## BACKGROUND INFORMATION ON THE PROCEDURE

### 1. Submission of the dossier

The applicant Novartis Europharm Ltd. submitted on 25 July 2006 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Galvus, 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 30 January 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 tests or studies.

**Scientific Advice**
The applicant received Scientific Advice from the CHMP on 21 November 2003, 24 June 2004 and on 22 October 2004. The Scientific Advice pertained to 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: **Bengt Ljungberg** Co-Rapporteur: **Pierre Demolis**

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

- The application was received by the EMEA on 25 July 2006.
- The procedure started on 16 August 2006.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 27 October 2006. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 31 October 2006.
- During the meeting on 14 December 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 15 December 2006.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 14 March 2007.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 27 April 2007.
- During the CHMP meeting on 24 May 2007 the CHMP agreed on a list of outstanding issues to be addressed in writing and in an oral explanation by the applicant.
- During the meeting on 16-19 July 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 Galvus on 19 July 2007. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 16 July 2007.