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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/00010912/202112

Period covered by the PSUR: 29 June 2021 To: 28 December 2021

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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 tinnitus from clinical trial(s), the literature, and spontaneous reports including in the majority of cases a close temporal relationship, the PRAC considers a causal relationship between COVID-19 Vaccine (ChAdOx1-S [recombinant]) and tinnitus is at least a reasonable possibility. The PRAC concluded that the product information of products containing COVID-19 Vaccine (ChAdOx1-S [recombinant]) (Vaxzevria) should be amended accordingly.

Moreover, based on available data on paraesthesia and hypoaesthesia from spontaneous reporting including in the majority of cases a close temporal relationship occurring mainly in the context of reactogenicity reactions, the PRAC considers a causal relationship between COVID-19 Vaccine (ChAdOx1-S [recombinant]) and paraesthesia and hypoaesthesia 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.