**61(3) Notifications regarding nationally approved medicinal products in Norway**

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| **DESCRIPTION OF THE MEDICINAL PRODUCT** |
| Product name:       |
| Strength:       | Pharmaceutical form:       |
| MAno:       |
| Approved pack sizes:       |

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| **BACKGROUND/DESCRIPTION OF THE PROPOSED CHANGES** |
|       |

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| **ATTACHMENTS** |
| [ ]  Mock-ups of the labelling (new version)[ ]  Latest approved mock-ups [ ]  Package leaflet with tracked changes |

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| **OTHER INFORMATION** |
| [ ]  I confirm that the proposed changes do not affect the SmPC[ ]  I confirm that there are no other changes than the tracked changes |

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| **MA-HOLDER** |
| Name and address:       |
| Contact person:       |
| E-mail:       | Telephone:       |

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| Date:       | Sent by:       |