BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Aventis Pharma S.A. submitted on 29 November 2006 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Docetaxel Winthrop, through the centralised procedure according to Regulation (EC) No 726/2004.

The legal basis for this application refers to Article 10c of Directive 2001/83/EC, as amended – relating to informed consent from the marketing authorisation holder for the authorised medicinal product Taxotere (EU/1/95/002/001-002).

Scientific Advice:

The applicant did not seek scientific advice at the CHMP.

Licensing status:

The initial product, Taxotere, has been given a Community Marketing Authorisation on 27 November 1995.

The Rapporteur and Co-Rapporteur appointed by the CHMP and the evaluation teams were:
Rapporteur: Eric Abadie Co-Rapporteur: Harald Enzmann

2. Steps taken for the assessment of the product

- The application was received by the EMEA on 29 November 2006.
- The procedure started on 24 December 2006.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 26 January 2007. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 26 January 2007.
- The Rapporteur circulated a Joint Assessment Report to all CHMP members on 12 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 Docetaxel Winthrop on 22 February 2007.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decision on 20 April 2007