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, 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
Marketing Authorisation Transfer - H / EMA/T/0000302442	- Transfer of a marketing authorisation - transfer of marketing authorisation from BPL	24/10/2025	21/11/2025	SmPC, Labelling and	

[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).

	Bioproducts Laboratory GmbH to Kedrion S.p.A.			PL	
Variation type IA_IN / EMA/VR/0000287079	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	21/07/2025	N/A		
Variation type IA_IN / EMA/VR/0000286201	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	16/07/2025	N/A		
Article 61(3) / EMA/N/0000282603	- Notification acc. Article 61(3) - Accepted Update of the package leaflet with revised contact details of local representatives.	15/07/2025	21/11/2025	PL	
Variation type II / EMA/VR/0000264724	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 B.II.d.2 Change in test procedure for the	19/06/2025	21/11/2025		

	finished product - B.II.d.2.d Other changes to a test procedure (including replacement or addition) - Accepted 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 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 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 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 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 B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the				

	manufacturing process of the active substance - B.I.b.2.e Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate - Accepted B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.b Replacement or addition of a site where batch control/testing takes place for a biological/immunological product and any of the test methods performed at the site is a biological/immunological method - Accepted				
Variation type IA / EMA/VR/0000275727	This was an application for a group of variations. B.II.c.2 Change in test procedure for an excipient - B.II.c.2.a Minor changes to an approved test procedure - Accepted B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted	03/06/2025	N/A		
Variation type IB / EMA/VR/0000265336	B.II. FINISHED PRODUCT - B.II.z Other variation - Accepted	30/04/2025	N/A		

Variation type IA_IN / EMA/VR/0000263378	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	08/04/2025	N/A		
Variation type IA_IN / EMA/VR/0000255934	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	07/03/2025	N/A		
Article 61(3) / EMA/N/0000247523	- Notification acc. Article 61(3) - Accepted 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.	04/03/2025	21/11/2025	PL	
Variation type IA / EMA/VR/0000249722	B.II. FINISHED PRODUCT - B.II.z The information in 3.2.A.1 has to be changed as in the provided floor plans an indicated	04/03/2025	N/A		

	meeting room will be changed to a storage room - Refused				
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		