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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): respiratory syncytial virus, glycoprotein f, recombinant, stabilised in the pre-fusion conformation, adjuvanted with as01e

Procedure No. PSUSA/00000031/202411

Period covered by the PSUR: 3 May 2024 to 2 November 2024

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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 $AS01_E$, the scientific conclusions of PRAC are as follows:

In view of available data on Guillain-Barré syndrome from clinical trial(s), the literature, spontaneous reports including in some cases a compatible temporal relationship and the information from the SCCS performed by FDA, the PRAC considers that a causal relationship between respiratory syncytial virus, glycoprotein f, recombinant, stabilised in the pre-fusion conformation, adjuvanted with $AS01_E$ and Guillain-Barré syndrome is at least a reasonable possibility. The PRAC concluded that the product information of products containing respiratory syncytial virus, glycoprotein f, recombinant, stabilised in the pre-fusion conformation, adjuvanted with $AS01_E$ 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 $AS01_E$ 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.