EMA/56000/2021

Praxbind

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
IA/0022	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	08/01/2021	n/a		

[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).

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

IAIN/0021/G	This was an application for a group of variations. 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 B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	07/01/2021		Annex II and PL	
II/0020	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	17/09/2020		SmPC, Labelling and PL	
R/0019	Renewal of the marketing authorisation.	28/05/2020	27/07/2020	SmPC, Annex II, Labelling and PL	Based on the review of data on quality, safety and efficacy, including all variations introduced since the marketing authorisation was granted, the benefit-risk balance of Praxbind in its approved indication(s) (please refer to the Summary of Product Characteristics) remains favourable and therefore the renewal of the marketing authorisation is recommended, subject to the conditions as detailed in Annex II. The renewal is recommended to be granted with unlimited validity.
PSUSA/10435 /201910	Periodic Safety Update EU Single assessment - idarucizumab	14/05/2020	n/a		PRAC Recommendation - maintenance
IB/0017/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of	16/03/2020	n/a		

	manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place 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				
IB/0016	B.II.z - Quality change - Finished product - Other variation	02/08/2019	n/a		
PSUSA/10435 /201810	Periodic Safety Update EU Single assessment - idarucizumab	16/05/2019	n/a		PRAC Recommendation - maintenance
II/0014/G	This was an application for a group of variations. B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	04/04/2019	n/a		

	B.I.a.2.c - Changes in the manufacturing process of the AS - The change refers to a [-] substance in the manufacture of a biological/immunological substance which may have a significant impact on the medicinal product and is not related to a protocol				
PSUSA/10435 /201804	Periodic Safety Update EU Single assessment - idarucizumab	31/10/2018	n/a		PRAC Recommendation - maintenance
IB/0012	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	24/08/2018	02/08/2019	SmPC and PL	
IB/0013	B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate	16/08/2018	n/a		
PSUSA/10435 /201710	Periodic Safety Update EU Single assessment - idarucizumab	17/05/2018	n/a		PRAC Recommendation - maintenance
II/0007	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	09/11/2017	06/07/2018	SmPC	
PSUSA/10435 /201704	Periodic Safety Update EU Single assessment - idarucizumab	26/10/2017	n/a		PRAC Recommendation - maintenance
IB/0008/G	This was an application for a group of variations. B.II.f.1.b.2 - Stability of FP - Extension of the shelf life of the finished product - After first opening	20/07/2017	06/07/2018	SmPC, Annex II, Labelling and PL	

	(supported by real time data) B.II.f.1.d - Stability of FP - Change in storage conditions of the finished product or the diluted/reconstituted product				
PSUSA/10435 /201610	Periodic Safety Update EU Single assessment - idarucizumab	05/05/2017	n/a		PRAC Recommendation - maintenance
IB/0006	B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol	03/04/2017	13/07/2017	SmPC	
IB/0005	B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data	23/03/2017	n/a		
PSUSA/10435 /201604	Periodic Safety Update EU Single assessment - idarucizumab	27/10/2016	n/a		PRAC Recommendation - maintenance
IB/0003	B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol	27/07/2016	13/07/2017	SmPC	
IB/0002	B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data	27/07/2016	n/a		