# **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 via** [**CESP**](https://www.afmps.be/sites/default/files/content/annex_ix_e-sumbission_through_the_cesp_1.pdf) **following the exact procedure**

**Send your questions** [**mailto:umn@fagg-afmps.be**](mailto:umn@fagg-afmps.be)