



IRISH MEDICINES BOARD

**UPDATE ON NATIONAL MONITORING EXPERIENCE WITH
GARDASIL**

9th December 2010

The HSE human papillomavirus (HPV) Schools Immunisation Programme commenced in May 2010 and it is estimated that approximately 60,000 doses of Gardasil have been administered up to the end of November 2010 as part of the programme. At this stage in this year's School Programme, the majority of girls vaccinated have now received the second dose of the three dose vaccination schedule.

The Irish Medicines Board (IMB) has received a total of 107 reports of adverse events associated with use of Gardasil up to the end of November 2010, 98 of which were received since the beginning of the Schools Immunisation Programme. 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 consistent with the expected pattern of adverse effects for the vaccine, as described in the product information and include cases of injection site reactions, malaise, headache, dizziness, syncope (fainting), fatigue, skin reactions and gastrointestinal symptoms. There have been two reports of seizures, one occurring in a patient with a history of epilepsy.

Vaccination related events are amongst the most commonly reported effects and include reports of syncope (sometimes in conjunction with seizure-like movements) dizziness and hyperventilation.

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.