Filsuvez

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/0013	Transfer of Marketing Authorisation	08/07/2024	05/08/2024	SmPC, Labelling and PL	
IB/0012/G	This was an application for a group of variations. B.I.b.2.z - Change in test procedure for AS or	13/06/2024	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).

	starting material/reagent/intermediate - Other variation B.I.b.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation				
IB/0011	C.I.7.b - Deletion of - a strength	29/05/2024	05/08/2024	SmPC, Labelling and PL	
IA/0009/G	This was an application for a group of variations. 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)	29/02/2024	n/a		
PSUSA/10446 /202307	Periodic Safety Update EU Single assessment - birch bark extract (centrally authorised products)	08/02/2024	n/a		PRAC Recommendation - maintenance
II/0006	Update of sections 4.8 and 5.1 of the SmPC in order to update clinical information based on final results from study EASE (BEB-13); this is a double-blind, randomised, placebo (vehicle) controlled trial to evaluate efficacy and safety of birch bark extract on top of standard of care in paediatric and adult patients with epidermolysis bullosa. In addition, the MAH took the opportunity to introduce minor changes to the PI.	14/12/2023	25/01/2024	SmPC and Annex II	Please refer to Scientific Discussion 'Filsuvez/H/C/005035/II/0006'.

	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
N/0008	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	17/10/2023	25/01/2024	PL	
PSUSA/10446 /202301	Periodic Safety Update EU Single assessment - birch bark extract (centrally authorised products)	31/08/2023	n/a		PRAC Recommendation - maintenance
IA/0005	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	13/04/2023	n/a		
PSUSA/10446 /202207	Periodic Safety Update EU Single assessment - birch bark extract (centrally authorised products)	09/02/2023	n/a		PRAC Recommendation - maintenance
IAIN/0003	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	20/10/2022	n/a		
IB/0001/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	04/10/2022	09/10/2023	SmPC, Labelling and PL	

	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				