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Olanzapine Glenmark

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
WS/1831	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.3.z - Change(s) in the SPC, Labelling or PL intended to implement the outcome of a procedure	25/06/2020		SmPC, Labelling 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).

	concerning PSUR or PASS or the outcome of the assessment done under A 45/46 - Other variation				
IG/1195/G	This was an application for a group of variations. B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	31/01/2020	n/a		
WS/1650	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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	12/09/2019		SmPC and PL	
T/0029	Transfer of Marketing Authorisation	13/12/2018	31/01/2019	SmPC, Labelling and	

				PL	
IA/0030	B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size	10/12/2018	n/a		
N/0028	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	07/11/2018	31/01/2019	Labelling	
IG/0900	B.II.c.3.z - Change in source of an excipient or reagent with TSE risk - Other variation	12/03/2018	n/a		
IG/0906/G	This was an application for a group of variations. B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	02/03/2018	n/a		
IG/0770/G	This was an application for a group of variations. B.II.a.1.a - Change or addition of imprints, bossing or other markings including replacement, or addition of inks used for product marking - Changes in imprints, bossing or other markings B.II.a.1.a - Change or addition of imprints, bossing or other markings including replacement, or addition of inks used for product marking - Changes in imprints,	23/02/2017	23/10/2017	SmPC and PL	

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IB/0024/G	This was an application for a group of variations. B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets,	15/02/2017	23/10/2017	SmPC, Labelling and PL	

	ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes				
IG/0698	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	07/10/2016	23/10/2017	SmPC and PL	
IG/0608	A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release)	23/10/2015	n/a		
WS/0656/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.III.1.a.1 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.II.d.1.d - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter B.II.d.2.d - Change in test procedure for the finished	26/02/2015	n/a		

	product - Other changes to a test procedure (including replacement or addition) B.II.d.1.c - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.II.d.1.d - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter				
IG/0517	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	27/01/2015	n/a		
R/0019	Renewal of the marketing authorisation.	26/06/2014	19/08/2014	SmPC 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 Glenmark continues to be favourable.
WS/0446/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.	25/04/2014	n/a		

	- B.I.a.3.a. - to change the batch size of the active substance - B.III.2.a.1. - to change the active substance specification B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size B.III.2.a.1 - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - AS				
IB/0017/G	This was an application for a group of variations. B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes	06/03/2014	19/08/2014	SmPC, Labelling and PL	
IG/0412/G	This was an application for a group of variations. A.1 - Administrative change - Change in the name and/or address of the MAH A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	17/02/2014	19/08/2014	SmPC, Annex II, Labelling and PL	

WS/0424	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Update of section 4.8 of the Summary of Product Characteristics (SmPC) and relevant section of the Package Leaflet (PL) to include "amnesia, epistaxis, abdominal distension, arthralgia, high gamma glutamyl transferase transferase, high uric acid, pyrexia and dysarthria", as new undesirable effects in line with the reference medicinal product. 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, update of the Product Information in line with the latest QRD templates. 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	23/01/2014	19/08/2014	SmPC, Annex II and PL	The CHMP reviewed the proposed revision for the Product Information that were submitted in line with the reference medicinal product and accepted all the proposed changes.
IG/0241	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	07/12/2012	n/a		
WS/0319	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.	15/11/2012	10/12/2012	SmPC, Annex II, Labelling and PL	Following changes to the SmPC of the reference medicinal products Zyprexa and Zyprexa Velotab, section 4.8 of the Olanzapines SmPC was updated to add urinary retention as an uncommon adverse drug reaction in patients taking

	Update of the Summary of Product Characteristics (SmPC) in line with the reference medicinal products. Update of SmPC section 4.8 to add urinary retention as an undesirable effect and to reflect this change in the section 4 of the PL. Additional changes were also made to align the Product Information texts with version 8 of the QRD template. 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				olanzapine. Section 4 of the PL was updated accordingly. Additional changes were also made to align the Product Information texts with version 8 of the QRD template.
WS/0285	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. This Work Sharing Application (WSA) updated sections 4.4 and 4.8 of the Summary of Product Characteristics(SmPC) in order to update the safety information in line with the following changes as adopted by the CHMP for the reference products. Update of SmPC section 4.4 to include metabolic monitoring frequency examples following the assessment of the latest PSURs and RMP. Update of the frequency of venous thromboembolism (VTE) in SmPC section 4.4 and 4.8 following PHVWP recommendation to include warnings about the risk of venous thromboembolism. Sections 2 and 4 of Package Leaflet (PL) were updated in accordance.	20/09/2012	25/10/2012	SmPC and PL	Further to the assessment of safety data, the Product Information (section 4.4 of the SmPC and section 2 of the PL) has been updated to add examples of monitoring of blood glucose, lipids, weight in patients taking olanzapine. In addition warning on the risk of blood clotting (venous thromboembolism) was made consistent throughout olanzapine products. The frequency of VTE was also recalculated and as a result assessed as uncommon in SmPC sections 4.4 and 4.8 and PL section 4.

	Corrections were also made to the PI in different languages (CZ, DE, HU, NO, SP, PT). 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				
IG/0217	B.II.b.4.b - Change in the batch size (including batch size ranges) of the finished product - Downscaling down to 10-fold	19/09/2012	n/a		
IG/0202/G	This was an application for a group of variations. B.II.b.2.b.1 - Change to batch release arrangements and quality control testing of the FP - Not including batch control/testing B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site 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	23/08/2012	25/10/2012	Annex II and PL	
WS/0262	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Extension of shelf-life of the finished product from 21 months to 30 months.	21/06/2012	16/07/2012	SmPC	

	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)				
IG/0174	B.II.b.4.b - Change in the batch size (including batch size ranges) of the finished product - Downscaling down to 10-fold	18/05/2012	n/a		
N/0007	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	17/04/2012	16/07/2012	Annex II and PL	The Marketing Authorisation Holder (MAH) took the opportunity to remove DDPS version number in Annex II and to add local representatives in Annex IIIB.
WS/0202	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Following PhVWP/CHMP conclusions of June 2011, update of the Summary of Product Characteristics (SmPC) and Package Leaflet (PL) 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. 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	19/01/2012	27/02/2012	SmPC and PL	There is evidence to suggest that the newborn babies of mothers treated with antipsychotics during the third trimester of pregnancy may suffer adverse effects (primarily extrapyramidal side effects and/or withdrawal effects). Whilst there is limited data available for some antipsychotics, this is likely to be a class effect. In addition to the inclusion of neonatal drug withdrawal syndrome as listed adverse reaction, section 4.6 of the SmPC and section 2 and 4 of the PL were updated in accordance with the PhVWP/CHMP class labelling recommended wording, as follows: SmPC: Neonates exposed to antipsychotics (including olanzapine) during the third trimester of pregnancy are at risk of adverse reactions including extrapyramidal and/or withdrawal symptoms that may vary in severity and duration following delivery. There have been reports of agitation, hypertonia, hypotonia, tremor, somnolence, respiratory distress, or feeding disorder. PL: The following symptoms may occur in newborn babies, of mothers that have used [NAME] in the last trimester (last

					three months of their pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.
IG/0123	B.II.b.2.b.1 - Change to batch release arrangements and quality control testing of the FP - Not including batch control/testing. B.II.b.2.b.1 - Change to batch release arrangements and quality control testing of the FP - Not including batch control/testing	07/12/2011	27/02/2012	Annex II and PL	
IG/0082	A.4 - Administrative change - Change in the name and/or address of a manufacturer or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS	19/08/2011	n/a		
IG/0077	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	11/07/2011	n/a		
WS/0068	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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	16/12/2010	24/01/2011	SmPC and PL	Changes have been made to the product information of the generic products to bring it in line with that of the reference product. The reference product information was updated in July 2010. The updates included changes to sections 4.4 (deletion of a sentence in the warning related to liver function) and 4.8 (modification of the information on levels of prolactin hormone observed in the short-term clinical studies) of the Summary of Product Characteristics. Additional changes were made to the reference product

	product - Implementation of change(s) for which NO new additional data are submitted by the MAH				information in accordance with the QRD template (version 7.3.1). The Product Information of the generic products has been amended accordingly.
WS/0002	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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	18/03/2010	26/05/2010	SmPC, Labelling and PL	Following changes to the SmPC of the reference medicinal products Zyprexa and Zyprexa Velotab, sections 4.4, and 4.8 of the Olanzapine Glenmark Europe SmPC were updated. In the section 4.4 a warning on sudden cardiac death was included. Moreover, urinary incontinence as an uncommon adverse drug reaction and revised information on elevated plasma prolactin concentrations and related clinical manifestations were included in the section 4.8. Section 4 of the Package Leaflet has been amended accordingly. Additionally, minor editorial changes were introduced in SmPC sections 4.8, 5.1 and throughout translations of the Product Information in line with the reference medicinal products.