BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company INFAI, Institut für biomedizinische Analytik & NMR-Imaging GmbH, submitted on 13 August 1996 to the European Agency for the Evaluation of Medicinal Products (EMEA), an application to obtain Marketing Authorisation for the medicinal product Helicobacter Test INFAI following the Centralised Procedure and falling within the scope of 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 as follows:

Rapporteur: Dr. H. Pittner Co-Rapporteur: Dr. W.F. van der Giesen

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 23 September 1996.
- The Rapporteur's first assessment report was circulated to all CPMP Members on 11 November 1996. The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 13 November 1996.
- During the plenary meeting on 20-22 January 1997, the CPMP agreed on the consolidated list of questions to be sent to the company.
- The company submitted the responses to the consolidated list of questions on 13 February 1997.
- The Rapporteur/Co-Rapporteur circulated a joint assessment report dated 13 March 1997 on the company's responses to the list of questions to all CPMP Members.
- On 25 March 1997, the Rapporteur circulated further assessment report on the company's responses to the remaining clinical issues.
- The CPMP, during its meeting on 14-17 April concluded that the responses provided by the company were satisfactory. The reference to one single laboratory for performance of the analysis was discussed. It was agreed that qualified laboratories should be in the position to carry out the analysis provided that a suitably validated method is used. Consequently, the relevant information on Analysis of breath samples and testing specification was included in the Summary of Product Characteristics (section 6.7), and in the Package Leaflet as a tear-off part (section 13).
- The CPMP adopted on 16 April 1997 a positive opinion for granting of a Marketing Authorisation for Helicobacter Test INFAI.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decision on 14 August 1997.