BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant, N.V. Organon, submitted on 29 December 1998 an application for a Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Orgalutran 0.25 mg / 0.5 ml solution for injection. After agreement by the CPMP of 21-23 July 1998, this medicinal product is referred to Part B of the Annex to Council Regulation No (EC) 2309/93 of 22 July 1993.

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

Rapporteur: Dr M. Toivonen Co-Rapporteur: Dr H. van Bronswijk

Licensing status:

The product was not licensed in any country inside or outside the EU at the time of submission of the application.

2. Steps taken for the assessment of the product

- The procedure started on 29 January 1999.
- The Rapporteur's first assessment report was circulated to all CPMP Members on 1 April 1999.
- The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 9 April 1999.
- During the May 1999 meeting the CPMP agreed on the consolidated list of questions to be sent to the applicant. This was sent to the applicant on 19 May 1999.
- The applicant submitted the responses to the consolidated list of questions on 5 October 1999.
- The GMP inspection request was cancelled during the October CPMP meeting based on written clarifications from the applicant regarding quality issues.
- The Rapporteur/Co-Rapporteur circulated the response assessment report on the applicant's responses to the list of questions to all CPMP Members on 25 November 1999.
- The applicant gave an oral explanation on 14 December 1999 during the CPMP meeting and the remaining issues were presented by the company and discussed.
- The List of outstanding issues was adopted at the CPMP meeting on 14 December 1999.
- The applicant provided supplementary information on 6 January 2000.
- During the January 2000 meeting the CPMP, in the light of the overall data submitted and the scientific discussion within the committee, issued a positive opinion by consensus for granting a Marketing Authorisation to Orgalutran on 19 January 2000.
- During the January 2000 CPMP meeting a letter of undertaking has been adopted.
- The CPMP Opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 17 May 2000.