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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): elasomeran

Procedure No. EMEA/H/C/PSUSA/00010897/202112

Period covered by the PSUR: 30/06/2021 To: 31/12/2021

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for elasomeran, the scientific conclusions of CHMP are as follows:

Extensive swelling of vaccinated limb

In view of available data on Extensive swelling of vaccinated limb, including a high number of spontaneous reports with a close temporal relationship, and in view of a plausible mechanism of action, the PRAC considers that a causal relationship between elasomeran and extensive swelling of vaccinated limb is at least a reasonable possibility. The PRAC concluded that the product information of products containing elasomeran 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 elasomeran the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing elasomeran 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.