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
IB/0035	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	20/11/2024		SmPC and PL	
IB/0033	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	10/07/2023	25/01/2024	SmPC	

[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).

IA/0034/G	This was an application for a group of variations. A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release) B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier	07/07/2023	n/a		
IB/0032	B.II.c.3.a.2 - Change in source of an excipient or reagent with TSE risk - From TSE risk material to vegetable or synthetic origin - For excipients or reagents USED in the manufacture of a biol/immunol AS or in a biol/immunol medicinal product	08/06/2023	n/a		
IB/0031	B.I.a.1.k - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - New storage site of MCB and/or WCB	25/04/2023	n/a		
IB/0029	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	18/01/2023	25/01/2024	SmPC	Product information section 6.3 is updated to reflect the shelf-life extension of the finished product Praxbind 2.5 g/50 mL solution for injection/infusion (EU/1/15/1056/001) as packaged for sale from 3 years to 4 years when stored at 2 - 8°C.
IB/0030	B.II.c.3.z - Change in source of an excipient or reagent with TSE risk - Other variation	16/01/2023	n/a		
IB/0028/G	This was an application for a group of variations.	22/09/2022	n/a		

	B.II.e.2.z - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other variation B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier				
PSUSA/10435 /202110	Periodic Safety Update EU Single assessment - idarucizumab	10/06/2022	n/a		PRAC Recommendation - maintenance
IB/0026	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	06/12/2021	n/a		
IA/0025	B.III.2.a.2 - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Excipient/AS starting material	08/10/2021	n/a		
PSUSA/10435 /202010	Periodic Safety Update EU Single assessment - idarucizumab	10/06/2021	n/a		PRAC Recommendation - maintenance
N/0024	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	31/05/2021	29/09/2021	PL	
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	08/01/2021	n/a		

	Member State				
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	29/09/2021	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	29/09/2021	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.	16/03/2020	n/a		

	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 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	04/04/2019	n/a		

	the AS - Minor change in the manufacturing process of the AS 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.	20/07/2017	06/07/2018	SmPC, Annex II, Labelling	

	B.II.f.1.b.2 - Stability of FP - Extension of the shelf life of the finished product - After first opening (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			and PL	
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		
