European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

London, 27 July 2006
Doc.Ref. EMEA/CHMP/274938/2006

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

Common name**: *Human Papillomavirus Vaccine [Types 6, 11, 16, 18] (recombinant, adsorbed)***

On 27 July 2006 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Silgard, suspension for injection, intended for prevention of cervical cancer, precancerous or dysplastic lesions, and genital warts caused by HPV types targeted by the vaccine. The applicant for this medicinal product is Merck Sharpe & Dohme.
The active substances of Silgard are the virus-like particles of the recombinant major capsid (L1) protein of Human Papillomavirus types 6, 11, 16, and 18 (Viral Vaccine, J07BD52). The antigens of the vaccine act profilactically by stimulating an immune response against the above-mentioned disease.

The benefits with Silgard are its vaccination against cervical and EGL lesions due to HPV infection (types 6, 11, 16 and 18). The most common side effects are pyrexia, pain, erythema and swelling at the injection site.

The approved indication is: “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) casually related to Human Papillomavirus (HPV) types 6, 11, 16 and 18. 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 adolescent. Protective efficacy has not been evaluated in males”.

Detailed conditions for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.
The CHMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Silgard and therefore recommends the granting of the marketing authorisation.

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* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

** Applicants 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.

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