Malta, 19 February 2009
Circular No. P05/2009

Re: The EMEA recommends continued vaccination with Gardasil

The European Medicines Agency (EMEA) has reviewed the available information on the two cases of status epilepticus with myoclonus (repeated and prolonged seizures and loss of consciousness) reported in two girls vaccinated with the cervical cancer vaccine Gardasil in Spain.

Based on the current data, the Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that the cases are unlikely to be related to vaccination with Gardasil and that the benefits of Gardasil continue to outweigh its risks. Therefore the Committee is recommending that vaccination with Gardasil should continue in accordance with national vaccination programmes in Member States.

Both girls were vaccinated with the same batch of Gardasil, became ill shortly after vaccination, and are now improving. Following the two cases, the Spanish public health authorities stopped vaccination with the batch of Gardasil concerned as a precautionary measure on 9 February 2009. The Italian authorities also stopped vaccination with this batch shortly thereafter. The distribution of the entire batch was stopped on 10 February 2009.

The CHMP and its Pharmacovigilance Working Party are investigating this situation further. The marketing authorisation holder has been requested to provide a full analysis of the batch, as well as further information on the vaccine's side effects, any similar cases, and possible ways in which Gardasil could be linked to the cases seen in Spain. Following assessment of all of the available data, the CHMP will determine whether further action is needed.

Gardasil, from Sanofi Pasteur MSD SNC, is a vaccine for the prevention of cervical cancer and other pre-cancerous diseases caused by human papillomavirus (HPV). It has been authorised in the European Union (EU) since September 2006. Around three million girls in Europe have been vaccinated with this vaccine since it was first authorised.

As part of its continuous monitoring of medicines, the CHMP recommended an update of the Product Information for Gardasil in January 2009, to reinforce information on syncope (fainting) as a side effect of vaccination with Gardasil, indicating that it is sometimes accompanied by tonic-clonic movements (seizures). This opinion has been forwarded to the European Commission, for the adoption of an EU-wide decision.

The Medicines Authority has participated in these discussions held at the EMEA and is in agreement with the full **press release** issued by the EMEA, attached here for your perusal.