BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Bristol-Myers Squibb Pharma EEIG submitted on 30 September 2004 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Baraclude (entecavir), through the centralised procedure. The eligibility to the centralised procedure by the CHMP was agreed upon on 29 July 2004.

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

Rapporteur: Dr. B. Ljungberg Co-Rapporteur: Dr. E. Abadie

Scientific Advice:

The applicant did not seek scientific advice at the CHMP.

Licensing status:

A new application was filed in the following countries: USA (30/09/2004).
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 application was received by the EMEA on 30 September 2004.
- The procedure started on 18 October 2004.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 30 December 2004. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 28 December 2004.
- During the meeting on 14 – 17 February 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 February 2005.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 18 November 2005.
- The Rapporteurs circulated the Joint Assessment Report on the applicant’s responses to the List of Questions to all CHMP members on 2 January 2006.
- During the CHMP meeting on 23-26 January 2006, the CHMP agreed on a list of outstanding issues to be addressed in writing by the applicant. The final consolidated List of Outstanding issues was sent to the applicant on 26 January 2006.
- The applicant submitted the responses to the CHMP list of outstanding issues on 13 February 2006.
- The Rapporteurs circulated a Joint Assessment Report on the applicant’s responses to the List of outstanding issues to all CHMP members on 3 March 2006.
- Based on preliminary responses provided by the applicant on 10 March 2006, the Rapporteurs circulated an updated Joint Assessment Report to all CHMP members on 17 March 2006.
- During the CHMP meeting on 20-23 March 2006, the CHMP agreed on a second list of outstanding issues to be addressed in writing by the applicant. The final consolidated List of Outstanding issues was sent to the applicant on 23 March 2006.
- The applicant submitted the responses to the second CHMP list of outstanding issues on 31 March 2006.
- The Rapporteurs circulated a Joint Assessment Report on the applicant’s responses to the List of outstanding issues to all CHMP members on 10 April 2006.
- During the meeting on 24-27 April 2006, the CHMP, in the light of the overall data submitted and the scientific discussion within the Committee, issued a positive opinion for granting a

©EMEA 2006

Marketing Authorisation to Baraclude on 27 April 2006. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 24 April 2006.

- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 26 June 2006.

©EMEA 2006