EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Olanzapine Cipla

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion / Notification[1] issued on	Commission Decision issued[2] / amended on	Product Information affected[3]	Summary
IB/0014	Update of section 4.8 of the SmPC and relevant section of the PL to include “amnesia, epistaxis, abdominal distension, arthralgia, GGT high, uric acid high, pyrexia and dysarthria”, as new undesirable effects. The frequencies of currently labelled undesirable effects have also been revised throughout sections 4.4 and 4.8 of the SmPC and relevant sections of the PL. In addition, Annex II has been brought in line with the latest QRD template.	28/11/2013		SmPC, Annex II, and PL	

[1] Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.
[2] A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.
[3] SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

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	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH				
IAIN/0015	C.I.8.a - Introduction of or changes to a summary of Pharmacovigilance system - Changes in QPPV (including contact details) and/or changes in the PSMF location	24/10/2013	n/a		
T/0013	Transfer of MA from Neopharma Ltd. 57 High Street, Odiham Hampshire RG29 1LF United Kingdom to Cipla (EU) Ltd Hillbrow Road Esher Surrey KT10 9NW Transfer of Marketing Authorisation.	02/04/2013	14/05/2013	SmPC, Labelling and PL	
R/0011	Renewal of the marketing authorisation.	19/07/2012	01/10/2012	SmPC, Annex II, Labelling and PL	Based on the CHMP review of the available information and on the basis of a re-evaluation of the benefit risk balance, the CHMP was of the opinion that the quality, safety and efficacy of this medicinal product continues to be adequately and sufficiently demonstrated and therefore

					considered that the benefit risk profile of Olanzapine Neopharma continues to be favourable.
IAIN/0010/G	This was an application for a group of variations. B.II.b.2.a - Change to batch release arrangements and quality control testing of the FP - Replacement or addition of a site where batch control/testing takes place B.II.b.2.a - Change to batch release arrangements and quality control testing of the FP - Replacement or addition of a site where batch control/testing takes place	03/05/2012	n/a		
IAIN/0012/G	This was an application for a group of variations. A.5.a - Administrative change - Change in the name and/or address of a manufacturer responsible for batch release B.II.b.2.b.1 - Change to batch release arrangements and quality control testing of the FP - Not including batch control/testing	03/05/2012	n/a	Annex II and PL	
IB/0009	Following PhVWP/CHMP conclusions of October 2011 update of the Summary of Product Characteristics (SmPC) and Package Leaflet (PL) in line with the reference medicinal product regarding the inclusion of metabolic monitoring frequency examples following the assessment of the latest PSURs and RMP and to update the frequency of Venous thromboembolism (VTE) following PhVWP recommendation to include warnings about the risk of venous thromboembolism. In addition, corrections in the Danish, Estonian,	07/02/2012	n/a	SmPC and PL	

	Finnish, French, Latvian, Polish, Portuguese and Slovenian annexes have been made in line with the reference product Zyprexa. C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data are submitted by the MAH				
IB/0008	Following PhVWP/CHMP conclusions of June 2011, update of the Summary of Product Characteristics (SmPC) and Package Leaflet (PL) in line with the reference medicinal product regarding the use of antipsychotics during the third trimester of pregnancy and risk of abnormal muscle movements and/or withdrawal symptoms in newborns in accordance with the PhVWP/CHMP class labelling recommended wording. In addition, corrections in the Bulgarian and Estonian annexes have been made. C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data are submitted by the MAH	03/01/2012	n/a	SmPC and PL	
IB/0007	Update of section 4.4 (deletion of a sentence in the warning related to hepatic function) and 4.8 (modification of the prolactin information in the footnote) of the Summary of Product Characteristics following assessment of the same change for the reference product. Additional changes have also been	27/10/2010	n/a	SmPC and PL	

	made to the Product Information in accordance with the QRD templates (version 7.3.1). C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data are submitted by the MAH				
IB/0006	Update of the sections 4.8 and 4.4 of the Summary of Product Characteristics (SPC) in line with the Product Information of the reference product regarding sudden cardiac death, urinary incontinence and information on elevated plasma prolactin concentrations and related clinical manifestations. Section 4 of the package leaflet has also been amended accordingly. Additionally, editorial changes were made in the relevant sections of the Product Information in line with the reference medicinal product. C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data are submitted by the MAH	22/03/2010	n/a	SmPC and PL	
II/0005	Update to section 4.8 of the Summary of Product Characteristics (SPC) in line with the Product Information of the reference medicinal product. An editorial change was made in section 4.4 of the SPC. Update of Summary of Product Characteristics	24/09/2009	13/10/2009	SmPC	The SPC was updated to align it with that of the reference medicinal product. This followed a change to the SPC of the reference medicinal product via the following procedure: Zyprexa (EMEA/H/C/000115/II/0099).

II/0004	Update to sections 4.4, 4.9 and 5.1 of the Summary of Product Characteristics (SPC) in line with the Product Information of the reference medicinal product Zyprexa. Update of Summary of Product Characteristics	25/06/2009	16/07/2009	SmPC	Following changes to the SPC of the reference medicinal product Zyprexa, sections 4.4, 4.9 and 5.1 of the Olanzapine Neopharma SPC were updated. Recommendations on monitoring of patients for signs and symptoms of hyperglycaemia, worsening of glucose control and weight gain were added to section 4.4 and new information on acute overdose was added to section 4.9. Section 5.1 of the SPC was also updated with regard to details of the ATC code. The summary of the above mentioned changes may be found in the EPARs (module 8B) of Zyprexa (II/96) and Zyprexa Velotab (II/68).
II/0003	Update of Section 4.8 of the SPC in line with the reference medicinal product. Some minor editorial changes have been introduced to keep the SPC in line with that for the reference product. Update of Summary of Product Characteristics and Package Leaflet	23/10/2008	21/11/2008	SmPC	Following a change to the SPC of the reference medicinal product, Section 4.8 of the SPC of Olanzapine Neopharma were updated to align them with those of the reference medicinal product to include new data regarding changes in bodyweight, glucose and lipid levels over time in adults and adolescents. The summary of the above mentioned changes may be found in the EPARs (module 8B) of Zyprexa (II/92) and Zyprexa Velotab (II/61).
II/0002	Update of Sections 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SPC in line with the reference medicinal product. The Product Information was updated in accordance with the latest QRD templates. Update of Summary of Product Characteristics, Labelling and Package Leaflet	24/07/2008	02/09/2008	SmPC, Labelling and PL	Following a change to the SPC of the reference medicinal product, Sections 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SPC of Olanzapine Neopharma were updated to align them with those of the reference medicinal product to include data from studies conducted in adolescent population with schizophrenia and bipolar I disorder (manic or mixed episodes). The summary of the above mentioned changes may be found in the EPARs (module 8B) of Zyprexa (II/83) and Zyprexa Velotab (II/52).

II/0001	Update of section 4.4 and 4.8 of Summary of Product Characteristics and relevant section of the Package Leaflet. Update of Summary of Product Characteristics and Package Leaflet	24/04/2008	10/06/2008	SmPC and PL	Following a change to the product information of its reference medicinal product, the SPC and PL of Olanzapine Neopharma was updated to align it with it. Both existing warnings on diabetes and lipids alterations in section 4.4 of the SPC have been updated. In addition, section 4.8 of the SPC was amended to add the term "glycosuria" and "fatigue" as commonly occurring events, to amend the frequency of hyperglycaemia from very rare to rare, and to add further information in relation to weight gain, elevated glucose levels, elevated triglyceride levels and elevated cholesterol levels. The Package Leaflet was amended accordingly.