Filsuvez

Procedural steps taken and scientific information after the authorisation*

*Due to the Agency`s update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, please also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
Variation type IB /	C.I.11 Introduction of, or change(s) to, the	15/05/2025			To provide a revised RMP version following the

[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).

EMA/VR/0000249374	obligations and conditions of a marketing authorisation, including the risk management plan - C.I.11.z Other RMP changes (e.g. agreed wording + template change) - Accepted C.I.11.z (IB) - To provide a revised RMP version following the withdrawal of the marketing authorisation for Episalvan (birch bark extract), as recommended within procedure EMEA/H/C/PSUSA/00010446/202207. Furthermore, the final report milestone for the study "Filsuvez Observational Safety Registry Based Study (FOSteR)" has been updated to 2032, along with other recommendations received following the post-authorisation measure MEA 001.				withdrawal of the marketing authorisation for Episalvan (birch bark extract). Furthermore, the final report milestone for the study "Filsuvez Observational Safety Registry Based Study (FOSteR)" has been updated to 2032, along with other recommendations received following the post-authorisation measure MEA 001.