Uplizna

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
IB/0009	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	08/02/2024		SmPC	

[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/0008	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	08/02/2024	n/a		
PSUSA/10996 /202306	Periodic Safety Update EU Single assessment - inebilizumab	11/01/2024	n/a		PRAC Recommendation - maintenance
IA/0006	B.II.f.1.e - Stability of FP - Change to an approved stability protocol	02/08/2023	n/a		
IB/0005	B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data	07/07/2023	n/a		
PSUSA/10996 /202212	Periodic Safety Update EU Single assessment - inebilizumab	06/07/2023	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	19/04/2023		Annex II and PL	
PSUSA/10996 /202206	Periodic Safety Update EU Single assessment - inebilizumab	12/01/2023	n/a		PRAC Recommendation - maintenance
T/0001	Transfer of Marketing Authorisation	23/05/2022	29/06/2022	SmPC, Labelling and PL	