BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The Applicant Glaxo Group Limited submitted on 17 December 1999 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Trizivir film-coated tablets, through the centralised procedure. After agreement by the CPMP on 23 September 1999, this medicinal product has been referred to Part B 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: Dr. D. Brasseur Co-Rapporteur: Dr. E. Abadie

Licensing status:

The product was not licensed in any country at the time of submission of the application.

Scientific advice:

The Applicant did not seek scientific advice at the CPMP

2. Steps taken for the assessment of the product

- The procedure started on 21 January 2000.
- The Rapporteur's first assessment report was circulated to all CPMP Members on 31 March 2000. The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 10 April.
- The Rapporteur circulated a List of Questions to all CPMP members and the Applicant on the 8 May 2000.
- The Applicant submitted the responses to the List of Questions on 11 May 2000.
- The (Co) rapporteur's joint assessment report was circulated on the 18 May 2000.
- The Co-Rapporteur's assessment report of study CNAAB3005 was circulated to all CPMP members on the 15 June 2000.
- During the CPMP meeting on 27 June 2000, outstanding issues were addressed by the Applicant during an oral explanation before the CPMP. The list of outstanding issues can be found in Annex 6.
- During the meeting on 27-29 June 2000 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 Trizivir on 29 June 2000.
- On 10 August Glaxo Group Ltd. submitted a valid application for an Urgent Safety Restriction (USR) for Ziagen (abacavir). This USR provided new information on hypersensitivity reactions involving an interruption of therapy for any reason. The USR for Ziagen was implemented on the 11 August.
- On the 29 August 2000 the European Commission informed the EMEA that the decision making process for Trizivir had been suspended and asked the CPMP to evaluate the consequences for Trizivir of the USR made for Ziagen (abacavir) during the September CPMP meeting in order to provide the Commission with an updated opinion.
- During the meeting on 19-21 September 2000 the CPMP, in the light of the overall data submitted, the oral explanation by the applicant in front of the CPMP, and the scientific discussion within the Committee, issued a revised positive opinion for granting a Marketing Authorisation to Trizivir on 21 September 2000.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 28 December 2000.

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