BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Bristol-Myers Squibb Pharma Belgium Sprl submitted on 02 February 2005 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Luminity, through the centralised procedure.

The legal basis for this application refers to:
Article 8.3 of Directive 2001/83/EC, as amended - complete and independent application, (i.e. complete dossier with administrative, quality, non-clinical and clinical data).

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

Licensing status:
Luminity has been given a Marketing Authorisation in Canada on 28 December 2000, in the United States on 31 July 2001, in Mexico on 23 June 2004, in Chile on 23 August 2004, in Colombia on 01 September 2004, in Brazil on 6 September 2004, in Israel on 07 July 2005, in Argentina on 30 August 2005 and in Venezuela on 17 November 2005.
A new application was filed in the following countries: Egypt, Korea, Singapore and India.

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

Rapporteur:	Patrick Salmon	Co-Rapporteur:	Concepción Prieto Yerro

2 Steps taken for the assessment of the product

- The application was received by the EMEA on 2 February 2005.
- The procedure started on 21 February 2005.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 10 May 2005 (Annex 1). The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 17 May 2005 and 23 May 2005 (Annex 2).
- During the meeting in June 2005, 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 June 2005 (Annex 3).
- The applicant submitted the responses to the CHMP consolidated List of Questions on 14 January 2006.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 27 February 2006 (Annex 4).
- During the CHMP meeting in March 2006, the CHMP agreed on a list of outstanding issues to be addressed in writing and/or in an oral explanation by the applicant, and questions for the CHMP Scientific Advisory Group (SAG) for Diagnostics (Annex 5).
- The applicant submitted the written responses to the questions for the CHMP Scientific Advisory Group (SAG) for Diagnostics on 09 May 2006.
- During a meeting of the CHMP SAG for Diagnostics on 23 May 2006, experts were convened to address questions raised by the CHMP. During this meeting the applicant presented the applicant's views on the questions related to Luminity (Annex 6).
- The applicant submitted full written responses to the CHMP List of Outstanding Issues on 05 June 2006.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Outstanding issues to all CHMP members on 20 June 2006 and 21 June 2006 (Annex 7).

- During the CHMP meeting in June 2006, outstanding issues were addressed by the applicant during an oral explanation before the CHMP.
- During the meeting on 24-27 July 2006, 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 Luminity on 27 July 2006. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 25 July 2006 (Annex 8).
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 20 September 2006.