



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

**Return by registered post to:**

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

Or

**Return by e-mail to:**

[narcotics@fagg-afmps.be](mailto:narcotics@fagg-afmps.be)

**Only when provided with the correct qualified electronic signatures (NO SCANS)**

Pursuant to art. 15 of the royal decree of 06.09.2017 regulating narcotic and psychotropic substances

CHANGES to the details appearing on the licence for narcotics and/or psychotropic substances	
Licensee name:	Licence number:
Name of the person responsible for the licence:	
Signature:	
Name of a manager or a statutory responsible person <sup>1</sup> :	
Signature:	

<sup>1</sup> If the applicant is a legal entity, the application will be signed by a statutory authorised natural person within the legal entity making the application. If the applicant is a hospital, public or an educational institution, the application will be signed by a manager within this institution who is authorised to do so according to the articles of association of the institution at which he/she is employed.

Change type			
A	<p><b>Name and/or address details of the registered office</b></p> <p><b>Please attach an official proof:</b></p> <ul style="list-style-type: none"> <li>- an extract from the Belgian Government Gazette;</li> <li>- an official letter from the civil-law notary if the change has not yet been published in the Belgian Government Gazette.</li> </ul> <p>If the legal entity or the address of the location of activities also changes, you must request a new licence using the appropriate form on the FAMHP's website.</p>	Previous details:	New details:
C	<p><b>Responsible person</b></p> <p>Cancel/replace a responsible person. Attention: it is advised to have at least 2 responsible persons</p> <p>Add a new responsible person: <b>enclose a certificate of good conduct article 596.1 of the Belgian Code of Criminal Procedure, which is no more than 3 months old.</b></p> <p>(a licence may mention no more than four responsible persons)</p>	Name of the responsible person to be cancelled/replaced, when applicable:	<p>Name of new responsible person, when applicable:</p> <p>Telephone/Mobile phone:</p> <p>email:</p> <p>Signature:</p>
D	<p><b>Expansion of the activity</b></p> <p>Import*</p> <p>Export*</p> <p>Transport</p> <p>Handover</p> <p>Expansion/modification of the comment (s) to clarify the scope of the license</p> <p>* within the framework of this legislation, the imports and exports border is Belgium (and not the European Union)</p>	Explanation of the new activity:	

		<p>Due to the existence of import limits, if indicating <b>IMPORT</b>, for each imported 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):</p>
<p><b>E</b></p>	<p><b>Expansion of the licenced substances:</b>  (Common) name of the substance(s):</p>	<p>Explanation of the planned activity with this (these) new substance(s):</p> <p><b>If this (these) substance(s) will be imported</b>, an estimate must be provided of the annual quantities to be imported (due to the existence of import limits), <b>as well for this year as for the next year:</b></p>
<p><b>MANDATORY DOCUMENTS TO BE ENCLOSED WITH THIS APPLICATION – CRITICAL FOR APPLICATION ACCEPTANCE</b></p> <p>Any required documents indicated for each change type</p> <p>If the changes impact the organisation procedure: the updated version of this procedure</p> <p><b>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.</b></p> <p>(* signature via ID card or see -<a href="https://economie.fgov.be/fr/themes/line/commerce-electronique/signature-electronique-et">https://economie.fgov.be/fr/themes/line/commerce-electronique/signature-electronique-et</a>. Company tokens are usually not qualified electronic signatures and may be considered inadmissible.)</p>		

## 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](mailto: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.**