



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

23 June 2016  
EMA/CHMP/389753/2016  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (post authorisation)

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### Cervarix

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

On 23 June 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Cervarix. The marketing authorisation holder for this medicinal product is GlaxoSmithKline Biologicals.

The CHMP adopted an extension to the existing indication as follows <sup>2</sup>:

Cervarix is a vaccine for use from the age of 9 years for the prevention of premalignant **ano-**genital lesions (cervical, vulvar, ~~and~~ vaginal **and anal**) ~~lesions~~ and cervical **and anal** cancers causally related to certain oncogenic Human Papillomavirus (HPV) types.

For information, the full indications for Cervarix will be as follows:

"Cervarix is a vaccine for use from the age of 9 years for the prevention of premalignant ano-genital lesions (cervical, vulvar, vaginal and anal) and cervical and anal cancers causally related to certain oncogenic Human Papillomavirus (HPV) types. See sections 4.4 and 5.1 for important information on the data that support this indication.

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

Detailed recommendations 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 a decision on this change to the marketing authorisation has been granted by the European Commission.

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<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

<sup>2</sup> **New text in bold, removed text as strikethrough**

