



## IRISH MEDICINES BOARD

### IMB Update on Pandemic A(H1N1)v vaccines (2)

The European Commission on the recommendation of the European Medicines Agency (EMA) has granted licences for three vaccines against influenza A(H1N1)v for use in the EU. These vaccines are:

**Celvapan (Baxter),  
Focetria (Novartis),  
Pandemrix (GlaxoSmithKline).**

Two of these vaccines, **Celvapan** and **Pandemrix**, will be made available in Ireland by the Department of Health and Children and HSE in accordance with the national immunisation strategy for the pandemic. These 'pandemic' vaccines were licensed using the so-called 'mock-up' approach. This approach involved the development of 'mock-up' vaccines in advance of the pandemic, based on information generated with a different virus strain that could have itself caused a pandemic (an H5N1 influenza virus strain). Once the A(H1N1)v virus strain causing the current pandemic was identified by the World Health Organization (WHO), the manufacturers were able to replace the H5N1 strain in the 'mock-up' vaccines with the H1N1 strain resulting in the final 'pandemic' vaccines for use now. The 'pandemic' vaccines were licensed on the basis of information on quality, safety and immunogenicity, including information from clinical trials involving more than 6,000 subjects, generated at the time of the licensing of the mock-up vaccines, as well as on information relating to the change in strain from H5N1 to H1N1. Further clinical trials in adults and in children are ongoing and more results will become available in the coming weeks and months.

Details of the Product Information for each of the vaccines are available on the IMB and EMA websites, as is an EU explanatory document on the scientific considerations regarding the licensing of the pandemic vaccines. Extensive amounts of new safety and efficacy data are expected from the widespread use of the vaccines in vaccination programmes across the EU. Procedures are in place to allow for the rapid review of all such data and it is likely that the product information will be updated at regular intervals.

**Healthcare Professionals are requested to monitor the IMB and EMA websites throughout the pandemic for updated information as it becomes available.**

As limited safety data on novel H1N1 influenza vaccines are currently available, additional pharmacovigilance activities are essential to monitor and assess their safety with widespread use. The IMB recommends that healthcare professionals should, where feasible, report adverse reactions using the **on-line reporting system ([www.imb.ie](http://www.imb.ie))**.

During the pandemic it will be particularly important to identify and respond to any serious adverse reactions, as this information will help guide the safest and most effective use of these medicines. The IMB requests that healthcare professionals provide details of:

- Vaccine brand name
- Batch number
- Dates of initial and second (if applicable) vaccination
- Date of onset of the reaction
- Treatment received
- Outcome of the reaction
- Relevant medical history
- Age and gender of the patient

For clusters of reactions, please provide details of the vaccination setting and any relevant information on in-use conditions.

In relation to the pandemic vaccines, the IMB requests that healthcare professionals particularly report the following suspected adverse reactions/post-immunisation events:

- Serious unexpected adverse reactions
- Adverse events of special interest (AESI): Neuritis, convulsions, anaphylaxis, encephalitis, vasculitis, Guillain-Barré syndrome, Bell's palsy, demyelinating disorders, vaccination failure.

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