



Flu Pandemic, a call for action and coordination

Flu pandemic is an international threat that needs Community level mechanisms to ensure that there is effective coordination at every stage of an influenza outbreak. This will effect a considerable reduction in morbidity and mortality in Europe. To this end, the European Commission has adopted a Commission working paper on Community influenza Pandemic Preparedness and Response plan (COM 2004 201 final). In the working document, the Commission describes the different stages of the pandemic and proposes different actions to be taken either at the European Union or Member States level. The Commission hopes to initiate a political debate with the working document that will result in concrete actions that could take the form of recommendations or binding measures.

Vaccination represents the most effective way of controlling influenza during interpandemic periods. Antiviral drugs could play a role in the initial period of a pandemic but in the middle to long term they do not represent the most efficient approach to controlling the disease. Within the EU we benefit from the presence of five vaccine manufacturers that represent 70% of the worldwide production of influenza vaccines (50% of that production is distributed outside the EU). European vaccine manufacturers are, therefore, global suppliers. With the current levels of vaccines supply it is inevitable that there would be shortages in the event of a pandemic. Therefore, Europe needs to ensure an adequate and timely supply of influenza pandemic vaccines.

Solutions to ensure adequate vaccine supply:

The European Vaccine Manufacturers have put forward an action plan to address the public health requirements posed by an influenza pandemic. The points below are linked and cover the main issues that may impact the timely availability of influenza vaccines in a pandemic situation:

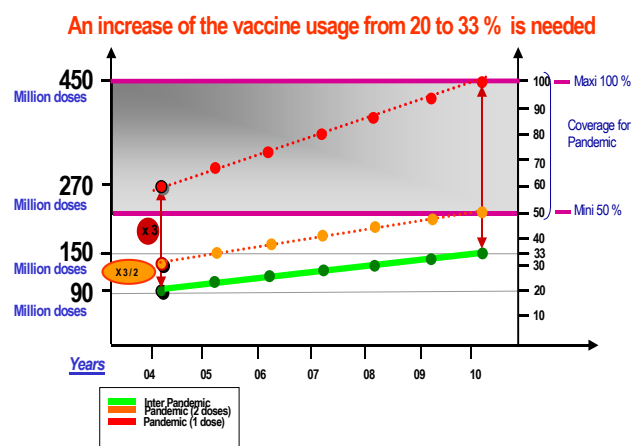
** Need for fast-track regulatory approval*

EVM members are committed to develop a flu vaccine. Once a pandemic starts it is vital that an appropriate vaccine is made available as quickly as possible. One way in which development time may be kept to a minimum is by the production of a regulatory dossier using a 'mock' monovalent vaccine strain. When this 'mock' dossier has been established, the pandemic vaccine strain can be substituted, expediting regulatory approval.

** To maximize the supply capacity*

A total of 450 million European citizens should potentially be protected in case of pandemic. This is not possible today since current production capacities are linked to influenza vaccine usage in interpandemic periods. Member States should anticipate their pandemic needs and adapt proportionally their interpandemic use of influenza vaccines. Based on reasonable assumptions, to

adapt production capacities in order to protect 50 to 100% of the population in case of a pandemic, vaccine production during the interpandemic period should be raised from current 90 million doses (20% of population) to about 150 million doses (33% of population). To achieve more than 50% coverage will also depend on the clinical and technical development of the mock-up vaccine and the characteristics of the pandemic strain.



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 Members:

[Aventis Pasteur](#)
[Aventis Pasteur MSD](#)
[Baxter](#)
[Berna Biotech](#)
[Chiron Vaccines](#)
[GSK Biologicals](#)
[Solvay Pharma](#)
[Wyeth](#)



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EVM is a specialised group within the European Federation of Pharmaceutical Industries and Associations

***Equitable distribution.**

As recognized by the Commission working document, equity of access may be at risk due to measures imposed by the MSs to provide protection for their own populations. Facilities for vaccine manufacture exist in 5 Member States and a mechanism to distribute vaccines inside and outside the EU, according to public health needs, should be established prior to a pandemic. Supply agreements between Member States and EVM companies, with the support of EC, should be set-up in advance of a pandemic to prevent supply disruption between the various Member States and ensure equitable access to European citizens.

*** Liability.**

European Vaccines manufacturers are committed to comply with requirements related to the quality of the vaccine. In a pandemic situation, exposure to liability differs from normal marketed vaccines, relating to a vaccine developed in emergency and used in mass vaccination campaigns.

The points outlined above will help to reduce the risk of inadequate, inequitable and delayed supply. But, clear coordination, in this special situation, to ensure adequate and timely supply of influenza pandemic vaccines in and outside Europe will be required.

EU financial support is needed

The USA has already committed public funding to develop pandemic vaccines and in this respect is ahead of the European Union. EVM members are committed to developing, and obtaining the marketing authorisation of pandemic vaccines. To achieve this objective, manufacturers have to develop a mock-up vaccine, which will never be brought to the market but which is essential to speed-up the approval of a pandemic vaccine. EVM members would like the Commission to consider allocating financial support to help the development of this prototype vaccine

The vaccine manufacturers would also ask the European Union to consider support in the areas below:

- To encourage MSs to increase vaccine coverage rates according to their pandemic needs and to levels that would allow comprehensive cover in the event of a pandemic.
- To put in place a legal instrument that would temporarily waive manufacturers' liability for the pandemic vaccine.

Major Vaccine Perception Survey

EVM has undertaken a major survey on the perception of vaccines and vaccinations.

The aims of the survey were:

- To develop a database for vaccine related issues for European countries.
- To measure usage patterns and attitudes towards vaccines and vaccinations.
- To track usage patterns and attitudes over time using repeat surveys.

The survey was carried out in 5 major European countries. Interviews were conducted with paediatricians and general practitioners (and also nurses/hygienists in those countries where they play a major role in vaccine administration). Views amongst the general public were also sought, including two subgroups; parents (having at least one child) and the elderly. In total, 5828 interviews were made.

The results of the survey will be collated and presented shortly.