

Pharmaceuticals Europe

Pandemic Flu playing our part to help the world prepare



Our commitment

Recent cases of birds and other animals dying from avian influenza in Europe and elsewhere have heightened concerns that the world could be on the brink of a flu pandemic. According to the World Health Organization (WHO), as of April 2007, H5N1 has now been responsible for 172 human deaths in 11 different countries. As a result many countries have introduced or updated their pandemic preparedness plans.

As a leading producer of vaccines and antiviral medicines, GSK is fully committed to playing its part in helping governments and international organisations prepare for a pandemic. We have recently invested €1.7 billion in expanding our manufacturing and research capabilities into both vaccines and antivirals.

In addition we understand the concerns of developing countries around securing access to vaccines. We therefore support the WHO's call for the creation of an H5N1 stockpile for vulnerable low income countries who lack the resources to purchase vaccines. This stockpile would be financed by supranational organisations and donors and GSK would provide the stockpile with vaccines at preferential prices.

Developing a pandemic influenza vaccine

Influenza pandemics occur when a new virus emerges, normal or seasonal vaccines do not provide proper protection, and a completely new vaccine is required. While H5N1 is a highly pathogenic virus which is common in birds and has caused serious illness and death in humans, it currently lacks the ability to be easily passed from human to human. Therefore there is no human pandemic strain of the influenza virus, however, this could change if H5N1 mutates to spread easily between humans.

GSK is developing a pre-pandemic H5N1 vaccine and in March this year we published data which showed that our vaccine was effective against different strains of H5N1. The vaccine was shown to provide “cross protection” against H5N1 and through the use of adjuvant technologies (which increase the body’s immune system) was effective at low doses.

GSK has filed its pre-pandemic vaccine in Europe and Governments are now in a position to consider stockpiling H5N1 vaccines in advance of a pandemic situation. Prior to this development it was thought that it would take up to six months to produce the first vaccines once a pandemic had been declared.

A flu pandemic will cross national borders and no country can expect to escape its effects. The challenges of a potential pandemic can only be met by the public and private sectors working together in partnership. The industry has already invested significant resources in the development of new vaccines and technologies, such as pre-pandemic vaccines.

Governments can help support the continued development of these vaccines by ensuring the widest possible access to vaccines across the world. Other areas for consideration include:

- Financing R&D for technical and clinical activities to accelerate flu vaccine development
- Committing funds to flu pandemic preparedness ahead of any pandemic occurring
- Entering into purchase agreements for pre-pandemic vaccines suitable for a proactive vaccination policy to minimise the impact of a pandemic on the population
- Entering into advance purchase agreements for the pandemic vaccines
- Ensuring the right regulatory balance – specific surveillance programmes must be put in place to monitor the safety and efficacy of the new pandemic vaccines, but it would be inappropriate for normal liability rules to be applied once a pandemic occurs. More appropriate rules need to be put into place before a pandemic occurs
- Increasing seasonal flu vaccination programmes.





Antivirals

Vaccines are the most effective way of protecting people from pandemic flu. But antivirals also have a role to play in helping treat or reduce the impact of the disease, especially in the early stages of an outbreak.

GSK's antiviral, *Relenza*® (zanamivir) is an inhaled prescription medicine for the treatment of influenza. Until recently, the demand for *Relenza*® has been very limited, but research has suggested that the class of antivirals to which *Relenza*® belongs might be effective against H5N1.

This has led to an increase in demand from Governments wanting to stockpile antivirals for use in the event of a pandemic.

Ensuring all countries are prepared

A pandemic could start in any country, but some low income countries are more vulnerable than others. In addition to expanding our own production capacity we have signed a voluntary licence with a Chinese manufacturer, Simcere, to allow them to produce zanamivir for the world's poorest countries and those most likely to be at the epicentre of a pandemic.

Working with the World Health Organization

It is in all our interests to try to contain a pandemic, or at least reduce the speed at which it would otherwise spread. If a pandemic does occur, the WHO will play a pivotal role in coordinating the global response. GSK stands ready to help.





Continuing to play our part

By continuing to invest in research and development, and increasing antiviral and vaccine manufacturing capacity, we are demonstrating our commitment to helping Governments and international organisations prepare for a pandemic. That commitment will be maintained.



Key facts

- Our mission is to improve the quality of human life by enabling people to do more, feel better and live longer
- We are a research-based pharmaceutical company
- 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
- We believe GSK remains the only pharmaceutical company researching both new vaccines and treatments for HIV and AIDS, TB and malaria – the World Health Organization's three priority diseases
- Globally our business employs over 100,000 people in 116 countries
- We supply one quarter of the world's vaccines and have 20 vaccines in clinical development
- Over 15,000 people work in our research teams to discover new medicines
- We screen about 65 million compounds every year in our search for new medicines.



For more information please see gsk.com