DG Inspection/Autorisations Division/Specially Regulated Substances Entity/Narcotics team

Send BY REGISTERED POST to:

Federal Agency for Medicines and Health Products
DG Inspection – Authorisations Division - Narcotics Team
Avenue Galilée 5/03
1210 BRUSSELS

Or

Send BY EMAIL to: narcotics@afmps.be
Only when provided with the correct qualified electronic signatures (NO SCANS).

END USER LICENCE APPLICATION FORM FOR NARCOTIC DRUGS AND/OR PSYCHOTROPIC SUBSTANCES FOR SCIENTIFIC AND/OR ANALYTICAL PURPOSES (LABORATORIES)

Pursuant to art. 11 of the Royal Decree of 06.09.2017 regulating narcotic drugs and psychotropic substances

☐ **RENEWAL OF LICENCE NUMBER:**

☐ **NEW APPLICATION**

1. IDENTIFICATION OF THE APPLICANT

Registered office

Name:	
Legal form:	
Company number:	
Address:	
Telephone:	

Place in Belgium where the intended substances will be kept

(in cases of multiple activity sites, it is required to submit one application for each activity site)

Name/department:	
Address:	
Telephone:	

Correspondence address (Contact name and address for receipt of import or export authorisations)

Full name:	
Address:	

Responsible persons (maximum of four) designated by the applicant
(they are assumed to be up-to-date on the legislation on this topic and the statutory obligations, cf. art. 9 and and art. 10 of the royal decree of 06.09.2017 regulating narcotics and psychotropic substances)

Name	Phone / Mobile	E-mail	Signature
1.			
2.			
3.			
4.			

Contact person
(one of the above responsible persons who serves as a point of contact for the FAMHP for the licence)

Name:	

2. ACTIVITIES (indicate as appropriate)

Note: imports and exports within the framework of this legislation are also applicable within the European Union

☐ Possession (is both physical and non-physical, must always be indicated)

☐ Procurement (is both purchase and acquisition)

☐ Import

☐ Export (please indicate for what you are requesting export):

☐ Transport (please indicate for what you are requesting transport):

☐ Handing over (please indicate for what you are requesting handing over):

. B TA E and M TI ATI
(for an overview of the substances and appendices, see the FAMHP website):

For the purchase and possession of ME I I E in the conte t of activities such as anaesthesia of LAB RAT RY A IMAL , no end user licence is required as long as the medicines have been lawfully obtained by a RE RI TI .

Please indicate below for which substances you are requesting a licence and provide a brief description of the intended use of these substances. An indication of scientific and/or analytical purposes is insufficient. If the usage differs per substance, you must specify this per substance in the organisation procedure attached to this application. This will avoid additional queries from the FAMHP and possible delays in processing your licence.

To icology laboratories can apply for a licence for ALL certified substances and should not list these separately. ursuant to article 2 of the royal decree of . .2 regulating narcotics and psychotropic substances, these laboratories must however pass on the results of analyses of these substances e cept for cannabis, T and T -A to the Belgian Early arning ystem on rugs BE , on a daily basis.

REASON for the licence application***:**

***: If this space is not sufficient, please add an appendix signed by 1 of the** responsible persons **and by a statutory manager.**

Intended quantities

Intended supplier s

B TA E (indicate as appropriate):

☐ **toxicology laboratory: licence application for ALL substances listed in appendix I, II, III, IV in the aforementioned royal decree.**

☐ **application for specific substances, listed below:**

I I ATI F BA I B TA E :
(the name of the base substance as mentioned in the appendices of the R.D.)

. ME T T BE ATTA E

lease chec this thoroughly because without these documents, your application will be inadmissible.

- ☐ **Certificates of good conduct as per the template in article 596.1 of the Belgian Code of Criminal Procedure (no more than three months old) for the responsible persons**
- ☐ **Organisation procedure as specified in article 11(§2) of the aforementioned royal decree**

. I E by the legal entity s statutory responsible person if this is a government authority, educational institute or hospital, this will be the director or rector for agreement with the contents of this fully completed form

Full name:	
Position:	
Email:	**Phone/Mobile:**
Signature:	**Date:**

Practical information

- **Return the fully completed and signed application form along with the required documents:**

  - **BY REGISTERED POST, only if the original form has been signed (no copy or scan) to:**

    Federal Agency for Medicines and Health Products
    DG Inspection – Authorisations Division - Narcotics Team
    Avenue Galilée 5/03
    1210 BRUSSELS

  - **BY EMAIL, only if the form has been provided with ALL the necessary qualified electronic signatures AFTER it has been completed in full, to narcotics@fagg-afmps.be** (signature via ID card or see https://economie.fgov.be/fr/themes/line/commerce-electronique/signature-electronique-et) **Company tokens are usually not qualified electronic signatures and may be considered inadmissible.**

    The signature can be added by double-clicking on the signature field. Once signatures have been added, it is no longer permitted to edit the form, so please complete the form in full before adding the signatures. If the form does need to be changed again, the signatures must be re-applied. Otherwise, the application will be inadmissible.

- The treatment of this licence application is subjected to **a fee** as specified **on the FAMHP website.**
  This fee is invoiced **afterwards** by the FAMHP.
  By default, the invoice is sent to the address of the registered office and includes the name of the contact person for this licence. If it needs to be sent to a different address or if it needs to include for example an order number, please indicate this below:

IMPORTANT:
Applications that are not completed correctly, in full and with due care may be inadmissible.