Skilarence

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
N/0031	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	22/09/2022		Labelling and PL	
R/0030	Renewal of the marketing authorisation.	16/12/2021	21/02/2022	SmPC, Annex II, Labelling	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Skilarence in the approved indication remains favourable

[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).

				and PL	and therefore recommended the renewal of the marketing authorisation with unlimited validity.
PSUSA/10647 /202103	Periodic Safety Update EU Single assessment - dimethyl fumarate (psoriasis)	28/10/2021	n/a		PRAC Recommendation - maintenance
IAIN/0028/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 B.II.c.1.c - Change in the specification parameters and/or limits of an excipient - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	17/05/2021	21/02/2022	Annex II and PL	
IB/0027	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	01/04/2021	21/02/2022	SmPC, Annex II, Labelling and PL	
N/0026	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	25/01/2021	21/02/2022	PL	
PSUSA/10647 /202006	Periodic Safety Update EU Single assessment - dimethyl fumarate (psoriasis)	14/01/2021	n/a		PRAC Recommendation - maintenance
IB/0025/G	This was an application for a group of variations.	22/12/2020	n/a		

	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place B.I.a.1.i - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Introduction of a new site of micronisation				
N/0024	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	30/11/2020	21/02/2022	PL	
IA/0023/G	This was an application for a group of variations. B.I.c.z - Container closure system of the AS - Other variation 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.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.b - Change in the specification parameters and/or limits of an AS, starting	29/10/2020	n/a		

	material/intermediate/reagent - Tightening of specification limits				
PSUSA/10647 /201912	Periodic Safety Update EU Single assessment - dimethyl fumarate (psoriasis)	23/07/2020	09/10/2020	SmPC and PL	Please refer to Skilanrece EMEA/H/C/PSUSA/00010647/201912 EPAR: Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation
N/0021	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	13/05/2020	19/08/2020	PL	
II/0019	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	17/04/2020	n/a		
PSUSA/10647 /201906	Periodic Safety Update EU Single assessment - dimethyl fumarate (psoriasis)	16/01/2020	n/a		PRAC Recommendation - maintenance
IB/0016/G	This was an application for a group of variations. B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	07/10/2019	n/a		
IA/0017	A.6 - Administrative change - Change in ATC Code/ATC Vet Code	26/08/2019	19/08/2020	SmPC	

IB/0015/G	This was an application for a group of variations. B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes 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	26/07/2019	19/08/2020	SmPC, Labelling and PL	
PSUSA/10647 /201812	Periodic Safety Update EU Single assessment - dimethyl fumarate (psoriasis)	11/07/2019	n/a		PRAC Recommendation - maintenance
IA/0014/G	This was an application for a group of variations. B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.a.4.c - Change to in-process tests or limits applied during the manufacture of the AS - Deletion of a non-significant in-process test	26/04/2019	n/a		
II/0008/G	This was an application for a group of variations. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission	28/03/2019	20/06/2019	SmPC and PL	

	of studies to the competent authority C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority				
N/0012	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	06/03/2019	20/06/2019	PL	
PSUSA/10647 /201806	Periodic Safety Update EU Single assessment - dimethyl fumarate (psoriasis)	17/01/2019	n/a		PRAC Recommendation - maintenance
IB/0011	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	03/01/2019	n/a		
IB/0010/G	This was an application for a group of variations. B.I.z - Quality change - Active substance - Other variation 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.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting	29/11/2018	n/a		

	material/intermediate				
PSUSA/10647 /201712	Periodic Safety Update EU Single assessment - dimethyl fumarate (psoriasis)	12/07/2018	n/a		PRAC Recommendation - maintenance
IA/0007	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	28/06/2018	n/a		
IAIN/0006	B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes	20/06/2018	20/06/2019	SmPC, Labelling and PL	
IA/0005	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)	02/05/2018	n/a		
IB/0003	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	21/03/2018	n/a		
IB/0002	B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF	09/01/2018	n/a		
IA/0001/G	This was an application for a group of variations. B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor	23/11/2017	n/a		

	changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure				