FILSPARI

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/0002	Update of sections 4.8 and 5.1 of the SmPC based on final results from study 021IGAN17001 (PROTECT) listed as a specific obligation in Annex II; this is a randomized, multicenter, double-blind parallel-group, active control study of the efficacy and safety of sparsentan for the treatment of immunoglobulin A nephropathy. The Package Leaflet is updated	27/02/2025	23/04/2025	SmPC, Annex II, Labelling and PL	Please refer to Scientific Discussion 'Filspari-H-C-II-002'

[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).

	accordingly. As a result of this variation, the SmPC, Annex II and PL are also updated to reflect the completion of the specific obligation and the CHMP recommendation to grant a marketing authorisation no longer subject to specific obligation. The RMP version 1.0 is agreed. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.4 and to introduce editorial changes. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
PSUSA/11060 /202408	Periodic Safety Update EU Single assessment - sparsentan	13/03/2025	n/a		PRAC Recommendation - maintenance
R/0004	Renewal of the marketing authorisation.	12/12/2024	12/02/2025		
IB/0003	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	03/09/2024	n/a		
IB/0001	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	26/06/2024	12/02/2025	SmPC, Labelling and PL	