IRISH MEDICINES BOARD

UPDATE ON NATIONAL MONITORING EXPERIENCE WITH GARDASIL

21st October 2010

The HSE human papillomavirus (HPV) schools immunisation programme commenced in May 2010 and it is estimated that up to 17,000 doses of Gardasil have been administered up to the end of September 2010. The Irish Medicines Board has received a total of 34 reports of adverse events associated with use of Gardasil up to the end of September 2010, 25 of which were received since the beginning of the schools immunisation programme in May 2010.

The reports have been consistent with the expected pattern of adverse effects for the vaccine, as outlined in the product information, and include cases of injection site reactions, malaise, headache, myalgia, fatigue, gastrointestinal symptoms and skin reactions (including urticaria).

Vaccination related events such as dizziness and syncope are among the most commonly reported reactions and healthcare professionals are reminded that vaccines should be carefully observed for an appropriate period of time after administration of Gardasil (see Summary of Product Characteristics for further information).

Hypersensitivity reactions have also been received including two reports of anaphylactic-type reactions in patients, both of whom recovered without sequelae.

Anaphylaxis is a very rare side effect of most 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.

The IMB together with the European Medicines Agency will continue to monitor closely the safety of Gardasil during continued use in Ireland. The balance of risks and benefits for the vaccine remains positive.

Adverse reactions may be reported using the online Adverse Reaction Report form. A downloadable version of the Adverse Reaction Report form is also available, which can be filled in manually and sent to the IMB by freepost.

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 includes information from any Irish reports notified to the IMB by the Marketing Authorisation holder for Gardasil (Sanofi Pasteur MSD).

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 Gardasil, including information on recognised adverse effects, is provided in the product information, copies of which are available on the European Medicines Agency website (http://www.ema.europa.eu).