12 December 2024
EMA/62447/2025
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): respiratory syncytial virus, glycoprotein f, recombinant, stabilised in the pre-fusion conformation, adjuvanted with as01e

Procedure No. EMEA/H/C/PSUSA/00000031/202405

Period covered by the PSUR:
02/11/2023 To: 02/05/2024

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 respiratory syncytial virus, glycoprotein f, recombinant, stabilised in the pre-fusion conformation, adjuvanted with as01e, the scientific conclusions of PRAC are as follows:

In view of available data on injection site necrosis from spontaneous reports, including at least 7 cases with a close temporal relationship, and in view of a plausible mechanism of action, the PRAC considers that a causal relationship between respiratory syncytial virus, glycoprotein f, recombinant, stabilised in the pre-fusion conformation, adjuvanted with as01e and injection site necrosis is at least a reasonable possibility. The PRAC concludes that the product information of products containing 'respiratory syncytial virus, glycoprotein f, recombinant, stabilised in the pre-fusion conformation, adjuvanted with as01e' 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 respiratory syncytial virus, glycoprotein f, recombinant, stabilised in the pre-fusion conformation, adjuvanted with as01e, the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing respiratory syncytial virus, glycoprotein f, recombinant, stabilised in the pre-fusion conformation, adjuvanted with as01e 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.

In addition, the CHMP has the following comments on the PRAC assessment report:

CHMP notes that the mechanism or risk factors for the occurrence of "injection site necrosis" following vaccination with respiratory syncytial virus, glycoprotein f, recombinant, stabilised in the pre-fusion conformation, adjuvanted with as01e remain uncertain: the event could be vaccine, antigen, adjuvant or procedure related. This, however, does not impact the conclusion of the PRAC, which CHMP confirms. Additionally, editorial amendments to section 4.8 of the SmPC have been introduced to integrate the requested updates. This has been agreed by the CHMP.