Rimmyrah

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 / EMA/VR/0000362892	Outcome: Q.I.a.1 Change in the manufacturing site of a starting material/intermediate used in the manufacturing process of the active	17/08/2026			

[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).

	substance or change in the manufacturing site (including where relevant quality control testing sites) of the active substance - Q.I.a.1.z Other variation - Accepted				
Variation type IB / EMA/VR/0000343923	Outcome: Q.II.f.1.b) Extension of the shelf life of the finished product - Q.II.f.1.b.5 Extension of the shelf life of the finished product based on extrapolation of stability data in accordance with relevant stability guidelines - Accepted	15/06/2026		SmPC	
Variation type IB / EMA/VR/0000338190	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 active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Q.I.b.2.d) Other change to an analytical procedure (including replacement or addition) for the active substance - Accepted	21/04/2026			

Variation type IA / EMA/VR/0000334304	Outcome: This was an application for a group of variations. 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 - Refused Q.II.d.2 Change to analytical procedure for the finished product - Q.II.d.2.a) Minor change to an approved analytical procedure - Refused	09/03/2026			
Variation type IB / EMA/VR/0000325891	Outcome: Q.II.b.5 Change to in-process control or limits applied during the manufacture of the finished product - Q.II.b.5.z Other variation - Accepted	02/03/2026			
Variation type IA / EMA/VR/0000322245	Outcome: This was an application for a group of variations. B.II.e.6 Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different	20/01/2026			

	plastic used)) - B.II.e.6.b Change that does not affect the product information - Accepted 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 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 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 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.d Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) - Accepted A. ADMINISTRATIVE CHANGES - A.4 Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of				

	Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) - Accepted A. ADMINISTRATIVE CHANGES - A.4 Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) - Accepted				
Variation type IB / EMA/VR/0000314772	Outcome: B.II.f.1.b Extension of the shelf life of the finished product - B.II.f.1.b.5 Extension of the shelf-life of a biological/ immunological medicinal product in accordance with an approved stability protocol - Accepted	09/01/2026	25/06/2026	SmPC	
Variation type II / EMA/VR/0000246182	Outcome: B.II.e.1.b Change in type of container or addition of a new container - B.II.e.1.b.2 Sterile medicinal products and biological/ immunological medicinal products - Accepted	10/07/2025	25/06/2026	SmPC, Labelling and PL	The SmPC has been updated as follows: addition of a new presentation "Rimmyrah 10 mg/ml solution for injection in pre-filled syringe". The Labelling and PL have been updated accordingly.