Kesimpta

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
N/0024	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	10/01/2025	n/a		
II/0022	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	12/12/2024		SmPC, Labelling 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).

IAIN/0026/G	This was an application for a group of variations. 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 A.7 - Administrative change - Deletion of manufacturing sites	03/12/2024		Annex II and PL	
PSUSA/10927 /202309	Periodic Safety Update EU Single assessment - ofatumumab	25/04/2024	20/06/2024	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10927/202309.
IA/0021	A.7 - Administrative change - Deletion of manufacturing sites	18/06/2024	n/a		
N/0019	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	18/03/2024	20/06/2024	PL	
IAIN/0018	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	28/02/2024	n/a		
IB/0017/G	This was an application for a group of variations. B.I.b.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation B.I.b.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other	22/02/2024	n/a		

	variation B.III.2.a.2 - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Excipient/AS starting material B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)				
II/0013/G	This was an application for a group of variations. C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data A.6 - Administrative change - Change in ATC Code/ATC Vet Code	18/01/2024	20/06/2024	SmPC and PL	
IAIN/0016	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	04/01/2024	n/a		
IB/0014	B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation	21/11/2023	n/a		
PSUSA/10927 /202303	Periodic Safety Update EU Single assessment - ofatumumab	26/10/2023	n/a		PRAC Recommendation - maintenance

PSUSA/10927 /202209	Periodic Safety Update EU Single assessment - ofatumumab	14/04/2023	n/a		PRAC Recommendation - maintenance
IB/0010	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	15/03/2023	n/a		
II/0006	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	09/02/2023	22/09/2023	SmPC	
IAIN/0011	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	13/01/2023	22/09/2023	Annex II and PL	
PSUSA/10927 /202203	Periodic Safety Update EU Single assessment - ofatumumab	27/10/2022	n/a		PRAC Recommendation - maintenance
IB/0008	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	21/10/2022	n/a		
II/0007	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	20/10/2022	22/09/2023	SmPC	
PSUSA/10927 /202109	Periodic Safety Update EU Single assessment - ofatumumab	05/05/2022	n/a		PRAC Recommendation - maintenance

IB/0004/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 B.II.f.1.d - Stability of FP - Change in storage conditions of the finished product or the diluted/reconstituted product	22/03/2022	24/05/2022	SmPC and PL	
IA/0002	B.I.c.2.c - Change in the specification parameters and/or limits of the immediate packaging of the AS - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)	02/11/2021	n/a		
IA/0001	A.6 - Administrative change - Change in ATC Code/ATC Vet Code	12/05/2021	24/05/2022	SmPC	