EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 December 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): SARS-CoV-2, B.1.351 variant, prefusion Spike delta TM protein, recombinant

Procedure No. EMEA/H/C/PSUSA/00011035/202305

Period covered by the PSUR:
09 November 2022 To: 09 May 2023

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for SARS-CoV-2, B.1.351 variant, prefusion Spike delta TM protein, recombinant, the scientific conclusions of PRAC are as follows:

In view of available data on dizziness from clinical trials, spontaneous reports, including in some cases a close temporal relationship, the PRAC considers a causal relationship between SARS-CoV-2, B.1.351 variant, prefusion Spike delta TM protein, recombinant and dizziness is at least a reasonable possibility. The PRAC concluded that the product information of products containing SARS-CoV-2, B.1.351 variant, prefusion Spike delta TM protein, recombinant should be amended accordingly.

Having reviewed the PRAC recommendation, the CHMP agrees with the PRAC overall conclusions and grounds for recommendation.

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

On the basis of the scientific conclusions for SARS-CoV-2, B.1.351 variant, prefusion Spike delta TM protein, recombinant the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing SARS-CoV-2, B.1.351 variant, prefusion Spike delta TM protein, recombinant 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.