Imfinzi

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/10723 /202404	Periodic Safety Update EU Single assessment - durvalumab	12/12/2024	12/02/2025		Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10723/202404.
II/0067/G	This was an application for a group of variations. B.I.c.z - Container closure system of the AS - Other	17/10/2024	12/02/2025	Annex II	

[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).

	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.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product				
IB/0072	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	09/10/2024	n/a		
WS/2463	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	27/06/2024	26/07/2024	SmPC, Annex II and PL	

	editorial changes. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one				
IAIN/0068/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	18/07/2024	12/02/2025	SmPC and PL	
II/0066	Update of sections 4.2, 4.4, and 4.8 of the SmPC in order to include rhabdomyolysis as an extension of the myositis and polymyositis medical concept based on post marketing data and literature. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	30/05/2024	26/07/2024	SmPC	Section 4.2 of the SmPC is amended to include rhabdomyolysis together with immune-mediated myositis/polymyositis in the table for treatment modifications for durvalumab or durvalumab in combination with tremelimumab. Section 4.4 of the SmPC is updated to include rhabdomyolysis in the subsection for other immune-mediated adverse reactions. Rhabdomyolysis is added to the grouped term analysis for calculation of the frequency of Adverse Drug Reaction for myositis (uncommon) in section 4.8 of the SmPC. For more information, please refer to the Summary of Product Characteristics.
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	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.

	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				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/10723 /202304	Periodic Safety Update EU Single assessment - durvalumab	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/10723/202304.
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 editorial changes. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	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.
II/0057	Extension of indication to include IMFINZI as monotherapy for the treatment of adults with	12/10/2023	15/11/2023	SmPC and PL	Please refer to Scientific Discussion: Imfinzi

	unresectable hepatocellular carcinoma (uHCC), based on final results from study D419CC00002 (HIMALAYA); this was a randomized, open-label, multi-center phase III study of durvalumab and tremelimumab as first-line treatment in patients with unresectable hepatocellular carcinoma (HIMALAYA). As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 9.1 of the RMP has also been submitted. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one				EMEA/H/C/004771/II/0057.
IAIN/0060	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	13/07/2023	15/11/2023	Annex II and PL	
IA/0059	A.7 - Administrative change - Deletion of manufacturing sites	12/05/2023	n/a		
R/0055	Renewal of the marketing authorisation.	23/02/2023	24/04/2023	SmPC, Annex II and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Imfinzi in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IB/0056	B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	30/01/2023	n/a		

II/0052	Update of section 4.2 of the SmPC in order to update the recommendation for dose modification for 'other immune-mediated adverse reactions' as well as immune-mediated encephalitis, meningitis, Guillain-Barré syndrome and myasthenia gravis based on the National Comprehensive Cancer Network (NCCN) guideline recommendations (2022). C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	15/12/2022	30/01/2023	SmPC	SmPC new text The table on recommended treatment modifications in case of immune-mediated adverse reactions was updated as follows: immune-mediated meningitis has been added as a separate row, requiring intervention and permanent discontinuation for Grade 3 or 4, and intervention and withholding dose for Grade 2; immune-mediated encephalitis has been added as a separate row, requiring intervention and permanent discontinuation for Grade 2 – 4; immune-mediated Guillain-Barré syndrome has been added as a separate row, requiring intervention and permanent discontinuation for Grade 2 – 4; 'myasthenia gravis' was changed to 'immune-mediated myasthenia gravis', requiring intervention and permanent discontinuation for Grade 2 – 4; other immune-mediated adverse reactions row was updated to require intervention and withholding dose for Grade 2 or 3. For more information, please refer to the Summary of Product Characteristics.
II/0045	Extension of indication to include IMFINZI in combination with tremelimumab for the first line treatment of adults with advanced or unresectable hepatocellular carcinoma (uHCC), based on final results from Study D419CC00002 (HIMALAYA); This was a randomized, open-label, multi-center phase III study of durvalumab and tremelimumab as first-line treatment in patients with unresectable hepatocellular carcinoma. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in	15/12/2022	30/01/2023	SmPC and PL	Please refer to Scientific Discussion: Imfinzi EMEA/H/C/004771/II/0045.

	accordance. In addition, the MAH took the opportunity to implement minor editorial changes in the SmPC and Package Leaflet. Version 8.1 of the RMP has also been submitted. The variation leads to amendments to the Summary of Product Characteristics and Package Leaflet and to the Risk Management Plan (RMP). C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one				
II/0041	Extension of indication to include first-line treatment, with Imfinzi in combination with tremelimumab and platinum-based chemotherapy, of adults with metastatic NSCLC with no sensitizing epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) positive mutations, based on final results from Study D419MC00004 (POSEIDON); This was a Phase III, randomised, multicentre, open-label, comparative global study to determine the efficacy and safety of tremelimumab and durvalumab or durvalumab in combination with platinum based chemotherapy for first-line treatment in patients with metastatic NSCLC. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet. Furthermore, the PI is brought in line with the latest QRD template	15/12/2022	30/01/2023	SmPC and PL	Please refer to Scientific Discussion: Imfinzi EMEA/H/C/004771/II/0041.

	version 10.2. Version 8.1 of the RMP has also been submitted. The variation leads to amendments to the Summary of Product Characteristics and Package Leaflet and to the Risk Management Plan (RMP). C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one				
II/0054	Submission of final report from non-clinical study ONC4736-PB-0401 (Profiling of Biomarkers Relevant to Immunotherapies in Pediatric Solid Tumors). C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	12/01/2023	n/a		Not applicable
II/0046	Extension of indication to include IMFINZI in combination with gemcitabine and cisplatin for the first-line treatment of adults with unresectable or metastatic biliary tract cancer (BTC), based on the second interim analysis from the ongoing pivotal study D933AC00001 (TOPAZ-1); a phase III randomized, double-blind, placebo-controlled, multi-regional, international study conducted to assess the efficacy and safety of durvalumab in combination with the current standard of care Gemcitabine/Cisplatin for the first-line treatment of patients with locally advanced or metastatic BTC. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC have been updated and the Package	10/11/2022	16/12/2022	SmPC and PL	Please refer to Scientific Discussion: Imfinzi EMEA/H/C/004771/II/0046.

	leaflet has been updated accordingly. Version 7.2 of the RMP has also been submitted. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one				
IAIN/0058	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	13/12/2022	30/01/2023	SmPC and PL	
PSUSA/10723 /202204	Periodic Safety Update EU Single assessment - durvalumab	01/12/2022	n/a		PRAC Recommendation - maintenance
II/0051	B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product	10/11/2022	n/a		
IA/0053	A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release)	18/10/2022	n/a		
II/0050	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	29/09/2022	16/12/2022	SmPC	
PSUSA/10723 /202110	Periodic Safety Update EU Single assessment - durvalumab	23/06/2022	22/08/2022	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10723/202110.

IB/0048	B.II.g.4.b - Changes to an approved change management protocol - Minor changes that do not change the strategy defined in the protocol	10/08/2022	n/a		
IB/0047/G	This was an application for a group of variations. B.I.a.4.c - Change to in-process tests or limits applied during the manufacture of the AS - Deletion of a non-significant in-process test B.I.a.1.k - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - New storage site of MCB and/or WCB B.I.e.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	08/08/2022	n/a		
II/0034	Update of sections 4.4 and 4.8 of the SmPC in order to reflect the outcome of the re-defined process to identify and calculate immune-mediated Adverse Event (imAE) rates from clinical study and pooled datasets within the durvalumab development programmes. In addition, the MAH implemented minor editorial corrections to sections 4.4 and 5.1 of the SmPC. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	23/06/2022	22/08/2022	SmPC	
II/0039/G	This was an application for a group of variations. C.I.4 - Change(s) in the SPC, Labelling or PL due to	22/04/2022	13/06/2022	SmPC	

	new quality, preclinical, clinical or pharmacovigilance data C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
IB/0043	B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate	20/04/2022	n/a		
IAIN/0044/G	This was an application for a group of variations. A.6 - Administrative change - Change in ATC Code/ATC Vet Code C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	06/04/2022	13/06/2022	SmPC and PL	
PSUSA/10723 /202104	Periodic Safety Update EU Single assessment - durvalumab	16/12/2021	28/02/2022	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10723/202104.
II/0040	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	17/02/2022	13/06/2022	SmPC	
II/0036	B.I.e.2 - Introduction of a post approval change management protocol related to the AS	17/02/2022	n/a		
IB/0038/G	This was an application for a group of variations.	08/12/2021	n/a		

	B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product B.II.g.4.b - Changes to an approved change management protocol - Minor changes that do not change the strategy defined in the protocol				
IA/0037	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	29/10/2021	n/a		
II/0030/G	This was an application for a group of variations. Update of sections 4.2. and 4.4 the SmPC in order to change posology recommendations for management of immune-mediated adverse reactions and amend an existing warning on Immune-mediated type 1 diabetes mellitus to include diabetic ketoacidosis; these changes are based on case studies reports, updated guidelines. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to make some minor corrections to section 4.8 of the SmPC. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	16/09/2021	19/10/2021	SmPC and PL	Changes to Section 4.2 were made to adjust treatment modifications and management recommendations for adverse reactions including: *Changes to corticosteroid dosing from 1 – 4 mg/kg/day to 1 – 2 mg/kg/day for pneumonitis, myositis/polymyositis, myocarditis, myasthenia gravis, and other immune-mediated adverse events *clarification on how to manage myasthenia gravis and Gastrointestinal immune-mediated adverse events *change to the timing for initiation of additional immunosuppressive therapy in steroid refractory from 3 – 5 days to 2 – 3. A warning that immune-mediated Type 1 diabetes mellitus can present with diabetic ketoacidosis which can be fatal if not detected early was included in section 4.4.

IAIN/0035	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	22/09/2021	28/02/2022	SmPC and PL	
II/0032	B.II.g.2 - Introduction of a post approval change management protocol related to the finished product	16/09/2021	n/a		
IB/0031/G	This was an application for a group of variations. B.II.f.1.b.3 - Stability of FP - Extension of the shelf life of the finished product - After dilution or reconstitution (supported by real time data) A.7 - Administrative change - Deletion of manufacturing sites	07/07/2021	19/10/2021	SmPC, Annex II and PL	The product information was updated to extend the shelf life after diluation and the manufacturers responsible for batch release were updated..
PSUSA/10723 /202010	Periodic Safety Update EU Single assessment - durvalumab	10/06/2021	n/a		PRAC Recommendation - maintenance
II/0028	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	29/04/2021	n/a		
IB/0029	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	24/03/2021	n/a		
II/0026	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	11/02/2021	19/10/2021	SmPC	
II/0023	Update of sections 4.2 and 5.1 of the SmPC in order to introduce a new posology regimen of 1500 mg every 4 weeks (Q4W) for the approved indication of	10/12/2020	11/01/2021	SmPC	Durvalumab doses of 10 mg/kg every 2 weeks or 1500 mg every 4 weeks were evaluated in NSCLC and ES-SCLC clinical studies. Based on the modeling and simulation of

	the treatment of patients with locally advanced, unresectable non-small cell lung cancer (NSCLC) whose tumours express PD-L1 on ≥ 1% of tumour cells and whose disease has not progressed following platinum based chemoradiation therapy. The RMP version 4.1 has also been submitted. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				exposure, exposure-safety relationships and exposure-efficacy data comparisons, there are no anticipated clinically significant differences in efficacy and safety between durvalumab doses of 10 mg/kg every 2 weeks or 1500 mg every 4 weeks in locally advanced NSCLC. Patients with a body weight of 30 kg or less must receive weight-based dosing, equivalent to durvalumab 10 mg/kg every 2 weeks or 20 mg/kg every 4 weeks as monotherapy until weight increases to greater than 30 kg.
IB/0025/G	This was an application for a group of variations. B.I.d.1.c - Stability of AS - Change in the re-test period/storage period or storage conditions - Change to an approved stability protocol B.II.f.1.e - Stability of FP - Change to an approved stability protocol	11/12/2020	n/a		
II/0024	Update of sections 4.4 and 4.8 of the SmPC in order to add immune thrombocytopenia to the list of adverse drug reactions (ADRs) with frequency (rare) following the MAH internal review; the Package Leaflet (PL) is updated accordingly. The MAH took the opportunity to correct information in the PL and to make editorial changes to the names of the manufacturer in Annex II and to units in Annex IIIA. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	10/12/2020	11/01/2021	SmPC, Annex II and PL	

PSUSA/10723 /202004	Periodic Safety Update EU Single assessment - durvalumab	26/11/2020	n/a		PRAC Recommendation - maintenance
II/0014/G	This was an application for a group of variations. Extension of Indication to include the use of IMFINZI in combination with etoposide and either carboplatin or cisplatin for the first-line treatment of adults with extensive-stage small cell lung cancer (ES-SCLC). As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 5.2 of the SmPC were updated. The proposed indication is supported by study D419QC00001 (CASPIAN), an ongoing Phase III randomised, multicentre, open-label, comparative study designed to determine the efficacy and safety of durvalumab, or durvalumab and tremelimumab, in combination with etoposide and platinum-based chemotherapy (EP) for the first-line treatment of patients with ES-SCLC. In addition, the MAH proposes to revise sections 4.4 and 4.8 of the SmPC to update the safety information based on the Durvalumab Pan-Tumour Pool, a safety dataset comprising of 9 clinical studies building on the existing safety database and summarising the safety information for durvalumab monotherapy characterised across tumour types in the durvalumab clinical program to date. The Package Leaflet is updated in accordance. The RMP version 2 has also been agreed. The MAH also took the opportunity of this group of variations to	23/07/2020	27/08/2020	SmPC and PL	Please refer to Scientific Discussion Imfinzi EMEA/H/C/004771/II/0014/G.

	update the PI in line with QRD template v10.1. The group of variations leads to amendments to the Summary of Product Characteristics and Package Leaflet and to the Risk Management Plan (RMP). C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one				
PSUSA/10723 /201910	Periodic Safety Update EU Single assessment - durvalumab	28/05/2020	27/07/2020	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10723/201910.
IAIN/0021	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	13/05/2020	27/07/2020	SmPC and PL	
IB/0020	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	30/04/2020	n/a		
IB/0018	B.II.b.4.f - Change in the batch size (including batch size ranges) of the finished product - The scale for a biological/immunological medicinal product is increased/decreased without process change (e.g. duplication of line)	29/04/2020	n/a		
IB/0019	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process	16/03/2020	n/a		

	of the AS				
PSUSA/10723 /201904	Periodic Safety Update EU Single assessment - durvalumab	12/12/2019	21/02/2020	SmPC, Annex II and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10723/201904.
IAIN/0015	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	10/12/2019	21/02/2020	SmPC and PL	
IB/0013/G	This was an application for a group of variations. B.II.b.2.z - Change to importer, batch release arrangements and quality control testing of the FP - Other variation B.II.b.2.z - Change to importer, batch release arrangements and quality control testing of the FP - Other variation B.II.b.2.z - Change to importer, batch release arrangements and quality control testing of the FP - Other variation	04/12/2019	n/a		
IB/0012	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	02/12/2019	n/a		
IB/0011	B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	11/10/2019	n/a		
II/0009	B.II.f.1.z - Stability of FP - Change in the shelf-life or storage conditions of the finished product - Other variation	12/09/2019	21/02/2020	SmPC and PL	

PSUSA/10723 /201810	Periodic Safety Update EU Single assessment - durvalumab	16/05/2019	n/a		PRAC Recommendation - maintenance
IAIN/0008	B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing	08/04/2019	21/02/2020	Annex II and PL	
II/0003	B.II.g.2 - Introduction of a post approval change management protocol related to the finished product	07/03/2019	n/a		
IB/0007	B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	28/02/2019	n/a		
IB/0006	B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place	21/02/2019	n/a		
II/0004	B.I.d.1.a.3 - Stability of AS - Change in the re-test period/storage period - Extension of storage period of a biological/immunological AS not in accordance with an approved stability protocol	31/01/2019	n/a		
II/0001	B.II.g.2 - Introduction of a post approval change management protocol related to the finished product	13/12/2018	n/a		
IB/0002	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure	30/11/2018	n/a		

	(including replacement or addition)				