26 January 2023
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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 (ChAdOx1-S [recombinant]) (Vaxzevria)

Procedure No. EMEA/H/C/PSUSA/00010912/202206

Period covered by the PSUR: 29 Dec 2021 To: 28 June 2022

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for COVID-19 Vaccine (ChAdOx1-S [recombinant]) (Vaxzevria), the scientific conclusions of CHMP are as follows:

In view of available data on **cutaneous vasculitis** from literature and spontaneous reporting including in the majority of cases a close temporal relationship and in some cases, a positive rechallenge, the PRAC agrees that a causal relationship between COVID-19 Vaccine (ChAdOx1-S [recombinant]) (Vaxzevria) and cutaneous vasculitis is at least a reasonable possibility.

The PRAC concluded that the product information of product containing COVID-19 Vaccine (ChAdOx1-S [recombinant]) (Vaxzevria) 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 (ChAdOx1-S [recombinant]) (Vaxzevria) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing COVID-19 Vaccine (ChAdOx1-S [recombinant]) (Vaxzevria) 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.