European Medicines Agency
Press office

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PRESS RELEASE
European Medicines Agency 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 (movements resembling a seizure). This opinion has been forwarded to the European Commission, for the adoption of an EU-wide decision.

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Notes:

1. The batch concerned has also been distributed in France, the Netherlands, Italy and Germany. However, it has not been used to date in Germany or in the Netherlands.
2. The approved indication in the EU for Gardasil is: "Gardasil is a vaccine for the prevention of premalignant genital lesions (cervical, vulvar and vaginal), cervical cancer and external genital warts (condyloma acuminata) causally related to Human Papillomavirus (HPV) types 6, 11, 16 and 18. The indication is based on the demonstration of efficacy of Gardasil in adult females 16 to 26 years of age and on the demonstration of immunogenicity of Gardasil in 9- to 15-year old children and adolescents. Protective efficacy has not been evaluated in males. The use of Gardasil should be in accordance with official recommendations."

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For more information on Gardasil, please see: http://www.emea.europa.eu/humandocs/Humans/EPAR/gardasil/gardasil.htm.

3. The same vaccine is also marketed in the EU as Silgard. For more information on Silgard, please see: http://www.emea.europa.eu/humandocs/Humans/EPAR/silgard /silgard.htm.
4. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu

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