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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): human papillomavirus 9-valent vaccine (recombinant, adsorbed)

Procedure No. EMEA/H/C/PSUSA/00010389/202206

Period covered by the PSUR: 09 June 2021 to 09 June 2022

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for human papillomavirus 9-valent vaccine (recombinant, adsorbed), the scientific conclusions of CHMP are as follows:

In 2014 Acute disseminated encephalomyelitis was included as an adverse event for qHPV (Gardasil) in the post-marketing Adverse Events section as based on the available evidence, a causal relationship between qHPV and the adverse event was at least a reasonable possibility. At the time of the Marketing Authorisation of 9HPV (Gardasil 9) a sentence was included in the SmPC section 4.8 to indicate that some adverse experiences had been spontaneously reported during post-approval use of qHPV vaccine and may also be seen in post-marketing experience with Gardasil 9. This latest sentence was relevant when the post-marketing experience with HPV9 was limited since the vaccines contain L1 HPV proteins of 4 of the same HPV types.

The MAH has continuously reviewed cases of Acute Disseminated Encephalomyelitis (ADEM). During this procedure, it has been concluded that this review has not raised new safety signal.

In view of available data on the reports and the comprehensive analysis of post-marketing experience to date, the PRAC considers that scientific evidence does not support a causal relationship between human papillomavirus 9-valent vaccine (recombinant, adsorbed) and Acute Disseminated Encephalomyelitis (ADEM). Based on this, a change to the SmPC section 4.8 to remove the sentence that refers to the possibility of observing the same adverse events for Gardasil and Gardasil 9 is agreed.

The PRAC concluded that the product information of products containing human papillomavirus 9-valent vaccine (recombinant, adsorbed) should be amended accordingly.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for human papillomavirus 9-valent vaccine (recombinant, adsorbed) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing human papillomavirus 9-valent vaccine (recombinant, adsorbed) is unchanged subject to the proposed changes to the product information

The CHMP recommends that the terms of the marketing authorisation(s) should be varied.