Tecentriq

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 /	This was an application for a variation	13/11/2025	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).

EMA/VR/0000287554	following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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.k New storage site of Master Cell Bank and/or Working Cell Banks - Accepted				
Variation type II / EMA/VR/0000290209	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	16/10/2025		SmPC and PL	SmPC new text Uveitis (frequency uncommon for atezolizumab monotherapy and rare for atezolizumab combination therapy), cytomegalovirus infection (frequency rare), sarcoidosis (frequency rare) arthritis (frequency common) and tenosynovitis (frequency uncommon) have been included in the adverse reaction table in section 4.8 of the SmPC. Uveitis has also been added to the existing warning on immune-mediated adverse reactions in section 4.4 of the SmPC. For more information, please refer to the Summary of Product Characteristics.

	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 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 comprised of 5 Type II Variations, based on safety reports, as follows: C.I.4: Update of sections 4.4 and 4.8 of the SmPC in order to add 'uveitis' in the warning section and to the list of adverse drug reactions (ADRs). C.I.4: Update of section 4.8 of the SmPC in order to add 'cytomegalovirus infection' to the list of ADRs with frequency 'rare'. C.I.4: Update of section 4.8 of the SmPC in order to add				

	'tenosynovitis' to the list of ADRs with frequency 'uncommon'. C.I.4: Update of section 4.8 of the SmPC in order to add 'arthritis' to the list of ADRs with frequency 'common'. C.I.4: Update of section 4.8 of the SmPC in order to add 'sarcoidosis' to the list of ADRs with frequency 'rare'. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce editorial and formatting changes to the PI, to bring it in line with the latest QRD template.				
Variation type IB / EMA/VR/0000294085	B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.z Minor change in the manufacturing process of a sterile finished product after the primary packaging step - Accepted	23/09/2025	N/A		
Variation type II / EMA/VR/0000245126	B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.b Substantial change to the manufacturing process of the active substance which may have a significant impact on the quality, safety or efficacy of the medicinal product - Accepted	24/07/2025	N/A		

Variation type IB / EMA/VR/0000272433	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.1 Change in the specification parameters and/or limits of the finished product - B.II.d.1.a Tightening of specification limits - Accepted B.II.f.1.b Extension of the shelf life of the finished product - B.II.f.1.b.5 Extension of the shelf-life of a biological/ immunological medicinal product in accordance with an approved stability protocol - Accepted	16/06/2025		SmPC	
Variation type II / EMA/VR/0000262253	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 Update of section 4.4 of the SmPC in order to amend an existing warning on infusion-related reactions with anaphylaxis based on	05/06/2025		SmPC and PL	SmPC new text The warning related to infusion-related reactions in Section 4.4 of the SmPC has been updated to include that anaphylaxis has been observed with atezolizumab: Infusion-related reactions have been observed with atezolizumab, including anaphylaxis. This is based on the review of Drug safety reports. For more information, please refer to the Summary of Product Characteristics.

	Drug safety report No. 1135433; the Package Leaflet is updated accordingly. The RMP version 32.1 is also agreed. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to bring the PI in line with the latest QRD template version.				
Variation type II / EMA/VR/0000245137	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 Update of section 4.8 of the SmPC in order to add ''Peripheral neuropathy'' to the list of adverse drug reactions (ADRs) of atezolizumab monotherapy with frequency ''common'', as well as, to add Immune thrombocytopenia to the existing ADR Thrombocytopenia of atezolizumab monotherapy and combination therapy based on post-marketing data and literature. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to bring the PI in line with the latest QRD template version 10.4.	27/03/2025		SmPC and PL	SmPC new text In section 4.8 of the SmPC: -Peripheral neuropathy has been added as a new ADR to the atezolizumab monotherapy column of the ADR table . -Immune thrombocytopenia has been added as a footnote to further define the existing ADR thrombocytopenia for both atezolizumab monotherapy and in combination of the ADR table. For more information, please refer to the Summary of Product Characteristics.