



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

BroPair 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, 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
Article 61(3) /	- Notification acc. Article 61(3) -	01/04/2025		PL	

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/N/0000258678	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.				
Variation type IA / EMA/VR/0000253346	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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	N/A		
Variation type IA / EMA/VR/0000245601	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.a Minor change in the manufacturing process	28/01/2025			

	of the active substance - Accepted				
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Medicinal product no longer authorised