10 April 2015
EMA/CHMP/722875/2014
Committee for Medicinal Products for Human Use (CHMP)

Prevenar

Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation

Active substance:PNEUMOCOCCAL POLYSACCHARIDE CONJUGATE VACCINE (7-VALENT, ADSORBED)

Procedure no.: EMEA/H/C/PSUSA/00002452/201408

Period covered by the PSUR: 17 August 2011 – 16 August 2014

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for PNEUMOCOCCAL POLYSACCHARIDE CONJUGATE VACCINE (7-VALENT, ADSORBED), the scientific conclusions of CHMP are as follows:

Due to the long-standing post marketing experience, the well characterised safety profile and the large exposure of the product the PRAC recommended to amend the PSUR frequency to 10-yearly and to amend Annex II accordingly to reflect the current QRD template sentence referring to the EURD list.

Therefore, in view of available data the PRAC considered that changes to the conditions of the marketing authorisation were warranted.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds recommending the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for PNEUMOCOCCAL POLYSACCHARIDE CONJUGATE VACCINE (7-VALENT, ADSORBED) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing PNEUMOCOCCAL POLYSACCHARIDE CONJUGATE VACCINE (7-VALENT, ADSORBED) is favourable subject to the proposed changes to the product information

The CHMP recommends that the terms of the Marketing Authorisation should be varied.