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 ACTIVITY LICENCE RENEWAL - NARCOTIC AND/OR PSYCHOTROPIC SUBSTANCES

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

RENEWAL OF THE LICENCE NUMBER:		**mandatory field!**

1. IDENTIFICATION OF THE APPLICANT

Registered office

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

Place where the intended substances are kept: identical as on as on the licence to be renewed ?

☐	YES NO → in this case it is not a renewal of the licence and a new licence must be applied for

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

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 art. 10 of the royal decree of 06.09.2017 regulating narcotics and psychotropic substances)

Name	Phone/mobile	Email	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 the appropriate responses)

To repeat: imports and exports within the framework of this legislation also apply within the European Union

☐ Identical as on licence to be renewed

☐ New activity is to be added, namely:

- ☐ provide
- ☐ transport (falls under the responsibility of the licensee)
- ☐ import annex Ic preparations – codeine (wholesaler –divider to whom BRONCHOSEDAL CODEINE is delivered from Germany)
- ☐ other:

3. Application SUBSTANCES and JUSTIFICATION

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

The (possibly updated) organisation procedure enclosed with this application must specify clearly the activity for each substance :

- **details of the substances:** such as legal appendix, eventual trade name, product type (API, authorised medicine, pharmaceutical ingredient …), packing size(s) if applicable
- **details of the activities**

☐ Identical as on licence to be renewed

Eventual remarks:

☐ Identical as on licence to be renewed, but following substances/preparations are not any longer of application and can be **removed**:

SUBSTANCE/PREPARATION: REASON:

☐ Identical as on licence to be renewed, but following substances/preparations must be **added**:

SUBSTANCE*/PREPARATION: REASON:

*if applicable: both the (common) substances name as the trade name with always mention of specific dosage(s) and packing size(s). This is also possible by adding a document in annex to this application form.

In case these products will be imported for the Belgian market/use within Belgium: if for this new substance no estimates of the provided annual quantities have been transmitted to the Narcotics team via the usual forms, then you must transmit these for the year of the renewal and – if the renewal does not start before 1 may – also for the following year):

There are some additional points for attention, when a new substance must be added, in cases of:	**The following information is required to make your application admissible and to enter data into the software**
☐ an **API** for import, distribution or manufacture (within the European Union)	Number API registration: (don't forget to notify each year the modifications of the API registration)
☐ a **pharmaceutical ingredient** for extemporaneous preparations	Licence number: If not licenced, please enclose the analysis certificate.
☐ an **IMP** for clinical trials	EUDRACT-number: Enclose an excerpt from the IMP dossier clearly indicating the name and composition. If the clinical trial is taking place in Belgium, enclose a copy of the letter of approval from the DG PRE authorisation of the FAMHP.
☐ a **medicine** not (yet) available on the Belgian market	Indicate the Belgian number of the marketing authorisation (MA) or the contact person at the DG PRE authorisation concerning this application, if intended for the Belgian market: or enclose of a scan of a foreign MA.
☐ another preparation (e.g. for laboratory applications	Please enclose an official manufacturer document with detailed contents of the preparation

4. DOCUMENTS TO BE ATTACHED

Please check this thoroughly because without these documents, your application will be considered 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 indicated on page 1
- ☐ **Actualised** organisation procedure as specified in article 11(§2) of the aforementioned royal decree
- ☐ Copy of the licence to be renewed
- ☐ Where applicable: the required documents as specified under "add a new substance".

5. SIGNATURE of a statutory manager of the legal entity endorsing the entirety of the contents of this completed form/licence to be renewed

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 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.

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