Omidria

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/10419 /202401	Periodic Safety Update EU Single assessment - phenylephrine / ketorolac	03/10/2024	n/a		PRAC Recommendation - maintenance
IB/0027	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	22/05/2024	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/0028/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites 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	12/04/2024	29/05/2024	SmPC, Annex II and PL	
IAIN/0026	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	27/11/2023	n/a		
IAIN/0025	A.1 - Administrative change - Change in the name and/or address of the MAH	24/11/2023	29/05/2024	SmPC, Labelling and PL	
IB/0024	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)	23/06/2023	29/05/2024	SmPC	
IA/0023/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites	01/06/2023	n/a		
T/0022	Transfer of Marketing Authorisation	03/02/2023	06/03/2023	SmPC, Labelling and PL	

PSUSA/10419 /202101	Periodic Safety Update EU Single assessment - phenylephrine / ketorolac	02/09/2021	n/a		PRAC Recommendation - maintenance
IA/0021	B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place	23/08/2021	n/a		
IB/0020/G	This was an application for a group of variations. B.III.1.a.5 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate of a non-sterile AS that is to be used in a sterile medicinal product, where water is used in the last steps of the synthesis and the material is not claimed to be endotoxin free 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 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 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	25/06/2021	n/a		

IAIN/0018	B.III.1.a.3 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from a new manufacturer (replacement or addition)	18/09/2020	n/a		
PSUSA/10419 /202001	Periodic Safety Update EU Single assessment - phenylephrine / ketorolac	03/09/2020	n/a		PRAC Recommendation - maintenance
R/0015	Renewal of the marketing authorisation.	28/05/2020	23/07/2020	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 Omidria in the approved indication remains favourable, but recommended that one additional five-year renewal be required based on the following pharmacovigilance grounds: Omidria was has not yet been sold in the EU, no post-marketing data from EU is available and therefore a second renewal is requested.
IB/0016	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)	17/02/2020	23/07/2020	SmPC	
IA/0014	B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place	11/12/2019	n/a		
IA/0013/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	11/12/2019	n/a		

	or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient A.7 - Administrative change - Deletion of manufacturing sites				
IAIN/0012/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	03/12/2019	23/07/2020	Annex II and PL	
PSUSA/10419 /201901	Periodic Safety Update EU Single assessment - phenylephrine / ketorolac	05/09/2019	n/a		PRAC Recommendation - maintenance
T/0010	Transfer of Marketing Authorisation	01/03/2019	25/03/2019	SmPC, Labelling and PL	
II/0008/G	This was an application for a group of variations. 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) B.II.b.1.f - Replacement or addition of a manufacturing site for part or all of the	07/03/2019	n/a		

	manufacturing process of the FP - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products B.II.e.4.c - Change in shape or dimensions of the container or closure (immediate packaging) - 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 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.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				
PSUSA/10419 /201807	Periodic Safety Update EU Single assessment - phenylephrine / ketorolac	14/02/2019	n/a		PRAC Recommendation - maintenance
PSUSA/10419 /201801	Periodic Safety Update EU Single assessment - phenylephrine / ketorolac	06/09/2018	n/a		PRAC Recommendation - maintenance
PSUSA/10419 /201707	Periodic Safety Update EU Single assessment - phenylephrine / ketorolac	08/02/2018	n/a		PRAC Recommendation - maintenance

IB/0006	B.II.f.1.z - Stability of FP - Change in the shelf-life or storage conditions of the finished product - Other variation	31/01/2018	07/01/2019	SmPC	
PSUSA/10419 /201701	Periodic Safety Update EU Single assessment - phenylephrine / ketorolac	01/09/2017	n/a		PRAC Recommendation - maintenance
IB/0003	B.II.f.1.z - Stability of FP - Change in the shelf-life or storage conditions of the finished product - Other variation	09/02/2017	18/01/2018	SmPC	
PSUSA/10419 /201607	Periodic Safety Update EU Single assessment - phenylephrine / ketorolac	09/02/2017	n/a		PRAC Recommendation - maintenance
PSUSA/10419 /201601	Periodic Safety Update EU Single assessment - phenylephrine / ketorolac	02/09/2016	n/a		PRAC Recommendation - maintenance