21 February 2013
EMA/CHMP/101703/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Cervarix

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

On 21 February 2013, 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 Cervarix. The marketing authorisation holder for this medicinal product is GlaxoSmithKline Biologicals S.A. 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 an extension to the therapeutic indication for the prevention of premalignant genital (cervical, vulvar and vaginal) lesions causally related to certain oncogenic Human Papillomavirus (HPV) types.

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 Cervarix will be as follows[2]:

Cervarix is a vaccine for use from the age of 9 years for the prevention of premalignant **genital (**cervical, **vulvar and vaginal)** lesions and cervical cancer causally related to certain oncogenic Human Papillomavirus (HPV) types. See section 5.1 for important information on the data that support this indication.

[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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8613
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union