



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Fubelv

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 IA_IN /	Outcome:	11/06/2026		SmPC, Annex	

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/0000351211	This was an application for a group of variations. E.4 Change in the name and/or address of the marketing Term name: E.4 authorisation holder, ASMF holder, storage site of the master and/or working cell bank, manufacturing site for an active substance, intermediate or finished product, 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 - E.4.b) The change in the name and/or address concerns a manufacturer(s) whose activities include batch release of the finished product - Accepted E.4 Change in the name and/or address of the marketing Term name: E.4 authorisation holder, ASMF holder, storage site of the master and/or working cell bank, manufacturing site for an active substance, intermediate or finished product, 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			II, Labelling and PL	
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	dossier - E.4.a) The change in the name and/or address concerns the marketing authorisation holder - Accepted				
Variation type IB / EMA/VR/0000348807	Outcome: Q.I.a.1 Change in the manufacturing site of a starting material/intermediate used in the manufacturing process of the active substance or change in the manufacturing site (including where relevant quality control testing sites) of the active substance - Q.I.a.1.i) Addition or replacement of a batch control/testing site of the active substance or starting material/intermediate used in the manufacturing of a biological active substance, applying a biological/immunological/immunochemical analytical procedure - Accepted	09/06/2026			
Variation type IB / EMA/VR/0000348690	Outcome: This was an application for a group of variations. Q.I.a.2 Change in the manufacturing process of the active substance, intermediate of an active substance or starting materials for biological active substance - Q.I.a.2.a) Minor change in the manufacturing process - Accepted Q.I.a.2 Change in the manufacturing process of the active substance, intermediate of an	09/06/2026			

	active substance or starting materials for biological active substance - Q.I.a.2.a) Minor change in the manufacturing process - Accepted Q.I.a.2 Change in the manufacturing process of the active substance, intermediate of an active substance or starting materials for biological active substance - Q.I.a.2.a) Minor change in the manufacturing process - Accepted Q.I.a.2 Change in the manufacturing process of the active substance, intermediate of an active substance or starting materials for biological active substance - Q.I.a.2.a) Minor change in the manufacturing process - Accepted Q.I.a.2 Change in the manufacturing process of the active substance, intermediate of an active substance or starting materials for biological active substance - Q.I.a.2.a) Minor change in the manufacturing process - Accepted Q.I.a.2 Change in the manufacturing process of the active substance, intermediate of an active substance or starting materials for biological active substance - Q.I.a.2.a) Minor change in the manufacturing process - Accepted Q.I.a.2 Change in the manufacturing process of the active substance, intermediate of an active substance or starting materials for biological active substance - Q.I.a.2.a) Minor change in the manufacturing process - Accepted				
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	change in the manufacturing process - Accepted Q.I.a.2 Change in the manufacturing process of the active substance, intermediate of an active substance or starting materials for biological active substance - Q.I.a.2.a) Minor change in the manufacturing process - Accepted Q.I.a.2 Change in the manufacturing process of the active substance, intermediate of an active substance or starting materials for biological active substance - Q.I.a.2.a) Minor change in the manufacturing process - Accepted Q.I.a.2 Change in the manufacturing process of the active substance, intermediate of an active substance or starting materials for biological active substance - Q.I.a.2.a) Minor change in the manufacturing process - Accepted				
Variation type IB / EMA/VR/0000348250	Outcome: This was an application for a group of variations. Q.II.d.2 Change to analytical procedure for the finished product - Q.II.d.2.d) Other change to an analytical procedure for a finished product (including replacement or addition) - Accepted Q.I.b.2 Change to analytical procedure for	03/06/2026			

	active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Q.I.b.2.e) Minor change to an analytical procedure for starting material/reagent/intermediate - Accepted				
Variation type IA / EMA/VR/0000349086	Outcome: This was an application for a group of variations. Q.II.e.4 Change in the specification attribute and/or acceptance criteria of the immediate packaging of the finished product - Q.II.e.4.b) Addition of a specification attribute to the specification with its corresponding analytical procedure - Accepted Q.II.b.5 Change to in-process control or limits applied during the manufacture of the finished product - Q.II.b.5.a) Minor changes of in-process control limits - Accepted Q.II.e.7 Change in manufacturer, sterilisation process or supplier of packaging components (when mentioned in the dossier) - Q.II.e.7.a) Addition or replacement of a manufacturer or supplier - Refused E. Administrative Changes - E.5 Deletion of manufacturing sites for an active substance, intermediate or finished product, storage of	02/06/2026			

	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.e.4 Change in the specification attribute and/or acceptance criteria of the immediate packaging of the finished product - Q.II.e.4.a) Change of specification acceptance criteria - Accepted Q.II.d.2 Change to analytical procedure for the finished product - Q.II.d.2.a) Minor change to an approved analytical procedure - Accepted Q.I.b.2 Change to analytical procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Q.I.b.2.a) Minor change to an analytical procedure for the active substance - Accepted				
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