Enjaymo

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
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	04/04/2024	n/a		
IA/0010	A.6 - Administrative change - Change in ATC Code/ATC Vet Code	04/04/2024		SmPC 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).

IA/0009/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites	21/03/2024	n/a		
PSUSA/11023 /202308	Periodic Safety Update EU Single assessment - sutimlimab	07/03/2024	n/a		PRAC Recommendation - maintenance
IB/0008	B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	30/01/2024	n/a		
IB/0007	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	27/11/2023	n/a		
PSUSA/11023 /202302	Periodic Safety Update EU Single assessment - sutimlimab	31/08/2023	n/a		PRAC Recommendation - maintenance
N/0005	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	25/08/2023	21/03/2024	PL	
IA/0004	B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits	02/06/2023	n/a		
IAIN/0002	A.1 - Administrative change - Change in the name and/or address of the MAH	13/04/2023	21/03/2024	SmPC, Labelling and PL	

IB/0001/G	This was an application for a group of variations. B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol	30/03/2023	21/03/2024	SmPC	