Application for a Change to Labels and/or Patient Information Leaflets not Connected with Changes to the SmPC

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| **PRODUCT DETAILS** |
| (Invented) Name: Active substance(s): Pharmaceutical form(s) and strength(s): PA number(s):      Pharmacotherapeutic classification (Group and ATC code):  | Name and address of MA holder:Name and address of contact: Telephone number:  Fax number:  Email:  Applicant's reference:       |

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| **CHANGES PROPOSED TO** *please tick Medical Pharmaceutical*Labels: TEXT [ ]  [ ] Leaflet: TEXT [ ]  [ ] Labels: LAYOUT [ ]  [ ] Leaflet: LAYOUT [ ]  [ ]  |

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| **OTHER APPLICATION(S)** *(Please provide brief information on any ongoing variation or other variation(s) submitted in parallel, or renewal application(s), or line-extension(s).)*Is this a first introduction of a multilingual label in Ireland for this product? Yes [ ]  No [ ] Please indicate which MS are involved in the cluster:  |

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| **BACKGROUND** (*Please give a brief background explanation for the proposed changes to the label and/or leaflet.)**For applications, provide one copy of either a scanned or pdf version of the approved colour mock-ups with changes highlighted and one scanned or pdf copy of the clean revised colour mock-ups.**For non-marketed products where colour mock-ups are not available, please provide a scanned or pdf copy of the approved text with changes highlighted and a scanned or pdf copy of the proposed text.* |

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| CHANGE FROM NON-MARKETED TO A MARKETED PRODUCTIs this variation to allow a change in the marketing status of the product? Yes **[ ]**  No **[ ]** If yes: Is this the first time full colour mock-ups are being submitted to the HPRA for approval? Yes **[ ]**  No **[ ]** Was the text of both the labelling and leaflet previously approved? Yes **[ ]**  No **[ ]** If yes, please provide the date **and documentary evidence** of this text approval. Date of approval:  |

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| **PRESENT** (*Please specify the precise wording and/or layout in the current label and/or leaflet.)* | **PROPOSED** (*Please specify the precise wording and/or layout in the proposed label and/or leaflet.)* |
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| **DECLARATION**I hereby submit a notification for the labels and/or leaflet of the above marketing authorisation to be varied in accordance with the proposals given above. I declare that (*please tick*):**[ ]**  There are no further changes than those identified in this application (except for those addressed in other applications submitted in parallel; such parallel applications should be specified under ‘Other Application(s)’);**[ ]**  The change(s) do not affect the Summary of Product Characteristics;**[ ]**  The change(s) will not adversely affect the quality, efficacy or safety of the product.Where applicable the following required documents for the notification(s) concerned have been submitted:**[ ]**  One copy of either a scanned or pdf version of the approved mock-ups with changes highlighted**[ ]**  One scanned or pdf copy of the clean revised colour mock-ups**[ ]**  Braille declaration **[ ]**  Package leaflet The change will be implemented from:**[ ]**  Next production run/next printing *(indicate approximate date):* **[ ]**  Date:  |
| Name of applicant: Status (job title):  | Signature of applicant:Date:  |