LOQTORZI

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:	31/07/2026		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/0000360410	C. Safety, efficacy, pharmacovigilance changes - C.z Other variation - Accepted To update sections 2 and 4.4 of the SmPC and section 2 of the PIL to add the statement for Polysorbate 80 in line with the current EC guideline "Excipients in the labeling and package leaflet of medicinal products for human use". The MAH also takes the opportunity to update section 6.6 of the SmPC and section 6 of the PIL to remove the reference to the use of 250 mL infusion bag, which is not applicable for clinical practice in Europe and to update section 5 of PIL to amend the terminology for "use after dilution". To update section 4 of PIL to remove duplicated side effect, and add clarification for certain side effects to align with SmPC.				
Article 61(3) / EMA/N/0000341695	Outcome: - Notification acc. Article 61(3) - Accepted Update to the abbreviations used for the expiry date and batch number in the product labelling, in line with the recommendations set out in QRD Appendix IV. In addition, the minimal particulars for small immediate packaging units have been realigned with the vial label text. Furthermore, local representative details have been added to the package leaflet, along with a correction	06/05/2026		SmPC, Labelling and PL	

	to text in section 6.6 of the SmPC.				
Variation type IA / EMA/VR/0000338671	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.c Addition of a new specification parameter to the specification with its corresponding test method - Accepted	24/03/2026			
Variation type IA / EMA/VR/0000323981	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.b Tightening of specification limits - Accepted B.II.d.2 Change in test procedure for the finished product - B.II.d.2.e Update of the test procedure to comply with the updated general monograph in the Ph. Eur. - Accepted	03/02/2026			
PSUR / EMA/PSUR/0000296630	EURD: PSUSA/00011094/202506 Active substance: toripalimab Outcome: Variation In view of the available data on the	29/01/2026	26/03/2026	SmPC and PL	Variation

	increased risk of immune-mediated adverse reactions in patients with pre-existing autoimmune disease (AID) from the literature and spontaneous reports, and in view of a plausible mechanism of action, the PRAC considers the relationship between toripalimab and an increased risk of Immune-mediated adverse reactions in patients with pre-existing AID is at least a reasonable possibility. The PRAC concluded that the product information for toripalimab should be amended accordingly.				
Variation type IA_IN / EMA/VR/0000293928	Outcome: B.II.b.2.c Replacement or addition of a manufacturer responsible for importation and/or batch release - B.II.b.2.c.1 Not including batch control/testing - Accepted	10/09/2025	26/03/2026	Annex II and PL	
Marketing Authorisation Transfer - H / EMA/T/0000254154	Outcome: transfer of marketing authorisation from TMC Pharma (EU) Limited to Topalliance Biosciences Europe Limited	12/03/2025	28/03/2025	SmPC, Labelling and PL	
PSUR / EMA/PSUR/0000336150	EURD: PSUSA/00011094/202512 Active substance: toripalimab Outcome: Maintenance	09/07/2026			Maintenance
PSUR / EMA/PSUR/0000257891	EURD: PSUSA/00011094/202412 Active substance: toripalimab Outcome:	10/07/2025			Maintenance

	Maintenance				