IRISH MEDICINES BOARD

UPDATE ON MONITORING EXPERIENCE WITH PANDEMIC H1N1 VACCINES

30 October 2009

The Irish Medicines Board (IMB) is providing this update as information becomes available across Europe in relation to monitoring experience with use of the pandemic H1N1 vaccines. A number of EU countries have commenced vaccination programmes for their "at risk" groups and at this point in time, it is estimated that over 500,000 doses of Pandemrix have been administered.

A number of suspected adverse reactions have been reported in association with use of the vaccines, which are in line with the expected pattern and include:

- Local reactions at the injection site, including soreness, redness and pain;
- Flu-like symptoms such as fever, fatigue, shivering, moderate/severe headache, joint pain and malaise;
- Nausea, vomiting, abdominal pain and diarrhoea;
- Dizziness and sleep disorders.

Of particular note, a small number of patients have experienced allergic reactions following vaccination, which in some cases was associated with anaphylactoid symptoms, requiring hospitalisation and treatment with adrenaline, corticosteroids and antihistamines.

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.

As is its normal practice with all medicines, the IMB will be evaluating and assessing all suspected adverse reactions reported and will continue to monitor experience from other countries. This assists the IMB to make informed decisions and take measures as it deems appropriate to continue to safeguard public health safety in relation to medicines. Therefore, healthcare professionals are requested to report any suspected adverse reactions directly to the IMB.

Suspected adverse reactions can be reported to the IMB by:

- Completing the online report on the IMB website (www.imb.ie)
- Downloading an adverse report form available on: http://www.imb.ie/EN/Safety--Quality/Online-Forms/Human-Medicine-Adverse-Drug-Reaction.aspx.
  Complete the form and send it to the IMB Pharmacovigilance Department;
- Contacting the IMB's Pharmacovigilance Department on 01-676 4971.

Further information on pandemic H1N1 vaccines is available from the IMB website at www.imb.ie