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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/0022	Transfer of Marketing Authorisation	05/07/2024	22/07/2024	SmPC, Labelling and PL	
IA/0023	B.II.e.2.a - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Tightening of specification limits	27/06/2024	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).

IAIN/0021/G	This was an application for a group of variations. B.II.e.2.z - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other variation 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.c.1.a - Change in the specification parameters and/or limits of an excipient - Tightening of specification limits 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	03/06/2024	22/07/2024	Annex II and PL	
IA/0019/G	This was an application for a group of variations. B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation	27/03/2024	n/a		
PSUSA/10924 /202307	Periodic Safety Update EU Single assessment - remimazolam	08/02/2024	n/a		PRAC Recommendation - maintenance

IB/0018	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	08/11/2023	n/a		
IB/0016/G	This was an application for a group of variations. B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	01/09/2023	n/a		
PSUSA/10924 /202301	Periodic Safety Update EU Single assessment - remimazolam	31/08/2023	n/a		PRAC Recommendation - maintenance
IB/0014/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.e - Stability of FP - Change to an approved stability protocol B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	15/06/2023	25/01/2024	SmPC	

IB/0015/G	This was an application for a group of variations. B.II.f.z - Stability of FP - Other variation B.II.f.1.e - Stability of FP - Change to an approved stability protocol	31/05/2023	n/a		
IAIN/0013/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.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	17/04/2023	25/01/2024	Annex II and PL	
IB/0011	B.II.f.z - Stability of FP - Other variation	12/04/2023	n/a		
X/0002	Annex I_2.(c) Change or addition of a new strength/potency Annex I_2.(d) Change or addition of a new pharmaceutical form	26/01/2023	31/03/2023	SmPC, Labelling and PL	
IAIN/0010	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	14/02/2023	n/a		
IAIN/0009	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	14/02/2023	25/01/2024	Annex II and PL	

	responsible for importation and/or batch release - Not including batch control/testing				
PSUSA/10924 /202207	Periodic Safety Update EU Single assessment - remimazolam	09/02/2023	n/a		PRAC Recommendation - maintenance
IB/0008/G	This was an application for a group of variations. B.I.d.1.b.3 - Stability of AS - Change in the storage conditions - Change in storage conditions of the AS B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation 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.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.d.1.z - Stability of AS - Change in the re-test period/storage period or storage conditions - Other variation B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - 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	10/01/2023	n/a		
PSUSA/10924 /202201	Periodic Safety Update EU Single assessment - remimazolam	15/09/2022	18/11/2022	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for

					PSUSA/10924/202201.
T/0006	Transfer of Marketing Authorisation	21/09/2022	07/10/2022	SmPC, Labelling and PL	
IA/0005/G	This was an application for a group of variations. B.II.c.2.a - Change in test procedure for an excipient - 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	06/07/2022	n/a		
IA/0004/G	This was an application for a group of variations. B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	24/06/2022	n/a		
PSUSA/10924 /202107	Periodic Safety Update EU Single assessment - remimazolam	24/02/2022	25/04/2022	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10924/202107.