BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Genzyme Europe B.V. submitted on 23 January 2004 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for ATryn, through the centralised procedure.

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

Rapporteur: E. Abadie Co-Rapporteur: I.Hudson

Licensing status:

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 application was received by the EMEA on 23 January 2004.
- The procedure started on 23 February 2004.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 5 May 2004. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 4 May 2004.
- During the meeting on 9-11 June 2004, the BWP adopted a first report to the CHMP.
- During the meeting on 22-24 June 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 24 June 2004.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 03 December 2004.
- The summary reports of the first and second inspection carried out at the site in Cambrex Bio Science in Massachusetts between 9-11 August 2005 and 12-14 December 2005 were issued on 02 December 2005 and 31 January 2006.
- The summary report of the inspection carried out at the GTC Biotherapeutics Farm in Massachusetts between 8-9 August 2005 was issued on 7 December 2005.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 14 February 2005.
- During their meeting of 8-9 March 2005, the BWP discussed the major outstanding quality questions and adopted a second report to the CHMP.
- During the CHMP meeting on 14-17 March 2005, the CHMP agreed on a list of outstanding issues to be addressed in writing and during an oral explanation before the CHMP.
- The applicant submitted the written responses to the list of outstanding issues on 8 July 2005.
- During their meeting of 7-9 November 2005, the BWP discussed the responses to the outstanding quality questions and adopted a third report to the CHMP.
- The Rapporteur circulated the Joint Assessment Report on the applicant's responses to the List of Outstanding issues to all CHMP members on 27 January 2006.
- During the CHMP meeting on 20-23 February 2006, outstanding issues were addressed by the applicant during an oral explanation before the CHMP.
- During the meeting on 20-23 February 2006, the CHMP, in the light of the overall data submitted and the scientific discussion within the Committee, issued a negative opinion for granting a Marketing Authorisation to ATryn on 22 February 2006.

3. Steps taken for the re-examination procedure

- The applicant received the CHMP opinion on 24 February 2006
- The applicant submitted written notice to the EMEA on 2 March 2006 to request a re-examination of the ATryn CHMP opinion of 22 February 2006.
- During its meeting on 20-23 March 2006, the CHMP appointed Dr Bengt Ljungberg as Rapporteur and Dr Gonzalo Calvo Rojas as Co-Rapporteur for the re-examination procedure.
- The detailed grounds for the re-examination request were submitted by the applicant on 24 April 2006. The re-examination procedure started on 25 April 2006.
- The Rapporteur's Assessment Report was circulated to all CHMP members on 9 May 2006. The Co-Rapporteur's Assessment Report was circulated to all CHMP members on 10 May 2006.
- An Ad hoc Expert Group meeting on ATryn was held on 29 May 2006 at the EMEA. During this meeting the applicant presented an oral explanation. A report of this meeting was forwarded to CHMP.
- During the CHMP meeting on 30 May 2006 to 1 June 2006, the applicant presented an oral explanation before the CHMP on the 30 May 2006.
- During the meeting on 30 May 2006 to 1 June 2006, the CHMP, in the light of the overall data submitted and the scientific discussion within the Committee, issued a final Opinion recommending the granting of the Marketing Authorisation under exceptional circumstances to ATryn on 1 June 2006.
- The CHMP opinion was forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decision on 28 July 2006.