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/0012	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	24/08/2018		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		

[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).

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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 (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	20/07/2017	06/07/2018	SmPC, Annex II, Labelling 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		