IMCIVREE

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, you may need to 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
Renewal - 5 year /		26/02/2026	23/04/2026	SmPC, Annex	

[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/R/0000302063				II and PL	
Variation type II / EMA/VR/0000257063	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted Update of section 4.8 of the SmPC in order to update information on immunogenicity and anti-drug antibodies (ADA) as a follow-up to the CHMP Assessment Report for procedure EMEA/H/C/005089/REC/006-007 and based on the updated Integrated Summary of Immunogenicity (ISI).	11/12/2025		SmPC	
Variation type II / EMA/VR/0000280831	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.13 Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority - Accepted Submission of the final report from study RM-493-022. This is a Phase 3 long-term extension trial of setmelanotide (RM-493) for patients who have completed a trial of setmelanotide for the treatment of obesity associated with genetic defects upstream of the melanocortin 4 (MC4) receptor in the leptin-melanocortin pathway.	13/11/2025			

Variation type IA / EMA/VR/0000307155	A.5 Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - A.5.b The activities for which the manufacturer/importer is responsible do not include batch release - Accepted	20/10/2025			
PSUR / EMA/PSUR/0000257865					