

## **GlaxoSmithKline and Cervical Cancer Prevention**

### **Continuing a Commitment to the Developing World**

#### **Introduction**

Worldwide, every two minutes a woman dies of cervical cancer<sup>1</sup>. Most cases and deaths, approximately 80%, occur in developing countries, where in the absence of cervical cancer screening programmes it is the leading cause of cancer deaths in women<sup>1</sup>. As with all its other vaccines, GlaxoSmithKline (GSK) is committed to make its cervical cancer vaccine – once registered – available to all women, no matter where in the world they live.

#### **Generating Data in Low Income Countries**

- GSK is conducting its own clinical trials to generate data in low income settings, which will be available in 2008. The company is also in discussions with organizations such as PATH regarding potential collaborations on demonstration projects that will generate data that could help to accelerate the introduction of HPV vaccines in the developing world. As part of its contribution to the collaboration with PATH, GSK will donate doses of its cervical cancer vaccine to the agreed upon demonstration projects.

#### **Registration of Cervical Cancer Vaccine in Low Income Countries**

- GSK demonstrated its commitment to making vaccines available to middle and low income countries through its registration strategy for its rotavirus vaccine by submitting the file to all countries – high, middle and low income – interested in registering the vaccine. This same strategy is now being used with the cervical cancer vaccine. To date the file has been submitted to 59 countries including Tanzania, and Uganda. In June 2007 Kenya became the first low income country to approve GSK's cervical cancer vaccine.

#### **WHO prequalification**

- In order to be eligible for purchase by UN agencies, a cervical cancer vaccine will have to be prequalified by the WHO. The file cannot be submitted to WHO until it has been approved by a WHO recognized national regulatory authority and files will only be accepted by WHO in January, May and September of each year. A cervical cancer vaccine will not qualify for "fast track" status, as it will be viewed as a novel vaccine. GSK will submit its application to the WHO for prequalification as soon as it has received EMEA approval and it should receive prequalification approximately one year after submission.

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<sup>1</sup> Ferlay J et al. Globocan 2002. IARC 2004.

# GLOBAL PUBLIC POLICY ISSUES

## Pricing

- Tiered pricing is a fundamental part of the GSK's vaccine business model and has been used for more than 20 years. As with its other vaccines, GSK will provide its cervical cancer vaccine at preferential prices to low income countries. The price for these countries will be determined by volumes, the length of time of a contract, and the guaranteed number of doses to be purchased by supranational organizations. The higher the volume, the longer the contract, and the greater the guaranteed number of doses, the lower the price.

## Conclusion

GSK is committed to making its cervical cancer vaccine – once registered – available to all women throughout the world. The factors stated above will play a role in determining when low income countries will introduce the vaccine and when supranational organizations will be ready to commit to purchasing it. GSK will continue to do all it can to accelerate the introduction and uptake of HPV vaccines in the low income countries.

## BACKGROUND

### **GSK's Commitment to Widespread Access to Vaccines**

GSK is one of the world's leading vaccine manufacturers. The vaccine business (GSK Biologicals) is located in Rixensart, Belgium and is the centre of all GSK's activities in the field of vaccine research, development and production. It is committed to developing and supplying vaccines to both industrialised and developing countries. In 2006, the company distributed more than 1.1 billion doses of vaccine to 169 countries. Seventy-five percent of these doses went to developing countries. GSK demonstrates its long-term commitment to the developing world through its research and development efforts, public-private partnerships, supply agreements, increased manufacturing capacity, and pricing mechanisms.

### **Research and Development**

GSK has one of the largest development pipelines in the vaccine industry. Of the more than 25 vaccine projects in the pipeline, approximately one-third are focused on diseases prevalent in the developing world. These include vaccines for pneumococcal diseases, meningitis, and dengue. GSK is the only company with vaccine development programmes for each of the "big three" global infectious diseases: HIV/AIDS, malaria, and TB.

### **Working in Partnership**

Developing a new vaccine is an extremely complicated process that can require an investment of more than €500 million. In comparison to industrialised countries, the demand and financing for vaccines is far less certain in developing countries. To reduce some of the financial risk and accelerate the development process, GSK is committed to working closely with Product Development Partnerships (PDPs). These PDPs are focused on developing and introducing new health technologies for low-income countries. In 2005, GSK entered into a partnership with the Malaria Vaccine Initiative (MVI) to continue the development of our vaccine candidate Mosquirix™, also known as RTS,S.

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That same year, it finalised agreements with the International Aids Vaccine Initiative (IAVI) and the Aeras Global TB Vaccine Foundation.

## **Supply Agreements**

The development of a vaccine against rotavirus, dengue, malaria, and other diseases is only part of the company's goal. To fully achieve the goal, these vaccines must get to the people who need them the most as quickly as possible. To do this, GSK has built strong relationships with leading international organizations that purchase vaccines for the low income countries. GSK is a major supplier of vaccines to UNICEF, the GAVI Alliance, and PAHO.

## **Pricing Mechanisms**

A fundamental component of GSK's vaccine business model is "tiered pricing," which the company has utilized for more than 20 years. For the public vaccine markets, GSK charges different prices for different groups of countries depending on Gross National Income (GNI). The price is on a sliding scale with the highest prices charged in the world's wealthier economies and the lowest prices in the world's poorest countries. The price at the lower end of the scale also takes into consideration the length of a contract and volumes to be purchased by an international organization for countries in the lower GNI categories.

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