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EMA to further clarify safety profile of human papillomavirus (HPV) vaccines

The European Medicines Agency (EMA) has started a review of HPV vaccines to further clarify aspects of their safety profile. These vaccines have been used in around 72 million people worldwide and their use is expected to prevent many cases of cervical cancer (cancer of the neck of the womb) and various other cancers and conditions caused by HPV. Cervical cancer is the 4th most common cause of cancer death in women worldwide, with tens of thousands of deaths in Europe each year despite the existence of screening programmes to identify the cancer early. The review does not question that the benefits of HPV vaccines outweigh their risks.

As for all licensed medicines the safety of these vaccines is monitored by the Agency's Pharmacovigilance Risk Assessment Committee (PRAC). The current review will look at available data with a focus on rare reports of two conditions: complex regional pain syndrome (CRPS, a chronic pain condition affecting the limbs) and postural orthostatic tachycardia syndrome (POTS, a condition where the heart rate increases abnormally after sitting or standing up, causing symptoms such as dizziness and fainting, as well as headache, chest pain and weakness).

Reports of these conditions in young women who have received an HPV vaccine have been previously considered during routine safety monitoring by the PRAC but a causal link between them and the vaccines was not established. Both conditions can occur in non-vaccinated individuals and it is considered important to further review if the number of cases reported with HPV vaccine is greater than would be expected.

In its review the PRAC will consider the latest scientific knowledge, including any research that could help clarify the frequency of CRPS and POTS following vaccination or identify any causal link. Based on this review, the Committee will decide whether to recommend any changes to product information to better inform patients and healthcare professionals. While the review is ongoing there is no change in recommendations for the use of the vaccine.

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More about the medicine

HPV vaccines are available in the European Union under the names Gardasil/Silgard, Gardasil 9, and Cervarix. Gardasil has been authorised since September 2006, and is approved in both males and females for preventing precancerous growths and cancer in the cervix and anus, and genital warts. It protects against 4 types of HPV (types 6, 11, 16 and 18). Gardasil 9 (approved in June 2015) is used similarly but protects against 9 types of the virus (6, 11, 16, 18, 31, 33, 45, 52 and 58). Cervarix has been approved since September 2007 for use in women and girls to protect against precancerous growths and cancer in the cervix and genital area. It is active against types 16 and 18 of the virus. Following their approval, the vaccines have been introduced in national immunisation programs in many countries worldwide.

More about the procedure

The review of HPV vaccines has been initiated by the European Commission at the request of Denmark, under Article 20 of Regulation (EC) No 726/2004.

The review is being carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which will make a set of recommendations. The PRAC recommendations will then be forwarded to the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which will adopt a final opinion. The final stage of the review procedure is the adoption by the European Commission of a legally binding decision applicable in all EU Member States.