Guidelines for application for authorisation of activities with euphoriant substances

17 November 2015

Applicants must submit the application form to the Danish Medicines Agency as an electronic scanned copy to the e-mail address virksomhedstilladelse@dkma.dk

General guidance for the application

At the top of the page, you must indicate whether it is a new application, renewal or change of application for authorisation of activities with euphoriant substances.

Every company is assigned a company number by the Danish Medicines Agency. Please indicate your company number, if possible.

Indicate briefly the reason for the need/cause of an authorisation under Clarifying remarks. This field must always be completed in case of new applications or variation applications.

Fill in the other items on page 1. Please note that we will send the electronic authorisation to the e-mail address stated in the application form.

The person responsible must sign the form, thereby confirming that the information on the application form is true and correct.

The application form for authorisation of activities with euphoriant substances is divided into three annexes:
Annex 1: Activities with euphoriant substances
Annex 2: Storage and distribution
Annex 3: Responsible vis-a-vis the Danish Medicines Agency

Please fill in each item as described below.

Annex 1:

Select the activities and the substances your company wishes to apply for by ticking the relevant boxes.

Indicate the names of the substances your company wishes to handle. If your company wishes to handle more than five substances, the field must be left blank.

Activities:

- ***Receipt and storage***. Only permits purchasing from Danish companies and stockholdings.
- ***Import***. Permits import of products from the EU/EEA and third countries.
- ***Export***. Permits export of products to the EU/EEA and third countries.
- ***Distribution***. Permits distribution of products in Denmark in intact original packaging. Does *not* permit dispensing for scientific use or clinical trials.
- ***Manufacturing of preparations***. Permits manufacture of e.g. solutions for analytical purposes, weighing out, repackaging and manufacture of medicines.
- ****Synthesis or other chemical changes***. Permits synthesis of a euphoriant substance or chemical change of a substance.
- ***Dispensing for scientific use***. Permits dispensing for scientific use.
- ***Dispensing for clinical trials***. Permits dispensing for clinical trials.
- ***Other***. If none of the above bullets cover the desired activity, you can describe the activity here.

* The responsible qualified person must be indicated on applications for authorisation of synthesis or other chemical changes. Please note that authorisation of this activity will be issued with an expiry date. Substances must be indicated for this activity.

Annex 2:

Please indicate the address(es) used for stockholding. If the stock is stored at another company or e.g. a stock hotel, these addresses must also be indicated.

Annex 3:

Indicate name and title of the person responsible for activities with euphoriant substances.

Foreign companies

Regarding applications from foreign companies for authorisation to distribute euphoriant substances, the Danish Medicines Agency will make a specific assessment in each individual case.

In general, authorisation for distribution is only granted to companies within the EU/EEA and in EFTA countries. In this connection we will take into account the principles on the free movement of goods among the member states. Consequently, the company is not required to be established in Denmark.

The assessment will be based on the following:

- In general, the foreign company can be granted authorisation for the activity distribution.
- Generally, all physical handling on Danish territory must be carried out by a Danish wholesaler – including accounts, application for certificates and reporting to the Danish Medicines Agency that must be made by the Danish wholesaler on behalf of the foreign company.
- The foreign company and the Danish wholesaler must have entered into a contract.
- Presentation of a valid company authorisation issued by the foreign authorities for activities with euphoriant substances for the foreign company applying for authorisation in Denmark.
- Presentation of a valid company authorisation for the handling of euphoriant substances and an authorisation for wholesale distribution of medicines, if relevant to the Danish wholesaler.

In accordance with the above, the Danish wholesaler must keep the accounts on behalf of the foreign company and make sure that the accounts are separated from the wholesaler's own accounts. When applying for certificates, the Danish wholesaler must apply on behalf of the foreign wholesaler, and this should appear clearly from the application.

Consequently, the following must be enclosed when foreign companies apply for authorisation to distribute euphoriant substances in Denmark:

- Contract with Danish wholesaler, from which it appears that the Danish wholesaler handles the accounts, application for certificates as well as reporting to the Danish Medicines Agency on behalf of the foreign company.
- A valid company authorisation issued by the foreign authorities for activities with euphoriant substances for the foreign company applying for authorisation in Denmark.
- A valid company authorisation for the handling of euphoriant substances and an authorisation for wholesale distribution of medicines, if relevant to the Danish wholesaler.