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/0037/G	This was an application for a group of variations. B.II.f.1.e - Stability of FP - Change to an approved stability protocol B.II.f.1.e - Stability of FP - Change to an approved stability protocol	29/11/2023		SmPC, Labelling and PL	

[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).

	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				
II/0032	Extension of indication to include treatment and prophylaxis of bleeding in children below 12 years of age with haemophilia B including previously untreated patients for Refixia based on results from studies NN7999-3774 and NN7999-3895. NN7999-3774 is a multicentre, open-label, non-controlled study evaluating the safety, efficacy and pharmacokinetics of nonacog beta pegol in previously treated children with haemophilia B, while NN7999-3895 is a multicentre, open-label, single-arm, non-controlled trial evaluating the safety and efficacy of nonacog beta pegol in previously untreated patients with haemophilia B. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1, 5.2 and 5.3 of the SmPC are updated. The Package Leaflet is updated accordingly. Version 5.2 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI. The variation leads to amendments to the Summary of Product Characteristics and Package Leaflet and to the Risk Management Plan (RMP). C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	22/06/2023	04/08/2023	SmPC and PL	Please refer to Scientific Discussion 'Refixia-H-C-004178-II-0032'

WS/2480	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.b.2.z - Change to importer, batch release arrangements and quality control testing of the FP - Other variation	13/07/2023	n/a		
IB/0033/G	This was an application for a group of variations. B.II.b.5.a - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	01/06/2023	n/a		
IB/0031	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	12/01/2023	n/a		
PSUSA/10608 /202205	Periodic Safety Update EU Single assessment - nonacog beta pegol	12/01/2023	n/a		PRAC Recommendation - maintenance
X/0027/G	This was an application for a group of variations. Annex I_2.(c) Change or addition of a new strength/potency B.II.d.1.e - Change in the specification parameters	13/10/2022	12/12/2022	SmPC, Labelling and PL	

	and/or limits of the finished product - Change outside the approved specifications limits range				
IB/0029	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	11/07/2022	n/a		
IB/0028	B.I.c.2.z - Change in the specification parameters and/or limits of the immediate packaging of the AS - Other variation	06/05/2022	n/a		
R/0025	Renewal of the marketing authorisation.	16/12/2021	21/02/2022	SmPC, Annex II, Labelling and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Refixia in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
PSUSA/10608 /202105	Periodic Safety Update EU Single assessment - nonacog beta pegol	13/01/2022	n/a		PRAC Recommendation - maintenance
IB/0024	B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation	09/07/2021	n/a		
PSUSA/10608 /202005	Periodic Safety Update EU Single assessment - nonacog beta pegol	14/01/2021	n/a		PRAC Recommendation - maintenance
IB/0023	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	27/11/2020	n/a		

IB/0022	B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	14/10/2020	n/a		
IB/0020	B.I.e.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	17/08/2020	n/a		
PSUSA/10608 /201911	Periodic Safety Update EU Single assessment - nonacog beta pegol	09/07/2020	n/a		PRAC Recommendation - maintenance
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 variation	19/02/2020	n/a		
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	19/11/2019	n/a		

	material/intermediate/reagent - Tightening of specification limits				
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 starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate	30/10/2018	n/a		
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	25/09/2018	n/a		

	changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate				
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.	11/08/2017	n/a		

	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				