SomaKit TOC

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
N/0029	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	19/03/2024		PL	
N/0027	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	28/09/2023	06/02/2024	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).

PSUSA/10552 /202212	Periodic Safety Update EU Single assessment - edotreotide	06/07/2023	n/a		PRAC Recommendation - maintenance
IB/0024	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	21/02/2023	n/a		
IAIN/0025	A.1 - Administrative change - Change in the name and/or address of the MAH	13/02/2023	06/02/2024	SmPC, Labelling and PL	
PSUSA/10552 /202112	Periodic Safety Update EU Single assessment - edotreotide	21/07/2022	19/09/2022	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10552/202112.
N/0023	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	04/05/2022	19/09/2022	PL	
R/0019	Renewal of the marketing authorisation.	16/09/2021	12/11/2021	SmPC, Annex II, Labelling and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of SomaKit TOC in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
PSUSA/10552 /202012	Periodic Safety Update EU Single assessment - edotreotide	22/07/2021	16/09/2021	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10552/202012.
IB/0020	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	09/06/2021	16/09/2021	SmPC	
IB/0021	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale	06/05/2021	16/09/2021	SmPC	

	(supported by real time data)				
IAIN/0017/G	This was an application for a group of variations. 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 A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release B.II.e.6.b - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that does not affect the product information	10/12/2020	16/09/2021	Annex II and PL	
II/0015	Update of sections 4.4, 4.5 and 4.6 of the SmPC in order to amend an existing warning extending the period during which close contact with infants and pregnant women should be restricted, add information on interactions with glucocorticosteroids and extend the period during which breastfeeding should be interrupted. The Package Leaflet is updated accordingly. Additionally, the MAH took the opportunity to update the details of local representatives. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	03/09/2020	16/09/2021	SmPC and PL	Close contact with infants and pregnant women should be restricted during the first 12 hours after administration. Breastfeeding should be interrupted for 12 hours and the expressed feeds discarded. Repeated administration of high-doses of glucocorticosteroids prior to gallium (68Ga) edotreotide administration may cause insufficient SSTR2 expression for adequate visualization of somatostatin receptor-positive NETs.

IA/0016/G	This was an application for a group of variations. B.II.b.5.b - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and limits B.II.e.6.b - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that does not affect the product information	28/08/2020	n/a		
PSUSA/10552 /201912	Periodic Safety Update EU Single assessment - edotreotide	09/07/2020	n/a		PRAC Recommendation - maintenance
PSUSA/10552 /201906	Periodic Safety Update EU Single assessment - edotreotide	30/01/2020	27/03/2020	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10552/201906.
II/0011	B.II.e.1.a.3 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Sterile medicinal products and biological/immunological medicinal products	12/12/2019	27/03/2020	SmPC	
IA/0013	B.II.e.6.b - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that does not affect the product information	15/10/2019	n/a		
PSUSA/10552 /201812	Periodic Safety Update EU Single assessment - edotreotide	11/07/2019	n/a		PRAC Recommendation - maintenance

IB/0008/G	This was an application for a group of variations. B.I.a.1.a - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer 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 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.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method 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	21/01/2019	n/a		
PSUSA/10552 /201806	Periodic Safety Update EU Single assessment - edotreotide	17/01/2019	n/a		PRAC Recommendation - maintenance
N/0009	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	17/12/2018	01/10/2019	PL	

IB/0006	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	01/10/2018	01/10/2019	SmPC	
PSUSA/10552 /201712	Periodic Safety Update EU Single assessment - edotreotide	12/07/2018	n/a		PRAC Recommendation - maintenance
PSUSA/10552 /201706	Periodic Safety Update EU Single assessment - edotreotide	11/01/2018	n/a		PRAC Recommendation - maintenance
IB/0003	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)	12/06/2017	07/06/2018	SmPC	
N/0002	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	08/05/2017	07/06/2018	PL	
N/0001	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	05/04/2017	07/06/2018	PL	