Abasaglar

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 /	Outcome:	09/07/2026		SmPC,	

[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/0000349546	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.7 Deletion of: - C.7.a) a pharmaceutical form - Accepted C.7.a (Type IB) – To delete the Tempo Pen presentations from the Humalog, Lyumjev, and Abasaglar marketing authorisation (EU/1/96/007/046, 047; EU/1/20/1422/016, 017; EU/1/14/944/014, 015). In addition, the MAH took the opportunity to implement editorial changes to (1) correct the phrasing relating to 'Skin changes at the injection site' in the SL product information for Abasaglar, and (2) update the translation of 'pen' in the EL Annex A for Humalog and Abasaglar to comply with standard terms.			Labelling and PL	
Variation type IA_IN / EMA/VR/0000315488	Outcome: A. ADMINISTRATIVE CHANGES - A.1 Change in the name and/or address of the marketing authorisation holder - Accepted	21/01/2026		SmPC, Labelling and PL	
PSUR / EMA/PSUR/0000288220	EURD: PSUSA/00001751/202504 Active substance: insulin glargine Outcome: Maintenance	27/11/2025			Maintenance