Zessly

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 group of	19/06/2025		SmPC and PL	Update of sections 4.4 and 4.8 of the Summary of

[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/0000271864	variations. B.II.f.1 Change in the shelf-life or storage conditions of the finished product - B.II.f.1.z Other variation - Accepted C.I.2 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - C.I.2.a Implementation of change(s) for which no new additional data is required to be submitted by the MAH - Accepted				Product Characteristics (SmPC) in order to add post-procedural complications (including infectious and non-infections complications) to the list of adverse drug reactions (ADRs) with frequency not known and update treatment recommendations for patients with a planned surgical procedure based on a cumulative review of literature, clinical trial and registry data. The Package Leaflet (PL) is updated accordingly). B.II.f.1.z To including a sentence that describes temperature equilibration of refrigerated infusion bags prior to drug administration in section 6.6 of SmPC and section 6 (information for health care professionals) of the package leaflet. In addition the MAH had taken the opportunity to implement the excipient guidance for polysorbate in the annexes and to update the details of the local representatives in CZ, IT, CY and LU and to align the annexes to the latest QRD version.