IRISH MEDICINES BOARD

UPDATE ON NATIONAL MONITORING EXPERIENCE WITH PANDEMIC H1N1 VACCINES

Suspected Adverse Reactions to Pandemic (H1N1) 2009 Vaccines occurring in Ireland

12 November 2009

As of 12 noon on Wednesday 11th November 2009, 113 reports of suspected adverse reactions to the Pandemic H1N1 vaccines (Pandemrix and Celvapan) have been received by the Irish Medicines Board (IMB). A single report may include more than one suspected reaction.

All of the reports received to date were consistent with the expected pattern for the pandemic vaccines. The balance of risks and benefits is not affected by these data and the benefit-risk remains positive.

Pandemrix
The IMB has received 57 suspected adverse reaction reports associated with Pandemrix. The most frequently reported suspected adverse reactions were non-serious injection site reactions (e.g. pain, swelling, redness) and other expected reactions such as nausea, vomiting and flu-like symptoms (e.g. muscle pain, fever, fatigue and swollen glands). There have also been some reports of other recognised potential adverse effects of the vaccines which are also common to any vaccination and were generally non-serious - these included headache, dizziness, syncope (fainting episodes) and pins and needles.

The IMB has received seven suspected adverse reaction reports associated with the use of Pandemrix in pregnant women. The reported reactions were expected reactions including gastrointestinal symptoms, local injection-site reactions, flu-like symptoms (e.g. fever) and syncope.

Twelve suspected adverse reaction reports were associated with use in children and the majority involved injection site reactions, flu-like symptoms and vaccination related symptoms (including pallor and syncope).

The IMB has received six reports of allergic reaction to Pandemrix which required treatment. Allergic reactions are a recognised potential adverse reaction.

Celvapan
The IMB has received 53 adverse reaction reports in association with the use of Celvapan. As with Pandemrix, these include injection site reactions, flu-like illness, vaccination-related events (e.g. syncope (fainting episodes)) and allergic-type reactions.

Six reports were associated with use in pregnant women and included gastro-intestinal symptoms, non-serious allergic type reactions, flu-like symptoms (including fever) and syncope.

Seventeen reports were associated with the use of Celvapan in children and these included expected reactions such as gastrointestinal reactions, vaccination related reactions (e.g. pallor and syncope) and skin rashes.

There were four reports of suspected allergic reaction to Celvapan which required treatment. The IMB has received one report of a suspected anaphylactic reaction to Celvapan in a patient without a history of food/drug allergies. Symptoms resolved following treatment.

Brand Unknown
The vaccine brand was not reported in three cases and follow up to establish which product was used is underway. These cases include reports of flu-like symptoms and injection site reactions.

Advice to Healthcare Professionals
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.

Understanding the Data Reported to the IMB
These adverse reaction reports have been submitted to the IMB on a voluntary basis by healthcare professionals and members of the public, either through the online reporting tool available on the IMB website (www.imb.ie), or by post or telephone. This report also contains any Irish reports notified to the IMB by the Marketing Authorisation holders for Pandemrix (GSK) and for Celvapan (Baxter).

Reporters are encouraged to report *suspected* adverse reactions. In other words, the reporter does not have to be sure that the vaccine caused the reaction, a mere suspicion will suffice. Therefore the reports received may be true adverse reactions to the vaccine, they may be events related to the process of vaccination rather than to the specific vaccine itself, or they may be coincidental events which have occurred post-vaccination but which would have occurred anyway even if vaccination had not taken place (e.g. they may be due to an underlying medical condition). More information on Pandemrix and Celvapan, including information on recognised adverse effects, is provided in the production information, copies of which are available on the European Medicines Agency website (http://www.emea.europa.eu).