Alprolix

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
PSUSA/10499 /201709	Periodic Safety Update EU Single assessment - eftrenonacog alfa	26/04/2018	06/07/2018	SmPC	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10499/201709.
IA/0018	A.7 - Administrative change - Deletion of manufacturing sites	18/04/2018	n/a		
IB/0017	B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other	21/03/2018	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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	variation				
IB/0016	B.I.b.1.i - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Where there is no monograph in the European/National Ph. for the AS, a change in specification from in-house to a non-official/third country Ph.	15/03/2018	n/a		
IB/0015	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	05/03/2018	n/a		
IB/0014	B.II.z - Quality change - Finished product - Other variation	23/01/2018	n/a		
IB/0012	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)	15/12/2017	n/a		
PSUSA/10499 /201703	Periodic Safety Update EU Single assessment - eftrenonacog alfa	28/09/2017	n/a		PRAC Recommendation - maintenance
IA/0010	A.7 - Administrative change - Deletion of manufacturing sites	20/07/2017	n/a		
II/0006/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 B.I.a.2.a - Changes in the manufacturing process of	20/07/2017	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 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 B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation 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 B.I.c.1.c - Change in immediate packaging of the AS - Liquid ASs (non sterile) B.II.b.3.c - Change in the manufacturing process of the finished or intermediate product - The product is a biological/immunological medicinal product and the change requires an assessment of comparability				
IB/0009	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	20/06/2017	n/a		

IB/0007	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	13/06/2017	07/06/2018	SmPC, Labelling and PL	
PSUSA/10499 /201609	Periodic Safety Update EU Single assessment - eftrenonacog alfa	20/04/2017	23/06/2017		Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10499/201609.
IB/0002	B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method	14/12/2016	n/a		
N/0004	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	26/10/2016	23/06/2017	Labelling	
IAIN/0003	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	17/10/2016	n/a		
T/0001	Transfer of marketing authorisation from Biogen Idec Ltd to Swedish Orphan Biovitrum AB (publ). Transfer of Marketing Authorisation	25/08/2016	30/09/2016	SmPC, Labelling and PL	