20 July 2023
EMA/371629/2023
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 (Spikevax), elasomeran / imelasomeran (Spikevax bivalent Original/Omicron BA.1), elasomeran / davesomeran (Spikevax bivalent Original/Omicron BA.4-5)

Procedure No. EMEA/H/C/PSUSA/00010897/202212

Period covered by the PSUR:
16/06/2022 To: 16/12/2022

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 elasomeran (Spikevax), elasomeran / imelasomeran (Spikevax bivalent Original/Omicron BA.1), elasomeran / davesomeran (Spikevax bivalent Original/Omicron BA.4-5), the scientific conclusions of CHMP are as follows:

Myocarditis

In view of the available evidence on myocarditis and pericarditis from the literature and spontaneous reports, the PRAC considers that new information on the course and outcome of myocarditis and pericarditis are identified. The PRAC concludes that the product information of products containing elasomeran, elasomeran/imelasomeran, and elasomeran/davesomeran should be amended accordingly.

Use in immunocompromised subjects

In view of the available evidence on use in immunocompromised subjects from post-authorisation safety studies, literature and spontaneous reporting, the PRAC considers that use in immunocompromised subjects is no longer a safety concern. The PRAC concludes that the product information of products containing elasomeran, elasomeran/imelasomeran, and elasomeran/davesomeran should be amended accordingly.

Mechanical urticaria

In view of the available evidence on mechanical urticaria from the literature and spontaneous reports, including cases with a plausible temporal relationship, and in view of a plausible mechanism of action, the PRAC considers a causal relationship between elasomeran, elasomeran/imelasomeran, and elasomeran/davesomeran and mechanical urticaria to be at least a reasonable possibility. The PRAC concludes that the product information of products containing elasomeran, elasomeran/imelasomeran, and elasomeran/davesomeran 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 (Spikevax), elasomeran / imelasomeran (Spikevax bivalent Original/Omicron BA.1), elasomeran / davesomeran (Spikevax bivalent Original/Omicron BA.4-5), the CHMP is of the opinion that the benefit-risk balance of the medicinal products containing elasomeran (Spikevax), elasomeran / imelasomeran (Spikevax bivalent Original/Omicron BA.1), elasomeran / davesomeran (Spikevax bivalent Original/Omicron BA.4-5) 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.