Buvidal

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
PSUSA/459/202309	Periodic Safety Update EU Single assessment - buprenorphine (all formulations except implants)	30/05/2024	24/07/2024	SmPC, Labelling and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/459/202309.
II/0025	B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	20/06/2024	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).

IB/0028	B.II.c.2.d - Change in test procedure for an excipient - Other changes to a test procedure (including replacement or addition)	19/06/2024	n/a		
IB/0027	B.II.b.5.f - Change to in-process tests or limits applied during the manufacture of the finished product - Addition or replacement of an in-process test as a result of a safety or quality issue	23/05/2024	n/a		
IB/0026/G	This was an application for a group of variations. B.II.c.1.a - Change in the specification parameters and/or limits of an excipient - Tightening of specification limits B.II.c.1.a - Change in the specification parameters and/or limits of an excipient - Tightening of specification limits B.II.c.1.z - Change in the specification parameters and/or limits of an excipient - Other variation	24/04/2024	n/a		
IB/0022	B.II.e.2.z - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other variation	25/09/2023	n/a		
IA/0023	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	18/09/2023	n/a		
R/0021	Renewal of the marketing authorisation.	25/05/2023	26/07/2023	SmPC and PL	

IA/0020/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.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier	09/11/2022	n/a		
IB/0019/G	This was an application for a group of variations. B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size B.II.b.5.a - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits	05/10/2022	n/a		
IB/0018/G	This was an application for a group of variations. B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process 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 B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.b.3.a - Change in the manufacturing process of	04/03/2022	n/a		

	the finished or intermediate product - Minor change in the manufacturing process				
IB/0016/G	This was an application for a group of variations. B.II.c.2.d - Change in test procedure for an excipient - Other changes to a test procedure (including replacement or addition) B.II.c.1.b - Change in the specification parameters and/or limits of an excipient - Addition of a new specification parameter to the specification with its corresponding test method B.II.c.2.d - Change in test procedure for an excipient - Other changes to a test procedure (including replacement or addition) B.II.c.1.a - Change in the specification parameters and/or limits of an excipient - Tightening of specification limits B.II.c.1.b - Change in the specification parameters and/or limits of an excipient - Addition of a new specification parameter to the specification with its corresponding test method B.II.c.z - Change in control of excipients in the Finished Product - Other variation	05/11/2021	n/a		
II/0015/G	This was an application for a group of variations. B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale	23/09/2021	13/09/2022	SmPC	

	(supported by real time data)				
PSUSA/459/202007	Periodic Safety Update EU Single assessment - buprenorphine (all formulations except implants)	25/03/2021	19/05/2021	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/459/202007.
X/0008/G	This was an application for a group of variations. Annex I_2.(c) Change or addition of a new strength/potency 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)	25/03/2021	19/05/2021	SmPC, Annex II, Labelling and PL	
IAIN/0013/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites 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	27/10/2020	n/a		
IB/0012	B.II.e.2.z - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other variation	26/10/2020	n/a		

IA/0011	B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier	05/10/2020	n/a		
IAIN/0010	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	17/09/2020	19/05/2021	SmPC, Annex II, Labelling and PL	
IB/0009	B.II.g.5.b - Implementation of changes foreseen in an approved change management protocol - Requires further supporting data	08/09/2020	n/a		
II/0007/G	This was an application for a group of variations. B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range B.II.f.1.z - Stability of FP - Change in the shelf-life or storage conditions of the finished product - Other variation	18/06/2020	19/05/2021	SmPC	
IB/0006	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	04/03/2020	n/a		
II/0005	B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	13/02/2020	n/a		
IB/0004	B.II.f.1.z - Stability of FP - Change in the shelf-life or storage conditions of the finished product - Other variation	13/12/2019	12/06/2020	SmPC	

IA/0003/G	This was an application for a group of variations. B.II.d.2.b - Change in test procedure for the finished product - Deletion of a test procedure if an alternative method is already authorised 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	29/11/2019	n/a		
II/0002	B.II.g.2 - Introduction of a post approval change management protocol related to the finished product	12/09/2019	n/a		
IB/0001	B.II.f.1.z - Stability of FP - Change in the shelf-life or storage conditions of the finished product - Other variation	21/06/2019	12/06/2020	SmPC	