DG Inspection/Authorisations Division/Specially Regulated Substances Entity/RD 12.04.1974 Team

Send BY POST to:
Federal Agency for Medicines and Health Products
DG Inspection – Authorisations Division – Substances RD 12.04.1974 Team
Avenue Galilée 5/03
1210 BRUSSELS

Or

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

APPLICATION FOR A LICENCE FOR SUBSTANCES R.D. 12.04.1974 FOR PURPOSES OTHER THAN SCIENTIFIC AND/OR ANALYTICAL (e.g. activities related to sale or manufacturing)

According to art. 1 of the royal decree dated 12 April 1974 regarding some operations in connection with substances with hormonal, anti-hormonal, anabolic, beta-adrenergic, anti-infectious, anti-parasitic or anti-inflammatory effects, last revised by the R.D. dated 4 February 2002 (B.S. dated 28 February 2002).

☐ RENEWAL OF LICENCE NUMBER: indicate as appropriate**: NL/FR**

☐ NEW LICENCE REQUEST

1. IDENTIFICATION OF THE APPLICANT

Registered office

Trade name*:	
Legal form*:	
Company number*:	
Address*:	
Telephone:	

Accounting information (contact person and address for mailing the invoice).

Name*:	
Address:	
E-mail*:	
VAT-number:	
Extra information that needs to be mentioned on the invoice*:	

2. Activities (please indicate that which is applicable)

Note: all activities with **medicines** regulated by a Manufacturing and Importation Authorisation (« MIA ») or Wholesale Distributor Authorisation (« WDA ») are exempted. API's are not exempted.

☑ Be in possession of	☑ Acquiring by payment or at no cost
☐ Import	☐ Export
☐ Transport	☐ Manufacturing of raw materials (not of medicine)
☐ Offering for sale	☐ Sale

Note: import and export are regarded as in relation to the Belgian territory.

*: Mandatory field

3. ACTIVITY SITE

The various addresses where the substances are stored and/or being used.
At least 1 mandatory. If this space is not sufficient, please add an attachment.

Name/department:	
Address:	
Name/department:	
Address:	
Name/department:	
Address:	
Name/department:	
Address:	
Name/department:	
Address:	
Name/department:	
Address:	
Name/department:	
Address:	
Name/department:	
Address:	

4. DETAILS OF THE PERSON(S) CHARGED WITH THE RESPONSIBILITY FOR PERFORMING THE OBLIGATIONS DETERMINED BY THE AFOREMENTIONED DECREE (these persons are assumed to be up-to-date on the legislation on this topic and the statutory obligations)
At least 1 mandatory.

Name	Signature

5. CONTACTPERSON (for any communications from the FAMHP such as circulars or additional questions)
Mandatory fields.

Name	E-mail	Tel./mobile

6. SUBSTANCES and JUSTIFICATION

Please indicate on the next page the substances for which you are applying for a licence and provide below a brief description of the reason/the project for applying for this licence. **This will avoid additional questions from our service and potential delays in processing your licence application.** If this space is not sufficient, please add an attachment.

REASONS for applying for this licence:

SUBSTANCES:
Substances and their corresponding CAS-number for which the licence is being requested (art. 1, §1 and §3 of the R.D. 12 April 1974, last revised by the R.D. dated 4 February 2002).
In case of insufficient space, you may add an appendix to the application, to list the relevant substances and their corresponding CAS-number. At least 1 mandatory.

SUBSTANCE	CAS- number (Chemical Abstracts Registry Number)

7. SIGNATURE of **at least one** statutory or legally responsible person of the legal entity endorsing the entirety of the contents of this completed form. If this person cannot be found in the CBE, legal proof that this person is authorized to sign must be enclosed.	
Name:	Name:
Position:	Position:
E-mail:	E-mail:
Date:	Date:
Signature:	Signature:

Practical information

- Return the fully completed and signed application form:
  - **By 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 - Substances RD 12.04.1974 Team
    Avenue Galilée 5/03
    1210 BRUSSELS

  Or

  - **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:**
    substances_HAA@fagg.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 fee amount** is indexed annually and can be viewed at any time on the FAMHP website.
- **Every modification** (responsible persons, address, substances…) needs to be communicated to us (by post or e-mail) **within 15 days** by a responsible person mentioned on the licence. The form to be used for this is available on the FAMHP website.