



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Alymsys

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/0038	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)	14/11/2024	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).



IB/0037	B.I.e.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	23/09/2024	n/a		
IB/0036/G	This was an application for a group of variations. B.II.z - Quality change - Finished product - Other variation B.I.z - Quality change - Active substance - Other variation	09/08/2024	n/a		
IB/0035	B.I.e.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	17/07/2024	n/a		
IAIN/0034	A.1 - Administrative change - Change in the name and/or address of the MAH	17/04/2024	17/04/2025	SmPC, Annex II, Labelling and PL	
IB/0030	B.I.e.4.b - Changes to an approved change management protocol - Minor changes that do not change the strategy defined in the protocol	28/02/2024	n/a		
IB/0032	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	01/02/2024	n/a		
IB/0026	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	22/12/2023	n/a		

N/0031	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	20/12/2023	17/04/2025	PL	
IB/0029/G	This was an application for a group of variations. B.III.2.a.2 - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Excipient/AS starting material B.I.b.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation 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.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)	04/12/2023	n/a		
IB/0027	B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place	09/11/2023	n/a		
IA/0028	A.7 - Administrative change - Deletion of manufacturing sites	31/10/2023	n/a		

II/0022	B.I.e.2 - Introduction of a post approval change management protocol related to the AS	14/09/2023	n/a		
IB/0024/G	This was an application for a group of variations. B.I.b.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	11/07/2023	n/a		

	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure				
IB/0023	B.I.e.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	28/06/2023	n/a		
IB/0025	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	27/06/2023	24/07/2023	SmPC and PL	
IB/0020	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	18/04/2023	24/07/2023	SmPC	Product information section 6.3 is updated to reflect the shelf-life extension of the finished product Almysys 25 mg/mL concentrate for solution for infusion (EU/1/20/1509/001-002) as packaged for sale from 30 months to 36 months when stored at 5 °C ± 3 °C and kept in the outer carton.
IB/0021	B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation	21/03/2023	n/a		
PSUSA/403/202202	Periodic Safety Update EU Single assessment - bevacizumab	13/10/2022	12/12/2022	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/403/202202.
IB/0019/G	This was an application for a group of variations. B.I.e.5.c - Implementation of changes foreseen in an	17/10/2022	n/a		

	approved change management protocol - For a biological/immunological medicinal product B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product				
IB/0018/G	This was an application for a group of variations. B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure 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.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation	27/09/2022	n/a		
IB/0017/G	This was an application for a group of variations. 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) B.III.2.a.2 - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Excipient/AS starting material B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-	24/08/2022	n/a		

	significant specification parameter (e.g. deletion of an obsolete parameter) B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation				
IB/0016	B.II.g.4.b - Changes to an approved change management protocol - Minor changes that do not change the strategy defined in the protocol	08/08/2022	n/a		
IB/0014	B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation	19/07/2022	n/a		
IB/0013/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 A.6 - Administrative change - Change in ATC Code/ATC Vet Code	05/07/2022	12/12/2022	SmPC and PL	C.I.2.a – To update sections 4.2 and 6.6 of the SmPC to reinstate the statement “do not shake”.
IA/0015	A.7 - Administrative change - Deletion of manufacturing sites	30/06/2022	n/a		
II/0010	B.I.e.2 - Introduction of a post approval change management protocol related to the AS	16/06/2022	n/a		
IA/0012/G	This was an application for a group of variations.	08/06/2022	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.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 B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier				
II/0007/G	This was an application for a group of variations. B.I.e.2 - Introduction of a post approval change management protocol related to the AS B.II.g.2 - Introduction of a post approval change management protocol related to the finished product	24/03/2022	n/a		
IA/0009	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	07/02/2022	n/a		
II/0005	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	13/01/2022	n/a		
IAIN/0008	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	11/01/2022	n/a		

N/0006	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	15/12/2021	29/06/2022	PL	
II/0004/G	This was an application for a group of variations. B.II.b.4.c - Change in the batch size (including batch size ranges) of the finished product - The change requires assessment of the comparability of a biological/immunological medicinal product or a new bioequivalence study B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	16/09/2021	n/a		
IB/0002	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	08/07/2021	29/06/2022	SmPC and PL	
IB/0003	B.I.e.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	07/07/2021	n/a		
IAIN/0001	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	18/05/2021	n/a		