BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Teva Pharma B.V submitted on 04 December 2006 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Olanzapine Teva, 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 application legal basis 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 mg, 5 mg, 7.5 mg, 10 mg, 15 mg and 20 mg coated tablets

- Marketing authorisation holder: Eli Lilly Nederland B.V.
- First authorisation: Date (yyyy-mm-dd) 1996-09-27
  Member State (EEA)/Community: Community

■ Reference medicinal product authorised in the Community/Member State where the application is made:

Film-coated tablets:

- Product name, strength, pharmaceutical form:

Zyprexa 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg and 20 mg coated tablets

- Marketing authorisation holder: Eli Lilly Nederland B.V.
- Marketing authorisation number(s):EU/1/96/022

Orodispersible tablets:

- Product name, strength, pharmaceutical form:

Zyprexa Velotab 5, 10, 15, 20 mg orodispersible tablet

- Marketing authorisation holder: Eli Lilly Nederland B.V.
- Marketing authorisation number(s): EU/1/99/125

■ Medicinal Product used for bioequivalence study

- Product name, strength, pharmaceutical form: Zyprexa 10 mg coated tablet
- Marketing authorisation holder: Eli Lilly Nederland B.V.
- Member State of source: United Kingdom
- Product name, strength, pharmaceutical form: Zyprexa 20 mg coated tablet
- Marketing authorisation holder: Eli Lilly Nederland B.V.
- Member State of source: Germany
- Product name, strength, pharmaceutical form: Zyprexa Velotab 10 mg orodispersible tablet
- Marketing authorisation holder: Eli Lilly Nederland B.V.
- Member State of source: United Kingdom
- Product name, strength, pharmaceutical form: Zyprexa Velotab 20 mg orodispersible tablet
- Marketing authorisation holder: Eli Lilly Nederland B.V.
- Member State of source: Germany

The Rapporteur appointed by the CHMP was:

Rapporteur	Dr. B. van Zwieten – Boot

Scientific Advice:

The applicant did not seek scientific advice at the CHMP.

Licensing status:

Olanzapine Teva 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 December 2006.
- The procedure started on 27 December 2006.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 20 March 2007 .
- During the meeting on 23-26 April 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 26 April 2007.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 25 July 2007.
- The Rapporteur circulated the Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 21 September 2007 .
- During the meeting on 15 – 18 October 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 Teva on 18 October 2007. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 9 October 2007.