BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant GlaxoSmithKline Biologicals S.A. submitted on 2 December 2004 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Rotarix, through the centralised procedure. The eligibility to the centralised procedure was agreed upon by the EMEA/CHMP on 19 November 2004.

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

Rapporteur: P. Neels Co-Rapporteur: E. Skovlund

Licensing status:

Rotarix has been given a Marketing Authorisation in Mexico on 12 July 2004.

2. Steps taken for the assessment of the product

- The application was received by the EMEA on 2 December 2004.
- The procedure started on 20 December 2004.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 2 March 2005. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 1 March 2005.
- The BWP during its meeting of 11-13 April 2005 adopted the BWP Report to be transmitted to the CHMP for endorsement.
- During the meeting on 18-21 April, 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 21 April 2005.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 9 August 2005.
- The summary report of the inspection carried out at the manufacturing site Rixensart on 1 June 2005 was issued on 8 August 2005.
- The Rapporteurs circulated the Joint Assessment Report on the applicant’s responses to the List of Questions to all CHMP members on 22 September 2005.
- During the CHMP meeting on 13 October 2005, 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 4 November 2005.
- The Rapporteurs circulated the Joint Assessment Report on the applicant’s responses to the List of outstanding issues to all CHMP members on 25 November 2005.
- During the meeting on 13-14 December 2005, 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 Rotarix on 14 December 2005.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 21 February 2006.