European Medicines Agency
Evaluation of Medicines for Human Use

London, 01 April 2008
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)

OPINION FOLLOWING AN ARTICLE 29(4)[1] REFERRAL FOR

Menitorix

Common Name: *Haemophilus influenzae* type b polysaccharide (polyribosyl ribitol phosphate) conjugated to tetanus toxoid and *Neisseria meningitidis* serogroup C (MenC) polysaccharide conjugated to tetanus toxoid

BACKGROUND INFORMATION

Menitorix, 5 micrograms PRP with 12,5 micrograms TT, 5 micrograms PSC with 5 micrograms TT in the form of Powder and Solvent for Solution for Injection is a vaccine, indicated for the prevention of invasive diseases caused by *Haemophilus influenzae* type b (Hib) and *Neisseria meningitidis* group C (MenC) in infants from the age of 2 months and children up to the age of 2 years.

GlaxoSmithKline Biologicals submitted applications for mutual recognition of Menitorix, 5 micrograms PRP with 12,5 micrograms TT, 5 micrograms PSC with 5 micrograms TT in the form of powder and solvent for solution for injection, on the basis of the marketing authorisation granted by the United Kingdom on 19 December 2005. The Mutual Recognition Procedure started on 17 October 2006. The Reference Member State was the United Kingdom and the Concerned Member States were Belgium, Greece, Ireland, Poland and Spain. These Member States were not able to reach an agreement in respect of the Mutual Recognition of the Marketing Authorisation granted by the Reference Member State. The United Kingdom referred the reasons for disagreement to the EMEA on 29 March 2007.

Public health objections were raised because no immunological correlates of protection were established for MenC conjugates and because the submission of data on pre-licensure effectiveness were required to cover infant and toddler use. Furthermore, it could not be accepted that no data on the use of Menitorix or on antibody persistence beyond the second year of life was provided. These objections were considered to be of serious public health concern.

The arbitration procedure started on 26 April 2007 with the adoption of a list of questions. The Rapporteur was Dr Ian Hudson and Co-Rapporteur was Dr Michał Pirożynski. The Marketing Authorisation Holder provided written explanations on 19 July 2007 and on 17 October 2007.

During their November 2007 meeting, the CHMP, in the light of the overall data submitted and the scientific discussion within the Committee, was of the opinion that the benefit/risk ratio is favourable for Menitorix, that the objections raised by Greece, Poland and Spain should not prevent the granting of a Marketing Authorisation and that the Summary of Product Characteristics, labelling and package leaflet of the Reference Member State should be amended. A positive opinion was adopted by consensus on 15 November 2007.

[1] Article 29(4) of Directive 2001/83/EC, as amended.

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The list of the product names concerned is given in Annex I. The scientific conclusions are provided in Annex II, together with the Summary of Product Characteristics in Annex III.

The final opinion was converted into a Decision by the European Commission on 01 April 2008.