BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Boehringer Ingelheim International GmbH, Germany submitted on 9 October 1997 to the European Agency for the Evaluation of Medicinal Products (EMEA) an application for the marketing authorisation of the medicinal product Telmisartan Boehringer Ingelheim Pharma KG falling within the scope of Part B of the Annex of the Council Regulation (EEC) 2309/93, of the 22 July 1993.

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

Rapporteur: Prof. S. Garattini Co-Rapporteur: Prof. A. Hildebrandt

Licensing status

Telmisartan 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 27 October 1997.
- The Rapporteur's assessment report was circulated to all CPMP Members on 19 January 1998. The Co-rapporteur's assessment report was circulated to all CPMP Members on 19 January 1998.
- The CPMP consolidated list of questions was adopted on 23 February 1998.
- The responses to CPMP the consolidated list of questions was received on 21 April 1998
- The joint Rapporteur-Co-Rapporteur assessment report on the responses to the CPMP consolidated list of questions was circulated on 26 May 1998.
- During its June 1998 meeting, the CPMP discussed and adopted a list of issues to be addressed by the company during a hearing.
- The evaluation clock was stopped on 23 June 1998.
- The company submitted additional information regarding outstanding points for clarification regarding quality aspects on 30 June 1998.
- An addendum to the joint Rapporteur-Co-Rapporteur assessment report was received on 7 July 1998.
- A hearing was held at the CPMP meeting on 21 July 1998, to address the remaining outstanding issues.
- The CPMP, during its meeting on 21-23 July 1998, considered the responses provided by the company and discussed the recommendations presented by the Rapporteur. Amendments to the Summary of Product Characteristics were discussed.
- During the meeting on 21-23 July 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 for Telmisartan Boehringer Ingelheim Pharma KG on 23 July 1998**.**
- The European Commission issued on 16 December 1998, a Marketing Authorisation valid throughout the European Union.