



IRISH MEDICINES BOARD

**UPDATE ON NATIONAL MONITORING EXPERIENCE WITH
GARDASIL**

9th February 2011

The HSE human papillomavirus (HPV) Schools Immunisation Programme commenced in May 2010. It is estimated that at least 115,000 doses of Gardasil have been distributed and approximately 90,000 administered up to the end of January 2011 as part of the programme. At this stage of the programme, the majority of girls have now received the second dose of the three dose vaccination schedule.

The Irish Medicines Board (IMB) has received a total of 314 reports of adverse events associated with use of Gardasil up to the end of January 2011. Vaccination related events are amongst the most commonly reported effects and include reports of syncope (fainting), dizziness, anxiety and hyperventilation. 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. A single report may include more than one suspected reaction.

The majority of the reports have been non-serious and consistent with the expected pattern of adverse effects for the vaccine, as described in the product information and include cases of malaise, headache, dizziness, syncope (fainting), fatigue, skin and injection site reactions and gastrointestinal symptoms. There have been four reports of seizures, 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 four reports of anaphylactic-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.

No new risks have been identified for Gardasil during monitoring of national use. The balance of benefits and risks for the vaccine is positive.

Administration of the second doses of Gardasil is now complete in this year's Schools Immunisation Programme and as national reporting experience has been consistent with the known safety profile of the vaccine, the IMB will discontinue publication of regular updates. National use of Gardasil will continue to be monitored and a further update will be provided following completion of the third and final vaccination following the introduction of the Schools Immunisation Programme and thereafter, as appropriate.