



David Byrne

*"Influenza is a very concrete example where we can put in practice our objective to upgrade our responses to health threats. We have been fortunate to escape any epidemics over the past years, but we may not be so lucky in the future. And therefore we need to decide today what we may need to do together tomorrow .... I am satisfied that Europe has taken the lead on preparedness planning."*

**David Byrne**, Commissioner for Health and Consumer Protection, commenting on the results of the conference on "Preparedness planning in the EU: Influenza and other health threats", November 2001

## POSSIBILITY OF AN INFLUENZA PANDEMIC

More people have died of flu than of any other disease in Europe, and millions still have to be treated annually to combat the disease.

**Flu pandemics** occur at any time of year and affect populations in all parts of the world. Pandemics occur when a new influenza A virus emerges, with no existing antibodies to the virus anywhere in the world. Because so many people are infected during a pandemic, millions of severe and fatal illnesses usually occur.

**Flu epidemics** are seasonal outbreaks. In the Northern Hemisphere they occur between late autumn and early spring. Two or three different strains of influenza may circulate during the winter months of the Northern and Southern hemispheres, and throughout the year in Equatorial countries.

On average, influenza pandemics occur every 25 years. In the 20th century, 3 major worldwide influenza pandemics occurred in 1918, 1957, and 1968.

It is estimated that during the Spanish Flu pandemic in 1918-1919, 2 billion people in the world had become infected with influenza, and between 20 to 40 million people died. The total number of deaths in Europe was estimated to be around 2.3 million. In February 1957, the Asian flu pandemic occurred and although it was not as devastating as the Spanish Flu, infection rates were high and thousands died.

Then in early 1968, the Hong Kong flu pandemic broke out and, although it was the mildest flu pandemic in the 20th century, still nearly 34,000 people died.

## TACKLING INFLUENZA VIRUSES



The above diagram shows how influenza germs spread through the air when someone coughs

Since new strains of the influenza virus are continually emerging and changing in the community each year, new vaccines must be produced annually to match or "fit" the currently circulating flu virus strains to be effective.

Since 1948, the WHO has coordinated a global alert system against influenza. National Influenza Centres in 83 countries that monitor influenza activity in all regions of the world. Information on new virus strains is then immediately sent to the WHO Collaborating Centres on Influenza (Atlanta, London, Melbourne and Tokyo) to identify the viruses circulating around the world.

The results from the influenza network are reviewed and recommendations then made by WHO. These recommendations are then endorsed by the European Agency for the Evaluation of Medicinal Products (EMA), and passed on to vaccine manufacturers for development and supply of the appropriate vaccine in Europe.

Working alongside the WHO global influenza alert system, the European Influenza Surveillance Scheme (EISS) helps reduce the burden of disease associated with influenza in Europe by collecting and exchanging timely information on influenza activity, providing relevant information about influenza to health professionals and the general public, contributing to the annual determination of the influenza vaccine content and contributing to European influenza pandemic preparedness activities.

Furthermore, the establishment of an EU-wide surveillance system, like the proposed European Centre for Communicable Disease Control, will play a vital role in future in strengthening virological and epidemiological surveillance in Europe.

## WHAT IS INDUSTRY DOING TO BE PREPARED?

The European vaccine industry is committed to working with EU and national authorities to make the influenza preparedness plan a reality. To that end, the European Vaccine Manufacturers are:

- Setting up a dedicated group of experts with the aim of ensuring vaccine supply in the shortest time frame possible;
- Contributing to the WHO Global Agenda on Influenza Surveillance and Control and to the Community Preparedness and Response Plan;
- Working together with the European Agency for the Evaluation of Medicinal Products (EMA) in preparing a technical dossier for timely submission and approval of a pandemic vaccine;
- Investing in research and development of new vaccine production methods, including development of vaccination schedules, dosages and formulations.

## TACKLING THE PANDEMIC

The WHO has stressed the necessity for countries to ensure in advance the availability of vaccines for a pandemic.

National health ministries are ultimately the ones responsible for defining their nations' demands for pandemic vaccines. It is therefore in their interest to forecast their nation's inter-pandemic and pandemic needs, and their expected sources

of supply. This information is vital for vaccine companies, who will be in a position to define better their needs for long-term investments to increase production and to develop their ability to sell and distribute their vaccines. In addition to EU country demands for pandemic vaccines, there are also the global needs for yearly flu epidemic vaccines that need to be met independently of pandemic vaccines.

## PRODUCTION CAPACITY CONSTRAINTS

Due to the dynamic nature of the influenza virus strains that are changing unpredictably from year to year, the influenza vaccine demands a new formulation each year, and cannot be stockpiled. Flu vaccine production capacity is based on current vaccine demand, so that a sudden increase in high demand for flu vaccine during a pandemic could result in shortages in production capacity. Production, purification and formulation equipment and facilities are specifically designed for influenza vaccines, and manufacture of additional vaccine could not be readily transferred to pro-

duction facilities that are used for other vaccines.

In order to increase production capacity to meet pandemic needs, the use of flu vaccine during inter-pandemic years could be expanded to include larger segments of the population (such as risk groups, young children and adults over 50 years of age). Not only would this help in reducing flu incidence during seasonal epidemics, in accordance with good public health practice, but would also result in scaled-up production capacity to meet the eventual need for pandemic vaccines.

## TOWARDS PREPAREDNESS IN EUROPE

In November 2001 the European Commission invited experts from all over Europe to express their views on ways to improve preparedness for an influenza pandemic at the European Community level. This resulted in the establishment of the Community Influenza Pandemic Preparedness Group, which is chaired by the Commission and composed of Member States' experts on influenza, representatives from the European Influenza Surveillance Scheme, from EMA and from the WHO. The main role of this group is to advise the Commission and its committees on public health actions and risk assessment.

One of the most important means of reducing the impact of an influenza pandemic is timely vaccination. In order to achieve this, the European Vaccine

Manufacturers support the need for a Community Influenza Preparedness Plan, under the leadership of the European Commission, to address the following objectives:

- Increase vaccination coverage during the inter-pandemic years, thereby increasing production capacity so that when a pandemic threat appears, vaccine manufacturers will be in a higher production mode to meet market demands;
- Facilitate vaccine registration and manage country demand and distribution;
- Strengthen virological and epidemiological surveillance of influenza;
- Support R&D of pandemic vaccines (e.g., new production technologies).

### EVM member companies:

Aventis Pasteur | Aventis Pasteur MSD | Baxter | Berna Biotech | Chiron Vaccines | GlaxoSmithKline Biologicals  
PowderJect Pharmaceuticals | Solvay Pharmaceuticals | Wyeth Vaccines