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 E-MAIL to: narcotics@fagg-afmps.be
Only when provided with the correct qualified electronic signatures (NO SCANS).

According to article 15 of the royal decree of 06.09.2017 regulating narcotic and psychotropic substances

CHANGES to the details appearing on the activity licence for narcotic and/or psychotropic substances	
Licensee name:	**Licence number:**
Name of person responsible for the licence: **Signature:** **Name of statutory manager[1]:** **Signature:**	

[1] If the applicant is a legal entity, the application is signed by an authorised natural person within the requesting legal entity. If the applicant is a hospital, public or educational institution, the application is signed by a supervisor within this organisation, who is authorised to do so by virtue of the articles of association of the organisation where he or she works.

Change type			
A	**Name and/or address details for registered office** **Enclose an official proof:** - **excerpt from the Belgian Government Gazette;** - **official letter from the civil-law notary if the change has not yet been published in the Belgian Government Gazette.** If the legal entity or the address of the place of performance changes as well, you must apply for a new licence using the appropriate form on the FAMHP website.	Old details:	New details:
B	**Change in responsible person** **Indicate the appropriate responses:** ☐ delete a responsible person. Attention: it is advised to have at least 2 responsible persons ☐ add a new responsible person: **enclose a certificate of good conduct article 596.1 of the Belgian Code of Criminal Procedure, which is no more than 3 months old.**	Name of the responsible person to be deleted when applicable:	Name of new responsible person when applicable: Phone/mobile: email: Signature:
C	**Expansion of the activity** **If applying for a change to a "Wholesale Distributor Authorisation" (WDA) or a "Manufacturing and Importing Authorisation" (MIA) as well, this change must be approved FIRST before your application can be deemed admissible.** **Indicate the appropriate responses:** ☐ import for the Belgian market/use within Belgium* ☐ import for re-export*	Explanation of the new activity:	

	☐ export* ☐ transport ☐ manufacture of raw materials/APIs ☐ manufacture of medicines ☐ manufacture of Investigational Medicinal Products (IMPs) ☐ manufacture – (re)package ☐ offer for sale ☐ provide ☐ sell ☐ expansion/modification of the comment (s) to clarify the scope of the license * within the framework of this legislation, the import/export border is Belgium (not the European Union)	Due to the existence of import limits, if indicating **IMPORT for the Belgian market/use within Belgium, for each import substance under your licence,** you must provide an estimate of the annual quantity to be imported (this is also possible by adding a document in annex): - Estimate of the quantities to be imported during this year - Estimate of the quantities to be imported next year:
D	**Expansion of the licensed substances:** (Common) name of substance(s): Trade name of preparation(s): (where applicable)	Explanation of the planned activity with these new substance(s): **If this (these) substance(s) will be imported for the Belgian market/use within Belgium**, an estimate must be provided of annual quantities (due to the existence of import limits), **as well for this year as for the next year** (this is also possible by adding a document in annex):

E	There are additional points for attention 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 magisterial preparations:	Licence number: If not licenced, you have to enclose the analysis certificate.
	☐ an **IMP** for a clinical trial:	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):	Enclose an official manufacturer document with detailed contents of the preparation.

MANDATORY DOCUMENTS TO BE ENCLOSED WITH THIS APPLICATION – CRITICAL FOR APPLICATION ACCEPTANCE

☐ Any required documents indicated for each change type

☐ If the changes impact the organisation procedure: the updated version of this procedure

Note: if using qualified* electronic signatures, it is no longer permitted to change the document once the signatures have been applied. If changes do need to be made after this, the signatures must be re-applied to the document. Otherwise, the application will be inadmissible

* 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.**

Practical information

- If 2 new responsible persons are appointed and therefore both have to sign the form (which is not foreseen), you can send 2 forms at once which will be treated as 1 change.

- 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 change 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.