BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Glaxo Group Ltd, United Kingdom 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 Pritor 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 Pritor on 23 July 1998**.**
- The European Commission issued on 11 December 1998, a Marketing Authorisation valid throughout the European Union.

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