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
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		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	Periodic Safety Update EU Single assessment -	12/01/2023	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).

/202205	setmelanotide				
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 the range of the currently approved pack sizes	31/10/2022		SmPC, Labelling and PL	
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.	12/05/2022	n/a		

	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 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	