Riltrava Aerosphere

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.I HUMAN AND VETERINARY MEDICINAL	30/09/2025		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/0000295901	PRODUCTS - C.I.z Other variation - Accepted C.I.z – to update sections 4.2, 4.4, 4.5, 4.8, 5.1, 6.5 of the SmPC, Annex II, Labelling and sections 4 and 6 of the Package Leaflet to include the same text changes as approved for Trixeo Aerosphere during the EU licence renewal procedure EMA/R/0000245136. The MAH also took the opportunity to include correction of typographical errors, minor formatting adjustments, and to align with specific changes agreed by local health authorities for the IT, LT and BG annexes as already done during the Trixeo Aerosphere renewal process.			II, Labelling and PL	
Variation type IA / EMA/VR/0000295389	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.f Changes to quality control testing arrangements for the active substance-replacement or addition of a site where batch control/testing takes place - Accepted	23/09/2025	N/A		
Variation type IB / EMA/VR/0000264393	This was an application for a variation following a worksharing procedure according	24/07/2025	N/A		

	to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.b Addition of a new specification parameter to the specification with its corresponding test method - Accepted				
PSUR / EMA/PSUR/0000257877	- -				Maintenance