EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

SCENESSE

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/0024	Transfer of Marketing Authorisation	08/02/2019	20/03/2019	SmPC, Labelling and PL	
IB/0022	B.II.b.1.f - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the FP - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal	25/01/2019	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).

	products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products				
PSUSA/10314 /201806	Periodic Safety Update EU Single assessment - afamelanotide	17/01/2019	n/a		PRAC Recommendation - maintenance
PSUSA/10314 /201712	Periodic Safety Update EU Single assessment - afamelanotide	12/07/2018	n/a		PRAC Recommendation - maintenance
S/0019	3rd annual re-assessment.	26/04/2018	n/a		The CHMP, having reviewed the evidence of compliance with the specific obligations and the impact of the data submitted by the MAH on the benefit/risk profile of the medicinal product, concluded that marketing authorisation of SCENESSE should be maintained.
II/0018	C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment is required	08/03/2018	n/a		
II/0017	B.II.c.1.d - Change in the specification parameters and/or limits of an excipient - Change outside the approved specifications limits range	25/01/2018	n/a		
PSUSA/10314 /201706	Periodic Safety Update EU Single assessment - afamelanotide	11/01/2018	n/a		PRAC Recommendation - maintenance
IA/0015	A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder	10/08/2017	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/10314 /201612	Periodic Safety Update EU Single assessment - afamelanotide	06/07/2017	n/a		PRAC Recommendation - maintenance
IB/0013	B.II.f.1.e - Stability of FP - Change to an approved stability protocol	10/05/2017	n/a		
S/0011	Annual re-assessment.	21/04/2017	n/a		
PSUSA/10314 /201606	Periodic Safety Update EU Single assessment - afamelanotide	12/01/2017	n/a		PRAC Recommendation - maintenance
PSUSA/10314 /201512	Periodic Safety Update EU Single assessment - afamelanotide	07/07/2016	n/a		PRAC Recommendation - maintenance
S/0007	1st Annual Re-assessment	26/05/2016	n/a		The CHMP, having reviewed the evidence of compliance with the specific obligations and the impact of the data submitted by the MAH on the benefit/risk profile of the medicinal product, concluded that Marketing Authorisation of Scenesse should be maintained.
IA/0008	B.II.d.1.d - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter	03/03/2016	n/a		
PSUSA/10314 /201506	Periodic Safety Update EU Single assessment - afamelanotide	14/01/2016	n/a		PRAC Recommendation - maintenance
IB/0006	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life	01/12/2015	12/08/2016	SmPC	

	of the finished product - As packaged for sale (supported by real time data)				
IA/0005	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	04/09/2015	n/a		
IAIN/0003/G	This was an application for a group of variations. A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release) B.II.b.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing	21/08/2015	n/a		
IAIN/0002/G	This was an application for a group of variations. A.1 - Administrative change - Change in the name and/or address of the MAH 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 B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP -	27/07/2015	12/08/2016	SmPC, Annex II, Labelling and PL	

	Replacement/addition of a site where batch control/testing takes place B.II.b.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing				
IB/0001	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	16/06/2015	n/a		