## BACKGROUND INFORMATION ON THE PROCEDURE

### 1. Submission of the dossier

The applicant Novartis Europharm Limited submitted on 01 December 2006 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Eucreas, 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 21 September 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 bibliographic literature substituting or supporting certain tests or studies.

The applicant applied for an indication treatment of type 2 diabetes mellitus.

**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 were:

Rapporteur: **Bengt Ljungberg** Co-Rapporteur: **Pierre Demolis**

### 2. Steps taken for the assessment of the product

- The application was received by the EMEA on 01 December 2006.
- The procedure started on 24 January 2007.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 13 April 2007. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 17 April 2007.
- During the meeting on 24 May 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 24 May 2007.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 13 July 2007.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 31 August 2007.
- During the meeting on 17-20 September 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 EUCREAS on 20 September. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 17 September 2007.