IMJUDO

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/11038 /202404	Periodic Safety Update EU Single assessment - tremelimumab	12/12/2024	14/02/2025	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/11038/202404.
N/0011	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	11/12/2024	14/02/2025	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).

IB/0010/G	This was an application for a group of variations. B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.e.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	09/10/2024	n/a		
IAIN/0008/G	This was an application for a group of variations. C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	10/07/2024	14/02/2025	SmPC and PL	
IA/0007	B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation	09/07/2024	n/a		

WS/2650	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Update of section 4.2 and 4.4 of the SmPC in order to simplify current dosing recommendations. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	25/04/2024	27/05/2024	SmPC	SmPC new text In section 4.4, for Grade 3 or 4 events of immune-mediated pneumonitis, an initial dose of 2-4 mg/kg/day methylprednisolone or equivalent should be initiated followed by a taper. For Immune-mediated colitis/diarrhea, a footnote is included in Table 2 to clarify that in Grade 3 events for patients on IMFINZI + tremelimumab, tremelimumab is to be permanently discontinued while durvalumab can be resumed once the event has resolved. For more information, please refer to the Summary of Product Characteristics.
PSUSA/11038 /202310	Periodic Safety Update EU Single assessment - tremelimumab	16/05/2024	n/a		PRAC Recommendation - maintenance
PSUSA/11038 /202304	Periodic Safety Update EU Single assessment - tremelimumab	14/12/2023	16/02/2024	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/11038/202304.
WS/2543	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Update of sections 4.2, 5.1 and 5.2 of the SmPC in order to include paediatric information based on final results from study D419EC00001 "Phase I/II, Open-Label, Multicenter Study to Evaluate the Safety, Tolerability, and Preliminary Efficacy of Durvalumab Monotherapy or Durvalumab in Combination with Tremelimumab in Pediatric Patients with Advanced Solid Tumors and Hematological Malignancies". In addition, the MAH took this opportunity to introduce	14/12/2023	16/02/2024	SmPC	Based on the results from study D419EC00001 in children and adolescents, sections 4.2, 5.1, and 5.2 have been updated. The efficacy and safety of of durvalumab in combination with tremelimumab in children were assessed but not established. Currently available data are reported in the SmPC. In the dose-expansion phase, an Overall Response Rate of 5.0% (1/20 patients) was reported in the evaluable for response analysis set. No new safety signals were observed relative to the known safety profiles of durvalumab and tremelimumab in adults. For more information, please refer to the Summary of Product Characteristics.

	editorial changes. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
IG/1659	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	04/09/2023	16/02/2024	Annex II and PL	
II/0001	Extension of indication to include in combination with durvalumab and platinum-based chemotherapy, the first-line treatment of adults with metastatic non-small cell lung cancer (NSCLC) with no sensitising EGFR mutations or ALK positive mutations for Imjudo, based on the final analysis from the pivotal study D419MC00004, a Randomised, Multi-center, Open-Label, Comparative Global Study to Determine the Efficacy of Durvalumab or Durvalumab and Tremelimumab in Combination with Platinum-Based Chemotherapy for First-Line Treatment in Patients with Metastatic Non Small-Cell Lung Cancer (NSCLC) (POSEIDON). As a consequence, sections 2, 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2, 5.3 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. In addition, the MAH took the opportunity to include minor editorial changes. The variation leads to amendments to the Summary of Product Characteristics and Package Leaflet. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or	22/06/2023	04/08/2023	SmPC, Labelling and PL	Please refer to Scientific Discussion 'Imjudo-H-C-6016-II-0001'

	modification of an approved one				