



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

TALVEY

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification ¹ issued on	Commission Decision Issued ² / amended on	Product Information affected ³	Summary
PSUSA/99/202408	Periodic Safety Update EU Single assessment - talquetamab	27/03/2025	02/06/2025	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s) for PSUSA/99/202408.
IB/0015	B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	06/02/2025	n/a		

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).



II/0012/G	This was an application for a group of variations. B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier B.I.a.4.e - Change to in-process tests or limits applied during the manufacture of the AS - Deletion of an in-process test which may have a significant effect on the overall quality of the AS B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	03/10/2024	n/a		
IB/0013	B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data	30/09/2024	n/a		
PSUSA/99/202402	Periodic Safety Update EU Single assessment - talquetamab	05/09/2024	n/a		PRAC Recommendation - maintenance
IAIN/0011	B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing	24/06/2024	02/06/2025	Annex II and PL	
IB/0010	B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate	19/06/2024	n/a		

R/0005	Renewal of the marketing authorisation.	25/04/2024	13/06/2024		The CHMP, having reviewed the available information on the status of the fulfilment of Specific Obligations and having confirmed the positive benefit risk balance, is of the opinion that the quality, safety and efficacy of this medicinal product continue to be adequately and sufficiently demonstrated and therefore recommends the renewal of the conditional MA for TALVEY, subject to the Specific Obligations and Conditions as laid down in Annex II to the opinion.
IB/0008	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	31/05/2024	n/a		
IB/0007/G	This was an application for a group of variations. C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation A.6 - Administrative change - Change in ATC Code/ATC Vet Code	16/04/2024	02/06/2025	SmPC, Labelling and PL	
IB/0006	B.I.z - Quality change - Active substance - Other variation	03/04/2024	n/a		
IB/0004	B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol	12/03/2024	13/06/2024	SmPC	
IAIN/0003	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging	15/02/2024	n/a		

	site				
IB/0002	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	04/01/2024	13/06/2024	Annex II	
IB/0001/G	This was an application for a group of variations. B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol	23/11/2023	13/06/2024	SmPC	