BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant GlaxoSmithKline submitted on 22 May 2003 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Quintanrix, 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: P.Neels Co-Rapporteur: P.Rossi

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 procedure started on 23 June 2003.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 12 September 2003. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 12 September 2003.
- During the meeting on 21-22 October 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 23 October 2003.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 15 April 2004.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 18 May 2004.
- During the CHMP meeting on 23 June 2004, 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 list of outstanding issues on 3 September 2004.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of outstanding issues to all CHMP members on 24 September 2004.
- During the meeting on 19-21 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 Quintanrix on 21 October 2004. The applicant provided the letter of undertaking dated 19 October 2004 on the follow-up measures to be fulfilled post-authorisation.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 17 February 2005.