

BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Unigene UK Limited submitted on 22 August 1997 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMA) for Forcaltonin, in accordance with the centralised procedure falling within the scope of Part A 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: Prof. Hildebrandt Co-Rapporteur: D. M. Teeling

Licensing status:

Forcaltonin 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 26 September 1997
- The Rapporteur's first assessment report was circulated to all CPMP Members on 5 December 1997. The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 8 December 1997.
- Comments on points not covered by the Assessment report were due on 6 January 1998.
- During the meeting on 27 January 1998 the CPMP agreed on the consolidated list of questions to be sent to the company. The final consolidated list of questions was sent to the company on 27 January 1998.
- The company submitted the responses to the consolidated list of questions on 20 July 1998
- The Rapporteur and the Co-Rapporteur circulated the joint response assessment report on the company's responses to the list of questions to all CPMP Members on 28 August 1998.
- At the beginning of September 1998, the company submitted to all CPMP Members an expanded data set on the alpha-amidating enzyme (AE). The Rapporteur circulated an analysis of the data set on 10 September 1998.
- During the meeting on 15-17 September 1998 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 Forcaltonin on 17 September 1998.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 11 January 1999.

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