Zubsolv

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/0026	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	20/11/2024	n/a		
PSUSA/2113/ 202309	Periodic Safety Update EU Single assessment - buprenorphine / naloxone	30/05/2024	26/07/2024	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for

[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).

					PSUSA/2113/202309.
IA/0024	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	18/10/2023	n/a		
IAIN/0023	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	05/10/2023	26/07/2024	Annex II and PL	
IB/0021	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	04/09/2023	26/07/2024	SmPC and PL	
IA/0022	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	27/06/2023	n/a		
IA/0020	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	24/04/2023	n/a		
R/0019	Renewal of the marketing authorisation.	19/05/2022	27/07/2022	SmPC, Annex II, Labelling and PL	

IB/0018/G	This was an application for a group of variations. B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation B.II.b.5.c - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test	28/01/2022	n/a		
IAIN/0017/G	This was an application for a group of variations. 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 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)	18/01/2022	n/a		
II/0015	B.II.d.1.f - Change in the specification parameters and/or limits of the finished product - Deletion of a specification parameter which may have a significant effect on the overall quality of the finished product	02/09/2021	n/a		
IAIN/0016	To update section 4.4 of the SmPC and section 2 of the PL to include sleep-related breathing disorders. C.I.3.a - 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	07/06/2021	27/07/2022	SmPC and PL	

	assessment done under A 45/46 - Implementation of wording agreed by the competent authority				
T/0014	Transfer of Marketing Authorisation	04/03/2021	22/03/2021	SmPC, Labelling and PL	
IB/0013	B.II.c.1.z - Change in the specification parameters and/or limits of an excipient - Other variation	22/12/2020	n/a		
IB/0012	B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	22/12/2020	n/a		
IB/0011	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)	22/12/2020	22/03/2021	SmPC	
IA/0010/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 specification limits 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 A.7 - Administrative change - Deletion of manufacturing sites	04/12/2020	n/a		
IAIN/0009	C.I.z - Changes (Safety/Efficacy) of Human and	17/09/2020	22/03/2021	SmPC and PL	

	Veterinary Medicinal Products - Other variation				
PSUSA/2113/ 201909	Periodic Safety Update EU Single assessment - buprenorphine / naloxone	14/05/2020	n/a		PRAC Recommendation - maintenance
IB/0007	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	19/02/2020	n/a		
IAIN/0006	B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site	25/07/2019	n/a		
IAIN/0005/G	This was an application for a group of variations. B.I.a.3.b - Change in batch size (including batch size ranges) of AS or intermediate - Downscaling down to 10-fold 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 B.II.c.1.c - Change in the specification parameters and/or limits of an excipient - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)	31/05/2019	n/a		

T/0004	Transfer of Marketing Authorisation	15/03/2019	17/04/2019	SmPC, Labelling and PL	
T/0003	Transfer of Marketing Authorisation	12/11/2018	17/12/2018	SmPC, Labelling and PL	
IB/0002/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.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation B.II.e.4.a - Change in shape or dimensions of the container or closure (immediate packaging) - Non-sterile medicinal products	02/05/2018	n/a		
IB/0001/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.1 - Change in pack size of the finished	02/02/2018	17/12/2018	SmPC, Labelling and PL	

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