



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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
IB/0041	B.II.a.3.a.1 - Changes in the composition (excipients) of the finished product - Changes in components of the flavouring or colouring system - Addition , deletion or replacement	17/12/2024		SmPC, Labelling and PL	
N/0040	Minor change in labelling or package leaflet not	30/09/2024		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).



	connected with the SPC (Art. 61.3 Notification)				
IB/0039	B.II.e.7.z. - Change in supplier of packaging components or devices (when mentioned in the dossier) - Other variation	13/09/2024	n/a		
IB/0038	B.II.b.4.z - Change in the batch size (including batch size ranges) of the finished product - Other variation	04/06/2024	n/a		
X/0035	Annex I_2.(c) Change or addition of a new strength/potency Annex I_2.(d) Change or addition of a new pharmaceutical form	14/09/2023	23/11/2023	SmPC, Labelling and PL	
IB/0036/G	This was an application for a group of variations. B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits 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) 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. A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites	02/08/2021	n/a		
IB/0030/G	This was an application for a group of variations. 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 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. B.II.e.1.a.1 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Solid pharmaceutical forms 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 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	30/08/2019	n/a		
IG/1105/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site 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		
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. 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 B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	01/04/2016	n/a		
II/0011/G	This was an application for a group of variations. B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range 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. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site	16/03/2015	n/a		
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	

