BACKGROUND INFORMATION ON THE PROCEDURE

1 Submission of the dossier

The applicant Procter & Gamble Pharmaceuticals – Germany GmbH submitted on 25 October 2004 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Livensa, 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

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

Rapporteur: Tomas P Salmonson Co-Rapporteur: Josef Suko

Licensing status:

The product was not licensed in any country at the time of submission of the application.

2 Steps taken for the assessment of the product

- The application was received by the EMEA on 25 October 2004.
- The procedure started on 15 November 2004.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 25 January 2005. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 25 January 2005
- During the meeting on 14-17 March 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 17 March 2005.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 11 November 2005. Responses to the questions raised on the restricted part of the ASMF were submitted by the ASM on 10 November 2005
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 29 December 2005.
- During the CHMP meeting on 23-26 January 2006, the CHMP agreed on a list of outstanding issues to be addressed in writing and if necessary in an oral explanation by the applicant.
- The applicant submitted the responses to the CHMP a list of outstanding issues on 10 March 2006. The Active Substance manufacturer submitted the responses to the outstanding issue relating to the restricted part of the ASMF on 13 March 2006.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of outstanding issues to all CHMP members on 31 March 2006.
- The Rapporteurs circulated a revised Joint Assessment Report on the applicant's responses to the List of outstanding issues to all CHMP members on 21 April 2006.
- During the meeting on 24-27 April 2006, the CHMP, in the light of the overall data submitted, the Committee agreed to the applicant's request for 1-month extension of clock-stop in order to allow for finalisation of the Product Information.
- The Rapporteurs circulated an assessment Report concerning the Product Information to all CHMP members on 3 May 2006.
- The Rapporteurs circulated a revised assessment Report concerning the Product Information to all CHMP members on 22 May 2006.

- During the meeting on 29 May - 1 June 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 Livensa on 1 June 2006. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 31 May 2006.
- The European Commission granted a marketing authorisation valid throughout the European Union for Livensa on 28 July 2006.