BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Merck Sharp & Dohme Ltd. submitted on 25 April 2007 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for ISENTRESS, through the centralised procedure falling within the Article 3(1) and point 3 of Annex of Regulation (EC) No 726/2004. The eligibility to the centralised procedure was agreed upon by the EMEA/CHMP on 18 October 2006.

The legal basis for this application refers to:

Article 8.3 of Directive 2001/83/EC, as amended - complete and independent application

The application submitted is a complete dossier composed of administrative information, complete quality data, non-clinical and clinical data based on applicants' own tests and studies and/or bibliographic literature substituting/supporting certain test(s) or study(ies).

Scientific Advice:
The applicant received Scientific Advice from the CHMP on 29 July 2005 and on 29 September 2006. The Scientific Advice pertained to quality, non-clinical and clinical aspects of the dossier.

Licensing status:
A new application was filed in the following countries: USA.
The product was not licensed in any country at the time of submission of the application.

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

Rapporteur: I. Hudson
Co-Rapporteur: P. Demolis

2. Steps taken for the assessment of the product

- The application was received by the EMEA on 25 April 2007.
- Accelerated Assessment procedure was agreed-upon by CHMP on 26 April 2007.
- The procedure started on 23 May 2007.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 26 July 2007. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 6 August 2007.
- During the meeting on 17-20 September 2007, 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 17 September 2007.
- During the meeting on 17-20 September 2007, the CHMP agreed to a request from the applicant for a 1 month clock stop to submit responses to the List of Questions.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 22 October 2007.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 1 November 2007.
- During the meeting on 12-15 November 2007, the CHMP, in the light of the overall data submitted and the scientific discussion within the Committee, issued a positive opinion for granting a conditional Marketing Authorisation to ISENTRESS on 15 November 2007. In accordance with Article 3(2) of Regulation (EC) 507/2006 the CHMP in its opinion has proposed a conditional Marketing Authorisation in accordance with Article 6 of Regulation (EC) 726/2004 after having consulted with the applicant. The applicant provided the letter of

undertaking on the specific obligations and follow-up measures to be fulfilled post-authorisation on 13 November 2007.

- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 20 December 2007.