BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Novartis Europharm Limited submitted on 1 July 2004 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Xolair, in accordance with the centralised procedure falling within the scope of Part A 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. Tomas Salmonson Co-Rapporteur: Dr. Gonzalo Calvo Rojas

Scientific Advice:

The applicant received Scientific Advice from the CHMP on 25 July 2002. The Scientific Advice pertained to clinical aspects of the dossier.

Licensing status:

Xolair has been given a Marketing Authorisation in Australia on 31 May 2002 and USA on 20 June 2003.

2. Steps taken for the assessment of the product

- The application was received by the EMEA on 1st July 2004.
- The procedure started on 19 July 2004.
- The Applicant provided updated clinical information on 21 September 2004 after uncovering an error in counting historical exacerbations in a pivotal study (2306).
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 11 October 2004. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 12 October 2004.
- The BWP issued a report to the CHMP on 5 November 2004.
- During the meeting on 16-18 November 2004, 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 18 November 2004.
- During the meeting on 16-18 November 2004, the CHMP agreed on a GCP inspection request which was revised at December 2004 CHMP meeting.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 10 February 2005.
- The integrated GCP inspection report was circulated to Rapporteurs on 11 March 2005 and to all CHMP members in the March Post-mail. It was also sent to the applicant on 15 March 2005.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 21 March 2005.
- During the CHMP meeting on 18-21 April 2005, the CHMP agreed on a list of outstanding issues to be addressed in writing and/or in an oral explanation by the applicant.
- The Applicant submitted the responses to the List of Outstanding Issues on 10 May 2005.
- During the CHMP meeting on 23-26 May 2005, the CHMP agreed on a list of questions to be addressed by experts.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Outstanding Issues to all CHMP members on 30 May 2005.
- On 8 June 2005, an Ad-hoc expert group meeting was held at the EMEA to answer to the above-mentioned list of questions. The Applicant was invited to present their view during this meeting. The report of the Ad-Hoc expert group meeting was sent for information to the CHMP and the Applicant on 16 June 2005.
- The Rapporteurs circulated an update of Joint Assessment Report on the applicant's responses to the List of Outstanding Issues to all CHMP members on 16 June 2005.

- During the CHMP meeting on 20-23 June 2005, the applicant's oral explanation on the outstanding issues before the CHMP was cancelled.
- During the meeting on 25-28 July 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 Xolair on 27 July 2005. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 26 July 2005.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 25 October 2005.