BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Sanofi-Aventis Deutschland GmbH submitted on 29 June 2006 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Insulin Human Winthrop through the centralised procedure.

The legal basis for this application refers to Article 10(c) of Directive 2001/83/EC, as amended – relating to informed consent from a marketing authorisation holder for the authorised medicinal product Insuman (EU/1/97/030/028/084).

Licensing status:
The initial product, Insuman, has been given a Marketing Authorisation on 21 February 1997.

The Rapporteur and Co-Rapporteur appointed by the CHMP and the evaluation teams were:
Rapporteur: Pieter Neels Co-Rapporteur: Frits Lekkerkerker

2. Steps taken for the assessment of the product

- The application was received by the EMEA on 29 June 2006.
- The procedure started on 21 July 2006.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 27 September 2006. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 03 October 2006 (revised 12 October 2006).
- During the meeting on 16-18 October 2006, the CHMP agreed on the consolidated List of Questions to be sent to the applicant. The final consolidated List of Questions was sent to the applicant on 19 October 2006.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 24 October 2006.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 13 November 2006.
- During the meeting on 13-16 November 2006, the CHMP, 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 Insulin Human Winthrop on 16 November 2006. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 10 November 2006.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 17 January 2007.