BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant GlaxoSmithKline Biologicals S.A. submitted on 8 May 2003 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Fendrix, in accordance with the centralised procedure falling within the scope of Part A of the Annex to Council Regulation No (EEC) 2309/93 of 22 July 1993.

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

Rapporteur: Pieter Neels Co-Rapporteur: Lars Gramstad

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 8 May 2003.
- The procedure started on 26 May 2003.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 25 July 2003. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 5 August 2003.
- During the meeting on 23-25 September 2003, 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 26 September 2003.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 8 July 2004.
- The Rapporteurs circulated the Joint Assessment Report on the applicant’s responses to the List of Questions to all CHMP members on 1 September 2004.
- During the CHMP meeting on 13-16 September 2004, the CHMP agreed on a list of outstanding issues to be addressed in writing by the applicant.
- During the meeting on 18-21 October 2004, 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 Fendrix on 21 October 2004.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 2 February 2005.