



COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
POST-AUTHORISATION SUMMARY OF POSITIVE OPINION*
for
SILGARD

International Nonproprietary Name (INN): *human papillomavirus vaccine [types 6, 11 16, 18]*
(*recombinant, adsorbed*)

On 30 May 2008 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion** to recommend the variation to the terms of the marketing authorisation for the medicinal product Gardasil. The Marketing Authorisation Holder for this medicinal product is Merck Sharp & Dohme Ltd.

The CHMP adopted the extension of the therapeutic indication to include the prevention of high-grade vaginal dysplastic lesions (VaIN 2/3).

Detailed conditions for the use of this product will be described in the updated Summary of Product Characteristics (SPC) 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 follows:

“Silgard 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 (see section 5.1).

The indication is based on the demonstration of efficacy of Silgard in adult females 16 to 26 years of age and on the demonstration of immunogenicity of Silgard in 9- to 15-year old children and adolescents. Protective efficacy has not been evaluated in males (see section 5.1).

The use of Silgard should be in accordance with official recommendations”

* 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.

** Marketing Authorisation Holders may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.