EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

NYXTHRACIS

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/0009	A.2.a - Administrative change - Change in the (invented) name of the medicinal product for CAPs	14/12/2022		SmPC, Labelling and PL	
PSUSA/10885 /202203	Periodic Safety Update EU Single assessment - obiltoxaximab	27/10/2022	n/a		PRAC Recommendation - maintenance

[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).

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IAIN/0007/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 procedure 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	27/09/2022	21/11/2022	Annex II and PL	
PSUSA/10885 /202109	Periodic Safety Update EU Single assessment - obiltoxaximab	07/04/2022	n/a		PRAC Recommendation - maintenance
S/0004	Annual re-assessment.	24/02/2022	n/a		
IB/0003/G	This was an application for a group of variations. 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 B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS - replacement or addition of a site where batch control/testing takes place B.I.b.2.b - Change in test procedure for AS or starting material/reagent/intermediate - Deletion of a test procedure for the AS or a starting	13/12/2021	21/11/2022	SmPC	SmPC has been updated to reflect extension of shelf life from 6 years to 7 years.

	material/reagent/intermediate, if an alternative test procedure is already authorised 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.g.5.b - Implementation of changes foreseen in an approved change management protocol - Requires further supporting data				
IAIN/0002	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	04/11/2021	21/11/2022	Annex II and PL	
PSUSA/10885 /202103	Periodic Safety Update EU Single assessment - obiltoxaximab	30/09/2021	n/a		PRAC Recommendation - maintenance