ELOCTA

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
IAIN/0058	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	11/11/2024		Annex II 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).

IB/0057	B.II.b.2.z - Change to importer, batch release arrangements and quality control testing of the FP - Other variation	09/10/2024	n/a		
N/0055	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	08/10/2024	n/a		
IB/0053	B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	10/09/2024	n/a		
IA/0054/G	This was an application for a group of variations. A.z - Administrative change - 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.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	22/07/2024	n/a		
IB/0052/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.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	15/07/2024		SmPC	
PSUSA/10451 /202306	Periodic Safety Update EU Single assessment - efmoroctocog alfa	11/01/2024	n/a		PRAC Recommendation - maintenance

IB/0050	B.II.b.4.f - Change in the batch size (including batch size ranges) of the finished product - The scale for a biological/immunological medicinal product is increased/decreased without process change (e.g. duplication of line)	18/04/2023	n/a		
PSUSA/10451 /202206	Periodic Safety Update EU Single assessment - efmoroctocog alfa	12/01/2023	n/a		PRAC Recommendation - maintenance
IA/0049/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient	18/11/2022	n/a		
IB/0047	B.z - Quality Change - Other variation	27/06/2022	n/a		
PSUSA/10451 /202106	Periodic Safety Update EU Single assessment - efmoroctocog alfa	13/01/2022	n/a		PRAC Recommendation - maintenance
IA/0045/G	This was an application for a group of variations. B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)	29/06/2021	n/a		

	B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation A.7 - Administrative change - Deletion of manufacturing sites				
IB/0043	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	05/05/2021	n/a		
IA/0044/G	This was an application for a group of variations. A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient 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)	14/04/2021	n/a		
PSUSA/10451 /202006	Periodic Safety Update EU Single assessment - efmoroctocog alfa	14/01/2021	n/a		PRAC Recommendation - maintenance
II/0039	Update of sections 4.8, 5.1 of the SmPC to include the results of study 997HA306 in previously untreated patients which have previously been assessed as an Article 46 paediatric submission and renewal (EMEA/H/C/003964/R/0036). Additionally, minor changes are included in the Package Leaflet.	14/01/2021	06/01/2022	SmPC and PL	Section 5.1 of the SmPC has been updated to include the results of study 997HA306 in previously untreated patients (PUPs). Section 4.8 of the SmPC has been updated to include “Papular rash” and “device related thrombosis” as common adverse drug reactions in PUPs.

	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
IB/0041	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	14/09/2020	n/a		
R/0036	Renewal of the marketing authorisation.	25/06/2020	19/08/2020	SmPC, Labelling and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Elocta in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IB/0038	B.II.z - Quality change - Finished product - Other variation	24/06/2020	n/a		
IAIN/0037/G	This was an application for a group of variations. 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 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 B.IV.1.b - Change of a measuring or administration device - Deletion of a device	27/03/2020	n/a		

PSUSA/10451 /201906	Periodic Safety Update EU Single assessment - efmoroctocog alfa	16/01/2020	n/a		PRAC Recommendation - maintenance
IAIN/0034	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	26/08/2019	n/a		
IB/0032	B.II.b.4.f - Change in the batch size (including batch size ranges) of the finished product - The scale for a biological/immunological medicinal product is increased/decreased without process change (e.g. duplication of line)	10/07/2019	n/a		
II/0030	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	06/06/2019	09/07/2019	SmPC and PL	
PSUSA/10451 /201812	Periodic Safety Update EU Single assessment - efmoroctocog alfa	14/06/2019	n/a		PRAC Recommendation - maintenance
PSUSA/10451 /201806	Periodic Safety Update EU Single assessment - efmoroctocog alfa	17/01/2019	n/a		PRAC Recommendation - maintenance
II/0026	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	13/12/2018	09/07/2019	SmPC	The MAH submitted the results of the study 8HA01EXT evaluating the long-term safety and efficacy of ELOCTA in the prevention and treatment of bleeding episodes and for perioperative management. Section 4.8 and 5.1 were updated to update information regarding prophylaxis regimens, paediatric population, and immunogenicity.
X/0021	Annex I_2.(c) Change or addition of a new	20/09/2018	07/12/2018	SmPC, Annex	

	strength/potency			II, Labelling and PL	
IA/0029	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)	27/09/2018	n/a		
PSUSA/10451 /201712	Periodic Safety Update EU Single assessment - efmoroctocog alfa	14/06/2018	n/a		PRAC Recommendation - maintenance
IA/0025/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites 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	16/04/2018	n/a		
IB/0022	B.I.a.3.e - Change in batch size (including batch size ranges) of AS or intermediate - The scale for a biological/immunological AS is increased/decreased without process change (e.g. duplication of line)	28/03/2018	n/a		
IB/0023	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.	22/02/2018	n/a		

IB/0019	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	07/02/2018	n/a		
N/0020	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	30/01/2018	07/12/2018	PL	
PSUSA/10451 /201706	Periodic Safety Update EU Single assessment - efmoroctocog alfa	11/01/2018	n/a		PRAC Recommendation - maintenance
IB/0018	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	16/11/2017	07/12/2018	SmPC and Annex II	
II/0016/G	This was an application for a group of variations. 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.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation 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	16/11/2017	n/a		

A31/0006	Pursuant to Article 31 of Directive 2001/83/EC, Germany initiated a procedure on 6 July 2016 based on concerns resulting from the evaluation of data from pharmacovigilance activities. The PRAC was requested to assess the potential impact of the results of the SIPPET study (which concluded that recombinant factor VIII medicines had a higher incidence of inhibitor development than plasma-derived medicines), and to issue a recommendation as to whether the marketing authorisations of these products should be maintained, varied, suspended or revoked. The EMA concluded in September 2017 that there is no clear and consistent evidence of a difference in the incidence of inhibitor development between the two classes of factor VIII medicines: those derived from plasma and those made by recombinant DNA technology. Due to the different characteristics of individual products within the two classes, EMA concluded that the risk of inhibitor development should be evaluated individually for each medicine, regardless of class. The risk for each product will continue to be assessed as more evidence becomes available.	14/09/2017	16/11/2017	SmPC and PL	Please refer to the assessment report: human coagulation factor VIII - EMEA/H/A-31/1448
IB/0015	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	06/07/2017	n/a		

PSUSA/10451 /201612	Periodic Safety Update EU Single assessment - efmoroctocog alfa	06/07/2017	n/a		PRAC Recommendation - maintenance
II/0012/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes 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	22/06/2017	n/a		
IB/0014	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	27/04/2017	n/a		
II/0010	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	23/02/2017	n/a		
IB/0011	B.II.e.6.b - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that does not affect the product information	16/01/2017	n/a		

II/0008/G	This was an application for a group of variations. B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product B.I.a.1.j - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Replacement or addition of a site where batch control/testing takes place and any of the test method at the site is a biol/immunol method B.I.a.1.j - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Replacement or addition of a site where batch control/testing takes place and any of the test method at the site is a biol/immunol method 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.3.c - Change in batch size (including batch size ranges) of AS or intermediate - The change requires assessment of the comparability of a biological/immunological AS	15/12/2016	n/a		
PSUSA/10451 /201605	Periodic Safety Update EU Single assessment - efmoroctocog alfa	01/12/2016	n/a		PRAC Recommendation - maintenance
N/0009	Update of the QRD code content. Minor change in labelling or package leaflet not	26/10/2016	31/05/2017	Labelling	

	connected with the SPC (Art. 61.3 Notification)				
IB/0004/G	This was an application for a group of variations. A.6 - Administrative change - Change in ATC Code/ATC Vet Code C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	05/07/2016	31/05/2017	SmPC	
IB/0003	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	07/06/2016	n/a		
IAIN/0005	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	02/06/2016	n/a		
T/0002	Transfer of the Marketing Aughorisation Transfer of Marketing Authorisation	24/02/2016	23/03/2016	SmPC, Labelling and PL	Transfer of the Marketing Aughorisation from Biogen Idec Ltd to Swedish Orphan Biovitrum AB (publ).
IAIN/0001	C.I.8.a - Introduction of or changes to a summary of Pharmacovigilance system - Changes in QPPV (including contact details) and/or changes in the PSMF location	09/12/2015	n/a		