NeoRecormon

Procedural steps taken and scientific information after the authorisation*

*Due to the Agency`s update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, please also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
Variation type IB /	C.I HUMAN AND VETERINARY MEDICINAL	01/05/2025		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).

EMA/VR/0000262770	PRODUCTS - C.I.z Change(s) in the SmPC, labelling or package leaflet of human medicinal products in order to adapt to a recommendation of a competent authority , e.g. a Core SmPC, following the assessment of an Urgent Safety Restriction etc. Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon. - Accepted C.I.z (Type IB) – to update the section 4.4 of the SmPC and section 2 of the Package Leaflet as per EMA's new polysorbate excipient labelling requirement. In addition, QRD version 10.4 update was applied in section 6 of the Package Leaflet where the contact details of the following countries were also updated: Luxembourg, Malta, Bulgaria, Cyprus, Greece. UK (NI) was removed accordingly. Labelling was updated with minor editorial corrections. Furthermore, MAH applied some editorial corrections in the following languages: IT, MT, DA, NL, LV, BG, HR, CS, ET, DE, HU and SL. Finally, the MAH has also taken the opportunity to replace the word EXP for expiry date and Lot for batch number instead of local language variants in Annex IIIA and Annex IIIB, in line with the global standardized preprints initiative in all the languages (except Bulgaria, Germany, Italy			Labelling and PL	

	and Poland).				