**Annex-2 Template for the Applicant declaration**

**APPLICATION FOR THE INCLUSION OF MOBILE TECHNOLOGY FEATURE IN MRP/DCP PROCEDURES**

|  |  |
| --- | --- |
| Procedure number (s) |  |
| Name of the medicinal product in the RMS |  |
| Name of the active substance |  |
| Applicant |  |

1. **Type of Application**

* Initial application for the inclusion of mobile technology
* Follow-up application[[1]](#footnote-1) to an approved mobile technology

1. **Declaration of the content**

*The Applicant is requested to*

*1) Specify the information to be linked via Mobile technology feature*

*2) Provide the URL linking such information (not needed when the information is provided via NCA website)*

*3) Provide a list of the MSs where the mobile technology will be included*

1. **Intended location of the Mobile Technology feature in the product information**

*Applicant should declare the location of the mobile technology within the Product information (e.g. inner lid/inner flap of the carton, Package Leaflet, etc)*

1. **Intended final user of the information provided via Mobile technology feature**

* Health Care Professionals
* Patients

1. **Type of information to be provided**

* PL
* SmPC
* Educational material for Health Care Professionals
* Educational material for patients
* Complementary information

In case complementary information is ticked, please confirm that supportive documents are provided for its assessment:Yes No

1. **Location of the information to be provided via Mobile technology feature (Links)**

* NCA websites (MSs requiring link to their websites are detailed in Annex 1)
* Website created by MAH specifically for the Mobile technology feature.
* Standalone PDF document

1. **Applicant’s declaration**

The undersigned certifies by the present declaration that the proposed Mobile technology feature and its contents:

* Comply with Article 62 of Directive 2001/83 EC and with the specifications stated in the CMDh Position Paper on the use of Mobile technology to provide information about the medicinal product and with the requirements resulting mandatory from EU- Commission or CMDh Decisions after PSUSA or Referrals.
* Will remain unchanged after approval. Any changes to the content of the materials after approval will be the subject of a new submission excepting for the updates of the product information resulting from the approved modifications

*NOTE: Product information and educational materials will be updated after approval/implementation of variations according to the timelines established in the CMDh BPG on variations*

* Will be provided via link to the NCA website when is mandatory
* Will remain valid while the authorisation of the mobile technology is in place
* The non-statutory information ‘complementary information’ as well as the additional risk minimisation measures (i.e. educational material), will be adapted and approved nationally after EOP if required by individual member states. The informing sentence as stated in the CMDh Position Paper on the use of Mobile technology will be included in the PL

On behalf of *<Applicant/MAH name>,*

*Authorised signatory*

1. 1Modifications related to the layout of the dedicated platforms created by the MAH do not required follow-up. As a reminder, no elements of promotional nature can be included. [↑](#footnote-ref-1)