Sunosi

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
T/0022	Transfer of Marketing Authorisation	21/08/2023	22/09/2023	SmPC, Labelling and PL	
IAIN/0020	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging	13/06/2023	n/a		

[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).

	site				
IA/0019	A.7 - Administrative change - Deletion of manufacturing sites	22/03/2023	n/a		
IAIN/0018	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	13/12/2022	22/09/2023	Annex II and PL	
PSUSA/10831 /202203	Periodic Safety Update EU Single assessment - solriamfetol	27/10/2022	n/a		PRAC Recommendation - maintenance
T/0016	Transfer of Marketing Authorisation	26/08/2022	07/10/2022	SmPC, Labelling and PL	
IB/0017	B.II.b.4.e - Change in the batch size (including batch size ranges) of the finished product - More than 10-fold increase compared to the originally approved batch size for immediate release (oral) pharmaceutical form	03/10/2022	n/a		
IA/0015/G	This was an application for a group of variations. 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.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold	07/07/2022	n/a		

	compared to the originally approved batch size				
PSUSA/10831 /202109	Periodic Safety Update EU Single assessment - solriamfetol	07/04/2022	n/a		PRAC Recommendation - maintenance
IA/0013/G	This was an application for a group of variations. B.II.e.4.a - Change in shape or dimensions of the container or closure (immediate packaging) - Non-sterile medicinal products B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS 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	13/12/2021	07/10/2022	SmPC, Labelling and PL	
PSUSA/10831 /202103	Periodic Safety Update EU Single assessment - solriamfetol	28/10/2021	n/a		PRAC Recommendation - maintenance
IB/0011	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)	05/10/2021	07/10/2022	SmPC	To change the shelf-life in section 6.3 of the Summary of Product Characteristics from 4 to 5 years.
II/0009	Update of section 4.8 of the SmPC in order to add hypersensitivity reactions to the list of adverse drug reactions (ADRs) following confirmation of a post marketing safety signal for hypersensitivity. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement editorial	01/07/2021	19/10/2021	SmPC and PL	The list of adverse drug reactions in section 4.8 of the SmPC is updated following confirmation of a post marketing safety signal for hypersensitivity reactions which have occurred with one or more of the following: rash erythematous, rash, urticarial. For more information, please refer to the Summary of

	changes and to bring the PI in line with the latest QRD template version 10.2. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				Product Characteristics.
PSUSA/10831 /202009	Periodic Safety Update EU Single assessment - solriamfetol	09/04/2021	n/a		PRAC Recommendation - maintenance
IA/0008	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	15/12/2020	n/a		
IB/0006	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	18/11/2020	n/a		
PSUSA/10831 /202003	Periodic Safety Update EU Single assessment - solriamfetol	01/10/2020	n/a		PRAC Recommendation - maintenance
IA/0005/G	This was an application for a group of variations. 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 B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP -	21/09/2020	n/a		

	Replacement/addition of a site where batch control/testing takes place B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.f - Change in test procedure for the finished product - To reflect compliance with the Ph. Eur. and remove reference to the outdated internal test method and test method number B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier				
II/0004	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	10/09/2020	n/a		
IB/0003/G	This was an application for a group of variations. 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.b.4.b - Change in the batch size (including batch size ranges) of the finished product - Downscaling down to 10-fold 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) B.II.f.1.e - Stability of FP - Change to an approved stability protocol	21/08/2020	19/10/2021	SmPC and Annex II	

IB/0001	B.II.d.2.z - Change in test procedure for the finished product - Other variation	30/03/2020	n/a		