



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## Yuflyma

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification <sup>1</sup> issued on	Commission Decision Issued <sup>2</sup> / amended on	Product Information affected <sup>3</sup>	Summary
IB/0045	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	09/12/2024		SmPC and PL	
IB/0044	B.I.b.1.z - Change in the specification parameters	08/11/2024	n/a		

<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).



	and/or limits of an AS, starting material/intermediate/reagent - Other variation				
IB/0039/G	<p>This was an application for a group of variations.</p> <p>B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)</p> <p>B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)</p>	16/10/2024	n/a		
IB/0041	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	14/10/2024		SmPC and PL	
IB/0040/G	<p>This was an application for a group of variations.</p> <p>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</p> <p>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</p>	20/09/2024		SmPC, Labelling and PL	
N/0037	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	25/07/2024	25/09/2024	PL	

II/0035/G	<p>This was an application for a group of variations.</p> <p>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</p> <p>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</p>	30/05/2024	n/a		
IB/0038	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	29/05/2024	n/a		
IB/0036	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	27/03/2024	25/09/2024	SmPC	
IB/0034	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	27/02/2024	n/a		
IB/0033	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	29/01/2024	n/a		

N/0032	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	11/01/2024	25/09/2024	PL	
X/0022	Annex I_2.(c) Change or addition of a new strength/potency	14/09/2023	15/11/2023	SmPC, Labelling and PL	
IB/0031	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	04/10/2023	25/09/2024	PL	
IB/0030	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	07/09/2023	n/a		
IB/0029	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	06/09/2023	n/a		
PSUSA/10783 /202212	Periodic Safety Update EU Single assessment - adalimumab	31/08/2023	n/a		PRAC Recommendation - maintenance
IAIN/0028/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 -	17/07/2023	15/11/2023	Annex II and PL	

	Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing 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				
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	28/04/2023	n/a		
IA/0026	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)	11/04/2023	n/a		
IB/0020/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.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.b.2 - Stability of FP - Extension of the shelf life of the finished product - After first opening (supported by real time data)	25/01/2023	20/02/2023	SmPC and PL	Product information SmPC section 6.3 is updated to reflect the shelf-life extension of the finished product Yuflyma 80 mg/0.8 mL (EU/1/20/1513/013-015) as packaged for sale from 30 months to 3 years when stored at 2 - 8°C. Product information SmPC section 6.4 and PIL section 5 updated to reflect shelf-life extension of the finished product Yuflyma 80 mg/0.8 mL after first opening from 30 days to 31 days when stored at 25 °C.

IAIN/0023	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	20/01/2023	n/a		
IAIN/0021	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	13/01/2023	n/a		
IB/0019/G	<p>This was an application for a group of variations.</p> <p>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</p> <p>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</p> <p>B.II.d.1.d - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter</p> <p>B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)</p> <p>B.II.d.2.b - Change in test procedure for the finished product - Deletion of a test procedure if an alternative method is already authorised</p>	31/08/2022	n/a		
IB/0018	B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological	28/07/2022	20/02/2023	SmPC, Labelling and	

	medicinal product in accordance with an approved stability protocol			PL	
IB/0016	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	27/06/2022	n/a		
IA/0017	B.I.c.z - Container closure system of the AS - Other variation	22/06/2022	n/a		
IB/0015/G	This was an application for a group of variations.  B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	13/06/2022	n/a		
IA/0014/G	This was an application for a group of variations.  B.I.c.2.b - Change in the specification parameters and/or limits of the immediate packaging of the AS - Addition of a new specification parameter to the specification with its corresponding test method 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	14/03/2022	n/a		
IB/0013	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	11/03/2022	20/02/2023	SmPC and PL	

	stability protocol				
IB/0012	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	03/03/2022	n/a		
IA/0011/G	<p>This was an application for a group of variations.</p> <p>B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure</p> <p>B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)</p> <p>B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)</p> <p>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</p> <p>B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS</p> <p>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</p>	18/02/2022	n/a		



X/0005	<p>Extension application to introduce a new strengths of 80 mg solution for injection.</p> <p>Version 1.1 of the RMP has also been submitted.</p> <p>Annex I_2.(c) Change or addition of a new strength/potency</p>	16/12/2021	16/02/2022	SmPC, Labelling and PL	
II/0009/G	<p>This was an application for a group of variations.</p> <p>B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site</p> <p>B.II.b.2.z - Change to importer, batch release arrangements and quality control testing of the FP - Other variation</p> <p>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</p> <p>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</p>	20/01/2022	n/a		
IB/0010	B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological	01/12/2021	16/02/2022	SmPC and PL	To extend the shelf-life of the finished product Yuflyma, 40 mg, Solution for Injection and include editorial changes in

	medicinal product in accordance with an approved stability protocol				the PI and Annex A.
N/0008	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	11/10/2021	16/02/2022	Labelling and PL	
IB/0007	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	13/07/2021	n/a		
II/0002	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	01/07/2021	n/a		
IAIN/0006/G	<p>This was an application for a group of variations.</p> <p>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</p> <p>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</p>	04/06/2021	16/02/2022	Annex II and PL	
IB/0004	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following	29/04/2021	19/05/2021	SmPC, Labelling and	

	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			PL	
IAIN/0003	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	06/04/2021	19/05/2021	SmPC and PL	
IAIN/0001	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	24/03/2021	n/a		