BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Merck Sharp & Dohme Ltd. submitted on 8 September 2006 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Xelevia, 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 13 October 2005

The legal basis for this application refers to:

A - Centralised / Article 8(3) / New active substance.

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 tests or studies.

Xelevia is a duplicate application of Januvia.

Scientific Advice:
The applicant received Scientific Advice for Januvia from the CHMP on 22 January 2004 and on 24 June 2004. The Scientific Advice pertained to preclinical and clinical aspects of the dossier.

Licensing status:
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 and the evaluation teams were:
Rapporteur: **Frits Lekkerkerker** Co-Rapporteur: **Harald Enzmann**

2. Steps taken for the assessment of the product

- The application was received by the EMEA on 06 July 2006.
- The procedure started on 17 September 2006. Start date was in alignment with the re-start of the Januvia procedure after the submission of the responses to the D120 LoQ.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 20 October 2006 (Annex 4.1).
- During the CHMP meeting on 13-16 November 2006, the CHMP agreed on a list of outstanding issues to be addressed in writing by the applicant (Annex 4.2).
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Outstanding Issues to all CHMP members on 12 January 2007 (Annex 4.3)
- During the meeting on 22-24 January 2007, the CHMP, in light of the overall data submitted and the discussion within the Committee, issued a positive opinion for granting a Marketing Authorisation to Xelevia on 24 January 2007. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 23 January 2007 (Annex 4.4).