Hefiya

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
WS/2764/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.z - Changes (Safety/Efficacy) of Human and	12/12/2024		SmPC, Labelling and 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).

	Veterinary Medicinal Products - Other variation 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				
WS/2630	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.e.2 - Introduction of a post approval change management protocol related to the AS	11/04/2024	n/a		
WS/2675	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.e.3.z - Change in test procedure for the immediate packaging of the finished product - Other variation	04/04/2024	n/a		
WS/2591/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.13: Submission of the final report from study RABBIT. This is a German registry for the long-term observation of therapy with biologics in adult patients with rheumatoid arthritis.	11/01/2024	n/a		The safety profile of adalimumab is well characterised, and no new safety issues were identified in the 3 category 3 studies. No SmPC updates were necessary.

	C.I.13: Submission of the final report from the British Association of Dermatologists Biologics and Immunomodulators Register (BADBIR). This is a registry to investigate the long-term safety outcomes of psoriasis patients treated with biologic therapy. C.I.13: Submission of the final report from the Inflammatory Bowel Disease Registry (UK-IBD). This registry was used to identify adverse reactions to Hyrimoz in a cohort of inflammatory bowel disease patients managed in a real-world setting. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority				
N/0051	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	18/12/2023	12/08/2024	PL	
IB/0049	B.I.b.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation	02/10/2023	n/a		
IAIN/0048/G	This was an application for a group of variations.	19/09/2023	12/08/2024	Annex II and	

	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.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.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.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.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			PL	

PSUSA/10783 /202212	Periodic Safety Update EU Single assessment - adalimumab	31/08/2023	n/a		PRAC Recommendation - maintenance
IB/0046	B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes	07/08/2023	12/08/2024	SmPC, Labelling and PL	
IB/0045/G	This was an application for a group of variations. 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	26/07/2023	n/a		
IB/0044	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	13/06/2023	n/a		
IG/1628/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.II.e.1.b.3 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Deletion of an immediate packaging container without a complete deletion of a strength or pharmaceutical form	02/06/2023	n/a		
IB/0042	B.II.e.3.b - Change in test procedure for the immediate packaging of the finished product - Other	28/04/2023	n/a		

	changes to a test procedure (including replacement or addition)				
X/0036/G	This was an application for a group of variations. Annex I_2.(c) Change or addition of a new strength/potency 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 same 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.7 - Administrative change - Deletion of manufacturing sites 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.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.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	26/01/2023	31/03/2023	SmPC, Annex II, Labelling and PL	

	B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation B.I.b.2.d - Change in test procedure for AS or starting material/reagent/intermediate - Substantial change to or replacement of a biological/immunological/immunochemical test method or a method using a biological reagent for a biological AS 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 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 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				
IG/1601	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	22/03/2023	n/a		
R/0038	Renewal of the marketing authorisation.	15/12/2022	06/02/2023	SmPC and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Hefiya in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IB/0039	B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	18/10/2022	n/a		
N/0037	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	15/07/2022	06/02/2023	PL	
IG/1480	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)	02/02/2022	n/a		
IB/0034	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing	20/10/2021	n/a		

	authorisation, including the RMP - Other variation				
IB/0033	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	01/10/2021	19/10/2021	SmPC and PL	
WS/1908/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation B.I.b.2.d - Change in test procedure for AS or starting material/reagent/intermediate - Substantial change to or replacement of a biological/immunological/immunochemical test method or a method using a biological reagent for a biological AS B.II.d.1.c - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method	22/07/2021	n/a		
IB/0031	B.II.f.1.d - Stability of FP - Change in storage conditions of the finished product or the diluted/reconstituted product	08/06/2021	19/10/2021	SmPC, Labelling and PL	Type IB (B.II.f.1.d) - Removal of the 'do not shake' warning from the PI. Article 61(3) notifications - Update of local representatives

					list included in the patient information leaflet.
IG/1400/G	This was an application for a group of variations. B.III.2.b - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier	31/05/2021	n/a		
WS/2025	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	09/04/2021	n/a		
IG/1380	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	26/03/2021	19/10/2021	SmPC and PL	
IB/0027	B.IV.1.z - Change of a measuring or administration device - Other variation	11/11/2020	n/a		
IG/1290	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	05/10/2020	19/02/2021	SmPC and PL	
PSUSA/10783 /201912	Periodic Safety Update EU Single assessment - adalimumab	03/09/2020	n/a		PRAC Recommendation - maintenance

IG/1288	B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits	27/08/2020	n/a		
IB/0023	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	20/07/2020	19/02/2021	SmPC and PL	
IB/0021/G	This was an application for a group of variations. B.I.a.3.e - Change in batch size (including batch size ranges) of AS or intermediate - The scale for a biological/immunological AS is increased/decreased without process change (e.g. duplication of line) 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	17/06/2020	n/a		
IA/0022	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	08/06/2020	n/a		
X/0013	Annex I_2.(c) Change or addition of a new strength/potency	30/01/2020	27/03/2020	SmPC, Annex II, Labelling and PL	
IG/1190/G	This was an application for a group of variations.	26/03/2020	n/a		

	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.c - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test				
WS/1765	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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	05/03/2020	19/02/2021	SmPC	
IB/0017	B.II.f.1.z - Stability of FP - Change in the shelf-life or storage conditions of the finished product - Other variation	10/12/2019	n/a		
IA/0016/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) A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites	26/09/2019	n/a		

	(excluding manufacturer for batch release)				
WS/1643/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation B.I.a.4.a - Change to in-process tests or limits applied during the manufacture of the AS - Tightening of in-process limits B.I.a.4.b - Change to in-process tests or limits applied during the manufacture of the AS - Addition of a new in-process test and limits	19/09/2019	n/a		
N/0015	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	30/08/2019	27/03/2020	Labelling	
IA/0014	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	31/07/2019	n/a		
PSUSA/10589 /201812	Periodic Safety Update EU Single assessment - adalimumab (biosimilars)	11/07/2019	n/a		PRAC Recommendation - maintenance
IA/0011	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	11/06/2019	n/a		

IB/0010/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 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	23/05/2019	08/07/2019	SmPC and PL	
WS/1565	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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	28/03/2019	08/07/2019	SmPC, Annex II, Labelling and PL	

IB/0007/G	This was an application for a group of variations. B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation B.I.a.4.a - Change to in-process tests or limits applied during the manufacture of the AS - Tightening of in-process limits 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.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.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method B.I.b.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation	21/03/2019	n/a		
IB/0006	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	19/02/2019	08/07/2019	SmPC	
WS/1479/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.	17/01/2019	n/a		

	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.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.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				
IAIN/0005/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	20/12/2018	n/a		
IB/0004	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	27/11/2018	n/a		
IAIN/0003	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	14/11/2018	n/a		

IB/0002/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	15/10/2018	08/07/2019	SmPC, Annex II, Labelling and PL	