BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Novartis Europharm Ltd. submitted on 5 September 2006 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Sprimeo, through the centralised procedure under Article 3 (2) (a) of Regulation (EC) No 726/2004. The eligibility to the centralised procedure was agreed upon by the EMEA/CHMP on 23 February 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 test(s) or study(ies)

Scientific Advice:
The applicant received Scientific Advice from the CHMP on 3 June 2004. The Scientific Advice pertained to non-clinical and clinical aspects of the dossier.

Licensing status:
A new application was filed in the following countries: USA, Canada.
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: Giuseppe Nisticó
Co-Rapporteur: János Borvendég
CHMP Peer reviewers: Alar Irs, Karl Broich

2. Steps taken for the assessment of the product

- The application was received by the EMEA on 5 September 2006.
- The procedure started on 27 September 2006.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 11 December 2006. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 8 December 2006.
- During the meeting on 22-24 January 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 25 January 2007.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 15 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 21-24 May 2007, the CHMP agreed on a list of outstanding issues to be addressed in writing by the applicant.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of outstanding Issues to all CHMP members on 9 June 2007.
- During the meeting on 18-21 June 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 Sprimeo on 21 June 2007. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 15 June 2007.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 22 August 2007.