BAQSIMI

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/0016	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	28/05/2024		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).

T/0014	Transfer of Marketing Authorisation	31/01/2024	16/02/2024	SmPC, Labelling and PL	
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
PSUSA/10826 /202207	Periodic Safety Update EU Single assessment - glucagon (for centrally authorised product only)	09/02/2023	n/a		PRAC Recommendation - maintenance
PSUSA/10826 /202201	Periodic Safety Update EU Single assessment - glucagon (for centrally authorised product only)	01/09/2022	n/a		PRAC Recommendation - maintenance
PSUSA/10826 /202107	Periodic Safety Update EU Single assessment - glucagon (for centrally authorised product only)	10/02/2022	n/a		PRAC Recommendation - maintenance
PSUSA/10826 /202101	Periodic Safety Update EU Single assessment - glucagon (for centrally authorised product only)	02/09/2021	n/a		PRAC Recommendation - maintenance
N/0007	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	18/06/2021	16/02/2024	Labelling	
PSUSA/10826 /202007	Periodic Safety Update EU Single assessment - glucagon (for centrally authorised product only)	11/02/2021	n/a		PRAC Recommendation - maintenance
IA/0006/G	This was an application for a group of variations. B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test	02/02/2021	n/a		

	procedure 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 B.II.d.2.a - Change in test procedure for the finished product - 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 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 B.II.d.2.a - Change in test procedure for the finished product - 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 B.II.c.2.a - Change in test procedure for an excipient - Minor changes to an approved test procedure B.II.c.2.a - Change in test procedure for an excipient - Minor changes to an approved test procedure B.II.c.2.a - Change in test procedure for an excipient - Minor changes to an approved test procedure B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS				

PSUSA/10826 /202001	Periodic Safety Update EU Single assessment - glucagon (for centrally authorised product only)	03/09/2020	n/a		PRAC Recommendation - maintenance
IAIN/0004	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	06/07/2020	n/a		
IA/0002	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	17/04/2020	n/a		