

Pharmaceuticals Europe

GSK protecting against disease through vaccines



The Value of Vaccines

Foreign substances in the body, known as antigens, prompt an immune response. A vaccine is an antigenic preparation used to establish immunity to a disease. With the exception of clean drinking water, no other human health intervention has the impact of vaccination in reducing infectious diseases. Each year, vaccines prevent up to three million deaths and save 750,000 children from disability. Vaccination also contributes to social and economic development by reducing disease outbreaks and the loss of productivity, decreasing hospitalisations and the need for expensive treatments, and limiting the long term effects of disease on society.

Innovative vaccines

We produce around 25 marketed vaccines. More than half are combination vaccines to protect children, adolescents and adults against between two and six diseases at the same time. We are proud of our pipeline of new products which is one of the most robust in the industry with approximately 20 vaccines currently in clinical development.

New vaccines

In the next five years, we expect to launch new vaccines in four diseases: an HPV (Human Papilloma Virus) to prevent cervical cancer, a pre-pandemic flu vaccine and an improved seasonal flu vaccine for older people, and a meningitis combination vaccine for infants.

Every second, more than 35 people somewhere in the world are protected with a GSK vaccine. We supply one quarter of the world's vaccines.

Innovative technologies

Our unique expertise in adjuvant technology could make a difference in protecting against killer diseases like malaria, cervical cancer and pandemic flu. Adjuvant systems activate different parts of the immune system and enhance the immune response, for example they can induce:

- a strong immune response to complex diseases like malaria
- long-term protection against the HPV virus which causes cervical cancer, and
- a broader immune response for a pre-pandemic flu vaccine to be effective.

Diseases of poor countries

GSK is the leading supplier of vaccines to the developing world. We dedicate substantial proportions of our research and development programmes to diseases which affect the poorest countries and are proud to be the number one provider of vaccines to UNICEF. These vaccines are often delivered in partnership with UNICEF, GAVI Alliance and Pan-American Health Organization (PAHO) at highly preferential prices.

We have been working on a malaria vaccine for over 20 years. A clinical trial conducted in Mozambique showed unprecedented results promising the world's first effective malaria vaccine for children. If the results of current trials continue to be promising, this vaccine will enter pivotal Phase III trials in mid-2008 and is expected to be submitted for registration by late 2010 and launch as early as 2011.

In March 2007 we announced the submission of a regulatory file to European Medicines Agency (EMA) for the combination vaccine candidate *Globorix*TM (diphtheria, tetanus, pertussis, hepatitis B, Haemophilus influenzae type b, Neisseria meningitidis serogroups A and C). This vaccine candidate could be available as early as 2008 and has the potential to break the cycle of meningitis epidemics in Africa.





“I’d like to thank Jean-Pierre Garnier for GSK’s incredible commitment to R&D on malaria and on other neglected diseases. It would make a huge difference if more companies follow GSK’s example”

Bill Gates, who supports the Malaria Vaccine Initiative through the Bill & Melinda Gates Foundation

Public-private partnerships (PPPs)

Innovative partnerships enable public institutions and private companies to make joint contributions to the investment needed to discover and develop new vaccines.

We have been exploring two new public-private partnerships as a means of developing an AIDS vaccine. One of these is an agreement with the International AIDS Vaccines Initiative (IAVI) and the other is a partnership with the Institut Pasteur, a non-profit private foundation dedicated to the prevention and treatment of infectious diseases. At the same time, we are continuing to develop our own candidate vaccine. A partnership has also been set up with the AERAS Foundation, a major participant in the fight against TB, to continue to develop our candidate vaccine for tuberculosis (TB). In addition we have signed a new agreement with the Malaria Vaccine Initiative to continue to develop our candidate vaccine against malaria until it is filed, hopefully around 2010.

Priority to the most affected countries

As far as possible, we carry out our clinical studies in the countries with the greatest medical need. This strategy enables us to vaccinate and monitor people who would otherwise generally only have limited access to healthcare, and also to encourage rapid registration in these countries.

One such example is *Rotarix*™, a rotavirus vaccine for children, which was first registered in Latin America, where the disease burden is very high. Rotavirus is responsible for severe gastroenteritis which kills one child every minute, predominantly in countries with poor access to healthcare. Today this vaccine is licensed in 97 countries including France, Estonia, Czech Republic and Germany.

Price differentiation policy

For over 20 years we have operated a price differentiation policy so that everyone can benefit from our vaccines. By adapting prices to countries’ financial capabilities, volumes ordered and long-term contracts, we are able to distribute vaccines worldwide whilst maintaining the investment needed to continue research and development into new vaccines.

Transparency

Since 2004, we have taken the industry lead in publicising the results of our clinical studies once products are marketed. In 2005 GSK became a pioneer when we put the results of over 90 studies online. Today, GSK’s Clinical Trial Register www.ctr.gsk.co.uk contains over 2,000 study summaries. Information about vaccines in development can also be accessed through the National Institute of Health site in the United States: www.clinicaltrials.gov.





Shared expertise

To promote appropriate and effective vaccination programmes, we invest in training for healthcare professionals to become experts in vaccinology. In 2005 experts from GSK gave training in over 20 countries at the request of local ministries of health and universities.

Since 2002 we have supported the work of the Network for Education and Support in Immunisation (NESI) to promote vaccinology training for healthcare staff in the poorest countries.

Responding to global medical needs

For each vaccine that we create, we also produce a specific development, registration and distribution strategy. This strategy depends on the circumstances, such as setting up partnerships, registration priorities in countries and price differentiation according to the markets.



Key facts

- GSK Biologicals is one of the world's leading vaccine producers. Our Rixensart site in Belgium is the base for GSK's vaccine research, development and production
- Over 1.1 billion doses of vaccine were distributed to 169 countries in 2006
- 9 in every 10 doses were distributed in developing countries
- Over 25 vaccines available worldwide and over 20 vaccines in clinical development
- GSK Biologicals has close to 8,000 employees worldwide and over 1,500 scientists
- GSK has a dedicated group within its pharmaceutical R&D organisation which focuses on diseases of the developing world and has also invested more than two decades in the effort to develop a malaria vaccine. GSK was awarded the 2006 Frost & Sullivan Global Excellence Award in Malaria Prevention and Treatment for its commitment to reducing the burden of malaria in developing countries.



For more information please see
<http://science.gsk.com/pipeline/index.htm>