

GlaxoSmithKline, Pandemic Preparedness and Developing Countries

GSK remains committed to supporting governments and health authorities around the world with their pandemic planning and responses, as demonstrated during the 2009 H1N1 pandemic and GSK's endorsement of the WHO PIP (Pandemic Influenza Preparedness) Agreement adopted by the World Health Assembly in May 2011. This commitment includes addressing the needs of developing countries and their concerns over timely access to medical interventions.

In recent years, GSK has invested significantly in the development and increased manufacturing capacity of our adjuvanted pandemic vaccines and antiviral, *Relenza*TM. This enabled us to supply substantial quantities of these essential products during the H1N1 pandemic to many developing countries, through donations or at reduced (tiered) prices. GSK has agreed to provide similar support at the time of the next pandemic, via the 2011 PIP Agreement.

Pandemic Vaccines

GSK's pandemic vaccine development, particularly in using antigen-sparing adjuvant technology, allowed for the provision of substantial quantities of pandemic vaccines during the 2009/10 pandemic. At the time, GSK's offer of H1N1 vaccines included:

- an undertaking to donate 60 million vaccine doses to the WHO for developing countries (of which just over 24 million were actually required).
- a commitment to ringfence 10% of GSK's global H1N1 vaccine production capacity for supply to developing countries at tiered prices according to their World Bank Gross National Income classification.

GSK has also demonstrated its willingness to extend influenza vaccine manufacturing globally via technology transfer programmes. For example, in June 2009 we announced a joint venture in China with Shenzhen Neptunus, which became a 100% GSK-owned operation in mid-2011. This initiative will result in the development and manufacture of seasonal and pandemic influenza vaccines in China.

Antivirals - *Relenza*TM (zanamivir)

Running up to the H1N1 pandemic, GSK invested substantially in increased production capacity for *Relenza*TM, resulting in a threefold increase in our previous maximum capacity.

This new capacity was achieved by increasing production levels of *Relenza*TM *Diskhaler*TM from 60 million treatment courses to 90 million. We also built new capacity to produce 100 million treatment courses a year of an unlicensed alternative delivery version of *Relenza*TM which received Temporary Authorisation from a number of European regulatory authorities during the H1N1 pandemic.

To help support equitable access to *Relenza*TM by developing countries, GSK allocated a minimum of 10% of its *Relenza*TM production capacity for developing countries for sale at tiered prices. Included within this capacity was the offer to donate 2 million courses of *Relenza*TM to the WHO for use in developing countries during a pandemic. In the event, the WHO decided against activating GSK's offer during the H1N1 pandemic.

GSK remains committed to engaging in voluntary license discussions with any companies willing to manufacture and supply zanamivir-containing products for developing countries. For example, in 2006 we granted the Chinese manufacturer, Simcere, a Voluntary Licence for the manufacture and sale of zanamivir-containing products in China and a number of other developing countries, including all Least Developed Countries.

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