

## **BACKGROUND INFORMATION ON THE PROCEDURE**

### **1. Submission of the dossier**

The applicant Aventis Pasteur MSD submitted on 1 August 2000 an application for a Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMA) for HBVAXPRO, in accordance with the centralised procedure falling within the scope of Part A of the Annex to Council Regulation No (EEC) 2309/93 of 22 July 1993.

The Rapporteur and Co-Rapporteur appointed by the CPMP were:

Rapporteur: Dr. M. Haase

Co-Rapporteur: Dr. D. Brasseur

#### **Licensing status:**

HBVAXPRO has been given a Marketing Authorisation in the United States of America on 27 August 1999, Australia on 14 December 1999 and New Zealand on 16 December 1999

### **2. Steps taken for the assessment of the product**

- In its June meeting the CPMP agreed on an accelerated review for this application responding to the apparent urgent need to provide thiomersal-free hepatitis B vaccine mainly to the European paediatric population.
- The procedure started on 31 October 2000.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 20 November 2000 (Annex 1). The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 20 November 2000 for Part III and IV and 29 November for Part II (Annex 2).
- During the meeting on 12-14 December 2000 the CPMP agreed on the consolidated List of Questions to be sent to the applicant. The final consolidated List of Questions was sent to the company on 14 December 2000 (Annex 3).
- The applicant submitted the responses to the CPMP consolidated List of Questions on 21 December 2000
- The Rapporteur circulated the response Assessment Report on the company's responses to the List of Questions to all CPMP members on 8 January 2001 (Annex 5)
- During the meeting on 23-25 January 2001 the CPMP, in the light of the overall data submitted and the scientific discussion within the Committee, issued a positive opinion for granting a Marketing Authorisation to HBVAXPRO on 25 January 2001.