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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	05/05/2026		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/0000325887	variations. Q.II.e.1.a) Change in qualitative and quantitative composition of an approved container - Q.II.e.1.a.1 Solid pharmaceutical forms - Accepted Q.II.e.1.a) Change in qualitative and quantitative composition of an approved container - Q.II.e.1.a.1 Solid pharmaceutical forms - Accepted Q.II.e.6.a) Introduction of a new pack size or change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Q.II.e.6.a.2 Change outside the range of the currently approved pack sizes - Accepted			Labelling and PL	
Variation type IB / EMA/VR/0000322401	B.III.1.a European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - B.III.1.a.3 New certificate from a new manufacturer (replacement or addition) - 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.e Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate - Accepted	27/03/2026			

Variation type IB / EMA/VR/0000324940	This was an application for a group of variations. E. Administrative Changes - E.5 Deletion of manufacturing sites for an active substance, intermediate or finished product, storage of master and/or working cell bank, primary and/or secondary packaging site, manufacturer responsible for batch release, site where quality control takes place, and/or supplier of a packaging component, medical device (part), starting material, reagent and/or excipient (when mentioned in the dossier) - Accepted Q.II.b.2 Change to batch release arrangements and batch control testing of the finished product - Q.II.b.2.a) Addition or replacement of a batch control/testing site applying physicochemical and/or microbiological analytical procedures for the finished product - Accepted Q.II.b.2 Change to batch release arrangements and batch control testing of the finished product - Q.II.b.2.a) Addition or replacement of a batch control/testing site applying physicochemical and/or microbiological analytical procedures for the finished product - Accepted Q.II.b.2 Change to batch release arrangements and batch control testing of the finished product - Q.II.b.2.a) Addition or replacement of a batch control/testing site	04/03/2026			

	applying physicochemical and/or microbiological analytical procedures for the finished product - Accepted Q.II.d.1 Change in the specification attribute and/or acceptance criteria of the finished product - Q.II.d.1.c) Addition of a new specification attribute with its corresponding analytical procedure and acceptance criteria - Accepted Q.III.1.a) European Pharmacopoeial certificate of suitability to the relevant Ph. Eur. Monograph(*) - Q.III.1.a.1 New certificate of suitability (CEP) (including replacement or addition) - Accepted				
PSUR / EMA/PSUR/0000269013					Maintenance