A laboratory for

From its headquarters in Rixensart, GlaxoSmithKline Biologicals supplies around a quarter of all vaccines used throughout the world.

Denzil Walton

REUTERS

Vaccine development, GSK Biologicals' main area of expertise

Every year, 3 million deaths are prevented and 750,000 children are saved from disability by vaccines. Immunised children reportedly have significantly higher scores in IQ tests, language and maths. At a societal level, vaccinations decrease hospitalisations, reduce the need for expensive treatments, and limit disease outbreaks and the long-term effects of disease. With the exception of clean drinking water, vaccines are the most cost-effective intervention for economic development.

Vaccines have helped to bring many diseases under control. Examples are poliomyelitis, measles and smallpox. However, many diseases are still not preventable by vaccination. The search continues for vaccines to prevent some of the world's most common diseases such as cancer, HIV/Aids and malaria. One of the world's leaders in vaccine research, development and production – GSK Biologicals – is based in Rixensart, 20km south-east of Brussels. GSK Biologicals is the vaccine division of pharmaceutical company GlaxoSmithKline.

GSK Biologicals today supplies about a quarter of the world's vaccines. This translates into approximately three million vaccine doses delivered each day to 165 countries around the world. The company makes 30 vaccines that variously help protect people against malaria, hepatitis A and B, rubella, varicella, poliovirus, tetanus, measles, typhoid, influenza, diphtheria and meningitis. It also produces doses of combination paediatric vaccines, offering children protection against as many as six diseases with just one shot.

The company has recently developed a paediatric vaccine against rotavirus gastroenteritis, a disease which claims the life of one child every minute. "Our Rotarix™ vaccine is extremely important in our fight against this crippling form of gastroenteritis and is the only rotavirus vaccine that offers protection for infants as young as ten weeks of age," says Anne Walsh, vice-president of GSK Biologicals Global Communications. "This oral two-dose vaccine was first launched in 2005 in Mexico, followed by other countries that needed it most. Since then more than forty-three million doses have been distributed worldwide. Rotarix prevents millions of hospitalisations each year."

More recently, in March 2009, Synflorix™ was approved by the EU. This is GSK Biologicals' next generation paediatric vaccine against pneumococcal disease and middle ear infection. It is uniquely designed to target two major pathogens – *Streptococcus pneumoniae* and *Haemophilus influenzae* – which

sustaining life

currently lead to a huge healthcare burden. "Synflorix has the potential to prevent up to ninety percent of paediatric invasive pneumococcal disease in Europe," adds Walsh. "Middle ear infection is the most common reason for physician visits in children under three years."

The complexities of vaccine production

Worldwide, GSK Biologicals employs over 9,500 people, of whom 1,600 are scientists devoted to discovering new vaccines. Vaccines account for nearly 13 percent of the turnover of GlaxoSmithKline. But just what is involved in the complex process of developing a vaccine? The activities of GSK Biologicals in Rixensart are divided into six interacting departments.

The **Worldwide Regulatory, Epidemiology & Safety** department aims to ensure that every one of the vaccines produced by the company meets the highest standards of industry practice and safety. The department covers four main areas of expertise:

- Developing regulatory strategies for new and life cycle vaccines based on sound science
- Submitting vaccine registration dossiers and following up with health authorities worldwide
- Overseeing safety evaluation and risk management
- Anticipating clinical safety issues that may arise both before and after approval.

The **Research & Development** department gives the business its competitive edge, both in improving the quality of existing GSK vaccines and in generating ideas and concepts for innovative new products. Here, R&D scientists seek to push back boundaries in four disease areas: viral & allergy vaccines; bacterial vaccines; emerging diseases & HIV; and cancer vaccines. A substantial proportion of the R&D programme is oriented towards controlling diseases that hit the poorest countries hardest. At the moment clinical studies are being carried out to assess the efficacy of vaccines against TB, HIV/Aids, and malaria, while vaccines for dengue and other developing world diseases are at an earlier stage of development.

Operating in a truly global capacity, from Rio to Singapore, Germany to Nigeria, the **Worldwide Clinical Development** department is responsible for everything from setting up and monitoring clinical studies all over the world, to developing study protocols and creating reports. It sounds dry, but the department's work is as much about people as statistics. A key emphasis is on partnering with local hospitals and universities so that clinical trials can be conducted in the region where the vaccine will ultimately be used.

Once pioneering treatments have been developed, they are manufactured and distributed across the regions that need them most. Accomplishing this as efficiently and quickly as possible can quite literally be a matter of life and death. So it's no wonder that more than 70 percent of the workforce of GSK Biologicals is based within **Global Industrial Operations**. It's the essential business unit that manufactures and manages the entire vaccine supply process, from customer order to product dispatch on a global scale.

GSK Biologicals is determined to push back the frontiers of pharmaceutical knowledge to increase well-being and life expectancy around the world. For this to happen, the company's products must remain competitive in the marketplace. The **Global Biologicals Commercial Operations** department was created to maximise the company's sales and the value of its products in development. The department also maintains relationships with supranational organisations, sharing its expertise on government affairs, commercial and pricing issues, and the overall healthcare environment. Thanks to these relationships, six out of every ten doses go to supranational bodies for large-scale vaccination campaigns, largely in the developing world.

As GSK Biologicals continues to develop its business, it's vital to ensure that the most suitable structure is in place to support future growth. The company is in the enviable position of having a number of innovative products in the pipeline. However, the longer it takes to deliver these vaccines, the greater the potential cost in human lives. The newly created **Global Vaccines Development** division is responsible for organising this portfolio of upcoming vaccines as quickly as possible.

Vaccines for everyone

It is clearly important that vaccines should be made available to everyone who needs them. For GSK Biologicals, this means that they must not only develop and manufacture quality vaccines, they must also maintain investments in R&D and partner with organisations to accelerate vaccine R&D, financing, production and delivery.

> The search continues for vaccines to prevent some of the world's most common diseases such as cancer and malaria

To ensure that its vaccines reach the maximum number of people, wherever they live, a key aspect of GSK Biologicals' philosophy is to use pricing approaches which reflect a country's ability to pay.

"GSK Biologicals pioneered tiered pricing over twenty years ago," explains Walsh. "Basically it means that the price of a vaccine varies with a country's ability to pay. Typically, prices paid by the poorest countries are about ten to twenty percent of those paid in the richest countries."

GSK Biologicals' innovative Global Business Model – addressing the needs of the developing world – has led to the provision of vaccines to some of the most disadvantaged regions of the world at preferential prices. The company is a primary vaccine supplier for international organisations such as GAVI and UNICEF, and works closely with policy-makers to establish vaccination policies and ensure vaccines are available to all.