



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## Azacitidine Mylan

Procedural steps taken and scientific information after the authorisation

| Application number | Scope                                   | Opinion/<br>Notification <sup>1</sup> issued on | Commission Decision Issued <sup>2</sup> / amended on | Product Information affected <sup>3</sup> | Summary                                                                                                                                                                                                                                                                         |
|--------------------|-----------------------------------------|-------------------------------------------------|------------------------------------------------------|-------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| R/0019             | Renewal of the marketing authorisation. | 19/09/2024                                      | 29/11/2024                                           | SmPC, Annex II, Labelling and PL          | Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Azacitidine Mylan in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity. |

<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).



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| II/0020   | B.II.b.4.d - Change in the batch size (including batch size ranges) of the finished product - The change relates to all other pharmaceutical forms manufactured by complex manufacturing processes                 | 12/09/2024 | n/a        |             |  |
| IA/0018   | 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)                   | 25/04/2024 | n/a        |             |  |
| IAIN/0017 | C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation                                                                                                                     | 09/01/2024 | 29/11/2024 | SmPC and PL |  |
| IB/0016   | B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)                                                                          | 05/10/2023 | 29/11/2024 | SmPC and PL |  |
| II/0014   | 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                     | 25/05/2023 | n/a        |             |  |
| IA/0015   | 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                                         | 13/04/2023 | n/a        |             |  |
| IA/0013/G | This was an application for a group of variations.<br><br>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 | 03/03/2023 | n/a        |             |  |

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|             | <p>intermediate used in the manufacture of the AS or manufacturer of a novel excipient</p> <p>B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size</p> <p>B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits</p> |            |            |                 |  |
| IB/0011     | 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                                                                                                                                                                 | 17/02/2023 | 29/06/2023 | SmPC and PL     |  |
| IB/0012     | B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process                                                                                                                                                                                                                                                                                         | 13/02/2023 | n/a        |                 |  |
| IB/0010     | 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                                                                                                                                                                 | 24/06/2022 | 29/06/2023 | SmPC and PL     |  |
| IAIN/0009/G | <p>This was an application for a group of variations.</p> <p>B.II.b.2.a - Change to importer, batch release</p>                                                                                                                                                                                                                                                                                                              | 30/03/2022 | 08/07/2022 | Annex II and PL |  |

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|           | <p>arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place</p> <p>A.7 - Administrative change - Deletion of manufacturing sites</p> <p>B.II.b.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - 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> <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> |            |     |  |  |
| IB/0008/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.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation</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>                                                                                                                                                            | 04/01/2022 | n/a |  |  |

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| IA/0007   | B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 18/10/2021 | n/a        |             |  |
| IB/0006   | B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 14/10/2021 | n/a        |             |  |
| IB/0005/G | <p>This was an application for a group of variations.</p> <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> <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> | 23/07/2021 | 08/07/2022 | SmPC and PL |  |
| IB/0003   | 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                                                                                                                                                                                                                                                                                                                                                                                                                                        | 26/03/2021 | n/a        |             |  |
| IB/0004   | B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 16/03/2021 | n/a        |             |  |

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| IAIN/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.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 11/01/2021 | n/a        |                            |  |
| IAIN/0001/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.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.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.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 -</p> | 21/08/2020 | 12/08/2021 | Annex II, Labelling and PL |  |

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|--|-------------------------------------|--|--|--|--|
|  | Not including batch control/testing |  |  |  |  |
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