# Movymia

## 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/0028 | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 12/01/2022 | | PL | |
| IB/0030/G | This was an application for a group of variations.<br><br>B.II.b.2.a - Change to importer, batch release | 08/12/2021 | 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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| | arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place<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 | | | | |
| IB/0029 | B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation | 02/12/2021 | n/a | | |
| R/0024 | Renewal of the marketing authorisation. | 22/07/2021 | 16/09/2021 | SmPC, Labelling and PL | Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Movymia in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity. The RMP has been also updated (version 2.2). |
| N/0025 | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 13/08/2021 | | Labelling and PL | |
| IA/0026/G | This was an application for a group of variations.<br><br>B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits<br>B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure | 09/08/2021 | n/a | | |
| N/0023 | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 15/03/2021 | 16/09/2021 | PL | |

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| IB/0022/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>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 | 11/01/2021 | n/a | | |
| II/0020 | B.II.e.1.a.3 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Sterile medicinal products and biological/immunological medicinal products | 17/09/2020 | 16/09/2021 | SmPC, Annex II, Labelling and PL | |
| IAIN/0021 | B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site | 10/07/2020 | n/a | | |
| IB/0018/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.z - Changes in the manufacturing process of the AS - Other variation<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 | 05/05/2020 | n/a | | |

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| IAIN/0019 | 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 | 10/04/2020 | n/a | | |
| IB/0016 | B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation | 08/01/2020 | n/a | | |
| N/0015 | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 06/12/2019 | 13/05/2020 | PL | |
| IA/0014 | 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 | 26/06/2019 | n/a | | |
| II/0010 | Submission of the final clinical study report from Study RGB1023O31; a Phase III, multi-centre, randomised, active-controlled, parallel-group, comparative efficacy/safety study. An updated RMP version 1.4 was agreed during the procedure.<br><br>C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority | 14/06/2019 | n/a | | n/a |
| IB/0011 | 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 - | 28/05/2019 | 13/05/2020 | SmPC, Labelling and PL | |

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| | Device with CE marking | | | | |
| IA/0013 | 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) | 24/05/2019 | n/a | | |
| II/0012 | B.II.e.1.a.3 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Sterile medicinal products and biological/immunological medicinal products | 23/05/2019 | n/a | | |
| PSUSA/2903/ 201809 | Periodic Safety Update EU Single assessment - teriparatide | 16/05/2019 | n/a | | PRAC Recommendation - maintenance |
| IA/0008 | B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure | 12/12/2018 | n/a | | |
| N/0007 | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 11/12/2018 | 13/05/2020 | PL | |
| IB/0006/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.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder | 30/10/2018 | n/a | | |

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| | 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.z - Quality change - Active substance - Other variation<br>B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place<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.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 | | | | |
| 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 new additional data is required to be submitted by the MAH | 19/02/2018 | 19/04/2018 | SmPC and PL | |
| N/0004 | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 13/07/2017 | 19/04/2018 | PL | |
| IB/0002/G | This was an application for a group of variations.<br><br>B.I.a.2.z - Changes in the manufacturing process of | 05/04/2017 | n/a | | |

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| | the AS - Other variation<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 | | | | |
| IA/0001 | A.z - Administrative change - Other variation | 05/04/2017 | 19/04/2018 | SmPC, Labelling and PL | |