



IRISH MEDICINES BOARD

OVERVIEW OF NATIONAL MONITORING EXPERIENCE WITH GARDASIL

19 July 2011

The HSE human papillomavirus (HPV) Schools Immunisation Programme commenced in May 2010. During the first year of the programme, over 159,000 doses of Gardasil were distributed, with at least 145,000 doses administered up to June 2011. No new risks have been identified for Gardasil during monitoring of national use. The balance of benefits and risks for the vaccine is positive.

Prior to the introduction of the programme, the Irish Medicines Board (IMB) actively encouraged reporting of national experience with Gardasil through a variety of sources. These included direct communications with healthcare professionals involved in the programme and the publication of a special insert in the IMB's Drug Safety Newsletter ([Issue 37 – May 2010](#)).

A total of 416 reports of adverse events associated with use of Gardasil were notified to the IMB up to the end of June 2011. 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 Gardasil.

The majority of the reports received have been non-serious and consistent with the expected pattern of adverse effects for the vaccine, as described in the product information. Vaccination related events have been the most commonly reported effects with dizziness and/or headache described in a significant majority of the reports received. Other commonly reported symptoms included malaise, gastrointestinal symptoms, syncope and skin and injection site reactions. There have been five reports of seizure, two occurring in patients with epilepsy, one of whom was recently diagnosed prior to vaccination.

Reports of allergic-type reactions including skin rashes, urticaria and flushing have also been received. There have been six reports of anaphylactic/anaphylactoid-type reactions. All patients recovered following treatment. 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 first year of the Schools Immunisation Programme is now complete and as national reporting experience has been consistent with the known safety profile of the vaccine, the IMB will discontinue publication of regular updates. At this time too, reporters are advised that routine notification of expected, non-serious effects is no longer necessary. Reporters are requested however to continue to notify any suspected, serious adverse reactions that are considered of concern using the usual reporting options (available on www.imb.ie). The IMB will continue to monitor national experience with use of Gardasil. In the context of global safety data, the IMB will collaborate, as appropriate, with EU and International counterparts in the evaluation of these data, communicating nationally as necessary.

A very sincere thank you to those who have submitted reports for Gardasil. The IMB greatly appreciates the important contribution of healthcare professionals, consumers and patients in reporting their experience with vaccines and medicines.

Gardasil has been authorised for use across the European Union (EU) since 2006 and has been in widespread use in a number of member states since then. In addition to the European approval, it is registered and authorised for use in at least 131 countries worldwide, including approvals by both the US Food and Drug Administration (FDA) and the Therapeutic Good Administration in Australia (TGA). More than 65 million doses of the vaccine have been distributed world-wide. Visit the [European Medicines Agency](#) website for more information on Gardasil. Details of recognised adverse effects can be found in the product information (Summary of Product Characteristics and Package Leaflet) and the public assessment report.