Memantine Merz

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/0021	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	16/02/2024		Labelling and PL	
WS/2413/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No	25/05/2023	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).

	1234/2008. B.II.e.4.a - Change in shape or dimensions of the container or closure (immediate packaging) - Non-sterile medicinal products B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier				
IG/1597/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.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.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.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site 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 A.7 - Administrative change - Deletion of manufacturing sites	03/03/2023	n/a		

	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 importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place				
WS/1980	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	18/03/2021	04/04/2022	SmPC, Labelling and PL	
WS/1579	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.e.1.a.2 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Semi-solid and non-sterile liquid pharmaceutical forms	29/05/2019	12/06/2020	SmPC and PL	
PSUSA/1967/ 201809	Periodic Safety Update EU Single assessment - memantine	16/05/2019	n/a		PRAC Recommendation - maintenance
IG/0835/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	13/09/2017	n/a		

	material/intermediate/reagent - Tightening of specification limits 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				
R/0012	Renewal of the marketing authorisation.	18/05/2017	13/07/2017	SmPC, Annex II, Labelling and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Memantine Merz in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IG/0768/G	This was an application for a group of variations. 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 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)	06/03/2017	n/a		
IG/0767	A.7 - Administrative change - Deletion of manufacturing sites	06/03/2017	n/a		
N/0011	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	23/01/2017	13/07/2017	PL	

PSUSA/1967/ 201509	Periodic Safety Update EU Single assessment - memantine	14/04/2016	n/a		PRAC Recommendation - maintenance
WS/0804	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	25/02/2016	n/a		
N/0009	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	01/12/2015	13/07/2017	PL	
N/0007	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	29/07/2015	13/07/2017	PL	
WS/0668	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Following new data lock point, interim results of the Prostate Cancer study, 4 finalized studies and reformatting in compliance with the new template, submission of a revised and updated RMP version 7.1 (delete). This RMP update also introduces changes to the required additional Pharmacovigilance activity regarding the identified potential risk of prostate cancer by adjusting the due dates of agreed milestones. The final RMP version is 7.2.	23/04/2015	n/a		

	C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment is required				
PSUSA/1967/ 201409	Periodic Safety Update EU Single assessment - memantine	10/04/2015	n/a		PRAC Recommendation - maintenance
IAIN/0006	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	02/02/2015	n/a		
WS/0562	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 4.6 of the SmPC for Axura and Memantine Merz with information currently included in section 5.3 referring to the absence of adverse effects noted on non-clinical male and female fertility studies, as per the QRD template. In addition, all the annexes have been brought in line with the QRD template version 9 and linguistic amendments have been introduced in some translations, including a correction of the list of excipients for Iron oxide in the German version. The Croatian local representative has also been included in the package	25/04/2014	13/05/2015	SmPC, Annex II, Labelling and PL	

	leaflet. C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation				
PSUSA/1967/ 201309	Periodic Safety Update EU Single assessment - memantine	10/04/2014	n/a		PRAC Recommendation - maintenance
IG/0260	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	25/01/2013	n/a		