BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Teva Pharma GmbH submitted on 10 October 2003 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for AZILECT, through the centralised procedure. After agreement by the CHMP on 25 April 2003, this medicinal product has been referred to Part B of the Annex to Council Regulation No (EEC) 2309/93 of 22 July 1993 as amended.

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

Rapporteur: Prof. Cristina Sampaio Co-Rapporteur: Dr. David Lyons

Scientific Advice:

The applicant received Scientific Advice from the CHMP on 18 November 1999. The Scientific Advice pertained to clinical aspects of the dossier.

Licensing status:

A new application was filed in the following countries: USA.

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 27 October 2003.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 14 January 2004 (Annex 1). The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 12 January 2004 (Annex 2).
- During the meeting on 24-26 February 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 26 February 2004 (Annex 3).
- The applicant submitted the responses to the CHMP consolidated List of Questions on 19 April 2004.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 25 May 2004 (Annex 4).
- During the CHMP meeting on 22-24 June 2004, the CHMP agreed on a list of outstanding issues to be addressed in writing and/or in an oral explanation by the applicant (Annex 5).
- The applicant submitted the written responses to the CHMP consolidated List of Outstanding issues on 08 September 2004.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Outstanding Issues to all CHMP members on 1st October 2004 (Annex 6).
- During the CHMP meeting on 19-21 October 2004, outstanding issues were addressed by the applicant during an oral explanation before the CHMP.
- During the meeting on 16-18 November 2004, 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 AZILECT on 18 November 2004. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 16 November 2004 (Annex 7).