# Imrestor

## Procedural steps taken and scientific information after the authorisation

| Application number | Scope | Opinion/ Notification[1] issued on | Commission Decision Issued / amended on | Product Information affected[2] | Summary[3] |
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| R/0015 | Renewal of the marketing authorisation. | 16/07/2020 | 30/09/2020 | SPC, Annex II, Labelling and PL | The European Commission renewed the marketing authorisation for Imrestor. |
| II/0014 | B.I.e.2 - Introduction of a post approval change management protocol related to the AS | 23/04/2020 | n/a | | n/a |
| IB/0013 | 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 | 26/02/2020 | n/a | | n/a |
| II/0012 | B.II.g.2 - Introduction of a post approval change management protocol related to the finished product | 20/02/2020 | n/a | | n/a |
| IAIN/0011/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 | 16/12/2019 | 30/09/2020 | SPC, Annex II and PL | The Agency accepted the group of variations including the change in the name of the site responsible for the batch release of the finished product. The product information was also updated in accordance with the latest version of the QRD template. |

[1] Notifications are issued for type I variations (unless part of a group including a type II variation or higher procedure or a worksharing application). Opinions are issued for all other procedures.
[2] SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).
[3] Since October 2019 summary information is no longer published for variations that do not impact upon the product information

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| | responsible for batch release | | | | |
| IAIN/0010 | 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 | 22/11/2019 | 30/09/2020 | Annex II and PL | The Agency accepted the variation to add an alternative batch release site, to align Product Information with the latest QRD template and to delete the list of local representatives from the Package Leaflet. |
| IG/1040/G | This was an application for a group of variations.<br><br>C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the QPPV and/or QPPV contact details and/or back-up procedure<br>C.I.9.b - Changes to an existing pharmacovigilance system as described in the DDPS - Change(s) in the safety database and/or major contractual arrangements for the fulfilment of PhV obligations, and/or change of the site undergoing PhV activities<br>C.I.9.c - Changes to an existing pharmacovigilance system as described in the DDPS - Other change(s) to the DDPS that does not impact on the operation of the PhV system | 17/12/2018 | n/a | | n/a |
| T/0008 | Transfer of Marketing Authorisation | 20/09/2018 | 07/12/2018 | SPC, Labelling and PL | The European Commission transferred the marketing authorisation from 'Eli Lilly and Company Limited' to 'Elanco GmbH'. |
| IB/0007 | B.II.z - Quality change - Finished product - Other variation | 08/05/2018 | n/a | | The Agency accepted the variation to update the description of the scope of operations at a manufacturing facility. |
| II/0005 | B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - 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 | 05/10/2017 | n/a | | The Agency accepted the variation to add a quality control testing site of the finished product. |
| IB/0006 | 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 | 01/09/2017 | n/a | | The Agency accepted the variation to extend the shelf life of the active substance. |
| IB/0004 | 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 | 19/04/2017 | n/a | | The Agency accepted the variation to extend the storage period. |
| IB/0003 | B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product | 10/03/2017 | n/a | | The Agency accepted the variation to include an alternative manufacturing site. |
| IB/0002 | 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 | 12/01/2017 | n/a | | The Agency accepted the variation to change the retest period for the active substance. |

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| IB/0001 | 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) | 28/10/2016 | n/a | | The Agency accepted the variation to increase the batch size for Pegbovigrastim. |