Coagadex

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) -	04/03/2025		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/0000247523	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.				
Variation type IB / EMA/VR/0000247762	B.II.d.2 Change in test procedure for the finished product - B.II.d.2.d Other changes to a test procedure (including replacement or addition) - Accepted	27/02/2025	N/A		
Variation type IA_IN / EMA/VR/0000247536	B.V.a.1 Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - B.V.a.1.d Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product - Accepted	13/02/2025	N/A		
Variation type IB / EMA/VR/0000244811	B.V.a.1 Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - B.V.a.1.d Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product - Accepted	12/02/2025	N/A		