IMCIVREE

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
II/0034	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	03/04/2025		SmPC and PL	
PSUSA/10941 /202405	Periodic Safety Update EU Single assessment - setmelanotide	16/01/2025	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).

IB/0033	B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate	10/12/2024	n/a		
IB/0032	B.I.b.z - Change in control of the AS - Other variation	10/12/2024	n/a		
IB/0029	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	10/09/2024	n/a		
IB/0028	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	26/08/2024	n/a		
IB/0027	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	29/07/2024	n/a		
II/0018	C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	27/06/2024	26/07/2024	SmPC and PL	
PSUSA/10941 /202311	Periodic Safety Update EU Single assessment - setmelanotide	13/06/2024	n/a		PRAC Recommendation - maintenance
IB/0022	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	14/05/2024	26/07/2024	SmPC, Labelling and PL	

IA/0025	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	29/04/2024	n/a		
IB/0024	B.I.a.3.z - Change in batch size (including batch size ranges) of AS or intermediate - Other variation	29/04/2024	n/a		
IA/0023	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	15/03/2024	n/a		
IAIN/0020/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites 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	04/03/2024	26/07/2024	Annex II and PL	
IA/0021	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	29/02/2024	n/a		

PSUSA/10941 /202305	Periodic Safety Update EU Single assessment - setmelanotide	11/01/2024	n/a		PRAC Recommendation - maintenance
IB/0017	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	05/12/2023	n/a		
II/0015	Submission of the final report from study RM-493-014. This is a phase 2 treatment trial of setmelanotide in patients with rare genetic disorders of obesity. The requested variation proposed no amendments to the Product Information. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	26/10/2023	n/a		
PSUSA/10941 /202211	Periodic Safety Update EU Single assessment - setmelanotide	08/06/2023	n/a		PRAC Recommendation - maintenance
IB/0013	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	18/03/2023	22/09/2023	SmPC	Product information section 6.3 is updated to reflect the shelf-life extension of the finished product Imcivree 10 mg/ml solution for injection (EU/1/21/1564/0001-0002) as packaged for sale from 2 years to 3 years.
PSUSA/10941 /202205	Periodic Safety Update EU Single assessment - setmelanotide	12/01/2023	n/a		PRAC Recommendation - maintenance
IB/0012	B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside	31/10/2022	22/09/2023	SmPC, Labelling and PL	

	the range of the currently approved pack sizes				
II/0002/G	This was an application for a group of variations. To add the new therapeutic indication for the treatment of obesity and the control of hunger associated with genetically confirmed Bardet-Biedl syndrome (BBS). As a consequence, sections 4.1, 4.2, 4.8, 5.1, 5.2 and 5.3 of the SmPC and sections 1, 3 and 4 of the PL are updated accordingly. The updated RMP version 1.0 has also been submitted. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	21/07/2022	02/09/2022	SmPC and PL	Please refer to Scientific Discussion 'Imcivree-H-C-005089-II-02-G'
IB/0010	B.I.z - Quality change - Active substance - Other variation	28/07/2022	n/a		
IB/0008	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	30/06/2022	n/a		
IA/0009	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	15/06/2022	n/a		

PSUSA/10941 /202111	Periodic Safety Update EU Single assessment - setmelanotide	10/06/2022	n/a		PRAC Recommendation - maintenance
II/0003	Update of sections 4.2, and 5.2 of the SmPC in order to change posology recommendations in patients with renal impairment, based on final results from study RM-493-029, a Phase I, open-label, single-dose study to evaluate the pharmacokinetics of setmelanotide in subjects with varying degrees of renal impairment; with secondary objectives to evaluate the safety and tolerability of a single dose of setmelanotide administered subcutaneously in subjects with varying degrees of renal impairment. The Package Leaflet is updated accordingly. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	22/04/2022	02/06/2022	SmPC and PL	Based on the submitted data and clinical considerations, new dosing recommendations (including information on dose titration with lowest starting dose and maximum dose) for patients with severe renal impairment have been added. No dosage adjustment is necessary for patients with mild or moderate renal impairment.
II/0006	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	12/05/2022	n/a		
II/0005/G	This was an application for a group of variations. B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.I.b.1.f - Change in the specification parameters and/or limits of an AS, starting	12/05/2022	n/a		

	material/intermediate/reagent - Change outside the approved specifications limits range for the AS				
IAIN/0007	A.1 - Administrative change - Change in the name and/or address of the MAH	30/03/2022	02/06/2022	SmPC, Labelling and PL	
T/0001	Transfer of Marketing Authorisation	24/09/2021	22/10/2021	SmPC, Labelling and PL	