BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Sanofi Pharma Bristol-Myers Squibb SNC, France submitted on 9 April 1997 to the European Agency for the Evaluation of Medicinal Products (EMEA) an application for the marketing authorisation of the medicinal product Plavix falling within the scope of Part B of the Annex of the Council Regulation (EEC) 2309/93, of 22 July 1993.

The Rapporteur and Co-rapporteur appointed by the CPMP were as follows:

Rapporteur: Prof. M. Forte Co-Rapporteur: Pharm. G. De Greef

Licensing status:

Plavix has been licensed in the USA since 17 November 1997.

2. Steps taken for the assessment of the product

- The Rapporteur's assessment report was circulated to all CPMP Members on 28 July 1997. The Co-Rapporteur's assessment report was circulated to all CPMP Members on 25 July 1997.
- The CPMP Consolidated list of questions was adopted on 24 September 1997.
- The responses to the consolidated list of questions were received on 8 December 1997.
- The Joint Rapporteur/Co-Rapporteur assessment report on the responses to the consolidated list of questions was circulated on 21 January 1998.
- The company submitted written responses on the outstanding chemical and pharmaceutical issues on 20 February 1998.
- During its meeting on 24 February 1998, the CPMP agreed on a list of outstanding clinical issues to be addressed by the company in an oral explanation.
- A hearing was held on 24 February 1998, to address the outstanding clinical issues.
- The CPMP, during its meeting on 23-25 February 1998, considered the responses provided by the company, and discussed the recommendations presented by the Rapporteur.
- The CPMP, during its meeting on 23-25 February 1998, considered the responses provided by the company to some of the clinical issues not to be satisfactory. Therefore, the CPMP requested additional written information to be submitted.
- On the basis of the responses provided by the company, the CPMP discussed and amended the Summary of Product Characteristics following additional oral explanations provided by the company on 24 March 1998.
- A letter of undertaking on the follow-up measures as requested by the CPMP, was signed by the applicant on 25 March 1998.
- During the meeting on 25 March 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**.**
- On 15 July 1998, the European Commission issued a Marketing Authorisation for Plavix.

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