Olanzapine Teva

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
N/0087	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	11/10/2021		PL	
IA/0085/G	This was an application for a group of variations. B.III.1.a.2 - Submission of a new/updated or	03/03/2021	n/a		

[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).

	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				
IA/0084	A.7 - Administrative change - Deletion of manufacturing sites	01/03/2021		Annex II and PL	
IA/0083	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	14/01/2021	n/a		
IB/0082	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	28/04/2020	31/07/2020	SmPC, Annex II, Labelling and PL	
IA/0081	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	12/12/2019	n/a		
IB/0080/G	This was an application for a group of variations. B.II.b.5.z - Change to in-process tests or limits	23/10/2019	31/07/2020	SmPC and PL	

	applied during the manufacture of the finished product - Other variation B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation				
IB/0079	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	23/07/2019	31/07/2020	SmPC, Labelling and PL	
N/0077	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	29/04/2019	31/07/2020	Labelling and PL	
IB/0078/G	This was an application for a group of variations. B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data 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	25/04/2019	n/a		
IA/0076	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	19/04/2018	n/a		

N/0075	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	19/02/2018	31/07/2020	PL	
N/0074	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	28/11/2017	19/02/2018	PL	
IA/0073	B.II.b.4.b - Change in the batch size (including batch size ranges) of the finished product - Downscaling down to 10-fold	11/05/2017	n/a		
IB/0072	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	15/03/2017	n/a		
IAIN/0071	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	07/02/2017	19/02/2018	SmPC and PL	
IA/0070	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	08/12/2016	n/a		
IAIN/0069/G	This was an application for a group of variations. B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method B.III.1.a.3 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from a	02/12/2016	n/a		

	new manufacturer (replacement or addition)				
IA/0068	B.III.2.a.2 - 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 - Excipient/AS starting material	07/10/2016	n/a		
IAIN/0067	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	21/07/2016	21/10/2016	SmPC, Labelling and PL	
IA/0066	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	15/06/2016	n/a		
IB/0064/G	This was an application for a group of variations. B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data 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	26/05/2016	n/a		
IA/0065/G	This was an application for a group of variations. A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites	18/03/2016	21/10/2016	Annex II and PL	

	(excluding manufacturer for batch release) A.7 - Administrative change - Deletion of manufacturing sites				
IAIN/0062/G	This was an application for a group of variations. B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished	11/11/2015	21/10/2016	SmPC, Labelling and PL	

	product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished				

	product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes				
IAIN/0063/G	This was an application for a group of variations. B.II.c.3.z - Change in source of an excipient or	09/11/2015	21/10/2016	SmPC, Labelling and PL	

	reagent with TSE risk - Other variation B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes				
IB/0061	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)	05/10/2015	21/10/2016	SmPC and PL	
IA/0060	B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier	01/07/2015	n/a		
T/0059	Transfer of Marketing Authorisation	12/03/2015	09/04/2015	SmPC, Labelling and PL	
IB/0058	B.II.e.1.z - Change in immediate packaging of the finished product - Other variation	27/01/2015	09/04/2015	SmPC, Labelling and PL	
II/0055/G	This was an application for a group of variations. 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)	22/01/2015	09/04/2015	SmPC, Annex II, Labelling and PL	

	A.7 - Administrative change - Deletion of manufacturing sites B.II.a.2.a - Change in the shape or dimensions of the pharmaceutical form - Immediate release tablets, capsules, suppositories and pessaries B.II.a.3.a.1 - Changes in the composition (excipients) of the finished product - Changes in components of the flavouring or colouring system - Addition , deletion or replacement B.II.a.3.b.2 - Changes in the composition (excipients) of the finished product - Other excipients - Qualitative or quantitative changes in one or more excipients that may have a significant impact on the safety, quality or efficacy of the product B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site B.II.b.1.e - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer				

	responsible for importation and/or batch release - Not including batch control/testing B.II.b.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing B.II.b.3.b - Change in the manufacturing process of the finished or intermediate product - Substantial changes to a manufacturing process that may have a significant impact on the quality, safety and efficacy of the medicinal product 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 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.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.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range B.II.e.2.b - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Addition of a new specification parameter to the specification with its corresponding test method B.II.f.1.a.1 - Stability of FP - Reduction of the shelf life of the finished product - As packaged for sale B.II.f.1.d - Stability of FP - Change in storage conditions of the finished product or the				

	diluted/reconstituted product B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing 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.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.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.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.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)				
IB/0056/G	This was an application for a group of variations. B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	03/10/2014	n/a		
IB/0054/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF B.I.b.1.c - Change in the specification parameters	16/09/2014	n/a		

	and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data 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/0057	Update of sections 4.4 and 5.1 of the SmPC in order to reflect the level of data available in adolescents with bipolar I disorder (manic or mixed episodes) or schizophrenia following the completion of a long-term safety study, to fulfil the requirement laid down in Article 46 of the paediatric regulation following the same change for the originator. The MAH took also the opportunity to align the Product Information with the QRD template (Version 9). 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	27/08/2014	09/04/2015	SmPC and PL	

IB/0053	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)	23/09/2013	28/02/2014	SmPC	
IB/0052	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	22/08/2013	28/02/2014	SmPC, Annex II and PL	
IAIN/0051	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	07/05/2013	n/a		
IB/0050/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	01/03/2013	28/02/2014	SmPC, Labelling and PL	

	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, 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				
R/0048	Renewal of the marketing authorisation.	20/09/2012	12/11/2012		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 Teva continues to be favourable.
IB/0049	Update of the section 4.8 of the SmPC to add urinary retention as an undesirable effect and to reflect this change in the section 4 of the PLs further to a cumulative review of "urinary retention" in temporal association with olanzapine treatment in line with the reference medicinal product. In addition, changes are proposed throughout the product information to bring it in line with version 8 of the QRD template. In addition, contact details for local representatives have been updated. Also, changes in the text for Czech Republic, Germany, Hungary, Norway, Portugal, Italy and Spain were implemented 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	20/09/2012	12/11/2012	SmPC, Annex II, Labelling and PL	
IAIN/0047/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	05/07/2012	n/a		

IAIN/0046/G	This was an application for a group of variations. B.I.a.1.a - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method B.I.c.3.b - Change in test procedure for the immediate packaging of the AS - Other changes to a test procedure (including replacement or addition)	25/06/2012	n/a		
IB/0045	B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation	19/04/2012	n/a		
IB/0044	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	13/01/2012	08/08/2012	SmPC and PL	

	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, contact details for local representatives in Malta and Italy have been updated. A correction related to the product name has been made in the Dutch annex. 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				
IAIN/0043	A.5.a - Administrative change - Change in the name and/or address of a manufacturer responsible for batch release	15/12/2011	17/02/2012	SmPC, Annex II and PL	
IAIN/0042/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 A.7 - Administrative change - Deletion of manufacturing sites	10/11/2011	17/02/2012	Annex II and PL	
IA/0041/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging	19/08/2011	n/a		

	site B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site				
IB/0040	Update of the section 4.4 of the Summary of Product Characteristics (deletion of a sentence in the warning related to hepatic function) and section 4.8 (modification of the prolactin information in the footnote). Additionally, for all EEA languages, linguistic changes were made inline with the reference product information annexes. Furthermore, for EEA languages (EL, IT, PL and SL), minor spelling and grammatical corrections were made. Additionally, for EEA language HU, labelling text was updated to add active substance to Section 1. The product information annexes were also updated according to the QRD templates (version 7.3.1). Local Technical Representative name and contact details in the PIL texts were updated. 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	12/11/2010	n/a	SmPC and PL	
IA/0039	B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits	06/08/2010	n/a	SmPC and PL	

IB/0038	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	31/03/2010	n/a	SmPC and PL	
II/0037	Update to section 4.8 of the Summary of Product Characteristics (SPC) in line with the Product Information of the reference medicinal products. An editorial change was made in section 4.4 of the SPC. Update of Summary of Product Characteristics	24/09/2009	19/10/2009	SmPC	The SPC was updated to align it with that of the reference medicinal products. This followed a change to the SPC of the reference medicinal products via the following procedures: Zyprexa (EMEA/H/C/000115/II/0099) and Zyprexa Velotab (EMEA/H/C/000287/II/0070).
II/0036	Update to sections 4.4 and 4.9 of the Summary of Product Characteristics (SPC) in line with the Product Information of the reference medicinal product Zyprexa. Section 5.1 of the SPC was also updated with regard to details of the ATC code.	25/06/2009	20/07/2009	SmPC	Following changes to the SPC of the reference medicinal product Zyprexa, section 4.4, 4.9 and 5.1 of the Olanzapine Teva 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

	Update of Summary of Product Characteristics				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/0034	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	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 Teva 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).
IB/0035	IB_07_c_Replacement/add. of manufacturing site: All other manufacturing operations ex. batch release IA_08_b_02_Change in BR/QC testing - repl./add. manuf. responsible for BR - incl. BC/testing	23/09/2008	n/a	PL	
II/0032	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 and Package Leaflet	24/07/2008	02/09/2008	SmPC 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 Teva 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).

IB/0033	IB_30_b_Change in supplier of packaging components - replacement/addition	07/08/2008	n/a		
IA/0031	IA_08_b_01_Change in BR/QC testing - repl./add. manuf. responsible for BR - not incl. BC/testing	11/06/2008	n/a	Annex II and PL	
IA/0030	IA_08_b_01_Change in BR/QC testing - repl./add. manuf. responsible for BR - not incl. BC/testing	11/06/2008	n/a	Annex II and PL	
II/0024	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" as commonly occurring event, 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.
IB/0028	IB_07_c_Replacement/add. of manufacturing site: All other manufacturing operations ex. batch release IA_08_b_02_Change in BR/QC testing - repl./add. manuf. responsible for BR - incl. BC/testing	10/06/2008	n/a	Annex II and PL	
IB/0027	IB_14_a_Change in manuf. of active substance without Ph. Eur. certificate - change in manuf. site	10/06/2008	n/a		

IA/0029	IA_32_b_Change in batch size of the finished product - downscaling down to 10-fold	29/05/2008	n/a		
N/0001	Update of the list of local representatives in section 6 of the Package Leaflet. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	07/03/2008	n/a	PL	
IB/0023	IB_42_a_01_Change in shelf-life of finished product - as packaged for sale	27/02/2008	n/a	SmPC	
IB/0021	IB_41_a_02_Change in pack size - change in no. of units outside range of appr. pack size	08/02/2008	08/02/2008	SmPC, Labelling and PL	
IB/0020	IB_41_a_02_Change in pack size - change in no. of units outside range of appr. pack size	08/02/2008	08/02/2008	SmPC, Labelling and PL	
IB/0019	IB_41_a_02_Change in pack size - change in no. of units outside range of appr. pack size	08/02/2008	08/02/2008	SmPC, Labelling and PL	
IB/0018	IB_41_a_02_Change in pack size - change in no. of units outside range of appr. pack size	08/02/2008	08/02/2008	SmPC, Labelling and PL	
IB/0017	IB_41_a_02_Change in pack size - change in no. of units outside range of appr. pack size	08/02/2008	08/02/2008	SmPC, Labelling and PL	
IB/0016	IB_41_a_02_Change in pack size - change in no. of units outside range of appr. pack size	08/02/2008	08/02/2008	SmPC, Labelling and	

				PL	
IB/0015	IB_41_a_02_Change in pack size - change in no. of units outside range of appr. pack size	08/02/2008	08/02/2008	SmPC, Labelling and PL	
IB/0014	IB_41_a_02_Change in pack size - change in no. of units outside range of appr. pack size	08/02/2008	08/02/2008	SmPC, Labelling and PL	
IB/0013	IB_41_a_02_Change in pack size - change in no. of units outside range of appr. pack size	08/02/2008	08/02/2008	SmPC, Labelling and PL	
IB/0012	IB_41_a_02_Change in pack size - change in no. of units outside range of appr. pack size	08/02/2008	08/02/2008	SmPC, Labelling and PL	
IA/0011	IA_41_a_01_Change in pack size - change in no. of units within range of appr. pack size	29/01/2008	29/01/2008	SmPC, Labelling and PL	
IA/0010	IA_41_a_01_Change in pack size - change in no. of units within range of appr. pack size	29/01/2008	29/01/2008	SmPC, Labelling and PL	
IA/0009	IA_41_a_01_Change in pack size - change in no. of units within range of appr. pack size	29/01/2008	29/01/2008	SmPC, Labelling and PL	
IA/0008	IA_41_a_01_Change in pack size - change in no. of units within range of appr. pack size	29/01/2008	29/01/2008	SmPC, Labelling and PL	
IA/0007	IA_41_a_01_Change in pack size - change in no. of units within range of appr. pack size	29/01/2008	29/01/2008	SmPC, Labelling and	

				PL	
IA/0006	IA_41_a_01_Change in pack size - change in no. of units within range of appr. pack size	29/01/2008	29/01/2008	SmPC, Labelling and PL	
IA/0005	IA_41_a_01_Change in pack size - change in no. of units within range of appr. pack size	29/01/2008	29/01/2008	SmPC, Labelling and PL	
IA/0004	IA_41_a_01_Change in pack size - change in no. of units within range of appr. pack size	29/01/2008	29/01/2008	SmPC, Labelling and PL	
IA/0003	IA_41_a_01_Change in pack size - change in no. of units within range of appr. pack size	29/01/2008	29/01/2008	SmPC, Labelling and PL	
IA/0002	IA_41_a_01_Change in pack size - change in no. of units within range of appr. pack size	29/01/2008	29/01/2008	SmPC, Labelling and PL	