Bemfola

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 /	C. Safety, efficacy, pharmacovigilance	23/03/2026		SmPC and 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/VR/0000325945	changes - C.z Other variation - Accepted C.z - to update section 2 of the SmPC and section 7 of the Labelling to implement changes to prevent potential dosing errors. Annex A have been updated in all languages in accordance with the request received from the EMA.				
Variation type IB / EMA/VR/0000316342	This was an application for a group of variations. B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.b Addition of a new in-process test and limits - Refused B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.b Addition of a new in-process test and limits - Accepted B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.b Addition of a new in-process test and limits - Accepted B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.a Tightening of in-process limits - Accepted B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process	25/02/2026			

	of the active substance - B.I.b.1.c Addition of a new specification parameter to the specification with its corresponding test method - Accepted B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.c Addition of a new specification parameter to the specification with its corresponding test method - 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.c Other changes to a test procedure (including replacement or addition) for a reagent, which does not have a significant effect on the overall quality of the active substance - Accepted 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 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 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 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 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 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 B.I ACTIVE SUBSTANCE - B.I.z Substantial updates to Mod. 3.2.S or the ASMF - Refused B.I ACTIVE SUBSTANCE - B.I.z Substantial updates to Mod. 3.2.S or the ASMF - Refused B.I ACTIVE SUBSTANCE - B.I.z Substantial updates to Mod. 3.2.S or the ASMF - Accepted B.I ACTIVE SUBSTANCE - B.I.z Substantial updates to Mod. 3.2.S or the ASMF - Accepted B.I ACTIVE SUBSTANCE - B.I.z Substantial updates to Mod. 3.2.S or the ASMF - Accepted				
Variation type IA / EMA/VR/0000314832	This was an application for a group of variations. B.II.e.3 Change in test procedure for the	08/12/2025			

	immediate packaging of the finished product - B.II.e.3.a Minor changes to an approved test procedure - Accepted B.II.e.1.b Change in type of container or addition of a new container - B.II.e.1.b.3 Deletion of an immediate packaging container that does not lead to the complete deletion of a strength or pharmaceutical form - Accepted				
PSUR / EMA/PSUR/0000248456		05/06/2025			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 remains unchanged and therefore recommends the maintenance of the marketing authorisation(s).