Rekovelle

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 /	Outcome:	13/05/2026			

[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/0000342342	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/0000342021	Outcome: 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	12/05/2026			
Variation type II / EMA/VR/0000315701	Outcome: C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted Update of section 5.1 of the SmPC to introduce dose comparability information based on data from study ADAPT-1. ADAPT-1 is a Phase III clinical trial with efficacy as the primary objective. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet,	12/02/2026		SmPC and PL	SmPC section 5.1 was updated with the information on dose comparability: In a phase 3 trial (ADAPT-1), comparing an initial daily dose of 15 micrograms follitropin delta to an initial daily dose of 225 IU follitropin alfa in a GnRH antagonist protocol using a conventional dosing regimen, a comparable ovarian response was observed with regards to number of oocytes retrieved, follicular development, and hormone levels. For more information, please refer to the Summary of Product Characteristics.

	to update the PI in accordance with the latest EMA excipients guideline, and to implement editorial changes to the PI.				
Variation type IB / EMA/VR/0000320777	Outcome: B.II.d.2 Change in test procedure for the finished product - B.II.d.2.a Minor changes to an approved test procedure - Accepted	27/01/2026			
Variation type II / EMA/VR/0000289589	Outcome: B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.b To move the sterilizing filtration from A/B to C - Accepted	16/10/2025			
Variation type IB / EMA/VR/0000300738	Outcome: 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	15/10/2025			
Variation type IA / EMA/VR/0000300736	Outcome: B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active	30/09/2025			

	substance - B.I.a.4.z Other variation - Accepted				
Variation type IA / EMA/VR/0000295822	Outcome: B.II.e.7 Change in supplier of packaging components or devices (when mentioned in the dossier) - B.II.e.7.b Replacement or addition of a supplier - Accepted	17/09/2025			
Variation type IB / EMA/VR/0000275050	Outcome: B.II.g.5 Implementation of changes foreseen in an approved change management protocol - B.II.g.5.c Implementation of a change for a biological/immunological medicinal product - Accepted	05/08/2025			
Variation type IB / EMA/VR/0000278711	Outcome: This was an application for a group of variations. B.I.e.5 Implementation of changes foreseen in an approved change management protocol - B.I.e.5.c Implementation of a change for a biological/immunological medicinal product - 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.a Minor changes to an approved test procedure - Accepted	22/07/2025			

Variation type II / EMA/VR/0000264396	Outcome: This was an application for a group of variations. B.II.d.2 Change in test procedure for the finished product - B.II.d.2.c Substantial change to, or replacement of, a biological/ immunological/ immunochemical test method or a method using a biological reagent or replacement of a biological reference preparation not covered by an approved protocol - Accepted B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.b Replacement or addition of a site where batch control/testing takes place for a biological/immunological product and any of the test methods performed at the site is a biological/immunological method - Accepted	19/06/2025			
Variation type IA / EMA/VR/0000278732	Outcome: B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.z Other variation - Accepted	11/06/2025			