I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant BRISTOL-MYERS SQUIBB PHARMA EEIG submitted on 29 April 2002 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for REYATAZ, through the centralised procedure. After agreement by the CPMP on 26 July 2001 , this medicinal product has been referred to Part B of the Annex to Council Regulation No (EEC) 2309/93 of 22 July 1993 as amended.

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

Rapporteur: Dr. Eric Abadie Co-Rapporteur: Dr. Ian Hudson

Scientific Advice:

The applicant did not seek scientific advice at the CPMP.

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 20 May 2002.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 1 August 2002. The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 26 July 2002.
- During the meeting on 17 – 19 September 2002 the CPMP agreed on the consolidated List of Questions to be sent to the applicant. The final consolidated List of Questions was sent to the applicant on 20 September 2002.
- The company submitted the responses to the CPMP consolidated List of Questions on 14 March 2003.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CPMP members on 2 May 2003.
- During the CPMP meeting on 20 – 22 May 2003, the CPMP agreed on a list of outstanding issues to be addressed in writing and/or in an oral explanation by the applicant.
- The company submitted the responses to list of outstanding issues on 1 September 2003.
- The Rapporteurs circulated the Joint Review on the applicant's responses to the List of outstanding Issues to all CPMP members on 9 October 2003.
- During the CPMP meeting on 21 - 22 October 2003, outstanding issues were addressed by the applicant during a hearing before the CPMP on 22 October 2003.
- During the meeting on 18 – 20 November 2003, 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 under exceptional circumstances to REYATAZ on 20 November 2003. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 19 November 2003.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 2 March 2004.

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II GENERAL CONDITIONS FOR THE MARKETING AUTHORISATION

1. Manufacturing authorisation holder

Manufacturer of the active substance

Manufacture and QC release of hard capsules and powder products; primary packaging for capsules and powder bottles:

Bristol-Myers Squibb, Swords Laboratories, Watery Lane, Swords, Co. Dublin, Ireland

Primary packaging for capsules blisters; secondary packaging including and QC release of finished product:

Bristol-Myers Squibb Manufacturing Company, Road #2, KM 56.4, 00617 Barceloneta, Puerto Rico

Manufacturer of the finished product

Manufacture and QC release of hard capsules and powder products; primary packaging for capsules and powder bottles:

Bristol-Myers Squibb, West Lloyd Expressway, Evansville, IN 47721-0001, USA

Inspected and by the MCA as part of a national inspection on 18 March 2002 for a number of centralised and national products was found to be in compliance with the Community Good Manufacturing Practice requirements.

Primary packaging for capsules blisters; secondary packaging including and QC release of finished product:

Bristol-Myers Squibb, Champ "Lachaud", La Goualle, F-19250 Meymac, France

Manufacturing Authorisation (dated 27/04/1997) and GMP Certificate (dated 16/06/2000) issued by the AFSSAPS are provided for this manufacturing and batch release site located in the EEA. Inspected by the AFSSAPS on 14 December 1999 and was found to be in compliance with the Community Good Manufacturing Practice requirements.

Manufacturer responsible for import and batch release in the European Economic Area

Bristol-Myers Squibb, Champ "Lachaud", La Goualle, F-19250 Meymac, France

Manufacturing Authorisation (dated 27/04/1997) and GMP Certificate (dated 16/06/2000) issued by the AFSSAPS are provided for this manufacturing and batch release site located in the EEA. Inspected by the AFSSAPS on 14 December 1999 and was found to be in compliance with the Community Good Manufacturing Practice requirements.

2. Conditions or restrictions regarding supply and use

Medicinal product subject to restricted medical prescription (See Annex I: Summary of Product Characteristics, 4.2)

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