BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Merck Sharp & Dohme Ltd. submitted on 3 September 2007 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for TESAVEL, through the centralised procedure according to Regulation (EC) No 726/2004.

The legal basis for this application refers to Article 10(c) of Directive 2001/83/EC, as amended, relating to informed consent from the marketing authorisation holder, Merck Sharp & Dohme Ltd, for the authorised medicinal product Januvia (EU/1/07/383/001-018).

Scientific Advice:
The applicant did not seek scientific advice at the CHMP.

Licensing status:
The initial product, Januvia, has been given a Community Marketing Authorisation on 21 March 2007.

The Rapporteur and Co-Rapporteur appointed by the CHMP and the evaluation teams were:
Rapporteur: **Pieter de Graeff** Co-Rapporteur: **Harald Enzmann**

2. Steps taken for the assessment of the product

- The application was received by the EMEA on 3 September 2007.
- The procedure started on 16 September 2007.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 18 October 2007. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 18 October 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 Marketing Authorisation to TESAVEL on 15 November 2007. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 14 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 10 January 2008.