EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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 vaccine (bivalent, recombinant)

Procedure No. EMEA/H/C/PSUSA/00000102/202311

Period covered by the PSUR:
30/05/2023 To: 30/11/2023

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for respiratory syncytial virus vaccine (bivalent, recombinant), the scientific conclusions of PRAC are as follows:

In view of available data on Guillain-Barré syndrome (GBS) from clinical trial(s), spontaneous reports including a close temporal relationship in 6 additional post-marketing cases, the PRAC considers a causal relationship between Respiratory Syncytial Virus [RSV] vaccine (bivalent, recombinant) and Guillain-Barré syndrome is at least a reasonable possibility. This is already reflected in the currently approved product information which includes GBS as rare adverse drug reaction in individuals ≥ 60 years of age in SmPC Section 4.8.

However the footnote [a] under the table describing the clinical trial cases has become outdated/surpassed and does not adequately reflect the cumulative evidence (including post-marketing cases) anymore. Consequently, the footnote is redundant and may be misleading to the health care provider and should be removed. The PRAC concluded that the product information of products containing Respiratory Syncytial Virus [RSV] vaccine (bivalent, recombinant) 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 vaccine (bivalent, recombinant) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing respiratory syncytial virus vaccine (bivalent, recombinant) 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.