Coagadex

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification[1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
N/0049	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	17/01/2023		PL	
IAIN/0048	B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer	21/12/2022		Annex II and 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).

	responsible for importation and/or batch release - Not including batch control/testing				
IAIN/0047	B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP	06/12/2022	n/a		
IAIN/0045	B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing	10/06/2022	n/a		
IAIN/0044	B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP	02/05/2022	n/a		
IA/0043	B.II.z - Quality change - Finished product - Other variation	18/03/2022	n/a		
IB/0042	B.III.2.b - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State	18/03/2022	n/a		
IAIN/0041	B.V.a.1.d - PMF - Inclusion of a new, updated or	10/12/2021	n/a		

	amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP				
PSUSA/10481 /202103	Periodic Safety Update EU Single assessment - human coagulation factor X	30/09/2021	n/a		PRAC Recommendation - maintenance
IAIN/0040	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	07/07/2021	n/a		
IAIN/0038	B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP	24/03/2021	n/a		
R/0031	Renewal of the marketing authorisation.	28/01/2021	17/03/2021	SmPC, Annex II, Labelling and PL	
IAIN/0037	B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing	16/03/2021	n/a		
IAIN/0036/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites	13/01/2021	17/03/2021	Annex II and PL	

	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release				
IAIN/0035	B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing	13/01/2021	n/a		
IB/0034	B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place	11/12/2020	n/a		
PSUSA/10481 /202003	Periodic Safety Update EU Single assessment - human coagulation factor X	01/10/2020	n/a		PRAC Recommendation - maintenance
IB/0029	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	07/08/2020	n/a		
IB/0027	B.II.z - Quality change - Finished product - Other variation	21/07/2020	n/a		
IAIN/0032	B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP	06/07/2020	n/a		
IAIN/0030	B.V.a.1.d - PMF - Inclusion of a new, updated or	11/06/2020	n/a		

	amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP				
N/0024	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	26/03/2020	n/a		
IAIN/0026	B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP	13/03/2020	n/a		
IAIN/0025	B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing	03/03/2020	17/03/2021	SmPC, Annex II and PL	
II/0023	B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method	16/01/2020	n/a		
PSUSA/10481 /201903	Periodic Safety Update EU Single assessment - human coagulation factor X	03/10/2019	n/a		PRAC Recommendation - maintenance
IAIN/0022/G	This was an application for a group of variations.	19/09/2019	n/a		

	B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP				
N/0020	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	30/07/2019	17/03/2021	PL	
IAIN/0019	B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP	19/07/2019	n/a		

IAIN/0021/G	This was an application for a group of variations. B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP	18/07/2019	n/a		

	B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP				
PSUSA/10481 /201809	Periodic Safety Update EU Single assessment - human coagulation factor X	11/04/2019	n/a		PRAC Recommendation - maintenance
T/0014	Transfer of Marketing Authorisation	15/03/2019	28/03/2019	SmPC, Labelling and PL	
IAIN/0016	B.IV.1.a.1 - Change of a measuring or administration device - Addition or replacement of a device which is not an integrated part of the primary packaging - Device with CE marking	20/03/2019	n/a		
N/0012	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	10/01/2019	28/03/2019	Labelling	
IA/0010	A.7 - Administrative change - Deletion of manufacturing sites	26/10/2018	n/a		
PSUSA/10481 /201803	Periodic Safety Update EU Single assessment - human coagulation factor X	04/10/2018	n/a		PRAC Recommendation - maintenance
II/0009	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	20/09/2018	28/03/2019	SmPC and PL	

II/0007	Update of section sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC in order to include safety and efficacy data in children aged less than 12 years of age based on final results from the study Ten02, a phase III open-label multicentre study to confirm the safety, pharmacokinetics and efficacy of BPL's high purity factor X in the prophylaxis of bleeding in factor X deficient children under the age of 12 years, provided in accordance with the agreed paediatric investigational plan. The Package Leaflet is updated accordingly. The RMP version 7.0 has also been submitted. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	26/07/2018	27/08/2018	SmPC and PL	Please refer to the Scientific Discussion Coagadex EMEA/H/C/003855/II/0007.
IB/0006	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	23/05/2018	n/a		
PSUSA/10481 /201709	Periodic Safety Update EU Single assessment - human coagulation factor X	12/04/2018	n/a		PRAC Recommendation - maintenance
IB/0005	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	14/12/2017	n/a		
IB/0003	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	14/11/2017	n/a		
PSUSA/10481	Periodic Safety Update EU Single assessment -	28/09/2017	n/a		PRAC Recommendation - maintenance

/201703	human coagulation factor X				
PSUSA/10481 /201609	Periodic Safety Update EU Single assessment - human coagulation factor X	06/04/2017	n/a		PRAC Recommendation - maintenance