Esbriet

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, you may need to 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.7 Deletion of: - C.I.7.a a pharmaceutical	10/12/2025		SmPC,	

[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/0000313265	form - Accepted C.I.7.a - to remove 'Esbriet 267 mg capsules' presentations EU/1/11/667/001, EU/1/11/667/002 and EU/1/11/667/003.			Labelling and PL	
Article 61(3) / EMA/N/0000264816	- Notification acc. Article 61(3) - Accepted Update of the labelling to implement changes to the prefixes for batch number in line with QRD Appendix IV and update of the package leaflet with revised contact details of local representatives and deletion of 'United Kingdom (Northern Ireland)' from the list of local representatives in line with the QRD template v10.4. Additionally, the MAH took the opportunity to introduce minor editorial amendments to the package leaflet.	08/04/2025		Labelling and PL	