Ogluo

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
IAIN/0014	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	04/10/2024		Annex II and PL	

[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/0013/G	This was an application for a group of variations. B.I.z - Quality change - Active substance - Other variation B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate 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.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	26/08/2024	n/a		
PSUSA/10826 /202307	Periodic Safety Update EU Single assessment - glucagon (for centrally authorised product only)	08/02/2024	n/a		PRAC Recommendation - maintenance
PSUSA/10826 /202301	Periodic Safety Update EU Single assessment - glucagon (for centrally authorised product only)	31/08/2023	n/a		PRAC Recommendation - maintenance
II/0011	B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	20/07/2023	n/a		
PSUSA/10826 /202207	Periodic Safety Update EU Single assessment - glucagon (for centrally authorised product only)	09/02/2023	n/a		PRAC Recommendation - maintenance

IB/0009	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)	01/02/2023	26/07/2023	SmPC	
IAIN/0007	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	07/10/2022	26/07/2023	Annex II and PL	
II/0005/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.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits 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)	15/09/2022	26/07/2023	SmPC	
PSUSA/10826 /202201	Periodic Safety Update EU Single assessment - glucagon (for centrally authorised product only)	01/09/2022	n/a		PRAC Recommendation - maintenance
IAIN/0006/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 A.1 - Administrative change - Change in the name and/or address of the MAH	11/07/2022	26/07/2023	SmPC, Labelling and PL	

PSUSA/10826 /202107	Periodic Safety Update EU Single assessment - glucagon (for centrally authorised product only)	10/02/2022	n/a		PRAC Recommendation - maintenance
T/0003	Transfer of Marketing Authorisation	04/11/2021	09/12/2021	Labelling and PL	
IAIN/0001/G	This was an application for a group of variations. 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 B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary 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.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	16/04/2021	n/a		