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

Send BY REGISTERED POST to:
Federal Agency for Medicines and Health Products
Avenue Galilée 5/03
1210 BRUSSELS

Or

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

APPLICATION FORM FOR NEW ACTIVITY LICENCE - NARCOTIC AND/OR PSYCHOTROPIC SUBSTANCES

According to article 11 of the royal decree of 06.09.2017 regulating narcotics and/or psychotropic substances

1. IDENTIFICATION OF THE APPLICANT

Registered office

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

Where applicable, indicate the licence number as referred to in article 24(§1) of the law dated May 7, 2004 related to experiments on human people (investigational medicinal products authorisation or IMP-authorisation) and article 12bis and ter of the Belgian medicines law of March 25, 1964 (wholesaler dealer's authorisation - WDA/Manufacturing authorisation - MIA):
The activity licence cannot be granted if these licences have not been obtained.

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)

Address:	
Telephone:	

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

Name:	
Address:	

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

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

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

Name:	

2. ACTIVITIES (indicate the appropriate responses)
Note: imports and exports within the framework of this legislation also apply within the European Union

- ☐ Possess (is both physical and non-physical; must also be indicated)
- ☐ Procure (is both purchase and acquisition)
- ☐ Sell/offer for sale
- ☐ Provide
- ☐ Manufacture of raw materials
- ☐ Manufacture of medicine (packages or in bulk)
- ☐ Manufacture of IMP
- ☐ Package/repackage
- ☐ Import for the Belgian market/use within Belgium*
- ☐ Import for re-export
- ☐ Export
- ☐ Transport (under the responsibility of the licensee)
- ☐ Other:

* If the "Import for the Belgian market/use within Belgium" box is ticked, then due to import limits by country, it is necessary to register this with the UN, cf.:
- "estimates" for narcotics,
- "assessments" for psychotropic substances:

an estimate is given below of the quantities to be imported annually FOR EACH substance for which a licence is requested.

3. Application SUBSTANCES and JUSTIFICATION

(for an overview of the substances + appendices, see the FAMHP website)

Please indicate below the substances for which you are applying for a licence and provide a brief description of the reasons for applying for this licence. **The organisation procedure enclosed with this application must specify the activity for each substance**, such as:

- use as a reference material/distribution as a medicine or pharmaceutical ingredient;
- only in possession as a retained sample or awaiting destruction;
- use in the manufacturing process (starting product, intermediary product or final product).

This will avoid additional questions from the Narcotics Team of the FAMHP and potential delays in processing your licence application.

REASON for licence application:

GROUP OF PRODUCTS

In certain cases, a license can be obtained for a group of products (indicate the appropriate responses)

☐ Licence application for ALL products covered by Annexes I, II, III and IV:
- ☐ Company that destroys products (incinerator) and therefore, has them temporary in possession.
- ☐ Company that centralises and temporarily stores products, already sealed by the FAMPH for destruction.
- ☐ Laboratory recognised/authorised for medicines analyses (agreement/authorisation n°:)
  and in addition analyses samples of seizures.

☐ Licence application for ALL products covered by Annexes I, IIb, IVb and IVc.
- ☐ Organiser of centralised collection in view of destruction according to article 46 of the R.D. of 06/09/2017.

☐ Licence application for ALL products covered by Annexes I, IIb, III, IVb and IVc.
- ☐ Laboratory recognised/authorised for medicine analysis (agreement/authorisation n°:).
- ☐ Wholesaler/dealer (specific indication on the WDA authorisation “2.3. full line wholesaler”).
- ☐ Holders of a preparation authorisation, namely n°: .

In all other cases, the specific products must be listed at page 4.
(for instance: manufacturers, distributors without indication « 2.3. full line wholesaler », R&D projects,… .)

INDICATION OF PREPARATIONS (do not fill in if an application for a group of products have been indicated)

- ☐ Preparations annex Ic - Codeine
- ☐ Preparations annex Ic - Ethylmorphine
- ☐ Preparations annex IVc- Tramadol
- ☐ Preparations annex Ic - Pholcodine
- ☐ Preparations annex Ic - Dihydrocodeine

INDICATION OF BASIC SUBSTANCES

(do not fill in if a request for a group of products have been indicated)
(just the name of the basic substance as indicated in the annexes to the royal decree)
If you need more room, you may add an appendix to the application, to list the relevant substances.

4. DOCUMENTS TO BE ATTACHED

Please check 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

5. SIGNATURE of a statutory manager of the legal entity endorsing the entirety of the contents of this completed form

Name:	
Position:	
E-mail:	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 copies or scans), to:**

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

  - **By E-MAIL, 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.