Lantus

Procedural steps taken and scientific information after the authorisation*

*Due to the Agency`s update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, you may need to also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
Variation type IB /	This was an application for a variation	05/03/2026		SmPC 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).

EMA/VR/0000310964	following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C. Safety, efficacy, pharmacovigilance changes - C.z Other variation - Accepted C.z – to update section 4.9 of the SmPC by removing the route of administration of glucagon in the PIs of insulin-containing medicinal products. The same rationale applies in section Hyperglycaemia and Hypoglycaemia of the Package Leaflet (What should you do if you experience hypoglycaemia). Additionally, the MAH takes the opportunity to reinstate the below texts for Apidra and Lantus ("Other side effects" section), which is the standard template sentence on "Other side effects" in PL, and that were omitted inadvertently in the PL: "Tell your doctor, pharmacist or nurse if you notice any of the following side effects:" Furthermore, the MAH has made some minor editorial corrections and formatting changes in the English SmPC and Package Leaflet of Lantus, Toujeo and Apidra. Finally, the MAH also took the opportunity to update the local representative information in the Package Leaflet as follows: • Apidra: UK-NI (deletion) and Iceland (name change) and Italy (telephone number change). • Lantus:				

	UK-NI (deletion) and Iceland (name change) and Italy (telephone number change). • Toujeo: Italy (telephone number change). • Insuman: Italy (telephone number change: adding the international country code as(+39)).				
Variation type II / EMA/VR/0000273346	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. A. ADMINISTRATIVE CHANGES - A.7 Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* - Accepted B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.d Substantial change to or replacement of a biological/ immunological/ immunochemical test method or a method using a biological reagent for a biological active substance - Accepted	27/11/2025			

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