# **Application form to request the re-evaluation of a Compassionate Use Program or a Medical Need Program**

## **Re-evaluation of**

 [ ]  Compassionate use program Provide our reference

 [ ]  Medical Need Program Provide our reference

## **General information of the program**

|  |  |
| --- | --- |
| Medicinal Product |  |
| Applicant |  |
| Address (headquarter) | Street: Postcode:City:Country: |
| Contact person (First Name/Name) |  |
| Phone/e-mail |  |  |
| To whom should the invoice be sent? (if different from contact person) Name/e-mail |  |  |
| Manufacturer (if different from Applicant) |  |
| Indication of the program |  |
| Approval date  |  |
| Has a MA been submitted in the CUP/MNP indication? If so, please provide the EMA dossier number |  |
| How many patients have been enrolled - since the approval of the program?- since the previous cut-off? |  |
| How many patients are currently treated via the program? |  |

## **Medicinal Product Information**

|  |  |
| --- | --- |
| Is there new relevant scientific information?**If yes, please develop in the protocol.** | [ ] Yes [ ] No |
| When is commercialisation in this indication expected? |  |
| Is there an intention to request reimbursement in this indication? If yes, when? |  |

## **Information on the Unmet Need**

|  |  |
| --- | --- |
| Are there new **reimbursed** alternative treatment options in Belgium?**If yes, please develop in the protocol.** | [ ] Yes [ ] No |
| Are there new clinical trials open for recruitment in the same indication in Belgium? **If yes, please provide references in the protocol** | [ ] Yes [ ] No |

## **Safety information**

|  |  |
| --- | --- |
| Latest PSUR/DSUR ? If not yet sent to FAMHP, please include in the submission |  |
| Were SUSARs observed within the program?Where SUSARs observed globally with the medicinal product? Did the list of expected adverse reactions change? If so please update in the protocol | [ ] Yes [ ] No[ ] Yes [ ] No[ ] Yes [ ] No |
| Are there new safety issues that impact the initial B/R? **If yes, the submission should be accompanied by a discussion of the current B/R and the current management of the identified and potential risks** | [ ] Yes [ ] No |

**Statement**

For and on behalf of Applicant’s name

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**

Signature: Date:

Authority/Position:

**Please provide the updated version of the following documents (please provide track changes and clean version) or declare that the previous submitted version of the document is still valid.**

[ ] Updated Protocol or [ ]  Previous submitted Protocol is still valid: please indicate the version number and the date

[ ]  Updated Summarized information for publication or [ ]  Previous submitted Summarized information for publication is still valid: please indicate the version number and the date

[ ]  Updated ICF or [ ]  Previous submitted ICF is still valid: please indicate the version number and the date

**Please provide the latest version of the following documents if not already submitted:**

[ ]  DSUR

[ ]  PSUR

[ ]  Line Listings of SUSARs (worldwide in clinical trials and CUP/MNP)

[ ]  Other:

**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 questions** **mailto:umn@fagg-afmps.be**