



IRISH MEDICINES BOARD

Update on National and EU Experience with the H1N1 Pandemic Vaccines

The Irish Medicines Board (IMB), together with the European Medicines Agency and National Competent Authorities across the EU, is continuously monitoring the safety profile of H1N1v pandemic influenza vaccines. With vaccination campaigns ongoing in the European Union, it is estimated that about 5 million people have been vaccinated so far.

At the November meeting of the Committee for Human Medicinal Products (November 16th-19th 2009), the European Medicines Agency (EMA) reviewed further data on the centrally authorised pandemic vaccines, Celvapan, Focetria and Pandemrix. The Agency has reaffirmed their positive balance of benefits and risks in the context of the current H1N1 influenza pandemic.

As of this time, the suspected adverse reactions most frequently reported to the IMB were injection site reactions (e.g. pain, swelling, redness) and other expected reactions such as nausea, vomiting and flu-like symptoms (e.g. pain, fever, fatigue and swollen glands), confirming the expected safety profile of the vaccines. There have also been some reports of other recognised adverse events which are also common to any vaccination - these included headache, dizziness, syncope, paraesthesia and transient limb weakness in the vaccinated limb.

This is similar to the experience in other Member States across the European Union. In addition to the common expected reactions, there have been some reports of allergic reactions including rare cases of anaphylaxis. The IMB wishes to remind healthcare professionals that, as with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of a serious allergic reaction and possibly a rare anaphylactic event following the administration of

the vaccine. An appropriate monitoring period should be observed in accordance with local guidance and recommendations relating to vaccination procedures. The IMB wishes to highlight that some of the allergic reactions occurred in patients without a history of anaphylactic reactions or known drug/food allergies.

The most recently available data on Pandemrix indicate that a single dose of this vaccine is able to trigger an immune response that may be sufficient to give protection against the H1N1 pandemic influenza in some age groups. Therefore a single dose may be used in adolescents and adults aged 13 years and over. For certain groups, those children under the age of 13 and immunocompromised patients, the recommendation remains that two doses should be given to ensure that their immune system responds adequately to the vaccination. Further data will become available in the coming months. The EMA also concluded that Pandemrix can be co-administered with non-adjuvanted seasonal flu vaccines.

Further immunogenicity data on Celvapan are awaited and, in the meantime, the recommendation remains that two doses should be given to all age groups.

More information on H1N1 vaccines including Pandemrix and Celvapan is provided in the production information, copies of which are available on the European Medicines Agency website (<http://www.emea.europa.eu>). Additional information is also available from the IMB website, with updates reflecting national monitoring experience published on a weekly basis.

Other pandemic related information is available from the websites of the Department of Health and Children, HSE and HPSC.

This section has been supplied by the IMB for use in MIMS Ireland. However, the IMB is independent and impartial to any other information contained in this directory