IRISH MEDICINES BOARD

Notice Information: - Advisory
01 April 2010

Part 1. Product Information

a)	Title:	Update: National Monitoring Experience with Pandemic H1N1 Vaccines
b)	Product Name/Type:	Pandemic H1N1 Vaccines

Part 2. Problem/Issue

a)	Problem/Issue:	The H1N1 vaccines in use in Ireland are Pandemrix and Celvapan and it is estimated that 1.1 million doses have been administered in Ireland to date. Since the start of the vaccination campaign 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 , or by post or telephone. Reports of suspected adverse reactions occurring in Ireland have also been notified to the IMB by the Marketing Authorisation holders for Pandemrix (GSK) and for Celvapan (Baxter). 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). Suspected adverse reaction reporting rates are highly variable and are dependent on many factors. Therefore these data cannot be used to determine the frequency of occurrence of adverse reactions to the H1N1 vaccines. In the past two weeks (Tuesday 16 March to Tuesday 30 March 2010), 27 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. The reports received to date remain consistent with the expected pattern of adverse effects for the pandemic vaccines. At least 42.3 million people have been vaccinated with the centrally authorised H1N1 vaccines in the European Economic Area and the balance of risks and benefits remains positive. As of 31 March 2010, the HSE vaccination clinics have closed. Due to t

the decreasing numbers of patients being vaccinated, and an expected reduction in the number of adverse reaction reports, the IMB will discontinue publication of routine updates. The safety of the H1N1 vaccines will continue to be monitored and further safety updates will be provided as appropriate.

A detailed report on the adverse reactions received by the IMB to date is available via the link below.

IMB National Monitoring Update (01/04/2010)