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feel better,
live longer

Corporate Responsibility Report



2011



How to use this report

Navigation tools at the top right of each page and within the report are available. Click on:

- Icons to move through, search or print the report.
- Section names to take you to the front of that section.
- Arrows in the content tables to go to that page.
- Underlined links to go to that page or to view additional information online

About our report

We report our CR performance annually as part of our commitment to be open and transparent about our business activities.

This year we have restructured our report around four core themes, which reflect the issues we see as most important for responsible and sustainable business growth. These also reflect the issues most commonly raised by our stakeholders.

The report is supported by and references further information online at www.gsk.com. Information on corporate responsibility is also included in our [Annual Report](#).

We welcome your feedback on any of the information in this report and we are always happy to discuss any questions you may have that may not be covered. Please contact us at: csr.contact@gsk.com.

Data

Data relate to worldwide operations for the calendar year 2011, except where stated.

Data in the environment and health and safety sections were independently assured by SGS. More information on our approach to external assurance is provided in the governance and management section on page [96](#).

Brand names appearing in italics throughout this report are trademarks owned by and/or licensed to GSK or associated companies.

Reporting standards

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.

Contents

Our approach

| | | | |
|--------------------------|-----------|-----------------------------|-----------|
| From our Chairman | 02 | What we do | 05 |
| From our CEO | 03 | How we create value | 06 |
| | | Responsible business | 07 |

Health for all

| | | | |
|--|-----------|-------------------------------------|-----------|
| Introduction | 09 | Developed countries | 29 |
| Research and development | 10 | Europe | 29 |
| | | USA | 30 |
| Improving access to healthcare – a global challenge | 12 | HIV/AIDS and ViiV Healthcare | 31 |
| Developing countries | 14 | Research and development | 31 |
| Increasing availability | 14 | Increasing access | 33 |
| Feature: Our approach to malaria | 16 | Community investment | 34 |
| Improving affordability | 21 | | |
| Preventing disease and raising awareness | 25 | | |
| Advocacy | 28 | | |
| Future plans | 28 | | |

Our people and communities

| | | | |
|---------------------------------|-----------|--|-----------|
| Introduction | 37 | Performance in 2011 | 47 |
| Working at GSK | 38 | Feature: Bringing science to the London 2012 Olympic and Paralympic Games | 48 |
| Engaging employees | 38 | PULSE and employee volunteering | 50 |
| Developing employees | 39 | | |
| Diversity at GSK | 40 | | |
| Health and safety | 41 | | |
| Our community investment | 46 | | |

Our behaviour

| | | | |
|--|-----------|--|-----------|
| Introduction | 53 | Clinical research | 64 |
| Ethical conduct | 54 | Patient safety | 66 |
| Preventing bribery and corruption | 54 | Supply chain | 68 |
| Marketing our products | 55 | The supply and distribution process | 69 |
| Feature: Changing the way we incentivise our sales teams in the USA | 56 | Our supplier standards | 70 |
| Publishing payments to healthcare professionals | 58 | Performance in 2011 | 71 |
| Publishing grants and donations | 58 | Security of supply | 72 |
| Training and awareness | 58 | Supplier diversity | 73 |
| Monitoring and compliance | 59 | Public policy and patient advocacy | 74 |
| Data privacy | 60 | Trade and industry associations | 74 |
| Research practices | 61 | Public policy activity in 2011 | 75 |
| Animal research | 61 | Political contributions and lobbying expenditure | 77 |
| | | Patient advocacy | 78 |
| | | Human rights | 80 |

Our planet

| | | | |
|--|-----------|---------------------------------------|-----------|
| Introduction | 83 | Waste | 88 |
| Carbon | 84 | Minimising use of materials at source | 89 |
| Supply chain | 84 | Environmental stewardship | 90 |
| Our operations | 84 | Environmental governance | 90 |
| Propellants | 85 | Compliance | 91 |
| Feature: Understanding the impact of our products | 86 | Performance in 2011 | 92 |
| Water | 88 | External assurance | 94 |
| Water in our operations | 88 | | |

Governance and management

| | | | |
|------------------------|-----------|-------------------------------|-----------|
| Introduction | 95 | Stakeholder engagement | 98 |
| Our approach | 96 | Performance | 99 |
| The value of CR | 97 | | |

From our Chairman

GSK has always believed that operating in a responsible and ethical way is essential for the success of its business. During 2011 we continued to examine our policies and operations to ensure that our approach to corporate responsibility supports the delivery of our business strategy and is consistent with our values.

This year we have made good progress. In my role as Chairman of both the Board and the Corporate Responsibility Committee, I am acutely aware of the pressures and challenges faced by the company and I receive regular reports of how these are being addressed.

During the year I was particularly pleased to see further commitments made to improve global access to our medicines, including agreements to supply large quantities of our vaccines to protect against rotavirus gastroenteritis and pneumococcal diseases such as pneumonia and meningitis to the poorest countries of the world at fractions of western prices. The company has also made substantive progress in other areas such as environmental sustainability and in supporting the communities in which we operate.

Much of this progress is due to the leadership of Sir Andrew and the executive team. The Board will continue to support and constructively challenge their thinking and the actions they take to operate a responsible values-based business.



Sir Christopher Gent
Chairman



Sir Andrew Witty (left) and Sir Christopher Gent (right).

From our CEO

Three-and-a-half years ago, we set out to fundamentally change GSK to create a different type of company, delivering sustainable financial performance and providing shared value to patients, consumers and governments.

Our record in 2011 demonstrates that we are succeeding, through increased sales and returns to our shareholders and significant progress in our research and development.

We remain committed to operating with transparency and responsibility. During the year we made multiple advances on our agenda to ensure that our behaviour and our actions meet or even exceed the expectations of society. Much of this is reflected in this report which is structured around four areas: Health for all, Our people and communities, Our behaviour and Our planet.

One of our key priorities is to continue to align our commercial success with forming new partnerships to tackle the healthcare needs of people in developing countries. This is particularly pertinent for vaccines, and tackling pneumococcal disease is a great example of how these partnerships make a difference. Early in 2011, GSK began supplying pneumococcal vaccines to Kenya through an innovative financing mechanism known as the Advance Market Commitment. This is the largest fund ever designed for a single vaccine and has dramatically increased sustainable access to this vaccine for babies across Africa.

This success was built upon mid-year when we announced a new pricing structure for our vaccine against diarrhoeal disease. We offered the GAVI Alliance our vaccine at a fraction of the cost of developed western markets. Millions of children living in the world's poorest countries are now set to receive it, which will save countless lives in the future. Importantly, this offer is sustainable over the long term because we are recouping the cost of goods and manufacture.

2011 also demonstrated that we are making significant progress to improve returns and productivity in R&D. We are seeing this productivity translate into real filings and approvals, with three medicines approved in 2011 and four more ready to file in 2012. These include our new MEK inhibitor for melanoma and a new four-valent flu vaccine.

We are also on the cusp of creating the world's first malaria vaccine. I have seen first-hand the devastating impact that this disease has on Africa, having lived there for several years in the 1990s. In October 2011, late-stage trials confirmed the promise we have seen so far, showing that the vaccine reduces the risk of malaria by half in African children aged 5-17 months. We also reiterated our commitment to price the vaccine at a level that covers costs and generates a small return of around 5% that will be ploughed back into research for the next generation of malaria medicines and vaccines.

During the year we also reached an agreement in principle with the US Government to resolve some long-standing legal issues around our sales and marketing practices for a settlement of \$3 billion. I know this was difficult, but is a necessary step towards resolving multiple, long-standing matters which do not reflect the company that we are today.

As part of an ongoing strategy, we continue to fundamentally change our procedures for compliance, marketing and selling, particularly in the USA. This will ensure that we operate with high standards of integrity and that we conduct our business openly and transparently. We will continue to innovate and to respond to the expectations of our stakeholders, and our new compensation system that rewards sales representatives in the USA on quality of service rather than sales volumes is one example.

We also made progress on implementing our environmental strategy which has been revised to set ambitious goals for our entire value chain – from raw materials to product disposal. We need to work in ways that enable business growth while protecting the natural resources for the future. For example, almost 40% of our carbon footprint derives from propellants when patients use our inhalers, and eliminating CFC gases from our products has substantially reduced inhaler emissions – from 24 million tonnes of CO₂ equivalents in 1998 to less than five million tonnes today.

None of this would be possible without the efforts of all of our employees. Investing in our people and communities underpins the long-term sustainability of our business, creating the right internal and external conditions to support our strategy. As a company, we are mindful of the potential pressures our employees face given the current global, political and economic environment. Despite these challenges, we remain committed to offering all of our employees a range of learning opportunities and tailored development and volunteering programmes. The PULSE programme, for example, gives employees the chance to join a non-profit or non-governmental organisation for a three- or six-month placement. There were 80 PULSE volunteers in 2011, up from 58 in 2010. I am delighted that nearly 200 employees from 26 countries have served as PULSE volunteers since the scheme began in 2009.

These changes and others we have made right across our business are laying the foundations for our future success. We have come a long way but we have by no means achieved everything we aspire to. We will continue to review our plans and commitments across each of the four areas, looking to establish further long-term goals and targets which will support meaningful measurement and demonstrate our commitment to responsible, values-based business. We will continue to be restless, to challenge ourselves and to ask what more we can do.



Sir Andrew Witty
Chief Executive Officer



Sir Andrew Witty hears from patients visiting a hospital in Uganda

What we do

We are a science-led global healthcare company. We make innovative products that are used by millions of people around the world. The products we develop and manufacture and the way we do this contributes directly to the health and well-being of patients and consumers, and indirectly to society and the economy.

GSK has three primary areas of business: Pharmaceuticals, Vaccines and Consumer Healthcare.

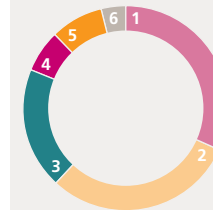
Our Pharmaceuticals business develops and makes available medicines to treat a range of serious infectious and chronic diseases. Our portfolio is made up of established brands and newer innovative patent-protected medicines.

Our vaccines business is one of the largest in the world, producing paediatric and adult vaccines against a range of infectious diseases. Many of these products use components in a single vaccine that help provide protection against multiple diseases.

Through our Consumer Healthcare business, we market a range of category-leading consumer health products in areas such as oral health, nutrition, wellness and skin health.

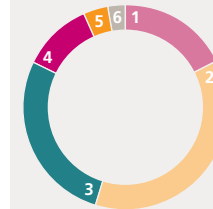
Our business is sustained through investment in R&D. In 2011 we spent £3.9 billion in our search to develop new medicines, vaccines and innovative consumer products.

Turnover by region



| | £bn |
|--------------------|-------------|
| 1 USA | 8.7 |
| 2 Europe | 8.3 |
| 3 Emerging Markets | 5.3 |
| 4 Asia Pacific | 1.8 |
| 5 Japan | 2.3 |
| 6 Other | 1.0 |
| Total | 27.4 |

Employees by region



| | No. |
|--------------------|---------------|
| 1 USA | 16,707 |
| 2 Europe | 38,696 |
| 3 Emerging Markets | 29,466 |
| 4 Asia Pacific | 7,039 |
| 5 Japan | 3,573 |
| 6 Other | 1,908 |
| Total | 97,389 |

Our Annual Report

You can read more about our business, our strategy and performance, as well as find detail on corporate governance and risk management in our 2011 Annual Report [online](#).



How we create value

We place great importance on what we achieve but also on how we achieve it. We believe business should play a greater role in tackling social, economic and environmental challenges.

Innovation

New medicines and healthcare products are needed by people across the globe to address the many illnesses that are still not well-controlled or treated. At the same time, scientific research is continuously uncovering new understandings about disease processes and technologies.

These two elements present us with the opportunity to investigate and develop new and improved treatments. We create value by applying science and technology to discover, develop, produce and distribute medicines, vaccines and consumer healthcare products.

Access

We are actively seeking new ways of delivering healthcare and making our products more available and affordable to people who need them, wherever they live. We do this not only because society expects us to and it is the right thing to do, but also because it is good for our business.

In our effort to expand access to our products, we have led the industry in adopting a flexible approach to pricing of our medicines and vaccines, based on a country's wealth and ability to pay. This has resulted in significant reductions in price and increases in demand for our products in emerging economies, representing a good outcome for patients, governments and our shareholders. In Western markets, we have developed new reimbursement approaches for our medicines, where we agree risk-sharing arrangements with payers.

Why we are different

We have fundamentally changed our business and our culture to help us grow, innovate and improve our performance. This affects the way we do business, the way we work with others and our relationship with our employees.

For our employees, the positive impact their contribution makes to people's lives is one of their key motivators to working at GSK.

We have a diverse and balanced portfolio across pharmaceuticals, vaccines and consumer healthcare products which provides us with a range of products to grow our business. The changes we have made to the shape of our business are intended to provide broadly-sourced sales growth and greater resilience in the face of market challenges.

We are developing new partnerships and approaches, adopting a mindset that is more innovative, open-minded and flexible. We value new and different perspectives: working with research charities, academia, companies and non-governmental organisations among others. We are being more flexible with our intellectual property and know-how stimulating progress in the search for new treatments.

We are also increasing consultation with patients and payers to ensure we develop medicines that healthcare systems will value and reward.

Approach to responsible business

Only by being a responsible business can we grow and create value for our shareholders and for society. Our strategy is designed to maximise performance and we are committed to operating with responsibility and transparency. Strong values and our people are central to our business success.

In this report, we have outlined our progress around four themes which reflect the issues we see as most important for responsible and sustainable business growth.

We are reviewing our plans and commitments across all four areas and plan to establish further targets and key performance indicators.

Responsible business



Health for all

Through investment in R&D, infrastructure and innovative pricing we are working with stakeholders to make our medicines, vaccines and consumer products available to as many people who need them as possible, regardless of where they live or their ability to pay.



Our planet

We are committed to minimising our environmental impact across our value chain and lifecycle of our products by setting ambitious goals to reduce our carbon footprint, water and waste.



Our people and communities

We respect all people and support our employees to reach their full potential. We make a positive difference to the communities in which we operate through economic contribution, investment, education programmes and partnerships.



Our behaviour

We are building a strong values-based culture. We recognise that we need to be open about what we do, how we do it and the challenges we face. Our actions are backed by robust policies and strong compliance processes. We expect the same standards from our suppliers, contractors and business partners.



Health for all

Improving people's health and well-being regardless of where they live or their ability to pay



Contents

| | | | |
|--|-----------|-------------------------------------|-----------|
| Introduction | 09 | Developed countries | 29 |
| Research and development | 10 | Europe | 29 |
| Improving access to healthcare – a global challenge | 12 | USA | 30 |
| Developing countries | 14 | HIV/AIDS and ViiV Healthcare | 31 |
| Increasing availability | 14 | Research and development | 31 |
| Feature: Our approach to malaria | 16 | Increasing access | 33 |
| Improving affordability | 21 | Community investment | 34 |
| Preventing disease and raising awareness | 25 | | |
| Advocacy | 28 | | |
| Future plans | 28 | | |

+ Click arrows above to go to each section →



Improving access to healthcare is one of society's most pressing social challenges.

Introduction

We want to make our products available, accessible and affordable for as many of the people who need them as possible. We aim to do this while generating the returns we need to sustain our business and invest in further research.

We understand and recognise the many barriers and obstacles there are on the path to better health and we are committed to finding new and innovative ways of tackling them. By working in partnerships, listening to others, and being prepared to change the way we do business, we are creating value for society, our business and shareholders.

Here we outline our global approach and contribution, going into more detail on our work in developing countries where the challenge of increasing access to healthcare is particularly difficult. However, access is not only an issue in the developing world and we also include examples of our work in developed countries.

Progress in 2011

- Invested £3.9 billion in global R&D in 2011, launched three new medicines and expect to report on 15 late-stage assets by the end of 2012 (page [10](#)).
- First results of the ongoing Phase III studies with our malaria vaccine candidate RTS,S showed it is able to reduce the risk of malaria by half in African children aged 5-17 months over a one-year period after vaccination (page [16](#)).
- New commitment to support research efforts in USA and Europe to tackle antimicrobial resistance. (page [11](#))
- Helped create a new coalition led by the World Health Organization (WHO) to control or eliminate 10 of the 17 neglected tropical diseases by 2020 (page [26](#)).
- Extended our albendazole donations to enable de-worming of school-age children in all endemic countries (page [26](#)).
- Co-founded and made significant commitments on intellectual property to WIPO Re:Search, a new coalition to stimulate research into diseases of the developing world (page [18](#)).
- Began six R&D projects at our open lab in Tres Cantos into diseases of the developing world, with seven more approved for 2012 (page [18](#)).
- Invested £3.8 million through partnerships with AMREF, CARE International and Save the Children to support training of frontline healthcare workers in the Least Developed Countries (page [20](#)).
- Expanded our work with the Healthstore Foundation to improve healthcare in rural and slum areas of Rwanda and Kenya by establishing a network of nurse run-clinics, setting a new target of 500 health posts staggered over a seven-year period (page [19](#)).
- Delivered over 80% of our vaccines for use in developing countries – 870 million doses (page [25](#)).
- Kenya and Ethiopia become first countries in Africa to introduce GSK's pneumococcal vaccine *Synflorix* through innovative financing mechanism (page [22](#)).
- New commitment to supply up to 125 million doses of GSK's anti-diarrhoeal vaccine *Rotarix* at 95% reduction to western market price (page [23](#)).
- Our US Patient Assistance Programs provided GSK medicines and vaccines worth \$115 million valued at cost (page [30](#)).
- ViiV Healthcare's licensees supplied more than 717 million tablets of their versions of *Epivir* and *Combivir* to low-income, Least Developed Countries and sub-Saharan Africa (page [33](#)).

Research and development

The most important contribution we make to improving health is through our research and development of new treatments, vaccines and consumer healthcare products.

We focus our R&D on products that contribute to society by addressing patient needs and where advances in science offer the best opportunities to discover new medicines and generate commercial returns.

To be successful over the long term, we need the investments we are making in our pipeline to lead to new medicines that will be valued by patients and those who pay for the treatments. Our 'Medicines Vision' process ensures that the voice of the customer is integrated with the medicine development strategy to optimise payer, patient and prescriber needs.

We invested £3.9 billion in R&D in 2011. Just over 75% of this expenditure was in pharmaceutical R&D with the remainder in vaccine and consumer healthcare research.

Our pipeline has around 30 assets in late-stage development and around 20 candidate vaccines in development, of which approximately one-third target diseases which are particularly prevalent in the developing world. You can read more about our pipeline and progress in our [Annual Report](#).

In 2011 we launched three new medicines: *Benlysta* for the treatment of systemic lupus erythematosus, *Horizant* for the treatment of moderate-to-severe restless legs syndrome and *Trobalt* for adjunctive treatment of partial-onset seizures. 2011 was the start of a critical two-year period for our pipeline, as we expect to deliver Phase III data (or 'read-outs') on 15 assets by the end of 2012.

To date we have positive read-outs supporting progression towards registration for several assets for diseases including: type 2 diabetes; chronic obstructive pulmonary disease (COPD) and asthma; hepatitis C; melanoma and malaria.

Our Discovery Performance Units (DPUs) are helping us to improve productivity in R&D. These are small, entrepreneurial, multidisciplinary teams responsible for discovering and developing potential new medicines in their specialist areas. They develop a three-year business plan and make a 'pitch' for funding of their projects in front of a Discovery Investment Board (DIB). In 2011 we completed the majority of the three-year progress reviews for the DPUs, so decisions have been made about the number and shape of the projects to continue.

There were more than 50 proposals for new DPUs in 2011, and four new areas that emerged. This will be our way of working in the future so we can remain flexible as the landscape changes.

Right across our R&D organisation, we form alliances with external groups to accelerate the discovery of new medicines and vaccines as well as to share scientific understanding and ultimately to improve patient care.

As well as significant partnerships to address neglected tropical diseases (NTDs), our main areas of collaboration include research into improving drug discovery, biotechnology, identifying patient safety issues and research on rare diseases. We signed seven new collaborations in 2011, giving us more than 50 external discovery partnerships that complement our internal discovery units.

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

Our focus on finding the best science, wherever it may be, led to the creation in 2011 of the Discovery Partnerships in Academia (DPAc) programme. DPAc is a new approach which aims to establish truly integrated partnerships with academic groups to undertake early drug discovery and translate innovative research into medicines that benefit patients.

In 2011 DPAc engaged with nearly 160 academic institutes in more than 20 countries around the world. In our vaccines business, 107 collaborations with external partners were ongoing in 2011 for prophylactic and therapeutic vaccines.

You can read more about our R&D, DPUs, medicines and vaccines pipeline progress and approvals in our [Annual Report](#) and on [our website](#).

Focus on the Patient

To guide our research, it is essential for us to understand what patients need. Our Focus on the Patient programme brings patients to GSK sites to speak directly to our R&D teams about their healthcare needs. This helps us make better medicines and inspires employees to do more to help improve patients' lives.

We hosted 11 patient insight seminars at our sites in 2011 under the theme of 'strengthening the patient voice at GSK'. These brought together more than 7,200 people, including GSK employees, healthcare professionals, patients and patient advocacy group representatives, to discuss a range of topics including epilepsy, ovarian cancer, asthma, immune thrombocytopenia, diversity in US clinical trials, acute lung injury, *Plasmodium vivax* malaria, Fabry disease, Crohn's disease, soft tissue sarcoma and COPD. We provide recordings of these seminars on a dedicated area of our intranet, enabling more employees to learn and benefit from these discussions.



Tackling antimicrobial resistance

Antibiotics are a cornerstone of modern medicine, not only for effectively treating common infections, but for ensuring that patients undergoing surgery or who are immuno-compromised (for example by chemotherapy, HIV or transplantation) are protected from infection. GSK has been a leading researcher and supplier of effective antibiotics for many years – our antibiotic, *Augmentin* remains in use around the world today 30 years since it was first launched.

However, the past 20 years have seen increasing resistance of infectious bacteria to antibiotics at the same time as a decline in antibiotic research. Only two new classes of antibiotics have been developed and launched in the last 30 years. The European Centre for Disease Prevention estimated that in Europe, 25,000 people die from resistant infections from five types of bacteria.⁽¹⁾

The discovery and development of new antibiotics takes many years and significant investment. Yet new antibiotics, once licensed, are generally used only when patients have failed to respond to existing treatments, limiting the commercial return needed to encourage continued research investment.

GSK is one of the few pharmaceutical companies with an active antibiotic R&D programme and we are committed to supporting efforts to tackle anti-microbial resistance.

In September 2011, GSK and the Biomedical Advanced Research and Development Authority (BARDA) in the USA agreed a \$38.5 million contract to support the development by GSK of a potential new antibiotic against both hospital Gram negative and bioterror pathogens.

BARDA is a group within the Office of the Assistant Secretary for Preparedness and Response in the US Department of Health and Human Services. We also supported the introduction of the Generating Antibiotics Incentives Now (GAIN) Act of 2011 in the House of Representatives in June 2011, which we believe could be a meaningful step towards addressing barriers to the research, development and approval of new antibiotics.

In November 2011, GSK welcomed the European Commission's 'Action plan against the rising threats from antimicrobial resistance', which promotes collaborative research to develop new antibiotics that will counter the growing threat from resistant bacteria. We share the European Commission's view that public-private collaboration, with the sharing of information and funding, offers the best way forward. We are committed to working under the [Innovative Medicines Initiative](#) (IMI) antibiotics programme in 2012 and teams from across GSK are looking for research partners in this area.

We believe that other approaches are also needed to support innovation in this area. For example, investment in research for new antibiotic products that would not otherwise be commercially viable could be encouraged by guaranteeing a financial agreement for success. We believe that regulatory approaches reflecting the unique challenges of developing treatments for multi-drug resistant infections are urgently needed.

⁽¹⁾ [European Centre for Disease Prevention, European Medicines Agency Joint Technical Report – The bacterial challenge: time to react \(2009\)](#).

Improving access to healthcare – a global challenge

Improving access to healthcare is one of society's most pressing social challenges.

Every year millions of 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 or vaccines. The cost of healthcare can be a barrier to access for patients in both the developed and developing world. Despite huge medical advances, there are still many conditions for which treatments do not exist or need to be improved.

These problems affect individuals and communities all around the world, but are most acute in developing countries and particularly in the world's Least Developed Countries (LDCs).

Access to Medicine Index

GSK was ranked top in the [Access to Medicine \(ATM\) Index](#) published in 2010, the second time the Index has been produced by the ATM Foundation. It provides an independent assessment of company efforts to improve access to medicines.

We are pleased that our progress has been recognised but know that there is still more that can be done. We continue to consider the recommendations in the ATM Index carefully when reviewing our approach. Publication of the next ATM Index is expected later in 2012.



There are many complex factors that hamper access to medicines in developing countries. Poverty is the single biggest barrier. In many countries people do not have enough food or clean water nor access to a functioning health system. Medicines for prevalent diseases may be lacking because of the limited commercial return on R&D for neglected diseases. Often there is no unified registration system for medicines which makes the process costly and complex, and individual authorities do not have sufficient capacity for numerous 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 a lack of political will for action, resulting in inadequate funding across the healthcare system. In middle-income countries the health system may be more developed, but differences in income levels can prevent access. These problems must not be an excuse for inaction; they indicate where action is most needed.

We want to help improve health through our own business activities, skills and resources and by acting as a catalyst for wider change across the industry and society. Our strategy focuses on where we can make the most difference and in particular improving affordability, availability, prevention and supporting vulnerable health systems. We are also focused on conducting and encouraging more investment in R&D. To achieve this we are:

- Working in a more open manner and better reflecting the needs of developing countries
- Pursuing flexible pricing strategies
- Working in innovative partnerships to try to reach people who would otherwise not have access to our medicines and vaccines.

We believe this is the right thing to do and know that our approach will contribute to our business success. By striving to meet society's healthcare needs, we also build trust in our business, which helps to safeguard our licence to operate in the long term.

Improving access to healthcare in emerging economies also helps us to build our business in increasingly commercially important markets such as Brazil, China, India, Indonesia and Russia. In the past, the majority of our revenue in these countries came from selling our medicines and vaccines to higher-income sectors of society. To achieve sustainable growth we need to go beyond the high-income sector, and increase access and affordability for patients at lower-income levels in all countries. This means ensuring that we have the right products at the right prices in the right places.

Wherever possible we work in partnership with companies, governments, international agencies, academic institutions, patient groups, NGOs and communities, providing our expertise, resources, medicines and vaccines to improve healthcare infrastructure and the availability of our medicines and vaccines. By working together we can achieve more for patients than we can alone.

Our approach reflects the different needs of each market which can vary significantly depending on poverty and income levels, coverage and quality of healthcare infrastructure, political commitment and the resources allocated to healthcare. However, there are common themes that we address across all regions:

Increasing availability. In addition to our research and development of innovative products we focus on tackling diseases particularly prevalent in developing countries, including neglected tropical diseases. We also work to improve availability of medicines by increasing product registration across our many markets. This includes new products, making sure that existing products are more widely available and broadening our portfolio to make it more relevant to the health needs of people in developing countries.

Strategic alliances and acquisitions help us to grow our business in developing countries and to bring a bigger range of affordable medicines to a wider population. We currently supply medicines and vaccines directly to the majority of the 49 LDCs. We are looking for opportunities to expand our presence into more countries in Africa in partnership with NGOs and UN organisations. For example, we recently relaunched GSK in Angola and Zimbabwe and have now established an initial distribution route to Somalia. Operating in fragile states is challenging but important in order to bring medicines to those who need them.

We invest 20% of our profits from our business in LDCs back into projects that strengthen the healthcare infrastructure in these countries and support innovative approaches such as the Healthstore Foundation (now One Family Health) Child and Family Wellness nurse run franchise health posts. Read more about our work with our partners on page [20](#).

Improving affordability. Pricing is one factor that impacts access to medicines and vaccines. We are adopting a range of innovative pricing models that reflect our commitment to work with governments and other stakeholders to deliver our medicines and vaccines to as many of the people who need them as possible. We are also seeking other methods to improve affordability such as innovative financing mechanisms and smaller pack sizes.

Being flexible in our pricing can help to build our business in emerging markets by increasing the overall volume of products we sell. 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. This is more challenging in an uncertain economic climate when governments seek to contain healthcare costs. We recognise this challenge and we are working with governments in Europe and the USA to find solutions. We seek to price medicines fairly in these countries and at a level that reflects their value to patients and payers. Read more about our approach on page [29](#).

Preventing disease. We work to tackle some of the root causes of disease and ill-health and to contribute to healthier communities around the world. For example, vaccines play a major role in preventing disease and have been acknowledged by the 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 year.⁽¹⁾ 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.

We also work in partnership with others to improve health, for example our partnership to eliminate lymphatic filariasis and our PHASE handwashing campaign, which you can read more about on page [27](#).

24%

Africa shoulders 24% of the global disease burden with only 3% of the global health workforce and 1% of the global health budget⁽²⁾

⁽¹⁾ Ehreth J. The Global Value of Vaccination. *Vaccine* (2003): 21 (7-8): 596-600.

⁽²⁾ World Health Organization World Health Report 2006: Working together for health.

Developing countries

The challenge of increasing access to healthcare is particularly difficult in the world's Least Developed Countries (LDCs), where often the disease burden is greatest but the resources to tackle it are lacking.

These countries have a population of over 800 million, more than half of whom live on less than \$1 a day. Challenges include weak infrastructure and supply chains to support provision of medicines and vaccines, small and overstretched health workforces, low population literacy levels and food insecurity. Many middle-income countries (MICs) such as Brazil, China, India, Indonesia and Thailand 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 non-communicable diseases such as asthma and diabetes.

Improving access to healthcare in developing countries requires a holistic approach embracing prevention, treatment and efforts to fundamentally strengthen health systems. All stakeholders need to contribute and we are committed to playing our part.

By investing in developing countries, including LDCs, we will help to ensure we have a sustainable and successful business in these regions that will grow as these countries develop.

We use the term 'developing countries' to include all of the Least Developed Countries as identified by the UN (currently 49 countries including South Sudan), the countries of sub-Saharan Africa and all low-income and middle-income countries as defined by the World Bank. This is a hugely diverse group and our approach reflects this.

Oversight and management

Improving access to healthcare is core to GSK's overall strategy and is prioritised from the highest levels of the company. Our CEO, Sir Andrew Witty, is closely involved and has often spoken publicly on our commitments. His views are set out in an [article](#) on global health issues published in 2011 in the leading US journal Health Affairs.

The President of GSK's Emerging Markets and Asia Pacific region, Abbas Hussain, leads our access efforts for developing countries. These are reviewed by the Corporate Executive Team and by the Corporate Responsibility Committee of the Board.

Our Developing Countries and Market Access (DCMA) operating unit was set up specifically to increase patient access to GSK medicines and vaccines while expanding our presence and building a sustainable business. Country managers for GSK's businesses in LDCs report into this unit, enabling a tailored, consistent and integrated approach to increasing access in these countries reflecting their specific needs. The unit is also working with GSK country managers in other developing countries to increase access through flexible pricing and other approaches. The DCMA unit aims to increase the availability of GSK medicines by broadening our portfolio to make it more relevant to the people in those countries, pricing it to increase access and unlock demand, contributing to education and awareness, and expanding our distribution and supply chain capability.

We have recently established Future Strategy Groups (FSGs) to review our approach to key business issues and address strategic challenges. These are led from our CEO's office and bring together senior managers and experts from around the business. In 2011 FSGs focused on topics such as neglected tropical diseases (NTDs) and access to medicines.

Increasing availability

Developing world R&D

There is an urgent need for newer and better medicines and vaccines for use in developing countries.

We are committed to finding innovative ways to help address this gap by integrating research for the developing world into our pharmaceutical and vaccine R&D organisations and by stimulating R&D beyond GSK's significant investment.

Within our Emerging Markets and Asia Pacific business unit which covers developing countries, we have a specialised R&D unit dedicated to developing drugs for patients in these countries and championing their needs throughout our R&D operations. It focuses on late stage clinical products that match the needs of patients in developing countries. Areas the unit is working on include:

- Adapting GSK products to better meet the needs of patients in developing countries.
- Creating better evidence based formulations (EBFs), fixed-dose combinations of generic medicines that offer improved clinical outcomes at a lower price consistent with the latest evidence from scientific literature and treatment guidelines.
- Partnering with research institutes and governments on innovative research and understanding long-term healthcare priorities through a mix of funding, technology transfer and talent development.
- Investigating new ways to reach patients including through smaller pack sizes and mobile phones.

We also have an R&D group focused specifically on diseases of the developing world (DDW), including NTDs, which prioritises research decisions on their socio-economic and public health benefits rather than on commercial returns. A significant portion of this drug discovery work takes place at our dedicated facility at Tres Cantos in Spain. A similar group is active in our vaccines organisation in Belgium.

We entered several new research partnerships focusing on DDW in 2011, these include:

- Two collaborations related to research in kinetoplastids, which are parasites responsible for serious diseases. For both collaborations we are providing access to our proprietary compound library.
- A collaboration to build on early stage Drug Discovery efforts for tuberculosis (TB).

We continue to play an active role in our commitment to support R&D efforts in developing new and better treatments for NTDs through collaborative partnerships such as with the Drugs for Neglected Diseases initiative (DNDi), a not-for-profit R&D organisation. We share knowledge, research and intellectual property with groups such as DNDi to support drug discovery efforts against diseases including sleeping sickness, visceral leishmaniasis and Chagas. GSK is a founder member of the WIPO Re:Search consortium (page [18](#)).

Highlights from our DDW R&D portfolio

Our R&D portfolio includes projects for a number of diseases of particular relevance to developing countries including: bacterial meningitis, Chagas disease, chlamydia, dengue fever, HIV/AIDS, human African trypanosomiasis, leishmaniasis, malaria, pandemic flu, pneumococcal disease and tuberculosis (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.

Highlights from our pipeline for the developing world are illustrated below:

| | |
|---------------------|---|
| HIV/AIDS | <p>ViiV Healthcare has an industry-leading pipeline of six potential anti-retroviral medicines, including five compounds in Phase II or Phase III development. Altogether there are 16 compounds under investigation for development as potential new HIV treatments.</p> <p>Read about ViiV Healthcare's progress with its Phase III development programme, and commitment to research and development to support populations hardest hit by the epidemic on page 31.</p> <p>We have also been involved in AIDS vaccine research for over two decades. We are now pursuing four separate vaccine strategies. A successful AIDS vaccine might combine several of these approaches:</p> <ul style="list-style-type: none"> • GSK's HIV vaccine candidate, F4/AS01, is currently in Phase II clinical trials in HIV-infected subjects to evaluate its safety and efficacy. • The F4/AS01 vaccine candidate will also be combined with a recombinant adenovirus 35 vector in a collaboration with the International AIDS Vaccine Initiative (IAVI). • GSK is 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 vector. A Phase I clinical trial started in 2010. <p>A collaborative discovery R&D programme that aims to identify an HIV envelope-based protein vaccine capable of producing broadly neutralising antibodies against HIV infection is being conducted with multiple partners.</p> |
| Malaria | <p>Read about progress of our malaria vaccine candidate on page 16.</p> <p>We are also developing tafenoquine, a potential treatment for the radical cure of <i>Plasmodium vivax</i> malaria, the most frequent and widely distributed cause of relapsing malaria. This affects millions of people each year mainly in South East Asia and Latin America. Tafenoquine, which is being developed in partnership with the Medicines for Malaria Venture (MMV), entered a Phase II/III study in 2011. An initial study to understand tafenoquine and G6PD deficiency (a common gene deficiency in areas where malaria is prevalent and which can affect the choice of malaria treatment) began in 2009 and interim results are expected in 2012.</p> |
| Tuberculosis | <p>TB is the world's second leading cause of death from an infectious disease. Working with the Aeras Global TB Vaccine Foundation and the Tuberculosis Vaccine Initiative, we are developing the M72 TB vaccine candidate. To date we have conducted Phase I and II trials in TB-naïve, TB-infected and BCG-vaccinated adults, as well as HIV positive adults taking a combination of anti-retrovirals. A Phase II trial in African infants is ongoing.</p> |
| Dengue fever | <p>Our joint R&D initiative with Fiocruz and the Walter Reed Army Institute of Research to develop a vaccine for dengue fever continued. Scientists from GSK and Fiocruz are working across facilities in Brazil and Belgium on this partnership which will also enhance Brazilian R&D capacity.</p> |

Feature: Our approach to malaria

The past decade has seen significant progress in the fight against malaria, leading some commentators to believe that a world with zero deaths from this disease is becoming possible.

Progress is certainly encouraging, with global deaths reduced by almost 40% and many African countries implementing extensive control programmes to limit transmission. Yet despite recent successes, half the world's population remains at risk of malaria and it still kills almost 800,000 people every year, most of whom are children under the age of five in sub-Saharan Africa.



Our approach

We believe that a comprehensive approach to malaria is required to scale up and use all established tools of control, while continuing to invest in the development and use of innovative new tools. The widespread introduction of impregnated bed nets has complemented the use of effective anti-malarial medicines, which in turn complement methods such as indoor residual spraying of insecticides. A successful vaccine could be the next weapon in the armoury.

A pivotal year

We believe that vaccines are the simplest and most cost-effective way to save lives, and 2011 was a landmark in GSK's near 30-year search for a malaria vaccine. In October, the first results from an ongoing large-scale trial were published in the *New England Journal of Medicine* and revealed that our malaria vaccine candidate, RTS,S, has the potential to reduce the risk of malaria by half in African children aged 5–17 months over a one year period after vaccination. We are developing RTS,S in partnership with the PATH Malaria Vaccine Initiative (MVI).

Subject to further evaluation of the safety, quality and efficacy of the vaccine candidate as well as its benefits and risks by the regulatory and public health authorities, these data bring us to the cusp of having the world's first malaria vaccine. This has the potential to significantly improve the outlook for children living in malaria endemic regions across Africa. The addition of a malaria vaccine to existing control interventions could potentially help prevent millions of cases. It could also reduce the burden on hospital services, freeing up much-needed beds to treat other patients who often live in remote villages, with little or no access to healthcare.

The trial is one of the final stages in evaluating the vaccine candidate in infants and young children before regulatory file submission. It is being conducted at 11 centres in seven countries across sub-Saharan Africa.

More results needed

Results in 6 to 12 week-old infants are expected by the end of 2012. If the required public health information, including safety and efficacy data from the Phase III programme is deemed satisfactory, the World Health Organization has indicated that a policy recommendation for the RTS,S malaria vaccine candidate is possible as early as 2015, potentially paving the way for decisions by African nations on introduction of the vaccine through national infant immunisation programmes.

Pricing

We have pledged that pricing will not be a barrier to those who could benefit most from a malaria vaccine. If approved and recommended for use, the eventual price of RTS,S will be set to cover the cost of producing the vaccine, together with a small return of around 5%. This will be reinvested in research and development for second-generation malaria vaccines or research into other neglected tropical diseases.

We have invested \$300 million in the vaccine so far and expect to invest another \$50–100 million over the next few years. We do not expect to recoup these costs through sales of the vaccine, as there is little or no market for the vaccine in developed countries. Our ability to make significant investment returns on other innovative medicines in our portfolio enables us to support this important work. We will also donate at least 12.5 million doses of the vaccine to MVI.

Partnership

No single organisation has the ability to defeat malaria on its own, but inroads are being made through the formation of innovative partnerships. RTS,S is being developed in partnership with MVI, which has received more than \$200 million in grants from the Bill & Melinda Gates Foundation to advance the clinical development of RTS,S, together with prominent African research centres

In collaboration with the Medicines for Malaria Venture (MMV), we are also developing tafenoquine, a potential treatment for the radical cure of *Plasmodium vivax* malaria, the most frequent and widely distributed cause of recurring malaria. This affects millions of people each year mainly in South East Asia and Latin America (see page 15).

Existing tools

We are also working in partnership with other organisations to increase the availability and uptake of preventative measures and improve management of malaria, particularly for young children and pregnant women.

Since 2001, we have committed more than £3 million through our African Malaria Partnership (AMP), to encourage behavioural change such as sleeping under insecticide-treated bed nets and seeking treatment in the early stages of disease.

In communities in Tanzania, Ghana, Nigeria and Kenya, we are currently working with partners and with national malaria control programmes to help build capacity of community health workers and mobilise families to become the frontline in the fight against malaria.

Open innovation

We need to think differently about how we conduct R&D and find new ways to work with key stakeholders. Partnership is essential and that is why we are pursuing an ‘open innovation’ approach, working with industry, academia, NGOs and governments. This includes:

- Sharing our expertise and resources with scientists from around the world through our Tres Cantos Open Lab
- Sharing intellectual property, know-how and research data to help stimulate research outside GSK
- Being more open with our data and DDW research to help stimulate research outside GSK.

Tres Cantos Open Lab

Our open laboratory at the Tres Cantos site in Spain has space for visiting scientists from universities, not-for-profit partnerships and other research institutes – such as the Barcelona Centre for International Health Research (CRESIB), Weill Cornell Medical College in the USA, and Imperial College, London – to work on their projects for the developing world, learn from our expertise and share our world-class facilities.

During 2011, six projects began at the open lab with seven more approved to begin in 2012. Ten of the projects are supported by the [Tres Cantos Open Lab Foundation](#), a charity established with £5 million in funding from GSK. Other projects are supported by partners such as the Bill & Melinda Gates Foundation.

A governing board of leading scientists is providing strategic direction for the foundation. All projects must contribute to research that helps discover new medicines for diseases of the developing world.

The open lab builds on the partnership approach we have always taken at Tres Cantos. Since the site was established in 2001 we have worked closely in public-private partnerships with groups such as the Medicines for Malaria Venture and the Global Alliance for TB Drug Development. There are more than 100 scientists working at the centre, and many of these posts are funded by our partners.

Sharing intellectual property

GSK is committed to sharing intellectual property and knowledge that may help to speed up research into NTDs.

In 2009 we helped to establish the Pool for Open Innovation against Neglected Tropical Diseases ([POINT](#)) to which we contributed patents and patent applications. We also committed to consider requests for access to our knowledge and experience. Under the terms of POINT, any medicines or treatments for NTDs developed using the pooled patents and intellectual property will be available to Least Developed Countries on a royalty-free basis. One of the current projects underway at our Tres Cantos Open Lab is the result of information shared via POINT.

GSK is also a founding member of [WIPO Re:Search](#), a new collaboration among private and public sector organisations designed to accelerate NTD research. Launched in 2011, this new platform provides a searchable public database of available compounds, resources, expertise, and knowledge that can be used by researchers. All treatments developed from intellectual property on the WIPO Re:Search website must be made available royalty-free in Least Developed Countries.

We are contributing patents and patent applications to WIPO Re:Search covering small molecules and formulations directed at developing treatments and delivery technologies for NTDs as well as 13,500 compounds which in screening have shown evidence of activity against malaria.

Since WIPO Re:Search will incorporate all the POINT data and information, we expect POINT will likely discontinue following a transition period.

Sharing research information

In 2010 we published research findings that could help identify potential new treatments for malaria. The research was the result of a year-long screening process in which five GSK scientists reviewed more than two million compounds in GSK’s chemical library to seek out those that could inhibit the malaria parasite. This process identified 13,533 compounds that showed greatest activity. More than 80% of these molecules are proprietary to GSK, and it is the first time they have been made available to the wider research community.

We have shared the compound set with 13 various groups and researchers, and we will encourage them to share their results as they become available. We aim to identify other datasets and make them publicly available to act as a catalyst to stimulate further research in DDW.

Strengthening healthcare infrastructure

The chronic shortage of trained frontline health workers in LDCs is recognised as one of the most fundamental constraints to achieving the Millennium Development Goals. The World Health Organization estimates a shortfall of at least one million frontline health workers, particularly in Africa and parts of Asia.

Increasing the number of frontline health workers is an immediate and cost-effective way to save lives and improve health outcomes, especially for mothers and children. For example, in some settings, a fully trained and well-supported community health worker can effectively deliver treatments, and provide health education to 5,000 children in a year.

We are committed to becoming a partner in finding solutions to healthcare delivery in the LDCs by reinvesting 20% of the profits made in these countries into local healthcare infrastructure and by supporting efforts to expand access to frontline healthcare workers.

We are supporting the Frontline Health Workers Coalition (FHWC), a new coalition of companies and NGOs urging greater, more strategic investment in frontline health workers in the developing world as the most cost-effective way to save the lives of mothers and children, and address AIDS and other global health threats.

We are also working with the Healthstore Foundation (transitioning to One Family Health), a private enterprise that has developed a Child and Family Wellness (CFW) franchise system that enables local nurses to own and operate a basic medical clinic in rural or slum areas of Africa. CFW clinics target the diseases and conditions that cause around 70% of all illness and death in local communities, including malaria, diarrhoeal disease and respiratory infections. They maintain a secure supply

of high-quality, affordable essential medicines in places where counterfeit and substandard drugs are common.

CFW franchisees receive support from HealthStore in the form of start-up loans, initial training, coaching, system-wide marketing support, peer network and recognition and technology innovations.

GSK is supporting expansion via a £970,000 grant to implement 60 CFW clinics in Rwanda. A second phase is planned with the ultimate goal of establishing 500 clinics by 2020.

Using mobile phones to tackle counterfeiting in Nigeria

Counterfeit medicines are illegal and often dangerous. The problem is global but most acute in the developing world, where regulation and law enforcement capacity is relatively weak. Counterfeit medicines account for around 10–30% of products sold in Africa.



GSK is piloting an innovative approach to protecting patients in Africa from counterfeit medicines using mobile phones, taking advantage of the high mobile phone penetration rate in Africa, on average above 50%.

In February 2011 we began using text messaging as part of a six-month pilot anti-counterfeiting programme in Nigeria with our antibiotic, *Ampiclox*. The pilot was run in collaboration with Nigeria's National Agency for Food and Drug Administration Control (NAFDAC). We place a scratch-off code on the back of the *Ampiclox* antibiotic pack; consumers send the code via a text message to a central NAFDAC toll-free phone number for verification; the mobile

service looks up the code and sends a verification text back to the consumer. There is also a toll-free phone number for consumers to call if they have any questions.

The response from consumers was enthusiastic: in all, we received 145,000 texts from 115,000 unique users, representing approximately 10% of use. Ninety per cent of texts returned a genuine confirmation, 2.5% received a counterfeit alert and others received a message indicating a duplicate PIN. More than 2,360 calls were made to the helpdesk, some of which helps us identify counterfeit *Ampiclox* blisters in the Nigerian market. We intend to roll out this approach to other products as well as in countries in East Africa.

Supporting vaccination training

Since 2002 we have supported the work of the Network for Education and Support in Immunisation (NESI) to promote vaccinology training for healthcare workers in sub-Saharan Africa, North Africa and the Middle East. NESI has become a key partner of organisations such as the WHO, UNICEF and GAVI who implement vaccination programmes in these regions. We also continue to support global public health training through the TropED network. TropED encompasses approximately 20 European universities and their institutional partners across the globe.

Reinvesting 20% of our profits in LDCs

In the world's LDCs, lack of basic healthcare infrastructure and qualified healthcare workers prevents millions of people from getting the treatment they need. At GSK, we reinvest 20% of the profits we make from our pharmaceutical and consumer healthcare businesses in LDCs back into local healthcare infrastructure. We partner with three leading NGOs – AMREF, CARE International and Save the Children – specifically to address the shortage of trained frontline healthcare workers. The funding available for investment in 2011 was £3.8 million, based on 2010 profits from our medicines and consumer healthcare products.

This has enabled us to initiate programmes to train up to 10,000 health workers. We have initiated projects in 25 countries (at the end of 2011), and are on track to implement a project in each profit-making LDC (34) by June 2012.

Our goals for 2012 include:

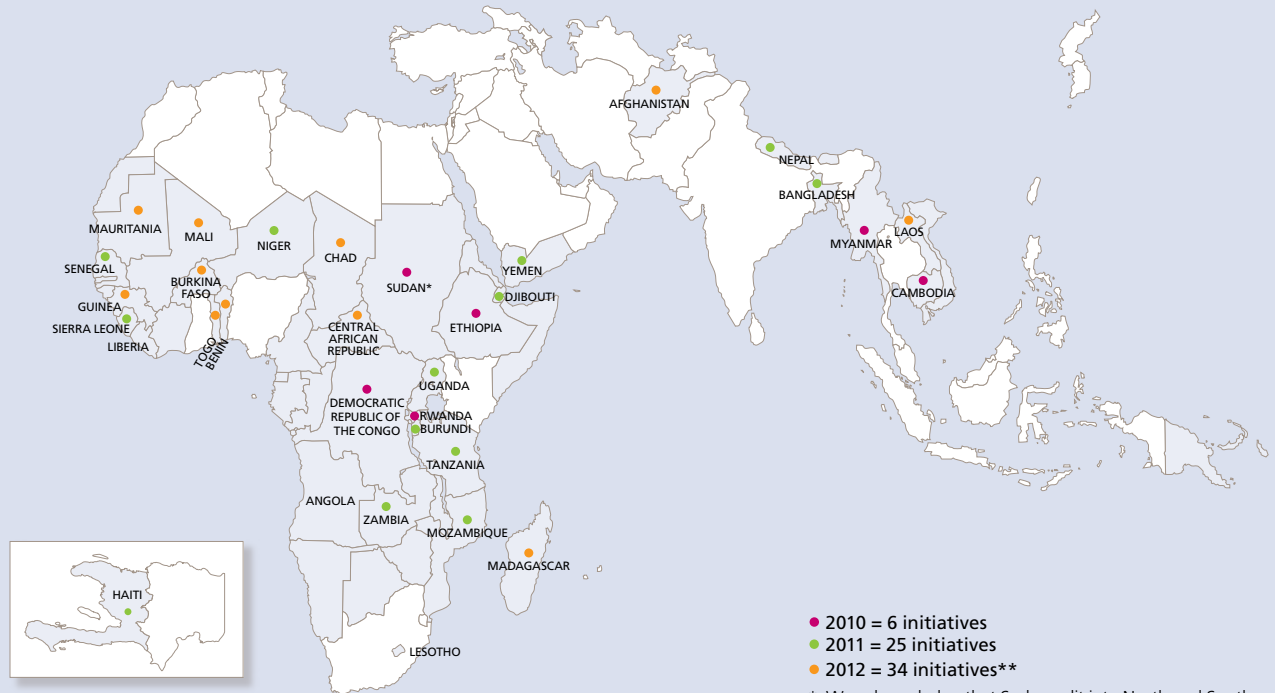
- Measuring the impact of projects, including the number of health workers trained and improvement in health indicators.
- Engaging other organisations to help achieve the WHO goal of one million health workers in developing countries by 2015.

Some examples of the activities this investment has supported are outlined here:

In Niger, one in six children dies before they are five. To help prevent this we are working with Save the Children in the Maradi region to conduct health education sessions in 1,175 communities. We are training 2,350 community health volunteers to deliver health and nutrition messages. The sessions will focus on the causes of malnutrition and ways of preventing common childhood diseases.

Lack of access to quality health facilities and services affects many poor women and newborn infants in the far-western region of Nepal. GSK is supporting an initiative led by CARE International to upgrade 20 local community health service centres to birthing centres with improved facilities and to provide training to mobilise 1,750 female community health volunteers.

We are supporting an innovative eLearning project in Tanzania to up-skill 1,000 nurses from remote regions, so they are better-informed about healthcare advances and best practices and able to provide a higher standard of care to rural communities. We are working closely with education institutions and the Ministry of Health and AMREF to develop these distance learning courses.



- 2010 = 6 initiatives
- 2011 = 25 initiatives
- 2012 = 34 initiatives**

* We acknowledge that Sudan split into North and South in 2011 and we are running programmes in each country.

**34 of the 49 LDCs made a profit in 2010, and will have a programme implemented by mid-2012.

Improving affordability

Innovative pricing

In the LDCs we cap the prices of our patented medicine and vaccines at no more than 25% of prices in the UK. To reflect the unique situation of HIV/AIDS, through ViiV Healthcare we offer not-for-profit prices for HIV/AIDS medicines in the LDCs, in all of sub-Saharan Africa and in all low-income countries, see page 33. We offer tiered pricing for GSK vaccines worldwide.

We have introduced similar price reductions in some non-LDCs to reduce the risk of product diversion. We want to reduce the likelihood of not-for-profit or preferentially priced medicines being illegally shipped back for sale in better-off countries as this undermines the purpose of reducing prices which is to improve access in these poor countries.

In middle-income countries we are implementing a range of approaches that balance our commercial objectives with the need to increase access to medicines for patients in these markets who cannot afford to pay. These include flexible pricing models, tailored products, and local sourcing and manufacturing arrangements.

We are also exploring opportunities to make medicines available in smaller pack sizes which can make them more affordable for patients who pay for their prescriptions.

Focus on non-communicable diseases

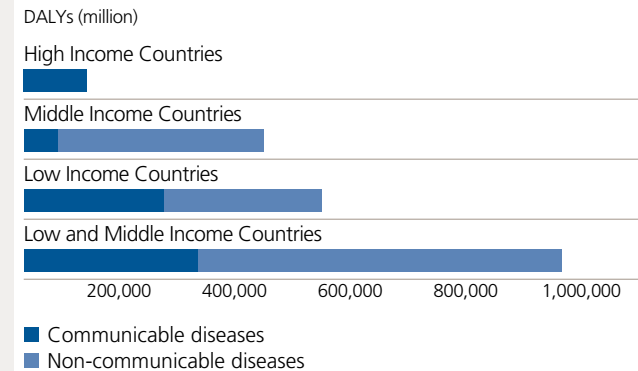
Non-communicable diseases (NCDs) are becoming more prevalent in developing countries as improvements in tackling childhood and infectious diseases lead to people living longer and because of changes in lifestyles. Cardiovascular disease, cancer, diabetes and chronic respiratory diseases already account for 63% of deaths in all countries, rich and poor and their prevalence is growing fastest in middle and low-income countries.⁽¹⁾ Increasing access to medicines for NCDs can be particularly challenging because of the cost of providing long-term or even life-long care. GSK is committed to finding innovative solutions to this challenge.

In September 2011, the UN General Assembly hosted a High Level Meeting in New York devoted to NCDs. GSK participated in the Meeting and worked with other members of IFPMA, the International Federation of Pharmaceutical Manufacturers and Associations, to publish a Framework for Action⁽²⁾ for the industry focused on the areas of prevention, innovation, access, capacity building and partnership. The key output of the meeting was a Political Declaration on the Prevention and Control of NCDs which provides a mandate for the UN, WHO, and Member States to make NCDs a priority.⁽³⁾ The Declaration also calls for a focus on prevention and fosters a multi-stakeholder approach.

We already include NCDs in many of our pricing and access initiatives and are looking for new ways to improve access within sustainable business models. Examples include our work to develop low-cost asthma products specifically for patients in the developing world (see page 28). This increased focus on NCDs may provide opportunities for further work with governments in non-traditional ways to try and expand access.

About NCDs NCDs represent 65% of the disease burden in developing countries⁽⁴⁾ as measured in Disability-Adjusted Life Years. DALYs are the accepted measure of disease burden, and one DALY is the equivalent of one lost year of 'healthy' life.⁽⁵⁾ See chart below.

The global burden of disease



⁽¹⁾ WHO Global status report on non-communicable diseases 2010

⁽²⁾ IFPMA Framework

⁽³⁾ Political Declaration on the Prevention and Control of NCDs

⁽⁴⁾ WHO Global Burden of Disease Report 2004, updated in 2008

⁽⁵⁾ Disability-Adjusted Life Years

Pricing caps in Least Developed Countries (LDCs)

Since 2009 we have reduced prices in LDCs for all GSK-patented products, (individual product lines and formulations), where we are the sole supplier in that market. Prices are capped at no more than 25% of their price in the UK (or in France for products not sold in the UK) provided this price covers our manufacturing costs so the offer is sustainable. Prices were reduced by an average of 45% and apply to the following brands:

- *Seretide* (asthma, chronic obstructive pulmonary disease – COPD)
- *Avamys* (rhinitis)
- *Flixotide* (asthma)
- *Malarone* (malaria)
- *Avodart* (benign prostatic hypertrophy)
- *Fraxiparine* (anti-coagulant)
- *Ultiva* (anaesthetic)
- *Arixtra* (venousthromboembolism – VTE)
- *Zeffix* (hepatitis B).

Sales volumes for the majority of products have increased significantly following the price decreases and we believe this has increased access to these products for more patients.

We have also reduced the prices of our off-patent antibiotics *Augmentin* and *Zinnat* by up to 50% in certain countries and seen an increase in sales volumes of over 100%. For example, we decreased the price *Zinnat* by up to 30% in Bangladesh, and volumes increased year-on-year across the product range by 50–80%.

Our vaccines sold in the small private market in LDCs are also offered at 25% of the Western European average. The GAVI Alliance and UNICEF, which purchase large volumes of vaccines for the world's poorest children, always benefit from GSK's lowest prices.

We measure the impact of price reductions through increases in sales volumes. We have also received anecdotal 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.

In some countries there have been cases where price reductions are not passed on to patients. We have worked with governments, the media, pharmacists and others in the pharmaceutical distribution network such as the Medicines Transparency Alliance to make sure that patients are aware of and benefit from the reductions, and we are beginning to see sales volumes increasing in those countries.

Pricing our vaccines

For over 20 years we have made our entire vaccine portfolio available for expanded immunisation programmes at preferential prices to developing countries 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 GAVI-eligible countries, prices can be as little as a tenth of those for developed countries. This model works for vaccines where demand is relatively predictable due to the nature of vaccination for prevention compared to the use of medicines for treatment. We are also introducing flexible pricing for vaccines sold directly to governments and other customers.

In 2011 we extended our Advance Market Commitment (AMC) agreement with the GAVI Alliance to speed access to our pneumococcal vaccine, *Synflorix*. We will now supply up to 480 million doses of *Synflorix* to GAVI-eligible countries by 2023. These will be priced at \$3.50, around 10% of the cost in developed markets. Respiratory pneumococcal disease is the leading cause of death in children under five in developing countries. The vaccine could help to protect up to 160 million children over the next decade. *Synflorix* has been introduced in Kenya and Ethiopia so far, with further launches expected in 2012. The AMC is designed to accelerate access to vaccines by stimulating R&D and manufacture of vaccines at affordable prices through long-term agreements with manufacturers. *Synflorix* has been introduced in Africa just 18 months after its introduction in Europe.

25% cap

On price of patented medicines and vaccines in LDCs compared to UK prices

45%

Average price reduction on 11 brands

Rotavirus infection is one of the leading causes of childhood mortality in developing countries. GSK is supplying its rotavirus vaccine, *Rotarix*, to the GAVI Alliance at \$2.50 per dose, a small fraction of developed world prices. We have committed to supply 125 million doses of *Rotarix* over the next five years, which will enable GAVI to meet its aim to expand rotavirus vaccination to 46 countries by 2015. In 2011 Sudan became the first country in Africa to introduce *Rotarix* with support from the GAVI Alliance.

Together our *Synflorix* and *Rotarix* agreements with GAVI will contribute the potential to immunise 250 million children by 2015. This will make a substantial contribution to achieving Millennium Development Goal 4 – reducing child mortality by two-thirds before 2015.

We also supply our portfolio of vaccines at affordable prices to the Pan American Health Organization (PAHO), which purchases on behalf of 35 middle-income developing countries in Latin America and the Caribbean. Through these arrangements we will help protect an estimated 3 million infants against rotavirus (*Rotarix*), an estimated 1.7 million babies against pneumococcal infections (*Synflorix*), and some 600,000 girls against cervical cancer (*Cervarix*).

Middle-income countries flexible pricing

Many middle-income countries (MICs) such as Brazil, China, India, Indonesia and Thailand are growing markets for GSK and represent an important source of future business. Our strategy is to grow our business in MICs by making our products more affordable to those at lower income levels which in turn increases the volume of products we sell. To do this, we are introducing flexible pricing approaches that take into account differences in economic status, demography, healthcare infrastructure and pricing regulations and patient affordability. Our flexible pricing approach includes:

- Improving affordability by linking pricing policy more closely to a country's Gross National Income (GNI)
- Introducing differential pricing within markets to reach new sectors of the population based on assessing patient ability to pay
- Working closely with health authorities and payers to agree innovative pricing programmes for medicines and other support, such as disease awareness campaigns
- Closely monitoring our prices compared to local competition and regularly reviewing this.

We have developed guidance on flexible pricing for all new products launched in our Emerging Markets and Asia Pacific (EMAP) region. Our Market Access and Pricing team works with local operating companies to establish the right pricing approach for each market and helps share information and best practices on market access.

We believe our approach is having an impact, and some examples of our innovative pricing approach from 2011 are outlined here:

- *Avamys* is our once-daily nasal spray for treating allergic rhinitis. We have reduced the price of *Avamys* by an average of 45% in over 40 MICs. Volumes of *Avamys* sold increased four-fold since we introduced flexible pricing in 2011. This increase in the number of packs sold has off-set the impact of lowering our prices, and has enabled us to reduce our cost of goods.
- We have introduced tiered pricing for oncology products such as *Tykerb*, our breast cancer treatment in 50 EMAP markets. For example, in India we reduced the price for *Tykerb* in July 2010 by 32% and have seen a growth of 128% in volumes over the previous year. Our data suggest that patient adherence to *Tykerb* treatment has improved by at least 10%.
- In Brazil, we decreased the price of our antibiotic treatment *Augmentin* by up to 50% in 2010 and volumes increased year-on-year across the range by over 50%.

250^m

Children potentially immunised by 2015 through GAVI agreements for *Synflorix* and *Rotarix*

\$3.50

Through AMC, *Synflorix* priced at 10% of cost in developed markets

Innovative financing models

Innovative financing can break down barriers to access by improving affordability for patients. For example, with our treatment for postmenopausal women at risk of bone fracture due to osteoporosis, *Prolia* (denosumab) – which is administered via injection every six months – we are piloting new Patient Access Schemes (PAS) in Argentina, Brazil, Chile, the Philippines, Singapore and the Ukraine. The PAS will benefit patients who pay part or all of their prescription costs and each market has adopted the approach best suited to its needs. For example in Argentina we launched a programme that allows patients to pay for *Prolia* in six ‘interest free’ instalments, reducing the initial expense and making *Prolia* more accessible to patients. This option now makes *Prolia* accessible to 43% of the population, an increase from 24%.

We are also introducing risk-sharing models in a number of markets. These can help to speed patient access to treatment where we may need to demonstrate the value of our products and help governments to manage their spending. For example, in Brazil we have launched a performance-based, financial risk-sharing scheme for our breast cancer treatment *Tykerb* (also known as *Tyverb*), giving access to more than eight million extra patients. The Brazilian government’s policy is not to reimburse oral oncology treatments such as *Tykerb*. Physicians therefore tend to prescribe intravenous (IV) treatments which can be more invasive and mean patients spend more time in hospital. Under the new scheme, *Tykerb* is prescribed to patients who are then assessed after 16 weeks of treatment.

Medical insurers will cover the cost of treatment for patients who respond beyond week 16, while GSK refunds the cost of treatment for those patients whose disease has progressed before week 16. The initiative demonstrates our belief in our product’s efficacy and its ability to deliver equivalent benefits to IV treatments at a lower cost and in a way that is more convenient for the patient.

We have introduced discount cards in Ukraine, Argentina, Chile and Vietnam that help groups of patients (such as senior citizens, disabled people or low-income patients with chronic diseases) who may not be able to afford the co-payment element of their prescription medicines.

We also partner with others, for example in Morocco we are working with the Lalla Salma Association, a cancer NGO, to provide our oncology medicines *Tykerb* and *Zofran* at a significantly reduced price. This means that patients with limited means and no insurance, estimated at around 50% of the population, can be treated at public hospitals with no charge.

Local manufacturing and strategic alliances

Achieving higher sales volumes can help to reduce the costs of goods which we can pass on as further price reductions, ultimately increasing access to our products. In addition, our commercial teams collaborate with our manufacturing organisation to explore local sourcing, manufacturing and licensing arrangements.

In our vaccines business we have a number of joint ventures and technology transfer arrangements. These can help to increase the supply and affordability of vaccines while enabling developing countries to develop their research and manufacturing capabilities, and increasing market access for GSK. Read more about our approach to technology transfer in our [position paper](#) online.

These arrangements include: our agreement with Binnopharm in Russia covering vaccines against human papillomavirus (HPV), rotavirus and Streptococcus; our long-standing partnership with Brazil’s Oswaldo Cruz Foundation covering polio, Haemophilus influenzae type b (Hib), measles, mumps, rubella, rotavirus and pneumococcal disease; and in China our initial joint venture with Shenzhen Neptunus, which is now a newly wholly-owned subsidiary, to develop and manufacture influenza vaccines.

Preventing disease and raising awareness

We make a major contribution to preventing disease and ill-health, with our most significant contribution through our vaccines business. Many of our other products, including for HIV/AIDS (through ViiV Healthcare, page 31) and diabetes, prevent diseases progressing into more severe forms. Our consumer products can help prevent tooth decay, help people stop smoking, and improve nutrition. Our PHASE community investment programme and our contribution to the Global Alliance to Eliminate Lymphatic Filariasis are also outlined below.

Vaccines

GSK vaccines are included in immunisation campaigns in 173 countries worldwide and of the 1.1 billion vaccine doses delivered in 2011, 870 million doses (more than 80%), were shipped for use in developing countries which include least developed, low- and middle-income countries. GSK is the leading vaccine supplier to organisations such as UNICEF and the Pan American Health Organization (PAHO).

In September 2011 we agreed to donate \$1 million worth of the cervical cancer vaccine *Cervarix* to the US-based Pink Ribbon Red Ribbon partnership so that more than 10,000 girls and women in Africa will have access to vaccination over the next five years. GSK also pledged \$50,000 to support Pink Ribbon Red Ribbon's programme operations, helping expand the availability of vital prevention, screening and treatment programmes for cervical and breast cancer in developing countries. The partnership is also focusing on integrating low-cost screening and treatment services and aims to reduce deaths from cervical cancer in participating areas of Africa by 25% over the next five years.

Raising awareness

A fundamental aspect of good health management is to ensure that people are well informed about how to avoid getting ill, and what to look out for if they fall ill. If people are not adequately informed, they will not take the right precautions, nor seek appropriate treatment when necessary. Malaria is a good example of this, where a significant effort has been invested to encourage people to sleep under insecticide treated bed nets, and to look for the early signs of malaria. These efforts have contributed significantly to the recent declines in mortality from malaria. See page 16.

In our pharmaceutical business, our flexible pricing approach is often accompanied by comprehensive campaigns to increase awareness and in turn make sure that the maximum number of patients can benefit from price reductions and increased access. One example of this is in Indonesia where we reduced the price across a number of our established brands by between 15–80%; setting prices at a realistic level reflecting the country's ability to pay. A disease education and media awareness campaign was supported by GSK and a launch event for physicians was held which was attended by the Minister for Health. These efforts as well as expansion of our healthcare professional coverage, from 5,000 to 16,000 covering 56 countries, have helped to increase access to our medicines. For example the volume of our *Seretide* asthma treatment has almost doubled in 2011 following an approximately 50% price reduction.

Furthermore we are working to raise awareness of disease and improve prevention and treatment in developing countries, for example in our PHASE handwashing programme.

Respiratory disease in the developing world

There is a clear medical need in the developing world for education and awareness of chronic respiratory conditions, in particular asthma. To assess the current reach of our respiratory business and fully understand the barriers to access, we have analysed asthma control, perception towards asthma and access to healthcare in various developing countries. This has revealed very high levels of poor asthma control, inadequate treatment, frequent hospitalisations for asthma attacks and stigma. It suggests that better training among healthcare professionals, public awareness campaigns and programmes targeted at addressing affordability and access issues would improve the respiratory problems in these markets.

We have responded with a number of approaches, including rolling out a programme of regional respiratory 'Masterclass' awareness and education sessions in key regions. We are also reviewing our supply chain for cost reduction opportunities, exploring innovative packs and presentations, and other approaches which may support access including filling gaps in our current product portfolio.

In addition, we came to a long-term agreement in 2011 to supply Ventolin inhalers to the Global Asthma Drug Facility (ADF). ADF is a procurement programme which aims to make essential asthma medicines available and affordable in low- and middle-income countries.

Our approach to neglected tropical diseases (NTDs)

More than one billion people are afflicted by one or more of the 17 NTDs listed by the World Health Organization (WHO). These diseases mainly affect people marginalised by poverty who live in remote rural areas, urban slums, or conflict zones with limited access to effective healthcare, clean water and sanitation, adequate nutrition, proper housing, transportation and education. The impact of NTDs prevents personal, community and national economic development and perpetuates poverty.

In January 2012, we joined other global pharmaceutical companies and leading organisations including the WHO, the Bill & Melinda Gates Foundation, the UK Department for International Development and the US Agency for International Development (USAID) in a new [united effort](#) to support developing countries to defeat NTDs. This coalition will support the ambitious goals set out by the WHO to control or eliminate 10 of the 17 NTDs by the end of the decade.

This includes eliminating five diseases: lymphatic filariasis (elephantiasis), guinea worm, blinding trachoma, sleeping sickness and leprosy, and controlling a further five: soil transmitted helminths (intestinal worms), schistosomiasis, river blindness, Chagas and visceral leishmaniasis by 2020.

Expanding our donation of albendazole

We expanded our albendazole donation programme which targets two NTDs, lymphatic filariasis (LF) and soil-transmitted helminths (STH or intestinal worms). We pledged to extend by an additional five years our commitment to donate 400 million albendazole treatments each year to the WHO to enable de-worming of school-age children in all endemic countries.

Through our established commitment to donate albendazole for as long as necessary until LF (also known as elephantiasis) is eliminated, we currently provide nearly 600 million tablets a year to help eliminate this disabling and debilitating parasitic disease spread by mosquitoes. Our work with the Global Alliance to Eliminate Lymphatic Filariasis is continuing to grow to help reach the more than one billion people at risk of LF. Since 1999 we have donated 2.6 billion albendazole treatments to more than 50 countries. In 2011 we shipped 603 million tablets for LF and soil-transmitted helminths (STH).

Several countries have completed their mass drug administrations for LF and are in the process of confirming absence of disease transmission. The overall economic benefit of the global LF

elimination programme during its first eight years is conservatively estimated at \$24 billion.⁽¹⁾

Intestinal worm infections can stunt growth and cause anaemia and malnutrition. They can impact a child's ability to learn and affect their performance at school. Scaling up our donation from 2012 will help achieve the WHO target of reaching 75% of the school children globally who live in countries where intestinal worms are endemic.

During 2011, we started to ship tablets for school-based de-worming, ahead of schedule, to Togo and Rwanda. We shipped to Mozambique, Namibia, Argentina and Guinea in preparation for 2012 activities and we announced that we will extend the programme beyond Africa to include all endemic regions. To meet these commitments we have invested in a new manufacturing line at our factory in South Africa.

With a collective commitment to donate up to one billion albendazole treatments each year, we aim to help countries fight both elephantiasis and intestinal worms.



1 billion

Albendazole treatments to be donated each year from 2012 through our commitments to target LF and STH infection

⁽¹⁾ The Economic Benefits Resulting from the First 8 Years of the Global Programme to Eliminate Lymphatic Filariasis (2000–2007). PLoS (Public Library of Science) NTDs, June 2010, Volume 4, Issue 6.

Measuring the impact of our PHASE programme

Every year three million people die of diarrhoeal disease, most of them children. The spread of this disease can be easily prevented by improving water quality and encouraging people to wash their hands. Our Personal Hygiene and Sanitation Education (PHASE) programme, run in partnership with NGOs, tackles both issues.

As well as improving local water pipes, pumps and other infrastructure, PHASE teaches children how to wash their hands and why it is important, using easy to understand books and story cards which are adapted to reflect everyday lives in each country. The programme encourages children to share what they have learnt with their families and communities.

Since PHASE began the programme has reached at least 1.4 million children with information about how to change their behaviour to keep healthy. In 2011 we conducted our second strategic review to assess its impact on behaviour and health. The research was carried out by the Water, Engineering and Development Centre, Loughborough University, UK.

It shows that the programme is continuing to change behaviour and reduce incidence of disease in the 16 countries where it has been implemented. For example, in Bangladesh, the number of families wearing sandals when using the latrine (to avoid worm infestations) increased from 6% to 78%. Reduction in diarrhoea incidence in participating schools reduced from 18.6% to 1.8%.⁽¹⁾

PHASE has most recently been implemented in high density urban settlements, for example Nairobi, Mumbai and Rio de Janeiro. In 2011 we extended our partnership with the Earth Institute's Millennium Villages Project to integrate oral healthcare into PHASE. Poor oral hygiene can be a significant problem in developing countries, affecting an individual's overall health and quality of life. Our aim is to introduce and test effective measures through behaviour change and promotion of good oral health practice, nutrition and eating habits.

In 2012 our goal is set up a model for integrating PHASE with school de-worming as part of the expanded albendazole donation programme (see page 26).

⁽¹⁾ PHASE Global Overview 2012 will be published on our website in June 2012.



Advocacy

When appropriate, we work with governments and policy makers and encourage changes in the policy environment that help to increase access to healthcare in a sustainable way. This includes working with companies in our sector to foster industry-wide approaches.

We support approaches that encourage: adequate investment in healthcare infrastructure; support for innovation; support for differential pricing; and adequate financing for mechanisms such as GAVI and the Global Fund to Fight AIDS, TB and Malaria. All these factors are critical to sustainably improving access for the long term.

Examples from 2011 include:

- Co-chaired the Gates/CEO Roundtable which led to the January 2012 NTD Conference in which we played a major role (page [26](#))
- Our CEO, Sir Andrew Witty, participated in an event at the US State Department which led to the formation of a coalition of private sector companies to help tackle the lack of frontline healthcare workers (page [19](#))
- Participated in the launch of the [G-Finder report](#) on R&D for neglected diseases

- Supported the development of a pilot Advance Market Commitment for a pneumococcal vaccine (page [22](#))
- Presented on behalf of the industry at the first meeting of the WHO's Consultative Expert Working Group on R&D financing first meeting
- Worked with the UK Government on global health issues, including as co-chair of the UK's Industry Government Forum on Access to Medicines and through participation in the Partners Forum of the UK Government's Global Health Strategy
- Participated in WHO Executive Board meetings and the World Health Assembly
- Participated as board members of the GAVI Alliance and Roll Back Malaria. We also participated in the [GAVI replenishment conference](#) on funding immunisation for children in developing countries
- Engaged with the Intergovernmental Meeting on Pandemic Influenza Preparedness
- Participated in numerous meetings and presented at events on access to medicines and intellectual property at the European and UK Parliaments and other venues.

Future plans

We believe there is more we can contribute to efforts to improve health in developing countries. During 2012 we will continue to develop a product portfolio more suited for the disease burden suffered by patients in developing countries. We will also continue to:

- Introduce flexible pricing strategies and work with others to increase access in middle-income countries (page [23](#))
- Seek more partnerships and encourage scientists to work with us at our research centre for diseases of the developing world in Tres Cantos, in Spain (page [18](#))
- Encourage others to consider innovative approaches and to realise the potential of WIPO Re:Search (page [18](#))
- Seek to further reduce prices for our patented medicines in LDCs (page [22](#))
- Reinvest 20% of profits we make from selling medicines in LDCs to help strengthen healthcare infrastructure in these countries and encourage others to consider similar schemes. (page [19](#))
- Integrate PHASE with school de-worming as part of the expanded albendazole donation programme (page [26](#)).

Read more online

We publish more detail [online](#) on key issues including:

- access and developing countries
- public health
- intellectual property
- product donations
- pricing, reimbursement and market access.

+ www.gsk.com/reportsandpublications-policies

Developed countries

Ageing populations and the rise in incidence of chronic diseases means that healthcare budgets are under strain in many developed countries.

We recognise that governments must balance the desire for healthcare equality with the need to manage limited financial resources. The ongoing financial crisis has made the task of increasing access to our products even more challenging.

We aim to work closely with governments, payers and healthcare systems to ensure our products are available and affordable. We seek to understand their needs and healthcare priorities and to make sure that we demonstrate the full value of our products through the R&D process and evidence-based data at the time of launch. This should allow a fair price to be set which reflects a medicine's proven value; and is affordable to customers and sustainable for GSK.

Europe

In Europe, the financial crisis has put unprecedented pressure on public budgets. To achieve the best results for patients, taxpayers and our industry, we believe we must work as a genuine partner with governments, helping them find solutions that bring value to healthcare systems and support cost-management while maintaining incentives for innovation.

To do this we support differentiated approaches that are tailored to a particular national context and allow companies to offer prices that take affordability concerns into account. Where appropriate, this can come in the form of innovative pricing approaches that enable access

to reimbursement of a medicine, subject to specified conditions. This can help to address uncertainties that may exist in some cases at the launch of a product about its performance or its budget impact. For example, in Italy, GSK will reimburse 100% of costs for *Tyverb*, our breast cancer therapy, in the case of failure or interruption of therapy during the first 12 weeks of treatment.

We are also working closely with governments to help them manage healthcare costs. For example in the Czech Republic the National Immunisation Committee had recommended universal mass vaccination with pneumococcal vaccines, but no government funding was available to implement this. A special team was set up within GSK Czech Republic to partner with payers, doctors, distributors, epidemiologists and politicians to help overcome this challenge and establish a new reimbursement and distribution system for pneumococcal vaccination. This included a reimbursement system funded by health insurance companies (HICs) and a new supply chain to distribute vaccines to clinics. Once the funding system was established, we offered a volume discount structure for our *Synflorix* pneumococcal vaccine that was accepted by all HICs. This is still in place and 90% of the newborn population are now covered by the new funding and distribution system.

GSK is committed to helping individual EU member states manage funding gaps while protecting the development of innovative value-adding medicines and vaccines. Through the European trade association EFPIA, we participated in discussions with national governments, the IMF, the European Commission and the European Central Bank. Agreements were reached to support these countries manage their pharmaceutical spending as one of the ways they will work towards meeting their overall financial commitments.

Demonstrating value through research

We are collaborating with the European Healthcare Innovation Leadership Network (EHILN) to improve understanding between different stakeholder groups as to what constitutes a medicine's value and to find ways to better demonstrate this through the research process.

We participated in a pilot project in 2010 in which stakeholders advised GSK on the development strategy for an early-stage diabetes product and how this could be refined to better demonstrate the medicine's value. A second pilot project was launched in December 2011 for an innovative oncology product. We are engaged in discussions with EU policy makers on the development of a consistent EU-wide approach to assessing the value of new medicines.

We have also established an Access to Medicines Centre of Excellence within our European pharmaceutical business, working with payers and healthcare systems to understand their thinking and needs. Insights gathered through advisory boards and regular engagements are brought into the R&D process to ensure the evidence they need is fully considered in the medicine development plans. Developing solutions to healthcare system challenges are a clear priority and direction for our business.

USA

In the USA, there are 44 million people living under the Federal Poverty Limit, and many more who have difficulty paying for healthcare. Some of these patients may be eligible for government programmes, such as Medicaid. Others still need assistance to obtain the prescription medications they need. GSK has several programmes that provide medicines for free to eligible patients who are uninsured, under-insured, or do not earn enough money to afford their medication.

In 2011 more than 478,000 patients received GSK medicines and vaccines worth \$115 million (£96 million) through our US programmes. This value is calculated using an average cost of goods rather than wholesale acquisition cost (a measure used by other pharmaceutical companies). We believe this approach to valuing medicines more accurately reflects the true cost to GSK. When valued at wholesale acquisition cost the value of the medicines through our US programmes would be \$585 million.

GSK operates several programmes for patients who meet certain eligibility requirements, including Commitment to Access (cancer treatments), Bridges to Access (other medicines for outpatients), Vaccines Access (covering our adult vaccines for hepatitis A, hepatitis B, tetanus, diphtheria, pertussis and cervical cancer) and GSK Access, which provides extra help for low-income seniors and disabled patients enrolled in Medicare Part D.

We are a member of Together Rx Access, an industry programme which gives uninsured US citizens 25–40% discounts on medicines from GSK. 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. In 2011 almost 3,000 patients received over 7,000 30-day prescriptions of GSK medicines through the Together Rx Access programme, giving patients discounts of more than \$308,000. Since its inception in 2002, Together Rx Access has given over 2.5 million patients savings totalling \$130 million across a wide range of products.

In 2011 we also launched a patient assistance programme for Benlysta, our lupus treatment which we are developing under a co-development and co-commercialisation agreement with Human Genome Sciences. This makes the medicine available at no cost for patients without insurance and who meet certain eligibility qualifications. We have also launched a co-payment assistance programme that will help other eligible patients with their out-of-pocket costs for *Benlysta*.

Please see page 34, for information on ViiV Healthcare's US patient assistance programmes.

Tackling chronic diseases

In the USA, the way healthcare is delivered and paid for is evolving. GSK is committed to helping identify solutions that will improve healthcare and reduce costs. We have a particular focus on chronic diseases, which are responsible for 75% of healthcare costs in the USA.

Under the current US system, a patient visits a number of different specialists who may not be aware of health services the patient has received from other healthcare providers, such as test results, treatments for other medical conditions, or prescribed medications. As a result, care can become episodic and uncoordinated.

GSK has teamed up with Community Cares of North Carolina in an innovative public-private collaboration called North Carolina First in Health. This aims to demonstrate how coordinated care can help reduce the cost of healthcare and improve patient outcomes. Other participants include State Health Plan of North Carolina, pharmacy chain Kerr Drug, SAS and Blue Cross Blue Shield of North Carolina, the state's largest health insurer.

First in Health uses a 'patient-centered medical home' model. This means that a patient's primary care physician coordinates with a patient's other healthcare providers using health information technology and care managers. This provides a more comprehensive picture of the patient's health and enables a more coordinated approach. GSK is enabling its employees in North Carolina to participate in the programme, and 1,200 employees have enrolled since it began in January.

HIV/AIDS and ViiV Healthcare

ViiV Healthcare, established by GSK and Pfizer in 2009, is an independent company solely focused on the needs of people living with HIV.

It is committed to delivering innovations and improvements for people living with HIV wherever they are in the world. This section outlines its approach and progress, and you can also find out more online at www.viivhealthcare.com.

ViiV Healthcare aims to re-energise the pharmaceutical industry's participation in HIV by having a deeper and broader understanding of the needs of those who live with the virus and those who treat them.

All GSK and Pfizer HIV medicines are marketed by ViiV Healthcare. It has a broad portfolio of 10 medicines, with annual sales of about £1.5 billion in 2011. This means it has the financial stability and the investment capital required to take a sustainable, long-term view of the HIV market.

Research and development

ViiV Healthcare is committed to the development of new products that target unmet medical needs in HIV. These include the treatment of children and those who are living longer and ageing with HIV, and then tackling problems such as drug resistance, complex treatment regimens and side effects associated with current treatments. ViiV Healthcare currently has 16 molecules under investigation for development as potential new HIV treatments including five compounds in Phase II or Phase III development.

Through its joint venture with Shionogi, ViiV Healthcare is developing a novel once-daily, unboosted investigational HIV integrase inhibitor (S/GSK1349572), known as '572' and a fixed dose combination '572-Trii' ('572+Epzicom/Kivexa'). Phase III clinical trials continued in 2011.

In HIV, simplification of therapy to once-daily dosing is a priority both in terms of patient quality of life, and potentially to improve outcomes. In October 2011, ViiV Healthcare launched the first large-scale Phase III clinical trial of once-daily dosing for *Celsentri/Selzentry* in combination with a protease inhibitor in HIV patients previously untreated with anti-retrovirals (ARVs).

This will evaluate a new approach of a two-drug versus three-drug once-daily combination of treatment in patients infected with CCR5-tropic HIV-1.

ViiV Healthcare is supporting international HIV collaborative research trials in resource-poor settings in partnership with a broad range of external organisations such as academic institutes, the WHO, the UK's Medical Research Council and the US National Institutes of Health. They focus on public health related issues such as prevention of mother-to-child HIV transmission, paediatric and adult treatment strategies, when to start treatment, and HIV-TB co-infection. ViiV Healthcare donates ARVs or provides financial support, as well as scientific input throughout the life of the study.

At the end of 2011, 95 trials were underway and a further 12 are planned, involving over 10,000 patients. Twenty-nine of these trials involve one or more African countries. Eight are paediatric studies, one of which will provide the first significant clinical data on the efficacy, safety and pharmacokinetics of ViiV Healthcare's NRTI scored tablets in a resource-poor setting.

16

Molecules in development as potential new HIV treatments

95

Trials underway at end of 2011 involving over 10,000 patients

Treatment of children with HIV/AIDS

Infants and children living with HIV/AIDS in developing countries often do not have access to effective treatment. At its launch in 2009, ViiV Healthcare committed £10 million to a paediatric innovation seed fund to support research and development to meet the needs of these patients. The fund supports partnerships with organisations that focus on the evidence base for paediatric care and treatment, the research and development of paediatric fixed-dose combination (FDC) products, and formulations for the treatment of infants and children living with HIV.

Joint efforts to improve access to therapy and care include:

- The ViiV Healthcare-Elizabeth Glaser Pediatric AIDS Foundation Partnership (EGPAF), which aims to increase early detection of HIV and improve access to ARV therapy for HIV-positive infants and young children; strengthen government leadership and policies around paediatric HIV/AIDS; and improve the quality and use of paediatric care. In 2011 the partnership sought to resolve a critical barrier in the treatment of children – improvement of early infant diagnosis and treatment in sub-Saharan Africa, with a focus on Lesotho, Swaziland and Malawi.

Through several initiatives the testing of HIV-exposed infants within eight weeks of birth, as recommended by the WHO, was successfully scaled up. The programme resulted in greater numbers of infants initiated on anti-retroviral treatment when testing HIV positive. The partnership catalysed new formal and informal collaboration with organisations delivering paediatric care and linkages between health facilities and communities were also strengthened.

- The ViiV Healthcare-amfAR TREAT Asia programme aims to optimise the quality of healthcare for infants and children living with HIV across Asia through the development of clinical data to support paediatric treatment guidelines. Since its initiation in 2010, TREAT Asia and its partners have been working to address knowledge gaps in paediatric care and treatment, establishing research studies, educational workshops and advocacy projects.
- A non-monetary Memorandum of Understanding with the Clinton Health Access Initiative (CHAI), aimed at developing an affordable new FDC for paediatric use.



Increasing access

ViiV Healthcare is committed to playing its part in addressing access to medicines challenges by taking an innovative, responsible and sustainable approach.

According to UNAIDS and the WHO, 47% (6.6 million) of the estimated 14.2 million people living with HIV eligible for treatment in low- and middle-income countries were accessing anti-retroviral therapy in 2010. UNAIDS and WHO are committed to reaching 15 million people living with HIV with anti-retroviral treatment by 2015 across the world. In total, UNAIDS estimates that 6.6 million people living with HIV in low- and middle-income countries now have access to HIV therapy, a 17-fold increase since 2003.

ViiV Healthcare recognises its part as a key stakeholder in this global effort. It is committed to working in partnership with the HIV community to address this challenge through industry-leading access initiatives which are continually evaluated to look for further improvements. ViiV Healthcare’s access to medicines approach covers all MICs, all low-income countries, all LDCs and sub-Saharan Africa – 135 countries in total.

This is done through a variety of approaches, based on the differing needs of people living with HIV in different parts of the world.

Innovative pricing

ViiV Healthcare offers its complete ARV portfolio at not-for-profit prices in all LDCs, the World Bank’s low-income countries, and all of sub-Saharan Africa. These countries, according to UNITAID, cover 75% of all the people currently living with HIV. The not-for-profit price of *Combivir* is now \$231 per patient per year (32 cents a day) compared to \$730 in 2001.

This is a significant improvement in affordability, but we recognise that no price is affordable for the world’s poorest communities without significant additional healthcare resources being made available.

In middle-income countries, where incomes are higher and infrastructure is more developed, we have a flexible pricing policy which factors in the gross domestic product (GDP) and the impact of the epidemic in each country to improve affordability. In these countries, which include some of the fastest growing economies in the world, there is a need for government commitment and accountability to scaling up the national response to the HIV epidemic.

In 2011 ViiV Healthcare shipped 642,000 tablets of not-for-profit *Combivir* and *Epivir* to developing countries, compared with 1.73 million in 2010. This decline in supply of ViiV Healthcare’s own ARVs is expected – and outweighed – through the volumes supplied by its licensees.

Voluntary licensing

Through its royalty-free voluntary licensing approach, ViiV Healthcare enables generics companies to manufacture and sell versions of its products in all LDCs, low-income countries and sub-Saharan Africa.

ViiV Healthcare has now granted 11 voluntary licences for its ARVs, an increase from eight when the company was formed. In 2011 its licensees supplied more than 717 million of its versions of *Epivir* and *Combivir* to African countries in 2011.

ViiV Healthcare anticipates that volumes of lamivudine through licensees will decrease following its patent expiry in 2012. Through its ongoing commitment to supporting affordable second line regimens, ViiV Healthcare anticipates generic versions of its broader portfolio and will endeavour to measure and report data in future reporting.

Supply of *Combivir* and *Epivir* tablets through licensees

Number of tablets (million)

| | |
|-------|-----|
| 2011* | 717 |
| 2010 | 594 |
| 2009 | 358 |
| 2008 | 279 |
| 2007 | 183 |

■ ViiV Healthcare licensees
 ■ GSK licensees

* 2011 data include additional licensees however comparable 2010 data are not available.

Data should be considered a conservative estimate of use. All licensees are not captured in the data and data do not include paediatric formulations such as syrup. ViiV Healthcare are also aware of significant use of zidovudine and lamivudine in generic fixed dose combinations.

Local partnerships and Technology Transfer

One approach taken by ViiV Healthcare in middle-income countries is creating partnerships with in-country pharmaceutical companies to manufacture our medicines locally – bringing the cost of the therapies down, while investing and sharing our expertise to build skills in the local economy. A partnership with Binnopharm in Russia which enables local secondary manufacture of ViiV Healthcare's ARVs for people living with HIV in Russia is an example.

The Medicines Patent Pool Foundation (MPPF)

The Medicines Patent Pool is one of several international community responses to meet the challenge of improving access to treatment and care for people living with and affected by HIV and AIDS.

The MPPF wrote to ViiV Healthcare (and all pharmaceutical companies working in HIV) in early December 2010 asking them to join formal discussions on the pool. ViiV Healthcare met with the MPPF in January and since then has held several constructive meetings and will continue the dialogue in 2012.

US patient assistance programmes

To improve access to HIV medicines for uninsured or low-income patients in the USA, ViiV Healthcare launched a patient assistance programme for HIV medicines in January 2011. This programme provides ViiV Healthcare HIV products at little or no cost to qualified patients with a household income of up to 500% of the US Federal Poverty Level. ViiV Healthcare is also piloting membership in Welvista, a non-profit programme which facilitates access to HIV medications for those currently on the waiting list for the US Government's AIDS Drug Assistance Program.

Community investment

ViiV Healthcare supports communities affected by HIV/AIDS through its Positive Action programme, the Positive Action for Children Fund and Positive Action Community Grants. Read more at www.viivhealthcareeffect.com.

Positive Action programme

The Positive Action programme was created in 1992 to work with marginalised and vulnerable communities, including young people, girls and women, sex workers, men who have sex with men, the homeless and injecting drug users.

ViiV Healthcare continues to make great progress through community partnerships, connections and collaborations with the broader HIV community. Funding enables these communities to:

- Tackle stigma and discrimination and reduce violence against at risk populations
- Test innovations in education, care and treatment
- Build the grass-roots capacity of these disproportionately affected communities.

In February 2011 the Positive Action programme and the International HIV/AIDS Alliance announced that their partnership, Vida Digna, would be extended to El Salvador and five additional countries in Central America, tackling stigma and discrimination against vulnerable populations and people living with HIV.

In the USA, the Positive Action Southern Initiative was extended to eight states. This is a collaborative, community-focused programme designed to address gaps in services or programmes that support care and treatment and address improving adherence among individuals living with HIV/AIDS.

Positive Action for Children Fund

In collaboration with our partners, our aim is to provide support and deliver prevention of mother-to-child transmission of HIV (PMTCT) services. Every year, we continue to form new partnerships with community focused organisations, striving to alleviate the devastating effects of the HIV/AIDS pandemic. The Positive Action for Children Fund is an integral part of ViiV Healthcare's commitment to communities affected by HIV and AIDS. In 2009 the company committed to invest £50 million (\$80 million) in the Fund over 10 years.

Since its launch in March 2010, the Positive Action for Children Fund has committed £10 million on 117 projects in 21 countries. Our partner organisations demonstrate their commitment and dedication to addressing mother-to-child transmission of HIV through innovation and by maximising local resources made available through various health systems. Such work is closely aligned with UNAIDS' Global Plan towards the elimination of new HIV infections among children by 2015 and keeping their mothers alive. It also works towards achieving the Millennium Development Goals set to reduce child mortality and improve maternal health.

Positive Action Community Grants

Positive Action Community Grants are given by ViiV Healthcare's local operating companies to HIV community organisations to support innovative programmes. You can read a case study about one such programme in Germany, Beats for Life, [online](#).

Vijana Tunaweza Newala

Globally, girls and young women are more likely to be HIV-positive than their male peers. ViiV Healthcare's Positive Action programme has funded a project in Newala – one of the least developed and poorly resourced districts of Tanzania – to tackle the fundamental causes of girls' vulnerabilities to HIV/AIDS.

Research for the project identified four key sources of these vulnerabilities: gender stereotyping, erosion of family and social support networks, exploitation and early sex, and limited communication and support. The project then launched a life skills education programme providing opportunities for girls to talk about sexual and reproductive health, empowerment, self-awareness, and other social and personal issues. Over a six-month pilot period, 60 sessions were held in schools and local communities, reaching more than 1,600 young people with information about pregnancy, HIV, self-esteem, puberty, love and sex, goal setting, and forming friendships.

A follow-up study showed the project helped bring about changes in attitudes towards sexual relationships and stimulated dialogue about girls' rights, their role in society, and how local communities can provide more educational support for girls.

The project, Vijana Tunaweza Newala, was run by the International Center for Research on Women (ICRW) and Taasisi ya Maendeleo Shirikishi Arusha (TAMASHA), in collaboration with Pact Tanzania. ViiV Healthcare is currently discussing ways to expand the reach of the programme with ICRW and their community partners in Tanzania.





Our people and communities

Supporting the development of our people and communities around the world



Contents

| | | | |
|---------------------------------|-----------|--|-----------|
| Introduction | 37 | Performance in 2011 | 47 |
| Working at GSK | 38 | Feature: Bringing Science to the London 2012 Olympic and Paralympic Games | 48 |
| Engaging employees | 38 | | |
| Developing employees | 39 | | |
| Diversity at GSK | 40 | | |
| Health and safety | 41 | PULSE and employee volunteering | 50 |
| Our community investment | 46 | | |

+ Click arrows above to go to each section →



We respect all people and support employees to reach their full potential. We aim to make a positive difference to the communities in which we operate through economic contribution, investment, education programmes and partnerships.

Introduction

Investing in our people and communities underpins the long term sustainability of our business, creating the right internal and external conditions to support our strategy.

Our employment practices are designed to create a work place culture in which all GSK employees feel valued, respected, empowered and inspired to achieve our goals.

Strong, prosperous communities create the right conditions for business growth. We want to be a catalyst for change, helping the many communities we work in to flourish as our business grows.

Values-based business

Our GSK values guide our work and we expect all our employees to:

- Commit to **transparency**
- Show **respect** for people
- Demonstrate the highest **integrity** in our conduct
- Be **patient-focused**.

Read more on how we apply our values on page [52](#).

Progress in 2011

- Continued focus on diversity and inclusion, 26% of our most senior managers are women and over 40% of our total workforce are employed in our Emerging Markets, Asia Pacific and Japan regions (page [40](#)).
- Extended our Employee Assistance Programme (EAP) to over 90% of our employees, providing access to counselling, mental health and emotional crisis support (page [42](#)).
- Reduced days lost to injury and illness from 5.21 to 4.34 per 100,000 hours worked, and set a new reportable injury and illness target for 2014 (page [44](#)).
- Engaged employees through our 'Idea Engine' facility, which generated 2,000 ideas for improving aspects of our business performance (page [38](#)).
- Extended our PULSE programme to give 80 employees from 22 countries the chance to contribute their skills to non-profit organisations through placements (page [50](#)).
- Used our involvement in the London 2012 Olympic and Paralympic Games to inspire a new generation of young scientists and improve the health and well-being of communities and employees (page [48](#)).
- Gave £204 million in global community investment, including £126 million in product donations valued at cost (page [46](#)).
- Donated products valued at £2.2 million to areas affected by the Japanese earthquake and £1.7 million in cash to the Japanese Red Cross (page [46](#)).

Working at GSK

We aim to create an inclusive, engaging working environment that empowers employees to contribute and to help us achieve our strategic business objectives. Key to this is our investment in development, our approach to flexible working and our innovative safety, health and well-being programmes.

An inclusive environment is good for business because it brings different knowledge, perspectives, experiences and working styles which enhance creativity and innovation at GSK. GSK employs over 97,000 people in 114 countries worldwide.

Our aim is for every GSK employee to feel engaged with their work and colleagues, and to understand the impact they have on delivery of our business objectives and performance. We know that one of the key motivators for our employees is that their contribution makes a positive impact on people's lives – giving a real sense of purpose.

Engaging employees

We believe the relationship between an employee and their line manager is the most critical factor in ensuring employee engagement. Our leadership programmes and manager training at every level aim to build leadership capability. We seek feedback about how managers are performing as leaders through our employee survey and 360-degree feedback processes. In 2011 2,000 of our most senior leaders took part in a 360-degree assessment to receive feedback on their performance from those they supervise as well as their colleagues, managers and peers.

We communicate regularly with our employees in order to provide up-to-date information on progress towards our goals and changes to our business, to listen to feedback and to stimulate innovative ideas.

We made improvements to our internal communications in 2011, for example improving connectGSK, our global intranet site, to help people obtain information more quickly and connect them with colleagues across the company.

The MyCEO section on our global intranet gives employees a chance to pose questions to Sir Andrew Witty and other members of the Corporate Executive Team (CET). Many CET members have blogs or Q&A pages to update staff in their parts of the business. They also communicate through face-to-face meetings and web-broadcasts. Regular broadcasts by Sir Andrew are screened in 80 GSK locations and available to watch on employees' computers.

By using our 'Idea Engine' facility employees can make suggestions for improving aspects of our business performance and vote on ideas put forward by colleagues. In 2011 we ran 17 campaigns, generating over 2,000 ideas and 15,000 votes. The campaigns covered a range of themes, from engaging employees with the new strategy in our Consumer Healthcare business to ideas for improving customer service in our new Core Business Services function.

The last few years have seen major changes in our business including new acquisitions and joint ventures, and restructuring including outsourcing, site closures and staff reductions in some markets. Our global footprint has changed with a reduction in the number of employees in western markets and an increase in employees based in emerging markets.

We are very conscious of the effect restructuring has on employees. Whenever possible we aim to achieve organisational and financial goals without eliminating jobs. We consult with employees and their representatives before implementing measures that affect our workforce.

Programmes such as Energy for Performance and Team and Personal Resilience help employees to sustain their energy levels, especially through times of change.

Developing employees

We want GSK to be an employer of choice. To achieve this we invest significantly in developing employees at every level from people in their early careers to those in senior management positions. We offer all of our employees a range of learning opportunities and tailored development programmes. For our employees to achieve sustainable high performance we encourage on-the-job learning through challenging project work, supported with more formal training programmes, mentoring and coaching, as well as volunteer programmes such as PULSE (page 50).

We have a number of development programmes to support new recruits in their early careers including industrial placements, apprenticeships and ESPRIT, our global MBA programme for postgraduates. We updated our university relations strategy to make sure we have access to greater numbers of talented graduates, supporting our ambition to increase graduate recruitment three-fold to 450 people per year by 2015. From 2012, we have committed to reimbursing 100% of uncapped tuition fees for all undergraduates recruited in the UK from 2015 onwards. This is an investment in the future of the company and more broadly in UK industry and young people.

We recently introduced Job+ Coaching, a programme where HR and business leaders coach colleagues who are not in their direct line of management. We trained 162 Job+ Coaches in 2011 who now coach approximately 538 employees in over 12 countries.* We also introduced Practical Coaching in the Workplace, a one-day programme designed to help other managers adopt a coaching culture with their teams. We believe our focus on coaching will help us to create an energised and resilient workforce and high-performing leadership.



*SGS verified

Pay for performance

We are open and transparent about how we reward our employees, management and our executive team.

We recognise and reward our employees' contribution to the success of the business. We offer competitive salaries that are based on industry benchmarks, incentives that acknowledge performance against annual objectives and company performance, and share ownership schemes.

Management and executive level remuneration is aligned with our business performance measures and supports the delivery of our strategic priorities with the emphasis on rewarding long-term performance.

Our Remuneration Committee sets remuneration policy and levels for our executive team, giving consideration to levels for the wider employee population. They have responsibility for ensuring it is appropriate but not excessive, and competitive with industry and wider market norms. The policy is structured to pay for performance based on a set of consistent and rigorous standards to reward achievement against our strategic priorities and is designed to ensure delivery of strong long-term financial performance and sustainable shareholder value.

We continuously evaluate our approach and consult with key shareholders annually on our proposals and policy. We listen carefully to their feedback and believe our current approach reflects this. This year we have enhanced disclosures in our [Annual Report](#), to provide further transparency and a clear overview of the total remuneration earned and available to our executive directors, which includes:

- The total remuneration of our Executive Directors for 2011, including the value of awards they have earned under long-term incentive plans. Total remuneration includes base salary, other benefits, and pay for performance elements (annual bonus and value from long-term incentive awards). The Committee does not want to reward failure and the 'payment for performance' principle ensures that incentive payouts are only made in circumstances where performance outcomes reflect genuine achievements against original targets.
- The level of total remuneration that could be earned from packages granted to our Executive Directors in 2012. Final values will be determined in three years time when actual performance is measured against targets however a number of scenarios are included to demonstrate the range of remuneration which could be achieved.

We are aware of the sensitive environment surrounding executive pay at a time of real economic challenge.

As one of Britain's largest companies, we recognise the leadership role we have and the importance of a balanced approach. It is also important that GSK, like other multinational companies, is able to compete globally and reward leadership and vision which is fundamental to our success, and that continued success is in the interests of our shareholders, and the global economy.

Our Leadership Development Framework supports the critical career stages in building our leadership pipeline and provides clarity around the skills and capabilities required at each key stage. We are extending attendance at our leadership programmes to more employees in emerging markets. For example, in 2011 30% of participants in the Leading Business programme for potential general managers were from emerging markets, and our First Line leadership programme was delivered in 12 languages in 28 countries.

Our Future Strategy Group (FSG) has proved valuable opportunities for high potential employees to work closely with the Corporate Executive Team. In 2011 34 employees undertook assignments in challenging areas such as access to medicines and malaria, gaining valuable experience of thinking and operating at an enterprise-wide level.

Thinking flexibly about the way we work enables us to attract and retain critical talent groups. This includes formal arrangements such as flexible hours, part-time working and job shares, as well as informal arrangements such as working from different locations. It empowers employees, helping them to optimise their effectiveness and better balance their work with other needs and commitments. We encourage flexibility, provided it also meets the broader needs of the business.

Diversity at GSK

Being an inclusive employer helps us to attract, retain and motivate a workforce which reflects the communities in which we operate.

We are committed to making employment at GSK accessible to people with disabilities and increasing the proportion of women and people from emerging markets in management positions. We measure the proportion of women in management positions worldwide and the proportion of ethnic minority employees in the UK and USA.

We aim for people with disabilities to be able to access the full range of recruitment and career opportunities. We partner with disability organisations such as the Employers' Forum on Disability in the UK and SERMES in Spain. In 2011 we signed the Employers' forum for Disability [Accessible Technology Charter](#). Supported by 17 other blue chip organisations and government departments, the charter aims to improve access to IT for people with disabilities and to spur more inclusive IT design.

We have a good representation of women in management positions. The percentage of women in higher level positions grew in 2011, reflecting our goal to increase the proportion of female employees at the most senior levels.

Our aspiration is to have more than 25% female representation on the Board by 2013. We currently have three women serving as Non-Executive Directors, representing 20% of the Board. We have three women on our Corporate Executive Team.

Women in management positions (%)

| | 2011 | 2010 | 2009 | 2008 | 2007 |
|----------|------|------|------|------|------|
| SVP, VP | 26 | 25 | 25 | 25 | 22 |
| Director | 38 | 37 | 36 | 36 | 35 |
| Manager | 42 | 42 | 42 | 41 | 40 |
| Total | 39 | 38 | 38 | 38 | 37 |

Ethnic minorities – UK and USA employees (%)

| | 2011 | 2010 | 2009 | 2008 | 2007 |
|-----|------|------|------|------|------|
| UK | 19.6 | 19.4 | 19.4 | 19.2 | 19.1 |
| USA | 21.9 | 20.5 | 20.4 | 20.5 | 20.1 |

The proportion of people we employ in our Emerging Markets, Asia Pacific and Japan regions has increased from 28% to 41% of our total employees in 2011. Around 10% of senior managers who report to our executive team came from these regions and we plan to increase this.

Ethnic minorities accounted for 19.6% of UK employees in 2011. The proportion of ethnic minorities of England and Wales was 12.5% in the 2001 Census. This is based on the UK Commission for Racial Equality definition, which encompasses those who do not identify themselves as White British. We also measure diversity in the UK by the number of employees who define themselves as non-white. In 2011 12.3% of employees were non-white, compared with 12.1% in 2010.

In the USA ethnic minorities are defined as Black or African American people, Hispanic or Latino people, Asian people, Pacific Islanders, American Indian people and Alaskan natives. The proportion of ethnic minority employees in the USA has increased and we continue to work towards the industry average defined by the North American Industry Classification System for Pharmaceutical and Medicine Manufacturing.

Our seven strategic EHS priorities

| | |
|---|--|
| Healthy, sustainable lives | Improving the health of employees and their families through disease prevention and health promotion. |
| Energised and resilient workers | Helping employees to manage their personal health and sustainability. |
| Sustaining high-performing leaders | Providing coaching to help people perform at their best by developing their own solutions and resources. Read more on page 39. |
| Healthy, high-performing workplaces | Enhancing the working environment to improve the quality of working life. |
| Zero serious accidents | Eliminating all serious incidents. |
| Embedding EHS beliefs and behaviours | Putting the right values and practices at the core of our culture to embed them in the way we do business. |
| Environmental sustainability | Reducing our environmental footprint. Read more on page 82. |

Health and safety

Health and safety management is integrated in GSK’s environment, health and safety (EHS) strategy. It supports business objectives by reducing the risk of harm and helping employees to be healthy, productive and energised.

A strategic review completed in 2011 set our new EHS aspirations as having a healthy, resilient, high-performing workforce, and achieving zero harm to people and the environment. We have identified seven strategic priorities to achieve this.

The CEO EHS and Sustainability Awards are a key tool for engaging employees on health, safety and environmental issues. We refreshed the awards in 2011 to reflect the new strategic priorities. In particular, we recognised projects that showed demonstrable benefits to the business in our strategic areas. This year we received 90 applications (30% more than in 2010).^{*} Winners are featured here and in the Our planet section on page 82.

A healthy, resilient, high-performing workforce

GSK has provided programmes that have a positive impact by improving people’s well-being and productivity for several years. These programmes, tools and resources help employees to lead healthier lives and to cope better with the stresses they may experience at work and at home. In 2012 we will pilot a new preventive healthcare services programme for employees and their families.

Resilience in Latin America

GSK’s Latin America region has used the Team Resilience programme and Energy for Performance (E4P) workshops to significantly reduce perceived workplace pressures.

Each country in the region introduced the Team Resilience programme following success with the sales force in Brazil. More than 5,000 employees have now benefited since 2008, while more than 1,000 have participated in E4P.^{*}

The programme enables employees to engage with their manager to reflect on the way they work, analyse pressure points and identify action to improve resilience. More employees now perceive lower pressure in six of the seven categories between 2008 and 2011.^{*}



Emotional and mental health and the ability to cope with pressure are just as important as physical well-being. Our Employee Assistance Programme (EAP) provides GSK employees with access to counselling and mental health and emotional crisis support. We extended EAP to 94% of employees in 2011, up from 52% at the beginning of the year.*

Our Energy and Resilience programmes help individuals and teams to be more effective by increasing their focus, energy and confidence and reducing tension, anxiety and fatigue. An additional 8,500 employees participated in one or more resilience programmes in 2011, bringing the overall participation to nearly 50,000 employees.*

Energy Coaching was a new programme in 2011 – one-on-one telephone coaching in three sessions, during which the coach helps employees to identify their energy needs and evaluate options to address them. Revitalize You!™ was another new programme, an intranet tool through which employees learn to recognise and manage emotional stress and mental distraction.

Energy and Resilience programmes have a measurable impact on employee behaviour. Our analysis has found that participants improved on aspects of desirable behaviour such as acting as a coach or mentor and setting specific targets. They also reported improved lifestyles, especially nutrition, resulting in feeling healthier and more energetic. For example, a follow-up study in GSK Canada demonstrated that employees had increased engagement with their work following Energy for Performance, with 80% saying the programme improved their job performance as much as three years later.*

Aiming for zero harm

While we aim for zero harm our immediate aspiration is zero serious incidents.

Risks to employees vary according to their roles but include chemical exposure, driving accidents and repetitive strain injuries. We operate rigorous procedures to eliminate hazards where practicable and protect employees where necessary, but the right culture is an essential starting point. Our Living Safety programme, initially launched in 2009, aims to change the perception of how safety is integrated into operations and to increase personal responsibility for safety. A Living Safety module on the intranet provides interactive tools to improve employees' understanding of risks and how to manage them.

Reducing our health and safety risks

We took steps in 2011 to improve risk recognition, injury root cause assessment, and general safety capabilities throughout GSK. There was a particular emphasis on machine, process and construction safety. We also launched a professional certification programme to improve health and safety skills in our EHS workforce. This will help us fill EHS talent shortages in developing markets in support of our EHS goals.

Hazardous materials used in the development and manufacture of pharmaceuticals continue to be a key risk in our operations (see page 90). Our three-year process safety plan aims to identify and reduce risk, train personnel in key process safety elements and improve performance. For instance, in our primary manufacturing sites we use process safety performance indicators such as the number and severity of incidents to ensure these risks are well managed.

CEO Awards

Resilience

GSK Taiwan's Energy for Performance programme won the CEO Sustainability Award for a Healthy, High-Performing Workforce. The programme strengthened personal and team resilience through a high-profile, holistic programme. Results included halving the employee turnover rate in 2010.

Zero Harm

R&D and manufacturing teams from Ware (UK), Evreux (France) and Zebulon (USA) jointly won the CEO Sustainability Award for Zero Harm with a project to automate the analytical testing of dry powder inhalers. Results included reduced exposure of analysts to solvent and active ingredients, no risk of repetitive strain injuries, improved data quality and consistency, and improved throughput and efficiency.

In 2011 we launched a process safety programme for secondary and consumer manufacturing. The programme identifies potential major hazards, develops risk reduction plans, provides process safety training and reviews key control systems. We completed 11 process safety diagnostics in 2011.* All secondary and consumer sites will be covered by the end of 2012.

We routinely perform audits to ensure we are reducing and managing our risks effectively. In 2011 there were 31 internal audits. The main themes were the control of high risk and non-routine activities, process safety, monitoring systems and control of pathological agents. The audits found that management of health and safety risks was generally adequate. They identified progress on process safety risks and machinery safety and found that improvement is needed on issues relating to risk management processes, self-inspection and monitoring systems.

In addition to internal audit work, we are enhancing site audits to help identify and control health and safety risks. These audits are carried out by site employees and help build a better risk assessing and monitoring culture. We trained 359 employees to carry out site-based audits at our manufacturing sites.*

The philosophy of 'Zero Access' to machines adopted at manufacturing sites in 2010 resulted in a 67% decrease in significant risks related to the operation of production machinery.* Zero Access aims to eliminate serious injuries and harm to employees related to machine safety. It ensures protective machine guarding is in place and lockout-tagout (LOTO) processes are in use to protect staff during operations. However, even with these protective measures in place, three employees suffered amputations in 2011 (page 44).

'Respirator Free' is an ongoing initiative to use engineering and process related controls to reduce the occupational exposure risk to harmful airborne powders. With the completion of projects in 2011, 60% of the tasks involving powder handling in our manufacturing facilities are now respirator free.*

Raising employee awareness of the importance of health and safety in our commercial and sales operations is challenging. This is a very diverse group of work environments in diverse geographies and situations ranging from offices in London to sales forces on motorbikes in India. In 2011 a needs assessment of field groups led to the development of specific training and tools in road and driver safety. We also launched an awareness campaign on the risks of injury from slipping and falling, one of the greatest contributors to injury related work loss (page 44).

Ergonomics

We have made exceptional progress in recent years in improving our ergonomic programme and continue to increase employee awareness. Our ergonomics website now encourages sites to submit their solutions to ergonomic problems, creating a library of examples that help other sites with similar situations. The next step, beginning in 2012, is to replace existing risk assessment applications with a single system more appropriate to open office design.

Alert approach halves injuries

Our Clifton, New Jersey site in the USA halved the rate of injury and illness in 2011 by creating a paradigm shift that changed employees' approach to 'near miss' incidents.* Employees decided to replace the term 'near miss' with 'safety alert', a term more likely to grab attention and provoke action.

The site director challenged each employee to submit at least one safety alert each quarter to achieve a total of 800 in the year, compared to only 129 in 2010. The thinking was that more alerts would lead to more action, preventing more accidents.

Employees responded enthusiastically, submitting more than 2,000 alerts in the year.* More importantly, safety improved. The site went nearly six months without a reportable injury.*

Health and safety performance*

Work related fatalities and serious injuries

Keeping our employees and contractors healthy and safe is our priority and is an essential part of being a responsible employer. Regrettably two of our employees died in 2011, one in Pakistan after feeling unwell during an off-site training programme. A second employee died and another was seriously injured when the car they were travelling in was ambushed in Nigeria.

Following any serious incident we review and assess our processes and where we can build on the guidance we give our employees. Guidance to recognising and responding to heart symptoms has been shared globally and further advice and measures to reduce car-jacking risks have been provided to our employees in Nigeria.

When performing routine activities at sites in India and Egypt, two operators suffered amputations from moving machinery. Another employee in India suffered a finger amputation during a motor vehicle accident. Our ‘zero-access’ and driver safety approaches are critical to preventing machine and road safety related serious injuries and harm to our employees (page 42).

Fines or penalties

No health and safety fines or penalties were assessed against GSK in 2011.

Injury and illness

We have set a new target for 2014 and our performance in 2011 demonstrates we have started to make progress. We expect this trend to continue with the expansion of our Living Safety programme and use of leading performance metrics to measure our performance.

The broad picture of injury and illness causes remains the same as in previous years. Our top three leading causes are slips/trips/falls, machinery-related injuries and musculoskeletal conditions (eg repetitive stress, strain, motion). While cases of mental ill-health account for less than 2% of all our incidents they continue to have the highest number of lost calendar days.

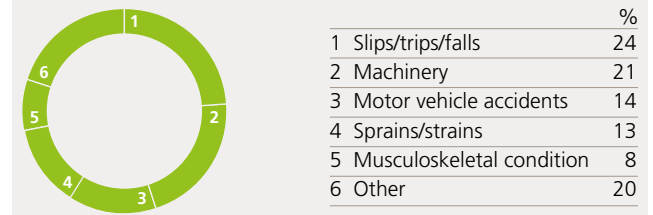
For more detailed breakdown of metrics and more data please see the detailed download available [online](#). Our environment, health and safety data in the CR Report is assured by SGS UK. Read its assurance statement and our response on page 94.

Reportable injury and illness rate

per 100,000 hrs worked



Leading causes of GSK reportable injuries and illnesses



Summary injury and illness data

| | 2011 | 2010 |
|---|-------|--------|
| Hours worked (millions) | 207.3 | 207.9 |
| Fatalities | 2 | 1 |
| Number of injuries and illnesses with lost time | 414 | 508 |
| Calendar days lost | 8,989 | 10,824 |
| Number of injuries and illnesses without lost time | 300 | 356 |
| Lost-time injury and illness rate (per 100,000 hrs worked) | 0.20 | 0.24 |
| Calendar days lost rate (per 100,000 hrs worked) | 4.34 | 5.21 |
| Reportable injury and illness rate (per 100,000 hrs worked) | 0.34 | 0.42 |

Notes:

- ⁽¹⁾ 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⁾ Lost calendar days are the days – including weekends – that employees could not work because of work-related injuries and illnesses. This helps provide a measure of the severity of the injuries and illnesses.
- ⁽⁴⁾ Reportable injuries and illnesses without lost time are incidents that did not result in time away from work. There are more serious than first aid but not serious enough to result in lost time.

EHS plans and targets

In 2012 we will be working in four priority areas:

- Enable Sustainable Business Performance** We will reduce our reportable injury and illness rate by 5% each year to the end of 2014. We will enhance EHS and leadership capability and engagement, expand Living Safety, improve our driver safety programme and produce simplified EHS management tools.
- Risk Reduction** We will simplify our EHS standards and policies, revise our EHS governance structure, introduce predictive ways to reduce risk and develop an ill-health absence risk reduction strategy.
- Behaviours and Values** We will launch an EHS Engagement Programme to drive our new ambitions. We will develop leading metrics to give advance warning of risks that will be the basis for targets to be set in 2012. This will include an EHS Culture Index and a metric based on ‘near miss’ reporting which will prevent more serious incidents.
- EHS operating model** We will enhance EHS critical capabilities, and assess and fill any competency gaps. We will also aim for rapid adoption of best practices and increased global consistency to identify and address gaps.

Read more online

We publish our positions online including:

- [Hazardous chemical management](#)
- [GSK and EU REACH Regulation](#)

Our community investment

Our community investment aims to improve health education and increase access to medicines and healthcare services. We target support where we can make the most difference.

Our approach includes funding innovative programmes that improve health through community engagement and behavioural change, donating medicines and expertise, and reinvesting some of our profits to improve healthcare infrastructure. We also invest in science education and support relief efforts following natural disasters.

We maximise the benefits of our community investment by working in partnership with NGOs and by selecting projects that enable us to use our expertise and resources. As well as benefiting communities, our investment strengthens our business by improving our reputation, boosting employee morale and helping us build relationships based on mutual understanding with a range of stakeholders.

The programmes we support are designed to have a long-term, sustainable impact. We set ambitious commitments and work with experienced partners.

Read more in the Health for all section of our report, which includes details and progress on our commitments to:

- Our long-term albendazole donation programme which targets two neglected tropical diseases the elimination of lymphatic filariasis (LF, also known as elephantiasis) and treatment of children for intestinal worms on page [26](#).
- Reinvest 20% of profits we make in Least Developed Countries (LDCs) back into healthcare infrastructure, partnering with three leading non-governmental organisations (NGOs) to address the shortage of trained frontline healthcare workers on page [19](#).
- Our Personal Hygiene and Sanitation Education (PHASE) programme, run in partnership with NGOs, which aims to reduce diarrhoeal disease by improving water quality and encouraging people to wash their hands on page [27](#).

We also encourage employees to get involved as volunteers through our Orange Day and PULSE initiatives and you can read more on page [50](#) about these.

Responding to the Japanese earthquake

Following the earthquake and devastating tsunami in Japan on 11 March 2011, GSK Japan mobilised 'Team Orange', employee volunteers who delivered food, blankets, face masks and other emergency products to people and our colleagues in affected areas in Tohoku district. An employee fundraising campaign raised £303,000 to support the ongoing reconstruction and recovery efforts.

We also contributed essential medicines and GSK Consumer Healthcare products to the affected areas valued at £2.2 million and donated £1.7 million in cash to the Japanese Red Cross. We also responded quickly to make sure that there were minimal disruptions to product supply, see page [72](#) for more detail.

We have created an 'Orange Scholarship' fund to support students affected by the earthquake. Thirty students studying pharmacy at two universities in Tohoku started receiving scholarships of 50,000 yen (approximately £410) per month until their graduation to help continue their studies at university.



Performance in 2011

Our global community investment was £204 million (\$328 million) in 2011. Overall giving remained constant between 2010 and 2011 after excluding our one-off donation of 24 million doses of H1N1 vaccination to the World Health Organization for use in developing countries in 2010.

We value donations at cost (average cost of goods) rather than wholesale acquisition cost (WAC), a measure used by some other companies, as we believe it is a more accurate reflection of the true cost to GSK. 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 benchmarking purposes we also report the WAC value of our donations. The total value of 2011 global giving using WAC for product donations was £474 million (\$764 million).

Our product donations (at cost) of £126 million are made through three main programmes:

- Our US Patient Assistance Programs to support low-income patients in the USA (£96 million)
- Our humanitarian product donations (£4 million)
- Our donation of albendazole tablets for the lymphatic filariasis (LF) elimination programme (£19 million)

You can read about our policy and principles that underpin our approach to product donations [online](#).

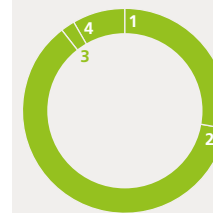
Over half of our cash giving of £57 million is targeted at health programmes. This includes our partnerships with AMREF, CARE International, Save the Children to support training of frontline healthcare workers, as part of our commitment to reinvest 20% of profits made in the Least Developed Countries. You can read more about these on page 20. We publish data about our charitable grants to patient groups (page 79) and grants over £10,000 [online](#).

Our US Patient Assistance Programs account for almost half of our overall giving and you can read more about these in more detail on page 30. Several factors impacted our US programmes in 2011 and we expect these to continue in 2012. These include the removal of several of our branded medicines given the commercial availability of low-cost generic products, a fall in patient enrolments due to changes to Medicare Part D, and our switch from retail to mail order which reduced our overall programme costs (and are included in our figures).

Participation in our PULSE programme continues to increase with a further £1 million invested in 2011. PULSE volunteers continue to receive their full GSK salary during placement. These along with programme operating costs represent a £3.3 million in-kind donation in 2011. We also began our investment in Olympics-related community programmes in 2011 such as Scientists in Sport and Your Personal Best which you can read about on the next page.

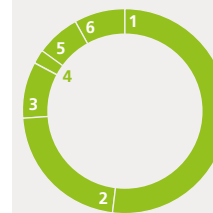
ViiV Healthcare has more than doubled its giving from £8 million in 2010 to £18 million in 2011, driven by expansion of its US patient assistance programme and continued funding of its Paediatric Innovation Seed Fund and Positive Action for Children Fund. You can read more about these on page 32 and 34.

Our giving in 2011



| | £m |
|--------------|------------|
| 1 Cash | 57 |
| 2 Product | 126 |
| 3 In-kind | 4 |
| 4 Management | 17 |
| Total | 204 |

Breakdown of our cash giving



| | % |
|------------------------|----|
| 1 Health | 52 |
| 2 Education | 22 |
| 3 Arts and culture | 9 |
| 4 Environment | 2 |
| 5 20% LDC reinvestment | 7 |
| 6 Other | 8 |

Help for Heroes

In the UK, GSK is supporting the new Phoenix Wellness Centre at Tedworth House Personnel Recovery and Assessment Centre in Tidworth, Salisbury for injured servicemen and women with the charity Help for Heroes. We will be providing funding of £1 million over the next five years in support of this programme.

Feature: Bringing science to the London 2012 Olympic and Paralympic Games

We are using the excitement generated by the London 2012 Olympic and Paralympic Games as an opportunity to advance scientific progress, inspire a new generation of young scientists and improve the health and well-being of communities and employees.

Some of this will be achieved through our official London 2012 partnership, but we are also going beyond this commitment to create a positive and lasting legacy.



Promoting fair play and advancing scientific progress

As the Official Laboratory Services Provider of the London 2012 Games, we are contributing our expertise in research and development to support the integrity of the Games and the health of athletes. Scientists from King's College London (KCL) will use the new World Anti-Doping Agency (WADA) accredited laboratory, established by GSK, to test for use of performance-enhancing drugs during the Games. We are helping to recruit over 100 PhD students, who will support KCL anti-doping experts to analyse over 6,000 samples – more than any tested during previous Games. GSK is currently working to secure a sustainable future for the laboratory in the hope that it could operate as a standalone business beyond the Games. GSK has also selected 10 employees who will manage Anti-Doping Control Centres at Olympic and Paralympic venues where athletes will provide their samples.

We will continue to help in the fight against doping after the Games and have committed to supply WADA with confidential information about medicines in early stage development that have the potential to be abused by athletes. This will allow them to develop testing techniques before these medicines are even marketed.

Inspiring young scientists

London 2012 has inspired GSK to create Scientists in Sport, a school outreach programme. Jointly developed with KCL and UK Anti-Doping (UKAD), this helps 11–14 year olds understand the role science will play in the Games and excites them about potential science careers. The children visit a university to participate in activities and hear about how science is used in sport.

At the same time we are running a UK-wide challenge for schools endorsed by the British Science Association, where teams can design a portable anti-doping kit to test for new substances. We have developed kits for GSK Science Ambassadors to use in our outreach programme and a range of free resources for teachers and pupils available at www.scientistsinsport.com. Our ambition is to reach every secondary school in the UK and get thousands of schoolchildren participating in our programmes.

Improving health and well-being in the community

We are using London 2012 as an opportunity to improve health and well-being through community initiatives such as [Your Personal Best](#). This initiative with NHS London will help to deliver a health legacy for London 2012 by inspiring the 7.78 million people aged over 55 with long-term health conditions to lead a more active lifestyle.

Motivating our employees

We have used our London 2012 partnership to recognise GSK employees who make a positive difference. We are using 100% of our ticket allocation for the Olympic and Paralympic Games to reward employees who are demonstrably living the joint GSK and Olympic/Paralympic ideals of integrity, equality, friendship and excellence.



Official Laboratory Services Provider

PULSE and employee volunteering

We contribute time and expertise, as well as money and products, to create positive change in the communities in which we operate. Our two volunteer programmes, PULSE and Orange Day, provide employees with the opportunity to make an impact and develop their knowledge and capabilities.

PULSE gives employees the chance to join a non-profit or non-governmental organisation (NGO) for a three- or six- month, full-time placement. It enables employees with leadership potential to develop professional skills in new and challenging environments while helping partner organisations to develop and implement strategic plans, improve their processes and operations, and enhance their communications and marketing.

We have worked with 58 [PULSE partners](#) supporting organisations that work on healthcare, education and environmental issues in areas of great need and that have a proven track record. In 2011 we started new partnerships with 15 NGOs, including CARE International, JEN (a Japanese emergency relief charity), and the Philadelphia Education Fund. There were 80 PULSE volunteers in 2011, up from 58 in 2010, with volunteers coming from 22 countries (17 countries in 2010). Nearly 200 employees from 26 countries have served as PULSE volunteers since 2009.

Six months after completing PULSE, nearly 80% of volunteers said that they were more energised by their work at GSK. Eighty-three per cent of volunteers' team members at GSK said that PULSE had enabled volunteers to share a different external perspective that had helped to inform or shape GSK's work, thinking or policy. In 2010, 86% of the NGO managers said that their volunteer's impact was sustainable six months after the PULSE assignment ended.

In a recent international corporate volunteering benchmark study by an independent organisation, PULSE emerged as top-of-class compared to over 20 other international corporate volunteering programmes. PULSE was differentiated from peer programmes for its breadth, scope and duration of assignments, as well as incorporating rigorous processes for measuring impact on partner organisations, GSK and our volunteers.

In 2012 we will evolve our programme and launch three 'PULSE Pillars', which will focus on multi-year, multi-volunteer projects, strengthening our contribution in three areas: malaria, access to health, and children. We will continue to improve our measurement to help us better understand the impact of PULSE. To further increase the diversity of PULSE volunteer and NGO participants we will continue to support the PULSE Local Hub in Japan and will establish PULSE Local Hubs in Latin America and India.

Our other major volunteer programme, Orange Day, gives employees one paid day off each year to volunteer for their chosen local community project. This year, thousands of US staff volunteered as part of the National Day of Service and Remembrance on the tenth anniversary of 9/11. Activities included packing more than 120,000 meals for people in Haiti, Kenya and Nicaragua and flood victims in the USA. The national day was initiated by [MyGoodDeed](#) a charity of which we are a founding sponsor.

200

PULSE volunteers since 2009

58

PULSE partner organisations

IMPACT Awards

Our annual IMPACT Awards recognise small and medium-sized charities that are providing excellent and innovative local community healthcare in the UK and in the Philadelphia and Raleigh/Durham regions of the USA.

Step Forward received £35,000 as the overall winner of the UK IMPACT Awards in 2011. This charity provides free and confidential advice and personal development services to disadvantaged young people in and around Tower Hamlets, London. Other winners, who received £25,000 each included Bryncynon Strategy in Cynon Valley, Wales, which develops innovative ways to improve public health services in a deprived community affected by the loss of the local coal mining industry.

In the USA, awards of \$40,000 are given to up to 10 organisations. This year these included Housing for New Hope, which helps homeless people to access healthcare services as part of their integrated approach to homelessness, and Phoenixville Healthcare Access Foundation, which assists uninsured and under-insured, lower-income individuals in obtaining dental, vision and prescription services.

The Awards are open to charities with an annual turnover of less than £1.5 million (UK) or between \$160,000 and \$3 million (USA). As well as the prize money, our IMPACT Assessment offers feedback and advice to each winner to help them strengthen their management plans.

In the UK the winning and highly commended organisations are invited to become part of the [IMPACT Awards Development Network](#), set up in 2008 to connect the winning charities and provide them with five days of organisational development training. The training is funded and hosted at GSK and is facilitated by The King's Fund, which has over 30 years' experience training senior leaders in the health sector.





Our behaviour

Behaving in an open and honest manner in all that we do



Contents

| | | | |
|--|-----------|--|-----------|
| Introduction | 53 | Clinical research | 64 |
| Ethical conduct | 54 | Patient safety | 66 |
| Preventing bribery and corruption | 54 | Supply chain | 68 |
| Marketing our products | 55 | The supply and distribution process | 69 |
| Feature: Changing the way we incentivise our sales teams in the USA | 56 | Our supplier standards | 70 |
| Publishing payments to healthcare professionals | 58 | Performance in 2011 | 71 |
| Publishing grants and donations | 58 | Security of supply | 72 |
| Training and awareness | 58 | Supplier diversity | 73 |
| Monitoring and compliance | 59 | Public policy and patient advocacy | 74 |
| Data privacy | 60 | Trade and industry associations | 74 |
| Research practices | 61 | Public policy activity in 2011 | 75 |
| Animal research | 61 | Political contributions and lobbying expenditure | 77 |
| | | Patient advocacy | 78 |
| | | Human rights | 80 |

+ Click arrows above to go to each section →



We are building a strong values-based culture. We recognise that we need to be open about what we do, how we do it and the challenges we face. Our actions are backed by robust policies and strong compliance processes.

Introduction

Our commitment to responsible, values-based business underlies everything we do including how we conduct and report our research, our sales and marketing practices, lobbying and policy activities and our relationships with suppliers.

We set high standards for our employees through our policies and compliance programmes and expect the same standards of our suppliers, contractors and business partners. Most importantly, we are building a culture in which decisions are guided by our values of: Transparency, Respect for People, Integrity and Patient-Focus.

Ethical conduct We are committed to performance with integrity. We are building a strong values-based culture by developing robust policies and compliance processes, by employing the right people, being clear about what we stand for and helping them in making ethical decisions.

Research practices Investment in R&D is at the core of our business and it is essential we meet consistently high ethical and quality standards in all that we do. We recognise that there are aspects of our research that can raise ethical concerns and we aim to be open about how we address these.

Supply chain An effective and responsibly managed supply chain is essential for us to provide our medicines and products to our patients and consumers. We aim to work with responsible suppliers and set expectations and standards for ethical conduct, labour practices, protection of human rights and for environment, health and safety management and performance.

Public policy and patient advocacy Through our public policy activity we support legislative measures and programmes that support scientific innovation and balance the interests of business with those of other stakeholders. We also work with patient and professional groups to help their members gain a stronger voice on healthcare.

Human rights We are committed to upholding the Universal Declaration of Human Rights, the core labour standards set by the International Labour Organization, and have signed the UN Global Compact. We aim to act responsibly across all our spheres of influence including our employees, suppliers, local communities and society more broadly.

Progress in 2011

- Developed new sales models – de-coupling the pay of our sales representatives in the USA from the number of prescriptions issued (page [56](#)).
- Updated our Global Code of Practice for Promotion and Customer Interactions bringing greater consistency in our operating practices across the company (page [55](#)).
- Publication of payments, grants and donations made to healthcare professionals and organisations in the USA. We continue to work towards disclosure in other markets (page [58](#)).
- Reached an agreement in principle with the US Government to conclude a number of ongoing investigations into sales and marketing practices for a settlement payment of \$3 billion. This is a necessary step towards resolving long-standing matters which do not reflect the company that we are today (page [55](#)).
- Reduced number of animals used by 9% in 2011 compared to 2010 (page [61](#)).
- Developed new ‘Scientific Engagement’ policy and standards to reinforce a clear distinction between our scientific dialogue and our promotional activity, ensuring we reflect our values in how we engage with others (page [63](#)).
- New commitment to disclose results summaries for investigational medicines after clinical study completion rather than after approval or termination of an asset (page [65](#)).
- Conducted 326 clinical quality assurance assessments covering GSK and external research carried out on our behalf (page [65](#)).
- Improvements made to patient safety system databases and monitoring (page [66](#)).

Ethical conduct

Ethical conduct is a priority for GSK. Failure to uphold high ethical standards can erode trust in our company and our products, damage our reputation and result in serious financial or legal consequences.

Our [Code of Conduct](#) sets out fundamental standards for all employees. It is supported by the [Employee Guide to Business Conduct](#), available in 22 languages, which helps employees make ethical decisions and emphasises our values: transparency, respect for people, integrity, and focusing on the patient.

Our compliance programmes aim to embed a values-based culture at GSK. In 2011 we launched 'One Compliance', an initiative to improve consistency in policy, implementation and monitoring across all our business units and the different countries in which we operate.

Preventing bribery and corruption

We do not tolerate bribery and corruption, as we make clear in our [Preventing Corrupt Practices policy](#) and our [Code of Conduct](#). Our performance is reviewed monthly by our Head of Governance, Ethics and Assurance and by our legal department. In 2011 we established an Anti-Bribery and Corruption Expert Forum which meets every two weeks to answer employee questions and advise on anti-bribery and corruption issues. Members of the forum include representatives from our Anti-Bribery and Corruption team, legal and compliance functions, as well as business representatives. Minutes of the meetings are distributed to the members of the forum as well as to compliance officers, who convey the key messages to employees. Where new guidance or documents are created as a result of the issues discussed, these are also posted on our intranet site which all employees can visit.

We enhanced our screening process in 2011 to reduce bribery and corruption risks associated with the use of third parties, including distributors and consultants who work on GSK's behalf in some markets. The screening, which includes background checks, is designed to identify any potential issues associated with third parties in higher risk categories (for instance those acting for and on behalf of GSK or interacting with government officials) before we agree to do business with them. Any issues raised during screening must be addressed which may mean not proceeding with a proposed relationship, the insertion of additional contractual clauses, or enhanced monitoring and training for the third party.

Our anti-bribery and corruption programme was audited by PricewaterhouseCoopers in 2011 and it concluded that risk in this area is well managed and recommended some enhancements. These related to our due diligence procedures and anti-bribery and corruption training programme and we will implement these recommendations during 2012.

Employees can read our anti-bribery policies and access our anti-bribery handbook and e-learning module via our intranet. The e-learning training is mandatory for all managers and employees working in certain functions, such as the legal department or in regions where there is a higher risk of corruption, and is supplemented by face to face training for employees in high risk roles. By the end of 2011, over 37,000 employees had taken the training. You can read our [Anti-bribery and corruption handbook](#) online.

We introduced anti-bribery and corruption audits in 2011, with their frequency and timing determined by regular risk assessments. These are designed to provide assurance that bribery and corruption risks are being adequately managed, and that our policies and procedures to mitigate risk are working effectively. The audits focus on areas that pose a high risk from a bribery and corruption perspective, including travel and entertainment expenses, petty cash, and the use of consultants.

Marketing our products

We market our prescription medicines and vaccines to healthcare professionals, hospitals and governments. Some people are concerned that marketing by pharmaceutical companies may exert undue influence on doctors, that sales representatives may not always give doctors full information about the products they are promoting, or that there may be promotion of medicines for unapproved uses. Our existing policies and updated Global Code of Practice for Promotion and Customer Interactions forbids these practices and other unethical conduct. We reinforce our policies through training and compliance procedures and by making sure that the way we pay sales teams reinforces our values. Read about remuneration of our sales teams overleaf.

In recent years we have fundamentally changed our procedures for compliance, marketing and selling in the USA to ensure that we operate with high standards of integrity and that we conduct our business openly and transparently. In 2011 we reached an agreement in principle with the US Government to conclude a number of ongoing investigations into sales and marketing practices for a settlement payment of \$3 billion. The final settlement and Corporate Integrity Agreement, which is expected to address civil and criminal liabilities and the Group's sales and marketing practices, remains subject to ongoing negotiation and is expected to be finalised in 2012. This is a significant step to resolving difficult and long-standing legal matters which do not reflect the company we are today. We are fully committed to ensuring appropriate promotion of our medicines and to the standards rightly expected of us.

Global Code of Practice for Promotion and Customer Interactions

To reflect our commitment to consistently high standards in sales and marketing, we reviewed and updated our Global Code of Practice for Promotion and Customer Interactions in 2011. The Code, which covers areas such as providing information and fees for service payments to healthcare professionals, samples, hospitality, grants and donations, will be rolled out in 2012 and published on our website. All employees who have contact with healthcare professionals, including our sales and marketing staff will be trained on the standards of the revised Code.

Our regional and local policies, standard operating procedures and other codes provide additional guidance to employees reflecting differences in regulations, market structures and national healthcare systems. They are at least as stringent as our Global Code, and in some regions and countries may be more restrictive. We will review and update all country-specific codes to make sure they incorporate the requirements of the new Global Code of Practice for Promotion and Customer Interactions.

In 2011 we further strengthened our standards governing how we share scientific and clinical data on the medicines we are developing, as well as those already available to patients, to ensure that there is a clear distinction between appropriate scientific dialogue and legitimate promotional activity. These new standards, introduced in April 2011, are referred to as 'Scientific Engagement', and they impact the way we engage in scientific activities, such as advisory boards, publications, scientific congress activities and medical education. You can read more about these standards on page [63](#).

We also strengthened a number of commercial practice policies in the USA in 2011, including enhancing oversight and review of educational reprints, publications, healthcare economic information and other materials used in promoting our medicines. Our US Pharmaceuticals business introduced a new policy governing support for US-based, non-profit healthcare organisations and centralised the management and funding support for these.

Direct-to-consumer marketing

We advertise our prescription medicines directly to consumers in the USA, New Zealand, Bangladesh and South Korea. Direct-to-consumer (DTC) advertising of prescription medicines is not permitted in other markets.

Promoting the use of prescription medicines directly to consumers has been subject to criticism. 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. All our DTC advertising in the USA is reviewed by legal, regulatory or medical specialists and new DTC television advertisements are submitted to the US Food and Drug Administration for review and comment prior to broadcast.

In 2011 we took the decision to stop television advertising in the USA for erectile dysfunction medicines. Although such advertising was legal, we made the decision to no longer advertise these medicines on television out of respect for viewers.

Feature: Changing the way we incentivise our sales teams in the USA

Our sales teams play an important role in providing physicians and other prescribers with up-to-date information on the safety and benefits of our medicines and vaccines. This information helps doctors make informed treatment decisions for their patients.

It is critical that everything our representatives do and say is in line with our values and puts the interests of patients first.



We have developed new sales models to align with the changing market and expectations of our customers. For example we have modified the structure of our US sales team and in 2011 we were the first company to de-couple the pay of our sales representatives in the USA from the number of prescriptions issued.

In the past, multiple sales professionals assigned to different products might call on a physician or health plan. Now, in many cases, one person may be responsible for a customer or a portfolio of products and will bring in specialists from the business when needed to provide support.

This change aligns with the changing healthcare environment in the USA where physician practices and hospitals are consolidating, and decision-making is increasingly centralised. We believe our new approach puts us in a strong position to meet the greater demand from patients, healthcare providers and payers for higher quality care, lower costs and better health outcomes.

Our new model for incentivising sales representatives who work directly with healthcare professionals aims to reward how well our sales representatives support their customers' needs to achieve better patient outcomes, rather than basing bonuses on individual or territory-based sales goals. Instead of measuring performance against individual sales targets we assess performance and determine bonuses on three factors: selling competency, customer evaluations, and the overall performance of the sales professional's business unit.

This change further aligns our incentives with our values of transparency, respect for people, integrity and patient focus. We have shared information about our new model with others, including the US Government.

In Europe we have also changed the way we reward pharmaceuticals field sales staff, replacing individual sales targets as the basis for reward with qualitative criteria, overall business financial achievement and individual-indexed performance measures.

3 factors

to assess performance

5,200

US sales representatives

Publishing payments to healthcare professionals

We make payments to healthcare professionals (HCPs) to help them participate in scientific conferences, to speak at meetings and conferences on behalf of GSK about products and disease or therapy areas relevant to us, to sit on and provide expertise at GSK advisory panels and to conduct GSK sponsored research. These services are valuable to our business and to improving patients' health, and GSK believes professionals should be fairly compensated if they provide services and expertise to us. However, payments must not be excessive and support must never be an inducement or reward for prescribing our products.

We have committed to publishing the payments we make to HCPs. In the USA, the payments made to HCPs for speaking and advisory services are published quarterly on our [US website](#). For the first three quarters of 2011, GSK paid 3,407 healthcare professionals a total of \$22.9 million, excluding research and development payments. Fourth quarter figures for 2011 will be published on 30 March 2012. You can read more about our commitment to and disclosure of research payments made to healthcare professionals and their institutions on page [64](#).

In 2011 we made a commitment to publish payments for services, grants and donations made to healthcare professionals and organisations outside of the USA during 2010. We remain fully committed to disclosing these payments. However, achieving this is challenging – systems and processes in each country need to be aligned to help us collate data across different systems and multiple currencies. We have been working to create and introduce appropriate processes that will ensure we can do this effectively and accurately. To enable robust and complete reporting consistently across the company we have taken the decision to delay disclosure.

At the beginning of 2011 we signed a statement with a number of other leading healthcare companies through the Association of the British Pharmaceutical Industry (ABPI) committing to report payments in the UK annually at an aggregate level. This will begin in 2013 for payments made in 2012 and will cover payments made to healthcare professionals for speaking and advisory services, as well as sponsorship. As a UK-based company, we will use this as the basis for our global standard across GSK while continuing to report payments at a named individual level in the USA.

Publishing grants and donations

GSK is regularly asked to make grants and donations to healthcare organisations to support a range of activities. Grants are monetary contributions which may be used to fund the attendance of the organisation's HCPs at a medical or scientific meeting by covering their expenses, to support research and to support independent medical education programmes. Donations are non-monetary contributions, such as medical equipment or textbooks, for the benefit of patients and healthcare organisations.

Separately we make community investment grants and product donations that are included in our disclosure of community investments (page [46](#)). Grants made to patient advocacy organisations are covered later in the section on page [78](#).

We publish grants and donations in the USA every quarter on our [US website](#) and have committed to extend this to all grants and donations outside of the USA. We will align our disclosure of grants and donations outside of the USA at an aggregate level to the same time frame as the disclosure of payments made to healthcare professionals outlined above, publishing figures in 2013 for grants and donations made in 2012.

Training and awareness

Training and awareness programmes help employees understand the importance of ethical conduct and of applying our policies in practice. Before hiring new recruits we carry out pre-employment checks to ensure they share GSK's values. We include questions on ethics and integrity in our guides that are used during employee interviews.

New employees complete induction training on the GSK [Code of Conduct](#) and specialised training is provided for employees working in R&D, manufacturing, and sales and marketing, where there are additional regulatory requirements.

Examples of training in 2011 included the launch of 'performing with integrity' programmes for new staff in the USA, and quarterly training for US senior employees on 'leading with integrity'. We also updated our coaching tool for US sales employees to include four questions on values and compliance to help supervisory staff better assess the ethical behaviour of their sales teams. We have updated our personal development programmes in the USA to include performance and development objectives relating to how employees implement our values.

We require all managers and employees who interact with healthcare professionals to confirm annually that they comply with our ethics policies. Our certification process will be supplemented with a new training programme for all employees to increase awareness, and we will introduce this during 2012.

Monitoring and compliance

All managers must ensure compliance with company policies in their areas of responsibility. Our Corporate Ethics and Compliance department monitors and tracks allegations and suspected legal, ethical or policy infractions. It ensures that all 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 and Risk Committee of the Board.

We are expanding our network of compliance officers and deputy compliance officers in our business units and regions. These roles are closely aligned with our businesses, working with them to identify and monitor business and product specific risks in the early, strategy phases of work to mitigate risk at the outset of projects. To increase the independence of our compliance teams, compliance officers are now funded by, and report directly to, our Corporate Ethics and Compliance department, rather than their local business unit.

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 and 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. Our Global Confidential Reporting Line is available in 70 different languages.

Addressing misconduct

In 2011 there were over 2,700 contacts made through our ethics and 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 reporting lines and offsite post office box (in the USA).

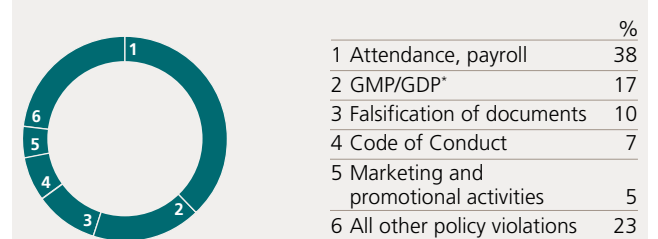
In 2011:

- 1,828 employees were disciplined for policy violations
- Of these, 308 were dismissed or agreed to leave the company voluntarily (known as separations)
- Other disciplinary actions included 1,520 documented warnings
- The 1,828 disciplinary actions included 66 cases of employees breaching sales and marketing codes
- These 66 cases resulted in seven dismissals or separations from the company. The remaining cases resulted in documented warnings.

In addition to appropriate discipline, employees staying with the company receive retraining and increased monitoring. In some cases retraining is extended to an employee's colleagues to prevent them from making similar mistakes.

We believe the increases seen in 2011 and in 2010 (1,742 employees disciplined) are due to the introduction of the 'Attendance and payroll' category in 2010. These attendance issues are mainly reported from our manufacturing business where we have implemented tighter controls to ensure we maintain and build on our strong track record of compliance. Additionally, our continued focus on manufacturing quality is seen through an increase in disciplinary numbers in the Good Manufacturing Practice/Good Distribution Practice (GMP/GDP) category in the same time period. Other categories have remained broadly consistent over that time.

Types of policy violations in 2011



Total violations in 2011=1,828

*GMP/GDP relates to Good Manufacturing Practice, Good Distribution Practice

Breaches of external codes

We collect information centrally on breaches of external industry or government promotional codes by our commercial businesses. A breach is defined as a sales or marketing infraction or violation of a law, obligation, code or standard resulting in a fine or censure of GSK by a government agency or industry association. Breaches are usually available publicly on industry group or regulator websites, and are often published in local news media.

We were found to be in breach of external codes 35 times in 2011 and 29 times in 2010. These included:

- Breaches of country specific regulations and codes – 37% in 2011. The majority related to new consumer product marketing and promotion regulations introduced by local Ministries of Health.
- Inappropriate promotion of pharmaceutical products – 35% in 2011. These related to strict regulations on advertising materials for promotion of pharmaceutical products which our local operating companies must adhere to.

We fully investigate every breach of an external code and take steps to prevent a reoccurrence which may include retraining or other corrective action, including disciplinary action. We aim to continually improve our processes to ensure compliance with industry codes and government regulations.

Data privacy

Data protection and security continues to be a high priority for GSK. We have established global privacy principles to ensure that all personal data are collected, used, processed, transferred and stored appropriately, securely and in line with legal requirements. We have created a Global Privacy Office to oversee our privacy processes and communicate best practices throughout GSK.

In 2011 we began to implement 'Binding Corporate Rules' standards on data privacy to improve the efficiency of transfers of personal data within the company and to increase confidence in the security of the personal data with which we are entrusted. These Binding Corporate Rules are a European Commission approved approach enabling companies to transfer personal data to affiliates located outside the European Economic Area in compliance with UK and European data protection regulations. Our Binding Corporate Rules cover personal data held on our employees, research subjects and healthcare professionals who we partner with in research.

In 2011, Epsilon, one of our marketing services suppliers, was the target of a malicious attack in which customer personal data was stolen – including names and email addresses. GSK was one of 100 companies affected by this security breach.

Our data breach incident response team assessed the situation, and we notified every GSK consumer affected by email within 11 days of the incident. We set up a hotline for questions and complaints and advised consumers to be on the look-out for unusual or suspicious emails.

Plans for 2012

As part of our One Compliance initiative, we will establish a Compliance Advisory Service that will advise senior leaders in the business on risk associated with emerging business strategies and will be responsible for promoting a values-based compliance culture within the business. We will also enhance our Compliance Operations functions and investigation capabilities as we continuously improve our compliance efforts.

In our US Pharmaceuticals business, we have created and will implement a 'Controls Centre of Excellence' in 2012 which will ensure alignment and compliance to regulatory requirements and company policies. This will mitigate risk, enhance governance and address our current and anticipated needs. This effort will drive accountability for business-driven controls, centralise monitoring and reporting and support the business to build and enhance its controls capability.

Read more online

- [GSK Code of Conduct](#)
- [Employee Guide to Business Conduct](#)
- [Anti-Bribery and Corruption Programme Handbook](#)
- [Anti-Bribery and Corruption Programme Third Party Guidelines](#)
- [GSK's Preventing Corrupt Practices Policy](#)
- [GSK and marketing practices](#)



www.gsk.com/responsibility

Research practices

It is essential that we meet consistently high ethical and quality standards for research and development in all parts of our business, and in all the countries where we operate.

Patient safety is always our priority. We evaluate the benefits and risks of our medicines at all stages of research and after a new product is approved for sale. We are also committed to transparency and to disclosing the results of our clinical research.

We recognise that there are aspects of our research which can raise ethical concerns, including those relating to animal and clinical research and the use of emerging technologies. We aim to address any concerns by being open about our approach and regularly engaging with academic scientists, regulators, policymakers and other stakeholders.

To ensure we apply recognised standards and principles of good medical science, integrity, and ethics to the discovery, development and marketing of GSK products, we have a system of principles, policies and accountabilities, known as medical governance. This framework ensures that:

- patient safety is our fundamental operating principle ahead of commercial or other interests
- our research is conducted in an objective, scientific and ethical manner that protects and informs patients, prescribers and payers
- promotional practices and all the information we provide on our products are ethical, accurate and balanced
- we meet our legal and regulatory obligations and support appropriate use of our products to maximise benefits and minimise risks for patients.

Overall responsibility for this framework sits with our Chief Medical Officer, who is supported by Medical Governance Boards across the business to ensure the consistent operation of medical governance.

In 2011 we developed a new GSK policy with guidance and clear accountabilities to re-enforce a clear distinction between scientific engagement and product promotion (page 63).

To guide our research we must understand the unmet medical needs of patients and focus our daily work on meeting these needs. Our Focus on the Patient programme helps us to do this by bringing patients to GSK sites to speak directly to our R&D teams about their specific healthcare needs. Read about our R&D and this programme on page 10.

Animal research

Animal studies remain a small but vital part of our research. In many cases they are the only method that can be used to demonstrate the effects of a potential new medicine in a living body before it is tested in humans. Animal research can also 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 evaluated in clinical trials. Some countries require additional animal testing for their market even though the medicines have been approved for use elsewhere.

When animals are necessary for our research, we are committed to acting ethically, providing for the animals' health and well-being, and practising good animal welfare. These principles are applied both to studies carried out within GSK facilities and to those conducted by external contractors on our behalf.

The 3Rs

Ultimately GSK would like to see the important benefits of research being applied to humans without the need for animal testing. But 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.

Our scientists apply the 3Rs principles of Replacement, Reduction and Refinement to all our biomedical research:

- **Replacing** animal research with other methods where possible
- **Reducing** the number of animals used while still providing information of a given amount and precision
- **Refining** techniques to minimise pain and distress and maximise animal welfare.

We encourage a 3Rs culture at GSK through regular training of staff involved the care and use of animals, raising awareness and encouraging best practice, and recognising employees who have made significant advances in implementing the 3Rs through our Animal Welfare Awards.

Progress in the 3Rs

Faulty genes cause or contribute to a number of serious and potentially fatal illnesses, such as cystic fibrosis and some forms of motor neuron disease. A valuable method in understanding potential treatments for these genetic disorders involves making small changes to the responsible genes of rodents so that scientists have a model of the human illness and can then examine how changes or experimental medicines may affect the development or control of the condition. However, this process also leads to the birth of animals that do not carry the modification and are therefore not suitable for the research.

In 2011 GSK scientists developed a method to sample and screen the DNA in the sperm of mice to determine which mice carried the desired modification. This means that the male mice most likely to pass on the required gene can be selected and used for breeding. This has led to an approximately 70% reduction in the number of animals bred to achieve a stable genetically modified line. The team that carried this out have shared their work through peer-reviewed scientific publications and presentations at conferences.⁽¹⁾

Over 95% of animals used in this type of biomedical research are rodents, the majority of which are mice. More detail can be found in our published position [online](#).

⁽¹⁾ Wilson & Sheardown, Transgenic Res. 2011 Apr;20(2):429-33.

Performance in 2011

In 2011 the number of animals used was 20% lower than in 2000 while the two main drivers of animal use – R&D investment and vaccine sales – have increased over the same period.

Animal use declined 9% in 2011 compared to 2010. We continue to see a year-on-year decrease since 2006, reflecting a number of factors including changing research priorities, fewer vaccines requiring testing on animals before batch release, and a continued focus on 3Rs initiatives. Animal research conducted by contractors on our behalf accounts for around 13% of our total animal use in 2011.

Most of the animals used in GSK research – including research carried out by contractors – are rodents, mainly rats and mice. Non-rodents account for 4.3% of the number of animals used.

Less than 0.2% of the animals we use are non-human primates and this number has decreased by one-half since 2009. We have made a voluntary commitment to no longer perform research on great apes.

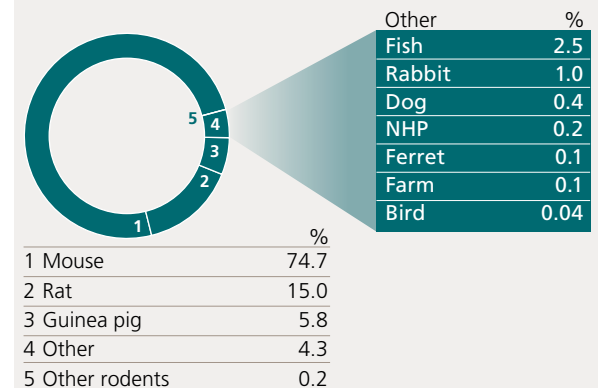
Through our Future Strategy Group programme (see page 96) we examined how we approach and conduct animal research on a global basis. The team drew on the views of 150 stakeholders, including welfare organisations and regulators. An integrated strategy was proposed focusing on delivering the highest quality of science with the least reliance on animals. It included building on our commitment to the development of innovative alternatives to animal research, optimising animal studies through enhanced scientific review, finding ways to maximise and harness the use of our research data, and bolstering our external collaborations in this area. This strategy was endorsed and approved in 2011 for global implementation.

Change in number of animals used by GSK compared to key drivers of animal use



R&D investment plus vaccine sales are the two main drivers of animal use. Figures are normalised to 2000, the first year of data after the formation of GlaxoSmithKline. Data include animal research conducted by external contractors on our behalf, data unavailable for 2000 and 2001.

Species used in GSK animal research 2011



NHP refers to non-human primates. Farm indicates use of pigs, goats and sheep.

Strategy, global governance and advocacy around animal research will be the responsibility of the Office of the Chief of Animal Welfare and Veterinary Medicine. This will be separate from departments responsible for daily care of our animals and accountable for delivering the objectives identified by the Future Strategy Group.

In 2011 we also assessed how one of our core principles for animal research – the need for all research to be reviewed by an ethical review panel – was being applied worldwide. We found a high level of consistency between topics that local committees look at during their review process, and agreed six supplementary principles to help local ethical review groups apply our policies in practice. These include the composition of ethical review panels, use of trained and competent personnel, and evaluation of alleviation of pain and distress.

GSK has animal research laboratories in Europe, Asia and North America. We aim for all of these to have achieved accreditation by the Association for Assessment and Accreditation of Laboratory Care (AAALAC) International. In 2011 we achieved accreditation for facilities in Hungary and France and our Sirtris facility in the USA. AAALAC accreditation now covers 92.5% of the animals housed in GSK facilities.

Our principles for scientific engagement

It is essential that our research and our products meet the needs of patients and reflect the latest scientific thinking. To achieve this, the development of medicines is carried out with discussion and exchange of scientific and medical information between GSK and outside experts and stakeholders. This helps to ensure that our research adds to scientific understanding and advances the care of patients. However, it is important that this legitimate scientific engagement does not and is not seen to have a promotional intent.

In 2011 we developed a new GSK policy and standards to reinforce a clear distinction between scientific dialogue and promotional activity. These new standards, introduced in April 2011, are called 'Scientific Engagement', and they govern the way we engage in scientific activities, such as advisory boards, publications, scientific congresses and medical education.

Five principles for Scientific Engagement have been adopted which reinforce our commitment that the intent and actions of scientific engagement will not stimulate or accelerate demand for GSK products, or gain favour with prospective prescribers or other customers. The principles ensure that GSK's values of transparency, integrity, respect and patient focus underpin our intentions and actions.

Scientific Engagement governs the way we engage in publishing our science in the scientific literature and present our science at scientific congresses; seek and gain advice from external stakeholders; provide medical information to answer unsolicited questions about our products; and provide or support medical education. The Scientific Engagement policy in these areas governs our approach before and after a product gains necessary authorisation and approval. In addition our approach to Scientific Engagement prior to product authorisation covers congress sponsorships and using digital

channels. It provides a strict framework to engage stakeholder groups including healthcare professionals, payers, patient advocacy and the media.

Our focus on Scientific Engagement has resulted in some changes to the way we work. For example we have strengthened the medical accountability and governance of scientific engagement activities and where appropriate ensured that the budget for these activities resides in the medical function. An example of a change we have made is to postpone disease awareness activities where we only have a product in development, until after product authorisation.

We firmly believe Scientific Engagement is fundamental if GSK is to develop medicines of value to patients. The strengthening of our standards is part of our ongoing commitment to continually evaluate how we conduct our business and ensures we reflect GSK's values in how we engage with stakeholders, including healthcare professionals, physicians, payers and patients.

Clinical research

Clinical trials in healthy volunteers and patients enable us to assess an investigational medicine's potential or further evaluate the medicine once it has been approved for marketing. We conduct clinical trials in accordance with the Good Clinical Practice (GCP) guidelines developed by the International Conference on Harmonisation and the principles contained in the World Medical Association Declaration of Helsinki on the Ethical Principles for Medical Research Involving Human Subjects (2008).

Trial protocols are reviewed by an ethics committee that is independent of GSK and is made up of members of the public, medical professionals and scientists. An ethics committee has the power to reject or stop a clinical trial.

We do not conduct clinical trials in countries when we know at the outset that we do not intend to pursue registration and make the product available for use in that country. GSK-sponsored clinical trials are conducted to the same ethical standards irrespective of where they take place, and we require any contract research organisation carrying out trial-related activities on our behalf to meet our standards.

The safety of clinical trial participants is of paramount importance, and we evaluate safety throughout each phase of a clinical trial programme. Potential clinical trial participants must voluntarily confirm their willingness to participate, after being informed about the study and its benefits and risks. This is known as informed consent. We aim to provide information for potential trial participants in a non-technical style that a lay person can understand. In 2011 we reviewed and updated our informed consent form to make it clearer for patients.

We use a variety of procedures to protect the confidentiality of research participants' data and to ensure that an individual's identifiable medical data are kept securely and protected from inappropriate use or disclosure. Read more about our approach to privacy on page [60](#).

We recognise that ongoing treatment of clinical trial participants with medicines at the end of a trial is sometimes required for the continued care of patients. In general, we are not responsible for the funding of 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 and specific circumstances the provision of medicines may be funded by GSK after the trial. Read more in our policy on clinical trials in the developing world [online](#).

Working with healthcare professionals to conduct clinical research

GSK conducts clinical trials by working with healthcare professionals who act as investigators for these studies.

Our policies require that all clinical trial investigators are selected solely on their qualifications to conduct good quality clinical research, and that their history of using or not using GSK products must not be taken into account. Payments are governed by contracts and any compensation reflects fair market value for the work performed or services provided. No payments are offered or made to influence investigators' judgement on enrolment or maintenance of a research participant in a clinical study. Gifts are not permitted to any healthcare professional involved in research projects for GSK.

We have made a commitment to disclose research payments made to healthcare professionals and their institutions. Our first annual disclosure was made in the USA in 2011 and captures payments for all phases of medicine discovery and development, including clinical trials. See our [US website](#) for more detail. Outside the USA, we will disclose payments to healthcare professionals and their research institutions on an aggregate basis, commencing with the publication in 2013 of payments made during 2012. Read more on page [58](#).

Training and auditing for clinical trials

All employees involved in GSK-sponsored clinical research receive training on Good Clinical Practice (GCP). Employees must complete the required training before undertaking any roles relating to clinical research. In 2011 there were 96,169 GCP-related training activities. Each of these represents the successful completion of an e-learning module or instructor-led course.

Our risk management and compliance framework includes independent audit and assessment of the conduct of clinical trials. Audits and assessments cover GSK systems and processes, as well as external contract research organisations and investigators conducting clinical research on our behalf. We report audit results quarterly to the R&D Compliance Board, and annually to the Risk Oversight and Compliance Council and the Audit and Risk Committee of GSK's Board of Directors.

In 2011 we conducted 326 clinical quality assurance assessments. For example:

- 173 investigator sites conducting GSK-sponsored clinical trials, representing around 5% of the sites that provide the primary data on which regulatory approval is based
- 9 GSK processes, including the process for review of clinical trial imaging data and the process for management of human biological samples
- 25 contract research organisations (CROs) carrying out clinical trials on GSK's behalf
- 7 GSK local operating companies involved in clinical trial activities
- 10 New Drug Application (NDA) Annual Reports were reviewed prior to submission to the US Food and Drug Administration (FDA) – these provide an update on the status of each study completed or in progress.

In addition, 34 investigations were conducted in response to suspected irregularities at investigator sites, CROs and our own local operating companies. GSK fully investigates any concerns or issues identified and takes corrective action where appropriate. Corrective and preventative actions might include for example re-training and increased monitoring. In cases where significant and persistent non-compliance is identified and where there is an impact on patient safety or the integrity of data, more severe action including termination of activities and reporting to regulators may be taken.

Regulatory authorities also performed 65 inspections of GSK and the investigators we use to conduct clinical trials in 2011.

In 2011, GSK completed its COMPAS trial (Clinical Otitis Media and Pneumonia Study) in Argentina, assessing efficacy of pneumococcal vaccine Synflorix. In January 2012 this trial was the subject of media coverage regarding the administrative conduct of the trial.

During regular monitoring in 2007–2008, we identified some administrative errors in the process of obtaining informed consent in a small proportion of 14,000 study participants. We proactively reported these to the national regulator and immediately put a corrective action plan in place with the trial centres and doctors involved. At no time was the safety of participants put at risk and the Regulator agreed that the trial could continue as planned.

We conduct clinical trials to the same high standards, irrespective of where in the world they are run. This includes the requirement to obtain informed consent from participants which is a fundamental principle of our behaviour. We continue to actively review our procedures to ensure best practice and minimise the risk of such errors occurring in the future.

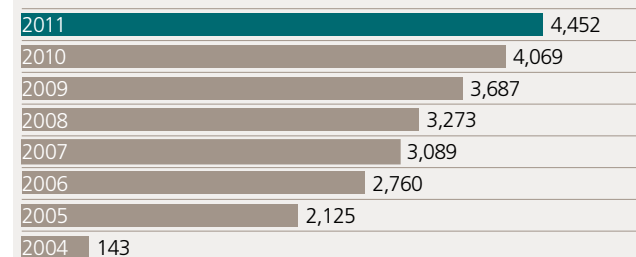
Public disclosure of clinical research

GSK is committed to the public disclosure of our clinical research that evaluates investigational or authorised medicines, irrespective of whether the results are perceived to be positive or negative for our medicines. We believe this is fundamental to advancing medical science and informing prescribers and patients about scientific findings relating to our medicines. This commitment is in addition to legal and regulatory requirements to disclose relevant data from clinical trials and safety information to regulatory authorities.

We disclose the results of research on our publicly accessible [Clinical Study Register](#) website, launched in 2004, which receives an average of 9,653 visitors a month, as well other databases and registers as required by laws and regulations (such as clinicaltrials.gov in the USA). Information available on the GSK site includes protocol summaries for all ongoing studies and summaries of results from completed clinical studies. Read more in our position on disclosure of clinical trial information [online](#).

Number of results summaries of GSK clinical trials on the GSK Clinical Study Register

Number of summaries (cumulative total)



During 2011 we changed our policy on the timing for the disclosure of clinical research of our medicines. Previously we aimed to disclose results summaries from trials of investigational medicines at the time of first approval or following termination of the investigational medicine. We have changed this approach to disclose results following completion of studies rather than following approval or termination of the medicine.

GSK made a commitment in 2009 to seek publication of the results of all clinical research that evaluates our medicines as full papers in peer reviewed scientific journals; these publications provide peer-reviewed context and interpretation of research data. We are putting in place the systems and resources to meet this commitment.

We have also committed to disclosing the full protocol for each study when the study is published as a full paper in the scientific literature, so that interested parties can see how the research was carried out.

Importantly, GSK's policy prohibits 'ghost writing' of journal manuscripts by requiring authorship and acknowledgements for scientific publications to be consistent with the requirements of the International Committee of Medical Journal Editors guidelines.

Patient safety

Patient safety is always our priority and we evaluate the benefits and risks of our medicines and medical devices at all stages of research, as well as after a new product is approved for sale.

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. Product safety is assessed in clinical trials before a product can be approved for marketing. Sometimes adverse events (possible side effects) may only be detected after approval when a product is being used by large numbers of patients. Policies and a governance framework are in place to help us detect and act on any adverse events. A dedicated team of scientists and healthcare professionals across the world have a specific role to monitor and communicate safety issues to regulatory authorities. We also work with government officials, industry partners and policymakers to enhance safety systems for medicines and vaccines.

Our Global Safety Board makes decisions on product safety issues; its remit is to ensure that safety is a focus throughout product development and to review safety of GSK products on the market. The board is chaired by the Chief Medical Officer and composed of senior physicians and scientists.

Improvements and innovation

We continue to improve our patient safety systems, safety databases and monitoring processes. For example, in 2011 we:

- Developed enhancements to enable rapid review of safety information from observational data sources.
- Worked with regulatory agencies and the Observational Medical Outcomes Partnership (OMOP), a public-private partnership, to understand how best to detect safety issues.
- Established a system that provides us with real-time alerts of sudden changes in the number of adverse event reports received each month for a particular product.
- Created a Pharmacovigilance Centre of Excellence to refine our approaches to medicine safety.

New capabilities

GSK is committed to providing transparent information on health issues to patients, healthcare providers and regulators. For example we are establishing new teams to focus on the clinical effectiveness of GSK medicines – assessing their benefits and risks in development and the post-approval period. GSK has several groups working to advance these capabilities internally and externally, and the goal of the new team is to achieve greater integration of these efforts. This will allow us to give better evidence of the clinical and comparative effectiveness of our medicines and build stronger regulatory files that inform physicians, regulators and payers of the value of our medicines.

Collaborations on patient safety

We work with government officials, industry partners and policy makers to enhance safety systems for medicines and vaccines. Two examples from 2011 of our many global collaborations include:

- We are co-founders of the international Serious Adverse Events consortium (iSAEC), a non-profit collaboration of over 20 partners including pharmaceutical companies, academic institutions and regulatory bodies which is working to improve patient safety by identifying genetic variants that predict adverse events. iSAEC's initial research focused on drug-induced liver injury and drug-induced serious skin rashes, and in 2011 globally agreed definitions of drug-induced liver injury⁽¹⁾ and an analysis of 50 drugs associated with serious skin toxicity were published.⁽²⁾
- Our participation in the Critical Path Institute's Predictive Safety Testing Consortium, an independent, non-profit organisation that brings together scientists from industry and academia to share and validate their safety testing methods under the guidance of the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA). Several studies sharing new ways to predict safety issues in clinical trials and post marketing will be published and shared with US and European regulators.

⁽¹⁾ Aithal, GP. et al. 2011. [Case Definition and Phenotype Standardisation in Drug-Induced Liver Injury](#). *Clinical Pharmacology & Therapeutics*, 89 (6) p.806.

⁽²⁾ Papay, J. et al. 2011. [Spontaneous adverse event reports of Stevens-Johnson syndrome/toxic epidermal necrolysis: detecting associations with medications](#). *Pharmacoepidemiology and Drug Safety*, Article first published online: 5 Dec 2011.

Benefit-risk management

We assess the balance between the benefits and risks of a particular medicine throughout its lifecycle – from early development, during clinical research and after the product is on the market. All available safety information is evaluated and documented 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. Plans are reviewed and updated regularly during clinical development and for a period after a product is approved for marketing.

Collecting and reporting safety data

We receive information on adverse events (possible side effects) from several sources, including patients and healthcare professionals, regulatory authorities and post-marketing clinical research. All GSK staff undertake mandatory training on adverse event reporting and are required to immediately report any issues relating to the safety or quality of our medicines. Read more about our expectations in [our Code of Conduct](#).

All adverse events reported to GSK are recorded on our global safety database and clinical trial database, and are investigated. We report potential safety concerns to regulatory authorities. Regulators in some countries also publish information on adverse events on the internet.

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 additional clinical research to further understand the concern, modifying the prescribing information, communications to physicians and other healthcare providers, and establishing specific methods to minimise risk – for example by 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 specialist committees review and approve the prescribing information for our medicinal products and ensure this is updated when appropriate.

Read more online

- [Clinical trials in the developing world](#)
- [Cloning technologies and stem cell research](#)
- [Disclosure of clinical trial information](#)
- [The care, welfare and treatment of animals](#)
- [The role of transgenic animals in biomedical research](#)
- [Use of Non-human Primates \(NHPs\) in the Discovery and Development of Medicines and Vaccines](#)

+ www.gsk.com/reportsandpublications-policies

Supply chain

Patients and consumers rely on us to provide an uninterrupted supply of medicines and products, manufactured to the highest-quality standards.

An effective and responsibly managed supply and distribution system is essential for us to get high-quality products to the right places at the right time. If we don't do this, then people's health may suffer and their lives may even be at risk. To protect the interests of our patients and consumers, we aim to work with responsible suppliers who meet the same quality, social and environmental standards as GSK.

Our manufacturing division has a strong track record of quality and compliance with current Good Manufacturing Practice (cGMP) requirements. We are committed to continuous improvement in our manufacturing processes and last year we invested over £400 million improving and updating our equipment. We average more than 130 inspections by regulatory agencies each year at over 80 manufacturing sites located in over 30 countries. We have had two US Food and Drug Administration (FDA) warning letters for cGMP deficiencies since 2000, the year GlaxoSmithKline was formed. The first concerned manufacturing issues at the Cidra facility in 2002 which were fully resolved before the site was closed in 2009 due to declining demand for the medicines made there.

During 2010 we finalised an agreement with the US Government with respect to their investigation and are in the process of negotiating a Corporate Integrity Agreement that will cover manufacturing compliance matters. The second warning letter was issued in 2011 and concerns manufacturing standards at our Worthing facility. Impacted manufacturing was suspended until additional controls had been implemented and production has now resumed. Patients, consumers and the quality of our products are always our priority.

Human rights in the supply chain

GSK strives to conduct business with third-party suppliers who share our commitment to high ethical standards and operate in a responsible and ethical manner.

Human rights clauses are included in all supplier contracts and covered by our Third Party Code of Conduct available [online](#). These include but are not limited to forced labour, child exploitation, slavery, workplace conditions, non discrimination, wages, benefits and working hours. Read our [human rights statement](#) online for more information on the clauses included in contracts.

We consider human rights issues during routine interactions with critical suppliers. Environmental, health and safety audits of potential new and existing critical suppliers also include questions that 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
- Rights for workers to organise and recognition of worker organisations.

We will not knowingly use suppliers who are responsible for human rights infringements. Where we identify human rights issues we make recommendations for how the supplier can improve performance and will follow-up where there are any significant gaps.

We are members of the Pharmaceutical Supply Chain Initiative (PSCI), an industry collaboration that has set out guiding principles and standards for suppliers that include human rights and labour issues. The PSCI is looking at ways to improve supplier standards, especially in emerging markets.

Our supply and distribution process



The supply and distribution process

The interests of patients and consumers must come first at every stage of the supply and distribution process:

Planning involves decisions on what we must make and deliver over the entire lifecycle of a product. This helps us configure the location, capability and capacity of our network of internal and third-party manufacturing sites in order to maximise efficiency and security of supply. Ensuring a continuous supply of high-quality medicines, vaccines and consumer healthcare products is essential to the patients and consumers who depend on our products, as well as to the success of our business

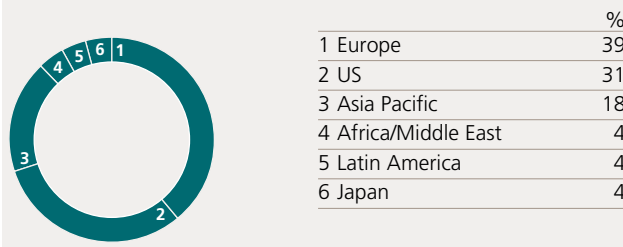
Buying involves GSK spending around £9 billion with suppliers. Around £2 billion of this is spent on active ingredients, chemical intermediates, packaging components and other materials that are directly required for the manufacture of our products. This is spent with 6,000 suppliers in 73 countries worldwide. We depend on our suppliers to consistently deliver value at low cost but also to produce their goods in a responsible manner. We support impartiality in all phases of the procurement cycle and our standard payment term for all suppliers is a minimum of 60 days from receipt of invoice.

Making our products requires the ingredients and materials we buy from suppliers to be fed into our network of over 80 manufacturing sites in 32 countries. We manufacture nearly 28,000 GSK products and produce approximately four billion packages annually, including tablets, creams, ointments, inhalers, injections and liquids. More than 26,000 people work for our Global Manufacturing and Supply (GMS) division. We also outsource just over 10% (in terms of production costs) of product manufacturing to third-party manufacturers who provide us with finished or part-finished product. Responsible manufacturing requires that the products we make, and that are made for us, are of a consistently high quality.

Distributing our products relies on working with other companies to ship to customers in 150 countries. Products must be stored correctly and handled carefully throughout distribution points and at their destination. This ensures patients and consumers get the full benefit of our products and it protects our reputation as a provider of high-quality, effective medicines, vaccines and consumer healthcare products.

Supplying our products means protecting our distribution system from disruption. We establish and maintain a contingency stock of active pharmaceutical ingredients and finished product for our most important products, and especially for medically critical products. We regularly assess supply chain risks and, where appropriate, ensure we can get key raw materials and ingredients from alternative suppliers if necessary. If we get this wrong, then there are possible ramifications for the health and well-being of our customers.

Regional distribution of total spend with all suppliers



Our supplier standards

Our supplier expectations and standards for ethical conduct, labour practices and protection of human rights, EHS management systems, and interactions with GSK employees are defined in our [Third Party Code of Conduct](#). The Code also requires that suppliers embed ethical standards within their own supply chains. We require new suppliers to accept and comply with the principles of the Code before they can do business with GSK.

The Code was further updated and strengthened in 2011 to reflect the requirements of the UK Bribery Act. We issued guidance to employees on the changes and added additional clauses on anti-bribery and corruption to our contract templates and purchase order terms and conditions. We believe that our policies and processes to ensure respect for human rights, outlined in this report, align with the requirements of the US California Transparency in Supply Chains Act, which came into effect at the beginning of 2012.

Working with suppliers

New suppliers are required to meet the expectations of our Third Party Code of Conduct as outlined above. Our procurement teams engage with existing suppliers to raise awareness about the Code and reinforce its ethical principles. All of our procurement staff with procurement responsibilities receive training on third-party management, which includes supplier compliance with our human rights standards. Our ethics training for all employees also covers standards in the supply chain.

Higher risk suppliers are identified and further assessed to identify suppliers that may require further engagement or monitoring. Higher risk suppliers are identified based on how critical they are to the supply chain, and what risk they pose to the business if they fail to meet our standards. The person with responsibility for GSK's relationship with the supplier must ensure any potential risk with their supplier is appropriately managed, and will work with procurement colleagues and internal audit to investigate any concerns. Procurement risks are integrated into GSK's overall risk management and compliance oversight process.

If there are problems with a supplier, we will work with them to improve the situation if possible but if there are intractable difficulties we will end our relationship with them.

Auditing suppliers

Before selecting new critical suppliers – those that are pivotal to our business – we conduct an audit of their environment, health and safety performance, risks and systems. Our audit tools also include questions that help us assess potential suppliers' performance against the human rights clauses included in supplier contracts.

If we identify significant gaps in a supplier's policies, systems or performance, we will take one of a number of courses of action. We will recommend the use of external consultants to support the supplier in making improvements and/or we may suspend or restrict supply until significant improvements are made. In some cases we may stop working with a supplier or decide not to work with a potential new supplier.

GSK supports suppliers to improve their standards

We work with suppliers to improve their standards, for example in 2011:

Audits identified a number of significant supply interruption risks as well as risks to life safety with one of our Indian suppliers with whom we have multiple supply agreements. These were escalated within GSK and as a result we have restricted our supply arrangements with this supplier until it provides evidence that environment, health and safety is being managed responsibly and that significant risks are being effectively managed. The supplier is now working to address these concerns and improve processes and controls.

We also carried out in-depth audits with two of our critical suppliers – one in Europe and one in India – focusing on specific key risks and reviewing their governance and risk management processes. This enabled us to build a closer, more productive relationship with these suppliers and to agree plans for improvement that will help to mitigate these risks. We will extend this approach in 2012 to other critical suppliers.

We are collaborating with others in our industry through the Pharmaceutical Supply Chain Initiative (PSCI) to give suppliers the information they need to meet industry expectations about labour, ethics and environmental, health and safety management systems. In 2011 PSCI members have been developing guidelines, tools and mechanisms to enable a shared approach to audits. Pilot audits have been proposed for 2012.

Quality audits

We conduct an audit of quality standards for all new manufacturing material suppliers. During 2011, over 1600 quality audits were performed on GSK's material supply chain (suppliers that provide ingredients that form part of our products), taking the coverage of quality audits to 88% of manufacturing material suppliers. Of the companies audited, 124 were not approved as GSK suppliers and 139 were approved providing they met certain conditions.

We have worked with a number of key suppliers to develop quality improvement plans designed to bring them up to the standards that GSK expects of them. Work to educate suppliers about our quality requirements continued throughout 2011, with training sessions taking place in Nigeria, South Africa, China, Indonesia, Pakistan, India and the Philippines.

GSK is part of Rx-360, an industry consortium that has agreed sector-wide standards for quality audits of product ingredient suppliers. This will mean that suppliers used by a number of companies will be audited once rather than multiple times by each, and that the results can be shared between the purchasing companies. In 2011 the consortium began auditing suppliers on behalf of its members and by the year-end had carried out 20 audits. All findings were non-critical.

Performance in 2011

We conducted environment, health and safety (EHS) audits on 49 existing and potential suppliers in 2011. Around 75% of these audits assessed suppliers in Asia.

The most significant EHS audit findings for suppliers occurred mainly in emerging markets and included: deficiencies in fire risk management and emergency response capabilities; absence of fundamental risk controls for process safety; inadequate control of exposure to hazardous substances; inadequate waste management and environmental controls; and gaps in compliance with regulations. Three out of five potential new suppliers we audited in 2011 failed to meet our minimum requirements.

Where we do find gaps and risks we consider the extent of these and may take a number of actions. These include restricting supply until significant improvements are made, not using a potential new supplier, or working with the supplier ensuring investment is made to address deficiencies. We always provide findings that will help suppliers to make improvements.

1,600

Quality audits of our manufacturing material suppliers

49

Environment, health and safety audits of current and potential suppliers

Supplier EHS audits 2007–2011 (existing and potential suppliers)

| | 2011 | 2010 | 2009 | 2008 | 2007 |
|------------------------|------|------|------|------|------|
| Americas | 4 | 5 | 11 | 6 | 10 |
| Europe | 7 | 5 | 13 | 18 | 8 |
| Asia | 38 | 29 | 46 | 28 | 37 |
| Africa | 0 | 0 | 0 | 1 | 0 |
| Total number of audits | 49 | 39 | 70 | 53 | 55 |

Number and types of supplier audited on EHS in 2011 (existing and potential suppliers)

| Type of supplier | Americas | Europe | Asia | Total |
|---|----------|--------|------|-------|
| Primary (raw materials, intermediates and pharmaceutical ingredients) | 0 | 5 | 29 | 34 |
| Contract Manufacturing (Pharmaceutical formulations) | 3 | 2 | 0 | 5 |
| Consumer Healthcare (excipients, actives, raw materials) | 1 | 0 | 9 | 10 |

Security of supply

Ensuring a continuous supply of high-quality medicines, vaccines and consumer healthcare products is essential to the health of those who depend on our products, as well as to the success of our business.

The most significant threat to security of supply during 2011 was the earthquake and tsunami in Japan. Within 24 hours we had mobilised a GSK crisis response team, which despite difficulties affecting communications, air, freight and road traffic, was able to monitor 112 suppliers in Japan, providing 131 materials to 45 GSK sites worldwide. In total only two materials went out of stock, both supplied from one site, and we were able to ensure that disruption to patients – and to our business – was minimal.

Anti-counterfeiting

An estimated one-third of all medicines, vaccines and healthcare products in some parts of the world may be counterfeit. These counterfeits are almost certainly not supported by quality control, testing or monitoring, and often contain little, if any, of the legitimate active ingredients needed. They might include impurities such as colourants or micro-organisms. This means that many patients in these countries may not be receiving the treatment they need. Or worse, they could be taking substances that actually cause them harm.

Counterfeiting poses a threat to patient and consumer health as well as a serious business threat to GSK and other pharmaceutical companies.

We use anti-counterfeiting packaging features such as holograms, security seals and complex background patterns that are difficult for counterfeiters to photocopy and scan. Read about a pilot anti-counterfeiting programme we are conducting using text messaging with our *Ampiclox* antibiotic in Nigeria on page [19](#).

GSK trains local staff on how to spot and report counterfeit products and we invest in measures to find serial offenders. Our analytical support team in the UK, for example, has been trialling a test that uses the vapour of fake toothpaste to link counterfeit samples found around the world. If the counterfeit manufacturer is later identified, it means that GSK will be able to provide evidence of the scale and scope of their illegal activities, which will hopefully result in stiffer penalties.

As a founding member of the Pharmaceutical Security Institute (PSI), GSK works closely with the wider pharmaceutical industry to investigate cases of counterfeiting, as well as with governments and international organisations. Various GSK teams work together to investigate suspected incidents of counterfeit GSK products, conduct forensic analysis and initiate legal action against offenders.

Partnering with suppliers in a crisis

When a major fire damaged a UK factory owned by one of our key suppliers in March 2011, the continuity of supply for 14 GSK products was at risk. The launch schedules for our new antiepileptic medicine, *Trobalt*, were also in jeopardy. But because of our good working relationship with the supplier, a potentially disastrous

situation became a good example of how a strong partnership with a supplier can benefit both companies.

Within six hours of the start of the fire, a crisis management team of GSK and experts from the supplier was set up. For each of the 14 products, a plan was put in place to resume production as quickly as possible. Some products and

equipment were transferred to the suppliers alternative factories, GSK sites, or other third-party manufacturers.

By working together we were able to maintain supplies of our medicines to patients, minimising disruption and impact to the business.

GSK anti-counterfeiting activity

| | 2011 | 2010 | 2009 | 2008 | 2007 | 2006 |
|---|------|------|------|------|------|------|
| Number of reported cases of counterfeit | 378 | 367 | 259 | 289 | 429 | 248 |
| Number of raids | 148 | 96 | 94 | 94 | 71 | 57 |
| Number of arrests | 181 | 132 | 129 | 84 | 127 | 94 |

Cases in 2011 included: our work with the Indian police to raid a factory near Delhi that was making a counterfeit version of the children's medicine *Calpol*, leading to two arrests; 14 raids carried out in Pakistan, resulting in the seizure of more than 10 different types of counterfeit medicines and a number of arrests; and raids at counterfeiting factories in China. With our help the Chinese Police concluded a long-term investigation by raiding two counterfeiting factories in Fuyang City, Guangdong Province and Yongcheng City, Henan Province. Twelve counterfeiters were arrested and counterfeit medicines to the value of 7.8 million RMB were seized. A network of Shanghai-based counterfeiters selling products over the internet was also broken up.

Counterfeiting is not just a problem in emerging markets. In the USA an offender was sentenced during 2011 to seven years in prison and ordered to pay GSK compensation of \$417,000 after we found that packs of the weight-loss treatment *Alli* sold on eBay contained dangerous levels of the controlled substance sibutramine. In the UK, a one-year sentence with fines was handed out to a pharmaceutical importer after a raid on his premises uncovered 800 packs of illegally imported *Seretide* that had been placed in counterfeit packaging.

Supplier diversity

Small companies and those owned by women or people who belong to minority groups are often under-represented in the supply chains of large companies.

GSK believes that small and diverse businesses have significant potential to meet our procurement needs, and we recognise the value they bring to their communities through job creation and revenue generation. Sourcing from diverse suppliers has benefits for GSK, too. It helps us comply with regulations in markets such as the USA, encourages innovation and exposes us to new perspectives and fresh ideas. Our supplier diversity programme is led from the USA, with support from our procurement teams worldwide.

In the USA, we are finding it a challenge to identify small diverse businesses that fulfil federal size standards while at the same time enabling us to reduce costs and consolidate our global suppliers. Our spend with small diverse suppliers decreased by about 11% in 2011, however we plan to increase spend with small diverse businesses in 2012 and beyond.

We will work with business advocacy organisations, such as the National Association of Veteran Business Owners, the US and UK National Minority Supplier Development Council, and the Women's Business Enterprise National Council to identify and develop small diverse businesses as suppliers, particularly through development and mentoring initiatives.

Our global supplier diversity initiatives outside the USA include sponsorship of the Global Link programme, which helps diverse suppliers around the world develop partnerships with local businesses, expand their capabilities and access new technology. In 2011 we targeted our efforts on the UK and South Africa.

Read more online

Read more about our standards in:

- Our [Third Party Code of Conduct](#).
- [Anti-Bribery and Corruption Programme Third Party Guidelines](#).
- Our [Human Rights Statement](#) including clauses in our supplier contracts.
- [GSK on the counterfeiting of healthcare products](#)

+ www.gsk.com/reportsandpublications-policies

Public policy and patient advocacy

Through our public policy activity we support legislative measures and programmes that encourage scientific innovation and balance the interests of business with those of other stakeholders. We also work with patient and professional groups to help their members gain a stronger voice on healthcare.

We recognise that some stakeholders have concerns about business lobbying and we aim to address these by being open about our approach and the issues we engage on.

Lobbying and public policy activities are conducted by our external affairs teams in our major regions and business units. They monitor proposed legislative reforms, policy developments and stakeholder concerns. They meet regularly with government officials and others, such as multilateral organisations and NGOs, to explain our views on public policy issues and also respond directly when GSK is asked to comment. Lobbying on issues affecting the whole of the pharmaceutical and consumer healthcare industry is sometimes conducted through trade associations and we may also hire lobbying consultants to support our public policy work.

Trade and industry associations

GSK is a member of many national, regional and international trade and industry associations. Membership of these groups can help to support the efficiency and effectiveness of our public policy work.

It is important that lobbying through trade and industry associations reflects our policies and values. We work with other members to set policies and may attend industry association meetings with governments and other stakeholders. If an association adopts a public policy position we do not agree with, we will not participate in advocacy activity related to that subject. We will also raise any concerns we may have about a particular advocacy position directly with the association management team.

Our industry association memberships include: Pharmaceutical industry organisations: Association of the British Pharmaceutical Industry (ABPI); European Federation of Pharmaceutical Industries and Associations (EFPIA); International Federation of Pharmaceutical Manufacturers and Associations (IFPMA); Japan Pharmaceutical Manufacturers Association (JPMA); Organisation of Pharmaceutical Producers of India (OPPI); Pharmaceutical Research and Manufacturers of America (PhRMA); China's R&D-based Pharmaceutical Association Committee (RDPAC).

Consumer industry organisations: the European Brands Association (AIM), Association of the European Self-Medication Industry (AESGP), the European Cosmetics Association (Colipa) and the Union of European Soft Drinks Associations (UNESDA).

General industry organisations: Intellectual Property Owners Association (IPO); International Chamber of Commerce (ICC); National Association of Manufacturers (NAM); Confederation of British Industry (CBI).

GSK's chief executive, Sir Andrew Witty, is currently president of the European Federation of Pharmaceutical Industries and Associations.

Our public policy activity in 2011

We believe that we conduct our advocacy work responsibly, make a valuable contribution to the debate on issues that impact our business, and work to balance the interest of business with other stakeholders.

We engaged on a wide range of issues around the world during 2011. These included healthcare reform, pricing and intellectual property issues.

The year was particularly challenging from a public policy perspective due to healthcare reforms in major markets and austerity measures being implemented in many countries arising from the economic crisis. Recognising the need for economic responsibility, we argued for an approach to cost-cutting measures that would achieve an appropriate balance between managing costs and incentivising innovation in the interests of patients, payers and our industry.

The examples here provide an insight into our approach and areas of focus during 2011:

Healthcare reform in the USA During 2011, in the wake of the passage of the 2010 Affordable Care Act, GSK submitted comments on a number of proposed regulations on healthcare reform implementation. We are supportive of the Act's goal to increase access to health insurance to a further 30 million Americans by 2020. We also support provisions of the law that expand access to preventive services and that promote the development of value-based care delivery models (such as Accountable Care Organizations and Patient Centered Medical Homes). We believe reforms should be implemented in ways that recognise the role of medicines and vaccines in reducing healthcare costs, improving health outcomes for patients, and reducing the prevalence and costliness of chronic disease.

Europe's healthy ageing initiative The European Union has set up a pilot public-private partnership on 'active and healthy ageing', which aims to increase the average number of healthy life years by two. Our chief executive is on the steering group of the partnership. In January 2011, GSK submitted two proposals for action to support the initiative – one on encouraging greater adherence to prescriptions among elderly people and the other on vaccination for the elderly. Our proposal on adherence to prescriptions was one of five actions that the Commission has now agreed to pursue and implement. GSK has been asked to lead this action through 2012 and beyond. Our proposal on supporting more comprehensive vaccination programmes for elderly people will be discussed in 2012.

Medicare Part D in the USA We have been involved in defending Medicare Part D, a federal prescription drug insurance programme for Medicare beneficiaries. In 2011 some federal lawmakers proposed that the pharmaceutical industry should pay mandated rebates in Medicare Part D as a way to reduce the annual budget deficit in the USA. GSK, along with industry partners such as PhRMA, was opposed to the proposal because it would have fundamentally altered the success of Medicare Part D's competitive market-based structure.

GSK met federal lawmakers to raise their awareness of the success of Medicare Part D and to explain how the current programme is already resulting in reduced healthcare costs. For example, a study in the *Journal of the American Medical Association* found that improved access and adherence to medicines resulting from Part D saves Medicare about \$1,200 per year in hospital, nursing home and other costs for each elderly person who previously lacked comprehensive prescription drug coverage – about \$12 billion per year in savings across Medicare.

Congressional leaders did not adopt mandated rebates in Medicare Part D in 2011, but may consider similar proposals in the coming years as they continue to look for ways to trim the federal budget in the USA. GSK and our industry partners will analyse new proposals as they become available and will continue to provide information to lawmakers on the importance of maintaining patient access to innovative pharmaceutical products and vaccines.

Patent litigation in Europe Discussions continued during 2011 on the proposed introduction of a single European patent and a centralised court for patent litigation. GSK supports the principle of a single EU patent as a potential way of reducing the cost of obtaining and maintaining European patents. Provided that the quality of the judicial process is consistently of the highest order, we also support the concept of a centralised court where disputes over European patents can be resolved on an EU-wide basis in a timely and cost-effective manner. GSK has been discussing the reform project for many years with the European Commission and others, and we will continue to be involved.

Support for regulatory cooperation between the European Union and China

China's regulatory environment for pharmaceuticals is evolving, and there is increasing cooperation between the European Union and China on these issues. GSK believes that a stronger regulatory environment in China that is aligned to international standards will protect the interests of patients and pharmaceutical companies. For example, under current regulations companies are required to repeat in China all clinical trials for new vaccines, even if these have been approved for marketing elsewhere. This delays registration of vaccines in China, and therefore delays Chinese patients' access to potentially life-saving products and vaccines available elsewhere.

In 2011 we supported the European Commission and EFPIA's cooperation with China on these issues. This included support for a workshop on 'Increased Cooperation in Clinical Trials and Quality Control – A Way forward to Foster Innovation, Competitiveness and Trade', held during an EU-China high-level regulatory meeting devoted to pharmaceutical and vaccines issues in May 2011.

Non-communicable diseases As a member of the International Federation of Pharmaceutical Manufacturers and Associations we helped develop [a 10-point framework for action](#) for the industry on non-communicable diseases, in advance of the September 2011 United Nations summit on this issue.

Tobacco dependence and cessation We encouraged EU governments to ensure that national smoking cessation strategies provide smokers with greater support and motivation to stop. GSK, which sells tobacco cessation products such as *Nicorette* and *Niquitin*, provides financial support to the Smoke Free Partnership (SFP), an organisation that aims to promote tobacco control and policy research at European and national levels. Thanks to a GSK grant, SFP has developed a Smoke-Free Policy Map for Europe.

Better oral health in Europe Oral diseases remain a major public health challenge in Europe representing 5-10% of annual public health spending and an estimated cost to EU member states of €70 billion a year. We sponsored a new Platform for Better Oral Health in Europe, a joint initiative of the European Association of Dental Public Health and the Association for Dental Education in Europe to raise awareness of oral health issues and their link to overall health, as well as to lobby for a common approach to European oral health policy.

Anti-counterfeiting in Europe We continued to advocate for a pan-European serialisation system for medicines which we believe is needed to reduce opportunities for counterfeit medicines to enter the EU supply chain. If introduced, a pan-European system would enable pharmacists across Europe to check whether a pack has already been dispensed elsewhere within the EU – and therefore help to detect counterfeits.

Patent reform in the USA We lobbied in support of the America Invents Act, patent reform legislation that became law in 2011. We believe modernisation of the US Patent and Trademark Office (USPTO) is necessary to create a predictable, equitable, efficient patent system; and to establish fair and reasonable boundaries for challenging patents at the USPTO and in the courts.

Oncology drug parity Some insured cancer patients in the USA have higher out-of-pocket costs if they are prescribed oral anticancer drugs (covered as a drug benefit) versus intravenous medicines (covered as a medical benefit). This disparity can lead to treatment decisions based on the dosage form rather than the most appropriate clinical option for the patient. We talked to patient organisations and legislators about the importance of eliminating cost disparities between oral and IV oncology medicines, and five states adopted oncology parity legislation in 2011.

Pricing in Saudi Arabia The Saudi Arabian government is reforming legislation governing the pricing of pharmaceutical products. GSK believes that a more transparent and easily understood system of pricing is needed to create stability in the marketplace and help improve access to medicines. Any new legislation should support the swift introduction of new and innovative products, reward innovation, and treat local and multinational companies equally. Working through trade associations, we advocated for more consultation on the proposed changes to make sure that any new system meets Saudi healthcare needs while addressing the long term need for a sustainable pharmaceutical industry. We also focused on specific issues such as proposals that would impose more significant price discounts on patented products (mostly produced by multinationals) than on generic medicines (mostly produced by local companies).

Faster patient access to medicines in Taiwan We worked with regulatory and health authorities to shorten the time it takes for new medicines to get to the market, for example by speeding up the process for agreeing reimbursement prices.

Political contributions and lobbying expenditure

GSK does not make corporate political contributions. In the USA some employees choose to make personal political contributions through the GSK Political Action Committee (PAC), which facilitates voluntary political contributions by eligible employees, in accordance with the Federal Election Campaign Act.

In 2011 the GSK employees' PAC contributed \$612,500 – 53% to Republicans, 45% to Democrats and 2% to unaffiliated or other party candidates running for state and federal offices.

In 2011 costs associated with lobbying of EU institutions were in the range of €800,000-€825,000 and we declare these in the EU Commission and European Parliament voluntary 'Register of Interest Representatives'. This includes running the Brussels advocacy office, salaries, external events, travel and accommodation, consulting costs and educational materials. This figure takes into account the proportion of employee time spent on representing GSK's interests. In order to avoid double reporting on the Register, the figure excludes trade association membership fees as responsibility for declaring these lie with the respective organisations.

In the USA, we spent \$5,436,000 on federal lobbying activities in 2011. 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 that provide a forum for policy analysis and debate. This includes think tanks in a number of countries, and certain groups in the USA that are organised under sections 501(c)(4), 501(c)(6) and 527 of the US Internal Revenue Code. GSK requires recipient organisations in the USA to agree to refrain from using any GSK funds to support or oppose federal, state and local candidates for political office.

Read more online

We publish our positions on key issues [online](#) including:

- Public health, access to healthcare and developing countries
- Pricing, reimbursement and market access
- Conducting our research and development
- Our anti-bribery and corruption programme
- Our approach to intellectual property and counterfeiting of healthcare products
- Environmental sustainability

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Patient advocacy

Patient groups – non-profit organisations founded by patients, care-givers, family members and health professionals – are important stakeholders for GSK. They engage with healthcare providers, governments, the media, and patients to promote improved treatment and services for patients. They also campaign on issues that affect patients' and care-givers' lives, including increasing access to quality medicines, services and information on disease. Some carry out research into the causes of and potential treatments for specific conditions.

We provide funding to patient groups to help with day-to-day running costs and defined events or activities. Our support also includes educational assistance, training for staff, and collaboration on disease awareness and prevention projects.

Our relationships with patient groups help us to better understand patient needs and their illnesses, which guides our R&D. In turn, our support helps patient opinions to be heard in the healthcare debate.

We have also set up advisory boards in the USA and Europe that include representatives from a wide range of patient groups. They also allow us to access the views of patient groups on subjects such as clinical trials, pharmacogenetics, information provided to patients and ethical issues.

Our engagement is not designed to market our products; indeed we have strict rules about never promoting a GSK medicine to a patient group and never seeking endorsement of a medicine from a patient group. We aim to be as transparent as possible about who we work with and the funding we provide, publishing information on our website.

Our standards for working with patient groups

All GSK employees and relevant third parties who work with patient groups must follow our guidelines and Standard Operating Procedures (SOPs). For example, we limit the amount of funding we can provide to 25% of a patient group's overall funding and state that relationships with patient groups must never be linked to promotion of our products. We also provide training so that employees understand our requirements.

We launched minimum standards on working with patient groups in Europe at the end of 2011 to help ensure that engagement with patient groups is prioritised and to underscore our commitment to being a patient-centric company. For example, the new standards state that the general manager of each country must meet a minimum number of patient groups each year and that employees should be trained on how to work to the highest ethical standards with patient groups.

In the USA our Advocacy & Alliance Development Center of Excellence coordinates our engagement and funding with patient advocacy groups and professional associations at the national, regional and state levels. A coordinated approach is particularly important during this period of significant healthcare reform. During 2011 the Center established a State Advocacy Team, which includes a team of six field-based staff who cover all states broken out into six regions.

We plan to extend the guidelines to our Emerging Markets and Asia Pacific region in the future.

Workshops and educational support

GSK holds regular workshops with patient groups. These feature sessions on how helping patients to adhere to their drugs regimens can improve treatment outcomes. In 2011 examples of sessions include:

- A workshop with patient group representatives from the European Breast Cancer Coalition (Europa Donna) and Independent Cancer Patients' Voice on how to manage the side effects of oral cancer drugs for metastatic breast cancer.
- A workshop on adherence to oral cancer treatment regimens with European patient groups.
- A meeting with members of LUPUS EUROPE (an umbrella organisation of 23 national lupus self-help organisations) to understand the needs of patients with lupus and how dialogue between patients and healthcare professionals can be improved, leading to better treatment outcomes.
- A seminar with patient advocates and academics on how to deliver affordable cancer care in high-income countries.

Patient Advocacy Leaders Summits

Our Patient Advocacy Leaders Summits (PALS) bring patient advocates together to discuss health policy issues and develop new skills and ways to expand their influence. Additionally, PALS strengthen patient advocacy organisations by educating advocates, creating connections and building a network of patient advocate organisations to improve the health of communities.

In the USA, we implemented a new approach to PALS during 2011, to provide more engagement at the local level. This included a series of Regional PALS (RPALS), held in six states focusing on aspects of healthcare reform such as the introduction of state health insurance exchanges. We also held an event for patient groups in Washington DC, exploring the role of national advocates in the implementation of healthcare reform.

In Europe we held PALS meetings in Bulgaria, Latvia, Germany, the Netherlands, and Switzerland.

European Patients' Academy on Therapeutic Innovation

A patient-led consortium funded by the European Commission and the trade association EFPIA is working to create a European Patients' Academy on Therapeutic Innovation (EUPATI), which will educate patient representatives on, among other things, the design and conduct of clinical trials, drug safety and risk-benefit assessment, and patient involvement in drug development.

GSK is an industry partner of EUPATI, contributing expertise as well as staff time and funding to the project which starts in February 2012.

Between 2012 and 2016, EUPATI will provide educational materials in six European languages targeting 11 European countries. It aims by 2016 to have released good practice guidelines for patient involvement, and to have held five annual conferences and at least five regional workshops. In addition, 100 leading patient advocates should have completed its courses and 100,000 individuals should have used the EUPATI internet library on therapeutic innovation.

Patient groups

We publish information on all [our work with patient groups](#) online in our Europe, Asia Pacific, and Emerging Markets regions, as well as information on our support for patient groups working globally, including details of the funding received.

We also voluntarily disclose our funding support on our [US website](#) and [detailed information for GSK Australia](#) and [Canada](#) can be found on their websites.

Human rights

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

We believe 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 have most direct control over human rights in our own operations and aim to act responsibly across all our spheres of influence which includes our employees, suppliers, local communities and society more broadly.

We recognise our industry has a unique role to play in efforts to improve health worldwide by developing safe and effective treatment for ailments that affect patients' health. We strive to make our medicines, vaccines and products as widely available as possible while running our business in a sustainable way.

We put safeguards in place to ensure that the human rights of people taking part in our clinical research are protected. These include the informed consent process and procedures to protect patient privacy. We are especially careful to protect the rights of children involved in our clinical trials. You can read more about our approach to clinical studies on page [64](#).

We respect and promote the rights of people in the communities near our operations and through our efforts to improve access to healthcare, working to help society more broadly fulfil its right to health. 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" and our activities to improve access to healthcare support this. You can read more about these in the Health for all and Our people and communities sections earlier in this report.

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 [online](#).

Maintaining high standards of human rights helps us get the best from our employees, supports our relationships with communities near our sites, ensures supplier contracts run smoothly and provide a reliable supply of high-quality products and protects our reputation. Read more in our human rights statement [online](#).

We note the Guiding Principles on Business and Human Rights endorsed by the United Nations Human Rights Council in June 2011. We believe they represent a valuable contribution to the debate regarding how companies can operationalise their human rights responsibilities through appropriate due diligence. Going forward, we will consider how best to respond to challenges set out in the principles.

Our approach to human rights

| | |
|--------------------|--|
| Employees | Our employment standards, which cover issues such as diversity, equal opportunities and health and safety, protect employees' human rights. Read more in Our People and Communities on page 38 |
| Suppliers | Our Third Party Code of Conduct requires suppliers, contractors and business partners to meet GSK standards for ethical standards and human rights. Environmental, health and safety (EHS) audits help us identify potential breaches of our human rights clauses. Read more in the supply chain section of Our behaviour on page 70 . |
| 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 put safeguards in place to ensure that the human rights of people taking part in our clinical research are protected. Read more in the research practices section of Our behaviour on page 64 . |
| Society | We can have an influence on human rights beyond our own operations. Our efforts to improve access to healthcare support society more broadly fulfil its right to health. Read more in Health for all on page 08 . |

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, Sudan and Syria. We share the UN's belief 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 ILO core standards. We observe all local laws and regulations.

Read more online

We publish our positions online including:

- Our [Human Rights Statement](#)
- [GSK on the Convention on Biological Diversity](#)

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Our planet

Growing our business while protecting the natural resources we all need for the future



Contents

| | | | |
|--|-----------|---------------------------------------|-----------|
| Introduction | 83 | Waste | 88 |
| Carbon | 84 | Minimising use of materials at source | 89 |
| Supply chain | 84 | Environmental stewardship | 90 |
| Our operations | 84 | Environmental governance | 90 |
| Propellants | 85 | Compliance | 91 |
| Feature: Understanding the impact of our products | 86 | Performance in 2011 | 92 |
| Water | 88 | External assurance | 94 |
| Water in our operations | 88 | | |

Click arrows above to go to each section →



We are committed to minimising our environmental impact across our value chain and lifecycle of our products by setting ambitious goals to reduce our carbon footprint, water and waste.

Introduction

We believe that it is possible to deliver sustainable business growth while protecting the resources we need for the future and safeguarding the environment.

We are implementing an environmental sustainability strategy across our entire value chain – from raw materials to product disposal. The strategy focuses on carbon dioxide and other emissions that contribute to climate change, water use, waste reduction, and environmental stewardship – which covers the other impacts of our materials and products. By 2050, we aim to have a carbon-neutral value chain.

We have started to deliver on the strategy that we revised in 2010. No simple set of measures will enable us to achieve our goals and many diverse actions will be needed, some of which are underway and some of which we will need to define.

Along this journey we will be transparent about our performance and our progress. For example we participate in the Carbon Disclosure Project (CDP) assessment, where we scored 93% on disclosure and received an 'A' rating for performance in 2011. We also achieved Carbon Trust Standard global certification for the second year in 2011.

The table shows results against our main environmental targets. More data are in the following pages and provided in the detailed data download available [online](#).

Our targets and 2011 performance

| | Performance (%) | | |
|--|-----------------|-------------------|------|
| | 2011 | Target (%) Note 1 | |
| | | 2015 | 2020 |
| Carbon | | | |
| Reduction in GSK's overall carbon footprint across the value chain | Note 2 | 10 | 25 |
| Water | | | |
| Reduction in water consumption across the value chain | Note 2 | – | 20 |
| Reduction in GSK's operational water consumption | 6.9 | 20 | – |
| Waste | | | |
| Reduction in waste to landfill from our operations | 25.5 | 25 | 100 |
| Reduction in total waste generated from our operations | 1.2 | 25 | 50 |
| Environmental Stewardship | | | |
| Mass efficiency of new pharmaceutical processes | 2.2 | 2.5 | 5 |
| Proportion of paper packaging from sustainable sources | Note 3 | 50 | 90 |

Notes:

⁽¹⁾ Targets for carbon, water and waste are absolute targets vs. 2010.

Mass efficiency and paper packaging are percentage targets.

⁽²⁾ Annual performance not available for our overall carbon footprint or water consumption – we will reassess our footprint across our value chain in 2015.

⁽³⁾ We are currently assessing our baseline for paper packaging.

Progress in 2011

- Reduced greenhouse gas emissions from our facilities by 5.3%; our overall CO₂ impact rose slightly due to increased production volumes which increased impact of travel and inhaler use by patients (page 84).
- Reduced water use by 6.9% and waste sent to landfill by 25% with 30 sites now sending zero waste (page 88).
- Developing a product carbon footprint approach that will be used with our individual products to identify carbon hotspots and measures to reduce them (page 86).
- Continued to pilot a take-back scheme for used inhalers in the USA and UK, reducing waste and greenhouse gas emissions (page 87).
- Recycled our own waste PET plastic to make new *Ribena* bottles (page 88).
- Received 'A' rating for performance and scored 93% on disclosure in Carbon Disclosure Project assessment (page 99).
- First office building certified as Gold under the LEED environmental rating system (page 85).
- Published a report, with partners, exploring the impact of climate change on health (page 89).

Carbon

Our long-term goal is for our entire value chain to be carbon neutral by 2050.

Analysis in 2010 examined our impacts across our value chain (see diagram) and estimated our total carbon footprint at about 14 million tonnes CO₂-equivalents.

The largest contributors to our carbon footprint are supply chain material inputs (5.7 million tonnes), propellants used in some of our inhalers (5.2 million tonnes) and our own operations (2.6 million tonnes). During 2011 we made good progress in developing plans for each of these areas, see page [92](#).

Supply chain

Understanding the carbon footprint of our supply chain is not straightforward as we use many varied and complex materials to make our products. To gain deeper insights we are working closely with key suppliers and the Carbon Trust Advisory consultancy to develop a product carbon footprint approach. This will be used for individual products to identify carbon hotspots and measures to reduce them. Our initial results show that the impacts vary widely from product to product, read more on page [86](#).

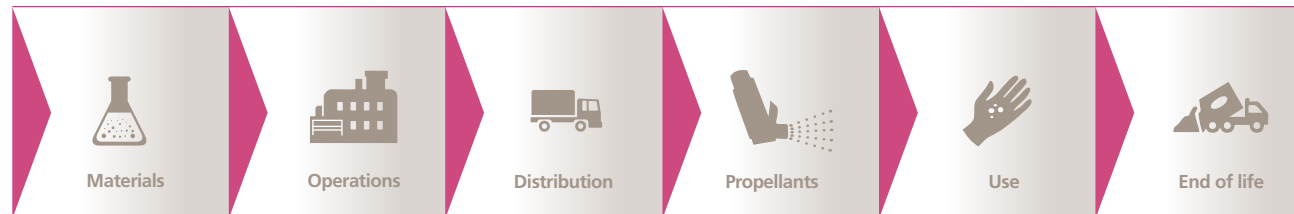
We have continued to make progress on sustainable sourcing, including engaging NGOs to help us shape our sourcing approach, and the development of a network of sustainability advocates in our procurement organisation.

Our operations

We reduced emissions of CO₂-equivalents from our own facilities by 5.3% in 2011. This includes energy and other production sources. Our main focus within our facilities has been on energy efficiency activities where we have seen a 7.2% decrease in CO₂-equivalent emissions. This has been offset by increases in our manufacturing and production volume. Production-related CO₂-equivalent emissions increased 5.4% and transport emissions increased 8.4%. The combined total reduction in facilities and transport emissions was 2.6%. Read more on page [92](#).

Combined heat and power (CHP) generation is playing a growing role in decreasing our carbon emissions. In 2011 we installed a further five CHP units, bringing the total to 16 operating units across 10 sites.

Managing impacts through the value chain



CHP has helped our site at Irvine in Scotland to reduce greenhouse gas (GHG) emissions by 12% over the past three years. The site, which makes the active ingredient for our antibiotic *Augmentin* in an energy-intensive process, aims to help secure its energy supplies from renewable sources by installing wind power. The first turbine should be operating early in 2013, with two to follow subject to planning approvals. Together they will deliver annual savings of 8,000 tonnes of CO₂-equivalents. We have also approved a £15 million project to convert waste to heat at our plant in Singapore, with estimated annual savings of 7,700 tonnes of CO₂-equivalents from 2014.

Saving energy is also a high priority in our office buildings. In 2011 the vaccine site at Sainte-Foy in Quebec became our first office building to be certified as Gold under the LEED environmental rating system. Our new pharmaceuticals headquarters building in Philadelphia is planned to meet even higher environmental criteria.

A central fund is available to help develop specific renewable energy and energy reduction projects. Over the past four years it has supported over 800 projects which have saved approximately 170,000 tonnes of CO₂-equivalents. Details of our energy and carbon reduction performance can be found in the data download available [online](#) and on the [Carbon Disclosure Project](#) website.

Burning waste biomass to fuel *Horlicks*

Our *Horlicks* factories in India use coal to generate power for the manufacturing process. This creates approximately 72,000 tonnes of CO₂-equivalent emissions a year, approximately 5% of the total for GSK's operations.

In 2011 sites began trials to switch from burning coal exclusively to blending it with waste biomass – a renewable resource. We have tested a number of options such as rice husk, pellets made from waste wood, sawdust, grain straw, cotton straw, and ground nut shells. If further trials in 2012 prove successful, we plan to blend up to 30% waste biomass at all three sites, avoiding 19,800 tonnes of emissions a year. In the longer term, we aim for 100% waste biomass for steam generation and investment in combined heat and power technology to generate our own electricity.

Using waste biomass could also contribute to the local economy by creating a market for waste that previously had limited value. For example the proposed pellet supplier works with a micro-entrepreneur scheme which produces incomes for local people.



Propellants

Eliminating CFC gases from our products (completed in 2010) has substantially reduced inhaler emissions – from 24 million tonnes CO₂-equivalents in 1998 to less than five million tonnes today. But more needs to be done because the replacement propellant is still a very powerful greenhouse gas (1,430 times more potent than CO₂). We increasingly supply dry powder inhalers which do not use a propellant, but some patients such as children find them difficult to use so we continue to improve standard propellant-containing inhalers.

During 2011 GHG emissions from propellants increased by 2.9%. This was primarily due to increased sales. We are currently investigating further improvements, including reducing the amount of propellant needed in an inhaler, and we are trialling take-back schemes which will also avoid some propellant releases. Read more overleaf.

80% reduction

Inhaler emissions reduced from 24 million tonnes CO₂-equivalents in 1998 to less than five million tonnes today

Feature: Understanding the impact of our products

When we analysed our carbon footprint across our value chain in 2010 this estimated our total footprint at about 14 million tonnes of CO₂ and highlighted the main contributors to be emissions in our supply chain and propellant release during use of our inhaler products.

We are building on this understanding and now need to know more about the impacts of our individual products.



We are developing a product carbon footprint approach and initial results show that these vary widely from product to product. This is demonstrated in the contrast between the carbon footprints of our propellant-based *Ventolin* inhaler and our *Advair Diskus* dry powder inhalers.

Carbon footprint of our respiratory products

The carbon footprint of *Ventolin* showed that we need to focus on reducing the release of the propellant HF134a into the atmosphere as this is responsible for more than 95% of its footprint (28 kg CO₂-equivalent per device). We are exploring a range of options including reducing the amount of propellant needed, capturing propellant lost during manufacturing, recycling used devices and investigating alternative propellants.

The analysis of our *Advair Diskus* dry powder inhalers footprint showed that we need to focus on the plastics used to make the device and the energy used in our own operations. Together these account for about 65% of the product footprint of the device (1 kg CO₂-equivalent per device). Our short-term improvement priorities are focusing on options to recycle the plastics in the device and improving energy efficiency in our own operations.



Taking back used inhalers

Collecting used inhalers avoids waste as well as greenhouse gas emissions and in 2011 we extended a US trial of an inhaler 'take-back' scheme to the UK. We work with pharmacists to encourage patients to return empty inhalers when they collect a new one. The pharmacist sends the inhalers to GSK's recycling partner, which separates the plastics for remanufacturing and captures any remaining aerosol propellant. The trial began in 2010 in the USA in 225 pharmacies in five cities.

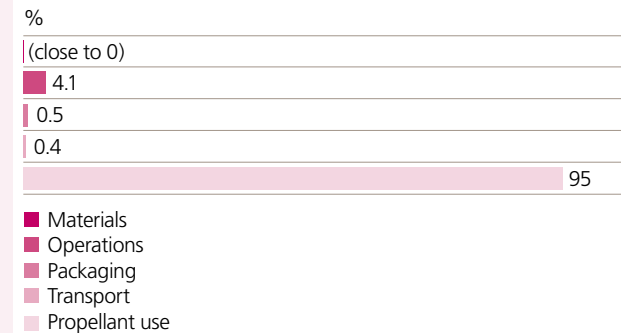
In the UK, we extended an initial trial with the Co-operative supermarket chain to 200 pharmacies. In the six-month trial, an estimated 10% of purchased inhalers were returned. Saving the propellant, which is a potent greenhouse gas, has avoided the equivalent of 35 tonnes of CO₂ emissions. We plan to expand the programme in 2012.

Impact of product use

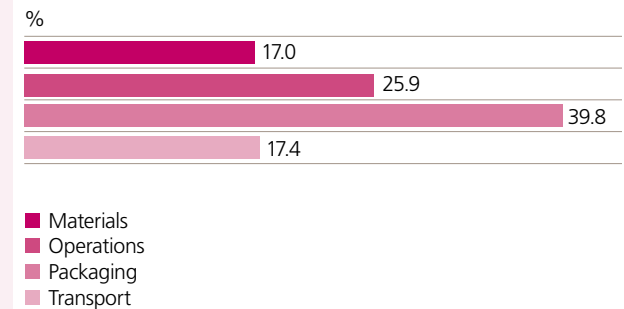
We also need to understand better the environmental impacts of our products when they are used by patients and consumers. In 2011 we commissioned a study of the use-phase carbon footprint of our top 20 products and based on this, estimate that our use-phase emissions are about one million metric tonnes of CO₂-equivalent, excluding the impact of propellants, *Horlicks* and our toothpaste products.

We learned that emissions from product use are very dependent on the type of product and how it is used. For example, for a prescription medicine the largest use-phase impact derives from the paper bag and labels attached to the medicines dispensed from the pharmacies.

Ventolin carbon footprint



Advair Diskus carbon footprint



Water and Waste

Water

Understanding the impact of our business and value chain on water is complex. Unlike carbon emissions whose impacts are global, water use has both local and global impacts and needs to take into account all users of a watershed as well as seasonality and water quality.

GSK is active in the UN CEO Water Mandate, where we are co-sponsors of work to develop disclosure guidelines. These guidelines will help companies to measure and communicate performance more effectively. We hope it will ultimately lead to a water footprint approach similar to the greenhouse gas protocol.

We are performing a high-level analysis across our entire value chain to quantify our overall water consumption and to identify areas of risk or concern. This will help us understand our water impacts better and identify opportunities to reduce our overall impact. The initial results suggest that the greatest contribution to our water footprint will come from the use of water associated with around 20 raw materials in our supply chain.

See also our work to reduce the spread of water-borne diseases on page [27](#).

Water in our operations

We continue site-level action to improve water use, with a 6.9% reduction in 2011, see more on page [93](#). We have developed a 'water kaizen' rapid improvement process to identify more efficient ways to use water. We piloted this approach at our Worthing and Maidenhead sites in the South-East of England and identified potential savings of more than 25%. Many of the opportunities are already being implemented without significant investment. Examples include fitting aerators to taps, decommissioning redundant equipment, optimising service water flows and fitting trigger guns to water hoses. Both sites are investigating other opportunities identified in the kaizen process, such as whether high grade waste water from one part of the plant could be used elsewhere instead of using additional potable water.

Waste

We continued to make progress in reducing the impact of waste in 2011 – total waste (hazardous and non-hazardous) fell by 1.2% and volumes to landfill were down by 25.5%. A total of 30 sites now send zero waste to landfill. Read more on page [93](#).

Innovations drive down waste in many ways. For example, employees at Xochimilco, Mexico, found a way to use the panelling from our refrigerated vaccines shipping packaging as an insulation material for the construction industry. Reusing these materials is avoiding 64 tonnes of waste a year, which we previously paid to send to landfill.

Recycling our waste

Another innovation in 2011 led to our own waste PET plastic being used to make bottles for *Ribena*. Previously, waste contractors disposed of approximately 700 tonnes of PET packaging trays used to deliver components to our sites at Ware, UK, and Evreux, France. Now this material is being recycled to create new *Ribena* bottles, saving approximately £700,000 and over 3,000 tonnes of CO₂-equivalent emissions a year.



Other examples of reducing packaging waste in 2011 include converting from glass to plastic bottles for *Horlicks*, reducing packaging material on consumer healthcare products, and converting from blister packs to film wrapping for our nasal spray *Flixotide*. We estimate these measures will avoid more than 10,000 tonnes of CO₂-equivalents a year.

We revised our Green Packaging Guide in 2011 to help designers avoid waste and choose the most sustainable option. The Guide includes sustainability assessment tools covering energy and water use as well as the carbon footprint of packaging materials and transport. A carbon tracker collects data to monitor progress.

Minimising use of materials at source

We continue to work on increasing the efficiency in the use of materials in our new pharmaceutical products. The average mass efficiency of the new primary processes transferred to manufacturing in 2011 was 2.2%, compared to our 2015 target of 2.5%, see page 93. We believe we can increase the mass efficiency of products transferred to manufacturing to 3% by 2015 through measures such as solvent recovery.

In 2011 we created a new R&D group working on second generation product development to improve the sustainability profile of the R&D and manufacturing portfolio of projects through the product lifecycle.

Driving sustainability through external engagement

We continue our collaboration with the GSK-Singapore [Partnership for Green and Sustainable Manufacturing](#). Through this programme, GSK proposes industry problems in sustainability for study, and the academic community prepares research proposals to solve these problems. Two rounds of proposals have been awarded, and the first symposium has been held. In 2011 we awarded another 14 grants to Singaporean researchers in different areas of sustainable manufacturing, amounting to about S\$8 million.

R&D has also worked with other industry partners to create a €20 million [Sustainable Chemistry](#) partnership with academia through the European Innovative Medicines Initiative, which will start work in 2012. GSK is also part of the American Chemical Society [Green Chemistry Institute Pharmaceutical Roundtable](#), where we collaborate with other pharmaceutical companies on green chemistry and engineering in

the pharmaceutical industry. In 2011 we co-published the Key Green Engineering [research areas](#) and [metrics](#) for green chemistry.⁽¹⁾

In 2011 we [published a report](#) with Accenture and the University of Oxford's Smith School of Enterprise and the Environment exploring the impact of climate change on health.⁽²⁾ We believe this is an important area which is little understood. The research suggested that while there may be some benefits from temperature changes, such as smaller malarial zones in parts of Africa, the overall impact will be negative. Climate change could threaten the lives and well-being of billions of people because extreme weather will directly increase disease and death and indirectly result in some regions struggling for sufficient food, clean water and sanitation. The world's poorest people are likely to be most affected. This research is a starting point and we welcome the opportunity to work with others to develop a better understanding of how the pharmaceutical industry needs to respond.

14 grants

To Singaporean researchers in areas of sustainable manufacturing

€20^m

Creation of Sustainable Chemistry Partnership through IMI

⁽¹⁾ These can be found online. [Research areas: Org. Process Res. Dev., 2011, 15 \(4\), pp 900–911. Metrics: Org. Process Res. Dev., 2011, 15 \(4\), pp 912–917.](#)

⁽²⁾ The report, [Climate Change and Health: Framing the Issue](#) is available in the publications section of our website.

Stewardship and Governance

Environmental stewardship

While the main themes of our environmental strategy are carbon, water and waste, we also work on a broad front of environmental issues, including eliminating the use of 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. In 2011 we used a total of 38 tonnes of such materials during development, compared to 73 tonnes in 2010.

Some refrigerants (CFCs) which are ozone depleting substances are still in use at 12 sites, so we have missed our target to eliminate CFC use by 2012. However in 2011 we reduced the mass of CFCs used by 24% compared to 2010, mainly due to CFC replacement. We will continue to pursue this in 2012.

We restated our policy on pharmaceuticals in the environment in 2011 to reflect the most recent scientific advances and our current practices. Our position remains that none of our compounds would be expected to cause any human health or environmental impacts, but we continue to build a deeper scientific understanding of the issues in order to address concerns. We are evaluating the amount of pharmaceuticals in the effluent from our manufacturing facilities. We also support voluntary and responsible programmes dealing with the safe disposal of unused medicines, which can be a source of pharmaceuticals in the environment.

Environmental governance

We made progress in 2011 on internal governance of environmental sustainability, internal and external engagement.

Responsibility for environmental sustainability rests with the Corporate Executive Team (CET), which formally reviews our performance each year. Read more about the Corporate Responsibility Committee, which also reviews our progress, on page [95](#).

Our new Sustainability Steering Team met quarterly in 2011. This consists of senior leaders from across the business who bring a commercial perspective to environmental debates and engage our local operating companies on the issues. This team is responsible for shaping our environmental strategy so that it is integrated into the business strategy and is both relevant and stretching. In 2012 we will integrate environmental sustainability through specific business unit goals, growing our environmental sustainability practitioner base and helping every employee to get involved through the creation of a network of site champions.

Environmental sustainability is a key part of our environment, health, safety and sustainability (EHSS) policy, which the CET approved in 2008. It covers fundamentals such as the approach to risk management, our ambition for sustainability and our commitment to transparency.

The CEO EHS and Sustainability Awards are a key tool for engaging employees. We refreshed the awards in 2011 to reflect the new strategies and aspirations. In particular, we recognised projects that showed demonstrable benefits to the business in our strategic areas. This year we received 90 applications (30% more than in 2010). In the Environmental Sustainability category, the entries came from more than 15 countries in the areas of carbon, water, waste and general environmental sustainability. Some examples of the awards include programmes for energy reduction in our operations, an improved manufacturing route for a new product, and water reduction initiatives at one site in Australia and one in the UK. Read about winners of the EHS categories on page [42](#).

Our External Stakeholder Panel, which provided advice on environmental sustainability and other environment, health and safety matters, met once in 2011. It will no longer meet in its current form and we are currently reviewing our approach, aiming to achieve deeper engagement with a more diverse and global group of stakeholders, in line with our strategy of working across the value chain.

Compliance

We remain vigilant to stay in full compliance with all environmental laws and regulations.

We incurred two environmental fines in 2011.

The largest was RM1,500 (Malaysian Ringgit, approximately £310) in Kuala Lumpur for insufficient space to store our scheduled waste prior to being collected for destruction.

The other fine was S\$200 (Singaporean dollars, approximately £100) at one of our sites in Singapore for potential of mosquito breeding in canvas sheets left outdoors that collected rain water.

Both events were followed by corrective actions that satisfied the requirements.

GSK has been advised that it may be a responsible party at approximately 27 environmental remediation sites, of which 12 appear on the US National Priority List created by the Comprehensive Environmental Response Compensation and Liability Act (Superfund).

In most instances GSK's involvement related to waste disposal sites where GSK is one of several responsible parties. GSK's potential liability varies greatly from site to site, and GSK routinely accrues funds to ensure that we meet our obligations.

Internal audit

We audit our operations, contract manufacturers and key suppliers based on the assessment of systems for managing significant risks and impacts, compliance with legislation and performance against our environment, health, safety and sustainability (EHSS) standards.

Members of the EHSS audit team are all certified ISO 14001 lead auditors and are part of the GSK Audit and Assurance function which provides an independent audit and assurance capability, separate from the management organisation. The function uses a risk-based audit process which follows the professional practices framework.

The need for audit is determined by modelling key risk indicators and trends in previous audit findings. The 2011 EHSS audit strategy prompted audits at 25 sites around the world which included a review of environmental management systems. In addition, the team carried out a theme audit of the management of hazardous waste across a number of R&D facilities.

In general, performance relating to the management of environmental risks was found to be well managed.

Read more about EHS audits of key suppliers in the Supply Chain section on page [71](#).

Read more online

We publish our positions online including:

- [Climate change](#)
- [The impact of climate change on health](#)
- [Genetically modified micro-organisms and EHS](#)
- [Nanomaterials](#)
- [Hazardous chemical management](#)
- [GSK and EU REACH Regulation](#)
- [GSK and the Convention on Biological Diversity](#)
- [Pharmaceuticals in the environment](#)
- [Ozone depletion and metered-dose inhalers for asthma](#)
- [Ozone depleting substances in plant and equipment](#)

www.gsk.com/reportsandpublications-policies

Performance in 2011

We have made progress on our environmental sustainability strategy, working towards our long-term aim to have a carbon neutral value chain by 2050.

Carbon

Our CO₂ impact from operations fell, mainly driven by investment in projects supported by the climate change programme. We also closed a number of facilities in 2011 but this was balanced by acquisitions and growth.

Our overall impact from operations, transport and inhaler use rose slightly due to increased production volumes which increased the impact of travel and inhaler use by patients.

More detailed information on our performance can be found in the data download available [online](#).

Climate change impact from operations, transport and inhaler use

| Million tonnes CO ₂ -equivalents | | | | Total | |
|---|-----|-----|-----|-------|-----|
| Target 2015 | | | | 6.2 | |
| 2011 | 4.8 | 1.4 | 0.5 | 0.3 | 7.0 |
| 2010 | 4.6 | 1.5 | 0.4 | 0.3 | 6.9 |

- Use of inhalers by patients
- Operations energy
- Travel and transport
- Other sources

Other sources include waste treatment-related releases, production releases, inhaler production losses and refrigerant losses. Travel and transport CO₂ (not CO₂-equivalent) exclude methane and N₂O emissions.

Performance data summary

| | 2011 | 2010 Note 1 | % change |
|--|---------------|---------------|-------------|
| Carbon (thousand tonnes CO ₂ -equivalents per annum) | | | |
| Carbon footprint | Note 2 | 14,000 | – |
| Climate change impacts from: | | | |
| – Raw materials | Note 2 | 5,660 | – |
| – Operations (operational energy and other sources) | 1706.5 | 1801.4 | -5.3 |
| – Transport | 484.2 | 446.8 | 8.4 |
| – Product transport | 218.8 | 186.5 | 17.3 |
| – Employee air travel | 96.5 | 95.8 | 0.7 |
| – Sales force vehicles | 168.9 | 164.5 | 2.7 |
| – Inhaler use by patients | 4,782 | 4,647 | 2.9 |
| Water (million cubic metres) | | | |
| Water use from operations | 17.4 | 18.7 | -6.9 |
| Waste (thousand tonnes) | | | |
| Total operational waste generated | 313.3 | 317.1 | -1.2 |
| – Total operational waste to landfill | 12.8 | 17.2 | -25.5 |
| Non-hazardous waste generated | 121.3 | 125.6 | -3.6 |
| Hazardous waste generated | 192.0 | 191.5 | 0.3 |

Notes:

⁽¹⁾ 2010 values have been restated from our previous report where some estimated data for December 2010 were included when actual data were not available in time for report publication.

⁽²⁾ We will reassess our carbon footprint across our value chain in 2015, annual performance is not available.

Water

Net water consumption has fallen due to a range of water saving and recycled water use initiatives across the business as well as some site closures. This reduction has been offset through business growth, particularly in consumer healthcare manufacturing and vaccines sites' expansion. More detailed information can be found in the data download available [online](#).

Net water consumption in our operations

Million cubic metres

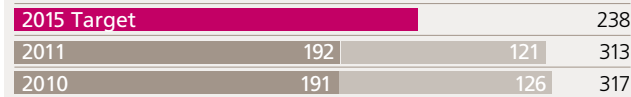


Waste

Total waste generated fell slightly, driven by non-hazardous waste reduction. This was achieved by waste reduction projects and changes in production. We have made big progress in our 'zero to landfill' programme rolled out across the business. The majority of waste is reused or recycled on-site, followed by incineration. Most of our recycled waste is solvents recovered on-site. More detailed information can be found in the data download available [online](#).

Total waste generated

Million kilograms



- Hazardous
- Non-hazardous

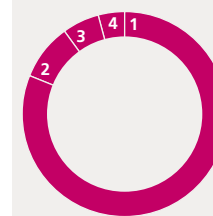
Excludes non-routine waste from construction and demolition.

Waste to landfill

Million kilograms



Destination of waste



| | % |
|-------------------------------------|----|
| 1 Reused/recycled | 82 |
| 2 Incineration no energy recovery | 9 |
| 3 Incineration with energy recovery | 6 |
| 4 Landfill | 4 |

Mass efficiency

Mass efficiency %

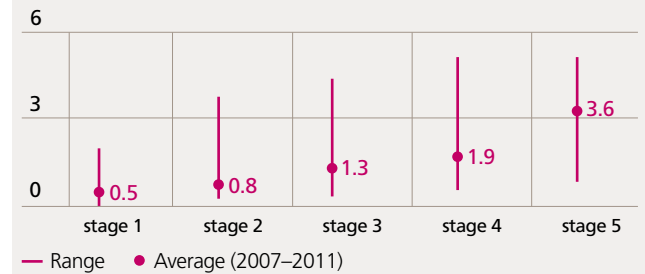


Chart shows the average and range of mass efficiency for each process development stage in our pipeline. Processes transferred from R&D to manufacturing during the 2007–2011 period average 3.6% mass efficiency. The mass efficiency of the primary processes transferred during 2011 averaged 2.2%. Stage 5 refers to transferred to manufacturing weighted average.

External assurance

Basis of reporting and external assurance

Energy and CO₂ emissions data are collected from all 78 of our pharmaceuticals and consumer healthcare manufacturing sites, 15 vaccines sites, 15 pharmaceuticals and consumer healthcare R&D sites, the UK headquarters building and 62 offices and distribution centres. Water and non-hazardous waste data are collected from all our manufacturing and vaccines operations, R&D and major office locations. Based on our materiality assessment, we do not collect hazardous waste and wastewater data from offices and sites that manufacture consumer healthcare and nutritional products, while volatile organic compound (VOCs) are reported only from sites that manufacture pharmaceuticals and contain R&D pilot plants. We use the Greenhouse Gas Protocol for all of our calculations of CO₂ emissions from energy use, propellants and refrigerants. We use CO₂ country factors for electricity published by the International Energy Agency in 2011.

This is the sixth year that SGS has reviewed the data in the environment section of our 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. For the site visits, there was special focus on sites that had been top contributors to environmental emissions the previous year, sites that had implemented innovative EHS projects, relatively new sites that had not been previously visited by SGS for data verification and sites that had difficulty submitting data in a timely manner.

Short form external assurance statement



SGS UNITED KINGDOM LTD'S SHORT FORM REPORT ON ENVIRONMENT, HEALTH AND SAFETY DATA IN THE GLAXOSMITHKLINE CORPORATE RESPONSIBILITY REPORT FOR 2011.

SGS United Kingdom Ltd was commissioned by GlaxoSmithKline (GSK) to conduct an independent assurance of the Environmental, Health and Safety data in its Corporate Responsibility (CR) Report for 2011. The scope of the assurance, based on the SGS Sustainability Report Assurance methodology, included 2011 environmental data contained in the 'Our planet' section of the report, 2011 Health and Safety data contained in the 'Our people and communities' section of the report and the detailed data table. The SGS logo can be found on each relevant page of the GSK CR Report to highlight the data included in the assurance scope.

The scope of our assurance was selected based upon those material issues identified by GSK, and include all Environment, Health and Safety Key Performance Indicators (KPIs) subject to corporate level improvement targets. The assurance included interview and document reviews at GSK facilities in London (UK), Irvine (UK), Slough (UK), Singapore, Poznan (Poland), Research Triangle Park (USA) and Biopharm (USA).

Assurance opinion

On the basis of the methodology described and the verification work performed, we are satisfied that the data collection and reporting processes in place are robust and that the Environmental, Health and Safety data contained within the GSK Corporate Responsibility Report 2011 is reliable and provides a fair and balanced representation of GSK's Environmental, Health and Safety activities in 2011. The assurance team is of the opinion that the report can be used by the Reporting Organisation's Stakeholders.

The full Assurance Statement is available [online](#).

Signed:

For and on behalf of SGS United Kingdom Ltd
Jan Saunders
Systems and Services Certification
United Kingdom, 3rd February 2012
www.sgs.com

GSK response to assurance

We are pleased with SGS's findings on good practice and its recognition of our robust data collection, analysis and reporting. We are committed to continue improving, with the ultimate goal of continued provision of accurate data to the public on our website. The data in the Corporate Responsibility Report can be used by sites to improve their management of their environmental, health and safety programmes. In 2012 we will continue working with all sites to improve their data submission, including providing comments for the explanation of trends in a complete and timely fashion.

Our responses to specific areas of the SGS full assurance statement can be found [online](#).

Governance and management

Our Board-level Corporate Responsibility Committee of Non-Executive Directors provides high-level guidance on our approach to corporate responsibility (CR) and reviews our policies and progress.

During 2011 the Committee members were Sir Christopher Gent (Chair), Dr Stephanie Burns, James Murdoch and Dr Daniel Podolsky. Going forward, James Murdoch has decided to step down from the Board at this year's AGM and will not be offering himself for re-election.

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

The Committee meets three times a year, receiving reports from member of CET and senior managers to review and ensure progress on meeting our CR Principles. The Committee reports its findings to the Board. You can read the 2011 CR Committee Report in the Governance section of our Annual Report [online](#).

To augment GSK's engagement with stakeholder opinion, in March 2009 Sophia Tickell was appointed as an independent external adviser to the Committee. Sophia is the co-founder and Director of Meteos, from which she directs the Pharma Futures Series, which aims to align better societal and shareholder value. She also sits on the Expert Review Committee of the Access to Medicines Foundation and is a member of the European Healthcare Innovation Leadership Network. Sophia has attended meetings of the Committee and provided independent advice and guidance on corporate responsibility matters to both the Chairman and CEO. In mid-2011, to avoid a conflict of interest with a new role which she was due to take on, Sophia decided to retire as an adviser to the Committee.

Our Principles

Our CR Principles are underpinned by our values and identify our key responsibility issues. They provide guidance on the standards to which GSK is committed and the CR Committee review our progress on meeting these commitments. Below we show how each of our Principles maps to one of the four key themes which we see as the most important for responsible and sustainable business growth.

Health for all

- Access to medicines
- Research and innovation

Our people and communities

- Employment practices
- Community investment

Our behaviour

- Standards of ethical conduct
- Products and customers
- Leadership and advocacy
- Human rights
- Engagement with stakeholders

Our planet

- Caring for the environment

More detail on each of the Principles is available [online](#)

Our approach

CR covers a diverse range of issues 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. Members of this team are senior managers with direct access to our Corporate Executive Team. We have a small central CR team which coordinates policy development and reporting specifically relating to CR, as well as communicating with responsible investors and other stakeholders.

Reviewing key business issues and strategic challenges

We have recently introduced Future Strategy Groups to review our approach to key business issues and address strategic challenges. These are led from our CEO's office, providing valuable opportunities for high-potential employees to work closely with the Corporate Executive Team. The groups work to bring together senior managers and experts from around the business and are designed to allow innovative thinking and the development of new approaches. In 2011 several FSGs were convened and included focus on areas such as our approach to malaria, access to healthcare and animal research. You can read more about our approach and progress on these areas in the Health for all and Research practices sections earlier in this report.

Audit and assurance

We assess many aspects of our responsibility performance through our internal and external assurance processes. Our Audit and Assurance department has responsibility for independently assessing, on a sample basis, the process and controls in place to comply with laws, regulations and company standards across GSK. Audits are focused on the key business risks areas for GSK.

The function has responsibility for independently assessing the adequacy and effectiveness of the management of significant risk areas and reporting outcomes to the Audit and Risk Committee in line with an agreed Assurance Plan.

Where issues are identified, the audit team will recommend improvements. GSK managers develop action plans to address the causes of non-compliance and address gaps in internal controls. The department tracks these plans through to completion and reports results to senior management and the Audit and Risk Committee.

Our Anti-Bribery and Corruption (ABAC) Programme builds on our values and standards to form a comprehensive and practical approach to compliance in this complex risk area. The programme is overseen by the ABAC team, who provide advisory support and routine audits of this risk (page 54).

To supplement our traditional audit programme, Strategic Risk Evaluations (SREs) are conducted in partnership with the business to evaluate areas where GSK's risk appetite and mitigation strategy are unclear or undefined based on the emerging nature of the risk or the risk maturity level of GSK's response.

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

External assurance

Our environment, health and safety reporting 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 on page 94.

Previously we assured one other section of our report every other year. We are in the process of reviewing our approach to assurance for the other sections of our CR Report.

Risk management

Our Risk Oversight and Compliance Council (ROCC) co-ordinates the management of significant business risks and oversees internal controls to ensure compliance with applicable laws, regulations and GSK policies. Non-financial and reputational risks are included in our core risk management processes.

Our most significant risks, including non-financial risks, and our risk management processes are described in our [Annual Report](#).

Some of our business growth is achieved through acquisition. We have due diligence processes in place which are designed to identify any risks posed by new business acquisitions, including ethical, social or environmental risks.

The value of corporate responsibility

The value of corporate responsibility

Being a responsible business benefits both GSK and the societies we operate in. It helps us operate efficiently, to gain the trust of our stakeholders, to create the products that patients and healthcare payers really need and to foster the right conditions for the growth of our business.

Operating responsibly and fully integrating our principles into business strategies for the longer term:

- Supports our licence to operate and so our ability to improve people's lives through our products.
- Builds trust in GSK and our products.
- Enhances our ability to attract, retain and motivate talented people. This is increasingly important as fewer young people in our major markets choose science-based careers.
- Supports constructive engagement with stakeholders. This helps us to prevent avoidable conflict and identify innovative approaches that benefit GSK and wider society.

- Facilitates greater access to markets and the ability to influence healthcare policy through improved relationships with regulators and healthcare payers. Working with governments to increase access and resolve healthcare challenges is particularly important.

- Helps us to anticipate and prepare for legislative changes and remain competitive.

- Helps maintain support for the intellectual property system by finding innovative ways to increase access to medicines.

- Reduces costs through increased environmental efficiency and more efficient use of resources.

We consider the following responsibility issues to be most material to GSK:

- The contribution we make to health and well-being through research, development, manufacture and sale of medicines, vaccines and consumer healthcare products.

- Increasing access by making our products more accessible and affordable.

- Investing in our people and the communities we operate in.

- Ensuring ethical standards in research and development and sales and marketing.

- Our environmental impact, particularly relating to climate change.

A number of factors influence our assessment including: 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; and public opinion.

Our Annual Report

You can read more about our business, our strategy and performance, as well as find detail on corporate governance and risk management in our 2011 Annual Report [online](#).



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 expectations. It provides an opportunity to voice our approach on responsibility issues, obtain important feedback and build trust. Most of this discussion takes place in the normal course of business. We provide training to help managers in our markets to communicate with local stakeholders on our approach to responsible business and transparency. Some of the ways we engage with stakeholders are outlined here and throughout this report.

| Stakeholder | Examples of how we engage |
|---------------------------------|---|
| Healthcare professionals (HCPs) | <ul style="list-style-type: none"> • Sales representative meetings • Interactions during clinical studies and at conferences • Engagement with professional organisations |
| Patients | <ul style="list-style-type: none"> • Meetings between GSK scientists and patients through our 'Focus on the Patient' programme • Our work with patient advocacy groups • Market research to understand patient needs |
| Governments and regulators | <ul style="list-style-type: none"> • Our public policy work • Advocacy on key issues such as access to healthcare |
| Investors | <ul style="list-style-type: none"> • Meetings with investors and participation in key sustainability indexes • Participation in the Carbon Disclosure Project |
| Employees | <ul style="list-style-type: none"> • Regular employee surveys • Consultation with employee representatives on changes to the business |
| Local communities | <ul style="list-style-type: none"> • Interactions at site level on a range of issues • Our community investment programmes |
| Multilateral agencies | <ul style="list-style-type: none"> • Engagement through our access to healthcare and public health initiatives |
| Non-governmental organisations | <ul style="list-style-type: none"> • Engagement on issues relating to access to medicines, community investment, public policy, and animal welfare |
| Scientific community | <ul style="list-style-type: none"> • Participation in academic collaborations • Participation in scientific debates |
| Suppliers | <ul style="list-style-type: none"> • Global and regional supplier review meetings • Meetings for diverse suppliers |
| Peer companies | <ul style="list-style-type: none"> • Pharmaceutical industry organisation meetings • Joint projects such as the Pharmaceutical Supply Chain Initiative |

Performance

GSK receives recognition and awards across all areas of our business. Here we provide a summary of our performance in key investor focused indexes and awards.



GSK was ranked top in the **Access to Medicine Index** for the second time in June 2010. The index ranking will be reviewed in 2012. It 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 continued as a member of the **Dow Jones Sustainability Index**, which covers the top 10% of sustainable companies in each sector. GSK was awarded Bronze class distinction in the 2011 survey published in 2012.



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. GSK was also rated top in the healthcare sector in the new FTSE4Good ESG Rating, scoring 4.6 out of a maximum of 5. The assessment scores companies on their approach and performance based on publicly available information.

CARBON DISCLOSURE PROJECT

The **Carbon Disclosure Project's (CDP)** Leadership Index ranked GSK 29th of more than 400 global companies in 2011 with a score of 93% on disclosure and an 'A' rating for performance.



In the **2011 Thomson Reuters Extel Sustainability and SRI Survey** GSK won the 'Leading Quoted Company for IR with Sustainability Investors' Award. This is based on votes from European fund managers and investment banks.

Front cover (from left to right)

Early stage research into new biopharmaceuticals takes place at our large R&D centre in Stevenage, UK. More than 12,500 people world-wide work in R&D in the search for new medicines, vaccines and consumer healthcare products. (George Brooks)

A mother and child wait outside a malaria clinic in Tanzania. Over 15,000 children in seven countries across sub-Saharan Africa are taking part in an ongoing large-scale trial to evaluate our malaria vaccine candidate, RTS,S. (Tom Whipps)

GSK is the Official Laboratory Services Provider for the London 2012 Olympic and Paralympic Games. Our school outreach programme Scientists in Sport aims to inspire young people into science by demonstrating the role that science plays in the Games. (David Tett)

Around 40% of our carbon footprint comes from propellants released during the use of our inhaler products. Our 'take-back' scheme, trialled in the US and UK, recycles returned empty inhalers – plastics for re-manufacturing and propellant for non-medical use. (Ian Enness)

Back cover

Visual inspection of vials at our Zhangjiang site in China. Quality is at the heart of all of our activities that support the discovery, supply and distribution of our products to patients and consumers. (Tom Whipps)

A man with lymphatic filariasis (LF, also known as elephantiasis) cares for his legs to limit the effects of this disabling disease. GSK donates its albendazole treatment through the World Health Organization led effort to eliminate LF. (Marcus Perkins)

A Red Cross doctor helps a victim from the Japanese disaster. GSK donated products worth £2.2 million and £1.7 million cash to the Japanese Red Cross. GSK Japan employee volunteers delivered food, blankets and other aid to affected areas. (AP Photo/The Yomiuri Shimbun, Masataka Morita)

GSK's PHASE programme, run in partnership with NGOs, works to improve water quality as well as educate communities on the importance of handwashing in reducing the spread of diarrhoea-related diseases. (Getty/Claudia Dewald)

Photo credits

- p02 From our Chairman – George Brooks
- p04 From our CEO – Tom Whipps
- p08 Health for all – Chris Martin (left), Tom Whipps (right)
- p11 Focus on the patient – George Brooks
- p16 Our approach to malaria – Tom Whipps
- p19 Using mobile phones to tackle counterfeiting in Nigeria – Tom Whipps
- p26 Our approach to neglected tropical diseases (NTDs) – Marcus Perkins
- p27 Measuring the impact of our PHASE programme – Chris Martin
- p32 Treatment of children with HIV/AIDS – Chris Martin
- p35 Vijana Tunaweza Newala- Jennifer McCleary-Sills/ICRW
- p36 Our people and communities – David Tett (left), George Brooks (right)
- p46 Responding to the Japanese earthquake – AP Photo/The Yomiuri Shimbun, Masataka Morita
- p48 Bringing science to the London 2012 Olympic and Paralympic Games – David Tett
- p51 IMPACT Awards – STAMP productions
- p52 Our behaviour – Tom Whipps (left), George Brooks (right)
- p56 Changing the way we incentivise our sales teams in the USA – Sean Locke/ Getty Images
- p82 Our planet – Thampapon Otavorn/123RF (left), Impress Photography (right)
- p85 Burning waste biomass to fuel Horlicks – Thampapon Otavorn/123RF
- p86 Understanding the impact of our products – Ian Enness
- p87 Understanding the impact of our products – Impress Photography
- p88 Recycling our waste – George Brooks



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- Annual Report
- Corporate Responsibility Report

Head Office and Registered Office
GlaxoSmithKline plc
980 Great West Road
Brentford, Middlesex TW8 9GS
United Kingdom
Tel: +44 (0)20 8047 5000
Registered number: 3888792

www.gsk.com +

