27 March 2015
EMA/CHMP/202995/2015
Press Office

Press release

Gardasil 9 offers wider protection against cancers caused by human papillomavirus (HPV)

Vaccine covers five more types of HPV than previously approved Gardasil vaccine

The European Medicines Agency (EMA) has recommended Gardasil 9 (human papillomavirus vaccine) for the prevention of diseases caused by nine types of human papillomavirus (HPV). This means that Gardasil 9 covers five more HPV types than Gardasil, one of two HPV vaccines available in the European Union (EU).

HPV is a group of viruses that commonly affects both men and women. Infection with some types of HPV can cause abnormal tissue growth including warts, and changes to cells. Persistent infection with certain types of HPV can also cause cancers of the cervix, anus, vagina and vulva, as well as cancers of the mouth and throat. Nearly 100% of cervical cancers, 90% of anal cancers, 70% of vaginal cancers and 15% of vulvar cancers are caused by HPV.

Gardasil 9 is recommended for use in boys and girls from nine years of age to protect against cervical cancer and pre-malignant cervical lesions, vulvar and vaginal cancers and pre-malignant vulvar and vaginal lesions, pre-malignant anal lesions and anal cancers and external genital warts covered by HPV types 6, 11, 16, 18, 31, 33, 45, 52 and 58.

Like Gardasil, it protects against the most common HPV types associated with disease (6, 11, 16, 18), but it also protects against five additional HPV types (31, 33, 45, 52 and 58).

Gardasil 9's recommendation is based on four main studies, which looked at the efficacy of Gardasil 9 in protecting against disease caused by HPV types 31, 33, 45, 52 and 58, and also assessed whether Gardasil 9 continued to protect against HPV types 6, 11, 16, 18 compared with Gardasil.

The safety of Gardasil 9 was evaluated in more than 23,000 people in seven clinical trials. The assessment also took into account experience from the use of Gardasil, which has been authorised in the EU since 2006. The most commonly reported adverse reactions were injection site pain, swelling, redness, and headaches.

Gardasil 9 is administered in three separate injections, with the initial dose followed by additional injections given two and six months later. All three doses should be given within a one-year period.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 8427 **Facsimile** +44 (0)20 3660 5555
E-mail press@ema.europa.eu **Website** www.ema.europa.eu

The company received scientific advice from the Committee for Medicinal Products for Human Use (CHMP) which pertained to clinical aspects of the company's application.

The opinion adopted by the CHMP at its March 2015 meeting is an intermediary step on Gardasil 9's path to patient access. The CHMP opinion will now be sent to the European Commission for the adoption of a decision on EU-wide marketing authorisation. Once a marketing authorisation has been granted, a decision about price and reimbursement will then take place at the level of each Member State considering the potential role/use of this vaccine in the context of the national health system of that country.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The marketing authorisation applicant for Gardasil 9 is Sanofi Pasteur MSD SNC.
3. Cervarix (human papillomavirus vaccine [types 16, 18]) was approved for use in the EU in 2007.
4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

Contact our press officer

Monika Benstetter

Tel. +44 (0)20 3660 8427

E-mail: press@ema.europa.eu