17 September 2020
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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): pneumococcal polysaccharide conjugate vaccine (adsorbed) - 13 valent

Procedure No. EMEA/H/C/PSUSA/00009263/202001

Period covered by the PSUR: 10/01/2017 to 09/01/2020

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for pneumococcal polysaccharide conjugate vaccine (adsorbed) - 13 valent, the scientific conclusions of CHMP are as follows:

In view of available data on spontaneous reports, including close temporal relationship, and in view of a plausible mechanism of action, the PRAC considers a causal relationship between pneumococcal polysaccharide conjugate vaccine (adsorbed) - 13 valent and anaphylaxis in children above the age of 5 years and adults is at least a reasonable possibility. Consequently the PRAC has updated section 4.8 of the SmPC to add the adverse reaction anaphylaxis with a frequency not known to the group of children above 5 years of age and adults.

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 pneumococcal polysaccharide conjugate vaccine (adsorbed) - 13 valent the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing pneumococcal polysaccharide conjugate vaccine (adsorbed) - 13 valent 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.