BACKGROUND INFORMATION ON THE PROCEDURE

1 Submission of the dossier

The Applicant Sanofi Pasteur MSD submitted on 26 May 2005 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Zostavax, through the centralised procedure. The eligibility to the centralised procedure was agreed upon on 16 September 2004.

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

Rapporteur: Manfred Haase Co-Rapporteur: Pekka Kurki

Scientific Advice:

The applicant did not seek scientific advice at the CHMP.

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 May 2005.
- The procedure started on 15 June 2005.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 1 September 2005. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 30 August 2005.
- During the meeting on 10-13 October 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 14 October 2005.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 18 November 2005.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 2 January 2006.
- The Biologics Working Party during its meeting of 17-18 January 2006 adopted the BWP Report to be transmitted to the CHMP for endorsement.
- During the CHMP meeting on 23-25 January 2006, 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 8 February 2006.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of outstanding issues to all CHMP members on 14 February 2006.
- The Biologics Working Party during its meeting of 13-15 February 2006 adopted the BWP Report to be transmitted to the CHMP for endorsement.
- During the meeting on 20-23 February 2006, outstanding issues were addressed by the applicant during a hearing before the CHMP.
- During the meeting on 20-23 March 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 Zostavax on 23 March 2006. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 22 March 2006.
- The European Commission granted a marketing authorisation valid throughout the European Union for Zostavax on 19 May 2006.