

25 April 2014
EMA/CHMP/253675/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Gardasil

human papillomavirus vaccine [types 6, 11, 16, 18] (recombinant, adsorbed)

On 25 April 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a variation to the terms of the marketing authorisation for the medicinal product Gardasil. The marketing authorisation holder for this medicinal product is Sanofi Pasteur MSD, SNC. They may request a re examination of the CHMP opinion, provided that they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The CHMP adopted a new indication as follows:

"Gardasil is a vaccine for use from the age of 9 years for the prevention of:

- premalignant genital lesions (cervical, vulvar and vaginal), premalignant anal lesions, cervical cancers and anal cancers causally related to certain oncogenic Human Papillomavirus (HPV) types
- genital warts (condyloma acuminata) causally related to specific HPV types.

See sections 4.4 and 5.1 for important information on the data that support this indication.

The use of Gardasil should be in accordance with official recommendations."

Detailed conditions for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.

For information, the full indication for Gardasil will be as follows²:

"Gardasil is a vaccine for use from the age of 9 years for the prevention of:

- premalignant genital lesions (cervical, vulvar and vaginal), **pre-malignant anal lesions**, cervical cancers **and anal cancers** causally related to certain oncogenic Human Papillomavirus (HPV) types

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the opinion.

² The text in bold represents the new or the amended indication.

- genital warts (condyloma acuminata) causally related to specific HPV types.

See sections 4.4 and 5.1 for important information on the data that support this indication.

The use of Gardasil should be in accordance with official recommendations."