Imraldi

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
IB/0070	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	23/01/2024		SmPC and PL	
IA/0069	B.II.f.1.e - Stability of FP - Change to an approved stability protocol	29/11/2023	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).

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II/0066/G	This was an application for a group of variations. B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method B.I.a.1.j - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Replacement or addition of a site where batch control/testing takes place and any of the test method at the site is a biol/immunol method	19/10/2023	n/a		
IAIN/0068/G	This was an application for a group of variations. 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 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)	09/10/2023	n/a		
PSUSA/10783 /202212	Periodic Safety Update EU Single assessment - adalimumab	31/08/2023	n/a		PRAC Recommendation - maintenance
IB/0067/G	This was an application for a group of variations.	26/07/2023	n/a		

	B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier				
IB/0064	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	28/04/2023	n/a		
IB/0063	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	31/03/2023	n/a		
IB/0062/G	This was an application for a group of variations. B.II.f.1.e - Stability of FP - Change to an approved stability protocol 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	24/03/2023		SmPC	
IA/0061	B.I.d.1.c - Stability of AS - Change in the re-test period/storage period or storage conditions - Change	08/12/2022	n/a		

	to an approved stability protocol				
IA/0060/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites	31/10/2022	31/03/2023	Annex II and PL	
IB/0058	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	18/10/2022	n/a		
IB/0059	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	12/10/2022	n/a		
IB/0056	B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation	08/08/2022	n/a		
IB/0055	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	08/08/2022	n/a		
IB/0054	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	08/08/2022	31/03/2023	SmPC	

IA/0057	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	05/08/2022	n/a		
IB/0051	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	06/07/2022	n/a		
IA/0053/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.I.d.1.c - Stability of AS - Change in the re-test period/storage period or storage conditions - Change to an approved stability protocol	09/06/2022	n/a		
IA/0052	B.II.e.6.b - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that does not affect the product information	24/05/2022	n/a		
R/0050	Renewal of the marketing authorisation.	24/02/2022	29/04/2022	SmPC and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Imraldi in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
II/0048/G	This was an application for a group of variations. B.II.a.5 - Change in concentration of a single-dose, total use parenteral product, where the amount of AS per unit dose (i.e. the strength) remains the	07/04/2022	31/03/2023	SmPC, Labelling and PL	The SmPC, labelling and package leaflet have been updated to reflect the introduction of an additional concentration of 40 mg/0.4 mL (same 40 mg strength) for the solution for subcutaneous injection in pre-filled syringe and pre-filled pen as additional presentations, the change in excipients

	same B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.a.3.b.3 - Changes in the composition (excipients) of the finished product - Other excipients - Change that relates to a biological/immunological product B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes				composition and shelf life and storage conditions for the finished product (12 months when stored at 5 ± 3°C and up to 31 days at 25°C): The additional presentations are packs of: - 1 pre-filled syringe, with 2 alcohol pads (EU/1/17/1216/010) - 2 pre-filled syringes, each with 1 alcohol pad (EU/1/17/1216/011) - 4 pre-filled syringes, each with 1 alcohol pad (EU/1/17/1216/012) - 6 pre-filled syringes, each with 1 alcohol pad (EU/1/17/1216/013) - 1 pre-filled pen, with 2 alcohol pads (EU/1/17/1216/014) - 2 pre-filled pens, each with 1 alcohol pad (EU/1/17/1216/015) - 4 pre-filled pens, each with 1 alcohol pad (EU/1/17/1216/016) - 6 pre-filled pens, each with 1 alcohol pad (EU/1/17/1216/017)
IA/0049	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)	22/11/2021	n/a		
IB/0047	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO	21/06/2021	09/07/2021	SmPC and PL	

	new additional data is required to be submitted by the MAH				
IB/0046/G	This was an application for a group of variations. 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 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 A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient 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) A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	04/05/2021	09/07/2021	SmPC, Annex II and PL	
IA/0045/G	This was an application for a group of variations. B.II.f.1.e - Stability of FP - Change to an approved stability protocol	19/04/2021	n/a		

	B.II.f.1.e - Stability of FP - Change to an approved stability protocol				
IAIN/0044	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	29/03/2021	09/07/2021	SmPC and PL	
IAIN/0043	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	26/03/2021	09/07/2021	Annex II and PL	
IA/0042	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	15/01/2021	n/a		
IB/0041	B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	22/12/2020	n/a		
II/0037/G	This was an application for a group of variations. 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.2.z - Changes in the manufacturing process of the AS - Other variation B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation A.4 - Administrative change - Change in the name	29/10/2020	22/01/2021	Annex II	

	and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient				
IB/0040/G	This was an application for a group of variations. 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 C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	14/10/2020	22/01/2021	SmPC, Annex II and PL	
IAIN/0039	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	09/10/2020	22/01/2021	SmPC and PL	
PSUSA/10783 /201912	Periodic Safety Update EU Single assessment - adalimumab	03/09/2020	n/a		PRAC Recommendation - maintenance

IB/0038	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	29/07/2020	n/a		
IB/0035	B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	27/04/2020	n/a		
IB/0033	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	20/03/2020	n/a		
IB/0034	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	29/01/2020	n/a		
IB/0032	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	18/01/2020	22/01/2021	SmPC	
IB/0031	B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	13/01/2020	n/a		
IB/0030	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	27/11/2019	n/a		

IB/0029	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	26/09/2019	n/a		
IB/0028	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	11/09/2019	n/a		
X/0019/G	This was an application for a group of variations. Annex I_2.(c) Change or addition of a new strength/potency C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	27/06/2019	26/08/2019	SmPC, Labelling and PL	
PSUSA/10589 /201812	Periodic Safety Update EU Single assessment - adalimumab (biosimilars)	11/07/2019	n/a		PRAC Recommendation - maintenance
IB/0027	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	25/06/2019	n/a		
IA/0026	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	06/05/2019	n/a		
IB/0023	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following	17/04/2019	26/08/2019	SmPC and Annex II	

	assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH				
IB/0022	B.II.f.1.d - Stability of FP - Change in storage conditions of the finished product or the diluted/reconstituted product	15/03/2019	26/08/2019	SmPC and PL	
II/0021	B.I.a.2.c - Changes in the manufacturing process of the AS - The change refers to a [-] substance in the manufacture of a biological/immunological substance which may have a significant impact on the medicinal product and is not related to a protocol	14/03/2019	n/a		
IA/0024/G	This was an application for a group of variations. 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) B.II.b.5.a - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits B.II.b.5.a - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits	21/02/2019	n/a		
IB/0020	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference	24/01/2019	12/02/2019	SmPC and PL	

	product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH				
IB/0018	B.I.d.1.b.3 - Stability of AS - Change in the storage conditions - Change in storage conditions of the AS	18/01/2019	n/a		
T/0015	Transfer of Marketing Authorisation	02/10/2018	29/10/2018	SmPC, Labelling and PL	
IB/0017/G	This was an application for a group of variations. C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	11/10/2018	12/02/2019	SmPC and PL	
IB/0014/G	This was an application for a group of variations. C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO	20/08/2018	28/09/2018	SmPC and PL	

	new additional data is required to be submitted by the MAH C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH				
IAIN/0013/G	This was an application for a group of variations. B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes	12/07/2018	28/09/2018	SmPC, Labelling and PL	
PSUSA/10589	Periodic Safety Update EU Single assessment -	12/07/2018	n/a		PRAC Recommendation - maintenance

/201712	adalimumab (biosimilars)				
IAIN/0012/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	06/06/2018	n/a		
II/0005/G	This was an application for a group of variations. 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.j - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Replacement or addition of a site where batch control/testing takes place and any of the test method at the site is a biol/immunol method B.I.a.1.j - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Replacement or addition of a site where batch control/testing takes place and any of the test method at the site is a biol/immunol method	25/05/2018	28/09/2018	Annex II	Annex II.A has been updated as follows: Name and address of the manufacturer(s) of the biological active substance(s) Biogen (Denmark) Manufacturing ApS Biogen Allé 1 3400 Hillerød Denmark

IB/0010	B.IV.1.a.1 - Change of a measuring or administration device - Addition or replacement of a device which is not an integrated part of the primary packaging - Device with CE marking	24/05/2018	28/09/2018	SmPC, Labelling and PL	
II/0007/G	This was an application for a group of variations. B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method	26/04/2018	n/a		
IB/0009/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site 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	23/04/2018	n/a		

II/0004	Submission of an updated RMP version 2.1 in order to indicate changes in the distribution method for the Imraldi Patient Alert Card (PAC)from being included in the Annex IIIA of the Product Information to be provided to patients by healthcare professionals by including the PAC in the physician educational material. The Annexes I, II, IIIA and IIIB of the PI are updated accordingly. 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 new additional data to be submitted by the MAH where significant assessment is required	12/04/2018	28/09/2018	SmPC, Annex II, Labelling and PL	The product information has been updated to change the Patient Alert Card (PAC) distribution; PAC will be given by the HCP and not included in the commercial package.
II/0002/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.d - Replacement or addition of a manufacturing site for the FP - Site which requires an initial or product specific inspection 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 B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP -	08/02/2018	28/09/2018	SmPC, Annex II, Labelling and PL	The Product information has been updated to introduce the new 40mg solution for injection in prefilled pen presentations.

	Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing B.II.e.1.b.2 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Sterile medicinal products and biological/immunological medicinal products B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes				
IB/0006/G	This was an application for a group of variations. C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference	23/01/2018	28/09/2018	SmPC and PL	

	product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH				
IA/0003	A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient	15/12/2017	n/a		
IA/0001	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)	12/09/2017	n/a		