Zalasta

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/0044/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	01/03/2024		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).

	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				
N/0043	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	03/02/2023		PL	
PSUSA/10540 /202203	Periodic Safety Update EU Single assessment - olanzapine	01/12/2022	n/a		PRAC Recommendation - maintenance
N/0041	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	07/12/2021		PL	
N/0040	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	17/05/2021		Labelling and PL	
IB/0039/G	This was an application for a group of variations. B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation 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 B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test	06/04/2021	n/a		

	procedure				
IA/0038	A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient	15/06/2020	n/a		
PSUSA/10540 /201903	Periodic Safety Update EU Single assessment - olanzapine	12/12/2019	21/02/2020	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10540/201903.
IB/0037/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites 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	12/08/2019	n/a		

IB/0035	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	04/06/2019	21/02/2020	SmPC, Labelling and PL	
N/0034	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	19/01/2018	21/02/2020	PL	
IB/0032	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	07/12/2017	n/a		
IA/0033	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	24/11/2017	n/a		
IB/0031	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	27/01/2017	18/05/2017	SmPC and PL	
PSUSA/2205/ 201603	Periodic Safety Update EU Single assessment - olanzapine	01/12/2016	n/a		PRAC Recommendation - maintenance
IA/0030/G	This was an application for a group of variations. B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	19/10/2016	n/a		

IB/0029	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	08/07/2016	18/05/2017	SmPC, Annex II, Labelling and PL	
IAIN/0027	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	22/07/2015	n/a		
IB/0026	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. In addition the phone number for the local representative in UK has been updated and minor editorial corrections have been made in all annexes. 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	05/09/2014	22/10/2015	SmPC, Labelling and PL	
IB/0025	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	28/02/2014	n/a		

IB/0024/G	This was an application for a group of variations. 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) B.II.f.1.d - Stability of FP - Change in storage conditions of the finished product or the diluted/reconstituted product	11/02/2014	26/08/2014	SmPC and PL	
IA/0023	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	15/11/2013	n/a		
IB/0022	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. 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	19/08/2013	26/08/2014	SmPC, Annex II and PL	
N/0021	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	09/07/2013	26/08/2014	Labelling and PL	

IB/0020	Consequential to the CHMP adoption of a variation to the Marketing Authorisation of Zyprexa (EMEA/H/C/xxxx/WS/0215), the MAH updated section 4.8 of the olanzapine SmPCs to add urinary retention as an undesirable effect. The PLs were changed in order to reflect this change in the section 4. The product information was updated according to version 8 of the QRD template. In addition some minor editorial changes were made in translations for the countries Czech Republic, Germany, Hungary, Norway, Portugal, Italy and Spain. The MAH also took the opportunity to correct details of local representatives. 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	26/09/2012	29/10/2012	SmPC, Annex II, Labelling and PL	
R/0019	Renewal of the marketing authorisation.	24/05/2012	26/07/2012	SmPC, Annex II 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 is 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 Zalasta continues to be favourable.

IA/0018	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	23/02/2012	n/a		
IB/0016/G	This was an application for a group of variations. Following PhVWP/CHMP conclusions of June 2011 update of the Summary of Product Characteristics (SrnPC) 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. Following CHMP conclusions of October 2011 update of the SmPC and Package Leaflet in line with the reference medicinal product. Update of SmPC section 4.4 to include metabolic monitoring frequency examples following the assessment of the Latest PSURs and RMP for the reference medicinal product. The Package Leaflet is updated accordingly. Update of the frequency of Venous thromboenibolism (VTE) in SmPC section 4.4 and 4.8 following PhVWP recommendation to include warnings about the risk of venous thromboembolism. The Package Leaflet is updated accordingly.	26/01/2012	26/07/2012	SmPC and PL	

	Corrections in the annexes have been proposed for the following countries: Bulgaria, Danemark, Czech Republic , Germany, Greece, Finland, Iceland, Norway, Portugal, Romania, Slovakia and Slovenia. These changes are 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 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/0017	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	23/01/2012	n/a		
IAIN/0015/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.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging	24/11/2011	26/07/2012	Annex II and PL	

	site B.II.b.2.b.1 - Change to batch release arrangements and quality control testing of the FP - Not including batch control/testing				
IB/0014	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	15/09/2011	n/a		
IB/0013	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)	16/03/2011	n/a	SmPC and Annex II	
IB/0012	Update of sections 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 resulting of a review of the company core data sheet. Additional changes were made to the Product Information and Annex II in accordance with the QRD templates (version 7.3.1.). At the same time MAH takes the opportunity to change telephone number for Latvia in the list of local representative of the Marketing Authorisation Holder. We also made minor QRD corrections in all translations and minor editorial changes in Danish, French, Dutch and Slovenian texts. 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	26/10/2010	n/a	SmPC and PL	

	product - Implementation of change(s) for which NO new additional data are submitted by the MAH				
IB/0011	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. Minor editorial changes were made to the EL annexes. Furthermore the details of the local representatives in the United Kingdom, Cyprus, Austria, Romania, Bulgaria, Estonia, Czech Republic, Hungary, Lithuania, Slovakia, France, Ireland, Malta, Portugal, Poland, Spain and Slovenia were updated. Additionally, editorial changes were made in the relevant sections of the Product Information. 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/0009	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.	24/09/2009	30/10/2009	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).

	Update of Summary of Product Characteristics				
II/0007	Update to sections 4.4, 4.9 and 5.1 of the Summary of Product Characteristics (SPC) in line with the reference medicinal product Zyprexa, and update to the Package Leaflet regarding the contact details for the local representatives for Cyprus and Greece. Update of Summary of Product Characteristics and Package Leaflet	25/06/2009	17/07/2009	SmPC and PL	Following changes to the SPC of the reference medicinal product Zyprexa, sections 4.4, 4.9 and 5.1 of the Zalasta 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 the details of the ATC code. The contact details of the local representatives for Cyprus and Greece was updated in the Package Leaflet. The summary of the above mentioned changes may be found in the EPARs (module 8B) of Zyprexa (II/96) and Zyprexa Velotab (II/68).
IA/0008	IA_07_a_Replacement/add. of manufacturing site: Secondary packaging site	15/05/2009	n/a		
II/0006	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	26/11/2008	SmPC	Following a change to the SPC of the reference medicinal product, Section 4.8 of the SPC of Zalasta 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/0005	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	24/07/2008	22/08/2008	SmPC, Annex II 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 Zalasta were updated to align them with those of the

	with the latest QRD templates. Update of Summary of Product Characteristics and Package Leaflet				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/0004	Update of section 4.4 and 4.8 of Summary of Product Characteristics (SPC) and relevant section of the Package Leaflet (PL). Update of Summary of Product Characteristics and Package Leaflet	30/05/2008	08/07/2008	SmPC and PL	Following changes to the SPC and PL of the reference medicinal product, the SPC and PL of Zalasta were updated to align it with that of the reference medicinal product. 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.
II/0003	Update of section 4.8 of the Summary of Product Characteristics (SPC) in line with the reference medicinal product. Update of Summary of Product Characteristics	21/02/2008	02/04/2008	SmPC	Following a change to the SPC of the reference medicinal product, the SPC of Zalasta was updated to align it with that of the reference medicinal product. Section 4.8 was updated to include 'fatigue'.
N/0001	Update of the local representative in Germany in section 6 of the Package Leaflet. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	11/01/2008	n/a	PL	

IA/0002	IA_32_b_Change in batch size of the finished product - downscaling down to 10-fold	05/12/2007	n/a		