Seffalair Spiromax

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 II /	Outcome:	23/07/2026		SmPC	The safety assessment in adolescents is based on

[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/0000347861	C. Safety, efficacy, pharmacovigilance changes - C.4 Change(s) in the summary of product characteristics, labelling or package leaflet due to new quality, preclinical, clinical or pharmacovigilance data. - Accepted Update of section 4.8 of the SmPC in order to update the description of adverse events in adolescents compared with those in adults, based on a safety data review. In addition, the MAH took the opportunity to introduce a minor editorial change to the PI.				the safety data generated from executed Seffalair Spiromax studies and demonstrates that the safety profile of the product in adolescents is similar to that observed in the adult population.
Variation type IA / EMA/VR/0000321392	Outcome: B.III.1.a European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - B.III.1.a.2 Updated certificate from an already approved manufacturer - Accepted	08/01/2026			
Renewal - 5 year / EMA/R/0000280812	Outcome: Renewal of marketing authorisation	16/10/2025	12/12/2025	SmPC, Labelling and PL	
Variation type IB / EMA/VR/0000267107	Outcome: B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.z Other changes - Accepted	21/05/2025			

Variation type IA / EMA/VR/0000258407	Outcome: B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.a Minor change in the manufacturing process - Refused	10/04/2025			
Article 61(3) / EMA/N/0000258664	Outcome: - Notification acc. Article 61(3) - Accepted Update of the package leaflet with revised details of local representatives and to delete United Kingdom (Northern Ireland) from the list of local representatives in line with QRD template v10.4. Additionally, the MAH removed the grey-shading for the manufacturer in section '6. Contents of the pack and other information' and took the opportunity to introduce a minor editorial amendment to the Lithuanian translation of the package leaflet.	03/04/2025	12/12/2025	PL	
Variation type IA / EMA/VR/0000253346	Outcome: B.III.1.a European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - B.III.1.a.2 Updated certificate from an already approved manufacturer - Accepted	25/03/2025			
Variation type IA / EMA/VR/0000245601	Outcome: B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.a	28/01/2025			

	Minor change in the manufacturing process of the active substance - Accepted				
PSUR / EMA/PSUR/0000268979	EURD: PSUSA/00010928/202501 Active substance: salmeterol / fluticasone propionate (for centrally authorised products) Outcome: Maintenance	04/09/2025			Maintenance