



# EVM Newsletter



Autumn 2006

## Influenza Pandemic Preparedness: A plan for action

Cooperation between the European Authorities, national public health bodies and manufacturers will be essential in the event of an influenza pandemic. The EVM (European Vaccine Manufacturers) have just published an updated version of an Influenza Pandemic Preparedness Plan that provides a framework for a joint collaboration between all stakeholders.

### An updated Preparedness Plan

Didier Hoch,  
EVM President



The updated Pandemic Preparedness Plan sets out those areas that require a collaborative effort

The original EVM Preparedness Plan was published in 2004. Since then a number of issues have been addressed while others remain unresolved. The updated Plan takes stock of the progress that has been made and is intended to encourage a dialogue between all the stakeholders. The Plan identifies three main strands

that contribute to pandemic preparedness:

- strengthening R&D activities,
- adapting production facilities
- evaluating alternative or complementary vaccination strategies.

### Strengthen R&D activities

The vaccine industry has undertaken an intensive research effort to assess a range of pandemic strains, vaccine types and production methods. Of the 31 prototype flu vaccines currently under development worldwide, about half have originated in

Europe (see website <sup>1</sup>). Although the most likely candidate seems to be the H5N1, it is impossible to predict which strain may breakthrough and cause a pandemic. Industry is therefore developing prototypes form a number of different stains.

Research effort has also been devoted to the development of different types of vaccine; these include inactivated whole virions, inactivated split viruses and purified surface antigens.

Production methods are also under review. Most prototype vaccines are produced on egg-based systems but others, such as cell culture systems, are being investigated.

R&D activities summary of prototype pandemic vaccines
<ul style="list-style-type: none"> <li>•12 prototype vaccines developed in EU</li> <li>•Strains used; H2N2, H5N1, H5N3, H7N1, H7N7,H9N2, ,</li> <li>•Types of vaccine:                             <ul style="list-style-type: none"> <li>➢Live cold-adapted or killed (whole virion, split, subunit, virosomal)</li> <li>➢Adjuvanted: alum, MF59</li> <li>➢Embryonated eggs or cell culture</li> </ul> </li> <li>•28 studies conducted by 13 companies worldwide</li> </ul>

Some clinical trials with prototype vaccines have now been completed leading to the submission of prototype dossiers to the regulatory authorities and others are anticipated in due course.

<sup>1</sup> [www.evm-vaccines.org/pdfs/ipd\\_table\\_R&D\\_projects\\_Europe\\_update\\_May2006.pdf](http://www.evm-vaccines.org/pdfs/ipd_table_R&D_projects_Europe_update_May2006.pdf)

## **EVM's mission:**

- to create a supportive environment for improved vaccine protection and coverage in the interest of the individual and the community;
- to promote vaccine R&D to meet new challenges for innovative vaccine applications against infectious and other types of diseases;
- to foster a favourable policy climate for the vaccine industry to bring new vaccines to the world.

### **EVM**

Baxter  
Berna, a Crucell Company  
GlaxoSmithKline  
Biologicals  
Novartis Vaccines  
Sanofi Pasteur  
Sanofi Pasteur MSD  
Solvay Pharmaceuticals  
Wyeth



<http://www.evm-vaccines.org>

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## **Vaccine production and supply**

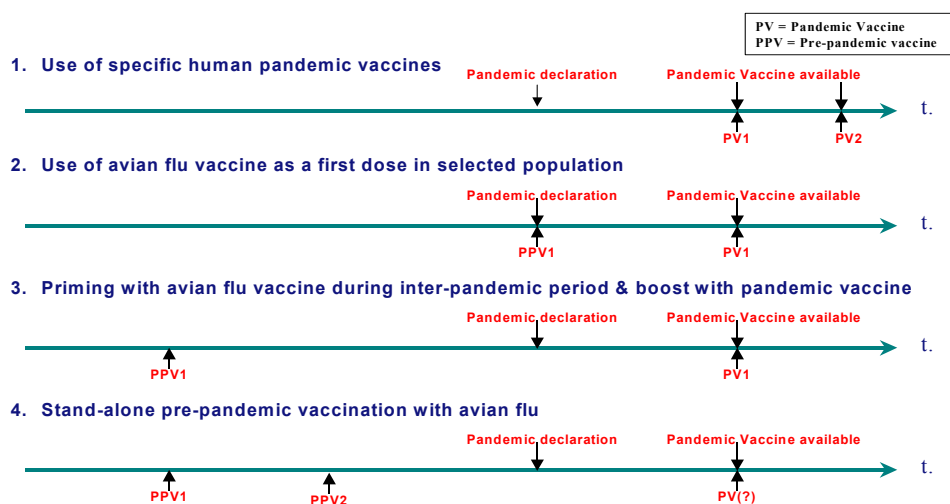
The supply of pandemic flu vaccines may be affected by several factors. The use of adjuvants reduces the amount of antigen required in each dose of vaccine, therefore increasing the number of doses in each production batch. The ability to produce pandemic vaccines is also linked to the production capability of seasonal flu vaccines since both are manufactured in the same facilities. Acknowledging the importance of seasonal flu vaccine production, the WHO have proposed a target of 75% coverage of high risk groups by 2010. There is an immediate public health advantage in broadening the uptake of seasonal flu vaccines and, over time, the capacity to produce pandemic vaccines will also be strengthened.

To build and validate a new vaccine production facility can take between 3 to 5 years. This long lead time means that it is essential for Member States to plan their seasonal flu requirements and share this information with the manufacturers – as requested by Commissioner Kyprianou.

## **Evaluate alternative vaccination strategies**

The “wait and see” strategy of developing a vaccine against the strain that emerges in a pandemic has the disadvantage that it will only be available after several months. A number of alternative strategies, based on the use of vaccination with pre-pandemic vaccines, are now being evaluated by the WHO and public health authorities. These strategies include the use of pre-pandemic vaccines that have been stockpiled, the use of a pre-pandemic vaccine during the inter-pandemic period, and a stand-alone programme consisting of 2 doses of a pre-pandemic vaccine given in advance of a pandemic. The various scenarios are shown below.

### **Vaccination strategy to control influenza pandemic**



The use of pre-pandemic vaccines before a pandemic is based on the assumption that their use would elicit a certain degree of cross protection against the pandemic strain. This, of course, needs to be scientifically evaluated and demonstrated.

### **Looking forward**

Collaboration between the EU authorities, member states and vaccine manufacturers needs to be strengthened in the following areas:

- EU support for additional research
- MSs implementation of the WHO target for vaccine coverage
- The evaluation of alternative pandemic vaccination strategies