BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Novartis Vaccines and Diagnostics GmbH & Co. KG submitted on 22 June 2006 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Optaflu, through the centralised procedure under Article 3 (2) (a) of Regulation (EC) No 726/2004. The eligibility to the centralised procedure was agreed upon by the EMEA/CHMP on 17 December 2004.

The legal basis for this application refers to:

Article 8.3 of Directive 2001/83/EC, as amended - complete and independent application.

Scientific Advice
The applicant received Scientific Advice from the CHMP on 21 March 2002, 29 July 2005, and 14 December 2005. The Scientific Advice pertained to quality and clinical aspects of the dossier.

Licensing status:
The product was not licensed in any country at the time of submission of the application.

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

Rapporteur: F. Lekkerkerker Co-Rapporteur: M. Haase

2. Steps taken for the assessment of the product

- The application was received by the EMEA on 22 June 2006.
- The procedure started on 19 July 2006.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 4 October 2006 . The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 3 October 2006.
- The BWP discussed Optaflu during their meeting on 6-8 November 2006 and adopted a BWP report to the CHMP.
- During the meeting on 13-16 November 2006, 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 16 November 2006.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 14 December 2006.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 26 January 2007.
- The BWP discussed Optaflu during their meeting on 12-14 February 2007 and adopted a BWP report to the CHMP.
- During the CHMP meeting on 19-22 February 2007, 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 19 March 2007.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Outstanding Issues to all CHMP members on 13 April 2007.
- During the BWP meeting of 16-18 April 2007 outstanding quality issues were addressed by the applicant in an Oral Explanation before the BWP. The BWP discussed Optaflu and adopted a BWP report to the CHMP.
- During the meeting on 23-26 April 2007 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 Optaflu on 26 April 2007. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 26 April 2007.

- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 01 June 2007.