BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Boehringer Ingelheim International GmbH, Germany submitted on 31 May 1996 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for SIFROL, through the centralised procedure. After agreement by the CPMP on 15-17 January 1996, 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 as follows:

Rapporteur: Dr. G. Jensen Co-Rapporteur: Dr. M. Toivonen

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 procedure started on 18 June 1996.
- During the 15-18 July 1996 CPMP meeting, a GMP inspection of the manufacturing site in Puerto Rico was agreed upon.
- The Rapporteur's first assessment report was circulated to all CPMP Members on 26-27 August 1996. The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 23 August 1996.
- An addendum to the Co-Rapporteur's first assessment report was circulated to all CPMP Members on 11 October 1996.
- During the meeting on 14-17 October 1996, 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 17 October 1996.
- The company submitted the responses to the consolidated list of questions on 4 March 1997.
- 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 17 April 1997.
- A hearing was held at the CPMP meeting on 13 May 1997, to address the remaining outstanding issues (therapeutic indication, long-term efficacy, retinal degeneration and gender differences with respect to dyskinesia).
- The CPMP, during its meeting on 17-18 June 1997 discussed the recommendations presented by the Rapporteur, considering the responses provided by the company were satisfactory. Amendments were discussed to the Summary of Product Characteristics on the Therapeutic indication and Special warnings and special precautions for use and Package Leaflet texts.
- During the meeting on 17-18 June 1997 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 SIFROL on 18 June 1997.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 14 October 1997.