BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Boehringer Ingelheim International GmbH submitted on 3 November 2004 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for APTIVUS 250 mg soft capsules through the centralised procedure. After agreement by the CHMP on 24 March 2004, 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 CHMP were:

Rapporteur: Dr. E. Abadie Co-Rapporteur: Dr. G. Kreutz

Scientific Advice:

The applicant received Scientific Advice from the CHMP on 25 January 2001 and 18 January 2002. The Scientific Advice pertained to non-clinical and clinical aspects of the dossier.

Licensing status:

The product was not licensed in any country at the time of submission of the application. It was licensed in the USA on 22 June 2005, in Mexico on 19 July 2005 and in Switzerland on 25 August 2005.

2. Steps taken for the assessment of the product

- The application was received by the EMEA on 3 November 2004.
- The procedure started on 15 November 2004.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 25 January 2005. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 25 January 2005).
- During the meeting on 14 – 17 March 2005, the CHMP 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 17 March 2005.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 15 April 2005.
- The Rapporteurs circulated the Joint Assessment Report on the applicant’s responses to the List of Questions to all CHMP members on 3 June 2005.
- During the CHMP meeting on 20-23 June 2005, the CHMP agreed on a list of outstanding issues to be addressed in writing and/or in an oral explanation by the applicant.
- The applicant submitted the responses to the CHMP list of outstanding issues on 1 July 2005.
- The Rapporteurs circulated the Joint Assessment Report on the applicant’s responses to the list of outstanding issues to all CHMP members on 19 July 2005.
- During the meeting on 25 – 27 July 2005, the CHMP, 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 APTIVUS on 27 July 2005. The applicant provided the letter of undertaking on the specific obligations and follow-up measures to be fulfilled post-authorisation on 27 July 2005.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 25 October 2005.