BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Glaxo Group Ltd. submitted on 14 June 2006 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Altargo, through the centralised procedure under Article 3 (2) (a) of Regulation (EC) No 726/2004. The eligibility to the Central Procedure was agreed upon by the EMEA/CHMP on 1 June 2006.

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 23 April 2004. The Scientific Advice pertained to non-clinical and clinical aspects of the dossier.

Licensing status:
A new application was filed in the following country: USA

The product was not licensed in any country at the time of submission of this application.

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

Rapporteur: **Frances Rotblat** Co-Rapporteur: **Karl Broich**

2. Steps taken for the assessment of the product

- The application was received by the EMEA on 14 June 2006.
- The procedure started on 19 July 2006.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 18 September 2006. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 29 September 2006.
- 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 25 January 2007.
- 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 5 March 2007.
- During the meeting on 19-22 March 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 Altargo on 22 March 2007. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 20 March 2007
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 24 May 2007.