

Access to medicines

Millions of poor people in both developed and developing countries struggle to get the medicines they need.

We are supporting efforts to improve access to medicines. This section explains our:

- Contribution to the developing world through research, preferential pricing, partnerships and voluntary licences, and community investment in important public health initiatives
- Pricing arrangements and discount cards for middle-income countries
- Patient Assistance Programs and discount cards to help uninsured patients in the US

We believe that our response is not only the right thing to do but makes good business sense. Companies that adapt their business practices to address such challenges will be the leaders of the future. In the competitive market for talented people this also helps us to attract and retain the best people.

Differential pricing increases affordability for patients whilst maintaining support for the intellectual property system. Intellectual property rights are essential to the pharmaceutical industry because without them we would not be able to invest in R&D for new medicines and vaccines.

By finding innovative ways to help poor people in developed and developing countries access our medicines, we are addressing ethical, reputational and commercial imperatives. For these reasons access to medicines is a strategic business driver of GSK.

We also support under-served communities worldwide through donations, funding and practical support. See [community investment](#).

Developing world

Poverty has caused a healthcare crisis in many parts of the developing world. Millions of people do not have access to reliable food and clean water, never mind adequate healthcare. Despite unprecedented resources being made available for public health, many governments are unable to fund the clinics and staff needed to deliver basic healthcare.

The World Bank estimates that \$14 per person per year is needed to provide the most basic health services. Yet the average spend in sub-Saharan Africa is just \$6. The African Region of the WHO suffers more than 24 percent of the global burden of disease, but has only 3 percent of the world's health workers. Migration of African health workers to wealthier markets is exacerbating this situation. Globally, there is a shortage of well over 4 million

healthcare workers. The AIDS pandemic is making the situation even worse, depriving communities of their greatest asset – healthy and productive people.

Tackling this crisis is a complex challenge, requiring visionary leadership. Poverty is a huge barrier to progress. Significant political will and extra resources are needed to aid development and build healthcare infrastructure. Disease programmes need to be well co-ordinated to ensure that health systems as a whole benefit.

We believe that it is the responsibility of governments and intergovernmental agencies, supplemented by the work of NGOs, to deliver healthcare in these countries. However, the pharmaceutical industry can play a significant role in supporting their efforts.

We make an important contribution through:

- Research and development into diseases disproportionately affecting developing countries. We believe GSK is currently the only company researching both new vaccines and treatments for HIV/AIDS, TB and malaria – the World Health Organization's three priority diseases. Much of this research is conducted through public private partnerships
- Preferential pricing; specially reduced prices for anti-retrovirals (ARVs), anti-malarials and vaccines. In 2006, we shipped more than 86 million *Combivir* and *Epivir* tablets at not-for-profit prices for the treatment of HIV/AIDS to the poorest countries of the world
- Seeking innovative partnerships; GSK has granted eight voluntary licences for the manufacture and supply of generic versions of our leading ARVs for treating HIV/AIDS in Africa, and is active in other partnerships such as Roll Back Malaria and Stop TB
- Community investment in public health initiatives and partnerships that foster effective healthcare including major programmes to tackle lymphatic filariasis, malaria, HIV/AIDS and diarrhoeal disease. See [community investment](#).

Research and development

The research and development (R&D) of new drugs and vaccines is an essential element in improving health in the developing world. There are still no effective treatments for some widespread and life-threatening diseases. Many existing treatments for diseases such as malaria are becoming less effective due to drug resistance.

For HIV/AIDS which affects both developed and developing countries, there is a commercial market for new treatments. This encourages investment into the required R&D. GSK is an industry leader in research into HIV/AIDS treatment and prevention.

However, for many diseases that disproportionately affect the developing world, the lack of resources for healthcare means there is often no viable commercial market for new treatments. Public private partnerships (PPPs) are helping to address this problem.

GSK collaborates with several PPPs including the Medicines for Malaria Venture (MMV), the Global Alliance for TB Drug Development (TB Alliance), the Aeras Global TB Vaccine Foundation (Aeras), the Malaria Vaccine Initiative (MVI) and the International AIDS Vaccine Initiative (IAVI).

GSK has created a dedicated group in our pharmaceutical R&D organisation to focus on

diseases of the developing world (DDW). This includes a DDW drug discovery centre at our Tres Cantos R&D site in Spain where over 100 scientists are based, and clinical development experts in the UK and US. DDW projects are prioritised according to their social and public health benefits rather than their commercial returns. A similar group exists in our vaccines organisation based in Belgium.

In total GSK is conducting R&D into 11 diseases of particular relevance to developing world¹. This includes 14 clinical programmes for medicines and vaccines against these diseases. Seven of these projects are for diseases that disproportionately affect developing countries. Some of these are summarised below.

¹ HIV/AIDS, malaria, leishmaniasis, dengue fever, hepatitis C, hepatitis E, N. meningitis, cervical cancer, TB, chlamydia and pneumococcal disease

Access to healthcare – whose responsibility?

Access to healthcare in the developing world remains a complex issue. We believe that only a holistic approach embracing prevention and treatment will work. All stakeholders have a role to play.

Pharmaceutical companies must make their medicines affordable to developing countries and invest in research into diseases of the developing world – new treatments are urgently needed.

Wealthy nations must give more. Welcome new funding is coming through from the Global Fund to Fight AIDS, TB and Malaria, the Gates Foundation, PEPFAR (The US President's Emergency Plan for Aids Relief) and others – but funds are still inadequate. Resources are needed to fund research, purchase medicines and to discourage the export of trained healthcare workers from developing countries.

Developing countries must show genuine political commitment to addressing stigma, removing import tariffs and prioritising healthcare in national budgets.

Middle-income countries must accept their responsibilities and not seek the lowest prices offered to the world's poorest countries.

We have developed a **Seven Point Plan** for a sustainable approach to improving healthcare in the developing world, which we use in our advocacy efforts. In 2006 these included:

- Submissions to the UK Department for International Development's (DfID) consultations on its White Paper 'Eliminating world poverty: Making governance work for the poor', and also to health strategy
- Submissions to the G8 governments ahead of the St Petersburg summit
- Face-to-face meetings with Hilary Benn, UK International Development Secretary, UN Secretary General Kofi Annan, UK Government officials, White House officials, EU officials and NGO representatives
- Interactions with UNAIDS, UNITAID (the new international drug purchase facility) and the World Health Organization

Development pipeline at end of 2006 for diseases relevant to the developing world*

Focus	Pre-clinical activity	Phase I	Phase II	Phase III	Marketed
HIV	✓ HIV-1 entry inhibitor NNRTI		integrase inhibitor		<i>Retrovir, Eпивir, Combivir, Ziagen, Trizivir, Agenerase, Kivexa, Telzir</i>
Vaccines	✓ Malaria (<i>P. vivax</i>) HIV Chlamydia	HIV (DNA-antiviral vaccine)	Malaria (<i>P. falciparum</i>) TB Hepatitis E Dengue Fever	<i>Synflorix</i> (pneumococcus disease) Cervarix (Cervical cancer) N.meningitis combinations	<i>Rotarix</i> – (rotavirus) <i>Havrix</i> – (Hepatitis A) Engerix-B – (Hepatitis B) <i>Twinrix</i> – (Hep A&B) <i>Infanrix/Tritanrix</i> – DTP family (Diphtheria, Tetanus, Pertussis) <i>Boostrix</i> – (DTP acellular) Polio Sabin – (Polio) <i>Priorix</i> – (Measles, Mumps and Rubella) <i>Typherix</i> – (Typhoid) <i>Hiberix</i> – (Haemophilus influenzae type b) <i>Mencevax ACW</i> – (meningitis)
Malaria	✓		tefenouquine	CDA	Lapdap, Halfan, Malarone
TB	✓				
Other	✓ Hepatitis C		sitamaquine (visceral leishmaniasis)		<i>Zentel</i> (de-worming agent) <i>Pentostam</i> (visceral leishmaniasis) Banocide (lymphatic filariasis – GSK India)

* more detailed information on our product pipeline can be found in the Annual Report

What's different about R&D for medicines for the developing world?

GSK scientists working on treatment projects for diseases disproportionately affecting developing countries make access to medicines a priority right from the start of the R&D process.

When researching new treatments we produce a Target Product Profile (TPP) – outlining the characteristics we are looking for in any new molecule. As well as safety and efficacy, a TPP for a new DDW treatment emphasises factors such as:

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

PROGRESS IN 2006

Malaria Vaccines

GSK has been working on a malaria vaccine for over 20 years. In 2005 clinical trials of our malaria vaccine for children showed that the vaccine remained efficacious over 18 months in reducing severe malaria by 49 percent in children. Several more years of clinical investigation are needed but these results indicate it has the potential to help save millions of children's lives. In 2006 additional phase II clinical trials of the vaccine were initiated in Mozambique, Kenya, Tanzania, Gabon and Ghana. These are supported by a grant from the [Malaria Vaccine Initiative at PATH](#) funded by the Bill & Melinda Gates Foundation, and will further evaluate the vaccine in different settings and with younger children. If these trials are successful, the partners will initiate a large-scale phase III clinical trial. If the results continue to be positive the vaccine could be submitted for regulatory approval as early as 2010.

Treatments

We are working closely with the [Medicines for Malaria Venture](#), which subsidises 30 scientists at our Tres Cantos facility, the World Health Organization (WHO) and academic partners to develop CDA, an affordable fixed-dose artemisinin combination treatment for drug-resistant malaria in Africa. In 2006 phase III clinical trials were initiated at several sites across Africa. An additional phase III study is planned for 2007 involving infants between the ages of three months and one year. We aim to submit CDA for regulatory approval in early 2008.

In March 2006, we identified a lead candidate (GW308678) to take forward into development from our pyridones project, along with a backup candidate (GW308121). These drugs have the potential to be highly active against drug-resistant strains of malaria and show none of the toxicity issues that affected a previous candidate in this class.

Significant chemical and pharmaceutical development was undertaken on the anti-malarial drug GSK369796 (n-tert butyl isoquine) and we plan to start clinical studies in humans when partner funding becomes available. The drug is relatively straightforward to synthesise and manufacture, and therefore has the potential to be relatively inexpensive.

Clinical data for tafenoquine, a new antimalarial being developed in partnership with the US Military, have shown that a tafenoquine-containing combination regimen may work faster than existing therapies in the treatment of *P. vivax* malaria and may also help to address concerns about emerging resistance to existing treatments. We are in discussions regarding the funding of additional development work for the treatment of *P. vivax* malaria and we plan to proceed with clinical development in 2007.

HIV/AIDS Vaccines

GSK is a leader in the global effort to develop an AIDS vaccine. We have been involved in AIDS vaccine research for more than two decades and today we are pursuing four separate vaccine technologies. A successful AIDS vaccine might need to combine several of these approaches.

GSK and the Institut Pasteur are working together to develop an AIDS vaccine by fusing genes from the HIV virus onto an existing measles vaccine. The project is being supported by a Euro 5.5 million (£3.7 million) grant from the European Union.

We are part of a public private partnership with the International [AIDS Vaccine Initiative](#) (IAVI) to develop an AIDS vaccine using nonhuman primate adenovirus vector technology. The collaboration – the first ever in AIDS vaccine research between IAVI and a major vaccine company – will facilitate research into vaccines against types of HIV that circulate predominantly in Africa.

GSK Biologicals also has an in-house AIDS vaccine development project using the company's proprietary adjuvant system technology. Two phase I clinical trials have been conducted with this vaccine, in the United States in partnership with the US National Institutes of Health's HIV Vaccine Trials Network, and the other in Belgium at Ghent University. These trials, completed in 2003 and 2005 respectively, demonstrated that the vaccine is safe and produces a strong immune response. A third phase I trial in 20 HIV-infected volunteers was initiated in late 2005 in collaboration with the Partners AIDS Research Center at Massachusetts General Hospital in Boston, and the results are currently being analysed. A follow-up approach explores a similar strategy using a new antigen named F4. A phase I clinical trial of the F4 vaccine candidate is scheduled to begin in the near future in Belgium.

Our fourth approach aims to develop an improved adjuvanted envelope (Env) protein vaccine able to produce neutralising antibodies that will provide lasting protection against infection with HIV. This approach is currently under preclinical evaluation.

Treatments

In December 2006 we discontinued the clinical development of brecaonavir, our protease inhibitor for patients with multi-drug resistant HIV infection. We were unable to develop an oral dosage formulation that could consistently deliver the correct dosage of brecaonavir to the patient.

Our scientists are working on new HIV medicines in several different drug classes. Our integrase inhibitor discovery programme is very active and the lead candidate 364735C, which is being developed in partnership with Shionogi, is currently in phase II development. New HIV-1 entry inhibitor and non-nucleoside reverse transcriptase inhibitor (NNRTI) candidates are entering the pipeline.

Experts at WHO and UNICEF have stated that access to appropriate ARV tablets (as opposed to ARV liquid formulations) would facilitate the treatment of children old enough to be able to swallow tablets. We are developing scored tablets for our key ARVs (*Epivir*, *Ziagen*, and *Combivir*) so they can be broken into two smaller doses suitable for the treatment of children. This will simplify treatment and help physicians and carers administer the right dose efficiently and safely to children. We expect to submit the scored tablets for registration in 2007.

We want to continue to play an important role in the treatment of HIV in children and we support four paediatric clinical studies involving 2,400 children in five resource-poor countries.

We provide ARVs through our international HIV Collaborative Research Trial programme to support clinical studies run by third parties. We are currently supporting 21 clinical studies involving 19,500 patients, of which 16 studies are taking place in sub-Saharan Africa. These include eight studies on prevention of mother-to-child transmission, one on prophylactic properties, the four studies on children mentioned above, four on HIV-TB co-infection, and four on adult treatment strategies. These studies are intended to advance knowledge about the use of ARVs in resource-poor settings and also help to increase access to ARVs.

Tuberculosis (TB)

TB kills two million people a year and is a leading cause of death among people with AIDS in the developing world. But no new drugs against TB have been discovered in more than 40 years.

Vaccines

GSK and the [Aeras Global TB Vaccine Foundation](#) are developing GSK's TB candidate vaccine. Early-stage clinical trials in the US and Belgium showed that the vaccine is safe and well-tolerated and produces a strong immune response. In 2006 we began additional trials involving adults previously infected with TB or vaccinated with Bacillus Calmette-Guérin (BCG). We plan to conduct further studies in Africa and other locations to test the safety and efficacy of the vaccine candidate in populations highly affected by TB.

Treatments

In 2005 we launched a joint drug discovery partnership with the [Global Alliance for TB Drug Development](#) (TB Alliance). The TB Alliance aims to accelerate the development of affordable drugs that will shorten treatment and be effective against multi-drug-resistant strains of TB. All compounds will be screened to ensure they can be taken with HIV treatments. The TB Alliance is supporting 25 full-time scientists working exclusively on the TB drug programme at Tres Cantos. GSK is contributing a matching number of staff and all remaining overhead costs. Around 1.5 million compounds have now been tested for anti-TB activity and we have four pre-clinical TB projects underway.

In partnership with Stellenbosch University in South Africa, GSK is supporting grant applications to fund a programme to identify "biomarkers" in people who may respond to specific treatments. Such biomarkers can be used to predict whether or not patients will respond quickly to treatment or if TB is likely to recur.

Rotavirus

Rotavirus infection is the leading cause of severe diarrhoea and vomiting (gastroenteritis) in children under two and kills around 600,000 children each year – one child every minute – mostly in developing countries. Our vaccine, Rotarix, for the prevention of rotavirus induced gastroenteritis, was launched in Mexico in January 2005 and has now been approved in 89 countries and is being registered in a further 26. Most registrations have been in the developing world. The vaccine is now part of national immunisation programmes for all newborn babies in eight developing countries including Brazil, El Salvador, Mexico, Panama and Venezuela. We have distributed 12.5 million doses since launch. Early in 2007, GSK received prequalification status for its rotavirus vaccine from the World Health Organization (WHO). This is required before UN organisations and [GAVI](#) (formerly known as the Global Alliance for Vaccines and Immunisation) can purchase a vaccine. This was timely as it complemented the decision by GAVI in late 2006 to provide funding to support the introduction of rotavirus vaccines in developing countries.

Cervical cancer

Cervical cancer is the most common cause of cancer deaths in women in the developing world. Current published data suggest that our Cervarix vaccine could reduce by 70 percent a woman's lifetime risk of developing cervical cancer. We applied for registration of the vaccine in Europe as well as 28 countries in our International region during 2006. We are on track to file for regulatory approval in the US by April 2007. We are committed to making *Cervarix* widely available, and will make it available to low-income countries at preferential prices through GSK's tiered pricing model for vaccines.

We are conducting clinical studies on the use of the vaccine in low income settings.

Leishmaniasis

Sitamaquine is our potential new once-a-day oral treatment for visceral leishmaniasis. This disease affects half a million people a year in the developing world and is usually fatal if untreated. GSK is providing all the funding for this project. A new treatment for visceral leishmaniasis is urgently needed, since current medicines are either impractical or becoming ineffective due to drug resistance or are simply unaffordable. Sitamaquine has shown good efficacy in phase II trials. The trials also suggest that a shorter treatment period can be achieved – perhaps up to half of the four weeks needed for current treatments. The low cost suggests that sitamaquine could be the first truly accessible treatment for visceral leishmaniasis which affects the poorest of the poor.

Public private partnerships (PPPs)

What is a PPP?

In a PPP, companies such as GSK provide the R&D, technology, manufacturing and distribution expertise. Academic institutions may also provide research and disease area knowledge. Public sector partners, governments, or organisations such as the Gates Foundation, help fund the development and delivery costs and ensure that medicines get to the people who need them. Funds are usually channelled through organisations such as the Medicines for Malaria Venture.

Why are PPPs needed?

GSK wants to invest in research to tackle diseases that blight the developing world. However, there is a dilemma. We must be profitable to sustain our business and to continue to develop new medicines. This business model does not work in cases where there is no prospect of a commercial return. Unfortunately, lack of resources means there is limited market for new treatments for diseases that disproportionately affect developing countries. The PPP model, in which business and the public sector work together, offers a solution.

How does the partnership work in practice?

Drug discovery takes place at our dedicated diseases of the developing world Discovery Centre at Tres Cantos. GSK provides the facilities and meets all the running costs. There are over 100 GSK scientists at Tres Cantos, half of whom are subsidised by our partner organisations – the Medicines for Malaria Venture (MMV) and the Global Alliance for TB Drug Development (TB Alliance).

As compounds move into clinical development, GSK provides the clinical, regulatory and manufacturing expertise and resources through our global R&D and supply network. Partners help fund the cost of running clinical trials and address issues of access and distribution. This reduces the costs of development and gets new products to patients faster. Research programmes are overseen by joint steering committees with representatives from GSK and our partners.

Does this affect the price of new treatments?

Importantly, under the terms of our agreement, we are committed to make any new treatments resulting from PPPs accessible to the developing world at affordable prices.

PREFERENTIAL PRICING

Poverty, lack of political will and insufficient medical infrastructure (hospitals, clinics and health workers) are the biggest barriers to accessing healthcare in developing countries.

The affordability of medicines is also important and there are two elements to this:

- The ability of governments or patients to pay for medicines. Governments and inter-governmental agencies must make significant additional financial resources available to solve this problem.
- The price at which medicines are sold – an area GSK can help to address.

We are making ARVs and anti-malarials available to developing countries at more affordable prices. This is a major commitment that we call 'preferential pricing'. It includes not-for-profit (nfp) prices for the world's poorest countries, and discounted prices for wealthier developing and middle-income countries, see page 23.

Other factors in the supply chain such as taxes, tariffs and distributor mark-ups can significantly increase the price of medicines. These factors are out of our control and should be addressed by governments.

For middle-income developing countries we continue to negotiate public sector prices on a case-by-case basis to improve affordability, see page 23.

GSK vaccines are also available at preferential prices. We use a tiered pricing structure for vaccines – prices for the developing world can be as little as a tenth of those for developed countries. We work with multinational organisations such as UNICEF, the World Health Organization and the Pan American Health Organisation, governments and non-governmental organisations, to provide appropriate and affordable vaccines for developing countries. This includes basic polio vaccines as well as specially developed combination vaccines that target several diseases. In 2006, of the 1.1 billion vaccines we shipped, around 75 percent went to the developing world. This is lower than in previous years due to the timing of some significant tenders.

Progress in 2006

We shipped 27 million tablets of nfp *Combivir* and 59 million tablets of nfp *Epivir* to the developing world compared with 45 million and 81 million tablets respectively in 2004 and 2005.

This decrease was expected and is primarily due to more customers purchasing ARVs from generic manufacturers including those licensed by GSK. This is a positive indication that our licensing policy is working.

In the last year generic manufacturers licensed by GSK have significantly increased their manufacturing capacity and ability to supply larger quantities of ARVs at lower prices. We welcome this trend as it gives customers in sub-Saharan Africa greater choice and contributes to better security of

supply. In 2006 our licencees supplied over 120 million tablets of their versions of *Epivir* and *Combivir* to Africa.

We will continue to look for new customers for our nfp ARVs in these countries and to regularly review our nfp prices. However, it may well be that our licencees are able to produce first-line ARVs at lower costs and will increase their share of the business.

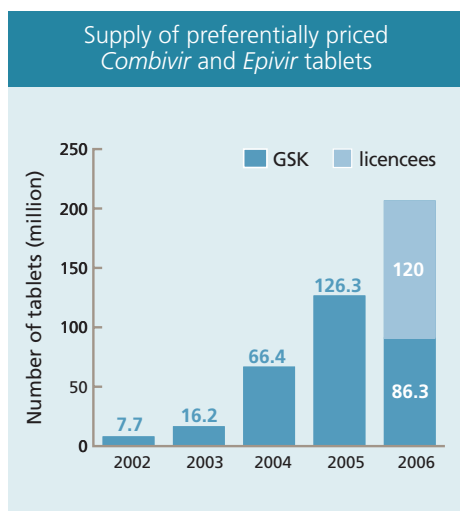
A massive scale-up in treatment for HIV/AIDS is planned by the global community in the next five years. We are negotiating agreements with contract manufacturers to ensure we have the capacity to contribute to meeting this demand.

The WHO published new treatment guidelines for patients with HIV. Our ARV abacavir is now recommended as a first-line treatment option. In May we reduced the nfp price of abacavir-containing ARVs by 30 percent and made our two new ARVs – *Kivexa* and *Telzir* – available at nfp prices.

There have been concerns that pharmaceutical companies are not doing enough to register essential medicines in developing countries and that this prevents these countries from taking advantage of preferential pricing offers. We continue to review the registration needs for our key ARVs in our 64 target developing countries to ensure that *Epivir*, *Retrovir* and *Combivir* are available as widely as necessary and possible.

A current focus is to also make abacavir and abacavir-containing ARVs available in these locations. We will prioritise our efforts where there is the greatest medical need – in particular the 15 PEPFAR countries and other developing countries with a significant HIV burden where high-quality alternatives to abacavir are not available.

Product diversion, where not-for-profit medicines are illegally shipped back for sale in wealthier countries, denies treatment to patients in poorer countries. Our anti-diversion measures include access packs (such as red rather than white tablets) for *Combivir*, *Epivir* tablets, *Epivir* solution, *Trizivir* and *Retrovir* solution which are now registered in more than 50 countries. GSK was the first company to receive a Positive Opinion (for *Epivir* and *Combivir* red coloured tablets) from the European Medicines Evaluation Agency (EMA) via the Article 58 regulatory procedure for medicines intended for use outside of the EU. This should serve to speed up registration of red coloured tablets in developing countries.



A report from the UN-led Accelerating Access Initiative (AAI), suggests that by September 2006 more than 738,000 people living with HIV/AIDS in developing countries were receiving treatment with at least one ARV supplied by the seven pharmaceutical companies in the AAI (compared with 221,000 people on treatment in 2004). This includes 424,000 patients in Africa.

Extending preferential pricing

We are considering extending our preferential prices in Africa to a wider range of products. However, a number of commercial factors and the overall market environment must be considered. The findings from our five country pilot study are informing this evaluation.

VOLUNTARY LICENSING AND PARTNERSHIPS

GSK wants to play its part in the global response to the HIV/AIDS pandemic. Our preferential pricing arrangements enable us to supply highly discounted, safe and quality products for as long as they are needed. In some situations voluntary licences also help to increase the supply of medicines.

Voluntary licences (VL) enable local manufacturers to produce and sell generic versions of our products. We granted our first VL in 2001 and have now negotiated eight licencing agreements for our ARVs in Africa. This includes a new licence agreed in 2006 with a South Africa company. Some of our VLs cover individual countries or trade blocks whilst others cover all of sub-Saharan Africa. VLs are not a universal solution to HIV/AIDS but a specific response to a particular set of circumstances.

A decision to grant a VL depends on a number of factors including the severity of the HIV/AIDS epidemic in that country, local healthcare provision and the economic and manufacturing environment. Selecting the most appropriate licensee is key. We need to be sure that the manufacturer will be able to provide a long-term supply of good quality medicines and will implement safeguards to prevent the diversion of medicines to wealthier markets.

There has been much discussion about the use of compulsory licences, under which intellectual property rights are taken away from rights holders. Compulsory licenses are one of the flexibilities in the World Trade Organisation's TRIPS agreement on intellectual property. GSK believes that widespread use of compulsory licences will undermine the intellectual property framework and be counter-productive in the long term. R&D into new treatments, especially where commercial markets exist, such as for HIV/AIDS, depends on protection for intellectual property.

MIDDLE-INCOME COUNTRIES

Middle-income countries are more economically developed but often have healthcare demands that outstrip their available resources. These challenges are made worse by a growing AIDS epidemic in many middle-income countries.

We can only afford to supply products at low prices in the world's poorest countries if we can still make an adequate return on them in wealthier markets. Nevertheless, we recognise that many middle-income countries need assistance.

We negotiate preferential pricing arrangements with middle-income countries on a case-by-case basis. This is done bilaterally through dialogue with governments. We believe this is the best approach since the disease burden, and resources available to address, it vary significantly from country to country and also within countries. These arrangements combine a viable and sustainable commercial return for GSK with improved affordability for the healthcare systems concerned.

For several more developed countries we are also introducing discount cards for senior citizens, see developed world.

Activity in 2006

Russia

We announced an agreement to supply ARVs to the Russian Government at discounted prices. This is the first direct, federal purchase of anti-retroviral medicines in Russia. During 2006 GSK supplied over 90,000 treatment packs to the Russian Government of its HIV medicines, *Combivir*, *Epivir* and *Ziagen* which were dispensed by hospital centres across the country. This agreement will contribute to the Russian Government's target of reaching 15,000 patients by the end of 2006. This target has been doubled to 30,000 in 2007.

China

In September 2006, we signed a voluntary licence with Simcere, a Chinese manufacturer, granting them the right to manufacture and sell zanamivir (*Relenza*) containing products in China, Indonesia, Thailand, Vietnam and all LDCs. *Relenza* is an anti-viral which can help treat influenza. More than half of all human cases of flu caused by the H5N1 virus have occurred in the Asia-Pacific region.

Our not-for-profit prices in summary

Which medicines?

All our HIV/AIDS (ARVs) and malaria treatments.

Which customers?

Public sector customers and not-for-profit organisations in all eligible countries and private employers in sub-Saharan Africa who provide treatment for non-insured staff.

Which countries?

All the Least Developed Countries and sub-Saharan Africa, as well as countries with eligible Global Fund and PEPFAR projects – over 100 countries in total. See eligibility for not-for-profit prices in the background section of our website for more details.

What does it cost?

Combivir, our leading ARV, is available at \$0.65 a day. Our nfp prices also include delivery and insurance costs.

How much?

Our nfp prices are applicable to orders of any size and are not dependent on large order quantities.

For how long?

Our nfp prices are sustainable – we do not make a profit on them, but we do cover our manufacturing and distribution costs. Therefore we can continue to supply them in the long-term.

Intellectual property rights in India

India has developed a large generics industry partly as a result of national legislation that did not permit patent protection for pharmaceutical products. In 2005, to comply with the WTO Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement, India introduced legislation that allowed for the patenting of pharmaceutical products. In the context of the access to medicines debate, some argue that this obligation on India will result in an end to the provision of cheap generics and undermine the future availability of affordable innovative products.

GSK believes that the intellectual property protection provisions set out in TRIPS are vital to the development of medicines to meet unmet medical needs around the world. A robust IP system is essential to encourage research-based companies to undertake risky and hugely expensive R&D to discover new and better medicines and vaccines. Most of the generic medicines already on the market in India will not be affected by the introduction of patent protection. They will continue to be available in India and elsewhere in the same way as they are today. We also believe that the public health safeguards in the TRIPS agreement will prevent access problems in the future.

The root cause of developing countries' inability to address their healthcare problems does not lie with the patenting system but with a lack of funding, a lack of political will and inadequate healthcare infrastructure. None of these factors is affected by intellectual property rights or by full implementation of TRIPS in India or elsewhere.

DEVELOPED WORLD

Access to medicines is not just an issue for the developing world. Even in developed countries some patients cannot afford the medicines they need. This is a particular problem in the US where many people do not have health insurance. GSK has developed Patient Assistance Programs and a discount savings card in the US to help patients without insurance.

We are also introducing discount savings cards in several middle-income countries to enable qualifying patients to obtain prescription medicines at a discount price.

Programmes in the US

Patient Assistance Programs provide prescription medicines to low-income, uninsured patients free or at minimal cost. GSK operates several programmes, including [Commitment to Access](#) which covers cancer treatments and [Bridges to Access](#) which covers other medicines for out-patients. Patients are registered through one phone call from a patient advocate and receive medicine at their local pharmacy or by mail order. In 2006, 402,000 patients received GSK medicines worth \$370 million through these programmes, compared with \$464 million in 2005. The value of the medicines is calculated using the wholesale acquisition cost (WAC).

This is a significant reduction from last year and reflects the introduction of a new drug benefit as part of the [US Medicare programme](#) – known as Medicare Part D. Prior to this, Medicare patients did not have prescription coverage for most medicines. Once a patient had enrolled in a Medicare Part D Plan, they became ineligible for our existing patient assistance programmes ([Bridge to Access](#) and [Commitment to Access](#)). However we still recognise that, even with this drug coverage, these patients may still need assistance. A new programme GSK Access provides the extra help some low income senior and disabled Medicare Part D patients need in getting their medicines. This programme allows those who spend \$600 out of pocket in 2007 for prescription medicines, and whose incomes are between 135 percent to 250 percent, (up to 350 percent for Oncology products) of the Federal Poverty Level to apply and if eligible obtain GSK medicine for free for the remainder of 2007. See www.gsk-access.com for more information. We expect this new programme to increase the number of patients in our assistance programmes during 2007.

In January 2005, GSK and nine other pharmaceutical companies created a discount savings programme to improve access to medicines for uninsured Americans who are not eligible for Medicare. The [Together Rx Access](#) card provides savings of 25-40 percent on more than 300 medicines. Approximately 37 million people, around 80 percent of the people in the US without prescription insurance, are eligible to enroll. The participating companies enrolled 469,888 people in 2006, who received 1.6 million 30-day prescriptions saving \$24million (based on WAC). Of these, GSK provided discounts of \$3.1 million to 98,955 patients through 31,737 30-day prescriptions.

Orange Cards in middle income countries

Our [Orange Card](#) in the Ukraine gives all asthma and chronic obstructive pulmonary disease patients who are under 25 or over 50, an average discount of 19 percent on the most popular presentations of GSK's [Seretide](#) asthma medicine. Asthma patients of any age who suffer disabilities or who are affected by the Chernobyl nuclear disaster are also eligible. Eligibility is assessed by the patient's doctor and patients can receive the medicine at participating pharmacies. A hotline number has been set up to help patients find their nearest pharmacy. In 2006 [Orange Card](#) discounts totalled \$119,722 (£65,000).

In Lithuania, our [Orange Card](#) gives senior citizens and the disabled an average discount of 40 percent on the patient co-payment on all GSK prescription medicines. So far more than 25,000 patients have applied for an [Orange Card](#) and over 200 pharmacies (20 percent of the pharmacies in Lithuania) are registered to participate. In 2006, 25,000 patients received discounts worth £150,000.

GSK's *Orange Card* in Bulgaria provides low-income patients with a discount on GSK medicines to treat chronic diseases such as asthma, chronic obstructive pulmonary disease and diabetes. We broadened the scope of our *Orange Card* in 2006 in response to changes in the Bulgarian reimbursement system which meant that 50,000 patients with chronic diseases could no longer access state assistance for their currently prescribed medicines. The *Orange Card* provides direct benefits (in the form of subsidy) to patients suffering from three important chronic diseases in Bulgaria – asthma, diabetes and benign prostate hyperplasia. The 2006 GSK investment in the *Orange Card* in Bulgaria is now Euro 4.5 million (£3.1million).

Summary of GSK discount programmes			
Country	GSK programme	Number of patients	Value of benefit to patients
US	Patient Assistance Programs – Free or minimal cost medicines for low-income, uninsured patients	402,000 received prescriptions	\$370 million (£200 million)
US	<i>Together Rx Access</i> – Discounts for all low-income uninsured patients. Joint industry programme	98,955 received prescriptions	\$3.1 million (£1.6 million)
Bulgaria	<i>Orange Card</i> – Discounts for low-income patients with chronic diseases	50,000 approx	Euro 4.5 million (£3.1 million)
Lithuania	<i>Orange Card</i> – Discounts for senior citizens and disabled people	25,000	£150,000
Ukraine	<i>Orange Card</i> – Discounts on asthma and COPD medicine for patients under 25 or over 50	not available	\$120,000 (£65,000)