# 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 |
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| IAIN/0034 | A.1 - Administrative change - Change in the name and/or address of the MAH | 17/04/2024 | | 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 | 28/02/2024 | 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).

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| | change the strategy defined in the protocol | | | | |
| 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 | | PL | |
| IB/0029/G | This was an application for a group of variations.<br><br>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<br>B.I.b.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation<br>B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation<br>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 | 04/12/2023 | n/a | | |

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| | an obsolete parameter) | | | | |
| 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.<br><br>B.I.b.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation<br>B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure<br>B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure<br>B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure<br>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 | | |

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| | B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure<br>B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure<br>B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure<br>B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure<br>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 Alymsys 25 mg/mL concentrate for solution for infusion (EU/1/20/1509/001-002) as packaged for sale from 30 |

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| | | | | | months to 36 months when stored at 5 ºC ± 3 ºC 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.<br><br>B.I.e.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product<br>B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product | 17/10/2022 | n/a | | |
| IB/0018/G | This was an application for a group of variations.<br><br>B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure<br>B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation<br>B.I.b.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation | 27/09/2022 | n/a | | |

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| IB/0017/G | This was an application for a group of variations.<br><br>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)<br>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<br>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)<br>B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation | 24/08/2022 | n/a | | |
| 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.<br><br>C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following | 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". |

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| | 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<br>A.6 - Administrative change - Change in ATC Code/ATC Vet Code | | | | |
| 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.<br><br>B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier<br>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<br>B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier | 08/06/2022 | n/a | | |
| II/0007/G | This was an application for a group of variations.<br><br>B.I.e.2 - Introduction of a post approval change management protocol related to the AS<br>B.II.g.2 - Introduction of a post approval change | 24/03/2022 | n/a | | |

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| | management protocol related to the finished product | | | | |
| 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.<br><br>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<br>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 | 08/07/2021 | 29/06/2022 | SmPC and PL | |

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| | 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 | | | | |
| 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 | | |