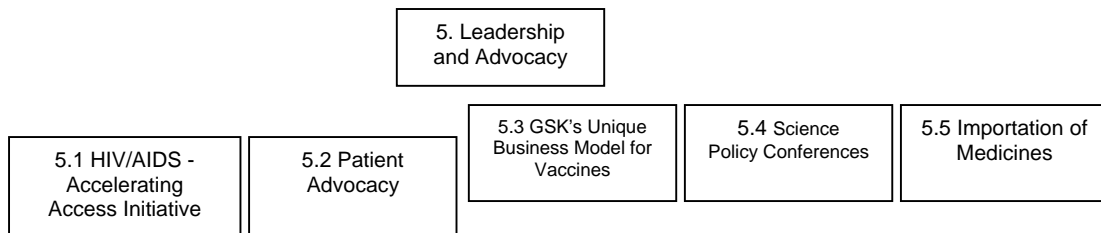


LEADERSHIP & ADVOCACY



Leadership 5

Leadership and Advocacy

Corporate responsibility principle

We will establish our own challenging standards in corporate responsibility, appropriate to the complexities and specific needs of our business, building on external guidelines and experience. We will share best practice and seek to influence others, while remaining competitive in order to sustain our business.

As a multi-national company we can use our influence and resources to address social issues and bring people together around a common cause. In some areas we can take a lead. For other issues, coordinated and sustained action by a group of stakeholders is required.

GSK participates in and leads several such partnerships. This section highlights five examples and gives a flavour of the wide range of projects we contribute to.

Further examples are featured throughout this report and the Corporate Responsibility section of this website and in our Media Room.

HIV/AIDS – Accelerating Access Initiative

GSK is a founder member of the Accelerating Access Initiative (AAI) formed in May 2000 as a Public Private Partnership between seven R&D based companies and five UN organisations (UNAIDS, WHO, WB, UNICEF and UNFPA)

The objectives of the AAI are to:

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

Data released in January 2005 by the AAI estimated that the number of patients in developing countries receiving ARV treatments supplied by the pharmaceutical companies in the AAI reached more than 333,000 by the end of September 2004. This includes 157,500 patients in Africa, a 50% increase since September 2003.

This increase is encouraging but much more needs to be done. The AAI companies are committed to working together to accelerate these trends and bring the benefits of HIV care and treatment to those in need. We will continue to work closely with affected communities, non-governmental organisations, the medical community, governments and multilateral organisations to improve existing initiatives and identify new opportunities.

GSK held the chairmanship of the AAI during 2004 and coordinated a process to review the initiative and ensure that it is as effective as possible in the fight against HIV/AIDS in developing countries.

Patient Advocacy

Patient advocacy groups provide their members with support and information on how to live with their disease, represent patient views and lobby on issues affecting patients' interests. They are an important stakeholder for GSK and we engage with them as part of our aim to be a patient-focused company.

Our annual Patient Advocacy Leadership Summit (PALS) is one of the ways we do this. The summit includes a forum for patient groups to learn more about GSK and tell us how we can better support their work. There are a range of workshops for attendees including sessions on media training and sharing best practice. Throughout the summit attendees receive information on GSK patient programmes, such as our *Orange Card* or disease management programmes.

In 2004, PALS was extended from the US to include patient groups worldwide. Over 400 people attended from 23 countries. Attendees represented 233 different advocacy organisations including those dedicated to mental health, HIV/AIDS, respiratory diseases, epilepsy, cancer, bone and joint diseases and diabetes.

Feedback from the event was very positive. For example 90% of attendees from Europe felt the event had been either an excellent or a good investment of their time. It also highlighted the key priorities for patients – more R&D, better information about their disease and access to the best available treatment.

GSK has a dedicated Global Advocacy Team which contributes to planning PALS and co-ordinates our interaction with patient groups. We have developed a code of conduct to guide our work with patient groups and a Patient Advocacy Manual of best practice for employees. This work is part of a company-wide effort. Other initiatives include 'Focus on the Patient' in R&D (see Focus on the Patient in the website for more information).

GSK's Unique Business Model for Vaccines

GSK's new rotavirus vaccine, *Rotarix*, received its first launch in Mexico in January 2005. As well as Mexico, *Rotarix* will be launched in other Latin American countries during 2005 and soon after in Asia Pacific countries. It has already been submitted for regulatory approval in more than 20 countries worldwide.

Rotavirus infection is the leading cause of severe diarrhoea and vomiting (gastroenteritis) in children under two. It affects children all over the world but is rarely fatal in developed countries. However in developing countries around 600,000 children die from rotavirus each year.

This is the first time that a major pharmaceutical company has focused the clinical and regulatory strategy for a vaccine first on a region of the world other than the European Union or US. The launch is part of GSK's unique strategy to deliver vaccines first to people with the greatest medical need.

"GSK has a solid track record of providing vaccines globally for more than 20 years and is constantly developing novel and unique approaches to ensure new vaccines get to those areas of the world who need them most as fast as possible", said Jean St ephenne, President and General Manager of GSK Biologicals. "In the case of *Rotarix*, we focused our clinical and regulatory strategy first on countries where the medical need for a rotavirus vaccine was one of the highest in the world."

Rotarix was tested in the largest phase III clinical trial ever performed for a vaccine. It involved 70,000 children, mostly in Latin America and Asia but also in US and Europe.

Science Policy Conferences

GSK R&D is sponsoring a series of annual science policy conferences in the UK on issues relating to the conduct of pharmaceutical and biomedical research. The aim is to promote discussion and dialogue between key stakeholders including policy makers, regulators, pharmaceutical companies, scientists, doctors and patient groups.

The first conference took place in 2003 and was organised in conjunction with the Department of Health and the National Institute for Clinical Excellence. It focused on how medicines are evaluated by regulators, pharmaceutical companies, patients and other stakeholders and looked at how the current system could be improved to address medical needs more effectively. It highlighted a potentially important role for the NHS as a source of research data for evaluating medicines in clinical practice.

In 2004 the conference was organised with the Department of Health and the Academy of Medical Sciences. It looked at issues influencing the quality of clinical research in the UK including the regulatory framework, funding mechanisms, the provision of infrastructure and the importance of adequate career development and training provisions. It highlighted actions needed to improve clinical research for the benefit of patients, for example, the need to increase patient involvement by putting more information on clinical research into the public domain.

Importation of Medicines

The price of brand name prescription drugs is often lower in other countries than in the US. For this reason, some people in the US have started to buy prescription drugs from abroad, often over the internet. The US Food and Drug Administration (FDA), which has not approved the drugs that foreign vendors offer for sale to Americans, has warned that this is illegal and unsafe.

GSK has consistently opposed this practice because of the increased safety risks to patients. Our view of the risks was confirmed in 2004 by a report from the Department of Health and Human Services (HHS) Task Force on Drug Importation, chaired by the Surgeon General Richard H. Carmona. The task force looked at safety issues around illegal drug importation and the potential for cost savings to be made if the practice were made legal. The full report can be found online at <http://www.hhs.gov/importtaskforce/>.

According to the report, drugs imported by consumers come into the US from a wide range of countries. These drugs are typically not approved by the FDA and may fail to conform in many aspects to the FDA-approved drugs available in the US. Specifically, the report found that, "Importation increases the opportunities for counterfeit and other substandard drugs to enter and be dispersed into the US drug distribution system... American consumers currently purchasing drugs from overseas are generally doing so at significant risk."

The Task Force concluded that it would be "extraordinarily difficult" to ensure that drugs imported by individual consumers meet the necessary standards for safety certification. Noting that the FDA does not have sufficient resource now to ensure the safety of personally imported drugs, the Report concludes that, "There is no realistic level of resources that could ensure that personally imported drugs are adequately inspected to assure their safety since visual inspection, testing and oversight of all personally imported prescription drugs are not feasible or practical at this time."

The Task Force report states that there are a number of new anti-counterfeiting technologies in development that, once they are universally adopted, may provide assurance on the safety and authenticity of prescription medicines. However it noted that, "widespread adoption of authentication technologies, while theoretically able to secure the US drug supply, is a daunting task that could raise the cost of imported drugs thereby reducing any expected savings from importation".

The report concludes that the cost of carrying out safety checks on imported medicine, and profits going to middlemen, would in large part offset the potential savings from differences in prevailing prices. Based on an analysis of actual data on drug prices and volumes, the Task Force found that, "Total savings to drug buyers from legalised commercial importation would be one to two percent of total drug spending and much less than international price

comparisons might suggest. The savings going directly to individuals would be less than one per cent of total spending. Most of the savings would likely go to third party payers, such as insurance companies and HMOs.”

The report findings have confirmed our view that patients should stick to trusted methods for saving money on approved medicines, such as savings cards, that are legal and safe. GSK is sensitive to patients’ concerns over costs and the lack of prescription drug coverage for the uninsured in the US. That is why we led the industry in establishing the first prescription savings card – the *Orange Card* - and are a founding member of the *Together Rx* programme.