**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: |