is to reduce VOC emissions per unit of sales by two per cent per year, which will give us a reduction of eight per cent by the end of 2010.

In 2009 we began a VOC reduction programme, concentrating on three sites that are responsible for about three-quarters of VOCs released from Primary Supply sites. Projects initiated included tank insulation and changing the pump technology. See [case study](#).

› [Back to top](#)

Corporate Responsibility Report 2009

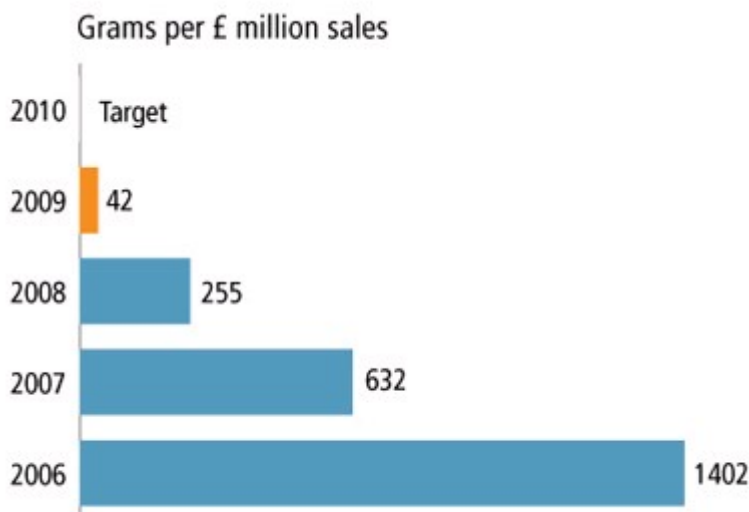
Emissions to air

Approach

Performance & plans

Ozone depletion

Ozone depletion potential from equipment and production (CFC-11 equivalent)



In 2009 ODP from equipment and production losses decreased 83.6 per cent to 1.0 thousand kilograms. This follows a similarly substantial reduction in 2008 and means we have almost met our 2010 target to eliminate losses of CFCs and HCFCs from production and equipment.

Two-thirds of CFC releases occur during production of inhalers. We estimate that 327 kilograms of CFC-11 equivalent were emitted from equipment. Releases during patient use of inhalers are now very small.

We maintain a register of the significant pieces of equipment that contain refrigerants and use this to track progress towards the target to eliminate CFCs and HCFCs from refrigeration equipment. We have 85 pieces of equipment containing more than one kilogram CFCs, amounting to 7,152 kilograms in total. Over 4,262 items of equipment contain other ODSs, with 4,753 kilograms of CFC-11 equivalent.

Explanation for trend

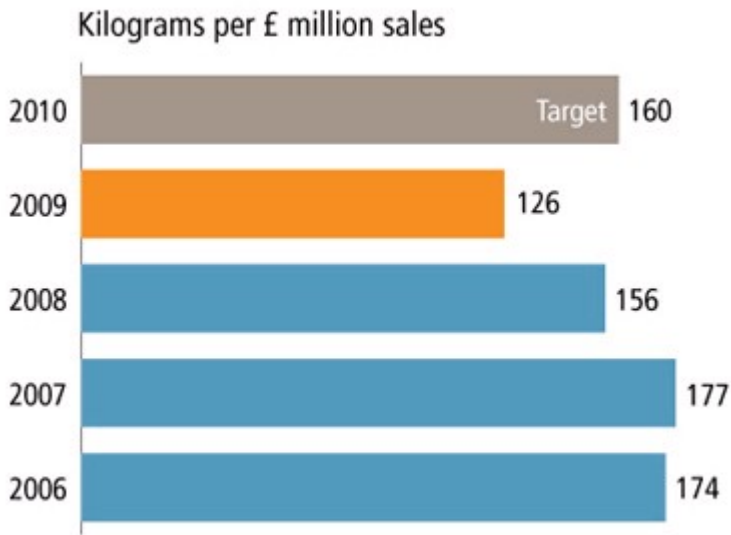
As production of CFC-containing inhalers decreases, the amount of gases lost during all stages of production and use also declines.



SGS verified

Volatile organic compounds

Volatile organic compound emissions



In 2009 volatile organic compound (VOC) emissions decreased 17 per cent to 3,100 tonnes. Emissions have now fallen by nearly 26 per cent since 2006. VOCs released to air per million £ sales decreased 19 per cent in 2009 which means we have achieved our target. This continues the trend of reductions from previous years and takes the total reduction per unit sales to 27.4 per cent since 2006.

Explanation for trend

Emissions of VOC to air are affected by the management of solvents and by the mix of products that are made in the year.

VOC emissions was one of our focus areas in 2009. We concentrated on the top three emitting sites which are in the UK, India and Singapore. The improvements in 2009 were mainly the result of changes to venting arrangements. Some projects initiated in 2009 will only take effect in 2010.

Our plans

Several projects defined in 2009 will be implemented in 2010. More projects will be initiated in 2010, such as changing the types of dryers and pumps and reducing leakage from tanks. We expect continuing improvement in VOC emissions from completed projects and from projects planned through 2011.



› [Back to top](#)

Corporate Responsibility Report 2009

Land

We are involved in a number of projects in the UK and the US to remediate sites with land contaminated due to past handling practices for chemicals. Practices now prevent contamination unless there are accidental releases but we have identified five sites in the UK and more than 50 sites¹ in the US that require some remediation. Most of them are waste disposal sites where GSK is one of several responsible parties.

GSK and its heritage companies have spent more than £100 million cleaning up more than 50 sites in the US over the last 20 years and are continuing to work on 25 of them.

1. These figures are not included in the data verification

› [Back to top](#)

Corporate Responsibility Report 2009

Supplier performance

GSK **selects suppliers** with an appropriate level of environmental, health and safety management systems control.

We want to understand the total environmental footprint of the processes used to make our products, so we are investigating our suppliers' impacts, including contract manufacturers.

GSK is committed to introducing sustainability concepts into the supply chain. Achieving this will require data collection and analysis, using the information in sourcing decisions, setting objectives and integrating into the current procurement performance review processes.

To support greater transparency, 17 key suppliers of active pharmaceutical ingredients (API) and intermediates were asked to provide data on energy usage, CO₂ emissions, waste disposal and water usage. Ten companies responded, with details for 15 manufacturing sites. We are not yet in a position to make a reasonable comparison to GSK production processes.

In 2008 the total energy used for production by these contract manufacturers was estimated at 1.5 million gigajoules with less than one per cent from sustainable sources. Resulting CO₂ emissions were 26,700 tonnes.

Our contract suppliers reported a total estimated disposal of 116,000 tonnes of solvent waste. They reused, recovered, or recycled 85 per cent of their solvent waste and incinerated 15 per cent. Less than one per cent went to landfill.

Water obtained from municipal sources, wells or boreholes and used for GSK processes totalled 579,000 cubic metres.

These data are not verified by SGS.

In addition to collecting data from suppliers, we are looking at a way to estimate the environmental footprint of our contract manufacturers. To do this, we are evaluating the resource consumption and waste generation of 39 process steps for outsourced manufacture of 15 products. The resources and energy consumed and waste generated were estimated by looking at detailed process descriptions and applying engineering standards, to complete energy and mass balances for each unit operation in the production process.

Unit operations included reactors, filtration and crystallisation. This method calculates the energy use and climate change impact based on the amount of material we purchase, which gives a high-level estimation of the environmental profile of suppliers when data are not available directly from the suppliers. For the sample of processes studied, we estimate that 76,700 gigajoules of energy and 4,643 cubic metres of water were used. The estimations can be refined as more information becomes available from the suppliers.

› [Back to top](#)

Corporate Responsibility Report 2009

Transparency

A commitment to open communications with all stakeholders is a key element of GSK's environmental sustainability policy and strategy.

We aim to be transparent about the environmental impacts of our products and processes and to engage stakeholders to understand and respond to their concerns. Reporting is an important aspect of transparency and [assurance](#) of environmental sustainability data helps to build trust with stakeholders.

As well as reporting progress against our environmental sustainability objectives, we respond to specific requests for information throughout the year and engage formally through the [Stakeholder Panel](#).

Reporting

Our primary objective in collecting environmental performance data is to help our operations manage environmental issues effectively. This is done through EHS Manager, a web-based information management system that also includes health and safety data.

We focus our external reporting on the environmental issues that are most relevant to GSK and of most interest to our stakeholders. See [Stakeholder engagement](#) for how we understand stakeholder views and respond to them in the report.

Basis of reporting

Targets and performance normalised by sales are based on a constant exchange rate, using the rate for 2009. This means that normalised figures for previous years are different to those shown in last year's report.

Data may also vary slightly from earlier reports because any errors found in data from prior years are corrected.

We use the Greenhouse Gas Protocol for all of our calculations of CO2 emissions from energy use. We also updated the factors for climate change emissions from propellants and refrigerants using WMO (World Meteorological Organisation), Scientific Assessment of Ozone Depletion: 2006, Global Ozone Research and Monitoring Project – Report No 50, 572 pages Geneva, Switzerland, 2007, (chapter eight).

Environmental data are collected from 77 of our Pharmaceuticals and Consumer Healthcare manufacturing sites, 14 vaccines sites, 19 Pharmaceuticals and Consumer Healthcare R&D sites, the US and UK headquarters buildings and 17 smaller offices and distribution centres. We collect environmental data from acquired entities in their first full year in the group, not in the year of acquisition.

› [Back to top](#)

Corporate Responsibility Report 2009

Summary data

This table is a summary of five years of environmental performance. For a breakdown of the components of each metric and more data see the [detailed data table](#).

	2005	2006	2007	2008	2009
Energy consumption from operations and transport (million gigajoules) ¹	19.4	26.4	26.4	26.2	25.3
Climate change impacts (thousand tonnes):					
– From operations	1966	2223	2226	2234	2166
– Inhaler use by patients ¹		4685	5200	4747	4243
– Total climate change impacts		7411	7796	7275	6676
Water use (million cubic metres)	21.8	22.1	20.7	19.6	19.2
Wastewater volume (million cubic metres)	16.6	11.8	10.9	10.7	9.7
COD (thousand tonnes)	18.7	15.9	14.3	14.9	13.0
Hazardous waste generated (thousand tonnes)	261.4	241.7	222.5	237.0	214.5
– Disposed (other than recycling)	67.8	71.0	72.6	53.9	48.4
Non-hazardous waste generated (thousand tonnes)	125.1	116.4	121.5	110.0	117.8
– Disposed (other than recycling)	41.2	37.9	38.0	33.4	31.2
Other waste generated (thousand tonnes)	77.9	28.1	37.7	18.9	52.7
– Disposed (other than recycling)	38.0	17.0	14.6	6.9	7.4
Volatile organic compounds emissions (thousand tonnes)	5.2	4.2	4.3	3.7	3.1
Ozone depleting substance releases (tonnes):					
– Production and refrigerant releases	54.0	33.5	15.4	6.1	1.0
– Patient use of inhalers	272.5	182.2	136.5	87.7	0
– Total ODS	326.5	215.7	151.9	93.7	1.0
Ozone depleting potential of refrigerants in equipment (tonnes) ¹		23.9	20.5	15.7	11.9

1. Some data not available in 2005

> [Back to top](#)

Corporate Responsibility Report 2009

Stakeholder engagement

While many sites engage with stakeholders locally through activities such as open days, newsletters and community projects, we have an Environment, Health and Safety Stakeholder Panel in the UK which has provided independent feedback on company-wide performance since 2005.

The panel is drawn from customers, suppliers, regulators, public interest groups and investors and was expanded in 2009 to include members from European regulatory and environmental organisations. Two senior EHSS representatives from GSK regularly participate and other GSK managers attend discussions on specific topics. The panel is facilitated by The Environment Council, an independent charity.

In 2009 we responded to panel suggestions by focusing on the challenges that the company faces, encouraging panel members' input and allowing more time for discussion by including fewer items on the meeting agenda. The panel met twice to debate issues including:

- EHS reporting
- The economics of ecosystems
- Water
- Packaging and waste
- Chemical exposure

We use feedback from the stakeholder panel to inform our Environmental Sustainability and Health and Safety programmes. The panel will also interact with the GSK Sustainability Council of senior managers from across the company.

› [Back to top](#)

Corporate Responsibility Report 2009

Assurance



Assurance statement

SGS UNITED KINGDOM LTD'S REPORT ON ENVIRONMENT, HEALTH AND SAFETY DATA IN THE GLAXOSMITHKLINE CORPORATE RESPONSIBILITY REPORT FOR 2009

NATURE AND SCOPE THE ASSURANCE

Plans and Performance – Targets table	Health and safety management
Audits and compliance - Performance	Safety Programmes - Ergonomics and driver safety
Climate change and energy – Performance and plans	Performance - Injury and illness rates
Transport and travel	Performance - Injury and illness causes
Water – Performance and targets	Performance - Fatalities and serious injuries
Wastewater – Performance and targets	Performance – Illness and injury milestones
Waste – Performance and targets	
Emissions to air – Performance and targets	Summary and Full Environment, Health and Safety data tables

The information in the GSK CR Report and its presentation are the responsibility of the directors and management of GSK. SGS United Kingdom Ltd has not been involved in the preparation of any of the material included in the CR Report. Our responsibility is to express an opinion on the data, graphs and statements within the scope of verification with the intention to inform all GSK's stakeholders. Financial data drawn directly from independently audited financial accounts has not been checked back to source as part of this assurance.

This report has been assured at a moderate level of scrutiny using our protocols for evaluation of content veracity. The assurance comprised a combination of interviews with relevant employees; documentation and record review at eighteen GSK locations during and at the end of the reporting year as follows:

- Interim site visits during October to December 2009 in Belgium (Rixensart, Wavre), China (Beijing, GSKT, TSKF), Germany (Dresden), India (Worli), Ireland (Dungarvan), Singapore (Jurong, Quality Road), Spain (Aranda), UK (Harlow R&D, Ware R&D, Weybridge), USA (Aiken);
- Interviews with EHS Director and Management Team for Primary Supply in November 2009 and January 2010;
- End of year site visits during January and February 2010 in UK (Montrose, Ulverston and Corporate CSR function in London).

The sites selected included those submitting high proportions of key data and all parts of the GSK business.

STATEMENT OF INDEPENDENCE AND COMPETENCE

The SGS Group of companies is the world leader in inspection, testing and verification, operating in more than 140 countries and providing services including management systems and service certification; quality, environmental, social and ethical auditing and training; environmental, social and sustainability report assurance. SGS United Kingdom Ltd affirm our independence from GSK, being free from bias and conflicts of interest with the organisation, its subsidiaries and stakeholders. The assurance team was assembled based on their knowledge, experience and qualifications for this assignment, and comprised auditors and assurers registered with IRCA, IEMA and EMAS Verifiers.

ASSURANCE OPINION

On the basis of the methodology described and the verification work performed, we are satisfied that the Environmental, Health and Safety data contained within the GSK Corporate Responsibility Report 2009 is reliable and provides a fair and balanced representation of GSK's Environmental, Health and Safety activities in 2009. The assurance team is of the opinion that the Report can be used by the Reporting Organisation's Stakeholders.

Summary of Findings

Key areas for improvement to data collection, submission and manipulation identified during the assurance process were addressed as far as possible to incorporate improvements into this report. These improvement opportunities are outlined below to enable further review to establish the need for system or process changes in future reporting cycles:

- Site level reporting of working hours was found to be undertaken using a variety of methods and in most cases required some minor modifications to ensure accuracy of data reported. We recognise that implementing a universal system for calculation of this data point may not be practical but investigation should be made to reduce the level of errors in reported information.
- We identified occasional misinterpretation of reporting categories. This tended to be in relation to exceptional circumstances but sites should be encouraged to request clarification of reporting categories to minimise errors.

In addition good practice was noted in the following areas:

- Increased comments and explanations made by sites inputting data to explain significant changes, estimations and calculations.
- The analysis of data at corporate level has made ongoing improvements including:
 - detailed review of reports illustrating significant changes in data on a site-by-site basis;
 - extensive requests to sites for explanations of significant changes in performance or anomalous data reported;
 - review of graphical display illustrating year-on-year trends for each KPI.

Recommendations for future data verification process include:

- Extending the EHS Director level review of performance to other supply chains;
- Expanding the scope of data verification to other parts of the report not currently assured.

Signed:

For and on behalf of SGS United Kingdom Ltd

› [Back to top](#)

Corporate Responsibility Report 2009

GSK response to assurance

This is the fourth year that SGS has reviewed the data in the environment section and the health and safety pages of the Corporate Responsibility Report. Its independent view of our processes has been very valuable and we have adopted its suggestions over the years, improving our processes.

Sites were selected for review from all of the GSK businesses. There was special focus on sites that had particular problems with data in the past years as suggested by SGS in its 2008 verification statement.

The data in the Corporate Responsibility Report can be used by sites to improve their management of their environmental programmes and their health and safety programmes. In 2009 we introduced a mid-year evaluation of the data to encourage sites to track their progress and to assist in the management of EHSS.

We continue to find challenges in collecting complete and accurate data in a timely fashion and are committed to improving with the ultimate goal of providing accurate data to the public on the website in real time.

Responses to key areas for improvement in 2009

- Improving site-level reporting of working hours:
This continues to be a challenge because there is not a single system to capture this information, leaving each site to devise its own process. We continue to try to improve this reporting by continued training and reminding reporters of errors
- Occasional misinterpretation of reporting categories:
This is a particular concern with waste data as it has several different categories. We will emphasise this in training this year and will enhance the on-screen definition details for these data points
- Extending the EHS Director level review of performance to other supply chains:
In 2009 we introduced a central review of the data for the active pharmaceutical ingredient manufacturing group by the EHS Director for that group. This helped us identify errors and understand the reasons for changes. We will request that the EHS Directors of other groups participate in the 2010 review.
- Expanding the scope of data verification to other parts of the report not currently assured:
We will evaluate the report to identify additional areas that may be appropriate for verification. These could include data about packaging and the data that we collect from suppliers.

› [Back to top](#)

Corporate Responsibility Report 2009

Case studies

A radical alternative manufacturing approach

The Innovative Manufacturing Initiative (IMI) is a visionary programme with a long-term goal to radically improve the way GSK manufactures active pharmaceutical ingredients (API).

GSK's R&D team at Stevenage in the UK has pioneered a ground-breaking manufacturing technology that will transform the way we develop chemical processes to improve the efficiency, control and environmental footprint of future pharmaceutical production.

The multidisciplinary team, based in Chemical Development, has successfully built and demonstrated what it believes is the world's first continuous manufacturing pilot plant from raw materials to API. This is the culmination of an eight-year project to develop leading edge technological solutions to meet the increasing demands of regulators for 'quality by design' manufacture and GSK's sustainability ambitions.

The long-term vision is to deliver a fully continuous manufacturing plant that provides a more economic, safer, energy efficient and environmentally benign production facility. We estimate that approximately 60 per cent of our manufacturing processes could be adapted to this new approach.

Continuous processing is used routinely in other industries such as oil and gas and is recognised as the most efficient method for large scale production. Pharmaceutical production is generally limited to traditional batch processing methods, where the manufacturing process is split into discrete stages (unit operations) over weeks or months to produce the API.

IMI uses continuous processing to run each of the unit operations concurrently, which eliminates the need for isolated chemical intermediates and reduces the elapsed time to hours or days. By combining creative chemistry design with IMI enabling technologies the manufacturing process is usually more efficient, reduces equipment cleaning times, and eliminates the need to store large volumes of intermediate materials, some of which may be unstable.

IMI processes are designed to use fewer solvents, facilitate recycling, remove operator exposure to chemical intermediates, and can significantly reduce aqueous waste streams. Hazardous chemistry that is not amenable to batch processing may be run continuously, offering greater potential for simpler and more sustainable processes.

The team at Stevenage completed construction of the continuous manufacturing pilot plant in 2008. The processes operated have material cost savings of between six and ten per cent compared to a similar batch process, along with a reduction in the number of unit operations. Continuous manufacturing facilities are also cheaper to construct, with a capital saving of up to 50 per cent compared to a batch plant, due to their significantly smaller footprint.

This approach is now being actively applied to the New Chemical Entity portfolio and redevelopment of older products to reduce manufacturing costs and environmental impacts.

This team won the Vanguard award in the CEO sustainability awards in 2009.

A sustainable route to antibiotic production

GSK's R&D team at Upper Merion, Pennsylvania, has developed an improved manufacturing process for an antibiotic currently undergoing late-stage clinical trials that will save substantial resources and make the move to full-scale commercial manufacturing financially viable. The team won first place in the CEO sustainability awards in 2009.

The antibiotic's complex structure meant that scaling up the process used to produce it in small volumes needed for clinical trials would have been expensive, wasteful and inefficient. The process also required the use of several hazardous and environmentally damaging substances.

The new process has reduced the number of stages from 12 to eight, bringing significant savings. Overall yields have increased 11-fold and there has been a 24-fold increase in mass efficiency (a measure of the efficiency with which materials are used). Manufacturing materials and waste have been cut by more than 95 per cent. Over the long term it is projected to cut production costs by more than 95 per cent as well.

Avoiding supply shortages and saving resources

Between April 2008 and June 2009 a team based at Worthing developed a second generation process for the production of calcium nadroparin, an anti-coagulant active ingredient used to stop blood clots forming. The success of the project significantly increased output and improved process efficiency, helping to avoid threatened supply shortages. The new process avoids consumption of other reagent materials, solvents and water.

The project originated with a small team that examined the feasibility of alternative ideas for improving the production process in 2008. The team identified two promising approaches and the second generation approach was identified as an opportunity to realise benefits in a relatively short period while remaining within the registered process details. This was successfully developed, resulting in pilot batches being completed in April 2009.

The second generation process was commercially validated from June and, compared to the original process, has achieved:

- 10-15 per cent increase in output
- 13 per cent reduction in ethanol usage
- 9-13 per cent reduction in water usage
- 9-13 per cent reduction of all other reagents
- 9-13 per cent reduction in vessel usage and plant time

The longer term goal was a more radical third-generation process that could further improve the process efficiency and environmental impact. This is still under development.

This team was a winner in the 2009 CEO sustainability awards.

Cutting emissions at Irvine

We expect that by 2010 a 50 per cent cut in emissions will be achieved at our site at Irvine in Scotland, continuing progress already made since 2006. An exercise in 2008 identified the top three sources of emissions and in 2009 we carried out the work, concentrating first on eliminating or reducing emissions at source, then recovering and reusing solvent vapour in vents. End-of-pipe techniques such as scrubbers, bio-filters or incinerators were ruled out as being too costly or not the best environmental option. In 2010, the first full year of implementation, we expect VOCs will reduce to 50 per cent of the level in 2006. Due to the value of the solvent recovered, this programme will have paid for itself within five years.

Sustainable growth, sustained responsibility

Energy savings are just one outcome of a project covering the three Biologicals sites in Belgium. The project embraces a range of sustainability initiatives seeking to minimise the environmental, health and safety risks and impacts. It includes improving the health and wellbeing of staff through a 'Wellness together' programme supporting health, safety, environment and community. Improved waste management and recycling facilities mean that 43 per cent of GSK Biologicals Belgium's non-hazardous waste is recycled.

On the energy front, GSK Biologicals' sites at Rixensart, Wavre and Gembloux achieved combined annual savings between 2007 and 2008 of almost 17,000 MWh and more than 4,000 tonnes CO₂ emissions. This

represented 11 per cent of GSK's total energy savings in 2008.

The savings were achieved through a number of measures including installing solar panels, automatic lighting, improved insulation and more efficient heating and ventilation systems. Meanwhile, the new vaccine quality control laboratory and office complex at Wavre will act as a blueprint for future facilities across GSK Biologicals.

The future users participated in the design of facilities and the choice of materials to ensure that the building would be functional and user-friendly. To ensure the safe and effective maintainability of the building, members of the local maintenance team also contributed to the design. The resulting laboratories are efficient, functional and ergonomic.

The building operates independently in terms of energy with its own production unit which minimises energy loss. It is largely made of glass with an active dual layer facade. The picture windows are double-glazed on the outside and single-glazed on the inside. The air ventilation extracted from the building passes through the two layers which increases the thermal insulation of the building. This air is then collected to heat the technical areas situated underneath the building. This double-layered system saves an estimated 30 per cent energy in office areas. The system also brings advantages in terms of the comfort for the users of the building. It is quieter than classic air conditioning and ensures a constant temperature throughout the building.

The quality control building is the first GSK Biologicals building in Belgium to implement this energy-saving system. It serves as a model for the numerous other buildings under construction that will also incorporate the latest technology to maximise renewable energy.

These achievements mean that GSK Biologicals Belgium is on track to achieve its target of a 20 per cent improvement in energy efficiency by 2012, compared with 1999.

These achievements were marked with first place in the CEO Environmental Sustainability awards in 2009.

Combined heat and power in Biologicals

The Biologicals business in Belgium embarked on a combined heat and power (CHP) programme using gas engines selected for their excellent efficiency and suitability for very big sites such as Wavre, as well as for smaller sites such as Gembloux.

Wavre is Biologicals' second largest manufacturing facility producing major vaccines for the global market. By 2010 Wavre will be the second-largest energy user in GSK, consuming over 250,000 MWh of energy per year. Gembloux is a smaller, associated site. These sites have an energy demand profile that favours CHP because they have continuous heat and power loads all year, a demand for hot water 24 hours per day summer and winter, and hot water that is centrally produced and distributed across the site. They also have a supply of natural gas.

Gembloux's CHP system went live in August 2009. Wavre is installing a CHP system in each of its power plants and the first came on stream at the end of 2009 with further units in 2010 and 2011. Savings at Gembloux will be 1,000 MWh. The two power plants at Wavre are expected to save 11,500 MWh/year and 3,000 tonnes CO₂. A third CHP plant is currently being designed.

Minimising materials and packaging

GSK's Consumer Healthcare business in India is the country's largest producer of nutritional healthcare products. After manufacturing, the business's biggest environmental impact comes from packaging. A cross-departmental team based at GSK's Guragon site has been identifying opportunities to reduce its environmental footprint.

The team has saved over 1,000 tonnes per year of packaging materials – around ten per cent of total packaging material. The savings come from redesigning packaging to use less material yet retain its strength, and through a wastage reduction programme for the entire supply chain.

Packaging savings are equivalent to annual energy savings of six million kWh, 5,000 tonnes of CO₂ and seven million litres of water.

The project has brought additional benefits by encouraging design teams to include sustainability considerations into the design of new packaging. The team has created a plan for achieving further reductions and has identified additional potential savings of 680 tonnes per year. A comprehensive sustainable packaging strategy is under development that includes the use of materials from renewable resources and recycling.

The team won second place in the CEO Environmental Sustainability awards in 2009.

Integrated transport strategy

Encouraging employees not to use their cars for their daily commute is helping GSK cut its carbon footprint while relieving congestion on the busy streets of west London, location of GSK's global corporate headquarters. It also gives employees an opportunity to save money and improve their fitness.

Led by our transport team, we have introduced a number of initiatives to encourage the use of public transport, cycling, car pooling and walking for employees at GSK House. Examples include:

We partnered with the charity Living Streets to develop walking maps of the area local that were launched during national Walk to Work Week, along with weekly lunchtime walks and free breakfasts for registered walkers.

We lease a fleet of shuttle buses powered by waste vegetable oil to ferry employees between GSK sites and local London Underground stations.

The award-winning GSK House cycle centre, run in partnership with cycling organisation WiZZBiKE, provides changing and drying facilities. WiZZBiKE employees offer cycling advice and operate a daily maintenance and repair service. WiZZBiKE also maintains a pool of bicycles for employees interested in cycling to work.

The initiatives have made headway cutting single-occupancy car use at GSK House from 81 per cent in 2004 to 56 per cent in 2009. By 2009 24 per cent of employees travelled to work by public transport. On average 300 employees use the peak time shuttles between GSK House and neighbouring underground stations, while more than 300 employees are registered cyclists.

This project was awarded third place in the CEO Environmental Sustainability awards in 2009.

› [Back to top](#)

› Home › Responsibility › Environmental sustainability › Q&As

Corporate Responsibility Report 2009

Q&As

Here we respond to questions raised by our stakeholders

Your inhaler products have a large environmental impact. What are you doing about this?

We have been phasing out CFCs from our inhaler products for the last 15 years, replacing these gases with HFAs which have a lower climate change impact (16 per cent that of CFCs). Less than two per cent of our inhalers now contain CFCs and we have committed to a complete phase-out by the end of 2010. As part of our new climate strategy, we are exploring ways to reduce the amount of HFAs released from our inhaler products and we are looking into alternative propellants.

We also offer dry powder inhalers for asthma sufferers which contain no greenhouse gases. These are not suitable for all patients, particularly children and the elderly, as they do not contain propellants and rely on a person's lung power for the active ingredients to be administered.

How can the pharmaceutical manufacturing process be made more efficient?

Making medicines is highly regulated and is complicated due to the number of process steps required. Despite these constraints we aim to increase the efficiency with which we convert raw materials to finished products, aspiring to achieve a level five times our performance in 2005 by 2020. One approach is to adopt continuous manufacturing rather than batch processing and we are the first pharmaceutical company to pilot such a process. (See a [case study](#)).

Are pharmaceutical residues present in drinking water and are they a risk to humans?

Our studies have shown that GSK pharmaceutical products are either not present in watercourses, or are present at low concentrations. Our risk assessments demonstrate that these concentrations do not pose a risk to human health or the environment. But we are not complacent and we continually monitor the latest scientific studies and findings to improve our risk assessment methodology.

› [Back to top](#)

Corporate Responsibility Report 2009

Our people

We employ over 90,000 people in 114 countries across the world. Our goal is for GSK to be recognised as an employer of choice through how we value and empower our people within our workplace culture.

We value our people through a commitment to good employment practices, including an inclusive and diverse workplace, and robust programmes for employee development, change management, employee communication, reward and recognition, and health and safety. Our employment policies apply to everyone who works at GSK and all employees are expected to understand and adhere to the principles outlined in the Spirit of GSK, which defines our mission, strategies, values and behaviours.

Also at GSK there is a particular focus on individual empowerment for all employees, which we define as trusting people to do their job by using good judgment within a clearly defined and understood framework of responsibility.

For the individual this means demonstrating the highest level of integrity, having clarity on their role, and ensuring they are accountable for their decisions.

For managers this means giving people the confidence to make decisions by providing clear direction, support and advice.

Empowerment enables better and faster decision making, creates a more agile and responsive organisation, and results in simplified processes. It also helps motivate people, encourages innovation, and improves our ability to deal with challenges.

In this section we explain:

- [The values and behaviours that underpin our ways of working](#)
- [Our approach to creating an inclusive and diverse workplace](#)
- [How we develop our people](#)
- [GSK's leadership strategy](#)
- [Our restructuring approach](#)
- [How we communicate with employees](#)
- [Our reward and recognition programmes](#)
- [Our approach to embedding a health and safety culture across GSK](#)

Employment awards

Some of the employment awards won by GSK in 2009:

- Achieved 100 per cent score on the Corporate Equality Index (US)
- Ranked fifth overall in Management Today magazine's Most Admired Company awards (UK)
- Listed in Working Mother magazine's Top 100 Companies (US)
- Ranked among the AARP (formerly the American Association for Retired Persons) Top 50 Companies

for Employees Over 50 (US)

- Britain's Top Employers 2009 (UK)
- Top 100 graduate employers (UK)
- Ranked tenth overall in Best Place to Work in Mexico
- Awarded the HRM Excellence Award by Employers federation of Pakistan
- Best Employer in Hungary, Slovakia, Czech Republic and Poland

› [Back to top](#)

Corporate Responsibility Report 2009

Our values and behaviours

Our mission is to improve the quality of human life by enabling people to do more, feel better and live longer.

In pursuit of that goal, we place great emphasis not only on what we achieve, but also on how we achieve. Our values and behaviours are integral to our performance.

GSK's values:

GSK's values are to:

- Show respect for people
- Be patient focused
- Commit to transparency
- Always demonstrate the highest integrity in your conduct.

These values underpin decision making at GSK and the way our employees are expected to work. In our values-based company, we seek people who have high integrity and will make good, honest decisions with patients in mind.

Our values and their relationship to GSK's policies are also described in our [Employee Guide to Business Conduct](#), updated in 2009.

GSK behaviours:

Changes in the healthcare market over the past decade mean we need to change our business model to one that is more centred on the needs of the customer and more innovative; how we perform as a collective organisation will determine our success. In order to be effective with growing complexity and speed of change in our external environment, GSK needs to create an internal learning culture that is embodied by six behaviours:

- **Flexible thinking**, because our work must allow for multiple options, perspectives, and potential scenarios to be built systemically into how we plan and make decisions
- **Enable and drive change**, because our ideas must be brought to life for the customer and ourselves to realise business growth
- **Continuous improvement**, because we must measure and improve our performance in order to regularly exceed customer expectations
- **Customer driven**, because we must build strategies that fundamentally raise the importance of customers in the organisation
- **Developing people**, because no one person can have all the answers, we must lead with people and create an environment that supports individual growth
- **Building relationships**, because a climate of trust and openness enables people to feel free to speak knowing they will be heard

Our values and behaviours are brought to life and embedded in the organisation in many ways:

- GSK completed a company-wide survey towards the end of 2009. More than 93,000 employees received invitations to participate in this online opinion survey to gather feedback about individual empowerment, employee engagement and our company values. The results will be available in early 2010.
- Our 360-degree feedback tool, which is mandatory for all senior leaders at GSK, measures individual and collective effectiveness against the values and behaviours
- CEO Andrew Witty speaks directly to GSK employees globally via real-time webcasts, reinforcing the importance of GSK values and highlighting employees who demonstrate effective use of behaviours
- Our programmes for leadership development, mentoring and coaching, as well as our Performance and Development Planning process, incorporate GSK values and behaviours

Corporate Responsibility Report 2009

Inclusion and diversity

Approach

Performance

We recognise the value that different knowledge, perspectives, experiences and working styles bring to GSK.

Our approach is based on respect for all employees. Our global inclusion and diversity strategy aims to create a working environment where all employees feel valued and included for the unique qualities they bring and empowered to contribute to their full potential.

The global inclusion and diversity strategy is sponsored by a senior executive who reports directly to the CEO.

In this section we outline our inclusion and diversity policies, explain our approach to gender diversity and disability, and describe GSK's employee resource groups.

Inclusion and diversity policies

Global policy on the equal and inclusive treatment of employees

We aspire to create a workplace culture that values and respects each and every employee. GSK does not condone harassment or discrimination, whether relating to race, colour, religion or belief, gender, sexual orientation, gender identity or expression, age, national origin, genetic make-up, disability or chronic health conditions. We protect all employees' privacy and confidentiality, and recognise their [human rights](#).

To help ensure adherence to equal and inclusive treatment of employees, GSK provides an anonymous ethics and compliance hotline for confidential disclosure of questionable and/or non-compliant behaviours.

Global HIV/AIDS policy

We do not discriminate against prospective or current employees based on HIV status and do not require medical testing as a prerequisite for employment. We maintain medical confidentiality at all times. We provide information and training to staff on HIV/AIDS prevention and addressing problems of stigma relating to the disease. We provide HIV/AIDS testing, voluntary counselling and treatment programmes, including free anti-retrovirals, to employees and their families in countries where these are not easily available via government healthcare programmes.

Disability

We work to ensure people with disabilities can access the full range of recruitment and career opportunities at GSK. In the UK, we partner with the Employers' Forum on Disability and strive to be a 'disability confident' organisation. Disability confident describes companies that create a culture of inclusion, remove barriers to access and make adjustments to enable individuals with disabilities to contribute as employees, customers and partners. We hold the 'Two Ticks' symbol from JobCentrePlus, which demonstrates GSK's commitment to employing disabled people.

Flexible work culture

We have identified flexible thinking as one of six critical behaviours for GSK employees, and supporting this we have some creative and agile work practices, including:

- Learning opportunities that teach flexible thinking skills

- Employment practices that support career development
- Benefits and rewards that reflect changing needs
- Performance-based flexible work practices and policies that meet both business and personal life needs

Working environments such as flex-time, part-time, and job-shares, as well as collaborative workspaces and technology, are growing tactics that further support our flexible work culture. We want employees to be empowered to discuss with their line manager what work environment will enable them to do their best work, and expect line managers to support this conversation.

Employee resource groups

GSK actively supports employee resource groups (also known as networks) to encourage professional growth and provide a forum where people with similar interests or backgrounds can meet, discuss shared experiences and work together to help make the company a more inclusive workplace. This helps engage and empower employees beyond their day-to-day responsibilities.

In addition, resource groups provide GSK managers with views and insights on diversity and help our media and marketing teams better understand our diverse customers and stakeholders.

GSK employee resource groups include:

- Asian, African American and Hispanic groups
- Cancer survivors
- Gay, lesbian, bisexual and transgender
- Mid-career and beyond
- Veterans, families and friends
- Young professionals
- Women

Each group has an executive sponsor who helps to set and achieve goals, obtain resources and promote its objectives. In the US, network leaders were given a two-day training course to further develop their leadership and strategic thinking skills.

Although most employee resource groups are in the US, the gay, lesbian, bisexual and transgender group also has a council in the UK and the young professionals group has councils in several countries, including Australia, UK, China, India, and Brazil.

Further information on our commitment to diversity – including GSK’s approach to customer and stakeholder diversity – is available on the [inclusion and diversity section of gsk.com](#).

An example of inclusion and diversity in action

GSK employees across the US are learning more about work issues faced by lesbian, gay, bisexual and transgender (LGBT) employees as part of an initiative to foster an increased sense of acceptance and inclusion at work.

Under the SafeZone programme, in 2009 six training sessions were facilitated to develop over 100 employees as 'LGBT advocates'. Led by a consultant from the University of Pennsylvania, participants discussed workplace challenges that can arise for the LGBT community and devised strategies to address them.

Additional resources are available to all employees, including internal and external web communities offering a variety of tools and resources that help create a more inclusive workplace.

› [Back to top](#)

Corporate Responsibility Report 2009

Inclusion and diversity

Approach

Performance

In 2009 we developed a new global policy on the equal and inclusive treatment of employees.

This policy raises the bar on the practice and application of equality and inclusion, with emphasis on the importance of inclusion in addition to diversity of knowledge, perspectives, experiences, working styles and genetics. We will raise awareness of the new policy during 2010.

Gender diversity

We have seen a continuing increase in the percentage of women across all levels of management at GSK. Women continue to account for 38 per cent of all management positions globally. We remain committed to maintaining this trend and further increasing the number of women in our managerial ranks, in line with our inclusive employment approach.

Gender diversity in management 2009

	% of positions held by women				
	2005	2006	2007	2008	2009
SVP, VP	21%	22%	22%	25%	25%
Director	33%	34%	35%	36%	36%
Manager	38%	39%	40%	41%	42%
Total	35%	36%	37%	38%	38%

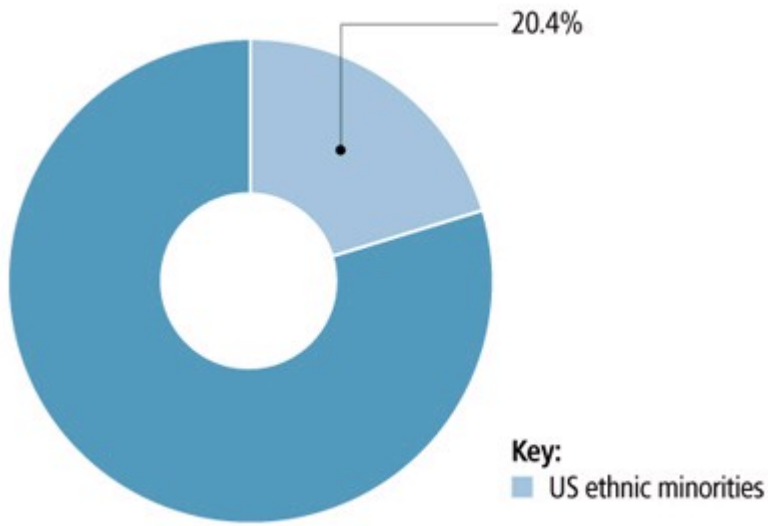
Ethnic diversity

In the US, minorities (defined as Blacks, Hispanics, Asians, Pacific Islanders, American Indians and Alaskan natives) made up 20.4 per cent of our workforce in 2009, compared with 20.5 per cent in 2008, 20.1 per cent in 2007 and 19.8 per cent in 2006. The US Census Bureau reports that the minority population accounts for 34 per cent of the nation's total population, as last reported in July 2008.

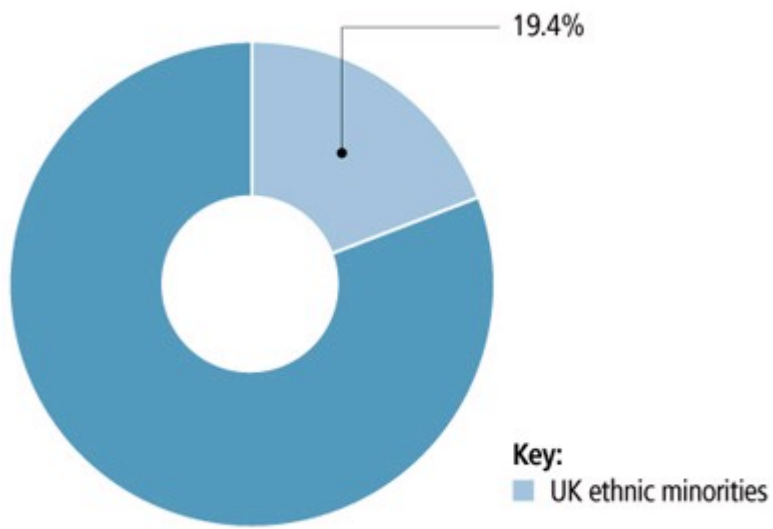
In the UK, ethnic minorities accounted for 19.4 per cent of employees in 2009 compared with 19.2 per cent in 2008, 19.1 per cent in 2007 and 18.3 per cent in 2006. Ethnic minorities accounted for 12.5 per cent of the UK population of England and Wales in 2001, the last UK Census. We use the UK Commission for Racial Equality definition of ethnic minorities. This includes anyone who does not identify themselves as White British, so this means people identified as White Irish, North American and European are included as minorities.

We also measure diversity in the UK by counting the number of employees that define themselves as non-white. In 2009, 12.2 per cent of employees defined themselves as non-white, compared with 12.1 per cent in 2008, 11.8 per cent in 2007 and 11.6 per cent in 2006.

Ethnic minorities (US)



Ethnic minorities (UK)



> [Back to top](#)

› Home › Responsibility › Our people › [Developing our people](#)

Corporate Responsibility Report 2009

Developing our people

Training and development opportunities help employees feel valued and engaged and enable them to advance their careers.

There are many aspects to career development at GSK. Our approach includes training, mentoring, coaching, performance appraisals and volunteering opportunities.

In support of our individual empowerment initiative, employees can use the EmpowerME intranet page to share what empowerment means to them, discuss issues and obtain the tools and inspiration they need to empower their teams and make confident decisions.

Training

GSK provides work-related training courses for all employees. In 2009 we offered learning programmes in 19 languages to GSK employees in over 100 countries. More than 8,000 of these programmes were offered via our online learning management system. We also offer project secondments to help employees learn new skills.

Read about our extensive [health, safety and environment training](#).

Mentoring and coaching

Our mentoring system provides support and inspiration to high-performing employees, helping to create future generations of leaders. In 2009 the top three tiers of GSK management made a commitment to mentor at least one employee each during 2010. We identify employees for mentoring through our talent review process. A variety of resources targeted to both mentors and mentees is available on GSK's mentoring web community.

Coaching is also an important component of employee development, especially among leaders in the company. We use both internal and external coaching resources to help accelerate development and enhance leadership skills.

Performance appraisals

The majority of our employees participate in performance appraisals through our Performance and Development Planning (PDP) process. PDP is a key people process within GSK. It is the basis for how we establish **what** we will achieve through our personal objectives, as well as **how** we will achieve through the GSK behaviours. The PDP process also encompasses development planning and a review of progress throughout the year against objectives, behaviours and development. Through this tool, individual contributions are aligned with GSK's business goals. Appraisals impact on reward and future career development.

Employee volunteering

We encourage employee volunteering at GSK. Volunteering not only provides much-needed support to communities and organisations around the world; it also helps GSK employees gain new experiences and skills, and in many instances helps deepen our understanding of patient needs – an important component of our [patient focused value](#).

Many GSK locations run volunteering programmes to make it easier for employees to get involved locally. Starting in 2009, GSK gives every employee one paid day off each year to volunteer in their community.

In April 2009 we launched PULSE, GSK's new volunteer initiative that gives employees an opportunity to make a significant difference in under-served communities at home or abroad. Transformational change can happen when employees use, share and pass on their professional skills and knowledge during a three to six month immersion experience within a non-profit or non-governmental organisation (NGO). Volunteers address a clear NGO need while developing their own leadership capabilities. The PULSE programme is a tangible expression of our culture and our values. It embodies our philosophy about improving the lives of others while supporting talent and development.

From our 2009 intake we had 58 PULSE volunteers on assignments with 25 NGOs such as Save the Children, AmeriCares, Direct Relief International and British Red Cross in 18 countries. Employees continue to receive their GSK salary during the placement, and in 2009 this represented an in-kind donation of £428,000.

› [Back to top](#)

Corporate Responsibility Report 2009

Leading people

Leaders play a critical role at GSK. The quality of leadership will make the biggest difference to our company in both execution of our strategy and our ability to live our values and behaviours.

In 2009 we developed a robust leadership strategy to identify and develop the highly skilled leadership cadre we need in place. The strategy looks at how we manage and invest in talented people to ensure effective succession planning and leadership at GSK.

We take a global approach to making the most of our talented workforce, looking at the quality, depth and breadth of our leaders across the world. This impacts all businesses and functions equally.

We develop and maintain realistic and ready lists of successors for critical roles. We need good succession plans, not just for senior roles but for all our critical positions across the organisation. In 2009 we completed succession plans for the top 320 critical roles in the organisation.

We are also using a systematic, disciplined approach to leadership development, providing tools and programmes to help leaders master skills needed to meet customer, employee and investor expectations.

We are targeting three groups of employees: first line leaders, middle management, and high potential talent. In 2009 we launched a First Line Leader programme for all new leaders, whether new to GSK or new to managing people.

We also launched a GSK-wide mentoring scheme where each senior leader will mentor at least one individual in 2010. Because mentors can forge connectivity between individuals and the broader organisation, they are instrumental in helping to engage and retain employees.

Leaders at GSK are expected to demonstrate [our values and behaviours](#) as they manage their teams, and are responsible for their team's understanding of our employment practices. They are accountable for developing talent and successors, and this is a high priority for every leader.

360-degree assessments provide leaders with objective feedback from those they supervise, and from colleagues, managers and others. The assessments are structured around GSK's values and behaviours, and help managers to reflect on how others perceive them and to improve relationships within and outside the company. In 2009 Andrew Witty's assessment included feedback from the GSK Board, shareholders and analysts on his performance as CEO.

We also have two self assessments that help leaders understand their preferences and career values. These are our Leadership Orientation Questionnaire and the Career Values Questionnaire.

› Home › Responsibility › Our people › [Restructuring](#)

Corporate Responsibility Report 2009

Restructuring

To improve the effectiveness and productivity of our operations and ensure the long term sustainability of GSK, the company will from time to time undertake restructuring programmes.

We are very conscious of the effect restructuring has on our employees and if options exist where we can achieve our financial goals and still preserve jobs we will do everything we can to do so. We consult with employees and their representatives before we implement measures that affect them, such as outsourcing, site closures and staff reductions. We always speak to affected employees first (except where local regulations do not allow it) and then our works councils, trade unions and other employee representatives as appropriate.

We aim to treat our employees with dignity and respect and offer a wide range of support for all affected employees. This includes a competitive severance package and outplacement support such as assistance in finding alternative employment, career counselling and retraining. We also work hard to maintain the morale of all other employees at GSK during any restructuring activity.

› [Back to top](#)

Corporate Responsibility Report 2009

Communication and consultation

Approach

Performance

Regular two-way communication with our employees is vital. It contributes to enhanced morale and productivity and reflects our values of transparency and respect for people.

We aim to keep everyone well informed and involved in company activities, and we provide opportunities to get their feedback. Our internal communications channels include:

- Face-to-face communications, for example through town hall style meetings, lunches with the Corporate Executive Team, conferences and team meetings
- The GSK Experience two-day induction programme for new starters in the UK and US. Other countries arrange their own induction programmes locally
- Spirit, our internal magazine, is available in print and on our intranet. In 2009 we introduced video interviews to give our employees a closer connection with the people, projects and products featured
- Our global intranet site, myGSK, provides updates on company and industry news, and a large range of information and resources for employees. myGSK has several features for employees, including:
 - myCEO, a dedicated part of the intranet where staff can pose questions to our Chief Executive Officer (CEO) and the other members of the Corporate Executive Team. Employees ask approximately 70 questions each month and our CEO's answers are posted regularly on the site
 - An interactive intranet feature, Your Story, which allows our employees to share stories about what inspires them and how this impacts their work with the company
- An email cascade system, where messages are sent to business leaders to share with employees, for example details of our latest financial results
- Surveys that enable us to monitor employee engagement and help us to track the impact of our internal communications

In addition, our business units communicate directly with employees through the intranet, town hall meetings and other face-to-face meetings, broadcasts and video messages.

Andrew Witty talks regularly to employees through global forums and broadcasts. His CEO Advisory Board, made up of employees from across the company, acts as an informal sounding board for ideas. Many members of the Corporate Executive Team also run live web chats and host Q&A sessions on their intranet communities, ensuring employees are aware of areas of concern within regions, business units and functional areas.

Employee surveys

Achieving our strategic goals requires an environment within GSK where our employees feel engaged, empowered and capable of performing with the highest levels of integrity. One of the mechanisms we use to achieve this is through employee surveys.

Consultation

In Europe our staff or works councils meet regularly, providing an opportunity for employees and company

management to discuss key issues and developments in the business. We also recognise trade unions for consultation and collective bargaining in many countries worldwide.

Our European Employee Consultation Forum, which includes employee representatives from 28 EU countries, works alongside national consultation processes and is governed by UK law. There is an operating sub-committee of six employee representatives which meets four times a year with six management representatives to receive updates and review proposals affecting the structure of the business. Extraordinary operating sub-committee meetings can be called should the need arise. The whole of the forum meets once a year at an annual meeting to receive a business update from senior GSK executives.

› [Back to top](#)

Corporate Responsibility Report 2009

Communication and consultation

Approach

Performance

CEO communications

During 2009 our CEO, Andrew Witty, hosted two global employee broadcasts, recorded live in front of an employee audience, broadcast to 75 countries at 130 different sites and with between 50 and 60,000 employees tuned in to each live event. At each broadcast, Andrew reviews the five strategic priorities giving examples of successes and shortcomings, and emphasises the importance of continuing to embed our organisational values and behaviours.

Each year, Andrew responds to more than 1,000 employee questions on his Let's Talk feature at the myCEO intranet site.

Communicating with our senior leaders

Andrew Witty hosted a global broadcast for GSK's top 200 leaders to update them on company news. The 2009 GSK Leadership Forum was also held online for the first time rather than as a face-to-face meeting, allowing us to extend the attendee list from the top 1,100 to the top 5,000 leaders in GSK.

Employee surveys

In 2009 we conducted two employee surveys. In early 2009, we conducted an Empowerment Survey to establish a baseline measure of how empowered our employees feel. At the end of the year we revised and conducted our internal online opinion survey where more than 93,000 employees were invited to provide feedback on individual empowerment, employee engagement and our company values. Highlights of the survey results will be included in the next update of our corporate responsibility report.

EmpowerMe

The EmpowerME community is an internal source for GSK employees to share ideas, discuss issues and celebrate empowerment. The aim of EmpowerME is to give employees the tools and inspiration needed to empower teams to make decisions with confidence and accountability.

In the last year, more than 150 postings have been shared on the EmpowerMe site. Sharing insights with colleagues around the world is just one of many ways in which GSK employees will become more empowered.

Consultation

Where appropriate, we consult with employees and their representatives before we implement measures that affect them, such as outsourcing, site closures and staff reductions. Linked to one of our core values, respect for people, we always speak to affected employees first (except where local regulations do not allow it) and then our works councils, trade unions and other employee representatives as appropriate.

At the 2009 annual meeting, held in June, the European Employee Consultation Forum heard about proposed changes within the European commercial operation, including the [formation of ViiV Healthcare](#), the new HIV joint venture with Pfizer, and the integration of Stiefel. They also received updates from the R&D, Global Community Partnerships and Finance departments.

We also discuss issues through national consultation forums. For example, the UK Information and

Consultation (I&C) Forum consists of 15 GSK-elected employee representatives and seven managers and meets three times a year. During 2009, the I&C Forum received updates about business transformation plans in the UK, the new global IT platform and changes to the UK benefits package, which include the ability for employees to purchase extra vacation days.

Our plans

We are continually reviewing the effectiveness of our communications and identifying areas for improvement. Employees are encouraged to ask questions and comment on the information we provide and the channels we use. As technology is updated, it is easier for us to encourage direct communication and discussion with employees.

In 2010 we will launch an updated company intranet that will further expand our use of technology, such as social media tools and personalised web pages. It is designed to encourage greater collaboration and communication across GSK and to break down barriers to good communication within the business.

› [Back to top](#)

› Home › Responsibility › Our people › [Reward and recognition](#)

Corporate Responsibility Report 2009

Reward and recognition

GSK offers employees a competitive salary based on industry benchmarks, as well as performance-related incentives and other benefits. This helps us to attract, retain and motivate the best people.

We reward employees for good performance against annual objectives and demonstration of those [GSK behaviours](#) appropriate to their role or development plan.

Our approach to reward and recognition is a programme called TotalReward that helps us recognise good performance and enables managers to share in GSK's success. We use feedback from managers to identify the types of reward that they prefer.

Components of TotalReward include:

- Pay, including base salary, bonus and recognition awards. Base salaries are allocated within defined bands for different employment levels
- Shares and savings such as pension provision and share schemes including long-term incentives for eligible employees
- Healthcare, vacation, childcare support and employee car ownership programmes

In 2009 a performance component was added to TotalReward. [Our Performance and Development Planning programme](#) helps employees identify what they need to do in order to perform better and achieve higher reward in future.

TotalReward applies to GSK managers around the world and all UK and US employees. The component parts of an employee's package will differ by country in accordance with local legislation and best practice.

Share ownership

Our share ownership schemes help to create a culture of ownership among our employees. GSK managers worldwide are eligible to participate in share programmes as part of their TotalReward package. In countries where all employees have the opportunity to own shares, there is a high level of participation. For example, in the UK 83 per cent of employees participate in our ShareReward scheme.

› [Back to top](#)

› Home › Responsibility › Our people › **Health and safety**

Corporate Responsibility Report 2009

Health and safety

Keeping our employees and contractors healthy and safe is a priority.

Our rigorous management system reduces the risk of harm to our employees and helps them stay healthy. It is part of our broader [environment, health, safety and sustainability \(EHSS\) programme](#). As well as being the right thing to do, this improves business performance by increasing attendance, improving productivity and reducing healthcare and insurance costs.

Our occupational health and safety target is to reduce reportable injuries and illnesses by five per cent a year from 2006 to 2010, and to be placed within the top quartile of comparable industry ratings by 2012.

This section explains our approach to:

- Health and safety management
- Hazard assessment and communication
- Safety programmes
- Health and wellbeing programmes
- Health and business continuity
- Training and awareness
- Performance in 2009

› [Back to top](#)

Corporate Responsibility Report 2009

Health and safety management

We manage health and safety through an integrated [environment, health, safety and sustainability \(EHSS\) management system](#), reviewed and updated in 2009. The system is aligned with recognised international standards such as ISO 14001 and OHSAS 18001.

This incorporates our EHS and sustainability vision and policy and associated standards. Our [EHSS Plan for Excellence](#) sets targets for improving EHSS performance up to 2015.

In parallel, GSK has created a new Centre of Excellence, called Health Safety & Performance, focused on human sustainability. The goal is to nurture a safe, healthy, resilient, energized and engaged workforce, to complement GSK's sustainable business and environmental practices.

Our focus for the next three to five years will be in three areas. First, we will nurture the transformation of our safety and health culture from compliance to values driven through a variety of cultural and organizational interventions. We will build individual and organisational accountability and empower the workforce to proactively address safety and health concerns in their work. Secondly, we will focus our greatest energy on those workplace and personal safety and health risks which have the highest toll on productivity, health, and cost at GSK. Through data analysis we have identified these as musculoskeletal / human factors issues, driver's safety, and depression. Finally, we will focus on top line growth of our global winning practices such as Living Safety, Personal and Team Resilience and Energy for Performance. We will also adapt these programmes to address both risks to safety and health.

We systematically assess and manage occupational health and safety risks and performance. When incidents do happen we identify root causes and take action to prevent reoccurrence. Addressing the causes of incidents helps to eliminate risks and hazards, and prevent future occupational injuries and illnesses. We employ health and safety professionals across sites, within business units and at the global level to manage health and safety risks.

Our occupational health and safety data are [independently assured under our EHSS assurance process](#).

Audits

We conduct occupational health and safety audits at our sites every one to four years, to assess their health and safety systems as well as their compliance with legislation and our EHSS standards. The frequency of audit visits is determined by the degree of risk at the site, its health and safety performance and the issues raised by previous audits. Audit results are presented to the Audit Committee of the Board of Directors.

In 2009 we audited 28 GSK sites and conducted follow-up visits at a further ten facilities. The average audit score was 81 per cent, up from 78 per cent in 2008 and on track towards our target of 82 per cent by 2010. Eleven sites demonstrated excellent health and safety management with scores of at least 80 per cent, with three of those achieving 90 per cent or above. No site achieved a score below our minimum of 50 per cent.

Overall, the areas of best performance included the commitment of sites to occupational health and safety, employee health management and fire safety. The weakest performance areas included ergonomics and machinery safety. Audits did not identify any critical health and safety risks at established GSK sites, but did reveal four such risks at newly acquired sites. We are monitoring these facilities to ensure that appropriate action is taken to mitigate risks and comply with our standards.

Read more about our overall [environment, health, safety and sustainability audits](#).

OHSAS 18001 certification

Thirty-one GSK sites (including 30 of our 77 Pharmaceuticals and Consumer Healthcare manufacturing sites, and one Consumer Healthcare R&D site) are certified to the international health and safety standard OHSAS 18001, including three sites which achieved certification in 2009.

In 2009 we evaluated the OHSAS 18001 certification programme and decided that certification does not benefit all sites equally. Instead, we will select sites for certification based on their performance in internal health and safety audits. High performing sites need not become certified. This is a change from our previous goal for all manufacturing sites to be jointly certified to OHSAS 18001 and environmental standard ISO 14001 by the end of 2010.

Our OHSAS 18001 certified sites are in Argentina, Australia, Brazil, China, Egypt, France, Germany, India, Japan, Kenya, Mexico, Panama, Philippines, Poland, Romania, Singapore, Spain, Saudi Arabia, Turkey, the US and the UK.

> [Back to top](#)

Corporate Responsibility Report 2009

Hazard assessment and communication

Assessment

Understanding the potential hazards posed by the materials we produce or use in research, development and manufacturing is essential to effectively manage health and safety risks and prevent damage to the environment.

Our occupational toxicologists and environmental scientists assess materials hazards throughout product development. Increasingly, we use computer-based modelling and in vitro methods instead of animal tests. We use hazard information to assign occupational and environmental exposure limits used in the design of systems to protect our employees' health and to protect the environment from chemical contamination.

Our hazard assessments help us meet regulatory requirements such as the new EU [Registration, Evaluation and Authorisation of Chemicals \(REACH\) legislation](#) and the Globally Harmonised System of Classification and Labelling of Chemicals (GHS).

Communication

We provide hazard information to enable our employees, contract manufacturing partners and customers to handle and dispose of our materials and products safely.

We develop safety data sheets for new materials and products as they progress through the development process. This ensures that health and safety information is readily available to our staff before they handle chemicals and to our customers when the product is launched to enable them to effectively control workplace risks.

We distribute safety data sheets via a website. This provides health, safety and environmental information for nearly 4,500 GSK materials and key manufacturing and process chemicals. It also includes over 2,200 safety data sheets for pharmaceutical, biological and consumer healthcare products. The information is regularly updated and is available in English, French, German, Italian, Portuguese and Spanish.

Safety data sheets for our products are available on our [website](#) and are also communicated directly to our customers via fax on demand, or through customer response centres.

Safe transport of materials

We transport materials that require special handling such as chemicals, biological and radioactive materials we use in research and manufacturing, and finished products. We have a network of employees trained to ensure materials are transported safely in compliance with national and international laws and conventions.

We use two systems that support tracking, classification and emergency information for the transportation of chemical, biological and radioactive materials. The GSK Shipper system is used by R&D sites, while manufacturing sites use the SAP system.

Understanding fire and explosion risks

Our in-house fire and explosion laboratory tests materials handled in R&D and manufacturing to determine the risk of fire or explosion. This work is primarily driven by the requirements of the EU regulations on explosive atmospheres (Directive 99/92/EC, ATEX 137). When manufacturing sites receive hazard data from the testing laboratories, they undertake risk assessments to design work practices that eliminate or reduce the risk of fires and dust explosions.

› [Back to top](#)

Corporate Responsibility Report 2009

Safety programmes

We operate a number of programmes to keep our employees and contractors safe:

Chemical exposure

We have rigorous procedures and controls to protect employees from exposure to chemicals.

Our goal is to make 80 per cent of existing operations involving the handling of hazardous compounds 'respirator free' by the end of 2012. We decided to extend our target (which previously was 2010) because we now focus on adapting operations with the highest degree of risk first, rather than those that will be easiest to adapt. All new facilities should be 'respirator free' from the start.

'Respirator free' means employees will not need to wear respiratory protective equipment for routine production tasks. Instead, sites will install technology that prevents the release of hazardous compounds into the work environment. For example, our facility in Cork, Ireland has a long established technical expertise in containment and ways of working for handling highly potent materials, and our penicillin facility in Pakistan has a special containment system. We have also developed a proprietary manufacturing technology which greatly reduces operator exposure to medicines as they are manufactured.

Each GSK site monitors air quality to assess exposure to hazardous compounds and implements controls to achieve our 'respirator free' goal. Our occupational hygienists, employee health staff and engineers work together at site, regional and global levels to reduce employees' exposure to chemicals.

By the end of 2009 our monitoring showed that 52 per cent of operations were 'respirator free'. For situations where it is not possible to be respirator free, employees will remain protected by appropriate respiratory and other equipment.

Process safety

Many of our products begin with the formulation and processing of hazardous materials such as flammable solvents and combustible powders. Our scientists look for opportunities to eliminate the use of these hazardous materials through our green chemistry and green technology programmes. Where substitution or elimination is not an option, we aim to ensure that safety is built into manufacturing, research and development processes, and that employees receive training to understand risks and implement appropriate controls.

Our engineers use an online system to assess the safety of process and plant designs, develop plant maintenance strategies, and share hazard information and control strategies across GSK.

In 2009 we updated our process safety management system and continued to integrate it into our EHSS management systems at all GSK sites. The system was updated in response to an explosion at our Irvine factory in 2006 which injured two employees and includes:

- New global engineering standards for process safety
- Assessments against the engineering standards, with gap analyses
- Upgraded and standardised process hazard identification and risk assessment techniques that represent current good practice
- Process safety performance indicators applied in the highest risk areas of the business

- Steps to embed process safety in the overall safety culture
- New training and competence programmes

Sites will implement the process safety management system by analysing the gaps between these six elements and their practices, and correcting any deficiencies. Implementation is overseen by our Director of Process Safety, a position established in 2008.

In 2009 there were around 70 process safety incidents but none of these resulted in injuries or environmental damage.

Safety engineering

Our safety engineering programme focuses on improving construction and plant safety and ensuring effective emergency response systems. We have developed online safety engineering guides to managing the risk of fire and explosion and to provide guidance on machine guarding and electrical hazards. These provide a standardised approach to managing safety risks across GSK. We work closely with our property insurance company to ensure that our sites are designed, constructed and maintained to eliminate or minimise incidents which would result in property loss or business interruption.

Safety is also built into and maintained at our sites through our: Risk Assessment and Control Processes, Construction Contractor Safety Programme, Capital Project EHS Review Process and our Emergency Response Programmes.

'Living Safety'

Our 'Living Safety' programme is designed to embed a strong safety culture throughout GSK. It is currently deployed in the manufacturing and research organisations where it teaches employees about the behaviours we expect them to demonstrate in their everyday work, to keep them and their colleagues safe. For example:

- Everyone, including contractors, is responsible for implementing the health and safety management system. Everyone must follow rules, report any potential risks they encounter and get involved in improving safety performance
- Supervisors play a vital role in ensuring GSK's health and safety standards are understood, implemented and maintained by their team (including contractors). Supervisors must ensure compliance with policies, encourage their team to get involved in improving safety performance and promote risk awareness
- Managers' attitudes to health and safety are important to employees. To set a good example, managers must establish high health and safety standards, communicate openly with employees about issues, quickly address any risks they identify and involve others in their efforts to improve safety performance.

Ergonomics and human factors

Musculoskeletal illnesses and repetitive strain injuries are some of the leading causes of time away from work. We have a target to reduce the number of these illnesses and injuries by five per cent each year through to 2010, and to be ranked within the top quartile of industry ratings by 2012.

Good workplace and job design, known as ergonomics and human factors, helps employees to do their jobs effectively while reducing the risk of musculoskeletal illnesses and injuries. Ergonomics and human factors, if applied properly, can reduce illnesses and injuries, as well as work performance errors and lost time.

There are 70 teams working across GSK to assess and manage the ergonomic risks in our existing operations and planned projects. Teams include members from manufacturing quality, safety, health and medical services. Teams work together to identify risks, develop solutions and share best practice globally through a dedicated ergonomics intranet community.

In addition, nearly 1,300 trained facilitators help to manage computer-based ergonomic risk assessments for almost 32,000 employees. The assessments give employees the opportunity to talk about discomfort they experience when using their computers, and discuss ways to reduce this discomfort and injury risk. Information about ergonomics computer best practice is also available to employees through our ergonomics community intranet pages.

In 2009 we focused on improving risk assessments and reducing ergonomics-related injury and illness by:

- Establishing a new system to quickly identify risks for employees who use computers most frequently, before they report any discomfort
- Creating and training new ergonomics improvement teams in Brazil, China, India and the US
- Continuing to put measures in place in our manufacturing operations, for example to limit injuries from manual lifting

We have achieved a 33 per cent improvement in the ergonomics-related injury and illness rate between 2006 and 2009. This is more than double our 15 per cent improvement target for the same time period.

Driver safety

Our sales representatives spend significant amounts of time driving and are at risk of being involved in road traffic incidents. Driving accidents are the most common cause of fatalities and caused the death one GSK employee in 2009. In 2009 15.9 per cent of the injuries with lost time were due to motor vehicle accidents, as were 15.3 per cent of the injuries without lost time. See [Fatalities and serious injuries](#).

We aim to reduce the risk of road traffic accidents through our global driver safety programme. This includes instructions and guidelines on driver training, vehicle selection, risk assessment and accident reporting. We have a motorbike rider safety manual for employees in countries where we provide motorbikes or scooters.

› [Back to top](#)

Corporate Responsibility Report 2009

Health and wellbeing programmes

GSK offers programmes to boost employee health and wellbeing. This helps sustain employee energy and engagement with their work and can contribute to improved productivity and performance.

Support for employee wellbeing at GSK includes flexible working options and initiatives such as health risk appraisals, screening for diabetes and hypertension, smoking control support, fitness and nutritional advice and immunisations. We focus on the leading causes of employee illness and disability such as depression, non-work-related injuries, heart disease, stroke and respiratory infections.

Increasingly we are focusing on ways to encourage team and personal energy and resilience in times of high pressure.

Energy and resilience

Resilience is described as the ability to be successful in a high-pressure, fast-paced and continuously changing work environment. Resilience helps prevent mental illness due to stress, a leading cause of ill health and disability at work. It also supports good performance.

Energy for Performance

When employees have energy they can focus better and work more efficiently. The Energy for Performance (E4P) programme teaches participants how to manage their physical and mental energy more effectively, and helps them develop habits that improve their performance at work.

In 2009 1,194 employees participated in E4P workshops. In total, 5,000 employees from 25 countries have attended E4P workshops between 2007 and 2009. Over 89 per cent reported significant improvement in their physical and mental performance and emotional energy. Participants found that their improved energy levels persisted for at least 12 months after the workshop.

Personal resilience

We run workshops for employees who want to enhance and build their personal resilience. Focusing on improving work and home life, the programme aims to help employees increase their focus, energy and confidence while also helping to reduce tension, anxiety and fatigue. Since the programme started in 2008, 1,288 employees have participated in the programme.

Team resilience

Healthy, collaborative and motivated teams are critical to business success. The team resilience programme helps employees and their managers to identify sources of pressure on their teams, such as process complexity or lack of workplace flexibility or accountability, and take action to address any concerns. The programme helps teams take more control of their work, and eliminate or manage the sources of pressure that can lead to ill health or inefficiency.

Since the programme began in 2003 it has been completed by teams in 51 countries, comprising 27,500 employees. Participants have identified positive outcomes, including more successful team work, more efficient machine operation and better sales. A 25 per cent drop in work-life conflict and a 21 per cent increase in satisfaction with GSK as an employer have also been recorded.

Wellbeing and work-life balance

GSK offers programmes to improve the health of employees and their families. We find this increases employee commitment and productivity and reduces absenteeism and the cost of ill health. Support varies between countries and according to local needs. Our sites use public health and GSK data to identify high-risk areas and investments that lead to significant health and cost improvements.

Programmes often include benefits such as on-site health and fitness centres, flexible working arrangements, immunisations, regular medical check-ups, assistance to stop smoking, disease screening and management, family support services and health education. We also assist employees suffering from chronic diseases to ensure they have access to the correct long-term treatment and support. Our programmes help local healthcare services by focusing on health education, prevention awareness and management of current conditions. We have created a network of GSK employee health professionals to share health and wellbeing best practice.

GSK also supports key public health efforts such as World AIDS Day, the World Health Organization's Health Day, Tobacco Free Day and Global Hand-washing Day.

› [Back to top](#)

Corporate Responsibility Report 2009

Health and business continuity

We have contingency plans in place to protect our employees and business in the event of natural disasters, man-made emergencies or a pandemic.

The rapid global spread of H1N1 influenza in 2009 demonstrated just how critical these measures are for ensuring that our business can continue to function and that we can continue to supply critical medicines to patients.

Our pandemic preparations are helping us protect more than 435,000 staff their dependants and key complementary workers in over 110 countries. Our stockpile of multiple antiviral medicines that can be used to prevent or treat pandemic flu, including *Relenza* and our pandemic vaccine, meant we could quickly treat any employees suffering from flu.

We have developed a special website accessible on our intranet and externally, that acts as a single source for all global and local flu information across GSK.

Before the H1N1 outbreak, we already offered employees annual seasonal flu vaccination in 95 per cent of our markets, as well as travel health programmes to help keep employees healthy and well when visiting other countries for work.

Read more about [our response to the H1N1 flu pandemic](#).

› [Back to top](#)

Corporate Responsibility Report 2009

Training and awareness

Training helps to create a workplace culture where occupational health and safety is taken seriously. Employees who are responsible for managing occupational health and safety issues at sites and business units receive regular training and in turn instruct employees about safe working.

We give training on our environment, health, safety and sustainability (EHSS) standards, as well as programmes such as process safety, chemical exposure protection, identifying risk, auditing and ergonomics. Sites develop and conduct training based on local needs and capabilities. Some use our internal learning tools, commercially available training programmes or locally available government or university sponsored training programmes.

We have developed a training framework that identifies gaps in employees' knowledge of health and safety and provides in-house and external training courses. Our health and safety professionals share knowledge and best practice via teleconferences, intranet communities, training programmes and discussion forums.

We raise awareness about employee health and safety issues through:

- Announcements on our myEHS Community intranet sites
- The CEO's Sustainability Awards programme
- Health and Safety Week celebrations held at site level, to inspire employees to address potential risks at work and at home.

In November 2009 we launched a new section on our company intranet that provides employees with access to over 20 EHSS training packages from across the business. By joining EHS Training Connect, employees become involved in a network of GSK's health and safety professionals and can learn from one another about health and safety best practice.

In 2009 we ran ten courses to train facilitators for our Living Safety programme, and two process safety courses. Several sites have completed machinery safety training, and more than 30 employees completed a training module on the control of hazardous substances.

› [Back to top](#)

Corporate Responsibility Report 2009

Performance

Performance

Data table

There were no safety-related fines or penalties in 2009

Injury and illness rates

Our main health and safety measure is the reportable injury and illness rate. We also measure the number of injuries and illnesses that result in lost days, as well as the number of days lost from these injuries and illnesses. This provides an indication of the severity of the incidents, although it is only a rough guide. We have set targets to improve injury and illness rates.

Injury and illness target

Injury and illness target	Progress 2006 to 2009
To reduce the reportable injury and illness rate by five per cent each year to the end of 2010	17 per cent (average of 5.4% per year)
To reduce the reportable musculoskeletal illness and injury rate by five per cent each year to the end of 2010	28 per cent (average of 9.3% per year)
To rank in the first quartile of an industry benchmark group	Fourth quartile

Data cover GSK employees and contract workers who we directly supervise. We report separately data for contractors who work on GSK sites but supervise their own staff in the [data table](#). Contractors' data are not externally verified.

Injury and illness data are collected from 78 of our Pharmaceuticals and Consumer Healthcare manufacturing sites, 14 vaccines sites, 29 Pharmaceutical and Consumer Healthcare research and development sites, the US and UK headquarters sites, 21 offices and sales groups with more than one million hours worked, and 61 of the smaller offices and distribution centres. In 2009 six sales and office sites did not report injury and illness data. We collect environmental data from acquired entities in their first full year in the group, not in the year of acquisition.

Reportable injury and illness rate

Reportable injury and illness rate



The reportable injury and illness rate continues to improve at an average of more than five per cent annually across GSK. In 2009 there were 792 injuries and 167 illnesses, resulting in a total reportable injury and illness rate of 0.47 per 100,000 hours worked. This was an improvement of 17 per cent, exceeding our target. Machinery safety projects at many manufacturing sites, and projects encouraging employee safety awareness, are examples of initiatives contributing to this improvement.

Our reportable ergonomics-related injury and illness rate has improved by 28 per cent since 2006.

While our reportable injury and illness rate continues to improve, the industry benchmark group also continues to improve. This means GSK remains in the lowest quartile of the industry benchmark. We will continue to implement safety programmes like such as Zero Access and Living Safety programmes to improve our position within the benchmark.



SGS verified

Injury and illness causes

The most frequent types of incident overall are ergonomic, mainly musculoskeletal illnesses and repetitive strain injuries, accounting for 24 per cent of all injuries and illnesses. We continue to expand our [ergonomics programmes](#) to address this cause of injury and illness.

The second most frequent reportable injuries are slips, trips and falls, which account for 21 per cent of all injuries and illnesses in 2009.

Injuries due to machinery accounted for five per cent of all injuries and illnesses. Our manufacturing sites are renewing their focus on machine safety to [continue improvements](#) in this area and have launched their 'Zero Access' machinery safety programme that will be implemented at all Secondary and Consumer Healthcare manufacturing sites during 2009 to 2012.

Road traffic accidents accounted for 13 per cent of all injuries and illnesses in 2009 and accounted for one fatality. [Driver safety](#) is a continuing area of focus especially in the sales force.

Mental ill health accounts for five per cent of all illnesses but these cases result in the highest number of days lost, at over 71 days per case on average or 29 per cent of the total number of days lost for all illnesses. This is being addressed by our [resilience programme](#).



SGS verified

Fatalities and serious injuries

Employee fatalities

Eight year trend in employee fatalities

2009	1
2008	2
2007	2
2006	1
2005	1
2004	2
2003	5
2002	3

In 2009 one of our sales employees in Egypt was killed while driving to a business meeting. The employee hit a traffic light while trying to avoid a pedestrian who had stepped into traffic.

In addition to the one employee death, a housekeeping contractor slipped and fell at our China commercial sales administrative offices and subsequently died due to injuries sustained from the fall.

In 2009 there were three amputations to GSK employees and one involving a contractor. All three employee amputations were machinery incidents where operators placed their hands into equipment that had not been switched off. A summary of the incidents follows:

- Amputation of right thumb while clearing a jam in a bottle packaging line
- Operator removed fixed guard and placed fingers in rotary valve resulting in amputation of middle and index finger of right hand
- Amputation of two fingers while clearing a jam on a palletiser
- Amputation of a finger of a contract worker when it was caught on an object in his truck

Machine guarding and the 'zero access' programme will continue to be emphasised.



Injury and illness milestones

All GSK operations strive to work without experiencing any lost-time injuries or illnesses. We issue certificates signed by business heads to sites that reach one million hours worked without a lost-time injury or illness. Sites that reach two or more million hours worked without a lost-time injury or illness are awarded certificates signed by our Chief Executive Officer.

Small sites with fewer employees can obtain a certificate for three or more years worked without a lost-time injury or illness.

Milestones achieved in 2009 for hours worked without a lost-time injury or illness:

- 1 million hours: 4 sites
- 3 million hours: 1 site
- 4 million hours: 3 sites

- 3 years: 1 site
- 5 years: 1 site

› [Back to top](#)

Corporate Responsibility Report 2009

Performance

Performance

Data table

See [detailed breakdown](#) for more data.

Employee Injury and illness

Injury and illness - GSK employees	2005	2006	2007	2008	2009
Hours worked (millions)	196.6	195.4	196.6	192.1	202.1
Fatalities	1	1	2	2	1
Number of injuries with lost time	554	568	583	522	490
Calendar days lost - injuries	11,627	11,307	11,391	11,680	9,415
Number of illnesses with lost time	82	97	98	64	35
Calendar days lost - illnesses	3,069	5,443	4,155	1,539	1,243
Number of injuries without lost time	462	449	393	324	301
Number of illnesses without lost time	321	288	263	192	132
Lost time injury & illness rate	0.32	0.34	0.35	0.31	0.26
Reportable injury & illness rate	0.72	0.72	0.68	0.57	0.47
Ergonomic lost time injury & illness rate	0.06	0.08	0.09	0.08	0.06
Ergonomic reportable injury & illness rate	0.16	0.18	0.18	0.16	0.12
Calendar days lost rate	7.47	8.57	7.91	6.88	5.27

Injury and illness - non GSK employees (not verified by SGS)	2005	2006	2007	2008	2009
Hours worked (millions)	22.8	22.9	26.1	22.4	24.8
Fatalities		0	2	0	1
Number of injuries and illnesses with lost time	98	89	59	75	39
Calendar days lost	1575	968	924	708	539
Number of injuries and illnesses without lost time	275	375	400	209	187
Lost time injury & illness rate	0.43	0.39	0.23	0.33	0.16
Reportable injury & illness rate	1.64	2.03	1.76	1.27	0.91
Calendar days lost rate	6.91	4.24	3.55	3.16	2.18

1. The occupational health and safety data cover both our employees and contract workers who are directly

supervised by GSK employees. We report a snapshot of injury and illness performance for the year. Cases may be added after the end of the year, so prior years may change

2. Lost-time injuries and illnesses are work-related injuries and illnesses that are serious enough to result in one or more days away from work
3. All rates are per 100,000 hours worked
4. Lost calendar days are the calendar days, including weekends, which employees could not work because of work-related injuries and illnesses. This helps to provide a measure of the severity of injuries and illnesses
5. Reportable injuries and illnesses without lost time are incidents that did not result in time away from work (lost time). They are more serious than first aid but not serious enough to result in lost time



SGS verified

› [Back to top](#)

› Home › Responsibility › Our people › [Case studies](#)

Corporate Responsibility Report 2009

Case studies

External business partners share GSK values

If you want to do business with GSK, then you must share our culture of inclusion and diversity.

That's the message we give suppliers, contractors and other third parties as we strive to ensure an inclusive and diverse working environment throughout our supply chain.

In 2009 we used inclusion and diversity criteria in the selection of vendors to provide us with global facility maintenance, catering and site security services. We assessed prospective suppliers' diversity figures, policies and programmes, and efforts to promote diversity in their own supply chains. The result was that three suppliers were awarded contracts from the list of vendors which bid for the contracts.

PULSE: Being the change

In 2009 we established a new employee volunteering programme called PULSE. In its first year PULSE provided the opportunity for more than 50 employees from around the world to take a three to six month break from their jobs at GSK to help others. Some travelled across the globe, from Azerbaijan to Bolivia, from El Salvador to Ethiopia, and from Tajikistan to Tanzania, whereas others worked closer to home.

Each PULSE volunteer works full time for a host non-governmental organisation (NGO), using their personal knowledge, skills and abilities to build a positive, sustainable change for their host. They are safe in the knowledge that they have the support of local management, their job will not be filled in their absence, and they will continue to receive their usual pay. The experience also helps PULSE volunteers accelerate their own leadership development, and they can bring lessons learned back to their roles at GSK.

Demand to take part in PULSE is high. We select volunteers who excel in their work at GSK, possess skills that could help the NGOs, and demonstrate flexibility, a desire to learn, and an awareness of community needs.

GSK EmpowerMe empowers all

From San Jose, Costa Rica, a GSK blogger writes about "Giving up control but not responsibility". In China, another offers his perspective on "What is behind empowerment", while in Switzerland a third shares "Lessons learned from other countries".

What all these employees have in common is that they are using the GSK EmpowerMe intranet community to share their stories of how they or their teams have felt empowered to make positive change.

For example, feeling inspired having watched a video on empowerment, the Costa Rican employee immediately looked for ways to empower others. She agreed with her staff to "give up control of making decisions if they were willing to step up to the plate and make some of their own decisions". At the same time, she made a commitment to provide her team with the mentoring and coaching they need to make effective decisions. The result is a highly motivated team with better decision-making skills and more trust.

Of the many employee postings on the EmpowerMe site, one message is clear: everyone has something important to contribute, and GSK can benefit greatly from bringing out the best in every employee.

› [Back to top](#)

Corporate Responsibility Report 2009

Q&As

Here we respond to questions raised by our stakeholders.

As you reduce your workforce, how will you ensure that your remaining employees are not faced with additional stress in their jobs?

We recognise that stress at work is an important issue. We have established programmes to help individuals and teams remain fully engaged physically, mentally, emotionally and spiritually at work and at home. We also have a variety of programmes that support team and personal resilience to help identify and manage the most significant sources of pressure at work and home. A variety of interventions are in place for employees to use on-site health and fitness centres, flexible working arrangements, employee assistance programmes, backup child care, family support services and health education.

Overlaying all of this GSK aims to simplify its operating model and create a culture of individual empowerment, where each employee takes responsibility for his or her own work. Empowering individuals to make decisions and carry out work without layers of bureaucracy will support the goal of reducing unwanted stress in jobs.

How is your Operational Excellence programme affecting employees?

Regrettably, our Operational Excellence (OE) programme involves job losses. For many of the jobs that remain, however, OE has also had positive impacts such as increasing the scope, impact and, in many cases, autonomy within jobs. This empowers staff with greater decision-making latitude. We do everything that we can to support employees who are leaving the company, including providing a competitive severance package and outplacement support such as assistance in identifying alternative employment, career counselling and retraining.

We also work hard to ensure the programme does not have a negative impact on the morale of other staff. We have produced a guide for managers with information on how to support employees during the uncertainty, anxiety and stress encountered during major organisational change.

What are you doing to increase the number of women in senior positions at GSK?

We are pleased that the percentage of women in management has increased incrementally over the last four years. However, we recognise that there is still room for improvement, especially in senior management positions and in roles within historically male-dominated disciplines such as science and engineering.

The percentage of women in management is increasing because we are committed to internal succession planning that ensures high-potential women are identified at every stage of their careers, and are provided with coaching, mentoring and clear career development opportunities.

Your health and safety performance is below the industry average. What needs to improve?

We know we need to improve our performance in this area. We have identified ergonomic improvements and the need to address attitudes and empowerment to act on health and safety in the workplace as key focus areas for improving our performance.

We are targeting our intervention, awareness and training programmes on these areas. We have also launched a toolkit, called 'Living Safety', to help sites get a 360-degree view of risks, attitudes, beliefs and behaviours. It is designed to embed a strong safety culture throughout GSK by teaching employees at all levels about the behaviours we expect them to demonstrate in their everyday work, to keep them and their colleagues safe.

This has been adopted by our Pharmaceutical and Consumer Healthcare manufacturing operations and is

being used selectively in other groups.

What progress have you made toward your 'respirator free' target?

We use the results of baseline monitoring of the level of exposure to chemicals in the workplace to define where new and upgraded engineering controls are needed to meet the target for employees in 80 per cent of operations to be able to work without needing to wear respiratory protection by 2012. Our initial target, set in 2005, was to achieve this by 2010. However, due to prioritisation of other safety and health initiatives, this target has been postponed to 2012. Nevertheless, we have made good progress and are committed to completing this programme. Furthermore, there are advantages to the postponement as it will allow us to take advantages of synergies with other programmes such as energy reduction.

We are adapting operations with the highest degree of risk first. Half our operations have now achieved this level of engineering control, pending completion of full verification monitoring. We continue to upgrade engineering controls to achieve 'respirator free' levels of control. For situations where engineering controls are not possible we will make sure appropriate respiratory protective equipment is used.

› [Back to top](#)

Corporate Responsibility Report 2009

Human rights

We are committed to upholding the UN Universal Declaration of Human Rights, the OECD Guidelines for Multi-National Enterprises and the core labour standards set out by the International Labour Organization. We are a signatory to the UN Global Compact, a voluntary global standard on human rights, labour, the environment and anti-corruption.

We believe that governments have a responsibility to define and enforce a legal framework for human rights in accordance with international laws and agreements.

Businesses also have responsibilities. We work hard to uphold human rights within our sphere of influence, which includes [employees](#), [suppliers](#), [communities](#) and [society](#). We have most direct control over human rights in our own operations.

As a marketer of medicines, we strive to make them as widely available as possible while running our business in a sustainable way. Our approach includes [research partnerships into diseases of the developing world](#) and [flexible pricing to make our products more affordable in developing countries](#).

We put safeguards in place to ensure that the human rights of people taking part in our clinical research are protected. This includes the [informed consent process](#) and procedures to [protect patient privacy](#). We are especially careful to protect the rights of any [children involved in our clinical trials](#).

We recognise and support the role that the Convention on Biological Diversity (CBD) plays in providing a framework for the conservation of biological diversity and for protecting the rights of countries and communities to access and share benefits arising from it. Read more about [our approach to the CBD and use of biological materials](#).

Maintaining high standards of human rights benefits our business by:

- Helping us get the best from our employees
- Supporting our relationships with communities near our sites
- Ensuring supplier contracts run smoothly and provide a reliable supply of high-quality products
- Protecting our reputation

More information on GSK and human rights

Human rights are relevant to many of the issues covered in this report. This section gives an overview of our approach. For more information:

See the [human rights clause](#) included in our contracts with suppliers

Read more about our [supply chain](#)

Read about our efforts to improve [access to medicines](#)

Read about our [investment in local communities](#)

Read about our [employment practices](#)

Read about the [informed consent process](#) and our approach to [clinical trials involving children](#)

Read our position statement on the [Convention on Biological Diversity](#)

› [Back to top](#)

› Home › Responsibility › Human rights › **Employees**

Corporate Responsibility Report 2009

Employees

Our employment standards on issues such as diversity, equal opportunities and health and safety protect employees' human rights.

As an employer we are:

- Committed to providing a fair salary and good employment conditions
- Committed to providing a healthy, safe and secure workplace for all employees and contractors
- Opposed to discrimination at work and committed to promoting respect for diversity
- Committed to promoting the personal development and dignity of every employee
- Respectful of employees' right to join an independent trade union and freedom of association
- Opposed to all forms of slavery and exploitative child labour and will work with appropriate partners to address this problem responsibly wherever we encounter it

In 2009 we introduced a new global policy on [equal and inclusive treatment of employees](#), designed to ensure consistently high standards across GSK. We will audit adherence with this policy alongside other human resources policies as part of a regular employment practices review.

Employees can report any concerns to their supervisor or line manager, to our human resources department or to our ethics and compliance office. They can also use our [Global Confidential Reporting line](#). No calls alleging human rights violations were made to the line in 2009.

Read more about our [employment practices](#).

› [Back to top](#)

› Home › Responsibility › Human rights › [Suppliers](#)

Corporate Responsibility Report 2009

Suppliers

As a buyer of raw materials, manufactured goods and services around the world, we require all our suppliers, contractors and business partners to meet the same standards on human rights as GSK.

[Human rights clauses](#) are included in our contracts. We conduct regular audits of existing suppliers and only engage new suppliers that meet our expectations. Our supply chain is large and complex, so we target our audits at the areas of greatest risk. We will not knowingly use suppliers who are responsible for human rights infringements.

We consider human rights issues during routine interactions with critical suppliers (contract manufacturers and suppliers that present the greatest risk to GSK in one or more key risk areas). [Environmental, health and safety \(EHS\) audits](#) of potential new and existing critical suppliers also include questions which help us identify potential breaches of our human rights clauses. Suppliers are asked for information on policies and practices relating to:

- Age limits for employees
- Discrimination against employees and the local population
- Prevention of abuse of individuals
- Wages, benefits and working hours (whether they meet the legal minimum)
- Rights for workers to organise and recognition of worker organisations

These questions do not contribute to the EHS audit score, but may be a reason not to progress business with a supplier. Where we identify human rights issues we make recommendations for how the supplier can improve performance. We require the supplier to submit regular progress reports and undertake further site visits to ensure they improve their performance.

We are members of the Pharmaceutical Supply Chain Initiative (PSCI), an industry collaboration that has set out guiding principles and standards for suppliers that cover human rights and labour issues. The PSCI is looking at ways to improve supplier standards, especially in emerging markets.

Read more about our [supply chain](#).

› [Back to top](#)

› Home › Responsibility › Human rights › **Communities**

Corporate Responsibility Report 2009

Communities

We respect and promote the rights of people in the communities near our operations. For example:

Local communities

GSK aims to have good relationships with all the communities around our sites and to operate in ways that do not infringe their human rights. We seek to minimise our impacts on the local environment and operate our sites safely. We aim to bring social and economic benefits to areas where we have a presence. Read more about our [investment in local communities](#).

UN Convention on Biological Diversity (CBD)

The Convention on Biological Diversity provides a framework for the conservation and sustainable use of biodiversity. It also promotes fair and equitable sharing of the benefits arising from the use of genetic resources, including those used in the research and development of new medicines and vaccines. GSK supports the CBD's role.

Given the diversity of biological materials and the many ways in which they are used in research and development, it is not possible to generalise the role they play in biomedical research or the fundamental value of any material to a particular project or product. Careful consideration is therefore needed when seeking to define, implement and monitor appropriate access to genetic resources and the sharing of benefits arising from their use.

In this context, we participate in ongoing international discussions on a possible legislative framework for access and benefit sharing provisions. Any legislation agreed needs to strike an appropriate balance that enables pharmaceutical companies to search for new compounds that might treat and cure disease, while at the same time protecting the interests of the countries and communities from where the genetic resources are sourced.

GSK is not currently involved in any product development using genetic resources collected since the CBD was ratified, nor are we currently looking for any such resources (known as bioprospecting). As a result, we have no access and benefit-sharing agreements in place.

It is possible that in future we may undertake development work using natural genetic resources indigenous to a particular country. In that instance, access to those resources would be obtained in accordance with the CBD, as reflected in local laws. We would ensure that relevant parties received agreed benefits from the use of the resources, for example monetary payments.

Read our position statement on the [Convention on Biological Diversity](#).

› [Back to top](#)

Corporate Responsibility Report 2009

Society

The UN Declaration of Human Rights states that 'everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including medical care'.

Improving healthcare is one of society's greatest challenges, particularly in the developing world. GSK contributes to healthcare worldwide by discovering new treatments and vaccines. We make a wide range of our products more affordable in developing countries through preferential pricing and voluntary licence agreements with generic manufacturers. We are also making a contribution in the Least Developed Countries through community investment projects that contribute to improvements in healthcare infrastructure. Our patient assistance programmes improve access for thousands of uninsured patients in the US.

We engage with governments, multilateral agencies, NGOs and other pharmaceutical companies to help improve access to medicines. Read more about our approach to [Access to medicines](#) and our [work with communities](#).

In May 2009, the former UN Special Rapporteur on the right to health, Paul Hunt, [published a review](#) of GSK's policies and practices on access to medicines following a series of in-depth interviews with our senior management¹. As well as identifying good practices and obstacles to improving access, the report makes a series of recommendations for how GSK, and the pharmaceutical industry more broadly, can support people's right to health. The report was presented by the current UN Special Rapporteur to the UN Human Rights Council in Geneva in June 2009. In his statement to the council, the UN Special Rapporteur welcomed our recent initiatives and commended us for our cooperative approach throughout the mission. In line with our long-standing position, he commented:

'The Special Rapporteur notes however, that because access to medicines is a shared responsibility, whether or not a pharmaceutical company is able to fully discharge all its right-to-health responsibilities will sometimes depend upon States, donors and others fulfilling their human rights responsibilities. There are other barriers hindering access to medicines in developing and developed countries which make it difficult for pharmaceutical companies to enhance access to medicines, and a few may be mentioned – weak health systems and regulatory environments, corruption and a lack of distribution channels.'

We welcome the Special Rapporteur's constructive engagement with GSK and [provided a response](#) to the report when it was presented to the UN Human Rights Council in Geneva in June 2009. Read more about how we are [engaging on the right to health](#).

1. <http://www2.ohchr.org/english/bodies/hrcouncil/docs/11session/A.HRC.11.12.Add.2.pdf>

Corporate Responsibility Report 2009

Activities in embargoed countries

Some stakeholders are concerned about GSK's business activity in countries that are subject to a trade embargo, such as Burma (Myanmar), North Korea, Iran and Sudan. We share the UN's belief (see box) that people should not be denied access to medicines because of the regime operating in their country.

We aim to provide medicines and vaccines in all countries that need and wish to purchase them, while observing any sanctions or trading controls which apply to those countries.

In many nations our long-standing commitment and presence pre-date the introduction of measures such as trade embargoes. During periods of government-imposed trade embargoes, we have ensured continuity of supply (subject to any specific legal restrictions) due to the demand for our products.

In embargoed countries, as in all countries where we do business, we support and are committed to upholding the Universal Declaration of Human Rights and the core standards set out by the International Labour Organization. We observe all local laws and regulations.

UN statement on the right to the highest attainable standard of health

Paragraphs relating to access to medicines in embargoed countries:

Paragraph 12: 'Health facilities goods and services must be accessible to everyone without discrimination, within the jurisdiction of the State party.'

Paragraph 41: 'Parties should refrain at all times from imposing embargoes or similar measures restricting the supply of another State with adequate medicines and medical equipment. Restrictions on such goods should never be used as an instrument of political and economic pressure.'

Paragraph 42: 'While only States are parties to the Covenant and thus ultimately accountable for compliance with it, all members of society – individuals, including health professionals, families, local communities, intergovernmental and non-governmental organizations, civil society organizations, as well as the private business sector – have responsibilities regarding the realization of the right to health. State parties should therefore provide an environment which facilitates the discharge of these responsibilities.'

Read the full [UN statement for the right to the highest attainable standard of health](#).

› Home › Responsibility › [Public policy and patient advocacy](#)

Corporate Responsibility Report 2009

Public policy and patient advocacy

The pharmaceutical industry is highly regulated. Government policy, legislation and regulations can have a significant impact on our business, so it is important that we engage with governments and other stakeholders in the legislative and policy process.

Through our public policy activity we work towards legislation and policy that encourage scientific innovation and balance the interests of business with those of other stakeholders. We also work with [patient groups](#) and professional groups to help give their members a voice in the healthcare debate.

We believe that we conduct our advocacy work responsibly and make a valuable contribution to the debate on public policy issues that impact our business, particularly those relating to research and development, the use of pharmaceuticals and healthcare.

We aim to increase stakeholder trust in GSK and, by being transparent about our lobbying and public policy work, to address concerns from some stakeholders that the pharmaceutical industry has too strong an influence over governments. We publish our annual public policy activity on this website and report on our key memberships of trade associations and US Federal and EU institution lobbying expenditures. We also publish information on our work with patient groups, including details of the [funding we provide](#). GSK does not make political contributions.

We provide information on our approach to working with doctors and healthcare professionals in the [Research practices](#) and [Ethical conduct](#) sections of this website.

› [Back to top](#)

Corporate Responsibility Report 2009

Our approach to external affairs

Employees involved in public policy work must abide by our [Employee Guide to Business Conduct](#) which is based on three principles:

- Partnership: we are committed to working with governments, regulatory authorities and other stakeholders in a constructive way
- Communication: as well as giving our views, we take on board any concerns from external audiences. This enables us to assess and improve our business practices
- Integrity: we base our public policy work on research, analysis and facts. We respect other opinions and look for constructive solutions. All of our external affairs work must be in line with our [Code of Conduct](#) and other relevant policies including those related to competition law, preventing corrupt practices and political contributions

We have external affairs teams in our major regions and business units that monitor proposed legislative reforms, policy developments and the concerns of stakeholders. They meet regularly with government officials and other stakeholders, for example multilateral organisations and NGOs, to explain our views on a range of public policy issues. We tailor our approach to suit different cultures and political traditions in the countries where we engage in the public policy process, while ensuring that our position in these discussions is fully consistent with GSK policies and our public policy statements. We ensure that the standards set out in our Guide to Business Conduct are applied globally.

Lobbying on issues affecting the whole pharmaceutical industry is sometimes conducted through trade associations. We may also hire professional lobbyists to support our public policy work

Trade associations

GSK is a member of many trade and industry organisations, including:

- Association of the British Pharmaceutical Industry (ABPI)
- BioIndustry Association (BIA)
- Biotechnology Industry Organization (BIO)
- British Pharma Group (BPG)
- Confederation of British Industry (CBI)
- European Federation of Pharmaceutical Industries and Associations (EFPIA)
- International Chamber of Commerce (ICC)
- Intellectual Property Owners Association (IPO)
- International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)
- Japan Pharmaceutical Manufacturers Association (JPMA)
- National Association of Manufacturers (NAM)
- Organisation of Pharmaceutical Producers of India (OPPI)
- Organization For International Investment (OFII)
- Pharmaceutical Research and Manufacturers of America (PhRMA)
- R&D-based Pharmaceutical Association Committee (RDPAC)

It is important that any lobbying conducted through trade associations reflects our policies and values. We work with other members to help set policies and may also attend lobbying meetings with governments and other stakeholders.

Sometimes we do not share the same views on a particular issue as other members of a trade association. If a trade association adopts a public policy position that we do not agree with, we will not participate in advocacy activity related to that subject. Senior GSK managers sit on the boards of the majority of industry trade associations of which we are members and raise any concerns we may have about a particular advocacy position.

› [Back to top](#)

› Home › Responsibility › Public policy and patient advocacy › **Public policy activity in 2009**

Corporate Responsibility Report 2009

Public policy activity in 2009

We engage with governments and other stakeholders on a wide range of issues that affect our industry.

We [publish our position](#) on key issues relating to corporate responsibility, including:

- Access to medicines in developing countries
- Ethical conduct of research and development
- Intellectual property
- The environment
- Public health
- Competitiveness
- Pricing, reimbursement and market access
- Counterfeiting of healthcare products

These are some of the key issues we engaged on during 2009:

- [Healthcare reform](#)
- [Access to healthcare and disease prevention](#)
- Regulations relating to [research practices](#)
- [Patient safety](#)
- [Intellectual property](#)
- [Pricing and competitiveness](#)

We are happy to discuss our position on these or any other issues with legitimate parties. Contact our corporate responsibility team at csr.contact@gsk.com

› [Back to top](#)

› Home › Responsibility › Public policy and patient advocacy › Public policy activity in 2009
› [Advocacy on healthcare reform](#)

Corporate Responsibility Report 2009

Advocacy on healthcare reform

US activity

Our principles for US healthcare reform

Organisations engaged: US Congress, the White House

Industry associations involved : PhRMA, BIO, NAM

GSK position: The US healthcare system provides the most advanced medical care available in the world, but for the many Americans who are uninsured or underinsured, access to healthcare can be sporadic and inadequate. Improvements are needed in the quality and affordability of care for all Americans, together with a commitment to reform healthcare to enable its long-term viability.

GSK supports the White House and Congress in achieving comprehensive healthcare reform to ensure Americans have access to high-quality, affordable coverage. That is why we support the agreement, put forward by industry group PhRMA to provide \$80 billion in costs savings over the next ten years.

Our principles for healthcare reform:

- Use the competitive market-based system to improve quality of care and patient outcomes, control overall healthcare costs, and encourage medical innovation
- Build upon the current public-private partnership with appropriate roles for both government and the private sector. This should include maximising the effectiveness of employer-sponsored health coverage as well as providing support for public programmes for people on low income, including Medicaid and the State Children's Health Insurance Program (SCHIP)
- Address improvements in financing and delivery of healthcare to achieve quality patient outcomes and contain costs across the spectrum of healthcare services
- Improve quality of care and reduce costs by focusing on prevention and personal responsibility, removing barriers to access, coordinating care, and improving the management of chronic disease. Chronic disease, much of which is preventable, accounts for 75 per cent of healthcare spending in the US. Healthcare reform must include the appropriate incentives to encourage wellness and prevention, manage chronic diseases more efficiently, and maintain strong incentives for continued medical innovation to meet unmet medical needs such as Alzheimer's disease

Read more about our [advocacy for increased investment in chronic disease prevention and treatment in the US](#).

Read our healthcare reform [position paper](#).

Update September 2010 (1 of 3)

In March 2010, US President Obama signed into law the Patient Protection and Affordable Care Act (PPACA), which significantly changes the provision of healthcare in the US. GSK supported the efforts of Congress and the Obama Administration to increase access, improve quality and reduce cost growth in the US health system.

The US government will now be the country's largest health insurance provider. Over 30 million more US citizens will have access to health insurance, resulting in coverage for 95% of the country's population by 2020. Some expanded rebates and discounts became effective immediately and further policy changes

will occur over the next few years as the new law is implemented.

GSK will now focus its public policy efforts on the interpretation and implementation of the PPACA. Our priority is to ensure that the legislation is implemented in ways that reflect the best interests of patients while preserving an environment that values medical research, development and innovation. We will continue to be guided by our principles on healthcare reform, see above.

A regulatory pathway for FDA approval of biosimilars

Organisations engaged: US Congress, the White House

Industry associations involved: BIO, PhRMA

GSK position: As part of US healthcare reform efforts, Congress is debating legislation that would create a regulatory pathway for the FDA to approve biosimilars (versions of biological medicines or vaccines, also called 'follow-on biologics', that are similar to the innovator products). Biologics are derived from living organisms, such as cell cultures, animals, fungi and plants and include vaccines and human insulin.

Proponents of the legislation claim that biosimilars could offer significant cost savings. Others believe the cost savings would be much less, due to the substantial expense associated with producing and testing biological products.

GSK supports legislation to establish a regulatory pathway for biosimilars, provided it:

- Ensures patient safety by requiring companies to provide adequate clinical data
- Offers fair incentives for continued biopharmaceutical research by requiring at least 14 years of data exclusivity to maintain incentives for innovation

Update September 2010 (2 of 3)

The new US Patient Protection and Affordable Care Act (PPACA, see above) created a regulatory pathway for the US Food and Drug Administration (FDA) to approve biosimilars.

We are reassured that the legislation recognises the importance of medical innovation and includes 12 years of data exclusivity from the date of licence for the innovator product.

The Act also provides the FDA with the authority to declare that a biosimilar is interchangeable with the innovator product. This allows pharmacists to substitute a biosimilar for the innovator product without consent from the prescribing healthcare practitioner.

GSK is encouraging the FDA to require all companies using the new regulatory pathway to:

- Provide clinical data to show that the safety and efficacy of a biosimilar is sufficiently similar to that of the innovator product.
- Establish a pharmacovigilance framework for identifying, evaluating and minimising any safety issues before and after regulatory approval.

Comparative effectiveness research

Organisations engaged: US Congress, the White House

Industry associations involved: PhRMA

GSK position: In February 2009, Congress allocated \$1.1 billion to expand the federal government's comparative effectiveness research (CER) efforts. CER is the comparison of two or more treatment options or healthcare delivery strategies to determine which is the most effective. US healthcare reform legislation would establish a national CER centre, either within a federal government agency or as an independent institute, dedicated to conducting and supporting CER.

We believe an independent, public-private CER institute could play a valuable role in improving health

outcomes and the healthcare system by helping to identify the most effective approaches and treatments, provided the CER institute adheres to these principles:

- In its design and use, CER should respect and support the central role of the healthcare professional and the patient in treatment decisions
- All stakeholders – including patients, healthcare professionals, public and private payers, and manufacturers – should have an opportunity to provide input into research priorities and design and have a voice in the governance of the CER institute
- A national CER institute should examine all aspects of healthcare, including differing approaches to care delivery, care management and benefit plan design
- The CER institute should focus its expertise on evaluating the clinical effectiveness of treatments but should not engage in cost-effectiveness analysis or issue coverage or treatment decisions or recommendations
- The institute should develop and champion robust and well-validated methodologies for evaluating data which inform clinical effectiveness assessments
- The institute should make the results of its clinical effectiveness assessments widely available to patients, providers, and payers for their use and consideration
- Because of genetic, gender, and age differences and other factors, individuals differ in how they respond to a treatment, so research results based on studies of populations might not hold true for a specific patient or subgroup of patients. CER must be explicitly designed, and the results communicated, with these differences in mind

Update September 2010 (3 of 3)

The US Patient Protection and Affordable Care Act (PPACA, see above) established the Patient-Centered Outcomes Research Institute (PCORI), a public-private, non-profit corporation that will sponsor and promote comparative clinical effectiveness research (CER).

GSK believes that PCORI can play a valuable role in improving health outcomes and the US healthcare system, by helping to identify the most effective treatments and approaches to care. The institute's stated mission, scope and governance structure are consistent with our principles for patient-centered care, as outlined above.

Asian activity

Healthcare reform in China

Organisations engaged: Chinese government; the pharmaceutical industry and other businesses in China; US and EU member state governments; European Commission; academics; Chinese think tanks

Industry associations involved: BPG, EFPIA, RDPAC, PhRMA, US-China Business Council, CPEA, CPA, CMDA

GSK position: Over half of healthcare bills are paid out of pocket in China, where there is a significant disparity between healthcare coverage in rural and urban areas, and the system is largely hospital-based.

The Chinese government plans to invest RMB 850 billion (\$125 billion, or around three per cent of GDP) to improve the country's healthcare system and narrow the current rural-urban healthcare gap.

Its plans for healthcare reforms include expanding basic medical insurance to cover 90 per cent of the population by 2011, establishing a network of local clinics and improving services in public hospitals. The government also plans to establish an essential drug system which will require healthcare institutions to purchase certain drugs to ensure they are available to the public in appropriate dosage forms, at an affordable price.

GSK welcomes the announced healthcare reforms, which should help to ensure better access to medicines and vaccines for Chinese patients, particularly those in rural areas. We are committed to working with Chinese authorities to meet these objectives and are reflecting this in our pricing and market access policies to ensure better access to our innovative drugs and vaccines across China.

We are also increasing our investment in China, including expanding our R&D activities and increasing technology transfers to enable local production. In 2009 we agreed joint ventures with Chinese company Shenzen Neptunus to develop and manufacture influenza vaccines for the Chinese market and Jiangsu Walvax Biotech Company to produce vaccines for measles, mumps, and rubella (MMR). Our investments should help to improve Chinese patients' access to innovative drugs and vaccines.

› [Back to top](#)

› Home › Responsibility › Public policy and patient advocacy › Public policy activity in 2009
› [Advocacy on healthcare and disease prevention](#)

Corporate Responsibility Report 2009

Advocacy on healthcare and disease prevention

Global activity

Safeguarding timely and unrestricted access to influenza viruses

Organisations engaged: World Health Organization (WHO), key developed and developing country governments, EU institutions

Industry associations involved: EFPIA (EVM), IFPMA (IVS), PhRMA

GSK position: The influenza virus is very unstable and can mutate quickly. Governments need to remain vigilant to the emergence of new strains of the virus and must share virus strains freely with other governments. The free sharing of viruses is in the best interests of global public health as it enables the development of vaccines in response. The WHO's Global Influenza Surveillance Network (GISN) recommends the content for influenza vaccines twice a year and recently acted well as the global alert mechanism for the H1N1 pandemic. The international community should unconditionally support the network, which relies on receiving information on virus strains from governments.

Despite the importance of timely and unrestricted access to viruses, Indonesia stopped sharing influenza viruses with the WHO in 2007, insisting on 'benefits' in exchange for access to viruses. In response, the international community – including the vaccine industry – spent 2008 mapping out a way to help developing countries prepare for a pandemic and much of late 2009 implementing the plan. Their response included product donations, technology transfer and tiered pricing.

Despite these extensive voluntary efforts, some member countries in the Intergovernmental Meeting (IGM) continue to call for a system of mandatory contributions. This system could oblige holders of any intellectual property rights derived from materials received from the GISN to grant a non-exclusive, royalty-free licence to the WHO that can be passed on to other licensees for implementation. An international agreement along these lines could undermine the spirit of voluntary collaboration that has resulted in the most comprehensive pandemic response ever.

GSK and the rest of the pharmaceutical industry continue to resist calls for a system of mandatory contributions. We are hopeful that a solution that assures industry access to potential pandemic viruses in return for an ongoing commitment to voluntary benefit sharing will be agreed during 2010.

Intellectual property and innovation for diseases of the developing world

Organisations engaged: World Health Organization, UK Government (Department For International Development, Department for Health, Intellectual Property Office), EU Commission, various other governments and NGOs

Industry Organisations Involved: IFPMA, PhRMA, EFPIA, ABPI, BPG, BIO

GSK position: Following the work of its Commission on Intellectual Property, Innovation and Public Health, the World Health Organization created an Intergovernmental Working Group (IGWG) to develop a Global Strategy and Plan of Action. This aimed to secure 'an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries, proposing clear objectives and priorities for research and development, and estimating funding needs.'¹

GSK supported the objectives of the IGWG, but much of the process and activity of some stakeholders was

focused more on attacking the intellectual property (IP) based model of innovation than on meeting the needs of patients in developing countries.

Our fundamental business model is based on respect for intellectual property. IP rights play a vital role in encouraging the innovation needed to develop new treatments and enabling us to generate the returns on investment needed to fund new research.

Attempts to weaken the IP environment were deflecting attention from seeking appropriate solutions for addressing the lack of R&D into diseases of the developing world for which few commercial opportunities exist, such as incentivising and prioritising R&D for these diseases and ensuring sustainable financing.

Working with a coalition of trade associations, we contributed to the development of a pragmatic Global Strategy and Plan of Action (GSPOA) agreed by consensus at the World Health Assembly in May 2009. Many of our current initiatives to improve healthcare in the developing world are aligned with the GSPOA and we will seek further opportunities to contribute to its implementation.

¹ WHA Resolution 59.24

US activity

Investment in chronic disease prevention and treatment

Organisations engaged: US Department of Health and Human Services, US Congress, White House, state legislators, Governors' Offices, various state health agencies, The Partnership to Fight Chronic Disease

Industry associations involved: PhRMA

GSK position: Chronic diseases such as diabetes, heart disease and lung disease account for three-quarters of healthcare spending. Relatively little is invested in prevention even though many chronic diseases and their costly complications are preventable and increasingly manageable. We are advocating a three-part approach to achieving lower-cost, higher-quality healthcare: increasing prevention, improving treatment, and accelerating research into better treatments for chronic disease. Healthcare providers need incentives to promote preventative services that address major causes of chronic disease such as obesity and smoking. Healthcare policy needs reform to better encourage and reward medical research into improved treatments for costly, unmet medical needs such as Alzheimer's disease. Preventing and better managing chronic diseases will reduce overall healthcare costs in the long term.

Read about our advocacy on [US healthcare reform](#)

Supporting a petition to protect Americans from fraudulent weight loss claims

Organisations engaged: US Food and Drug Administration

Industry associations involved: None. See below for the healthcare associations involved.

GSK position: In the US, two-thirds of adults are overweight or obese, increasing their risk of illnesses such as cancer, heart disease and type 2 diabetes.

There are dozens of dietary supplements on the market in the US which manufacturers claim can help people to lose weight. Most of these claims are not reviewed by the Food and Drug Administration (FDA) and are not supported by credible scientific evidence. Ineffective weight loss products can prevent people getting the support they need to lose weight. The US Federal Trade Commission's Consumer Fraud Survey recently highlighted that there were more victims of fraudulent weight-loss products, 4.8 million American consumers, than victims of any of the other frauds covered by the survey.

GSK manufactures *alli*, the only over-the-counter weight loss product that has gained FDA approval for safety and efficacy. In April 2008, GSK and three research and advocacy organisations (the American Dietetic Association, the Obesity Society and Shaping America's Health) submitted a citizen's petition to the FDA, asking it to provide greater protection for Americans from fraudulent weight loss claims.

The petition requests that the FDA treats weight loss claims in the same way as unsubstantiated claims of efficacy against disease, which are not permitted under the Dietary Supplement Health and Education Act. The petition calls for the FDA to require rigorous scientific evidence for any such claims. It also aims to raise

awareness and educate the public about the issue of fraudulent weight loss products.

In a separate development, in January 2009 the FDA demanded the recall of a large number of weight-loss supplement products and warned a number of companies that they might be liable for criminal charges. Among the FDA's complaints against 69 supplement products in the US was the illegal inclusion of regulated, unapproved or withdrawn prescription pharmaceuticals, including sibutramine and rimonabant (weight loss), phenytoin (anti-seizure) and phenolphthalein (laxative, previously withdrawn by the FDA due to carcinogenicity). GSK supports and will continue to work with the FDA to help protect the public from false and unsubstantiated weight loss claims and possibly unsafe products.

European activity

EU Health Council recommendation on seasonal flu vaccination coverage

Organisations engaged: Directorate General for Health and Consumers (DG Sanco), European Centre for Disease Prevention and Control (ECDC)

Industry associations involved: European Vaccine Manufacturers (EVM), national vaccine industry groups

GSK position: Seasonal flu is a preventable disease which can cause up to 200,000 deaths each year in Europe, depending on the severity of the season. Many of these deaths could be prevented by expanding vaccination coverage in Europe, which is currently too low.

The WHO urges member states to increase vaccination of high risk groups (over 65s, under 65s with certain medical conditions and healthcare workers) and to aim at vaccination coverage of at least 75 per cent in the elderly by 2010¹.

Despite vaccination of these groups being included in the national recommendations in all EU countries and reimbursed in most, coverage remains both low and variable:

- Coverage of elderly people (over 65 years old) ranges from 16 per cent in Poland to 78 per cent in the UK ²
- Coverage of risk groups under 65 years old (for example asthmatics, diabetics, cardiac) ranges from 11 per cent in Poland to 54 per cent in the UK ²
- Coverage of healthcare workers ranges from nine per cent in Poland to 29 per cent in the UK ²

The European Parliament has endorsed the WHO recommendations to increase coverage levels to 75 per cent in the above groups, but European usage has remained flat in recent years, unlike other regions where it has increased significantly.

We believe that seasonal vaccination coverage in Europe should be increased to the WHO target level of 75 per cent. As well as reducing deaths and illness this will help to increase vaccine manufacturing capacity, which is currently insufficient to meet the needs for pandemic vaccine supply (as recognised in European Parliament resolutions in 2005 and 2006).

Our advocacy was a key factor in driving for a proposal issued by the European Commission in July 2009 which calls on member states to develop concrete plans to increase their coverage rates up to the 75 per cent target level by 2015. Annual monitoring of coverage rates by all member states will be encouraged by the EU in order to monitor progress.

The proposal was adopted by the Health Council in December 2009.

¹ [WHO Position Paper on Influenza Vaccines, 19 August 2005](#),

² T. Szucs, Journal of Infection (2009) 58, 441–453

Asian activity

Engaging governments in Asia on the value of vaccines

Organisations engaged: Asia-Pacific Economic Cooperation (APEC) Forum

Industry associations involved: None

GSK position: Vaccines play a major role in preventing and eliminating disease but are still under-used in many countries. GSK has been engaging with governments and other stakeholders in Asia to raise awareness of the importance of investment in preventative health measures.

During 2009, on behalf of industry, GSK supported and organised a stakeholder perception survey for the Life Sciences Innovation Forum (LSIF), an official sub group of the Asia-Pacific Economic Cooperation Forum (APEC) established in 2002. APEC is the leading regional organisation for facilitating economic growth, cooperation, trade and investment in the Asia Pacific region, and an important forum for reaching senior government officials and policymakers from Asian countries.

Recently LSIF has focused on raising awareness among APEC governments of the need to invest in health innovation to help manage the increasing costs of ageing populations and the rising incidence of chronic disease. To support their work, GSK initiated a study of stakeholder perceptions to determine how they define the value of vaccines.

The survey assessed current perceptions among legislators, civil servants in health, finance and economic planning ministries, industry, medical key opinion leaders and vaccine advocacy groups in Thailand and Taiwan (known as Chinese Taipei in APEC). It showed that most stakeholders see the value of vaccines in prevention of death and serious illness from infectious diseases and as a means to reduce direct healthcare costs related to treatment of these diseases. However, there is low awareness of the positive impact of vaccines on workforce participation and productivity, and related benefits such as higher incomes and economic growth. There is little or no consideration of these benefits in vaccine policy-making, highlighting the need to make the investment case for vaccines among government agencies responsible for budget allocation.

The survey findings featured strongly in an LSIF report which was endorsed by APEC foreign and economic/trade ministers during their 2009 meeting in Singapore.

GSK welcomes the support of APEC ministers in continuing to raise awareness among government decision-makers in Asia about the need to invest in preventive measures as part of health policy. GSK is committed to ongoing dialogue with stakeholders across Asia, through continued involvement in the LSIF's important work.

› [Back to top](#)

› Home › Responsibility › Public policy and patient advocacy › Public policy activity in 2009
› [Advocacy on research practices](#)

Corporate Responsibility Report 2009

Advocacy on research practices

We regularly engage with policy makers and other stakeholders on issues and concerns relating to research practices and the research environment. Read more about [research practices](#).

US activity

Implementation of clinical trial registration requirements in the US

Organisations engaged: US Food and Drug Administration, US National Library of Medicine

Industry associations involved: PhRMA, BIO

GSK position: The Food and Drug Administration Amendments Act (FDAAA) of 2007 extends requirements to post protocol summaries of clinical trials being initiated in all diseases on the National Library of Medicine's website, clinicaltrials.gov. Previously this requirement related to serious and life-threatening diseases and conditions. The Act also includes requirements to post the results of clinical trials (other than phase I) of drugs approved for use in the US. Prior to these requirements, GSK voluntarily posted protocol summaries of all our clinical trials including phase I studies on clinicaltrials.gov.

The FDAAA stated that no more than three years after its enactment, information on clinicaltrials.gov may be expanded to include the following information (provided the Secretary of Health and Human Services determines that this type of summary can be included without being misleading or promotional):

- A summary of the clinical trial and its results that is written in non-technical language for patients
- A summary of the clinical trial and its results that is technical in nature

The FDAAA also includes language regarding the potential for study results to be posted for unapproved products at some point in the future.

Technical and lay summaries

We believe scientific journals should be the primary channel for technical summaries because they provide the necessary level of detail for technical audiences, and the information is subject to peer review. It is more appropriate for the results to be published by an independent source than by the research sponsor.

When studies are not published in journals, for example if they are not of enough interest to the journal's readers, we have voluntarily committed to summarising the study findings on our Clinical Study Register, providing the necessary context and interpretation to supplement the result summary.

We believe that producing lay summaries of individual trials raises a number of concerns that needs to be carefully considered. For example, producing lay summaries requires significant interpretation and judgement by the author, which in the absence of peer review, could result in concerns around the introduction of biases and potential conflicts of interest.

Timing of results reporting

Our policy is to report results for investigational medicines at the time of approval or within a year of the decision to terminate research into the compound. We believe that we should not be required to disclose results prior to approval as it would provide little benefit to patients and doctors. In the case of products that do not gain approval, disclosure within a year of termination of the compound helps other researchers to determine whether the development of a similar compound is likely to be successful and therefore helps

reduce unnecessary patient exposure in clinical trials.

European activity

Changes to disclosure on the European clinical trials database

Organisations engaged: European Commission

Industry associations involved: EFPIA

GSK position: Pharmaceutical companies in Europe are required to post clinical trials protocols on the European clinical trials database (EudraCT) as part of the application process for regulatory approval for the trial. The European Commission is proposing that parts of EudraCT be made publically available and the database expanded to include results information.

The Commission is also proposing that a discussion and interpretation of the trial results by the sponsor and competent authority is made public on EudraCT and that trial results should be made public within a year of the end of the trial, irrespective of whether the medicine has been approved.

We do not believe that these proposals are in the best interests of patients and the scientific community, and they could threaten our data exclusivity. We are highlighting our concerns with these changes for the reasons outlined in the US clinical trial registration requirements example above.

Advocacy on the revision of EU Variations Regulations

Organisations engaged: European Commission, European Parliament, EU Member States, National Regulatory Agencies, EMEA

Industry Associations involved: EFPIA, EVM, EuropaBio, national trade associations

GSK position: Once a medicinal product has been approved for marketing, all changes (for example in the manufacturing processes, or prescribing information) are considered as variations and must be handled according to a complex regulatory framework defined in EU law by the Variations Regulations. However, for historical reasons a large majority of products fell outside the EU legislation and were subject to divergent national rules and procedures. This lack of harmonisation places a significant administrative burden on industry and national regulatory authorities and adds unnecessary complexity. The objective of the revision of the Variations Regulations was to simplify the legislative framework, and to harmonise the rules so that they apply to all medicinal products.

GSK welcomed the revision and has advocated a simpler, clearer and more flexible framework for variations which:

- Reduces the number of regulatory events associated with post-approval changes and the associated regulatory burden
- Enables predictability of variations procedure timelines, in order that beneficial changes can be introduced in a timely manner
- Provides a legislative framework which accommodates 'flexible regulatory approaches' as outlined in the ICH Q8/Q9/Q10 guidelines
- Introduces a science and risk-based approach for managing post-authorisation changes
- Facilitates innovation and continual improvement in pharmaceutical manufacturing

The European Commission has adopted framework legislation and has recently finalised key supporting guidelines which are intended to ensure implementation in a manner which is consistent with these objectives.

Advocacy on the European Animal Directive

Organisations engaged: European Commission, European parliament, European Member States

Industry associations involved: ABPI, EFPIA

GSK position: The European Animal Directive, originally introduced in 1986, governs the use of animals for

experimental or other scientific purposes. It aims to establish a framework for all animal research activities within the EU. The European Commission has published a draft revision of the Directive which controls the use of laboratory animals and sets minimum standards for their housing and care.

GSK welcomes the review of the Directive and recognises the need for it to be revised to reflect advances in animal welfare and science. We welcome many of the recommendations in the draft revision, many of which are already integrated into our current practices. For example, we welcome the rules relating to the replacement, reduction and refinement in the use of animals in research (known as the 3Rs), and the need for animal welfare bodies in establishments that use animals in research.

It is essential that any legislative changes achieve high animal welfare standards while supporting an environment that allows research that leads to new medicines and vaccines to meet patients' needs. In this regard we have raised a number of concerns, for example the proposed restrictions on the use of non-human primates to those diseases that are considered life-threatening or seriously debilitating.

Read our [position statement on use of non-human primates in research](#).

Supporting a new approach to pharmacovigilance in the EU

Organisations engaged: European Commission, European Medicines Agency, UK Government

Industry associations involved: ABPI, EFPIA

GSK position: GSK seeks a new approach to pharmacovigilance regulation in the EU that will allow pharmaceutical companies and regulators to focus their resources on safety evaluation activities instead of compliance with unclear and complex regulatory demands.

New pharmacovigilance legislation should contain clear and concise provisions to simplify, strengthen and provide legal certainty to the EU legislative framework for pharmacovigilance. Specifically, it should:

- Contain a single set of simplified rules, and a single reporting point, for adverse drug reactions in the EU
- Require the reporting of all serious cases when an electronic reporting system is implemented
- Contain clear and flexible provisions that allow individual companies to appoint the number Qualified Persons for Pharmacovigilance (QPPVs) they require
- Provide consistent standards for inspections of company pharmacovigilance departments by EMEA and EU member state authorities

› [Back to top](#)

› Home › Responsibility › Public policy and patient advocacy › Public policy activity in 2009
› [Advocacy on patient safety](#)

Corporate Responsibility Report 2009

Advocacy on patient safety

US activity

Legislation on prescription medicine imports

Organisations engaged: US Department of Health and Human Services, Food and Drug Administration (FDA), US Congress, state Boards of Pharmacy, state legislators, governors' offices

Industry associations involved: BIO, PhRMA

GSK position: Current US law prevents prescription medicines from being imported to the US unless they have safety and cost savings certifications from the Secretary of Health and Human Services. Pending legislation would remove the safety and savings certification requirements, making it easier to legally import medicines. This would undermine the FDA's ability to protect the US distribution system from counterfeit and unsafe medicines that could harm patients. There is also no guarantee that consumers would save any money, as the Department of Health and Human Services has found that third-party payers such as insurance companies are most likely to benefit.

GSK supports safer alternatives to help patients afford their medicines. The Partnership for Prescription Assistance (PPA), for example, gives access to more than 475 public and private patient assistance programmes, for patients who lack prescription drug coverage. Read more about GSK's [Patient Assistance Programs](#).

Read about our advocacy on [US healthcare reform](#)

European activity

Enhancing patient safety through harmonised serialisation of pharmaceutical products in Europe

Organisations engaged: Patient groups, European Commission, European Parliament, EU member states, wholesalers, pharmacists, sick funds

Industry associations involved: EFPIA, local pharmaceutical trade associations, the Association of the European Self-Medication Industry (AESGP), EuropaBio

GSK position: The pharmaceutical supply chain in Europe is complex, with millions of packs moving around the region each year via numerous wholesaler intermediaries and traders. This creates a risk that counterfeit products enter the legitimate supply chain and makes detecting and tracing counterfeit medicines difficult. The World Health Organization has identified trade 'involving several intermediaries and free trade zones' as a key driver of counterfeiting activity.

In December 2008, the European Commission introduced a proposal to tighten supervision of the European supply chain and to mandate the introduction of safety features aimed at tracing and authenticating pharmaceutical products. A key outcome of the Commission proposal is likely to be the introduction of 'serialisation', whereby unique product identification codes are applied to prescription medicines to allow tracking and authentication prior to dispensing to the patient.

GSK welcomes the European Commission's plans. However, we believe that there are a number of areas where they could be strengthened to enhance patient safety, in particular:

- There should be a harmonised approach across Europe:

A standardised approach to identification and verification of medicines across the EU is essential in order for a pharmacist in any EU member state to check whether the pack has been dispensed before (helping them to detect duplicate, counterfeit products in the supply chain), whatever its country of origin. Without standardisation, identification and verification systems may differ between countries, making it more difficult to identify products originating in other countries. Around 150 million packs of medicines are currently parallel traded (bought from pharmaceutical companies in one member state and sold in another) each year within the EU

A system limited to national schemes would ignore the cross-border nature of counterfeiting and the principle of a single market

- The serialisation system should be based on a 2D Data Matrix and GSI Standards:

The 2-D Data Matrix (ECC-200) is currently the most efficient and effective data carrier available capable of meeting the needs of all stakeholders in the pharmaceutical supply chain. It is highly reliable, can be quickly read and enables a large amount of data to be stored in a small space compared to other methods. It is the only data carrier that could be implemented on all products within three to four years at a reasonable cost

The Commission proposal will be discussed and voted on by the European Parliament and Council under the co-decision procedure in the first half of 2010. We will use this consultation to advocate the need for European harmonisation.

Read our [position statement on counterfeiting](#).

› [Back to top](#)

› Home › Responsibility › Public policy and patient advocacy › Public policy activity in 2009
› [Advocacy on intellectual property](#)

Corporate Responsibility Report 2009

Advocacy on intellectual property

Global activity

Access and benefit sharing and a disclosure obligation in patent law

Organisations engaged: Secretariat to the Convention on Biological Diversity (CBD), Ad Hoc Working Group on Access and Benefit Sharing, UK Department for Environment, Food and Rural Affairs, DG Trade (European Commission), national European governments, US government, World Intellectual Property Organization and World Trade Organization

Industry associations involved: BIO, BPG, EFPIA, ICC, IFPMA, PhRMA

GSK position: Benefit sharing means the sharing of benefits arising from the use of genetic resources. The proposed International Regime on Access and Benefit Sharing is still under discussion within the Convention on Biological Diversity (CBD). We believe the outcome from the discussions – which have a formal deadline of October 2010 – should be consistent with the CBD Treaty. It should provide guidance on how to achieve access and benefit sharing objectives, rather than prescribing rules. It should apply only to genetic resources as defined in the CBD, not to a broader class of materials, and it should not extend to human genetic resources or to derivatives.

Pathogens, such as viruses, do not respect national borders and should be excluded from the scope of the International Regime. Article 2 of the CBD defines biological and genetic resources as those that have either 'actual or potential use or value for humanity'. However, pathogens present a threat to biodiversity and the overall ecosystem, hence societal efforts to eradicate or control pathogens. This means a reasonable interpretation of Article 2 should exclude pathogens from the scope of any Regime.

We believe that once countries have adopted local laws as envisaged by the CBD, they will receive the kind of protection and compensation envisaged under the Convention. This makes the introduction of a disclosure obligation, whereby patent applications would have to disclose the origin of genetic resources used in an invention, unnecessary. A disclosure obligation would also create legal and commercial uncertainties for researchers and companies developing products using genetic resources, discouraging innovation and ultimately leading to fewer benefits to share.

Read our position statement on [Proposals for a Disclosure Requirement in Patent Applications](#).

Read our position statement on the [Convention on Biological Diversity](#).

US activity

US patent system reform – Federal legislation

Organisations engaged: Patent and Trademark Office (PTO), US Congress

Industry associations involved: BIO, Coalition for 21st Century Patent Reform, PhRMA

GSK position: A patent law framework that provides business certainty over a long period and promotes investment is essential to the research-based pharmaceutical industry and a wide range of other manufacturers that have long lead times from research to market. The US Congress has made progress in drafting legislation that provides meaningful patent reform while preserving the incentives necessary to sustain innovation and spur the creation of high-wage, high-value jobs. Thoughtful compromise on key issues, including post-grant review and damages, should allow the bill to move further through the legislative

process in the near future.

GSK is working with a coalition of research-based companies, manufacturers, universities and small inventors to promote US patent reform that stimulates investment in research and strengthens the patent system. We support patent reforms that are clear, provide business certainty, improve the quality of patents and remove subjectivity in litigation issues.

European activity

Creation of a UK patent box and taxation of foreign profits made by British companies

Organisations engaged: UK Government Office of Life Sciences, HM Treasury

Industry associations involved: Confederation of British Industry (CBI), The Hundred Group, Association of the British Pharmaceutical Industry (ABPI), BioIndustry Association (BIA)

GSK position: In July 2007, the UK Treasury published draft proposals to change the way foreign profits of UK companies are taxed and as part of this impose UK tax on income attributed to intellectual property (IP), wherever in the world the income is generated.

This proposal gave us serious cause for concern, as a high percentage of profits in the pharmaceutical industry are attributed to patents. GSK has operations around the globe, managed by approximately 460 subsidiaries and only four per cent of our sales are in the UK. If implemented, the draft proposal would potentially have increased our global tax rate by several percent. GSK's global tax rate is already one of the highest in the pharmaceutical sector and any increase would make our business less competitive. Our [Annual Report](#) provides more detail on our tax rate.

The relatively high corporation tax burden in the UK has historically contributed to our decision to increase investment, primarily in manufacturing, in countries with more competitive rates of tax, such as Singapore, Ireland and Belgium.

We accepted the need to reform the tax rules for foreign profits, but urged the government to think again about the proposal to tax global income attributed to IP. With the support of the ABPI, BIA, and CBI, we proposed that the government introduces a 'patent box' which would provide a low rate of tax on income attributed to IP as this would encourage research-based companies to invest in the UK.

In the December 2009 Pre-Budget Report, the government announced that it will introduce a patent box in the UK, following a consultation period. GSK welcomes this development and has since announced that we will invest an additional £500 million in the UK assuming that the consultation delivers an effective patent box.

Asian activity

Healthcare and intellectual property in India

Organisations engaged: Relevant agencies in the Indian government; members of the pharmaceutical industry and the wider business community in India; Indian academics and civil society representatives; US and EU member state governments; European Commission

Industry associations involved: BPG, EFPIA, Organisation of Pharmaceutical Producers of India (OPPI), PhRMA

GSK position: We believe that India's tremendous strengths in science and pharmaceuticals, coupled with its rapid economic growth, offer the government an opportunity to tackle some fundamental characteristics of its healthcare system and policy base. Further improvements in India's intellectual property (IP) regime to the level provided in the EU and US could further encourage investment in collaborative R&D, without constituting a major barrier to access. We believe that reform and increased investment in the Indian healthcare system, particularly in the areas of prevention and vaccination, should be a priority. We want to be active partners in addressing these challenges.

> [Back to top](#)

› Home › Responsibility › Public policy and patient advocacy › Public policy activity in 2009
› [Advocacy on pricing and competitiveness](#)

Corporate Responsibility Report 2009

Advocacy on pricing and competitiveness

European activity

Office of Life Sciences

Organisations engaged: UK Government Office of Life Sciences, Department of Health

Industry associations involved: Association of the British Pharmaceutical Industry (ABPI), BioIndustry Association (BIA), British In Vitro Diagnostic Association (BIVDA) and Association of British Healthcare Industries (ABHI)

GSK position: Following the impact of the global financial crisis on the UK economy, the government has been working to assess what action could be taken to ensure less reliance on the financial sector and allow other sectors to make a greater economic contribution to the UK. The Office of Life Sciences (OLS) was established in February 2009 to find ways to strengthen the UK life sciences sector.

The OLS focused on three key areas:

- Take action to stem the decline in UK-based pharmaceutical manufacturing
- Create increased opportunities for collaboration between industry and academia and develop a stronger biotech base, to ensure the UK gains the maximum advantage from the pharmaceutical industry's increasingly open R&D model
- Improve the use of innovative new medicines in the National Health Service (NHS) and consequently the perception of the UK as a country that embraces medical innovation

We developed a series of proposals, in partnership with UK trade associations and other companies. GSK took a lead on the following proposals:

- **Patent box:** We proposed the creation of a 'patent box' in the UK to provide a low rate of corporation tax on income attributed to patents. Read more about the creating of a [patent box](#). The government announced in December 2009 that it will introduce a patent box
- **Creation of life science clusters to promote industry-academic collaboration:** We believe more could be done to encourage greater collaboration between industry and academia in the life science sector. In January 2010, the government announced plans for a new UK Life Sciences Super Cluster supported by £1 million of government investment. This will bring together industry, academia and the NHS, helping deliver the next generation of medicines and technologies needed to support patients with chronic diseases. In addition, GSK and the Wellcome Trust, in partnership with the government, will fund the development of a biosciences park at GSK's R&D site in Stevenage.
- **Innovation pass:** The government has agreed to ring-fence funding for new technologies, used in small patient populations, that have the promise of delivering real patient benefit but that at launch do not have the data available to show cost-effectiveness to the extent required by the National Institute for Health and Clinical Excellence (NICE). Those medicines that receive an 'innovation pass' will be funded on the NHS for three years before needing to go to NICE for formal review. Consultation was launched in November 2009 and we anticipate the first medicines will be funded through this new system in 2010

› [Back to top](#)

› Home › Responsibility › Public policy and patient advocacy
› **Political contributions and lobbying expenditures**

Corporate Responsibility Report 2009

Political contributions and lobbying expenditures

GSK does not make corporate political contributions. Here we disclose voluntary political contributions made by our US employees through a Political Action Committee and our Federal lobbying expenditure costs, as well as costs of lobbying EU institutions.

Political Action Committee contributions

In accordance with the Federal Election Campaign Act, GSK established a Political Action Committee (PAC) that facilitates voluntary political contributions by eligible employees.

The PAC is not controlled by GSK. Decisions on the amount and recipients of contributions are made by participating employees exercising their legal right to pool their resources and make political contributions. All PAC contributions are voluntary and contributions are subject to strict limitations. For example, the GSK PAC may not contribute more than \$5,000 per election to an individual candidate for federal office.

The PAC is run by a governing board of participating GSK employees from across the company. As required by law, PAC contributions are reported to the Federal Elections Commission (FEC). In 2009 the GSK employees' PAC contributed £540,541 - 50.2 per cent to Republicans, 49.7 per cent to Democrats and 0.2 per cent to unaffiliated or other party candidates running for state and federal offices.

Lobbying expenditure

Europe

In December 2008, GSK signed up to the European Commission's new code of conduct and the voluntary register of organisations working to influence EU institutions. In the 'transparency register of interest', we declared the costs associated with lobbying of EU institutions to be in the range of €750,000-800,000 in 2009. This includes running of the Brussels advocacy office, salaries, external events and educational materials. This figure takes into account the proportion of employee time spent on interest representation.

US

We report our US lobbying expenditures to the US Congress in accordance with the Lobbying Disclosure Act 1995. We spent \$8.76 million in federal lobbying activities in the US during 2009. This includes the costs of salaries and benefits for all employees registered to lobby the US government; use of lobbying consultants; support for lobbying contacts such as planning activities and research; running the GSK Washington DC government affairs office; support staff; and the portion of trade association fees associated with federal lobbying. We also report our state lobbying expenses, in line with applicable state laws.

Contributions to policy groups

GSK contributes to various groups which provide a forum for policy analysis and debate. This includes think tanks in a number of countries, and '527' organisations in the US.

Corporate Responsibility Report 2009

Patient advocacy

Patient groups are non-profit organisations founded by patients, care-givers, family members and health professionals.

They provide their members with information about their condition and guidance on how to live with their disease. They engage with healthcare providers, governments and the media to promote improved treatment and services for patients and campaign for change on issues that affect patients' and carers' lives. Some carry out vital research into the causes and potential treatments for specific conditions.

GSK works with a wide range of patient groups in disease areas such as cancer, asthma, diabetes, Alzheimer's disease, multiple sclerosis and HIV/AIDS. GSK and patient groups share a common concern that healthcare systems should focus on preventing, treating and managing disease. Both parties believe that patients should have access to quality medicines, services and information on disease.

Patient groups are important stakeholders for GSK and we engage with them as part of our commitment to be a patient-focused company. Our relationships with patient groups are mutually beneficial. They help us to better understand patient needs and their illnesses. We work with patient groups to strengthen their support for patients throughout their illness, from diagnosis to chronic treatment and end-of-life care. [Our support](#) helps patients make their voice heard in the healthcare debate, alongside other stakeholders.

Our approach

We support patient groups across the world in a number of different ways. These include:

- Providing core funding to support the day-to-day running of the group
- One-off donations to help patient groups conduct a specific event or activity, for example a breast cancer awareness day
- Educational support
- Training staff in management skills and disease education
- Working together on disease awareness/prevention projects

Our relationship with each patient group is defined by a written agreement specifying how the group will use our funding to benefit its members.

Some stakeholders are concerned that pharmaceutical companies use patient groups as a way of marketing their products. Our support for patient groups is not designed to market our products but to influence factors that dictate whether or not new medicines are made available to patients, and whether patients have access to the kind of treatments that they need. We are committed to maintaining the highest ethical standards and transparency in this area.

We have developed detailed guidance and Standard Operating Procedures (SOPs) for employees in each of our major regions. These policies, used in conjunction with GSK's patient advocacy manual, ensure that GSK employees who work with patient groups comply with applicable laws and regulations and our standards. [Read a summary of our SOP](#) We want to raise standards across the whole of our sector and we collaborate with other companies and industry groups to develop industry-wide standards.

All employees, and outside agencies working for GSK that are likely to interact with patient groups, must abide by our guidelines and SOPs. We provide training so that our employees understand our requirements.

Our patient advocacy teams in Europe and our Asia Pacific, Japan and Emerging Markets region coordinate interaction with patient groups and adherence with our policies and global principles. In the US, patient

advocacy is decentralised across our Public Policy and Advocacy function as well as R&D, communications and marketing. In 2009 we took steps to consolidate patient advocacy activities by grouping all policy related activities under our Public Policy and Advocacy function.

Employees in all regions can access our patient advocacy resource intranet site. In Europe, we also publish a newsletter to raise employee awareness about internal and external developments relating to patient groups.

In the US, we are developing a customer relationship management system to improve coordination between employees working with external groups. This system will enable employees to learn about past interactions with patient groups and help us to allocate resources to patient groups more efficiently. We piloted the database in 2009 and plan to launch the system across the company in 2010.

Encouraging independence

We believe that patient groups should be independent and we encourage them to seek financial support from as wide a range of organisations as possible. We ensure that the funding we give to patient groups is appropriate to their size.

Our guidelines state that GSK funding should make up no more than 25 per cent of a group's overall income. In the vast majority of instances the actual percentage is much lower. We allow some exemptions to the 25 per cent cap as some of the groups supported have limited incomes, so a small donation (for example £1,000) would exceed the limit, and because some groups have difficulty attracting funding because of the nature of their activity (for example, providing needle exchange for drug users). These cases must be approved by the general manager of each local operating company. We also encourage patient groups to seek funding from multiple sources and we hold workshops on how to make funding applications.

Corporate Responsibility Report 2009

Transparency

We believe that being transparent about our support for patient groups helps build trust with our stakeholders, including the groups themselves.

We publish information on all our work with patient groups in our Europe and Asia Pacific, Japan and Emerging Markets regions, as well as information on our support for patient groups working globally, including details of the funding received. See details of our [funding for patient organisations](#)

We were the first pharmaceutical company to publish this level of information and it goes beyond industry codes of practice that at most require a list of the groups funded.

Detailed information for GSK [Australia](#) and [Canada](#) can be found on their websites.

In the US from February 2009, we began publishing information on educational and charitable grants provided to health-related organisations, including hospitals, teaching institutions and patient advocacy groups. [The report](#) will be updated quarterly.

Working with patient groups

Our Standard Operating Procedures state that:

- Any involvement with a patient organisation must be declared and transparent
- GSK must neither seek patient organisation endorsement for its medicines, nor pay patient groups to endorse GSK services
- Medicines must not be promoted to patient organisations
- GSK must not create patient organisations, must not be the sole funding sponsor of a patient organisation, and should not provide more than 25 per cent funding to patient organisations. Exceptions may be allowed in the case of rare disease focus or start-up funding up to 50 per cent. However, these must be agreed directly with the local country or region general manager or head of regional government affairs
- GSK must not seek a direct return on investment from the funding of a patient organisation
- Any information on GSK pipeline compounds must be factual and non-promotional and provided to patient organisations as part of a scientific dialogue
- It is acceptable for GSK clinical trials or medical personnel to work with patient organisations to ensure optimal clinical trial recruitment, and to consult them on clinical trial design and protocols
- GSK must not directly sponsor patient organisation representatives to attend medical congresses, conferences and other healthcare professional events. Exceptions include where the representative is invited to speak at the conference or where the medical congress has a specific workstream designed for patients. GSK may sponsor representatives to attend non-medical congresses
- GSK may pay a modest honorarium or speaker fee to the patient organisation that an advisory board member or speaker represents
- Any third party working for GSK on a given project must be fully transparent about this relationship when interacting with a patient group on the project

› [Back to top](#)

› Home › Responsibility › Public policy and patient advocacy › Patient advocacy

› [Understanding patients](#)

Corporate Responsibility Report 2009

Understanding patients

To help us better understand patient needs we have set up advisory boards in the US and Europe that include representatives from a wide range of patient groups.

The advisory boards have independent chairs, meet regularly and are attended by senior GSK managers. The boards enable the voice of patients to be heard at the highest levels of GSK. They also allow us to access the views of patient groups and we seek feedback on subjects such as clinical trials, pharmacogenetics, information provided to patients and ethical issues.

In all regions we invite speakers from patient groups to meet GSK employees, including scientists, researchers and marketers, to discuss issues affecting their members. As well as improving our understanding of patient needs, it shows GSK employees the difference their work can make to people's lives. Read about how our [Focus on the Patient initiative](#) is helping us to better understand patient needs and develop better medicines.

We also engage with patient groups through Patient Advocacy Leaders' Summits (PALS). These bring groups together to discuss health policy concerns, develop new skills and/or ways to expand their influence. PALS can also give patient groups the opportunity to learn about GSK and tell the company how it can better support their work. In 2009 we were involved in running a total of 16 summits: five meetings in European countries, one in Japan and ten throughout the US.

Discussions at the 2009 PALS focused on a broad range of issues, including:

- Healthcare reform and health disparities in the US, including how the reform debate should include discussions of prevention, innovation and intervention efforts (US). See below for detail on our national PALS meeting and read more about our advocacy on [US healthcare reform](#).
- The contribution of vaccines to public health and how to overcome misinformation and misperceptions about immunisations (US)
- Mental health, prevention and wellness in the military (US)
- The role of patient organisations in scientific research. (Netherlands)
- Costs in the Swiss healthcare system, the implications for patients on the introduction of managed care systems and a new fee paying system in Swiss hospitals (Switzerland)
- Improving healthcare in Japan, including how to empower patients and improve working condition for hospital doctors (Japan)
- Patient access to medicines (Latvia)

European Patient Forum

In 2009 GSK co-sponsored the European Patient Forum's annual conference in Gothenburg with the pharmaceutical companies Pfizer and Amgen. This brought together approximately 50 patient groups and other stakeholders to exchange ideas about improving healthcare and increasing the involvement of patient organisations in the delivery of healthcare.

US National PALS meeting

The 2009 US National PALS meeting focused on healthcare reform and health disparities. Over 100 participants discussed how the reform debate should include prevention, innovation and intervention efforts. Speakers included a former US Surgeon General, and leaders of the minority health associations in the US. Following the event we held regional conferences and webinars which delved deeper into regional concerns

and addressed specific ways to overcome barriers to healthcare. More than 200 patient groups were represented across these events with approximately 700 participants in total.

› [Back to top](#)

Corporate Responsibility Report 2009

Advocacy in 2009

Here we describe some of the training and support activities we undertook in 2009 in partnership with patient groups.

Training and capability building in Europe

Helping patient groups to develop in Italy

Patient groups rely on funding to be able to support their members and carry out their vital advocacy work. It is important that they receive funding from a variety of sources so they remain independent and do not become reliant on a single donor.

In 2009 GSK organised a series of workshops to help Italian patient groups apply for and win public funding. After attending a GSK workshop, O.N.Da (The National Observatory for Women's Health), an Italian umbrella group which studies the main conditions affecting women, applied for and won €615,000 of funding from the European Health Programme. O.N.Da will use the funding to participate in a three-year project to promote early cervical screening to fight cervical cancer in EU. The AURORA project will focus on 'hard to reach groups', including young people, and minorities and people living in rural areas.

We are developing innovative ways to train patient groups in the skills they need to succeed. In 2009 we launched a web portal that Italian patient groups can use to access online training programmes. These include sessions on how to apply for and win funding and training on managerial skills chaired by a leading expert on non-profit organisations. The web portal means that patient group members do not have to travel to training sessions, which takes time and money and is often difficult because of health reasons. Patient groups can also use the portal to form virtual networks to collaborate and share experiences.

Fundraising training in Spain

GSK provided funding to enable the Foundation for Health Science, a training organisation, to run free workshops and seminars to inform patient groups how to seek donors and win funding.

The two-day training sessions were designed to equip patient group managers with the knowledge and skills to develop a successful fundraising campaign. The course provided specific advice on how to tailor an organisation's approach when contacting private individuals, corporate, public organisations and international donors.

Training the trainer in Germany

We are supporting a training programme to help members of national patient organisation Kindernetzwerk e.V to work more efficiently and to develop media and communications skills. Kindernetzwerk is made up of 175 regional patient groups in Germany, representing 120,000 parents with children suffering from chronic diseases.

In 2008 the organisation surveyed its members to understand the challenges they face now and in the future. This showed that parents are concerned that as well as caring for their sick child, they will struggle to cope with an increase in demands on their time as patient groups become more involved in healthcare in Germany.

GSK donated €20,000 for a training programme to enable Kindernetzwerk members to manage their time better and work more efficiently and effectively. The course was designed as a 'train the trainer' programme, so that volunteers from each group could pass on what they learnt to the rest of their patient group.

Other activities

Supporting breast cancer awareness in Australia

In 2009 we donated almost AUD \$100,000 to the McGrath Foundation, an organisation that funds specialist breast care nurses for Australian women living with breast cancer and raises awareness of the disease among women. The Foundation was co-founded by Jane McGrath, wife of cricketer Glenn McGrath; Jane McGrath has since passed away.

The funding will be used for a research project assessing levels of awareness and attitudes towards breast cancer among women aged 18 to 40. The Foundation will use the results of the study to inform media campaigns that educate younger women about the need for greater breast awareness and the dangers of breast cancer.

GSK's support will help establish the McGrath Foundation as an advocate for breast awareness, building on its core activity of providing funding for nurses.

Supporting veterans in the US

We are partnering with other organisations to raise awareness of the serious health issues that affect many veterans in the US. Together with the Washington Redskins professional football team we hosted a health screening event for veterans in the Redskins locker room at FedEx Field.

Veterans and other local participating patient groups were assessed for the risk of developing conditions such as diabetes, cholesterol, osteoporosis, prostate conditions, HIV, breast cancer and ocular disorders. Physicians and other healthcare professionals offered counselling services and 19 local and national health advocacy organisations also contributed.

We also partnered with The National Alliance on Mental Illness, hosting an event in New England that educated patients, family members, legislators and veterans' health groups on mental health issues that veterans and their families can experience.

› [Back to top](#)

Corporate Responsibility Report 2009

Q&As

Here we respond to questions raised by our stakeholders

How do you make sure that your lobbying activity doesn't contradict or undermine your corporate responsibility work?

Corporate responsibility is central to our business. We aim to ensure that all our lobbying activity reflects the values set out in this report as well as being sensitive to the views of our stakeholders. Employees involved in public policy must abide by our Employee Guide to Business Conduct which commits them to acting with honesty and integrity.

We have well-established public policy positions. These are developed through wide consultation and are approved by our Corporate Executive Team. Employees who lobby for GSK are closely involved in developing these positions. We believe transparency is key to building trust with our stakeholders and we disclose our [public policy positions](#) and lobbying expenditure in Brussels and Washington on our website.

Does GSK make political contributions through so-called '527' organisations?

Yes, we support a number of '527' organisations such as the Democratic Governors Association and the Republican Governors Association. A '527' organisation is a US tax-exempt organisation created primarily to influence policy development and promote issue discussion. '527' organisations are prohibited from making expenditures to directly advocate the election or defeat of any specific candidate.

GSK has no influence over how '527' organisations use GSK contributions; however, our support enables the organisation to develop and advocate policy positions and us to participate in their functions and to debate and discuss important issues for GSK with other organisations, the public and policy makers.

Contributions to '527' organisations are not defined as political contributions and so are not subject to our policy to stop all corporate political contributions.

Isn't your support for patient groups just another marketing tool?

No. GSK neither promotes medicines to patient groups nor would ever ask a patient group to endorse a GSK medicine. We work with patient groups in a number of areas, including improving how clinical trials are run, disease awareness initiatives, and on the bigger agenda of ensuring that all new medicines are made available to patients.

When GSK provides funding, are you trying to 'buy' favours from the patient organisation?

No. We never ask for endorsement of any of our medicines or a return on investment for our support. We are careful that our support for an organisation does not compromise its independence and is based on trust and mutual respect, and complies with the highest standards of our code of conduct.

How do these groups maintain their independence if they receive significant funding from companies such as GSK?

We encourage patient groups to diversify their funding from sources in both the public and the private sector. Patient groups should never become dependent on any one funder from either sector. Our [guidelines](#) state that we should provide no more than 25 per cent of a group's overall income, except in exceptional circumstances.

› Home › Responsibility › [Our work with communities](#)

Corporate Responsibility Report 2009

Our work with communities

We donate money, time, medicines and equipment to support communities around the world.

Our programmes are long term and focus on addressing healthcare challenges and increasing access to medicines. We also invest in improving education, especially science education, and provide some support for art and environment initiatives.

In 2009 we committed to reinvest 20 per cent of our profits from the sales of our medicines in Least Developed Countries (LDCs) back into projects that strengthen healthcare infrastructure and help widen access to essential medicines in these countries.

We believe contributing some of our profits to benefit communities is part of being a responsible company. Community investment also brings us long-term business benefits by improving our reputation, boosting employee morale and helping us build good relations with governments. We do not use community investment as a way of generating sales.

We select projects that are relevant to our business and the skills of our people. This is where we can bring the most benefit to communities and GSK.

Most of our investment is made through non-profit organisations that are expert in healthcare and education. These organisations are best placed to understand local community needs and to target resources effectively. Donations are made at a company level and by individual sites.

We ask our partner organisations for our larger programmes to report annually on the progress of the projects supported by GSK, to ensure that the money we give has the greatest possible impact. We review results with our partners and identify any changes required to achieve the programmes' objectives.

In November 2009, we announced that we will be the Official Laboratory Services Provider as a supplier for the London 2012 Games. In the build-up to 2012, we will be working with the London Organising Committee of the Olympic Games and Paralympic Games (LOCOG) to provide facilities and equipment to enable Kings College London to operate a World Anti-Doping Agency (WADA) accredited satellite laboratory during the games.

This section describes our support for innovative projects in three areas:

- [Preventing disease](#)
- [Building the capacity](#) of communities and community organisations
- [Promoting education](#), particularly in science

› [Back to top](#)

Corporate Responsibility Report 2009

Community investment

In 2009 our global community investment was £163 million (\$254 million) compared with £124 million (\$229 million) in 2008, on a like for like basis.

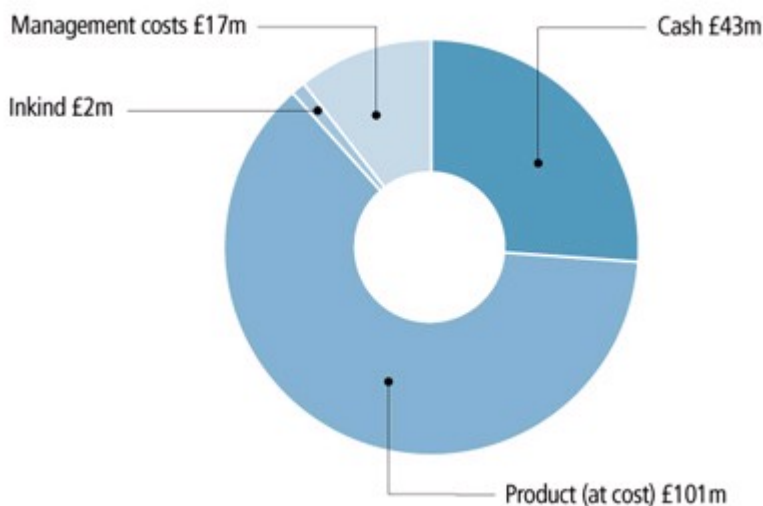
We maintained and increased our corporate giving levels despite the global economic crisis, knowing that our contributions are important for recipients and can be critical for the success of the initiatives to support them. The increase is due to expansion of our US Patient Assistance Programs, increased humanitarian product donations and scale up of our donation of albendazole for the lymphatic filariasis (LF) programme.

This is the second year we have valued donations using cost (average cost of goods) rather than the wholesale acquisition cost (WAC). This approach to valuing donations is a more accurate reflection of the true cost to GSK. We will continue to also report the WAC value of our donations for benchmarking purposes.

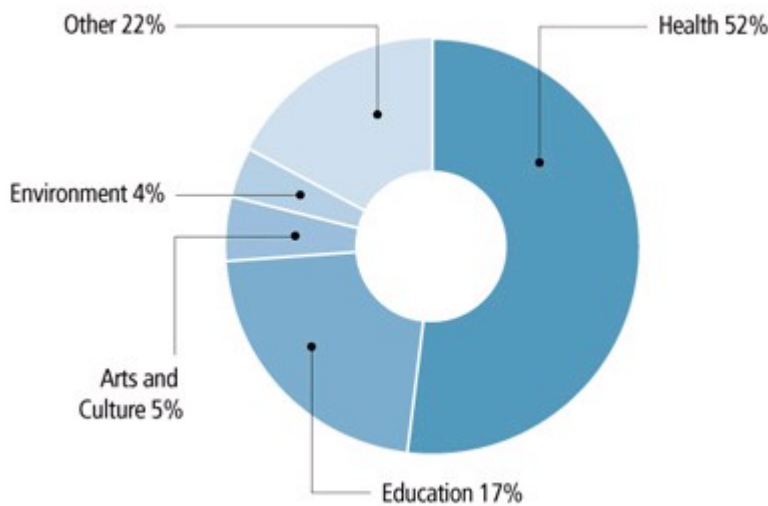
We belong to the UK's London Benchmarking Group (LBG) and the US Committee Encouraging Corporate Philanthropy (CECP). LBG guidelines report product donations at cost, whereas CECP guidelines report product donations at market value. For comparative purposes the total value of giving in 2009 using WAC for products would be £467 million (\$729 million) compared with £343 million (\$634 million) in 2008.

The giving figure is built up in the following way:

Method of giving (£ million)



Breakdown of cash giving (%)



Our product donations are made through three main programmes:

- Our Patient Assistance Programs to support low-income patients in the US, totalling £80 million (average cost of goods) in 2009
- Humanitarian product donations to under-served communities in 96 countries, including people affected by a series of natural disasters in Asia Pacific, totalling £8 million (average cost of goods) in 2009
- Donation of 425 million albendazole tablets (£13 million average cost of goods) for the lymphatic filariasis (LF) elimination programme

Following the outbreak of pandemic flu (H1N1) in 2009, we made a commitment to donate 60 million doses of our H1N1 vaccine to the World Health Organization for use in developing countries. For accounting purposes, we have provided for the full cost of these donations in 2009, although the delivery of the vaccines will take place mainly during 2010. For this reason our total global community investment figure for 2009 does not include the cost of the H1N1 vaccine donation, which will be reported as a product donation in 2010. Read more about [our response to pandemic flu](#).

We publish data about our charitable grants made to patient groups in our European, Emerging Markets and Asia Pacific regions. In 2008 we further increased transparency by publishing details of all our charitable grants over £10,000 (\$15,000). Find out more about [our grants](#).

We retained our CommunityMark in 2009 for ongoing work at the local and national level in the UK as well as for our larger international programmes. We were one of the first companies to achieve the Mark in 2008 for outstanding investment in the community. Following independent assessment, CommunityMark companies are awarded for a three-year period and monitored to ensure continued commitment and excellence. The Mark was founded by Business in the Community and is endorsed by UK government and voluntary sector leaders.

› [Back to top](#)

› Home › Responsibility › Our work with communities › [Employee involvement](#)

Corporate Responsibility Report 2009

Employee involvement

We encourage employees to be active in support for causes they care about and we run volunteering programmes to make it easier for them to get involved.

Employee volunteering

A company-wide employee volunteer initiative was launched in 2009 that gives every GSK employee one paid day off each year to volunteer for a good cause.

In 2009 our employees supported a wide range of charities and projects and held hundreds of group activities, including:

- Delivering 3,000 books and 30 computers to a school affected by the 2008 earthquake in Sichuan, China, as well as painting the library, fixing broken desks, and teaching science classes
- Clearing up rubbish, visiting schools, and planting trees and vegetables in Kibera, Kenya – Africa's largest slum
- Planting trees in Mexico
- Refurbishing nursing homes in Sri Lanka
- Volunteering in charity shops in the UK
- Distributing food to the homeless in North Carolina
- A series of US events to coincide with President Obama's nationwide service initiative, United We Serve, culminating on 11 September 2009 with a National Day of Service and Remembrance. On this date, nearly 100 GSK employees volunteered for a variety of projects in New York City.

In the Philippines, the volunteering day turned into a week of activities when employees came to the aid of communities affected by Typhoon Ondoy – including nearly 170 GSK staff. We put in place programmes to clean up colleagues' flooded homes and pack relief goods for donation, including 1,800 bags of food and toiletries which benefited around 700 families in the worst hit areas. Other GSK volunteers served up hot meals to 4,000 people over two days.

Read about our support for other [disaster relief efforts](#) in 2009.

PULSE

We also launched the PULSE Volunteer Partnership, an international programme that gives high-performing employees the opportunity to use their professional skills to support our non-profit partners for three to six months.

From our 2009 intake, we had 58 PULSE volunteers working in 18 different countries for 25 non-governmental organisations (NGOs).

Read more about [PULSE](#).

GSK Challenge Fund for AMREF

We set ourselves the challenge of raising £50,000 for the African Medical and Research Foundation

(AMREF). AMREF is a leading health development organisation in Africa, saving and transforming the lives of some of the world's poorest people. AMREF partners with GSK on our Positive Action and PHASE activities in Africa. Our CEO, Andrew Witty, kicked off the initiative in April 2009 by running the London Marathon to raise funds.

Employees were able to donate to the fund through a dedicated website, which highlighted that just £10 could buy ten rapid malaria testing kits that help to ensure prompt and effective treatment, while £20 would provide a health worker with a basic general medical kit.

We matched employee contributions to make a total donation of £50,000.

› [Back to top](#)

› Home › Responsibility › Our work with communities › [Preventing disease](#)

Corporate Responsibility Report 2009

Preventing disease

Infectious diseases kill millions of people in the developing world each year.

They cause misery, cost billions of dollars and slow economic growth. Preventing infection is more effective than treatment and can have significant social and economic benefits.

[Our vaccines](#) play a significant role in preventing disease.

We support innovative community approaches to disease prevention that are tailored to local settings and needs. For over a decade we have supported initiatives to [eliminate lymphatic filariasis \(LF\)](#) worldwide, as well as our handwashing programme [PHASE](#), to prevent diarrhoea-related disease.

We also support a wide range of [local programmes](#) to help prevent disease in the communities where we operate.

› [Back to top](#)

› Home › Responsibility › Our work with communities › Preventing disease
› **Eliminating lymphatic filariasis**

Corporate Responsibility Report 2009

Eliminating lymphatic filariasis (LF)

We have committed to donate as many tablets of albendazole, our anti-parasitic drug, as are needed to eliminate lymphatic filariasis (LF).

LF is a disfiguring disease prevalent in tropical and sub-tropical countries. Transmitted by mosquitoes, it can lead to severe swelling of the arms, legs, breasts and genitals, and thickening of the skin. LF is one of the world's leading causes of permanent disability, with an estimated 1.3 billion people (approximately one-fifth of the world's population) at risk of infection in over 80 countries. Considered a neglected tropical disease, LF disproportionately impacts poor and marginalised populations.

In 2009 we donated 425 million albendazole treatments to 28 countries, compared with 266 million treatments in 2008 (a 60 per cent increase). Since the programme began, we have donated over 1.4 billion albendazole tablets to LF-affected countries.

In 2009 we opened a new production line in Nashik, western India to help meet the increased worldwide demand. Once the Nashik facility is fully operational, we aim to manufacture 600 million tablets per year by 2010. Our enhanced manufacturing capacity means that in 2009 we were able to donate 180 million tables to India, the country with the largest LF burden, up from 130 million in 2008. The economic cost of LF in India is estimated to exceed US \$840 million due to treatment costs and reduced working time.

In 2009 we co-authored a paper in the *Annals of Tropical Medicine and Parasitology* about our ten-year collaboration with pharmaceutical company Merck & Co. Inc. to eliminate LF by donating anti-parasitic drugs that help stop transmission of the disease. Through the collaboration we also offer financial support and advice to those coordinating LF elimination efforts.

This year countries working to fight LF received a major boost through significant funding commitments made by the UK Department for International Development and the US Agency for International Development for control and elimination of neglected tropical diseases.

The albendazole tablets given to prevent LF have the additional benefit of treating intestinal worms. These parasites particularly affect children, causing anaemia and malnutrition, and stunting growth. We estimate that since the beginning of the LF programme, over 220 million albendazole treatments have been administered to children and over 190 million to women of child-bearing age. This will have had a positive impact on the overall health of those infected with intestinal worms.

To interrupt transmission of LF, the World Health Organization (WHO) recommends treating entire at-risk communities for at least five years with albendazole plus either Mectizan or diethylcarbamazine (DEC). Several countries have completed five annual mass drug administrations (MDAs), and are now in the process of monitoring their populations to evaluate the impact of the programme on the disease. Assessments conducted in Egypt, Togo and Vanuatu, a Pacific Island nation, showed that LF has been eliminated in most areas of these countries.

Programmes in Tanzania, Madagascar and Burkina Faso have also reported an unexpected benefit of the MDAs, beyond reducing infection rates. In these countries, some patients already infected with LF are describing an alleviation of symptoms after the MDAs, including reduced leg swelling and a reduction in frequency and length of acute attacks (spells of feverishness and loss of energy). Acute attacks are an incapacitating but all too frequent symptom of LF.

[Read more about our approach to LF and the patients who are living with the disease.](#)

› Home › Responsibility › Our work with communities › Preventing disease
› **Personal Hygiene and Sanitation Education**

Corporate Responsibility Report 2009

Personal Hygiene And Sanitation Education (PHASE)

Every year more than two million people die of diarrhoea-related disease, mostly children in developing countries. These deaths can often be easily prevented through better handwashing and sanitation.

PHASE is a school-based programme that helps to reduce diarrhoea-related disease by encouraging school children to wash their hands. We established PHASE in 1998 and since then we have invested over £4 million (\$7 million) in the programme. PHASE now operates in 16 countries and has reached over 700,000 children.

PHASE is run in partnership with the African Medical and Research Foundation (AMREF), Save the Children and the Earth Institute at Columbia University, as well as ministries of health and education in the countries where the programme operates.

In 2009 we extended PHASE to the slum areas of Mumbai, India with our partner Pratham. Our £320,000 investment over three years will provide Pratham with the technical support needed to implement PHASE in 23 municipal schools, reaching approximately 20,000 children and their households. Pratham will also introduce PHASE to the ten shelter homes it runs across India, which house a further 500 children.

We expanded our PHASE programme in Uganda in June 2009, and it now reaches 130,000 children in nearly 200 primary schools. Success stories to date include a reduction in absenteeism from 24 per cent to just 14 per cent, seemingly due to improvements in children's health, and better performance in primary school examinations as a result. There are now 17 per cent more latrines in local communities, and the percentage of households with their own handwashing facilities has increased from zero to 46 per cent. We are advocating for the incorporation of the initiative into national policy, so it can be replicated more easily and more sustainably worldwide. Already, 11 out of 17 local governments involved in PHASE have developed relevant by-laws.

We also launched a UK PHASE pilot project in three schools in Hounslow, Greater London, near our global headquarters. Through school assemblies and fun lessons, over 500 children learned about PHASE initiatives around the world and about the importance of washing their hands properly. We will expand the programme to a further 11 schools in early 2010.

Our aim is for PHASE to reach over one million children by 2010. As part of our continuing efforts, we plan to expand the programme to Brazil and the Philippines. In Brazil, the PHASE pilot project will reach 600 children at schools in the slums of Rio de Janeiro. The introduction of PHASE in the Philippines will build on the success of the existing Fit for School programme, also supported by GSK, which aims to improve children's health by teaching them about handwashing as well as toothbrushing and oral health. The programme also provides children with soap, toothbrushes and toothpaste, conducts two mass de-worming initiatives each year, and makes improvements to water and sanitation facilities. We will apply lessons learned from Fit for School so PHASE teaches children about oral health as well as handwashing.

In Mexico, PHASE won the 2009 award for community liaison best practice, from the Mexican Center for Philanthropy and Mexican Social Responsibility Alliance.

Supporting the Millennium Development Goals

In 2000 world leaders agreed the Millennium Development Goals (MDGs) to meet the needs of the world's poorest people. The MDGs include targets to halve extreme poverty and hunger by 2015, and improve education, health, gender equality and environmental sustainability.

As part of a project coordinated by Columbia University's Earth Institute, we have introduced PHASE to two Millennium Villages in Malawi and Senegal. Millennium Villages are research projects in African communities designed to find practical ways to meet the MDGs. The Senegal project brings PHASE to West Africa for the first time, and for it we are translating educational materials into French.

Global Hand-Washing Day

The second Global Hand-Washing Day was held during 2009. Over 900,000 schoolchildren in PHASE schools and adults participated in fun, handwashing-related activities to celebrate the day, including:

- In Mexico, more than 40,000 children took part in games, workshops, health rallies and community campaigns in 17 states across the country
- In Uganda, school health clubs made water containers from materials brought from home by students
- In India, a group of clowns hosted a three-hour handwashing event at Govandi, Mumbai's largest dumping ground

[Read more about PHASE and the Global Hand-Washing Day.](#)

› [Back to top](#)

Corporate Responsibility Report 2009

Local programmes

We support a wide range of programmes to help prevent disease in the communities where we operate. We fund these programmes at corporate and local level.

Below are just a few examples.

China – working to improve the health of migrant workers

China's industrial cities attract large numbers of temporary migrant workers, mostly from rural areas. Many lack education and access to public health services. They are among China's most vulnerable groups, and in migrant communities infectious diseases and occupational ill health are common.

We are supporting a health education programme in Shanghai, run by the Xintu Centre of Community Health Protection. The programme aims to improve the health of migrants and their families by raising awareness about health issues such as HIV/AIDS. We have provided funding of £250,000 over three years to this programme.

US – preventing childhood obesity

Childhood obesity is a major health concern in the US. We have donated \$495,000 to support a three-year project with North Carolina Prevention Partners to develop and test ways of raising awareness about obesity among students at elementary, middle and high schools in North Carolina.

The project has so far reached over 76,000 young people. We are also supporting expansion of the programme so that more people can learn about obesity remotely, using web-based training.

US – product donations to improve community health

In an effort to help bridge the oral care gap in the Appalachia region of Kentucky, where few families have access to dental care, we donated 10,000 toothbrushes and 30,000 tubes of toothpaste to families through a partnership with Kids First Dental Care.

We have made a pledge to provide additional support to the organisation, further assisting them in their efforts to provide access to comprehensive dental treatment for children in Kentucky.

UK – improving sexual health services for disabled people

We have donated more than £520,000 over three years to a Leonard Cheshire Disability project to give young disabled people better access to sexual health services. The project addresses knowledge and understanding gaps relating to disabled people's sexual health issues.

Over the three-year period, the organisation will run focus groups and workshops to identify key issues and will develop a range of materials to support sexual health workers who work with disabled people.

Preparing for when the funding stops

Most of our programmes run over a number of years, recognising that it takes time to build change. But from the start we plan for what will happen at the end of our funding.

We work hard with community organisations to bring results over the life of a project (usually around

three years) and to help organisations win funding from other sources to continue their work.

From the start we require our partners to work to a budget to make sure funding is spent effectively and makes a positive impact. We also ask our partners to demonstrate achievements by producing an annual progress report. These reports show evidence of success and are a crucial part of attracting new donors.

› Home › Responsibility › Our work with communities › Preventing disease
› **Responding to disasters around the world**

Corporate Responsibility Report 2009

Responding to disasters around the world

We provide humanitarian assistance in the form of cash and product donations in times of emergency and natural disasters. We give supplies of our products to humanitarian aid organisations so they can distribute them quickly and efficiently as soon as an event occurs.

Responding to the Earthquake in Haiti

Immediately following the devastating earthquake that struck Haiti in January 2010, GSK provided donations of medicines valued at over £1 million from stocks held in warehouses of our non-profit partners: AmeriCares, Direct Relief International, Health Partners International of Canada, MAP International, IMA World Health and Project Hope. The initial wave included urgently needed oral and topical antibiotics that were used immediately for first line treatment.

Subsequent product donations, to support medium to longer-term primary healthcare needs, have included antibiotics as well as respiratory and diabetes treatment. These are valued at approximately £6.5 million (WAC). Additionally, our consumer division provided a range of consumer products, including toothpastes, antacids, pain relievers and vitamins.

We donated £250,000 to the British Red Cross to meet the water and sanitation needs of those affected by the disaster. This will support up to 20,000 displaced people with the construction of 200 emergency latrines and distribution of essential hygiene kits. The provision of water and sanitation facilities is paramount and can reduce mortality and infection rates significantly.

We are committed to responding to the huge needs emerging in Haiti and will support the longer-term reconstruction and recovery efforts.

Responding to multiple natural disasters in the Asia Pacific region

In 2009 we donated products for humanitarian relief to many parts of the Asia Pacific region following a series of natural disasters there. In total we donated product worth \$13 million (average cost of goods). Our activities included:

- In Indonesia, we partnered with humanitarian relief agencies AmeriCares and the International Medical Corps to donate antacids, antibiotics, inhalers and paracetamol to people affected by the earthquake. We also donated funds towards the provision of water, food and sanitation, and made a further cash contribution to Save the Children's emergency appeal. The value of our combined contributions came to \$570,000. As part of GSK Indonesia's volunteer activities, employees also worked with the Red Cross to organise blood donations. We also provided \$250,000 to AmeriCares, who are collaborating on a project with the Ministry of Health Office of Health Provision, local hospital directors and NGO medical personnel to install a new water system and supply for Djamil Hospital, provide rehabilitation education and equipment for 300 people injured in the earthquake and help restore the capacity for hospitals and clinics damaged by the earthquake to treat patients
- After the Samoan earthquake and subsequent tsunami, we worked with the New Zealand government to assess the island's medical needs, and sent a donation of basic antibiotics at the request of the Samoan authorities. We also donated \$100,000 to the New Zealand Red Cross towards its continuing aid efforts
- Following Typhoon Ketsana, we worked with humanitarian aid givers, Direct Relief International, to help communities in Vietnam affected by the storm and the flooding it caused. We donated medicines and

funding to an outpatient hospital in Hue, Vietnam that delivers free medicines and runs clinics specialising in healthcare education including HIV/AIDS counselling

- In the Philippines, helping communities recover from flooding after Typhoon Ondoy, as part of our [employee volunteering activities](#).

Following the major tsunami in 2004 GSK pledged £2 million to support rehabilitation and reconstruction efforts in affected communities. We have supported a range of initiatives, many of which continue, enabling people to rebuild their lives, restore their livelihoods and have access to effective healthcare provision. These include:

- In Aceh Tengah, Indonesia, the provision of high-quality education to midwifery students attending the Takengon Midwifery Academy, to bring the quality of maternal and newborn care services in line with national standards
- In Thailand, support for 40 local fishing villages in Ranong, Phang Nga, and Krabi to help restore their livelihoods. We also funded a micro-credit programme helping families and communities rebuild their lives to achieve self sufficiency, increase life coping skills through health promotion and reduce poverty through individual and collective income generation schemes, as well as enable school-age children to attend school
- In Sri Lanka we funded projects with partners Direct Relief International, Guardian Foundation and Shilpa Children's Trust to help restore the healthcare system in tsunami-affected communities and improve service capacity beyond pre-tsunami levels. Projects include operating mobile clinics in coastal Ampara District for displaced persons in camps and affected towns and villages, the construction of a clinic and the provision of medical, dental, nutritional and psychosocial services for tsunami-affected children in southern Sri Lanka
- In Nias, Indonesia, we worked with Save the Children Indonesia to introduce its PHASE hand hygiene programme
- In Chennai, India, we provided funds to train 420 local young women as nursing assistants, as part of a long-term rehabilitation strategy addressing the acute shortage of trained medical personnel
- In December 2008, we began working with Leonard Cheshire Disability in Galle, Sri Lanka, to support people with disabilities (many of whom were disabled by the tsunami) to access rehabilitation services, mainstream education and livelihood opportunities

Travel packs for physicians involved in humanitarian relief

We support healthcare professionals who travel abroad to provide medical care to disadvantaged people, including during disaster relief efforts. In remote communities, a visit by a travelling doctor may be the only medical treatment available.

We donate essential medicines for inclusion in 'travel packs' that healthcare professionals (HCPs) can take with them on trips to affected areas. The packs contain broad-spectrum antibiotics and other medicines, as well as rehydration salts, vitamins and general medical supplies. In 2009 we extended the range of products the packs contain to include our consumer healthcare products such as analgaesics and antacids. Each pack contains over 500 treatments that can fight infection and treat common illnesses. The medicines in each pack are worth around \$14,000, but HCPs only need to pay a \$450 tax-deductible fee to Medical Assistance Programs (MAP) International, the NGO we partner with to distribute the packs to the HCPs most in need of support.

› [Back to top](#)

› Home › Responsibility › Our work with communities › [Building community capacity](#)

Corporate Responsibility Report 2009

Building community capacity

Lack of healthcare infrastructure – including clinics and trained healthcare professionals – and cultural attitudes are significant barriers to treatment in many developing countries.

Our global programmes help to build capacity for healthcare in developing country communities. [Positive Action](#), for example, works with communities affected by HIV and AIDS, while our [African Malaria Partnership](#) is improving prevention and access to malaria treatment. We support [local initiatives](#) that help overcome stigma, build the capacity of communities to provide healthcare and combat disease.

In 2009 we committed to reinvest 20 per cent of our profits from sales of our medicines in Least Developed Countries (LDCs) back into projects that widen access to essential medicines and strengthen the healthcare infrastructure of LDCs. Our sales in LDCs are relatively low, so this investment will be limited; however, we hope that our actions will encourage other companies operating in LDCs to adopt a similar approach.

We also provide [humanitarian relief](#) in times of emergency and natural disasters.

› [Back to top](#)

Corporate Responsibility Report 2009

Supporting healthcare in Least Developed Countries

We have committed to reinvest 20 per cent of our profits from sales of our medicines in Least Developed Countries (LDCs) back into projects that address priority healthcare challenges, provide support to governments to remove barriers that stop patients accessing quality healthcare, and strengthen basic healthcare infrastructure.

In 2009 we selected six LDCs for reinvestment. The initial activities are targeted primarily on improving maternal, newborn and child health – high priorities for the ministries of health and essential for achieving the Millennium Development Goals (MDGs), specifically goal four (reduce child mortality) and goal five (improve maternal health).

In total we reinvested £512,000 in 2009 and allocated another £300,000 to programmes that are yet to start. The table below summarises our reinvestment activities:

Region/ Country	Programme scope	Partner/ Programme Budget
Africa		
Ethiopia	Community-based health infrastructure and capacity building support to reduce maternal, neonatal and child mortality	Federal Democratic Republic of Ethiopia, Ministry of Health (£100,000/year for three years)
Democratic Republic of Congo	Health infrastructure support to improve neonatal and child health	Catholic Relief Services (CRS) (£100,000/year for three years)
Rwanda	Expanding a network of business format franchise nurse-run clinics to improve access to quality basic healthcare and essential medicines	HealthStore Foundation (£300,000 /year for three years)
Sudan	Motorcycle ambulances for pregnant women (one-year programme to commence in 2010)	Ministry of Health Sudan, NGOs, UNFPA, WHO and community leaders (US \$250,000)
Asia		
Myanmar	Water sanitation programmes in the schools of suburban areas	Partenaires, Organisation de Solidarité Internationale (US \$140,000)
Cambodia	Primary Healthcare Infrastructure Project – construction of health centre facilities	Plan International (US \$70,000)
Cambodia	Maternal and Child Survival Initiatives – community based health infrastructure (clinical training centre for midwives)	RACHA (US \$70,000)

Building a healthcare network in Rwanda

We are helping improve access to healthcare for people in rural Rwanda by supporting the HealthStore

Foundation's efforts to expand its Child Family Wellness (CFW) initiative to the country.

Our contribution is helping the NGO build a network of small pharmacies and clinics to make essential medicines and treatment more readily available to children and their families in remote areas. The organisation has already successfully established a similar healthcare network in Kenya.

Through the CFW micro-franchising model, trained nurses operate their own businesses to treat common diseases such as malaria and pneumonia, seeing around 20 patients on average every day. They can also provide health education and teach visitors about disease prevention.

The HealthStore Foundation aims to open 60 clinics across Rwanda by the end of 2012.

› [Back to top](#)

› Home › Responsibility › Our work with communities › Building community capacity
› **Combating HIV/AIDS – Positive Action**

Corporate Responsibility Report 2009

Combating HIV/AIDS - Positive Action

Positive Action works with community organisations to build capacity to counter the ignorance and stigma surrounding HIV through outreach, education and advocacy. In 2009 we provided over £1 million, funding projects in 46 countries across Africa, Asia, Latin America and Eastern Europe.

Through Positive Action, we pioneered support for vulnerable communities, including men who have sex with men, intravenous drug users, sex workers, migrants, young people, orphans and vulnerable children and marginalised poor rural women – groups who have limited human rights or public voice. It is essential to work with these groups if we expect to make a difference to this epidemic. Positive Action programmes involve grassroots organisations that are able to continue to support their communities after the projects have come to an end.

In July 2009, we launched a new Positive Action for Children Fund which will make £50 million (\$80 million) available over ten years to help prevent mother-to-child transmission of HIV and to support orphans and vulnerable children. This fund and our other Positive Action programmes will be managed by ViiV Healthcare, the [new GSK-Pfizer company focusing on HIV/AIDS](#).

During 2009, we supported 17 Positive Action programmes in 46 countries. Key projects include:

- Fighting stigma and discrimination in Mexico among vulnerable sectors of the population
- Bringing HIV education to vulnerable women in India through self-help groups
- Improving access to treatment in Kenya by promoting greater understanding and involvement of communities

From 2009, we are supporting the Staying Alive Foundation in its efforts to raise awareness about HIV/AIDS and its prevention among young people worldwide. The foundation, launched by television channel MTV in 2005, makes grants to organisations run by and for young people that work to prevent HIV infection and alleviate stigma and discrimination associated with the disease.

Also in 2009, we supported a journalist competition run by British newspaper The Guardian to raise awareness of health and development issues in poor countries. We sponsored a journalist to write about issues faced by people living with HIV/AIDS in Kenya. The winning story was published in a dedicated supplement in November 2009.

Read more about [Positive Action](#).

› [Back to top](#)

› Home › Responsibility › Our work with communities › Building community capacity
› **Combating malaria – Africa Malaria Partnership**

Corporate Responsibility Report 2009

Combating malaria – GSK African Malaria Partnership

Every year up to 500 million people are affected by malaria and over one million die from it, mostly young children in Africa. But the disease can be prevented by controlling the breeding of mosquitoes and using low-cost measures such as insecticide-treated nets. Malaria can be cured if treated promptly with effective medicines.

We established the GSK African Malaria Partnership in 2001 to improve the prevention and access to treatment of malaria in sub-Saharan Africa. Since then we have invested over \$3 million in initiatives to combat the disease.

In 2009 we extended our support for Mobilising for Malaria for an extra year. Mobilising for Malaria is an advocacy initiative to generate greater awareness, political commitment and sustained funding for malaria in Europe and Africa. National Coalitions Against Malaria have now been launched in the UK, Belgium, France, Ethiopia, Cameroon and Mozambique, bringing together advocates and activists from the public sector, NGOs, the media, the private sector and the political, academic and scientific communities. The extra year of funding will enable the National Coalitions to become better established and secure other sources of funding to sustain their activities.

The GSK African Malaria Partnership awarded four new grants in 2009, a total donation of £1.5 million over three years. They include:

- £624,000 to enable Save the Children UK to reduce malaria outbreaks in flood-affected communities in Kenya, by indoor spraying with insecticide, distributing bed nets, raising awareness in communities and at clinics, and training health professionals to prevent malaria and manage its symptoms
- £363,000 to Family Health International to increase community health workers' capacity to tackle malaria in Ghana, and raise community awareness about the disease
- £337,000 for an African Medical and Research Foundation (AMREF) project to train community health workers in Tanzania to prevent, treat and raise awareness about malaria in over 40 villages
- £182,000 to the Planned Parenthood Foundation of Nigeria, to reduce the prevalence of malaria in six communities, increase the use of bed nets and promote sanitation to reduce mosquito breeding sites

Read more about our [malaria programmes](#).

› [Back to top](#)

› Home › Responsibility › Our work with communities › Building community capacity
› **Local programmes**

Corporate Responsibility Report 2009

Local programmes

We support a wide range of programmes to build healthcare capacity in the communities where we operate. We fund these programmes at corporate and local levels.

Below are just a few local programme examples.

Building India's immunisation infrastructure

We are seeking to explore new and innovative approaches towards our philanthropic investment to ultimately play a greater role in helping to deliver better access to healthcare and education. As a step towards achieving this bold objective, we are developing a project that will seek to improve vaccine coverage among un-reached populations of the Mumbai urban slums that will serve as a framework to be implemented elsewhere. We hosted a workshop in Mumbai involving India's Ministry of Health and Family Welfare and NGOs including UNICEF and Save the Children. The workshop identified solutions for reaching remote communities with vaccine supplies, including the need for an improved cold chain and better information management systems, all of which are pivotal in delivering immunisations. The next phase is to partner with an NGO with local expertise to develop an intervention project in the urban slum areas, working alongside the Government of India.

Training nurses in Pakistan

Pakistan lacks qualified nurses, with just one available for every 4,000 patients. We have made a three-year commitment to support the Centre of Nursing Excellence, a programme to improve nursing education and the quality of maternal and child healthcare across the country. The centre admits 60 students each year for a six-month course on disease prevention. Over 30 nurses graduated in April 2009, and each is also qualified to pass on lessons learned to other nursing staff in their hospitals. Over three years, £277,000 has been allocated to this project.

Facilitating access to healthcare for disadvantaged children

We are the sole supporter of a Children's Health Fund (CHF) initiative in the US to ensure continuity of care for medically-underserved children with a high risk of disease. We have provided almost \$9 million to date for CHF programmes. The Referral Management Initiative eliminates the barriers, including distance, cost and cultural issues, that often prevent these children (many of whom are homeless) from receiving specialist healthcare.

Initially established in New York, the programme has grown and now also operates in Dallas, south Florida, Los Angeles, Philadelphia and Washington DC. It has already helped tens of thousands of disadvantaged children in need of specialist care. The initiative has succeeded in increasing the number of children referred to a specialist who actually make it to the appointment – from just five per cent when the programme began to 75 per cent today.

In 2009 we supported the CHF's pilot telemedicine project to help 400 patients in rural areas access specialist care at a Memphis hospital remotely, using state-of-the-art videoconferencing technology. The CHF acknowledged our support and affiliation in their annual report.

Support for advanced breast cancer sufferers

Breast cancer sufferers who play an active role in fighting their cancer can experience improved quality of

life, and may even improve their chances of recovery, according to the Cancer Support Community's Patient Active Concept. We contributed \$100,000 to help fund the Cancer Support Community's Frankly Speaking About Living with Advanced Breast Cancer initiative, a US national patient programme consisting of community seminars, support groups and online support.

Support with medicines

Senior PHARMAssist helps people aged 65 years and older in Durham, NC, to obtain the medicines they need and tap into other community resources that can support their health and independence. Over the past three years we have provided \$85,000 to support this important work. Programme evaluations have demonstrated that participants report reduced visits to the hospital and feel healthier.

Healthcare for the homeless in Pittsburgh

Through a \$500,000 grant over three years, we support Pittsburgh Mercy Foundation's Operation Safety Net, a healthcare outreach programme for the homeless population. Men and women living on the streets are given access to healthcare designed to meet their unique needs. The programme began in the Pittsburgh area and has expanded to a 19-partner Street Medicine International programme in the US, Europe, Asia, and Central and South America.

Home nursing for children with cancer in Greece

We are donating £300,000 over three years to Floga, a Greek association of parents of children with cancer, to develop a home nursing programme for children with cancer. The initiative enables children who need daily care to receive it at home from trained nurses, reducing the number of hospital visits required and substantially improving their quality of life.

Promoting healthy living for Dutch children

We are helping a Dutch health institute, NIGZ, to promote weight management strategies for young people at risk of developing obesity. Obesity is increasing in the Netherlands, and NIGZ encourages schoolchildren to be physically active and eat healthily. Our support (worth £300,000 over three years) will enable the organisation to raise awareness about obesity at schools in low-income areas. NIGZ will hold focus groups that bring together young people and teachers to design initiatives that inspire children to make healthy lifestyle choices.

Rewarding community healthcare organisations in the UK and US

Each year the GSK IMPACT Awards recognise voluntary organisations that have significantly improved the health of their local communities.

In the UK, ten winning charities receive £25,000 each and the overall winner is awarded an extra £10,000. Managers of winning organisations are trained in leadership, networking and fundraising skills. This helps strengthen small charities that are often unable to afford this vital skills training.

The GSK IMPACT Awards in the US provide support for charities that facilitate access to healthcare for underserved communities in Philadelphia and surrounding counties. In 2009 we launched a similar IMPACT awards programme near our Research Triangle Park facility. We awarded \$40,000 to each winning charity.

Read more about the [GSK IMPACT Awards](#) and the winning organisations.

› [Back to top](#)

Corporate Responsibility Report 2009

Supporting science education

In the UK and US, the numbers of young people choosing science subjects is falling and many students lack proficiency in either reading or mathematics.

As a result, both countries face a significant skills shortage.

The success of our business relies on us being able to recruit talented individuals, particularly those with science qualifications. We also want young people to make sound decisions about the science-related issues they come across in everyday life such as healthy eating, vaccinations and the value of medicines.

Our education programmes help make science more relevant to young people in the UK and US, stimulating their interest in science and encouraging them to pursue a science-related career. We also support the training and development of science teachers.

UK

Project ENTHUSE

Half of secondary school science teachers in the UK have had no subject training within the past five years. Project ENTHUSE, launched in 2009, aims to improve the continuing professional development of science teachers and helps them use the latest techniques to interest their pupils in science. We have committed £1 million, with a further £29 million coming from the UK government, the Wellcome Trust and eight other industry partners.

Teachers, assistants and technicians can apply for an ENTHUSE Award to study at the National Science Learning Centre at the University of York. The award covers course fees, travel and accommodation for up to 2,200 teachers each year. The schools receive funding to cover the cost of a replacement teacher during the course and a small grant to help implement new ideas when the teacher returns to the classroom.

ENTHUSE helped over 1,000 teachers and school science technicians in 2009 and aims to provide nearly 9,000 training days over a four-year period.

Royal Society of Chemistry

We will continue support for the Royal Society of Chemistry (RSC) programme to target science teachers who are not chemistry specialists and provide them with the key skills and confidence to be effective in their chemistry teaching. Through a funding commitment of £300,000 over three years, RSC teamed up with GSK to develop a course to help non-specialist chemistry teachers deliver quality chemistry education to 11-16 year olds. During the two-day residential course teachers have the opportunity to discuss health and safety issues, difficult chemical concepts, and new contemporary contexts for teaching chemistry. The RSC is a charity with a long standing reputation for delivering high-quality and highly regarded training for teachers.

US

America's Promise Alliance

The US national high-school dropout rate is greater than 30 per cent – and greater than 50 per cent for some minorities. We are helping to reduce this by supporting the America's Promise Alliance Dropout Prevention Initiative. The alliance is leading a national movement towards the goal that every American child will graduate from high school, ready for college, work and life. We have committed \$500,000 over three years to the initiative.

Institute for a Competitive Workforce (ICW)

We are working with the US Chamber of Commerce through the Institute for a Competitive Workforce to increase the business community's understanding of educational and workforce development issues. We hope the initiative will contribute to improvement in the quality of the US education system and the skills of its future workforce. We provided \$100,000 to support the ICW's 2009 Education and Workforce Summit in Washington, DC, attended by over 300 stakeholders.

North Carolina New Schools Project

We partner with the North Carolina New Schools Project to provide innovative teaching methods to ten STEM (science, technology, engineering, and math) schools. Some of the schools are located in areas especially hard-hit by the loss of agricultural and manufacturing jobs. We have provided \$515,000 to support this project with an aim to better prepare graduates for college, life and careers, and its success so far is evident from the fact that schools in the programme have half the dropout rate of other schools in North Carolina.

Opportunity Scholarship

We sponsor the Opportunity Scholarship programme through a \$1.2 million endowment which recognises individuals who have overcome adversity, including physical and sexual abuse, serious illness and personal loss, yet have pursued an education as a means of changing their lives. It provides scholarships as a means of removing one of the obstacles to continuing education: not being able to afford it. The initiative initially focused on North Carolina, but an additional \$1 million endowment was established in Philadelphia in 2009.

Philadelphia Education Fund

We are the lead corporate sponsor of the Philadelphia Math and Science Coalition, a partnership of 45 businesses, universities, the School District of Philadelphia and other non-profit organisations. The coalition develops highly qualified mathematics and science teachers through partnerships with schools, universities and corporations. Its aim is to improve the quality of mathematics and science teaching, so more students can succeed in further education and careers that require scientific backgrounds. We supported the programme with a \$300,000 donation over two years.

Science in the Summer

We are the sole supporter of Science in the Summer, a free education programme designed to get young people in Pittsburgh, Pennsylvania, Greater Philadelphia and North Carolina interested in science. Classes held in local libraries give children the chance to take part in hands-on experiments and courses ranging from genetics to oceanography. The programme began in 1986. In 2009, we invested \$558,000 across 173 sites where over 6,800 children participated in the programme.

› [Back to top](#)