# Palynziq

## 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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| IB/0028/G | This was an application for a group of variations.<br><br>B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product<br>B.II.b.1.a - Replacement or addition of a | 07/06/2022 | | SmPC | |

[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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| | manufacturing site for the FP - Secondary packaging site<br>B.II.e.1.z - Change in immediate packaging of the finished product - Other variation | | | | |
| IB/0027 | C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation | 30/05/2022 | n/a | | |
| IB/0025 | B.I.z - Quality change - Active substance - Other variation | 19/04/2022 | n/a | | |
| PSUSA/10761 /202105 | Periodic Safety Update EU Single assessment - pegvaliase | 27/01/2022 | 24/03/2022 | SmPC and PL | Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10761/202105. |
| IB/0026 | B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits | 21/02/2022 | n/a | | |
| IB/0023 | B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation | 02/12/2021 | n/a | | |
| II/0024 | B.II.g.2 - Introduction of a post approval change management protocol related to the finished product | 25/11/2021 | n/a | | |
| II/0019 | B.I.e.1.a - Introduction of a new design space or extension of an approved design space for the AS - One unit operation in the manufacturing process of the AS including the resulting IPCs and/or test | 02/09/2021 | n/a | | |

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| | procedures | | | | |
| PSUSA/10761 /202011 | Periodic Safety Update EU Single assessment - pegvaliase | 24/06/2021 | 18/08/2021 | SmPC and PL | Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10761/202011. |
| IB/0020/G | This was an application for a group of variations.<br><br>B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS<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.c - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure for a reagent, which does not have a significant effect on the overall quality of the AS | 05/08/2021 | n/a | | |
| IB/0021 | B.I.e.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product | 02/08/2021 | n/a | | |
| II/0017 | B.I.a.1.e (Type II): to introduce an additional site responsible for the preparation, testing and storage of the WCB.<br><br>B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a | 15/04/2021 | n/a | | |

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| | biological/immunological product | | | | |
| PSUSA/10761 /202005 | Periodic Safety Update EU Single assessment - pegvaliase | 28/01/2021 | 26/03/2021 | SmPC | Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10761/202005. |
| II/0014 | B.I.e.2 - Introduction of a post approval change management protocol related to the AS | 04/02/2021 | n/a | | |
| II/0015 | Submission of the final report from the non-clinical study BMN-165-18-080 listed as a category 3 study in the RMP.<br><br>C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority | 10/12/2020 | n/a | | |
| IB/0013/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.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product | 30/09/2020 | n/a | | |
| IB/0011/G | This was an application for a group of variations.<br><br>A.7 - Administrative change - Deletion of manufacturing sites<br>B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - | 14/09/2020 | n/a | | |

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| | Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place<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.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<br>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<br>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 | | | | |
| II/0007/G | This was an application for a group of variations.<br><br>Update of sections 4.4, 4.8 and 5.1 of the SmPC based on final results from studies 1655-003, a long-term extension of a Phase 2, open-label, dose-finding study and 165-302 a Phase 3, randomised, | 03/09/2020 | 26/03/2021 | SmPC | During long-term pegvaliase treatment, sustained clinically meaningful blood phenylalanine lowering effect was observed; and most adverse events rates decreased. |

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| | double-blind, placebo-controlled, four-arm, discontinuation study which are listed in the RMP as category 3 studies. The RMP version 2.0 has also been submitted.<br><br>C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data<br>C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data | | | | |
| PSUSA/10761 /201911 | Periodic Safety Update EU Single assessment - pegvaliase | 11/06/2020 | n/a | | PRAC Recommendation - maintenance |
| IB/0010 | B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation | 02/06/2020 | n/a | | |
| IB/0009/G | This was an application for a group of variations.<br><br>B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS<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.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process | 04/05/2020 | n/a | | |

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| | of the AS<br>B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS | | | | |
| II/0002 | B.II.g.2 - Introduction of a post approval change management protocol related to the finished product | 16/01/2020 | n/a | | |
| PSUSA/10761 /201905 | Periodic Safety Update EU Single assessment - pegvaliase | 16/01/2020 | n/a | | PRAC Recommendation - maintenance |
| IG/1141 | 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 | 12/12/2019 | n/a | | |
| IAIN/0006/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 intermediate used in the manufacture of the AS or manufacturer of a novel excipient<br>B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site | 11/12/2019 | n/a | | |
| IB/0004 | 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 | 07/11/2019 | n/a | | |

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| | data | | | | |
| IB/0003 | 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 | 08/10/2019 | n/a | | |