Q & A on vaccine development

29 April 2009

Is there a human vaccine against novel influenza virus A(H1N1)?

There is at present no vaccine available against the novel influenza virus A(H1N1). The only vaccines currently available are against the 2008/2009 strains of seasonal influenza.

Is the human seasonal influenza vaccine effective against novel influenza virus A(H1N1)?

It is not known for sure whether the current 2008/2009 human seasonal influenza vaccines can provide any protection against the A(H1N1) virus. Since this new influenza virus evolves rapidly it is important to develop a vaccine against the same virus strain that is causing the outbreaks in Mexico and other countries in order to provide maximum protection.

There are common features between the usual H1N1 human influenza viruses (covered by the seasonal vaccine) and the novel influenza virus A(H1N1) so one cannot rule out some level of cross-protection, but if so this is likely to be only partial.

How is a vaccine developed?

The virus is taken from an infected patient (via oral swab) and inserted into a fertilised chicken egg. The virus grows in the egg and then through laboratory processes the virus is taken out of the egg and manipulated and made into a seed strain. This seed strain is tested for safety and stability. Once this is established, the seed strain forms the basis for bulk production. A vaccine for human use can only be release once tested clinically. Dosages are then filled in vials and ready to use syringes following additional safety tests.

When will the A(H1N1) vaccine be ready?

The first step involves the creation of the seed strain – this is ongoing and will take 2-4 weeks.
This is followed by the bulk production phase which takes about 4 weeks. Once there is enough stable material available, a period of testing in humans is required for safety and efficacy. Only after this is confirmed will the first batches be released into the market. Following this, mass production and distribution can start. An optimistic forecast for this process is between 3-6 months. Priority will also be given to developing a single dose vaccine.

What is the Commission doing to support vaccine development?

The Commission is one of the world's most important supporters of flu vaccine research. Most of the support comes through the 7th R&D Framework programme and is used for to the development of new vaccination strategies. Uptake capabilities for new strains of public laboratories and commercial producers have been strengthened.

Since 2005 the Commission has been supporting under the EU Public Health Programme the FLUSECURE project which aims to improve pandemic influenza vaccine preparedness for the European population. FLUSECURE is based on a consortium of health institutes from 10 different EU Member States, coordinated by the Netherlands Vaccine Institute. They develop a library of safety tested reference pandemic vaccine strains and reagents for European vaccine manufacturers and participating institutes.

In order to develop a vaccine as quickly as possible FLUSECURE has started the production of seed strains for the H1N1 influenza virus by innovative reverse genetics in Denmark (the Statens Serum Institute), in Germany (the Robert Koch Institute and in the UK by the National Institute for Biological Standards and Control (NIBSC). This institute associated with the London WHO collaborating centre is one of the main centres for providing seed stocks to manufacturers for vaccine production globally.

A FLUSECURE network of clinical centres is operational and ready for trial studies, as soon as the first samples of the A(H1N1) in need of testing become available.

More information on FLUSECURE http://www.nvi-vaccin.nl/nvi_projectsites/?id=43

Will the development of A(H1N1) vaccine interfere with seasonal flu vaccine production?

As a matter of fact, this is the time of the year where preparations of the production of the seasonal vaccine for 2009/2010 are starting. Technical and manufacturing resources of the producers are already under high demand. The current recommendation is to continue with the preparations for seasonal vaccine until further results and data on the new A(H1N1) virus strain are available. A way out of the resource constraints would be to combine the novel strain vaccine with the proposed 2009/2010 seasonal vaccine, at least for part of the dosages to be put on the market.

For more information on vaccine development, please see the European Medicines Agency website http://www.emea.europa.eu/htms/human/pandemicinfluenza/novelflu.htm

For regular updates on EU action to tackle the influenza A(H1N1) virus see Commission website: http://ec.europa.eu/health/ph_threats/com/Influenza/novelflu_en.htm