BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Neopharma Ltd. submitted on 04 October 2006 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Olanzapine Neopharma, in accordance with the centralised procedure falling within the scope of the Annex to Regulation (EC) 726/2004 under Article 3 (3) – 'Generic of a Centrally authorised product'.

The legal basis for this application refers to Article 10(1).

The chosen reference product is:

■ Reference medicinal product which is or has been authorised for not less than 6/10 years in the EEA:
- Product name, strength, pharmaceutical form:Zyprexa 2.5/5/7.5/10/15/20 mg Coated Tablets
- Marketing authorisation holder: Eli Lilly Nederland B.V.
- First authorisation: 1996-09-27
- Member State (EEA)/Community: EU registration

■ Reference medicinal product authorised in the Community/Member State where the application is made:
- Product name, strength, pharmaceutical form: Zyprexa 2.5/5/7.5/10/15/20 mg Coated Tablets
- Marketing authorisation holder:Eli Lilly Nederland B.V.
- Marketing authorisation number(s): EU/1/96/022

■ Medicinal Product used for bioequivalence study (where applicable)
- Product name, strength, pharmaceutical form:Zyprexa, 10 mg, coated tablets
- Marketing authorisation holder:Eli Lilly Nederland B.V.
- Member State of source: UK

The Rapporteur appointed by the CHMP was:
Rapporteur: Dr Martin Votava

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.

2. Steps taken for the assessment of the product

- The application was received by the EMEA on 04 October 2006.
- The procedure started on 25 October 2006.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 11 January 2007.
- During the meeting on 19-22 February 2007, 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 23 February 2007.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 15 May 2007.
- The Integrated Inspection report of the GCP inspection carried out at the sites involved in the conduct of the bioequivalence study, between 16-19/01/06, was issued on 13 April 2007.
- The Rapporteur circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 8 June 2007.

- During the CHMP meeting on 19 July 2007, the CHMP agreed on a list of outstanding issues to be addressed in writing by the applicant.
- The Applicant submitted the responses to the CHMP List of Oustanding Issues on 16 August 2007.
- The Rapporteur provided their Report on the applicant's responses to the List of Oustanding Issues on 6 September 2007.
- During the meeting on 17-20 September 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 Olanzapine Neopharma.