



European Medicines Agency
Press office

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PRESS RELEASE

EMEA statement on the safety of Gardasil

The European Medicines Agency (EMA) has received reports of deaths in women who had previously received Gardasil, including two reports concerning the sudden and unexpected deaths of two young women in the European Union (EU). Gardasil is a vaccine approved in the EU for the prevention of cervical cancer and other diseases caused by human papillomavirus (HPV) types 6, 11, 16 and 18. It is estimated that about 1.5 million patients have been vaccinated with this HPV vaccine in Europe.

The two European cases were reported as part of the continuous monitoring of the safety of medicines. One of the cases occurred in Austria and the other in Germany. In both cases, the cause of death could not be identified. No causal relationship has been established between the deaths of the young women and the administration of Gardasil.

On the basis of the currently available evidence, the EMA's Committee for Medicinal Products for Human Use (CHMP) is of the opinion that the benefits of Gardasil continue to outweigh its risks and that no changes to its product information are necessary.

The EMA will continue to closely monitor the safety of Gardasil and take appropriate actions should new information emerge that has an impact on the benefit-risk profile of Gardasil.

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Notes:

1. The approved indication in the EU for Gardasil is: "Gardasil is a vaccine for the prevention of high-grade cervical dysplasia (CIN 2/3), cervical carcinoma, high-grade vulvar dysplastic lesions (VIN 2/3), 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." For more information on Gardasil, please see: <http://www.emea.europa.eu/humandocs/Humans/EPAR/gardasil/gardasil.htm>.
2. HPV types 6, 11, 16 and 18 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>.
3. This press release, together with other information on the work of the EMA, can be found on the EMA website: www.emea.europa.eu

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