BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company B.S.I.A. Ltd. submitted on 27 November 1996 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Pylobactell, through the centralised procedure. After agreement by the CPMP on 11 September 1997, this medicinal product was referred to Part B of the Annex to Council Regulation No (EC) 2309/93 of 22 July 1993.

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

Rapporteur: Prof. K Strandberg Co-Rapporteur: Dr H Pittner

Licensing status:

The product was not licensed in any country inside or outside the EU at the time of submission of the application.

2 Steps taken for the assessment of the product

- The procedure started on 19 December 1996.
- The Rapporteur's first assessment report was circulated to all CPMP Members on 27 February 1997. The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 28 February 1997.
- During the meeting on 15 April 1997 the CPMP agreed on the consolidated list of questions to be sent to the company. The final consolidated list of questions was sent to the Company on 16 April 1997.
- The company submitted the responses to the consolidated list of questions on 14 August 1997.
- During the meeting on 17-19 November 1997 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 B.S.I.A. Ltd. on 19 November 1997.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 7 May 1998.

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