

LIVOGLIVA

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
PSUSA/2903/202409	Periodic Safety Update EU Single assessment - teriparatide	08/05/2025	n/a		PRAC Recommendation - maintenance
R/0015	Renewal of the marketing authorisation.	27/02/2025	14/04/2025	SmPC and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of LIVOGLIVA in the approved indication remains favourable

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).



					and therefore recommended the renewal of the marketing authorisation with unlimited validity.
II/0013/G	<p>This was an application for a group of variations.</p> <p>B.I.a.1.j - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Replacement or addition of a site where batch control/testing takes place and any of the test method at the site is a biol/immunol method</p> <p>B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method</p> <p>B.II.b.2.z - Change to importer, batch release arrangements and quality control testing of the FP - Other variation</p> <p>B.II.b.2.z - Change to importer, batch release arrangements and quality control testing of the FP - Other variation</p> <p>B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure</p>	27/02/2025	n/a		
IA/0014/G	<p>This was an application for a group of variations.</p> <p>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</p>	20/09/2024	n/a		

	<p>manufacturer of a novel excipient</p> <p>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</p> <p>A.7 - Administrative change - Deletion of manufacturing sites</p> <p>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)</p> <p>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)</p> <p>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)</p>				
II/0012	B.II.g.2 - Introduction of a post approval change management protocol related to the finished product	05/09/2024	n/a		
IA/0011	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)	27/07/2022	n/a		
PSUSA/2903/202109	Periodic Safety Update EU Single assessment - teriparatide	05/05/2022	n/a	PRAC Recommendation - maintenance	

IB/0009	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	11/04/2022	n/a		
IB/0008/G	<p>This was an application for a group of variations.</p> <p>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</p> <p>B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure</p>	25/02/2022	n/a		
IB/0007	B.I.c.1.a - Change in immediate packaging of the AS - Qualitative and/or quantitative composition	17/02/2022	n/a		
IB/0006	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	10/01/2022	n/a		
IA/0004	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)	13/12/2021	n/a		
IB/0003	B.I.a.1.k - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - New	24/11/2021	n/a		

	storage site of MCB and/or WCB				
IAIN/0002/G	<p>This was an application for a group of variations.</p> <p>B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site</p> <p>B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site</p> <p>B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site</p>	10/12/2020	n/a		
IB/0001	B.II.f.1.a.1 - Stability of FP - Reduction of the shelf life of the finished product - As packaged for sale	03/11/2020	09/12/2021	SmPC	