Slenyto

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
II/0028	Extension of indication to include treatment of insomnia in children and adolescents aged 6-17 with Attention-Deficit Hyperactivity Disorder (ADHD), where sleep hygiene measures have been insufficient, based on results from phase III study NEU_CH_7911 and literature. As a consequence,	30/01/2025	17/03/2025	SmPC and PL	Please refer to the Scientific Discussion 'Slenyto H-C-4425-II-28'.

[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).

	sections 4.1, 4.2 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.2 of the RMP has also been approved. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one				
II/0025	Extension of indication to include treatment of neurogenetic disorders (e.g., Angelman syndrome, Rett syndrome, Tuberous sclerosis complex and Williams syndrome) for SLENYTO, based on Phase III study NEU_CH_7911, post-marketing data and literature; As a consequence, sections 4.1 and 4.8 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 2.0 of the RMP has also been submitted. As part of the application the MAH is requesting a 1-year extension of the market protection. The variation leads to amendments to the Summary of Product Characteristics and Package Leaflet and to the Risk Management Plan (RMP). C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	25/07/2024	26/08/2024	SmPC and PL	Please refer to Scientific Discussion 'Slenyto-H-C-4425-II-25'
PSUSA/1963/ 202309	Periodic Safety Update EU Single assessment - melatonin	16/05/2024	n/a		PRAC Recommendation - maintenance
N/0027	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	16/02/2024	22/07/2024	PL	

N/0024	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	24/11/2023	22/07/2024	PL	
IB/0022/G	This was an application for a group of variations. B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	15/08/2023	n/a		
IAIN/0023	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	13/07/2023	22/07/2024	Annex II and PL	
R/0021	Renewal of the marketing authorisation.	30/03/2023	05/06/2023	SmPC, Labelling and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Slenyto in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IA/0020/G	This was an application for a group of variations. 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 A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder	25/10/2022	n/a		

	or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient				
PSUSA/1963/ 202009	Periodic Safety Update EU Single assessment - melatonin	10/06/2021	n/a		PRAC Recommendation - maintenance
II/0017	The update of the product information to reflect information from children treated with Circadin during the French RTU program and the known safety profile of Circadin authorised for adults. C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	18/02/2021	02/06/2022	SmPC, Annex II and PL	The Product Information is updated to reflect relevant information from paediatric French program and the known safety profile of Circadin in adults. For more information, please refer to the Summary of Product Characteristics.
IB/0018	B.I.e.5.b - Implementation of changes foreseen in an approved change management protocol - Requires further supportive data	03/11/2020	n/a		
IA/0016	B.II.e.1.b.3 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Deletion of an immediate packaging container without a complete deletion of a strength or pharmaceutical form	26/05/2020	21/04/2021	SmPC, Labelling and PL	
IB/0015	B.II.f.1.z - Stability of FP - Change in the shelf-life or storage conditions of the finished product - Other variation	13/03/2020	21/04/2021	SmPC	
IB/0014	B.I.e.4.b - Changes to an approved change management protocol - Minor changes that do not change the strategy defined in the protocol	13/03/2020	n/a		

II/0010	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	31/10/2019	n/a		
IB/0012	B.II.f.1.z - Stability of FP - Change in the shelf-life or storage conditions of the finished product - Other variation	22/08/2019	24/02/2020	SmPC	
N/0011	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	11/06/2019	24/02/2020	PL	
IB/0009/G	This was an application for a group of variations. B.II.b.1.e - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products 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 B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.b.4.z - Change in the batch size (including batch size ranges) of the finished product - Other variation	03/06/2019	n/a		
IB/0008/G	This was an application for a group of variations. B.II.b.1.e - Replacement or addition of a manufacturing site for the FP - Site where any	21/05/2019	n/a		

	manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products 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 B.II.b.4.z - Change in the batch size (including batch size ranges) of the finished product - Other variation				
N/0007	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	29/04/2019	24/02/2020	PL	
T/0004	Transfer of Marketing Authorisation	04/01/2019	11/03/2019	SmPC, Labelling and PL	
IB/0006	B.II.f.1.z - Stability of FP - Change in the shelf-life or storage conditions of the finished product - Other variation	19/02/2019	24/02/2020	SmPC	
IB/0005	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	04/01/2019	11/03/2019	SmPC and PL	
IB/0003	B.II.f.1.z - Stability of FP - Change in the shelf-life or storage conditions of the finished product - Other variation	04/01/2019	11/03/2019	SmPC	
IB/0002	B.II.f.1.z - Stability of FP - Change in the shelf-life or storage conditions of the finished product - Other variation	16/11/2018	11/03/2019	SmPC	

IB/0001	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	14/11/2018	11/03/2019	SmPC, Labelling and PL	