BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Novartis Europharm Ltd. submitted on 1 February 2006 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Sebivo (telbivudine) 600 mg film-coated tablets, through the centralised procedure under Article 3 (2) (a) of Regulation (EC) No 726/2004. The eligibility to the centralised procedure was agreed upon by the EMEA/CHMP on 14 December 2005.

The legal basis for this application refers to:

Article 8.3 of Directive 2001/83/EC, as amended - complete and independent application

The application submitted is a complete dossier composed of administrative information, complete quality data, non-clinical and clinical data based on applicants' own tests and studies and/or bibliographic literature substituting/supporting certain test(s) or study(ies).

The applicant applied for the following indication: treatment of hepatitis B.

Scientific Advice
The applicant did not seek scientific advice at the CHMP.

Licensing status:
The product was not licensed in any country at the time of submission of the application.

The Rapporteur and Co-Rapporteur appointed by the CHMP were:
Rapporteur: E. Abadie
Co-Rapporteur: I. Hudson
CHMP Peer reviewers: G. Calvo Rojas, J. Borvendeg

2. Steps taken for the assessment of the product

- The application was received by the EMEA on 1 February 2006.
- The procedure started on 1 March 2006.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 16 May 2006. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 3 May 2006.
- During the meeting on 26-28 June 2006, 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 29 June 2006.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 12 October 2006.
- The Integrated Inspection Report of the Good Clinical Practice inspection carried out in October 2006 at two investigator sites located in Thailand (10-13/October 2006) and China (16-19/October/2006) of the pivotal study NV-02B-007, was issued on 30 November 2006.
  The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 21 November 2006.
- During the CHMP meeting on 11-14 December 2006, the CHMP agreed on a list of outstanding issues to be addressed in writing by the applicant. The final list of outstanding issues was sent to the applicant on 13 December 2006.
- The applicant submitted the responses to the CHMP list of outstanding issues on 16 January 2007.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the list of outstanding issues to all CHMP members on 13 February 2007.

- The Rapporteurs circulated an updated Joint Assessment Report on the applicant's responses to the list of outstanding issues to all CHMP members on 16 February 2007.
- During the meeting on 19-22 February 2007, 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 to Sebivo on 22 February 2007. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 20 February 2007.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 24 April 2007.