National Submission Form for Direct Healthcare Professional Communications and Communication Plans for Marketing Authorisation Holders

Please complete the communication plan below when submitting a direct healthcare professional communication (DHPC) to the HPRA and submit it to medvigilance@hpra.ie. Please refer to the ‘Guide for Marketing Authorisation Holders on Direct Healthcare Professional Communications’ for further details on HPRA requirements.

1. SubMISSION DETAILS

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| --- | --- |
| **Marketing authorisation holder(s)** |  |
| **Joint DHPC (Y/N)** |  |
| **MAH contact point (name, telephone, email address)** |  |
| **Medicinal product(s) concerned (include PA/EU numbers)** |  |
| **Regulatory context**  *Indicate if communication is outcome of a variation, referral, PSUSA, signal procedure, etc., (include EU/MR/National procedure number as applicable).* |  |

1. DHPC Communication Plan <DRAFT/FINAL>

|  |  |
| --- | --- |
| **Safety concern and purpose of communication**  *Consider using title of DHPC to describe the safety concern.* |  |
| **Active substance(s)** |  |
| **DHPC recipient healthcare professional groups**  *Identify target audience, e.g. general practitioners, dermatologists, hospital pharmacists, community pharmacists, etc.* |  |
| **Other recipients[[1]](#footnote-2) to receive copies of the DHPC**  *Identify any additional organisations or recipients that should receive copies of the DHPC, e.g. professional societies, national clinical leads, patient organisations, etc.* |  |
| **Dissemination mechanism**  *Describe dissemination method(s).* |  |
| **Timing of communication**  *Indicate if communication is immediate or deferred due to being linked to another event, e.g. product launch, approval of other additional risk minimisation measures, etc.* |  |
| **Dissemination date agreed at EU level (as applicable)** |  |
| **Date of submission of national DHPC to the HPRA for approval** |  |
| **Dissemination date of DHPC nationally** |  |
| **Date of approval by the HPRA** |  |

1. Attached documents[[2]](#footnote-3)

|  |  |
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| **Core DHPC and communication plan agreed by PRAC/CHMP/CMD(h), as applicable** | N/A |
| ***<Draft><Final>* national DHPC1**  *(Including HPRA national DHPC identifier at the top of the first page of the DHPC)* |  |
| ***<Draft><Final>* national communication plan3**  *(See national communication plan template below)* |  |

1. *Please include The Case Manager, Vigilance Assessment Section, Human Products Monitoring Department, Health Products Regulatory Authority, Kevin O’Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, on the distribution list.* [↑](#footnote-ref-2)
2. *The proposed national DHPC and communication plan should undergo a comprehensive quality control check before submission to the HPRA.* *The DHPC and communication plan may require amendment prior to final approval. A final version of both should be submitted to the HPRA on approval.*

   *3The communication plan may need to be updated during assessment. A final version should be submitted on approval.* [↑](#footnote-ref-3)