Kirsty

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/0013	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	30/11/2023		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/0012	Transfer of Marketing Authorisation	03/08/2023	30/08/2023	SmPC, Labelling and PL	
IB/0009	B.II.b.4.f - Change in the batch size (including batch size ranges) of the finished product - The scale for a biological/immunological medicinal product is increased/decreased without process change (e.g. duplication of line)	14/07/2023	n/a		
IB/0011	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	07/07/2023	n/a		
N/0010	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	17/05/2023	30/08/2023	PL	
PSUSA/1749/202209	Periodic Safety Update EU Single assessment - insulin aspart	14/04/2023	n/a		PRAC Recommendation - maintenance
PSUSA/1749/202109	Periodic Safety Update EU Single assessment - insulin aspart	05/05/2022	n/a		PRAC Recommendation - maintenance
IA/0007	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	18/03/2022	n/a		

II/0003/G	This was an application for a group of variations. B.II.e.1.a.3 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Sterile medicinal products and biological/immunological medicinal products B.II.e.2.z - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other variation	13/01/2022	n/a		
IA/0006/G	This was an application for a group of variations. B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation	21/12/2021	n/a		
IAIN/0004/G	This was an application for a group of variations. B.I.e.3 - Deletion of an approved change management protocol related to the AS 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	06/12/2021	n/a		
IB/0002	B.IV.1.z - Change of a measuring or administration	12/10/2021	n/a		

	device - Other variation				
IAIN/0001	A.2.a - Administrative change - Change in the (invented) name of the medicinal product for CAPs	16/07/2021	22/07/2022	SmPC, Annex II, Labelling and PL	To change the invented name of the medicinal product from Kixelle to Kirsty.