

## **Pandemic Preparedness**

### **Roche takes steps to assist pandemic preparedness**

Roche, the manufacturer of the oral influenza antiviral Tamiflu, has been working for many years with multiple stakeholders to strengthen global pandemic preparedness.

### **Ensuring a sustainable supply of Tamiflu**

- As of August 2010, Roche fulfilled government pandemic orders amounting to 220 million treatment courses of Tamiflu'
- Roche has sufficient global manufacturing capacity for Tamiflu to enable governments to stockpile for a potential pandemic. Up to 400 million treatment courses can be supplied annually if required
- Roche has agreements with 19 external contractors from around the world to produce substantial quantities of Tamiflu ingredients as well as the finished product to ensure a robust supply chain

### **Increasing access to Tamiflu**

Roche has undertaken a number of initiatives to increase access to Tamiflu, notably:

- Implementing a differentiated pricing policy for governments for capsules and Active Pharmaceutical Ingredient (API)
- Extending the shelf-life of Tamiflu from five to seven years in a number of markets including the US and Europe
- Developing smaller capsules for children
- Reprocessing expired capsules through a method being developed to extract the active pharmaceutical ingredient and repackage the content to 're-set the clock' for shelf life
- Providing stability data to governments to help them extend the shelf-life of their stockpiles

### **Support for developing countries**

Roche works to ensure access to Tamiflu in developing countries in a number of ways, including:

- Donation of millions of treatment courses to the WHO to establish a rapid response stockpile for containment of a pandemic as well as regional stockpiles for use in pandemic situations. In total Roche has donated 10.9 million courses of treatment
  - 2004: 250,000 packs
  - 2005: 3 million packs (held by Roche until WHO requested their distribution in May 2009)
  - 2006: 2 million packs (regional stockpiles provided to WHO)
  - 2009:
    - An additional 5 million packs to replace the 2005/2006 donations which were distributed early in the 2009 pandemic to countries in need
    - An additional 650,000 courses of paediatric treatment (2009)
- No patents are held for Tamiflu in the world's Least Developed Countries including the African subcontinent
- Offering a tiered pricing policy distinguishing between developed and developing countries
- Creating the Tamiflu Reserves Program which provides Tamiflu and storage of pandemic stockpiles for developing countries at a significantly reduced price
- Granting sub-licences to three manufacturers (Hetero, Shanghai Pharma and HEC) to produce generic Tamiflu (oseltamivir) for pandemic use in China, India and developing countries
- Knowledge transfer granted to a South African manufacturer, Aspen Pharmaceuticals, to produce oseltamivir for pandemic use in Africa

### **Contributing to scientific knowledge**

- Diagnostic kit developed for detecting the pandemic (H1N1) 2009 virus by Roche Applied Science
- Clinical studies and pharmacovigilance activities in place to collect data on the use of Tamiflu in the current pandemic situation