NOTIFICATION FOR PRODUCT INFORMATION AMENDMENT UNDER ARTICLE 61(3)

(NOT ACCOMPANYING A VARIATION CHANGE)

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| [ ]  **NATIONAL AUTHORISATION IN DC or MR Procedure**  **Product Information amendment number1: \_\_\_/\_\_/\_\_\_\_\_\_\_\_\_/\_\_\_\_/\_\_/\_\_\_\_****Reference Member State**[ ] AT [ ] BE [ ] BG [ ] CY [ ] CZ [ ] DE [ ] DK [ ] EE [ ] EL [ ] ES [ ] FI [ ] FR [ ] HR [ ] HU [ ] IE [ ] IS [ ] IT [ ] LI [ ] LT [ ] LU [ ] LV [ ] MT [ ] NL [ ] NO [ ] PL [ ] PT [ ] RO [ ] SE [ ] SI [ ] SK [ ] XI **Concerned Member State(s)**[ ] AT [ ] BE [ ] BG [ ] CY [ ] CZ [ ] DE [ ] DK [ ] EE [ ] EL [ ] ES [ ] FI [ ] FR [ ] HR [ ] HU [ ] IE [ ] IS [ ] IT [ ] LI [ ] LT [ ] LU [ ] LV [ ] MT [ ] NL [ ] NO [ ] PL [ ] PT [ ] RO [ ] SE [ ] SI [ ] SK [ ] XI [ ] NONE |
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1 [Number](https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/procedural_guidance/Program%20Files/Documentum/CTS/docbases/EDMS/config/temp_sessions/Program%20Files/Documentum/CTS/docbases/EDMS/config/temp_sessions/Program%20Files/Documentum/CTS/docbases/EDMS/Documents%20and%20Settings/ambrosea/Local%20Settings/Temporary%20Internet%20Files/OLK7A/Number) to be completed by the Marketing Authorisation Holder, reflecting the correct consequential Mutual Recognition or Decentralised Procedure Number according to the CMDh Standard Operating Procedure for Article 61(3) Changes to Patient Information.’ (<http://www.hma.eu/>).

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| (Invented)Name: Active substance(s): Pharmaceutical form(s) and strength(s): MA number(s)2: Pharmacotherapeutic Classification(Group & ATC Code): |  | Name and address of MA holder:Name and address of Contact:Telephone number:Fax number: E-mail:Applicant's reference: |

2 Indicate the MA numbers affected (a range may be appropriate).

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| **BACKGROUND:***Please give brief background explanation for the proposed changes to your label and/or package leaflet (PL). Provide the following: one full colour mock-up of the current approved label/PL, two full colour mock-ups of the proposed label/PL (one copy to be annotated with the proposed changes and one clean copy).* We intend to apply multilingual packaging for the following new ‘clusters’ of member states: *<free text*3>*<When appropriate, please indicate:* We intend to prepare EU full/reduced harmonised labelling text for a multilingual packaging. We intend to use EU full harmonised labelling text (no text reductions required) for a multilingual packaging. > |

3 Add here which ‘clusters’ of MS will be grouped on each multilingual pack e.g. IE/NL/MT, IS/NO/EE, this does not preclude further clusters later on request.

The following amended product information proposals are provided in the relevant sections of the EU-CTD format:

[ ]  Labelling

[ ]  Package leaflet

[ ]  Mock-ups4

4 see Chapter 7 of Volume 2A of the Notice to Applicants

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| **Declaration of the Applicant:**I hereby submit an application for the labels and/or package leaflet of the above Marketing Authorisation to be amended in accordance with the proposals given above. I declare that (*Please tick)*: [ ]  The required amended actual size colour mock-ups have been supplied; [ ]  There are no other changes than those identified in this application; [ ]  The change(s) do not affect the Summary of Product Characteristics; [ ]  The change(s) will not affect the safe use of the product or require user Acceptance testing to be undertaken;  Change will be implemented from:[ ]  Next production run/next printing (*indicate approximate date*) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ]  Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
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| Fees paid *(if applicable) amount/currency:\_\_\_\_\_*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*Please specify fee category under National rules* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Main Signatory5**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Print name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Second Signatory** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Print name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  | Status (Job title) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Status (Job title) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

5The main signatory is mandatory

Please quote the MR or DC product information amendment number, the name of the medicinal product and the MA number in any future correspondence.