# Oprymea

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/0043 | 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 | 20/08/2024 | | 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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| IB/0042 | 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 | 03/05/2024 | | SmPC and PL | |
| N/0041 | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 28/07/2023 | | PL | |
| N/0040 | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 10/01/2023 | | PL | |
| IB/0039 | B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation | 09/06/2022 | n/a | | |
| N/0038 | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 22/02/2022 | | PL | |
| IA/0037/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.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)<br>B.I.b.2.a - Change in test procedure for AS or | 04/11/2021 | n/a | | |

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| | starting material/reagent/intermediate - Minor changes to an approved test procedure<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.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure<br>B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size<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.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure | | | | |
| IB/0036 | 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 | 18/08/2020 | n/a | | |
| IB/0035 | 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 | 30/06/2020 | 31/07/2020 | SmPC, Annex II, Labelling and PL | |
| IB/0034 | B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale | 29/10/2019 | 31/07/2020 | SmPC | |

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| | (supported by real time data) | | | | |
| IA/0033 | B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure | 06/06/2019 | n/a | | |
| IA/0032 | B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure | 12/03/2019 | n/a | | |
| IA/0031 | B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure | 20/09/2018 | n/a | | |
| IB/0030/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.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site<br>B.II.b.1.e - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products | 18/06/2018 | n/a | | |
| IB/0028 | 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 | 26/01/2018 | 12/03/2018 | SmPC and PL | |

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| | new additional data is required to be submitted by the MAH | | | | |
| IB/0027 | C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation | 06/11/2017 | 12/03/2018 | SmPC and PL | |
| IA/0026 | B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure | 12/06/2017 | n/a | | |
| IB/0025 | 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 | 23/04/2017 | 26/07/2017 | SmPC and PL | |
| IB/0024 | 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 | 19/07/2016 | 26/07/2017 | SmPC, Annex II, Labelling and PL | |
| IB/0023 | B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation | 30/11/2015 | n/a | | |
| IB/0022/G | This was an application for a group of variations.<br><br>B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation | 21/07/2015 | n/a | | |

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| | B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process | | | | |
| IB/0019 | To introduce a new initiation pack (EU/1/08/469/054) containing 7 tablets of 0.26 mg, 7 tablets of 0.52 mg and 7 tablets of 1.05 mg for Oprymea prolonged release tablets.<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 | 26/06/2015 | 06/07/2016 | SmPC, Labelling and PL | |
| IA/0021 | 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 | 13/05/2015 | n/a | | |
| IA/0020 | B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure | 13/05/2015 | n/a | | |
| X/0017 | To add new strengths 2.62 mg and 3.15 mg prolonged-release tablets.<br><br>Annex I_2.(c) Change or addition of a new strength/potency | 18/12/2014 | 17/02/2015 | SmPC, Labelling and PL | |
| N/0018 | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 28/07/2014 | 17/02/2015 | PL | |

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| IB/0016 | 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 | 15/05/2014 | 17/02/2015 | SmPC, Labelling and PL | |
| IAIN/0015 | B.II.d.1.h - Change in the specification parameters and/or limits of the finished product - Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur. for the finished product | 23/01/2014 | n/a | | |
| X/0014 | Annex I_2.(d) Change or addition of a new pharmaceutical form | 19/09/2013 | 11/11/2013 | SmPC, Annex II, Labelling and PL | |
| R/0012 | Renewal of the marketing authorisation. | 21/02/2013 | 09/03/2013 | Annex II and PL | The CHMP reviewed the available data on the safety and efficacy of pramipexole, including all variations introduced since the marketing authorisation was granted, and based on these data considered that the risk-benefit balance of Oprymea in the treatment of the signs and symptoms of idiopathic Parkinson's disease, alone (without levodopa) or in combination with levodopa, i.e. over the course of the disease, through to late stages when the effect of levodopa wears off or becomes inconsistent and fluctuations of the therapeutic effect occur (end of dose or "on off" fluctuations) remains favourable. The product information was updated in line with the latest QRD template and to update the local representative of Portugal.<br>The CHMP recommended the renewal of the Marketing Authorisation with unlimited validity. |

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| IB/0013/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 are 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 are 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 are submitted by the MAH | 01/02/2013 | 09/04/2013 | SmPC, Annex II, Labelling and PL | Implementation of changes approved in the reference product for procedures WS-128, WS-311 and WS-326:<br>WS-128 - Update of section 4.8 of SmPC in order to add safety information related to cardiac failure.<br>WS-311 - Update of section 4.8 of the SmPC in order to include inappropriate antidiuretic hormone secretion as an adverse drug reaction. Furthermore, a more detailed description of the outer appearance of the immediate release tablets was included in the Package Leaflet corresponding to the information provided in the SmPC. The PI was brought in line with the latest QRD template.<br>WS-326 - Update of sections 4.4 and 4.8 of the SmPC in order to update the safety information by implementing class labelling for the risk of impulse control disorders. The Package Leaflet was updated accordingly.<br>The MAH also took the opportunity to update the list of local representatives for Malta, Spain, France, Ireland, Romania, Italy and Latvia. |
| IB/0011/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 are 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 are submitted by the MAH | 28/01/2011 | n/a | SmPC, Annex II and PL | Variation type IB C.I.2.a<br>Update of the SPC sections 4.5., 4.6 and 4.8 to include the results of an in depth evaluation of hOCT2 inhibitors (implementation of agreed wording of FUMs for Sifrol and Mirapexin) and SPC section 4.8 to include new side effects and revise frequency categories on assessment of PSUR 13. The Package Leaflet has been updated accordingly.<br><br>Variation type IB C.I.2.a<br>Update of the SPC section 5.3 to include non-clinical information concerning delayed sexual development observed in rats as agreed in the assessment of FUMs for Sifrol Mirapexin. |

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| | | | | | In addition, the MAH corrected minor errors in Annex I and Annex II to be in line with the originator.<br>Amendment of Danish Product Information Text according to linguistic corrections made by originator.<br>Update of telephone number of local representative in Estonia.<br>In addition removal of version number in Annex II.B for Pharmacovigilance system. |
| IA/0010/G | This was an application for a group of variations.<br><br>B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site<br>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<br>B.II.b.2.b.2 - Change to batch release arrangements and quality control testing of the FP - Including batch control/testing | 09/12/2010 | n/a | Annex II and PL | |
| IB/0007 | 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) | 29/09/2010 | n/a | SmPC | |
| IB/0006/G | This was an application for a group of variations.<br><br>Variation type IB, C:I:2.A:<br>Update of the SPC for the immediate release | 26/08/2010 | n/a | SmPC and PL | Sections 4.4, 4.2 & 5.1 of the SPC of Oprymea were updated to align it with that of the reference medicinal product. This followed changes to the SPC of the reference medicinal product (Sifrol) via the following procedures: |

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| | formulations as requested by the CHMP following the assessment of FUM 018.5 (results of study 248.629) to update information regarding augmentation to reflect the study results in section 4.4.<br><br>Variation type IB, C:I:2.A:<br>Update of section 5.1 of the SPC to include results from study 248.644, in line with article 46 of the paediatric legislation. In addition, the description of the paediatric population in section 4.2 and 5.1 of the SPC is updated to be in line with the current QRD requirements.<br><br>Package Leaflet has been harmonised accordingly.<br><br>Moreover, the MAH took the opportunity to introduce further changes in line with the current QRD template, and update the details of the local representatives for Austria, Cyprus, Greece, Latvia, Lithuania, Poland, Romania and United Kingdom for all presentations. In addition, minor editorial change has been made in Portuguese PL and minor formal changes have been introduced throughout the PI.<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 are 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 | | | | EMEA/H/C/133/WS/0003 and EMEA/H/C/133/II/0056." |

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| | product - Implementation of change(s) for which NO new additional data are submitted by the MAH | | | | |
| II/0004 | Update, in line with the reference medicinal product of section 4.8 of the Summary of Product Characteristics to include the terms "dyspnoea" and "pneumonia". The Package Leaflet is being updated accordingly.<br><br>Update of Summary of Product Characteristics and Package Leaflet | 23/07/2009 | 13/08/2009 | SmPC and PL | Section 4.8 of the SPC of Oprymea was updated to align it with that of the reference medicinal product. This followed changes to the SPC of the reference medicinal product via the following procedure: EMEA/H/C/133/II/52 (Sifrol). |
| II/0001 | The Marketing Authorisation Holder applied for the addition of a new manufacturer of the active substance.<br><br>Change(s) to the manufacturing process for the active substance | 29/05/2009 | 08/06/2009 | | |
| II/0003 | Update, in line with the reference medicinal products, of section 4.8 of the SPC with the terms compulsive shopping, vomiting, restlessness, amnesia, visual disturbance, hyperphagia, syncope and weight decrease. The frequency for the terms hypersexuality and pathological gambling has also been included. In addition, compulsive shopping has been added to section 4.4 of the SPC, and new headings have been added to Sections 4.4 and 4.5 of the SPC. The PL is being updated accordingly.<br><br>Update of Summary of Product Characteristics and Package Leaflet | 23/04/2009 | 15/05/2009 | SmPC and PL | Following a change to the Summary of product Characteristics (SPC) of the reference medicinal product Sifrol, sections 4.4 and 4.8 of the SPC of Oprymea were updated to align them with those of the reference medicinal product. The changes basically consisted of adding the new adverse drug reaction (ADR) terms compulsive shopping, vomiting, restlessness, amnesia, visual disturbance, hyperphagia, syncope and weight decrease to section 4.8 of the SPC and to add the frequency for the terms hypersexuality and pathological gambling to section 4.4 SPC.<br>A more detailed summary of the scientific discussion leading up to the above mentioned changes could be found |

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| | | | | | in the EPAR (module 8b) of Sifrol (II/48). |
| II/0002 | Update of the Detailed Description of the Pharmacovigilance system (DDPS) in Module 1.8.1 of the Oprymea Marketing Authorisation, in accordance with the current pharmacovigilance guideline.<br><br>Update of DDPS (Pharmacovigilance) | 22/01/2009 | 26/02/2009 | Annex II | With this type II variation the MAH submitted an update of the DDPS as requested by the CHMP upon granting of the initial Marketing Authorisation. The CHMP concluded that the updated DDPS (version 000001/15) fulfils the legislative requirements and therefore recommended to update Annex II accordingly. |