



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Skytrofa

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/0036	Update of section 5.1 of the SmPC in order to update efficacy and safety information following the request by CHMP in the outcome for procedure EMEA/H/C/005367/P46/003.1 based on final results from the paediatric study CT-301EXT (enlIGHten). In addition, the MAH took the opportunity to bring the	22/05/2025		SmPC	This open-label study has confirmed the efficacy of the medicinal product for patients on long-term treatment with the medicinal product. For more information, please refer to the Summary of Product Characteristics.

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).



	PI in line with the latest QRD template version 10.4. C.I.3.b - Change(s) in the SPC, Labelling or PL intended to implement the outcome of a procedure concerning PSUR or PASS or the outcome of the assessment done under A 45/46 - Change(s) with new additional data submitted by the MAH				
PSUSA/10969 /202408	Periodic Safety Update EU Single assessment - lonapegsomatropin	13/03/2025	n/a		PRAC Recommendation - maintenance
IB/0035	B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol	06/02/2025		SmPC and PL	
PSUSA/10969 /202402	Periodic Safety Update EU Single assessment - lonapegsomatropin	17/10/2024	12/12/2024	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10969/202402.
IB/0034	B.I.d.1.z - Stability of AS - Change in the re-test period/storage period or storage conditions - Other variation	06/12/2024	n/a		
IB/0032/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.d.z - Stability of AS - Other variation	11/11/2024	n/a		

IB/0031	B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	11/07/2024	n/a		
IB/0029/G	This was an application for a group of variations. B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size B.I.d.1.z - Stability of AS - Change in the re-test period/storage period or storage conditions - Other variation	28/06/2024	n/a		
IB/0028	B.I.d.1.z - Stability of AS - Change in the re-test period/storage period or storage conditions - Other variation	25/06/2024	n/a		
II/0025/G	This was an application for a group of variations. B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.b.4.c - Change in the batch size (including batch size ranges) of the finished product - The change requires assessment of the comparability of a biological/immunological medicinal product or a new bioequivalence study	16/05/2024	n/a		
IA/0027	B.I.a.4.a - Change to in-process tests or limits applied during the manufacture of the AS - Tightening of in-process limits	24/04/2024	n/a		

PSUSA/10969 /202308	Periodic Safety Update EU Single assessment - lonapegsomatropin	11/04/2024	n/a		PRAC Recommendation - maintenance
II/0024	Type II (B.II.d.1.e) - To change the osmolality specification limits from "260 – 331 mOsmol/kg" to "242-308 mOsmol/kg" in the specifications of the finished product. B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	07/03/2024	n/a		
IB/0026	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	12/01/2024	n/a		
II/0019/G	This was an application for a group of variations. B.I.a.2.b - Changes in the manufacturing process of the AS - Substantial change to the manufacturing process of the AS which may have a significant impact on the quality, safety or efficacy of the medicinal product B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting	11/01/2024	22/02/2024	Annex II	

	material [-] used in the manufacture of a biological/immunological product				
IB/0022	B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol	31/10/2023	22/02/2024	SmPC	
IB/0021	B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size	18/10/2023	n/a		
PSUSA/10969 /202302	Periodic Safety Update EU Single assessment - lonapegsomatropin	28/09/2023	n/a		PRAC Recommendation - maintenance
IA/0020	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	19/09/2023	n/a		
IA/0017	A.7 - Administrative change - Deletion of manufacturing sites	12/05/2023	n/a		
IB/0016	B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	28/04/2023	n/a		
IB/0014	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	11/04/2023	n/a		
PSUSA/10969 /202208	Periodic Safety Update EU Single assessment - lonapegsomatropin	16/03/2023	n/a		PRAC Recommendation - maintenance

IB/0012	B.I.c.1.c - Change in immediate packaging of the AS - Liquid ASs (non sterile)	20/02/2023	n/a		
IAIN/0015/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	17/02/2023	n/a		
IAIN/0013	B.IV.1.a.1 - Change of a measuring or administration device - Addition or replacement of a device which is not an integrated part of the primary packaging - Device with CE marking	25/01/2023	22/02/2024	SmPC, Labelling and PL	
IB/0011	B.I.d.1.z - Stability of AS - Change in the re-test period/storage period or storage conditions - Other variation	20/12/2022	n/a		
PSUSA/10969 /202202	Periodic Safety Update EU Single assessment - lonapegsomatropin	13/10/2022	20/12/2022	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s) for PSUSA/00010969/202202
IB/0009	B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size	24/10/2022	n/a		
IB/0007	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other	05/10/2022	n/a		

	variation				
IA/0008	A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release)	14/09/2022	n/a		
IAIN/0006/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.2.a - Administrative change - Change in the (invented) name of the medicinal product for CAPs A.6 - Administrative change - Change in ATC Code/ATC Vet Code	24/08/2022	20/12/2022	SmPC, Labelling and PL	
IB/0004	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	22/07/2022	n/a		
IB/0005	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	21/07/2022	n/a		
IB/0003	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	27/06/2022	n/a		

IB/0002	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	07/06/2022	n/a		