BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Sanofi Pasteur MSD SNC submitted on 29 September 2004 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for ProQuad, through the centralised procedure. After agreement by the CHMP on 25 April 2002, this medicinal product has been referred to Part B 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: Dr. Manfred Haase Co-Rapporteur: Dr. Pasqualino 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 18 October 2004
- The Rapporteur's first assessment report was circulated to all CHMP Members on 28 December 2004. The Co-Rapporteur's first assessment report was circulated to all CHMP Members on 28 December 2004
- During the meeting on 14-17 February 2005 the CHMP agreed on the consolidated list of questions to be sent to the company. The final consolidated list of questions was sent to the company on 17 February 2005
- The company submitted the responses to the consolidated list of questions on 13 April 2005
- The summary report of the inspection carried out at the manufacturing site Marck & Co. Inc, 770 Sumneytown Pike, West Point, Pennsylvania 19486 between 8 – 10 February 2005 was issued on 2 May 2005
- The Rapporteurs circulated the response assessment report on the company's responses to the list of questions to all CHMP Members on 20 May 2005
- The Biologics Working Party during its meeting of 13 - 15 June 2005 adopted the BWP Report to be transmitted to the CHMP for endorsement
- During the CHMP meeting on 20-23 June 2005, the CHMP agreed on a list of outstanding issues to be addressed in writing by the company
- The Vaccines Working Party during its meeting of 6 - 7 July 2005 adopted the VWP Report to be transmitted to the CHMP for endorsement
- The company submitted the responses to the CHMP list of outstanding issues on 11 July 2005
- During the CHMP meeting on 25-28 July 2005, the CHMP agreed on a 2nd list of outstanding issues to be addressed in writing by the company
- The company submitted the responses to the 2nd list of outstanding issues on 29 August 2005
- The Rapporteurs circulated the Joint Assessment Report on the company's responses to the List of outstanding issues to all CHMP members on 2 September 2005
- The Biologics Working Party during its meeting of 5-7 September 2005 adopted the BWP Report to be transmitted to the CHMP for endorsement
- During the meeting on 12-15 September 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 ProQuad on 15 September 2005. The company provided

the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 12 September 2005

- Further to the outcome of the Standing Committee meeting held on 13 February 2006, the European Commission referred the Proquad CHMP opinion back to the CHMP on 15 February 2006 for further examination of the different storage conditions of the powder and the solvent.
- During the meeting on 21-23 February 2006, the CHMP, in the light of the overall data submitted and the scientific discussion within the Committee, issued a revised positive opinion for granting a Marketing Authorisation to ProQuad on 23 February 2006.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 6 April 2006.