# Benepali

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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| N/0083 | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 20/09/2024 | | PL | |
| IB/0082 | C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference | 27/08/2024 | | SmPC 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).

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| | product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH | | | | |
| N/0081 | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 08/08/2024 | | PL | |
| IA/0080 | B.I.a.4.a - Change to in-process tests or limits applied during the manufacture of the AS - Tightening of in-process limits | 22/07/2024 | n/a | | |
| II/0078 | B.II.h.1.b.1 - Update to the Adventitious Agents Safety Evaluation information - Replacement of obsolete studies related to manufacturing steps and adventitious agents already reported in the dossier - with modifications of risk assessment | 11/01/2024 | n/a | | |
| IB/0079 | C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH | 07/12/2023 | | SmPC and PL | |
| PSUSA/10795 /202302 | Periodic Safety Update EU Single assessment - etanercept | 12/10/2023 | 07/12/2023 | | Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10795/202302. |
| IB/0076 | B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation | 30/10/2023 | n/a | | |
| N/0077 | Minor change in labelling or package leaflet not | 12/09/2023 | 07/12/2023 | Labelling | |

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| | connected with the SPC (Art. 61.3 Notification) | | | | |
| IB/0074 | C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation | 25/05/2023 | n/a | | |
| IB/0073/G | This was an application for a group of variations.<br><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.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS | 26/04/2023 | n/a | | |
| II/0069 | B.II.f.1.c - Stability of FP - Change in storage conditions for biological medicinal products, when the stability studies have not been performed in accordance with an approved stability protocol | 12/01/2023 | 04/10/2023 | SmPC and PL | |
| IB/0072 | C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH | 06/01/2023 | 04/10/2023 | SmPC | |
| IB/0071/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 | 21/12/2022 | n/a | | |

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| | 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 | | | | |
| IB/0070/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.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) | 21/12/2022 | n/a | | |
| N/0068 | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 11/10/2022 | 04/10/2023 | PL | |
| II/0065/G | This was an application for a group of variations.<br><br>B.I.b.2.d - Change in test procedure for AS or starting material/reagent/intermediate - Substantial change to or replacement of a biological/immunological/immunochemical test method or a method using a biological reagent for a biological AS<br>B.I.b.2.d - Change in test procedure for AS or starting material/reagent/intermediate - Substantial change to or replacement of a biological/immunological/immunochemical test | 06/10/2022 | n/a | | |

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| | method or a method using a biological reagent for a biological AS | | | | |
| IB/0067/G | This was an application for a group of variations.<br><br>C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH<br>A.7 - Administrative change - Deletion of manufacturing sites | 16/09/2022 | 04/10/2023 | SmPC, Annex II and PL | C.I.2.a - To update section 5.1 of the SmPC in order to update clinical information based on final results obtained from a clinical paediatric study. |
| IB/0066 | C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation | 24/06/2022 | n/a | | |
| IB/0064 | 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 | 17/05/2022 | n/a | | |
| II/0063/G | This was an application for a group of variations.<br><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.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - | 12/05/2022 | n/a | | |

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| | Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method<br>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>A.7 - Administrative change - Deletion of manufacturing sites | | | | |
| IA/0062 | 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) | 17/11/2021 | n/a | | |
| IB/0061/G | This was an application for a group of variations.<br><br>C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH<br>C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH | 12/05/2021 | 31/01/2022 | SmPC and PL | |

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| IAIN/0060/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.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)<br>A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release<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 | 30/03/2021 | 31/01/2022 | Annex II and PL | |
| IAIN/0059 | 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 | 26/03/2021 | 31/01/2022 | Annex II and PL | |
| IB/0057 | C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation | 28/01/2021 | 31/01/2022 | Annex II and Labelling | |
| IB/0058 | B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other | 17/12/2020 | n/a | | |

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| | changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate | | | | |
| IA/0056 | B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure | 11/12/2020 | n/a | | |
| IA/0055 | A.7 - Administrative change - Deletion of manufacturing sites | 30/11/2020 | n/a | | |
| R/0053 | Renewal of the marketing authorisation. | 17/09/2020 | 18/11/2020 | 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 Benepali in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity. The product information (PI) is updated in accordance with the latest QRD template version 10.1. In addition, the MAH took the opportunity to align the PI of Benepali with the PI of the reference medicinal product Enbrel and to include Kaposi's sarcoma as an adverse reaction with a frequency 'not known' as per a PRAC recommendation on signal in July 2020 (EMEA/H/C/000262/SDA/173). |
| PSUSA/10795 /202002 | Periodic Safety Update EU Single assessment - etanercept | 03/09/2020 | n/a | | PRAC Recommendation - maintenance |
| IAIN/0052 | 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 | 18/12/2019 | 18/11/2020 | Annex II and PL | |

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| PSUSA/10452 /201901 | Periodic Safety Update EU Single assessment - etanercept (biosimilars) | 19/09/2019 | 14/11/2019 | SmPC and PL | Please refer to Benepali Erelzi EMEA/H/C/PSUSA/00010452/201901 EPAR: Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation |
| IB/0050 | B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation | 12/11/2019 | n/a | | |
| IB/0051/G | This was an application for a group of variations.<br><br>B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation<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 | 17/10/2019 | n/a | | |
| IB/0048/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.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation | 19/09/2019 | n/a | | |
| II/0042/G | This was an application for a group of variations. | 25/07/2019 | 14/11/2019 | Annex II | |

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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 | | | | |
| IB/0046 | C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation | 14/06/2019 | n/a | | |
| IB/0047 | C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH | 15/05/2019 | 14/11/2019 | SmPC and PL | |
| IA/0045/G | This was an application for a group of variations.<br><br>A.7 - Administrative change - Deletion of manufacturing sites<br>A.7 - Administrative change - Deletion of manufacturing sites | 02/05/2019 | n/a | | |
| IB/0043/G | This was an application for a group of variations.<br><br>B.I.a.4.z - Change to in-process tests or limits | 12/04/2019 | n/a | | |

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| | applied during the manufacture of the AS - Other variation<br>B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation | | | | |
| IAIN/0041 | C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation | 28/02/2019 | 14/11/2019 | SmPC and PL | |
| PSUSA/10452 /201807 | Periodic Safety Update EU Single assessment - etanercept (biosimilars) | 14/02/2019 | n/a | | PRAC Recommendation - maintenance |
| IB/0040 | 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) | 03/12/2018 | n/a | | |
| T/0038 | Transfer of Marketing Authorisation | 02/10/2018 | 08/11/2018 | SmPC, Labelling and PL | |
| PSUSA/10452 /201801 | Periodic Safety Update EU Single assessment - etanercept (biosimilars) | 06/09/2018 | n/a | | PRAC Recommendation - maintenance |
| II/0035 | B.I.a.1.c - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer uses a substantially different route of synthesis or manufacturing conditions | 12/07/2018 | n/a | | |
| II/0031/G | This was an application for a group of variations. | 26/04/2018 | n/a | | |

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| | 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>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 | | | | |
| IB/0036 | B.III.2.a.1 - 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 - AS | 15/03/2018 | n/a | | |
| PSUSA/10452 /201707 | Periodic Safety Update EU Single assessment - etanercept (biosimilars) | 08/02/2018 | n/a | | PRAC Recommendation - maintenance |
| IB/0033 | 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 | 06/02/2018 | 08/11/2018 | SmPC | |
| IB/0034 | C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH | 05/02/2018 | 08/11/2018 | SmPC and PL | |

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| IA/0032/G | This was an application for a group of variations.<br><br>B.I.a.4.b - Change to in-process tests or limits applied during the manufacture of the AS - Addition of a new in-process test and limits<br>B.I.a.4.c - Change to in-process tests or limits applied during the manufacture of the AS - Deletion of a non-significant in-process test | 15/01/2018 | n/a | | |
| IB/0030 | B.II.e.z - Change in container closure system of the Finished Product - Other variation | 19/12/2017 | 08/11/2018 | SmPC and Labelling | |
| II/0026 | 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 | 09/11/2017 | n/a | | |
| PSUSA/10452 /201701 | Periodic Safety Update EU Single assessment - etanercept (biosimilars) | 01/09/2017 | n/a | | PRAC Recommendation - maintenance |
| IB/0028/G | This was an application for a group of variations.<br><br>A.1 - Administrative change - Change in the name and/or address of the MAH<br>B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes<br>B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside | 25/07/2017 | 08/11/2018 | SmPC, Labelling and PL | |

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| | the range of the currently approved pack sizes | | | | |
| IB/0027 | C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH | 09/06/2017 | 08/11/2018 | SmPC, Labelling and PL | |
| X/0016 | Annex I_2.(c) Change or addition of a new strength/potency | 23/03/2017 | 31/05/2017 | SmPC, Labelling and PL | |
| IAIN/0025 | B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site | 24/04/2017 | n/a | | |
| PSUSA/10452 /201607 | Periodic Safety Update EU Single assessment - etanercept (biosimilars) | 09/02/2017 | n/a | | PRAC Recommendation - maintenance |
| II/0019/G | This was an application for a group of variations.<br><br>C.I.2.b - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Change(s) require to be further substantiated by new additional data to be submitted by the MAH<br>C.I.2.b - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Change(s) require to be further | 15/12/2016 | 27/01/2017 | SmPC, Annex II, Labelling and PL | |

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| | substantiated by new additional data to be submitted by the MAH | | | | |
| IAIN/0023 | B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site | 24/01/2017 | n/a | | |
| IB/0022/G | This was an application for a group of variations.<br><br>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<br>B.I.d.1.b.3 - Stability of AS - Change in the storage conditions - Change in storage conditions of the AS | 24/11/2016 | n/a | | |
| IB/0021 | B.II.f.1.z - Stability of FP - Change in the shelf-life or storage conditions of the finished product - Other variation | 17/11/2016 | n/a | | |
| IB/0017/G | This was an application for a group of variations.<br><br>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<br>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 | 03/10/2016 | n/a | | |
| IB/0015 | B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product | 30/09/2016 | n/a | | |

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| IAIN/0018 | B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site | 15/09/2016 | n/a | | |
| II/0008 | Submission of the final clinical study report for the 100 weeks open-label extension phase of study SB4-G31-RA, a phase III study, as safety follow-up to evaluate the long-term safety, tolerability, immunogenicity and efficacy of Benepali in subjects with RA treated previously with Benepali or Enbrel (category 3 study listed in the RMP) to fulfil MEA 001. In addition the MAH has taken the opportunity to update the RMP to reflect the changes introduced to Annex II of the Product Information during the Initial Marketing Authorisation procedure. The requested variation proposed amendments to the Risk Management Plan (RMP).<br><br>C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority | 15/09/2016 | n/a | | |
| IB/0012/G | This was an application for a group of variations.<br><br>B.I.a.4.a - Change to in-process tests or limits applied during the manufacture of the AS - Tightening of in-process limits<br>B.I.a.4.a - Change to in-process tests or limits applied during the manufacture of the AS - Tightening of in-process limits<br>B.I.e.5.c - Implementation of changes foreseen in an | 09/09/2016 | n/a | | |

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| | approved change management protocol - For a biological/immunological medicinal product | | | | |
| IB/0014 | 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 | 19/08/2016 | n/a | | |
| IB/0011/G | This was an application for a group of variations.<br><br>B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site<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 | 02/08/2016 | n/a | | |
| IA/0013/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.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) | 22/07/2016 | n/a | | |
| IAIN/0009/G | This was an application for a group of variations. | 29/06/2016 | n/a | | |

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| | B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site<br>B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site | | | | |
| IB/0010 | C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH | 28/06/2016 | 27/01/2017 | SmPC and PL | |
| II/0004 | B.II.g.2 - Introduction of a post approval change management protocol related to the finished product | 16/06/2016 | n/a | | |
| II/0003 | B.I.e.2 - Introduction of a post approval change management protocol related to the AS | 02/06/2016 | n/a | | |
| IA/0006 | B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process | 27/05/2016 | n/a | | |
| IAIN/0007 | B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site | 25/05/2016 | n/a | | |
| IB/0005 | C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO | 28/03/2016 | 27/01/2017 | SmPC, Labelling and PL | |

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| | new additional data is required to be submitted by the MAH | | | | |
| IB/0002/G | This was an application for a group of variations.<br><br>B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes<br>B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes | 16/02/2016 | 27/01/2017 | SmPC, Labelling and PL | |
| IAIN/0001/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 | 28/01/2016 | 27/01/2017 | Annex II and PL | |