Rebif

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:	02/09/2026		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/0000356900	C.3 Change(s) in the summary of product characteristics, labelling or package leaflet intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Article 45 or 46 of Regulation (EC) No 1901/2006, or the outcome of a PRAC signal recommendation, or to adapt to a joint recommendation of EU competent authorities (e.g. a Core SmPC, or following the assessment of an Urgent Safety Restriction etc.) - C.3.z Other variation - Accepted To update section 4.2 of the SmPC and section 3 of the PL removing the reference to availability of 22 micrograms cartridges for use with the RebiSmart electronic injection device, as these have been surrendered. In additional reference to the 44 microgram solution was added for clarity.				
Variation type II / EMA/VR/0000285044	Outcome: This was an application for a group of variations. 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.e Deletion of a specification parameter which may have	26/02/2026			

	a significant effect on the overall quality of the active substance and/or the finished product - 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.e Deletion of a specification parameter which may have a significant effect on the overall quality of the active substance and/or the finished product - 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.e Deletion of a specification parameter which may have a significant effect on the overall quality of the active substance and/or the finished product - 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.z Other changes - Accepted				
Variation type IB / EMA/VR/0000313648	Outcome: C.I.7 Deletion of: - C.I.7.b a strength - Accepted	13/02/2026		SmPC, Labelling and	

	To delete the 8.8 µg (2.4 m IU) + 22 µg (6 m IU) strength from the Rebif marketing authorisation (EU/1/98/063/007, EU/1/98/063/010, EU/1/98/063/017).			PL	
Variation type II / EMA/VR/0000290220	Outcome: 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 - Accepted B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.z Other variation - 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.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 B.II.h.1.b Replacement of obsolete studies	16/10/2025			

	related to manufacturing steps and adventitious agents already reported in the dossier - B.II.h.1.b.1 with modification of risk assessment - Accepted				