Tecentriq

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
N/0015	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	09/08/2018		PL	
II/0010	C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	31/05/2018	02/07/2018	SmPC	Please refer to Scientific Discussion 'Tecentriq-H-C-4143-II-0010'
PSUSA/10644 /201711	Periodic Safety Update EU Single assessment - atezolizumab	14/06/2018	n/a		PRAC Recommendation - maintenance

[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).

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact

II/0004	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	14/06/2018		SmPC, Annex II and PL	
IB/0009	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	09/04/2018	n/a		
IB/0008	B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	05/04/2018	n/a		
II/0002/G	This was an application for a group of variations. Update of sections 4.2, 4.4 and 4.8 of the SmPC in order to add myocarditis as a new adverse reaction, based on the results of a cumulative review of cases of suspected myocarditis provided in the drug safety report number 1080476. Consequently, the information regarding posology and special warnings have been updated. The Annex II and the Package Leaflet have been updated accordingly. The RMP version 2.1 has also been updated. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of change(s) which require to be further substantiated by	22/02/2018	04/04/2018	SmPC, Annex II and PL	Myocarditis occurred in < 0.1% (2/8,000) of patients across all atezolizumab clinical trials in multiple tumour types. The time to onset was 18 and 33 days. Both patients required corticosteroids and discontinued atezolizumab. Patients should be monitored for signs and symptoms of myocarditis. In addition treatment with atezolizumab should be withheld for Grade 2 myocarditis, and treatment with systemic corticosteroids at a dose of 1 to 2mg/kg/day of prednisone or equivalent should be started. Treatment with atezolizumab may be resumed if the event improves to ≤ Grade 1 within 12 weeks, and corticosteroids have been reduced to ≤ 10 mg prednisone or equivalent per day Treatment with atezolizumab must be permanently discontinued for Grade 3 or 4 myocarditis. In addition myocarditis has been added as a new adverse drug reaction under the SOC 'Cardiac disorders' with a rare frequency and 'immune-related myocarditis' has also been included in the guide for healthcare professionals and patient alert card in annex II.D and as a new important

	new additional data to be submitted by the MAH where significant assessment is required				identified risk in the RMP.
T/0006	Transfer of Marketing Authorisation	20/02/2018	07/03/2018	SmPC, Labelling and PL	
II/0001	B.II.g.2 - Introduction of a post approval change management protocol related to the finished product	14/12/2017	n/a		
IB/0003/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	10/11/2017	07/03/2018	SmPC, Labelling and PL	