



Editorial. The success of vaccination: a joint effort between public health authorities and industry

Vaccination is one of the biggest successes of public health. In Europe this is related to the strong involvement of public health authorities and progressive development of the vaccine industry. This success itself is not a given, nor a guarantee for the future. Due to vaccine efficacy, diseases are out of sight and individuals forget the collective vaccination benefits. Vaccines are the victims of their own success.

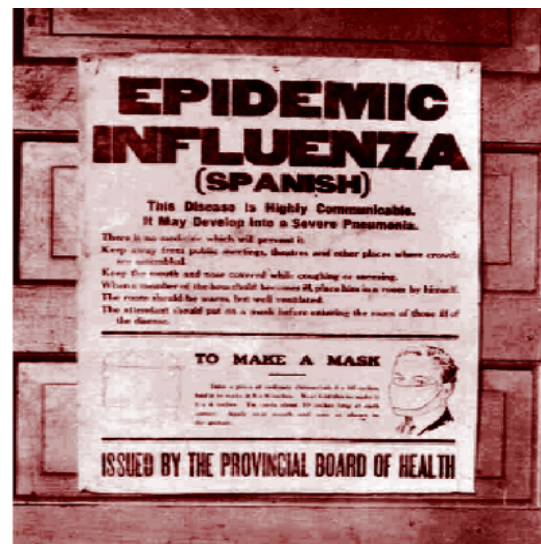
The vaccine industry is moving forward, seizing the opportunity of its bio-pharmaceutical origins to benefit from biotechnology innovations, and to integrate from the Pharma side quality and development processes. Therefore, vaccines are a promising innovative sector: as an example 3 to 7 new vaccines are going to be submitted for approval through the centralized procedure in the next 12 months. But the vaccine industry is unique, representing only 2 % of the pharmaceutical market and requiring long-term investment and development periods.

This is why a close relationship is necessary between public health authorities in Europe and European Vaccine Manufacturers. This will allow the sustainability of a favourable research and development environment to prepare the field for future new vaccines, and to accelerate the preparedness plan against serious health threats.

Didier Hoch, EVM President

Major health threats could be prevented through vaccination

The SARS outbreaks in 2003 demonstrated the need for a concerted approach in fighting epidemics in Europe, and resulted in the EU Council of Ministers' request for a plan on communicable diseases and health threats, including SARS, influenza and bioterrorism. <http://ue.eu.int/pressData/en/lsa/75655.pdf>. SARS warned the world that a threat of a new influenza pandemic should be taken seriously and that contingency plans should be made for its management and containment. In the event of influenza pandemic, the entire world population may be at risk. This is a major public health threat and a challenge for industry and public health authorities. Vaccination represents the most effective way of controlling influenza. Today, with advances in vaccine R&D and influenza surveillance, and ongoing influenza preparedness planning at various levels of government and industry, there is reason to hope that influenza pandemic in the 21st century would not inflict such devastation on the world's population, as did the Spanish flu of 1918.



Influenza pandemic preparedness planning

The World Health Organization (WHO) has recognised the need to work on influenza pandemic preparedness and to draw up a model plan http://www.who.int/gb/EB_WHA/PDF/WHA56/ea56r19.pdf. At the same time, national influenza pandemic plans are also being developed in many Member States and the EU is also moving ahead on this issue.

DG SANCO: http://www.europa.eu.int/comm/health/ph_threats/com/Influenza/influenza_en.htm

DG Enterprise: http://pharmacos.eudra.org/F2/pharmacos/Workshop_HPIV.htm

Influenza pandemic preparedness plans consist of identifying levels of alert and different phases for which specific actions have to be conducted as the crisis escalates:

- **Phase 0** corresponds to the interpandemic period where pandemic preparedness should actively be developed;
- **Phase 1** is the confirmation of the pandemic onset (starting vaccine production);
- **Phase 2**, worldwide spread of the epidemics. This represents the maximum production effort for the industry, during which manufacturers should ensure the quality of vaccine distribution (vaccine available 3-6 months after pandemic declaration);
- **Phase 3**, end of the first wave. Planning the production will represent the major challenge for industry which will have to anticipate both the possibility of a second wave or return to an interpandemic period;
- **Phase 4** may occur 3 to 9 months from first wave end, with a second wave of regional outbreaks;
- **Phase 5** is the end of the pandemic

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:

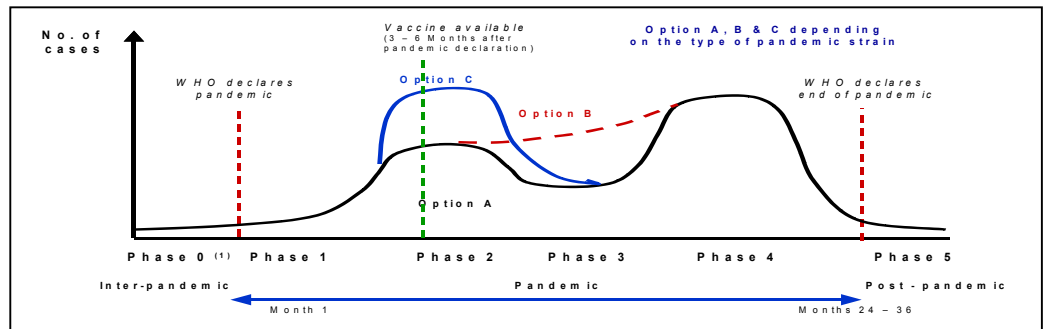
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<http://www.evm-vaccines.org>

info@evm-vaccines.org

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



(1) EVM modelling of the different pandemic faces (adapted from WHO influenza pandemic preparedness plan). Options A, B and C are possible different pandemic waves to be faced.

Challenges in developing and producing an influenza pandemic vaccine

Due to the nature of their genome, influenza viruses regularly undergo genetic mutations. Therefore, influenza vaccine composition must be reformulated annually to match or “fit” the currently circulating strains, and cannot be stockpiled for multi-year use. Flu pandemics occur when a variant of the influenza virus type A emerges in the absence of protective immunity to the virus variant among the world’s population http://www.who.int/csr/don/2004_01_14/en/. A specific pandemic flu vaccine will need to be developed rapidly and then produced in extremely large quantities. Current flu vaccine production is directed at each flu season’s vaccine demand, with no reserve capacity. Because production, purification and formulation equipment and facilities are specifically designed, the technology dedicated for other types of vaccines cannot be transferred to production facilities needed for a pandemic flu vaccine.

A key factor for meeting vaccine supply in the event of a pandemic threat could be achieved by strengthening established global vaccination programmes in the prevention of seasonal epidemics of influenza.

Equitable vaccine distribution

Today the European Union produces 70% of the world’s total influenza vaccine. A considerable proportion of this amount is exported – 40% of the doses used in Central and Eastern Europe, 60% of the doses used in Western Pacific and Southeast Asia, and virtually 100% of the doses used in Latin America, the Eastern Mediterranean, and Africa are imported. So, European vaccine producers have international commitments to serve many world regions, and these obligations will need to be honoured in emergency situations.

EVM contributions to pandemic preparedness planning

EVM is committed to working with public authorities at European and national levels to make the influenza preparedness plan a reality. To that end, EVM is:

- ❖ Investing in the R&D of new vaccine production methods and in the clinical evaluation of pandemic-like vaccines;
- ❖ Working with the European Agency for the Evaluation of Medicinal Products (EMA) to prepare a technical dossier for timely submission and approval of a pandemic vaccine;
- ❖ Working with the European Commission and Member States to set up a framework for the availability and supply of pandemic vaccines.

EVM Special Topics: Influenza Pandemic

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

EVM Briefing Sheet: Halting the influenza pandemic

http://www.evm-vaccines.org/290403_Flu_pandemic_final.pdf