Adempas

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
Article 61(3) /		22/05/2026		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/N/0000333716	Outcome: - Notification acc. Article 61(3) - Accepted Update of the package leaflet in several sections to align its text with the approved text in SmPC as well as with revised contact details of local representatives. Additionally, the MAH took the opportunity to introduce minor linguistic amendments to some of the translations.				
Variation type IA / EMA/VR/0000314723	Outcome: B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.a Minor change in the manufacturing process of the active substance - Accepted	28/11/2025			
Variation type IB / EMA/VR/0000304758	Outcome: This was an application for a group of variations. B.II.c.1 Change in the specification parameters and/or limits of an excipient - B.II.c.1.z Other changes - Accepted	03/11/2025			

	B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.e Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for nonsterile medicinal products - Accepted B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.a Replacement or addition of a site where batch control/testing takes place - Accepted B.II.b.4 Change in the batch size (including batch size ranges) of the finished product - B.II.b.4.z Other changes, including change from single batch size to a range of batch sizes - Accepted B.II.c.2 Change in test procedure for an excipient - B.II.c.2.b Deletion of a test procedure if an alternative test procedure is already authorised - Accepted				
Variation type IB / EMA/VR/0000285850	Outcome: B.II.f.1.a Reduction of the shelf life of the finished product - B.II.f.1.a.1 As packaged for sale - Accepted	06/08/2025		SmPC	
