



Preparing for Influenza pandemic: what has been done and what needs to be done to provide sufficient quantity of pandemic vaccines in time

Vaccination represents the most effective way of controlling influenza during interpandemic periods and in a pandemic is the most efficient approach to control the disease. The vast majority of today's influenza vaccine is produced in Europe, about 70% of the world's total influenza vaccine. The European Vaccine Manufacturers* (EVM) represent all the EU influenza vaccine producers and would therefore play an essential role in the development and manufacturing of influenza pandemic vaccines for the world.

The members of the European Vaccine Manufacturers are committed to contributing to global public health and to addressing the challenges posed by the threat of a worldwide influenza pandemic. EVM presented a proposal for an action plan to the European Commission in February 2004 http://www.evm-vaccines.org/pdfs/evm_pap.pdf.

Among the numerous activities contributing to influenza pandemic preparedness in Europe, one short-term priority is the development of prototype influenza pandemic vaccines. This represents a key intermediate step to establish the manufacturing process and the characteristics of future pandemic vaccines. It would require a full preclinical and clinical development, followed by registration through the centralized procedure, according to specific EMEA guidelines already in place.

In the event of a pandemic, a monovalent vaccine (one single strain instead three strains used in the annual vaccine) would be needed as soon as possible and produced in very large quantities. Most of EVM members are already working on the development of prototype influenza pandemic vaccines. This is an important step in the influenza pandemic preparedness plan, which will allow for a fast-track evaluation procedure once the pandemic arrives and will shorten the lead-time for pandemic vaccines. However, incentives from public health authorities would be helpful to ensure that all potential pandemic candidate vaccines, which may never be used, are developed. The EU contribution will also allow equitable distribution of pandemic vaccines all across and beyond Europe.

Nevertheless, there are other factors, such as the need to increase production capacity that should also be addressed before a pandemic arrives. Influenza vaccine capacity is linked to annual uptake due to the fact that influenza vaccine composition must be reformulated annually to match or "fit" the currently circulating strains, and cannot be stockpiled for use in following years.

* EVM members are: Baxter, Berna, Chiron Vaccines, GlaxoSmithkline Biologicals, Sanofi Pasteur, Sanofi Pasteur MSD, Solvay Pharmaceuticals and Wyeth Vaccines

Global demand for pandemic vaccines will result in increased pressure from health authorities, the medical community and the general public, all seeking access to vaccines. Scaling up additional production capacity has a very long lead-time, to build and validate new manufacturing plant is about 4 years, and this additional capacity therefore has to be in place before a pandemic occurs. Therefore, and in order to be able to protect the EU population in case of pandemic, is essential to increase influenza vaccine production during interpandemic years to match pandemic vaccine needs, as the European Commission and the World Health Assembly have already pointed out.

EVM is aware that health policies are the responsibility of individual member States, however, EVM is of the opinion that the European Commission should establish coordination at European level. Although the Commission has recognized the need to achieve the WHO coverage of 75% in the recommended age and risk groups, the Commission should also provide guidance and advice to Member States on the most appropriate way to implement this strategy. This will imply an adaptation of the national market structures to deliver the influenza interpandemic vaccine, such as full reimbursement and improving public health authorities communication to the target population, among others. In this respect, the Commission should consider drafting a proposal for Council Recommendation for influenza vaccines.

At the moment, the WHO target for annual flu vaccine is not achieved in most European countries and this should be the first element to be met. However, if the aim is to cover between 50 to 100% of the EU population in case of pandemic, then, public health authorities should consider progressively and, based on public health grounds, lowering the age of the recommendation to 50 and covering the paediatric population.

Furthermore, while some EU governments have put in place national pandemic preparedness plans including National Advance Purchase Commitments to establish national pandemic vaccine needs, others made little progress. This will, undoubtedly, also have an impact on the quantity of vaccines available once the pandemic arrives. In this respect, the Commission has included the cost of vaccines, drugs, medical products, equipment and infrastructure used during an emergency in the Commission proposal for a Regulation on the establishment of a EU Solidarity Fund. However, use of the fund is only permitted once the pandemic arrives. Access to the Fund should be made possible prior to the pandemic to allow for preventive measures to be taken. This will encourage Member States to establish the proper advance arrangements for combating the pandemic.

For further information on influenza pandemic preparedness, see EVM website: http://www.evm-vaccines.org/current_issues/influenza_pandemic.htm