EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 September 2013
EMA/CHMP/771740/2013
Committee for Medicinal Products for Human Use (CHMP)

Prevenar 13

pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed)

Procedure No. EMEA/H/C/001104/PSUV/090

Scientific conclusions and grounds recommending the variation to the terms of the Marketing Authorisation

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for Prevenar 13, the scientific conclusions of PRAC are as follows:

The identified risk of convulsion/seizures (as well as the additional event of HHE) is of concern. Reviews of convulsions/HHE have been made several times, most recently in an extensive cumulative review requested in the last PSUR and assessed in LEG027.1. This concluded that, while estimations of the incidence of seizures and HHE from the clinical trial program for 13vPnC are not possible given limitations related to the size of the database, the cumulative review of all adverse events reported for Prevenar 13 reveals increased rates for both overall neurological events, as well as the more specific conditions of convulsions and HHE, when comparing groups which reported use of Prevenar 13 with concomitant hexavalent vaccine to those which reported use of Prevenar 13 alone. Given that there are suggestions from the literature of increased risks associated with combination use of vaccines as well as the biological plausibility of a link between fever and certain neurological events, it appears that such an association between an increased risk of neurological events and receipt of coadministered Prevenar 13 and Infanrix hexa is possible. The data from this PSUR continue to support the conclusions from the cumulative review assessed in LEG027.1. Therefore, in view of available data regarding an increased risk of convulsion/seizures and HHE with concomitant administration of Prevenar 13 and Infanrix hexa, the PRAC considered that changes to the product information 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 Prevenar 13 the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance pneumococcal polysaccharide type 4, pneumococcal polysaccharide type 23f, pneumococcal polysaccharide type 7f, pneumococcal polysaccharide type 6a, pneumococcal polysaccharide type 5, pneumococcal polysaccharide type 9v, pneumococcal polysaccharide type 1, pneumococcal polysaccharide type 18c, pneumococcal polysaccharide type 19f, pneumococcal polysaccharide type 3, pneumococcal polysaccharide type 14, pneumococcal polysaccharide type 19a, pneumococcal polysaccharide type 6b [pneumococcal polysaccharide conjugate vaccine (adsorbed) - 13-valent] is favourable subject to the proposed changes to the product information.

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