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 /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.	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

[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).

	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 editorial changes. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				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.
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	22/06/2023	04/08/2023	SmPC, Labelling and PL	Please refer to Scientific Discussion 'Imjudo-H-C-6016-II-0001'

	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 modification of an approved one				