



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Pergoveris

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 /	B.IV.1.a Addition or replacement of a device	17/06/2025		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/0000267259	which is not an integrated part of the primary packaging - B.IV.1.a.1 Device with CE marking - Accepted			Labelling and PL	
Variation type II / EMA/VR/0000244228	<p>This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.</p> <p>B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.c The change refers to a biological / immunological substance or use of a different chemically derived substance in the manufacture of a biological/immunological substance, which may have a significant impact on the quality, safety and efficacy of the medicinal product and is not related to a protocol - Accepted</p> <p>B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.e The change relates to a biological active substance or a starting material/reagent/intermediate used in the manufacture of a</p>	05/06/2025			

	<p>biological/immunological product - Accepted</p> <p>B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.k New storage site of Master Cell Bank and/or Working Cell Banks - Accepted</p> <p>B.III.1.b European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/intermediate/or excipient - B.III.1.b.2 New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer - Accepted</p>				
Variation type IB / EMA/VR/0000255922	<p>This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.</p> <p>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</p>	22/05/2025	N/A		

	<p>procedure (including replacement or addition) for the active substance or a starting material/intermediate - Accepted</p> <p>B.II.d.2 Change in test procedure for the finished product - B.II.d.2.d Other changes to a test procedure (including replacement or addition) - Accepted</p>				
PSUR / EMA/PSUR/0000248455	- -				Based on the PRAC review of data on safety and efficacy, the PRAC considers that the risk-benefit balance of medicinal products containing follitropin alfa/lutropin alfa remains unchanged and therefore recommends the maintenance of the marketing authorisation. Changes of PSUR frequency are proposed