# PHEBURANE

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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| X/0035 | Annex I_2.(c) Change or addition of a new strength/potency<br>Annex I_2.(d) Change or addition of a new pharmaceutical form | 14/09/2023 | 23/11/2023 | SmPC, Labelling and PL | |

[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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| IB/0036/G | This was an application for a group of variations.<br><br>B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits<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.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF | 06/07/2023 | n/a | | |
| PSUSA/2758/ 202112 | Periodic Safety Update EU Single assessment - sodium phenylbutyrate | 01/09/2022 | n/a | | PRAC Recommendation - maintenance |
| IA/0033 | A.7 - Administrative change - Deletion of manufacturing sites | 10/12/2021 | 28/03/2022 | Annex II and PL | |
| IA/0032 | A.7 - Administrative change - Deletion of manufacturing sites | 30/08/2021 | n/a | | |
| IA/0031/G | This was an application for a group of variations.<br><br>A.7 - Administrative change - Deletion of manufacturing sites<br>A.7 - Administrative change - Deletion of manufacturing sites | 02/08/2021 | n/a | | |

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| IB/0030/G | This was an application for a group of variations.<br><br>B.IV.1.a.1 - Change of a measuring or administration device - Addition or replacement of a device which is not an integrated part of the primary packaging - Device with CE marking<br>C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation | 23/03/2021 | 28/03/2022 | SmPC, Labelling and PL | |
| N/0029 | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 28/09/2020 | 28/03/2022 | PL | |
| IAIN/0027 | B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site | 13/05/2020 | n/a | | |
| II/0025 | B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range | 28/11/2019 | n/a | | |
| PSUSA/2758/ 201812 | Periodic Safety Update EU Single assessment - sodium phenylbutyrate | 05/09/2019 | n/a | | PRAC Recommendation - maintenance |
| N/0024 | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 30/08/2019 | 12/06/2020 | PL | |
| IA/0023/G | This was an application for a group of variations.<br><br>B.II.e.1.a.1 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Solid pharmaceutical forms | 30/08/2019 | n/a | | |

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| | 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.a.3.b.1 - Changes in the composition (excipients) of the finished product - Other excipients - Any minor adjustment of the quantitative composition of the finished product with respect to excipients | | | | |
| IG/1105/G | This was an application for a group of variations.<br><br>B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site<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 | 06/06/2019 | 12/06/2020 | Annex II and PL | |
| II/0019 | B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation | 21/02/2019 | n/a | | |
| T/0020 | Transfer of Marketing Authorisation | 25/10/2018 | 26/11/2018 | SmPC, Labelling and PL | |
| IA/0018 | B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process | 03/08/2018 | n/a | | |

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| R/0017 | Renewal of the marketing authorisation. | 25/01/2018 | 21/03/2018 | 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 Pheburane in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity. |
| IB/0016 | B.II.f.1.d - Stability of FP - Change in storage conditions of the finished product or the diluted/reconstituted product | 20/07/2017 | 21/03/2018 | SmPC, Labelling and PL | |
| IB/0015 | B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation | 13/06/2017 | n/a | | |
| II/0014 | B.I.a.1.b - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Introduction of a manufacturer of the AS supported by an ASMF | 02/02/2017 | n/a | | |
| PSUSA/2758/ 201512 | Periodic Safety Update EU Single assessment - sodium phenylbutyrate | 02/09/2016 | n/a | | PRAC Recommendation - maintenance |
| IAIN/0013 | C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation | 09/06/2016 | 22/05/2017 | SmPC, Labelling and PL | |
| II/0009/G | This was an application for a group of variations.<br><br>B.I.b.1.f - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Change outside the approved specifications limits range for the AS | 01/04/2016 | n/a | | |

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| | B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range | | | | |
| II/0011/G | This was an application for a group of variations.<br><br>B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range<br>B.II.d.2.z - Change in test procedure for the finished product - Other variation | 25/02/2016 | n/a | | |
| IB/0010 | 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 data | 04/12/2015 | n/a | | |
| IG/0560 | C.I.8.a - Introduction of or changes to a summary of Pharmacovigilance system - Changes in QPPV (including contact details) and/or changes in the PSMF location | 20/05/2015 | n/a | | |
| IAIN/0006/G | This was an application for a group of variations.<br><br>B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site<br>B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site | 16/03/2015 | n/a | | |

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| IG/0509 | C.I.8.a - Introduction of or changes to a summary of Pharmacovigilance system - Changes in QPPV (including contact details) and/or changes in the PSMF location | 28/11/2014 | n/a | | |
| IB/0003 | B.II.f.1.z - Stability of FP - Change in the shelf-life or storage conditions of the finished product - Other variation | 09/12/2013 | 01/09/2014 | SmPC | |
| N/0004 | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 27/11/2013 | 01/09/2014 | PL | |
| IAIN/0002 | B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site | 10/09/2013 | n/a | | |
| IAIN/0001 | 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 | 10/09/2013 | 01/09/2014 | Annex II and PL | |