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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): COVID-19 vaccine (Ad26.COV2-S [recombinant]) (JCOVDEN)

Procedure No. EMEA/H/C/PSUSA/00010916/202202

Period covered by the PSUR: 24/08/2021 To: 24/02/2022

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for COVID-19 vaccine (Ad26.COV2-S [recombinant]) (JCOVDEN), the scientific conclusions of CHMP are as follows:

In view of available data on facial paralysis (including Bell's palsy) from clinical trial(s) and spontaneous reports including cases with a close temporal relationship and no other alternative explanation, the PRAC considers a causal relationship between 'COVID-19 vaccine (Ad26.COV2-S [recombinant]) (JCOVDEN) and facial paralysis (including Bell's palsy) is at least a reasonable possibility. The PRAC concluded that the product information of products containing 'COVID-19 vaccine (Ad26.COV2-S [recombinant]) (JCOVDEN) 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 COVID-19 vaccine (Ad26.COV2-S [recombinant]) (JCOVDEN) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing COVID-19 vaccine (Ad26.COV2-S [recombinant]) (JCOVDEN) 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.