



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## Hukyndra

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 |
|--------------------|--|--|--|---|---------|
| X/0026             | Annex I_2.(c) Change or addition of a new strength/potency   | 17/10/2024                                   | 12/12/2024   | SmPC, Labelling and PL                    |         |
| IA/0029/G          | This was an application for a group of variations.<br><br>B.II.d.2.a - Change in test procedure for the finished | 02/12/2024                                   | 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).



|           |  |            |            |                        |  |
|-----------|--|------------|------------|------------------------|--|
|           | <p>product - Minor changes to an approved test procedure</p> <p>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</p> <p>B.II.e.3.a - Change in test procedure for the immediate packaging of the finished product - Minor changes to an approved test procedure</p>                            |            |            |                        |  |
| IB/0028   | <p>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</p>  | 14/10/2024 | 12/12/2024 | SmPC and PL            |  |
| IB/0027/G | <p>This was an application for a group of variations.</p> <p>B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product</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> | 13/09/2024 | 12/12/2024 | SmPC, Labelling and PL |  |
| IAIN/0025 | <p>B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site</p>  | 05/06/2024 | n/a        |                        |  |

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|-----------|---|------------|------------|-------------|--|
| IB/0024   | B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation  | 04/04/2024 | n/a        |             |  |
| IB/0023   | B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation  | 04/04/2024 | n/a        |             |  |
| IA/0022/G | <p>This was an application for a group of variations.</p> <p>B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure</p> <p>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</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> | 15/03/2024 | n/a        |             |  |
| IB/0021   | 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   | 19/02/2024 | 12/12/2024 | SmPC and PL |  |
| WS/2625   | <p>This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.</p> <p>B.II.g.2 - Introduction of a post approval change management protocol related to the finished product</p>   | 08/02/2024 | n/a        |             |  |
| IB/0019/G | This was an application for a group of variations.  | 15/12/2023 | n/a        |             |  |

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|-----------|--|------------|------------|-------------|--|
|           | <p>B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation</p> <p>B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation</p>  |            |            |             |  |
| IB/0018/G | <p>This was an application for a group of variations.</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> <p>B.II.f.1.d - Stability of FP - Change in storage conditions of the finished product or the diluted/reconstituted product</p>   | 11/12/2023 | 12/12/2024 | SmPC and PL |  |
| IB/0017/G | <p>This was an application for a group of variations.</p> <p>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)</p> <p>B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation</p> <p>B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process</p> <p>B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process</p> <p>B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in</p> | 04/12/2023 | n/a        |             |  |

|                     |  |            |     |  |                                   |
|---------------------|--|------------|-----|--|-----------------------------------|
|                     | the manufacturing process  |            |     |  |                                   |
| IB/0016             | B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation   | 23/11/2023 | n/a |  |                                   |
| IA/0015             | B.II.f.1.e - Stability of FP - Change to an approved stability protocol  | 20/10/2023 | n/a |  |                                   |
| IA/0014/G           | This was an application for a group of variations.<br><br>B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure<br>B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure   | 20/10/2023 | n/a |  |                                   |
| IB/0013             | B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process   | 13/09/2023 | n/a |  |                                   |
| PSUSA/10783 /202212 | Periodic Safety Update EU Single assessment - adalimumab   | 31/08/2023 | n/a |  | PRAC Recommendation - maintenance |
| IB/0012/G           | This was an application for a group of variations.<br><br>B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process<br>B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size | 06/07/2023 | n/a |  |                                   |

|             |  |            |            |                       |  |
|-------------|--|------------|------------|-----------------------|--|
|             | B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size<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   |            |            |                       |  |
| IB/0010     | 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   | 05/04/2023 | n/a        |                       |  |
| N/0009      | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)   | 09/03/2023 | 17/07/2023 | PL                    |  |
| IAIN/0008/G | This was an application for a group of variations.<br><br>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<br>B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site | 13/01/2023 | 17/07/2023 | SmPC, Annex II and PL |  |
| IB/0006/G   | This was an application for a group of variations.<br><br>B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size   | 14/12/2022 | n/a        |                       |  |

|           |   |            |            |                       |  |
|-----------|---|------------|------------|-----------------------|--|
|           | B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation   |            |            |                       |  |
| IA/0007   | B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure   | 12/12/2022 | n/a        |                       |  |
| IB/0005   | 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)   | 23/09/2022 | n/a        |                       |  |
| IAIN/0004 | 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  | 28/07/2022 | 17/07/2023 | SmPC, Annex II and PL |  |
| IA/0003/G | <p>This was an application for a group of variations.</p> <p>B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure</p> <p>B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure</p> <p>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</p> | 25/05/2022 | n/a        |                       |  |

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|-----------|---|------------|-----|--|--|
| IA/0002/G | <p>This was an application for a group of variations.</p> <p>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</p> <p>B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure</p> | 25/04/2022 | n/a |  |  |
| WS/2238   | <p>This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.</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>  | 22/04/2022 | n/a |  |  |