BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Novartis Europharm Ltd. submitted on 8 February 2006 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Exforge, 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 14 December 2005.

The legal basis for this application refers to:

Article 10(b) of Directive 2001/83/EC, as amended – relating to applications new fixed combination products.

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 studies.

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

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: Steffen Thirstrup Co-Rapporteur: Alar Irs

2. Steps taken for the assessment of the product

- The application was received by the EMEA on 8 February 2006.
- The procedure started on 1 March 2006.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 22 May 2006 (Annex 4.1). The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 19 May 2006.
- During the meeting on 26-28 June 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 29 June 2006.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 9 August 2006.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 26 September 2006.
- During the CHMP meeting on 16 – 18 October 2006, the CHMP agreed on a List of Outstanding Issues to be addressed in writing by the applicant.
- The applicant submitted the responses to the CHMP consolidated List of Outstanding Issues on 24 October 2006.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Outstanding Issues to all CHMP members on 1 November 2006.
- During the meeting on 13 – 16 November 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 Exforge on 16 November 2006. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 24 October 2006.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 17 January 2007.