BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Krka, d.d., Novomesto submitted on 29 September 2006 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Zalasta, 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'.

Zalasta 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg and 20 mg tablets and Zalasta 5 mg, 10 mg, 15 mg, and 20 mg orodispersible tablets

The application legal basis for these presentations refer 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: Date (yyyy-mm-dd)1996-09-27 Member State (EEA)/Community: EU registration

Tablets

■ 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:Germany

Orodispersible tablets

■ Reference medicinal product authorised in the Community/Member State where the application is made:
- Product name, strength, pharmaceutical form:Zyprexa Velotab 5/10/15/20 mg Orodispersible Tablets
- Marketing authorisation holder: Eli Lilly Nederland B.V.
- Marketing authorisation number(s): EU/1/99/125

■ Medicinal Product used for bioequivalence study (where applicable)
- Product name, strength, pharmaceutical form:Zyprexa Velotab, 20 mg, orodispersible tablets
- Marketing authorisation holder:Eli Lilly Nederland B.V.
- Member State of source:Germany

Zalasta 7.5 mg orodispersible tablets

The application legal basis for this presentation refers to Article 10(3).

■ 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: Date (yyyy-mm-dd)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 Velotab 5/10/15/20 mg Orodispersible Tablets

▪ Marketing authorisation holder: Eli Lilly Nederland B.V.

▪ Marketing authorisation number(s): EU/1/99/125

■ Medicinal Product used for bioequivalence study (where applicable)

▪ Product name, strength, pharmaceutical form:Zyprexa Velotab, 20 mg, orodispersible tablets

▪ Marketing authorisation holder:Eli Lilly Nederland B.V.

▪ Member State of source:Germany

■ Difference(s) compared to the reference medicinal product:

☐ changes in the active substance(s)
☐ change in therapeutic indications
☐ change in pharmaceutical form
☒ change in strength (quantitative change to the active substance(s))
☐ change in route of administration
☐ bioequivalence cannot be demonstrated through

The Rapporteur appointed by the CHMP and the evaluation team were:

Rapporteur Prof. M. Lipnik-Štangelj

2. Scientific Advice:

The applicant did not seek scientific advice at the CHMP.

3. Licensing status:

Zalasta tablets has been given a Marketing Authorisation in Poland on 30 April 2004, Albania on 11 July 2006, Macedonia on 28 October 2005, Serbia and Montenegro on 5 April 2006.
Zalasta orodispersible tablets was not licensed in any country at the time of submission of the application.

4. Steps taken for the assessment of the product

- The application was received by the EMEA on 29 September 2006.
- The procedure started on 25 October 2006.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 16 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 22 February 2007.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 4 May 2007.
- The summary report of the GCP inspection carried out at MDS Pharma Services, Canada between 5-9 March 2007 was issued on 6 June 2007.
- The Rapporteur circulated the Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 14 June 2007.
- During the meeting on 16 – 19 July 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 Zalasta on 19 July 2007.