



## Lessons learnt during the pandemic flu A/H1N1v vaccination

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This workshop, organized by the Belgian Federal Agency for Medicines and Health Products (FAMHP) and the "Belgian inter-ministerial commissariat", brought together experts and stakeholders involved in pandemic influenza vaccination in 7 European countries, the EMA (European Medicines Agency), the WHO (World Health Organisation) and the ECDC (European Centre for Disease Prevention and Control). The objectives were to draw conclusions on lessons learnt, prioritize issues and identify solutions for future pandemics.

The pandemic vaccine licensure and the mock-up approach were discussed. The preparedness of the EMA and the availability of considerable amounts of data meant that the EMA could move quickly towards authorisation and provided evidence that these vaccines were not experimental. Three factors were considered to contribute to the possible lack of confidence among healthcare professionals, the general public and the media: the concern about the adjuvant in some vaccines, the perception that safety and efficacy data were insufficient and the lack of adequate data to base recommendations for vaccination of pregnant women. A further factor that may have undermined the public perception of the pandemic was the low virulence of the A/H1N1v pandemic virus so far when much of the anticipatory preparations had been based on expectations of a more severe virus such as H5N1.

The ECDC and the WHO warned that the A/H1N1v transmission will continue and that the virus is unpredictable. The implications for vaccination for seasonal influenza are under discussion. The WHO advises to continue vaccinating against A/H1N1v influenza, especially pregnant women who remain more vulnerable.

The experience from the 7 EU countries revealed a number of interesting observations:

- Decision-making on pandemic vaccination had involved many different partners in each country, requiring intensive coordination mechanisms.
- The age groups most affected by influenza morbidity were consistently children and young adults, while influenza mortality was mainly reported in the medical risk groups <65 years. In the elderly, the attack rate and number of deaths were low.
- Every country had used a wide range of communication channels. Reaching the General Practitioners was sometimes problematic, especially in those circumstances where internet use is lower.
- Population surveys had showed a lack of confidence in political authorities but a stronger level of confidence in the advice from physicians. Additionally, many health professionals were not confident in the H1N1 vaccines.

- A complex issue was the link between the declaration of the pandemic phases, the licensing circumstances and the vaccine contracts between countries and manufacturers. On the 'way in' to the pandemic, many industrialized countries had already put in place advance purchase arrangements with manufacturers for several years and these were automatically triggered once phase 6 was declared by the WHO, regardless of the countries' needs at that time. On the 'way out' from the pandemic, vaccines would become un-licensed in some areas of the world after the WHO declares that the phase 6 of the pandemic is over.
- Though guidelines were set by WHO, the Strategic Advisory Group of Experts (SAGE) in July 2009 and by ECDC to help standardize national policies, target groups for vaccination did differ between countries. The recommendations for target groups also evolved along the pandemic, according to disease burden, epidemic curve and vaccine availability. However, all countries included patients with chronic disease, pregnant women and healthcare workers, in accordance with WHO and ECDC priority groups. Vaccine uptake in target groups varied widely across countries but only preliminary data are available at this time.
- Monitoring of adverse events following immunization mostly rested on existing pharmacovigilance systems, but additional systems were set up for the pandemic vaccine in several countries.

Communication and information was a major issue; it needed to respond to the public concerns and required a high level of transparency over the disease burden, the reasons for prioritization and the safety of the vaccines. The areas requiring most international collaboration, such as monitoring of adverse events, vaccine coverage and vaccine effectiveness, received special attention from the international organizations.