BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Roche Registration Limited submitted on 9 February 2001 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Tamiflu, through the centralised procedure. After agreement by the CPMP on 27 January 1999, 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 CPMP were:

Rapporteur: Dr. Pekka Kurki Co-Rapporteur: Prof. Ana Cristina Sampaio

Scientific Advice:

The applicant received Scientific Advice from the CPMP on 25 June 1998. The Scientific Advice pertained to part IV of the dossier.

Licensing status:

Tamiflu has been given a Marketing Authorisation in U.S.A (27/10/99, 17/11/00, 14/12/00), Canada (23/12/99), Russia (10/07/00), Japan (12/12/00), Australia (13/09/00) and 27 additional countries.

2. Steps taken for the assessment of the product

- The procedure started on 27 February 2001.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 9 May 2001 The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 10 May 2001
- During the meeting on 27 June 2001 the CPMP 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 29 June 2001.
- The company submitted the responses to the CPMP consolidated List of Questions on 11 October 2001.
- The Rapporteurs circulated the response Assessment Report on the company's responses to the List of Questions to all CPMP members on 20 November 2001
- During the meeting on 12 December 2001 the CPMP agreed on a List of Outstanding issues to be sent to the applicant. The list was sent to the applicant on 14 December 2001.
- The company submitted the responses to the CPMP List of Outstanding Issues on 3 January 2002.
- An expert meeting was convened at the EMEA on 18 February 2002.
- During the meeting on 19-21 March 2002 the CPMP, 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 Tamiflu on 21 March 2002.
- The CPMP Opinion was forwarded in all official languages of the European Commission, which adopted the corresponding Decision on 20 June 2002.