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 PRODUCT Is 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: |