NOTIFICATION FOR PRODUCT INFORMATION AMENDMENT UNDER ARTICLE 61(3)

(NOT ACCOMPANYING A VARIATION CHANGE)

|  |
| --- |
| **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 |
|  |

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/>).

|  |  |  |
| --- | --- | --- |
| (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).

|  |
| --- |
| **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

|  |
| --- |
| **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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |

|  |  |  |
| --- | --- | --- |
| 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.