BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Sanofi Pasteur MSD, SNC submitted on 26 April 2005 an application for Marketing Authorization to the European Medicines Agency (EMEA) for RotaTeq, through the centralized procedure under Article 3 (2) a of Regulation (EC) No 726/2004. The eligibility to the centralized procedure was agreed upon by the EMEA/CHMP on 21 January 2005.

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

Rapporteur: Ian Hudson Co-Rapporteur: Bengt Ljungberg

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 26 April 2005.
- The procedure started on 18 May 2005.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 18 July 2005. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 26 July 2005.
- During the meeting on 12-15 September 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 15 September 2005.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 12 December 2005.
- The summary report of the inspection carried out at the following site: Merck & Co Inc. between 9-13 January 2006 was issued on 27 February 2006.
- The Rapporteurs circulated the Joint Assessment Report on the applicant’s responses to the List of Questions to all CHMP members on 20 January 2006.
- During the CHMP meeting on 20-23 February 2006, the CHMP agreed on a list of outstanding issues to be addressed in writing by the applicant.
- On 17 March 2006 outstanding issues were addressed by the applicant in writing.
- During a meeting of a Biologics Working Party on 05-07 September 2005, 13-15 February 2006 and 19-20 April 2006 experts were convened to address questions raised by the CHMP.
- During the meeting on 24-27 April 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 RotaTeq on 27 April 2006. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 27 April 2006.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 27 June 2006.