# 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 |
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| 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 | | 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 strength/potency | 20/09/2018 | 07/12/2018 | SmPC, Annex II, Labelling | |

[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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| | | | | 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.<br><br>A.7 - Administrative change - Deletion of manufacturing sites<br>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 | 07/02/2018 | n/a | | |

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| | material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate | | | | |
| 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.<br><br>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<br>B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation<br>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 | 14/09/2017 | 16/11/2017 | SmPC and PL | Please refer to the assessment report: human coagulation |

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| | on concerns resulting from the evaluation of data from pharmacovigilance activities.<br>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. | | | | 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 |

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| II/0012/G | This was an application for a group of variations.<br><br>A.7 - Administrative change - Deletion of manufacturing sites<br>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<br>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. | 15/12/2016 | n/a | | |

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| | 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<br>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<br>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<br>B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS<br>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 | | | | |
| 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.<br><br>Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 26/10/2016 | 31/05/2017 | Labelling | |

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| IB/0004/G | This was an application for a group of variations.<br><br>A.6 - Administrative change - Change in ATC Code/ATC Vet Code<br>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<br><br>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 | | |