**APPLICATION FORM FOR HOSPITAL EXEMPTION FOR ADVANCED THERAPY MEDICINAL PRODUCTS**

1. **Type of application**

Initial application for Hospital Exemption

Application for substantial modification(s)

Procedure number (as communicated by the FAMHP prior to submission):

1. **Information relating to the Hospital Exemption holder / Contact persons:**

**Proposed Hospital Exemption holder (applicant):**

Name/establishment:

Address:

Telephone:

E-Mail:

Contact person authorised to communicate on behalf of the applicant (if applicable):

Address:

Telephone:

E-Mail:

Attach a letter of authorisation for communication on behalf of the applicant

1. **Information relating to the advanced therapy medicinal product:**

**Proposed name** of the medicinal product (name + strength + pharmaceutical form):

**Route of administration:**

**Category:**

gene therapy medicinal product (as defined in part IV of Annex I to Directive 2001/83/EC as amended by Directive 2009/120/EC)

somatic cell therapy medicinal product (as defined in part IV of Annex I to Directive 2001/83/EC as amended by Directive 2009/120/EC)

tissue engineered product (as defined in Regulation (EC) No 1394/2007)

Combined advanced therapy medicinal product (as defined in Regulation (EC) No 1394/2007)

Yes  No

**Fulfilment of the Hospital Exemption criteria:**

the ATMP is prepared in Belgium according to an individual medical prescription

the ATMP is prepared on a non-routine basis

Expected number of patients to be treated, frequency of administration, number of released lots:

the ATMP is to be used in a hospital, in Belgium, under the exclusive professional responsibility of a medical practitioner

the same ATMP is not available for patients through a clinical trial or a compassionate use program (art. 6quater, §1, 2° of the law of 25 March 1964)

the same ATMP is not available for patients through an Hospital Exemption or a Marketing Authorisation, including through a medical need program (art. 6quater, §1, 3° of the law of 25 March 1964)

the same ATMP has already been administered to human

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| --- | --- | --- |
| **Qualitative and quantitative composition:** | | |
| QUALITATIVE COMPOSITION | QUANTITATIVE COMPOSITION | |
| Active substance(s): | Quantity : | Concentration: |
| Excipients:    Other component(s) (if any): | Quantity : | Unit: |

**Brief description of the finished product:**

**Container, closure and medical device(s):**

Description of the primary packaging (type of container, material and closure):

Shelf life of the ready-to-use product:

Medical device (if applicable):

- Name of the device:

- CE mark:

- Notified Body:

**Preparation of the Advanced Therapy Medicinal Product:**

For all sites involved in the manufacturing and analysis of the product, please indicate:

(company) name:

Administrative address

Address of the site:

Brief description of manufacturing steps performed:

If available**,** attach the certificate of good manufacturing practices for the preparation of advanced therapy medicinal products,\*

or indicate the predicted date of the inspection\*:

\* At the time of the submission of the application for Hospital Exemption, the certificate of good manufacturing practices for the preparation of advanced therapy medicinal products is not mandatory, however the holder of the Hospital Exemption should have a certificate available before starting the preparation of the ATMP (Art. 14. §1. 1° of RD of 08.01.2017). Please take contact with DG Inspection (olivier.pauwels@fagg-afmps.be) if the necessary measures have not been undertaken.

**Proposal of periodicity and duration of patient follow-up** (Art. 7. §1. 15° and art. 19 of RD of 01.08.2017)**:**

**Date and signature of the applicant:**

**Date: Signature:**