EMA/325611/2020

Refixia

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/0019	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	27/05/2020	n/a		
IB/0017	B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other	19/02/2020	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).

	variation				
IB/0016	B.I.z - Quality change - Active substance - Other variation	24/01/2020	n/a		
PSUSA/10608 /201905	Periodic Safety Update EU Single assessment - nonacog beta pegol	16/01/2020	n/a		PRAC Recommendation - maintenance
IB/0015	B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits	29/11/2019	n/a		
IB/0014	B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits	19/11/2019	n/a		
PSUSA/10608 /201811	Periodic Safety Update EU Single assessment - nonacog beta pegol	14/06/2019	n/a		PRAC Recommendation - maintenance
PSUSA/10608 /201806	Periodic Safety Update EU Single assessment - nonacog beta pegol	17/01/2019	n/a		PRAC Recommendation - maintenance
IG/1004	A.7 - Administrative change - Deletion of manufacturing sites	19/11/2018	n/a		
IB/0008/G	This was an application for a group of variations. B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.e - Change in test procedure for AS or	30/10/2018	n/a		

	starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate				
IB/0010/G	This was an application for a group of variations. B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits 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	25/09/2018	n/a		
IB/0009	B.I.e.4.b - Changes to an approved change management protocol - Minor changes that do not change the strategy defined in the protocol	19/09/2018	n/a		
PSUSA/10608 /201712	Periodic Safety Update EU Single assessment - nonacog beta pegol	14/06/2018	n/a		PRAC Recommendation - maintenance
IB/0005	B.I.e.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	14/03/2018	n/a		
IG/0870	A.7 - Administrative change - Deletion of manufacturing sites	27/11/2017	n/a		

IB/0003	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	16/10/2017	n/a		
IA/0002	B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits	08/09/2017	n/a		
IB/0001/G	This was an application for a group of variations. B.II.d.1.c - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method B.II.d.1.c - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method 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	11/08/2017	n/a		