## BACKGROUND INFORMATION ON THE PROCEDURE

### 1. Submission of the dossier

The company AstraZeneca, UK Limited submitted on 4 February 2003 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Faslodex, through the centralised procedure. After agreement by the CPMP on 21 September 2000, 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. Salmonson Co-Rapporteur: Dr. Toivonen

**Scientific Advice:**

The applicant received Scientific Advice from the CPMP on 17 December 1997. The Scientific Advice pertained to clinical aspects of the dossier.

**Licensing status:**

Faslodex has been given a Marketing Authorisation in USA on 25 April 2002 and in Argentina on 30 August 2002.

A new application was filed in the following countries: Canada and Brazil.

### 2. Steps taken for the assessment of the product

- The procedure started on 24 February 2003.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 6 May 2003. The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 16 April 2003.
- During the meeting on 24-26 June 2003, 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 26 June 2003.
- The applicant submitted the responses to the CPMP consolidated List of Questions on 11 August 2003.
- The Rapporteurs circulated the Joint Assessment Report on the applicant’s responses to the List of Questions to all CPMP members on 22 September 2003.
- During the CPMP meeting on 21-23 October 2003, the CPMP 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 CPMP list of outstanding issues on 3 November 2003.
- The Rapporteur circulated the Assessment Report on the applicant’s responses to the list of outstanding issues to all CPMP members on 10 November 2003.
- The CPMP convened a Therapeutic Advisory Group meeting on 17 November 2003 to provide advice on the clinical aspects of Faslodex.
- During the meeting on 18-20 November 2003, 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 Faslodex on 20 November 2003. The applicant provided a letter of undertaking on the follow-up measures to be fulfilled post-authorisation.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 10 March 2004.


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