Olanzapine Viatris

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
T/0061	Transfer of Marketing Authorisation	29/11/2024	19/12/2024	SmPC, Labelling and PL	
IG/1772	A.2.a - Administrative change - Change in the (invented) name of the medicinal product for CAPs	15/10/2024	09/12/2024	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).

IAIN/0059	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	08/08/2024	n/a		
N/0058	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	08/05/2024	09/12/2024	PL	
IB/0057	B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation	19/05/2023	20/06/2024	SmPC and PL	
N/0056	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	12/01/2023	20/06/2024	PL	
IAIN/0055	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	22/11/2021	28/11/2022	Annex II and PL	
T/0054	Transfer of Marketing Authorisation	15/09/2021	12/11/2021	SmPC, Labelling and PL	
IB/0053	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	06/07/2021	n/a		
IA/0052	A.7 - Administrative change - Deletion of manufacturing sites	05/03/2021	12/11/2021	Annex II and PL	

IB/0051	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	17/09/2020	n/a		
IA/0050/G	This was an application for a group of variations. B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure 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 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	31/07/2020	n/a		
IB/0049	C.I.3.z - Change(s) in the SPC, Labelling or PL intended to implement the outcome of a procedure concerning PSUR or PASS or the outcome of the assessment done under A 45/46 - Other variation	02/06/2020	28/08/2020	SmPC, Annex II, Labelling and PL	

IB/0048	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	31/07/2019	28/08/2020	SmPC and PL	
N/0047	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	07/03/2019	28/08/2020	PL	
IA/0046	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	14/11/2018	n/a		
T/0045	Transfer of Marketing Authorisation	19/09/2018	12/11/2018	SmPC, Labelling and PL	
IA/0044	B.II.e.1.a.1 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Solid pharmaceutical forms	13/07/2018	12/11/2018	SmPC, Labelling and PL	
IB/0043	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	12/12/2017	12/11/2018	SmPC and PL	
IAIN/0042	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	07/02/2017	25/07/2017	SmPC, Labelling and PL	

IA/0041	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)	12/12/2016	n/a		
IB/0040	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	21/07/2016	25/07/2017	SmPC, Labelling and PL	
IG/0647	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	11/01/2016	n/a		
IB/0038	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	02/07/2015	06/07/2016	SmPC, Labelling and PL	
IAIN/0037	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	16/03/2015	n/a		
IA/0036	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)	13/10/2014	n/a		
IB/0034/G	This was an application for a group of variations.	31/10/2013	19/08/2014	SmPC,	

	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.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.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			Labelling and PL	
IA/0035	A.7 - Administrative change - Deletion of manufacturing sites	24/10/2013	n/a		
IB/0033	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	19/08/2014	SmPC and PL	
R/0032	Renewal of the marketing authorisation.	21/03/2013	22/05/2013	Annex II	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 Mylan continues to be favourable. The CHMP was of the opinion that the renewal could be

					granted with unlimited validity.
IA/0031	A.5.b - Administrative change - Change in the name and/or address of a manufacturer of the finished product, including quality control sites (excluding manufacturer for batch release)	27/09/2012	n/a		
IB/0030	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	25/10/2012	SmPC, Annex II, Labelling and PL	
IB/0029/G	This was an application for a group of variations. 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	18/01/2012	03/08/2012	SmPC and PL	
IB/0028	To add a new unit dose pack size of 100x1 tablets for the 7.5mg film-coated tablets (EU/1/08/475/057). 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	12/10/2011	12/10/2011	SmPC, Labelling and PL	

	the range of the currently approved pack sizes				
IA/0027/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 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.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.b.1 - Change to batch release arrangements and quality control testing of the FP - Not including batch control/testing 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	12/10/2011	12/10/2011	SmPC, Annex II, 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				
IB/0023	B.I.d.1.z - Stability of AS - Change in the re-test period/storage period or storage conditions - Other variation	04/08/2011	n/a		
IB/0020	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)	06/07/2011	n/a	SmPC, Labelling and PL	
IB/0022/G	This was an application for a group of variations. 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.h - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition or replacement (excl. Biol. or immunol. substance) of a specification parameter as a result of a safety or quality issue B.I.c.2.b - Change in the specification parameters	05/07/2011	n/a		

	and/or limits of the immediate packaging of the AS - Addition of a new specification parameter to the specification with its corresponding test method 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				
IB/0021/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.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.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.	01/07/2011	01/07/2011	SmPC, Annex II, Labelling and PL	

	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.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				
IA/0024/G	This was an application for a group of variations. B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of	16/06/2011	n/a		

	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.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.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.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.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				
IA/0019/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	05/01/2011	n/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.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				
IB/0018	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	15/11/2010	n/a	SmPC	
IB/0017	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	20/07/2010	n/a		
IB/0016	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	
IB/0004	IB_33_Minor change in the manufacture of the finished product	22/01/2010	n/a		
IB/0003	IA_09_Deletion of manufacturing site IB_07_c_Replacement/add. of manufacturing site: All other manufacturing operations ex. batch release	22/01/2010	n/a		

IA/0015	IA_09_Deletion of manufacturing site	18/12/2009	n/a	Annex II and PL	
IA/0014	IA_09_Deletion of manufacturing site	18/12/2009	n/a	Annex II and PL	
IA/0013	IA_09_Deletion of manufacturing site	18/12/2009	n/a	Annex II and PL	
IA/0012	IA_09_Deletion of manufacturing site	18/12/2009	n/a	Annex II and PL	
IA/0011	IA_09_Deletion of manufacturing site	18/12/2009	n/a		
IA/0010	IA_09_Deletion of manufacturing site	18/12/2009	n/a		
IA/0009	IA_09_Deletion of manufacturing site	18/12/2009	n/a		
IA/0008	IA_09_Deletion of manufacturing site	18/12/2009	n/a		
IA/0007	IA_07_a_Replacement/add. of manufacturing site: Secondary packaging site	18/12/2009	n/a		
IA/0006	IA_05_Change in the name and/or address of a manufacturer of the finished product	18/12/2009	n/a	Annex II and PL	
IA/0005	IA_07_a_Replacement/add. of manufacturing site: Secondary packaging site	18/12/2009	n/a		
II/0002	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.	24/09/2009	23/10/2009	SmPC and PL	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:

	In addition, the Marketing Authorisation Holder took the opportunity to update the contact details for the local representative in Slovakia in the Package Leaflet and to introduce minor linguistic changes in the Bulgarian, Danish, Dutch, French, German, Greek, Hungarian, Italian, Latvian, Lithuanian, Polish, Portuguese, Romanian and Swedish Annexes. Update of Summary of Product Characteristics and Package Leaflet				Zyprexa (EMEA/H/C/000115/II/0099).
II/0001	Update to sections 4.4 and 4.9 of the Summary of Product Characteristics (SPC) in line with the Product Information of the reference product Zyprexa. Update of Summary of Product Characteristics	25/06/2009	17/07/2009	SmPC	Following changes to the SPC of the reference medicinal product Zyprexa, sections 4.4 and 4.9 of the Olanzapine Mylan 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. The summary of the above mentioned changes may be found in the EPARs (module 8B) of Zyprexa (II/96) and Zyprexa Velotab (II/68).