**Application form to request a compassionate use program or a medical need program**

**To be completed by the FAMHP**

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| Reception date of your application form by the FAMHP  FAMHP REF : |

Application for :

|  |  |
| --- | --- |
| Compassionate Use Program | Medical Need Program |

Amendment for an approved Compassionate Use Program (Provide our reference :      )

Amendment for an approved Medical Need Program (Provide our reference :      )

1. **Identification of the applicant :**

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| --- | --- | --- | --- | --- |
| The Applicant is responsible for program execution, the designation of a physician in charge of the inclusion of patients, keeping a central register of patients included and the recording of anonymised suspected serious adverse effects. | | | | |
| Status :  Manufacturer  Promotor  Other (Fill in) | | | | |
| Name |  | | | |
| Address (headquarter) | Street :  Postcode :  City :  Country : | | | |
| Contact person (First Name/Name) |  | | |  |
| Phone/fax/email |  |  |  | |

1. **Identification of the manufacturer (if different from the applicant) :**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name |  | | | |
| Address (headquarter) | Street :  Postcode :  City :  Country : | | | |
| Contact person (First Name/Name) |  | | |  |
| Phone/fax/email |  |  |  | |

1. **Identification of the Responsible Physician:**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| The responsible physician designated by the applicant, is in charge of checking the request to include a patient in the program. He has also to anonymise adverse reactions and communicate these anonymised adverse reactions to the responsible of the program (=applicant). | | | | | | | |
| Name / First name / Title | |  | |  | |  | |
| Clinical qualification, speciality | |  | | | | | |
| Clinical institution name | |  | | | | |  |
| Address | | Street :  Postcode :  City :  Country : | | | | | |
| Phone/fax/email |  | |  | |  | | |

1. **Ethics committee :**

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| The chosen Ethics committee must have a full accreditation as stated in art 11 of the national law (07 may 2004) concerning experiments on the human person. The list of these Ethics committees can be found on our website (http://www.fagg-afmps.be/en/human\_use/medicines/medicines/research\_development/ethic\_committee/) | |
| Ethics Committee with full agreement in Belgium | Name of institution :  Address :  Contact person : |

1. **Medicinal Product information :**

|  |  |
| --- | --- |
| Name of medicinal product |  |
| Active substance |  |
| [Target](file:///C:\Users\ese\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\VUYBT3PB\Target) population |  |
| Therapeutic Area | Choose a therapeutic area |
| Indication in the program | Provide a short description to describe the indication intended to treat |
| Pharmaceutical form |  |
| Route |  |
| Does the medicinal product already have a marketing authorization?  If yes, for which indication(s)? | YES  NO    Provide the authorized indication(s) |
| Is an application for the marketing authorization concerning the indication of this requested program submitted?  If yes, please give the EMA dossier number  If no, when do you have the intention to submit it? | YES  NO  EMA dossier number  When? |
| Do you request an early temporary reimbursement (cohort) ? | YES  NO |

**Statement**

For and on behalf of Applicant's name

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|  |
| I hereby certify that the information and documentation submitted with this notification is correct and all the information requested has been supplied. |
| **Date and signature of the applicant**   |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | | Signed: |  |  | Date: |  |  |  |  |  | |  |  |  |  |  |  |  |  |  | | Authority/Position : |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  |  | |

**Documents to be enclosed :**

Cover Letter

Application form

Protocol

The summarized information for publication

A medicinal product dossier

The Informed consent form in French and Dutch

An example of the labels

**Send your application (electronic version is strongly recommended) to** :

Federal Agency for Medicines and Health Products, R&D Division – Unmet Medical Need (08C0005)  
Eurostation II   
Place Victor Horta, 40 box 40   
1060 Brussels

**Send your question to UMN@fagg-afmps.be**