Tysabri

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 II /		10/04/2026		SmPC, Annex	Please refer to Scientific Discussion 'Product Name-

[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/0000315289	Outcome: C.I.3 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - C.I.3.b Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH - Accepted Update of sections 4.2, 4.4 of the SmPC, and Annex II in order to align with the revised content of the additional risk minimisation materials in the RMP following the PRAC recommendation in EU PSUR 23 for the Tysabri (EMEA/H/C/PSUSA/00002127/202408). The Package Leaflet is updated accordingly. The RMP version 35 has been submitted; the due date for the provision of the final CSR for category 3 PASS study 101MS412 is also revised.			II and PL	H-C-Product Number-II-Var.No' SmPC new text For more information, please refer to the Summary of Product Characteristics.
Variation type IB / EMA/VR/0000315888	Outcome:	09/01/2026		SmPC, Labelling and PL	

	B.II.e.5.a Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - B.II.e.5.a.2 Change outside the range of the currently approved pack sizes - Accepted				
Variation type IA / EMA/VR/0000314074	Outcome: This was an application for a group of variations. 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.5 Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - A.5.b The activities for which the manufacturer/importer is responsible do not include batch release - Accepted	25/11/2025		Annex II	

Variation type II / EMA/VR/0000262419	Outcome: This was an application for a group of variations. 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 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 A grouped application consisting of: C.I.4: Update of sections 4.4 of the SmPC in order to update a warning about PML in patients with prior treatment with immunosuppressive or immunomodulatory therapies based on final results from study 101MS411, listed as a category 3 study in the RMP; this is an observational study utilising data from the US Tysabri TOUCH programme and select EU MS registries to estimate the risk of progressive multifocal	02/10/2025		SmPC, Annex II, Labelling and PL	SmPC section 4.4 is updated to inform that data from an observational study demonstrated that there is no increased risk of PML for the group of patients switching to natalizumab from fingolimod, dimethyl fumarate, or teriflunomide when compared to the group of patients switching from either beta interferon or glatiramer acetate and that no information is available for other disease-modifying therapies. SmPC section 4.8 is updated to remove information on malignancies SmPC section 5.1 is updated to include a high-level summary of the design and main study results of the Tysabri Observational Program (TOP, IMA-06-02) Study For more information, please refer to the Summary of Product Characteristics.

	leukoencephalopathy (PML) and other serious opportunistic infections among patients who were exposed to an MS disease modifying treatment prior to treatment with Tysabri. C.I.4: Update of sections 4.8 and 5.1 of the SmPC in order to update safety and pharmacodynamic information based on final results from study IMA 06 02 (TOP) listed as a category 3 study in the RMP. This is an observational study to evaluate the long-term safety and impact on disease activity and progression of Tysabri as a single disease-modifying agent in patients with RRMS in a clinical practice setting. The RMP version 34.0 has also been adopted. Changes are also made to the PI to bring it in line with the current QRD template version. In addition, the list of local representatives in the PL is being revised.				
Variation type II / EMA/VR/0000268214	Outcome: 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.f Change outside the approved specifications limits range for the active substance - Accepted	17/07/2025			N/A

Variation type IB / EMA/VR/0000258487	Outcome: B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.z Other changes - Accepted	16/04/2025			
Variation type IB / EMA/VR/0000261321	Outcome: This was an application for a group of variations. 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 B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used	15/04/2025			

	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				