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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 mrna vaccine (nucleoside-modified) (Spikevax)

Procedure No. EMEA/H/C/PSUSA/00010897/202106

Period covered by the PSUR: 18 December 2020 to 30 June 2021

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for COVID-19 mRNA Vaccine (nucleoside-modified) (Spikevax), the scientific conclusions of CHMP are as follows:

Paraesthesia

In view of available data on paraesthesia from clinical trials and spontaneous reports including cases with a plausible temporal relationship, and in view of plausible mechanism of action, the PRAC considers a causal relationship between COVID-19 mRNA Vaccine (nucleoside-modified) (Spikevax) and paraesthesia is at least a reasonable possibility. The PRAC concluded that the product information of products containing COVID-19 mRNA Vaccine (nucleoside-modified) (Spikevax) 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

On the basis of the scientific conclusions for COVID-19 mRNA vaccine (nucleoside-modified) (Spikevax) the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing COVID-19 mRNA Vaccine (nucleoside-modified) (Spikevax) is unchanged subject to the proposed changes to the product information.

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