# **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 |  |
| Manufacturer |  |
| Indication of the program |  |
| Approval date |  |
| Has a MA been submitted in the CUP/MNP indication[[1]](#endnote-1)? 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 commercialization for this indication expected? |  |
| Is there an intention to request for a reimbursement in this indication? If yes please indicate the timelines |  |

## **Information on the Unmet Need**

|  |  |
| --- | --- |
| Are there new available 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:

**Documents enclosed and updated (please provide track changes and clean version):**

DSUR

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

IB

PSUR

Protocol

Summarized information for publication

ICF

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 to** [**umn@fagg-afmps.be**](mailto:umn@fagg-afmps.be)

1. [↑](#endnote-ref-1)