BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Hoechst Marion Roussel GmbH, Germany submitted on 1 October 1997 to the European Agency for the Evaluation of Medicinal Products (EMEA) an application to obtain a Marketing Authorisation in accordance with Annex II of Commission Regulation (EC) No 542/95 of 10 March 1995 (part VI) for the medicinal products Insuman (human insulin), solution for injection and suspension for injection, falling within the scope of Part A of the Annex of the Council regulation EC No. 2309/93.

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

Rapporteur: Pharm G. De Greef Co-Rapporteur: Dr. W.F. van der Giesen

Licensing status

On 21 February 1997, the European Commission issued a Marketing Authorisation valid throughout the European Union for the medicinal product Insuman.

The MAH will only place on the market the most recently authorised Insuman and not the one authorised in 1997. With regard to the dossier submitted to the EMEA by the applicant in 1997, cross-reference is made to the first centrally authorised Insuman, procedure number EMEA/H/C/119.

2. Steps taken for the assessment of the product

- The company Hoechst AG, Germany submitted on 29 November 1995 to the European Agency for the Evaluation of Medicinal Products (EMEA) an application to obtain a Marketing Authorisation in accordance with the Centralised Procedure for the medicinal product Insuman (Human insulin) falling within the scope of Part A of the Annex to Council Regulation No (EC) 2309/93 of 22 July 1993.
- The Rapporteur's initial assessment report was circulated to all members of the CPMP on 7 February 1996. The Co-Rapporteur's initial assessment report was circulated to all members of the CPMP on 9 February 1996.
- During the February CPMP meeting, the Rapporteur requested a clarification of the trade name issue since semi-synthetic human insulin of porcine origin from the same company is already on the market in several Member States.
- The CPMP agreed on the consolidated list of questions to be sent to the applicant on 13 March 1996.
- The applicant submitted the responses to the consolidated list of questions on 15 August 1996.
- The assessment of the responses was circulated to all CPMP members on 12 September 1996.
- The applicant provided additional information on 27 September 1996.
- Rapporteur's summary of the additional information provided by the company was circulated on 2 October 1996.
- On 11 October 1996 the company submitted additional information regarding the operation conditions. Furthermore, the company committed to a procedure for launch of Insuman (recombinant human insulin) in view of insulin products from porcine origin with the same tradename.

- The CPMP, during the meeting 14-16 October 1996, discussed whether it would be necessary to distinguish between the two different strengths or six different formulations by using a different colour. The company confirmed that they will differentiate Insuman preparations by different colour codes and where there are different strengths of the same type of insulin, the 100 IU/ml strength will have the full colour bar, but the 40 IU/ml strength will have a striped version of the bar in the same colour.
- The CPMP in the light of current scientific standards issued a positive opinion for granting a Marketing Authorisation to the different human insulin formulations on 16 October 1996.
- The Marketing Authorisation for Insuman was granted on 21 February 1997.