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
II/0034	Update of section 5.1 of the SmPC in order to update the long term efficacy and safety information based on the final results from study M-41008-41 (Dimeskin 1); this is a phase IV non-randomised, non-interventional, open label study in adult patients with moderate to severe chronic plaque psoriasis to further assess long-term (12 months) efficacy and safety of Skilarence in routine daily practice in Spain.	25/07/2024		SmPC and PL	Maintenance of efficacy has been observed during long-term treatment with dimethyl fumarate-containing products. In the pharmacokinetic and clinical studies the systemic exposure, efficacy and safety of Skilarence were shown to be comparable to the active comparator containing dimethyl fumarate. Hence it is reasonable to expect the long-term efficacy of Skilarence to also be comparable to dimethyl fumarate-containing products.

[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).

	In addition, the MAH took the opportunity to update the list of local representatives. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				For more information, please refer to the Summary of Product Characteristics.
PSUSA/10647 /202303	Periodic Safety Update EU Single assessment - dimethyl fumarate (psoriasis)	26/10/2023	n/a		PRAC Recommendation - maintenance
II/0032	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	31/08/2023	n/a		
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 and PL	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 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	17/05/2021	21/02/2022	Annex II and PL	

	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				
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. 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	22/12/2020	n/a		

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 material/intermediate/reagent - Tightening of specification limits	29/10/2020	n/a		
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	17/04/2020	n/a		

	material/intermediate/reagent - Change outside the approved specifications limits range for the AS				
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 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	28/03/2019	20/06/2019	SmPC and PL	
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 material/intermediate	29/11/2018	n/a		
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 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	23/11/2017	n/a		