EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



# Nonafact

## 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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| IB/0062 | C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation | 24/11/2016 | | SmPC, Annex II, Labelling and PL | |
| IAIN/0061 | B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP | 30/08/2016 | 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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| IB/0059/G | This was an application for a group of variations.<br><br>B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure<br>B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure | 20/05/2016 | n/a | | |
| II/0054 | 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 | 28/04/2016 | n/a | | |
| IAIN/0058/G | This was an application for a group of variations.<br><br>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<br>A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release | 22/03/2016 | | Annex II and PL | |
| IAIN/0060/G | This was an application for a group of variations.<br><br>B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes | 09/03/2016 | n/a | | |

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| | do not affect the properties of the FP<br>B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP | | | | |
| IA/0057 | B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure | 03/02/2016 | n/a | | |
| T/0055 | Transfer of Marketing Authorisation | 15/12/2015 | 28/01/2016 | SmPC, Labelling and PL | |
| IA/0056 | 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 | 07/01/2016 | n/a | | |
| IAIN/0053 | 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 | 08/12/2015 | n/a | | |
| IAIN/0052/G | This was an application for a group of variations.<br><br>B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP<br>B.I.b.2.a - Change in test procedure for AS or starting | 09/04/2015 | n/a | | |

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| | material/reagent/intermediate - Minor changes to an approved test procedure | | | | |
| IB/0049 | B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) | 18/02/2015 | n/a | | |
| IA/0050 | B.I.b.2.b - Change in test procedure for AS or starting material/reagent/intermediate - Deletion of a test procedure for the AS or a starting material/reagent/intermediate, if an alternative test procedure is already authorised | 22/01/2015 | n/a | | |
| IAIN/0051 | B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP | 19/01/2015 | n/a | | |
| IB/0048 | B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation | 10/12/2014 | n/a | | |
| IAIN/0047 | 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 | 19/11/2014 | n/a | | |
| IAIN/0046 | B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP | 10/06/2014 | n/a | | |

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| PSUSA/1617/201307 | Periodic Safety Update EU Single assessment - HUMAN COAGULATION FACTOR IX | 06/03/2014 | n/a | | PRAC Recommendation - maintenance |
| IAIN/0045/G | This was an application for a group of variations.<br><br>B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP<br>B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP | 27/02/2014 | n/a | | |
| IB/0043 | B.I.z - Quality change - Active substance - Other variation | 15/11/2013 | n/a | | |
| IB/0041 | 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 | 18/10/2013 | n/a | | |
| IB/0042 | B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation | 08/10/2013 | n/a | | |
| IA/0040 | 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 | 24/05/2013 | n/a | | |
| IB/0039 | B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of | 23/05/2013 | n/a | | |

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| | the AS | | | | |
| IAIN/0038/G | This was an application for a group of variations.<br><br>B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP<br>B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP | 25/01/2013 | n/a | | |
| IB/0036/G | This was an application for a group of variations.<br><br>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<br>B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure | 01/10/2012 | n/a | | |
| IAIN/0037/G | This was an application for a group of variations.<br><br>B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP<br>B.V.a.1.d - PMF - Inclusion of a new, updated or | 21/09/2012 | n/a | | |

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| | amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP | | | | |
| IAIN/0035 | B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP | 25/05/2012 | n/a | | |
| IA/0034 | B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP | 04/05/2012 | n/a | | |
| IB/0033 | B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS | 21/03/2012 | n/a | | |
| II/0032 | To replace a release test of the drug product.<br><br>B.II.d.2.c - Change in test procedure for the finished product - Replacement of a biological/ immunological/immunochemical test method or a method using a biological reagent | 15/03/2012 | n/a | | |
| II/0031 | Changes in the test method for "Activated Factor IX" and finished product release specifications.<br><br>B.II.d.2.c - Change in test procedure for the finished product - Replacement of a biological/ | 20/10/2011 | 20/10/2011 | | |

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| | immunological/immunochemical test method or a method using a biological reagent | | | | |
| IB/0030/G | This was an application for a group of variations.<br><br>B.V.a.1.b - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - First-time inclusion of a new PMF NOT affecting the properties of the FP<br>B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP | 23/09/2011 | n/a | | |
| IB/0029 | B.II.b.3.z - Change in the manufacturing process of the finished product - Other variation | 19/04/2011 | n/a | | |
| IA/0027 | B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP | 13/07/2010 | n/a | | |
| IB/0026 | C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation | 18/06/2010 | n/a | SmPC, Annex II, Labelling and PL | |
| 2PMF/0025 | Inclusion of the updated or amended Plasma Master File (Sanquin EMEA/H/PMF/000007/04) in the marketing authorisation dossier | 04/05/2009 | n/a | | |

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| IB/0024 | IB_38_c_Change in test procedure of finished product - other changes | 16/04/2009 | n/a | | |
| IA/0023 | IA_25_b_01_Change to comply with Ph. - compliance with EU Ph. update - active substance | 19/02/2009 | n/a | | |
| II/0022 | Changes in the in-process controls of the drug product<br><br>Change(s) to the test method(s) and/or specifications for the finished product | 25/09/2008 | 02/10/2008 | | |
| MF/0021 | 2PMF (2nd step of PMF certification procedure) | 01/07/2008 | n/a | | |
| IB/0020 | Change in the reference standard<br><br>IB_38_b_Change in test procedure of finished product - minor change, biol. active subst./excipient | 15/01/2008 | n/a | | |
| II/0017 | Update of Summary of Product Characteristics and Package Leaflet | 24/05/2007 | 30/10/2007 | SmPC and PL | Update of Section 4.4 and 4.8 of the SPC to bring them in line with the Note for Guidance on the Warning on Transmissible Agents for Plasma-derived medicinal products. The Package Leaflet has been updated accordingly. |
| II/0016 | Quality changes | 19/07/2007 | 24/07/2007 | | |
| MF/0018 | 2PMF (2nd step of PMF certification procedure) | 16/05/2007 | n/a | | |
| IA/0019 | IA_25_b_01_Change to comply with Ph. - compliance with EU Ph. update - active substance | 07/05/2007 | n/a | | |
| R/0012 | Renewal of the marketing authorisation. | 01/06/2006 | 25/07/2006 | SmPC, Annex II, Labelling and PL | The renewal was granted with unlimited validity, with a PSUR cycle of 3 years. |

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| MF/0013 | 2PMF (2nd step of PMF certification procedure) | 20/07/2006 | n/a | | |
| II/0011 | Quality changes | 23/03/2006 | 28/03/2006 | | |
| MF/0009 | 2PMF (2nd step of PMF certification procedure) | 25/01/2006 | n/a | | |
| II/0008 | Quality changes | 14/12/2005 | 21/12/2005 | | |
| IA/0007 | IA_28_Change in any part of primary packaging material not in contact with finished product | 12/04/2005 | n/a | | The MAH applied to change the colour of the sealing cap from red (article code 06-066) to turquoise (article code 06-070). The sealing cap does not contact the finished product. |
| N/0006 | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 16/12/2004 | n/a | PL | The MAH applied to update the list of local representatives to include the accession countries. |
| II/0005 | Update of or change(s) to the pharmaceutical documentation | 21/01/2004 | 26/01/2004 | | |
| I/0003 | 24_Change in test procedure of active substance<br>25_Change in test procedures of the medicinal product<br>24a_Change in test procedure for starting material/intermediate used in manuf. of active substance | 24/07/2003 | 05/08/2003 | | |
| I/0002 | 25_Change in test procedures of the medicinal product | 08/05/2003 | 14/05/2003 | | |
| I/0001 | 03_Change in the name and/or address of the marketing authorisation holder | 04/04/2003 | 12/05/2003 | SmPC, Labelling and PL | |