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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/0011/G	This was an application for a group of variations. B.I.a.4.c - Change to in-process tests or limits applied during the manufacture of the AS - Deletion of a non-significant in-process test B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	23/02/2023		SmPC, Annex II, Labelling and PL	

[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).

	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
IB/0013/G	This was an application for a group of variations. B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	07/02/2023	n/a		
IB/0012/G	This was an application for a group of variations. B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	12/01/2023	n/a		
PSUSA/10899 /202206	Periodic Safety Update EU Single assessment - atidarsagene autotemcel	12/01/2023	n/a		PRAC Recommendation - maintenance
IB/0009	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	26/08/2022		Annex II	

PSUSA/10899 /202112	Periodic Safety Update EU Single assessment - atidarsagene autotemcel	07/07/2022	n/a		PRAC Recommendation - maintenance
IAIN/0008/G	This was an application for a group of variations. A.1 - Administrative change - Change in the name and/or address of the MAH A.6 - Administrative change - Change in ATC Code/ATC Vet Code	23/06/2022		SmPC, Labelling and PL	
PSUSA/10899 /202106	Periodic Safety Update EU Single assessment - atidarsagene autotemcel	13/01/2022	n/a		PRAC Recommendation - maintenance
II/0004	B.I.b.1.g - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Widening of the approved specs for starting mat./intermediates, which may have a significant effect on the quality of the AS and/or the FP	16/12/2021	n/a		
IB/0006	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	08/11/2021	27/01/2022	Annex II	
IB/0003	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	07/06/2021	n/a		
IAIN/0002	A.3 - Administrative change - Change in name of the AS or of an excipient	23/04/2021	27/01/2022	SmPC, Labelling and PL	

IAIN/0001/G	This was an application for a group of variations. A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release 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	13/01/2021	27/01/2022	SmPC, Annex II, Labelling and PL	