



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

OKEDI

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/0017	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	12/08/2024		PL	
IA/0016/G	This was an application for a group of variations. B.II.e.2.c - Change in the specification parameters	24/07/2024	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).



	<p>and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)</p> <p>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</p>				
IA/0015	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	27/02/2024	n/a		
IA/0014/G	<p>This was an application for a group of variations.</p> <p>B.I.c.2.b - Change in the specification parameters and/or limits of the immediate packaging of the AS - Addition of a new specification parameter to the specification with its corresponding test method</p> <p>B.I.c.2.c - Change in the specification parameters and/or limits of the immediate packaging of the AS - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)</p>	11/01/2024	n/a		
IB/0013	B.II.e.7.z. - Change in supplier of packaging components or devices (when mentioned in the dossier) - Other variation	11/12/2023	n/a		
IA/0012	B.II.e.6.b - Change in any part of the (primary) packaging material not in contact with the finished	21/11/2023	n/a		

	product formulation - Change that does not affect the product information				
IA/0011	B.II.e.6.b - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that does not affect the product information	07/11/2023	n/a		
IA/0010/G	This was an application for a group of variations. B.II.e.2.c - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.II.e.2.c - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)	07/11/2023	n/a		
PSUSA/10985 /202302	Periodic Safety Update EU Single assessment - risperidone (centrally authorised products only)	28/09/2023	n/a		PRAC Recommendation - maintenance
IA/0009	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	01/08/2023	n/a		
IB/0007	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	26/05/2023	11/09/2023	SmPC and PL	

	new additional data is required to be submitted by the MAH				
PSUSA/10985 /202208	Periodic Safety Update EU Single assessment - risperidone (centrally authorised products only)	16/03/2023	n/a		PRAC Recommendation - maintenance
IB/0006	B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF	05/12/2022	n/a		
IA/0004/G	<p>This was an application for a group of variations.</p> <p>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</p> <p>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</p> <p>B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure</p> <p>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</p> <p>B.II.c.2.a - Change in test procedure for an excipient - Minor changes to an approved test procedure</p> <p>B.III.1.a.2 - Submission of a new/updated or</p>	21/10/2022	n/a		

	deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure				
IB/0003/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.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	23/07/2022	11/09/2023	SmPC, Labelling and PL	
IB/0002	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	17/05/2022	n/a		
IAIN/0001	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	06/04/2022	n/a		