Vumerity

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/0019	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	04/02/2025		PL	
IA/0018	B.II.f.1.e - Stability of FP - Change to an approved stability protocol	25/10/2024	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).

WS/2587	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Submission of the final report from Study 109MS401, a multicenter, global, observational study to collect information on safety and to document the drug utilization of Tecfidera (Dimethyl Fumarate) when used in routine medical practice in the treatment of Multiple Sclerosis (ESTEEM), listed as a category 3 study in the RMP (MEA007.6). Section 4.8 is updated to change the frequency category of DILI from "not known" to "rare". The PL is updated accordingly. The EU-RMP for Tecfidera is updated to version 17.0 and the EU-RMP for Vumerity is updated to version 3.0. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	05/09/2024		SmPC and PL	Update of section 4.8 of the SmPC of Tecfidera and Vumerity to change the frequency category of DILI from "not known" to "rare".
IB/0017	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	30/07/2024	n/a		
IAIN/0016/G	This was an application for a group of variations. 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	05/06/2024	26/07/2024	Annex II and PL	

	A.7 - Administrative change - Deletion of manufacturing sites 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)				
IB/0014/G	This was an application for a group of variations. B.II.f.1.e - Stability of FP - Change to an approved stability protocol B.II.f.1.a.1 - Stability of FP - Reduction of the shelf life of the finished product - As packaged for sale	03/01/2024	26/07/2024	SmPC	
IB/0012/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.a - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer	15/12/2023	n/a		
PSUSA/10143 /202303	Periodic Safety Update EU Single assessment - dimethyl fumarate, diroximel fumarate (multiple sclerosis)	30/11/2023	n/a		PRAC Recommendation - maintenance
IB/0013	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	23/10/2023	n/a		

IB/0011/G	This was an application for a group of variations. B.II.f.1.e - Stability of FP - Change to an approved stability protocol 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)	25/08/2023	26/07/2024	SmPC	
IA/0009	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)	20/02/2023	n/a		
IB/0008/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 compared to the originally approved batch size 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.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	06/02/2023	n/a		

IAIN/0007/G	This was an application for a group of variations. B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site 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.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 B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	07/11/2022	03/03/2023	Annex II and PL	
IB/0006	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	03/11/2022	n/a		
II/0005	Submission of the final report from study ALK8700-A301, A Phase 3 Open Label Study to Evaluate the Long-term Safety and Tolerability of ALKS 8700 in Adults with Relapsing Remitting Multiple Sclerosis listed as a category 3 study in the RMP. This is a multicentre, open-label study to evaluate the long-term safety, tolerability, and treatment effect over time of DRF administered for up to 96 weeks in adult participants with RRMS. The RMP version 1.2 has been agreed.	27/10/2022	n/a		

	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority				
IB/0004	B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation	13/06/2022	n/a		
IB/0003/G	This was an application for a group of variations. 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 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 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	02/05/2022	n/a		
IB/0002/G	This was an application for a group of variations. C.z - To update section 4.8 of the SmPC and section 4 of the PL, to add the adverse reaction 'Alopecia' with a frequency 'Common'. C.z - To update section 4.4, 4.8 and 5.1 of the SmPC, in order to update the text with regards to	30/03/2022	03/03/2023	SmPC, Annex II, Labelling and PL	

	the lymphocyte recovery. C.z - Safety, Efficacy, Pharmacovigilance changes - Other variation C.z - Safety, Efficacy, Pharmacovigilance changes - Other variation				
IA/0001/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.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	10/01/2022	n/a		