BACKGROUND INFORMATION ON THE PROCEDURE.

1. Submission of the dossier

The company SmithKline Beecham Biologicals S. A., submitted on 26 April 1996 to the European Agency for the Evaluation of Medicinal Products (EMEA), an application to obtain marketing authorisation for the medicinal product TWINRIX Paediatric, in accordance with the Centralised procedure falling within the scope of Part A of the Annex to Council Regulation No. (EC) 2309/93 of 22 July 1993.

Rapporteur and Co-Rapporteur appointed by the CPMP were:

Rapporteur: Dr. D. Jefferys Co-Rapporteur: Dr. M. Teeling

Licensing/authorisation status:

The Twinrix Paediatric was not licensed in any country inside or outside the EEC at the time of submission of the application.

2. Steps taken for the assessment of the product

- The Rapporteur's initial assessment report was circulated to all CPMP Members on 25 July 1996.
- The Co-Rapporteur's initial assessment report was circulated to all CPMP Members on 29 July 1996.
- During the BWP meeting on 2-3 September 1996, a BWP Report to the CPMP on Twinrix Paediatric was prepared and adopted.
- During the CPMP meeting on 10-12 September 1996, the draft-consolidated list of questions was adopted. The possibility of finalising a positive opinion was mentioned by the CPMP, having considered that it seemed unlikely that the company would have any difficulty in answering the List of Questions.
- The CPMP consolidated list of questions was sent to the Company on 11 September 1996.
- The company submitted the responses to the consolidated list of questions on 23 September 1996.
- The Rapporteur’s assessment report on the company’s responses to the consolidated list of questions was circulated on the 26 September 1996.
- The CPMP, during their meeting on 15-17 October 1996, discussed the recommendations presented by the Rapporteur and Co-Rapporteur, and concluded that the responses provided by the company were satisfactory. Amendments to the Summary of Product Characteristics and Package Leaflet texts were also discussed and finalised.
- The CPMP during their meeting of 15-17 October 1996, adopted positive opinions for the granting of a marketing authorisation for Twinrix Paediatric, monodose vial and prefilled syringe presentations, on 16 October 1996.

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