LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

Guidelines on registration as a broker of medicinal products

These guidelines describe how to complete the form for registration as a broker of medicinal products.

For information about the requirements for brokers of medicinal products, we refer to the Danish executive order on the distribution of medicinal products (Danish title: '*Bekendtgørelse om distribution af lægemidler*') – in the following the 'Danish GDP order' and the GDP Guidelines, which describe GDP for brokers of medicinal products. The rules apply to brokering of both human and veterinary medicinal products.

Effective from 1 January 2013, companies are required to register if they wish to broker medicinal products. Only companies with a legally registered address in Denmark can register in Denmark.

General guidance on registration

1. Before submission of the registration form
Before registration, the company must ensure that it complies with the requirements established in the Danish GDP order, including e.g. the setting up of a quality system, documentation for all inbound and outbound brokered medicinal products as well as having in place an efficient system for recalling medicines from the market. The requirements appear from parts 4 and 6 of the Danish GDP Order. Good Distribution Practice for brokers is described in the GDP Guidelines.

2. Submission of registration form

The registration form is filled in with the following information:

- **Tick** as appropriate to indicate if it is a first-time registration (New) or a change to an existing registration (Correction). If you are making changes to an existing registration, please indicate clearly the company number which appeared from the receipt from the previous registration.
- **Company name**
- **Site address(es)** where brokering takes place.
- **The company's registered main address** and contact details, including address, telephone number, email, website and CVR number.
- **Tick** to confirm that the registration has been completed correctly, that applicable law is complied with and that any changes to the registration will be notified to the Danish Medicines Agency immediately.
- **Contact person responsible for registration**, indicate name, title, telephone number and email address.
- **Place and date**
- **Signature**

The registration form should be accompanied by a cover letter or email explaining the background for the registration together with a description of the brokering of medicinal products.

The registration form is completed and submitted duly signed as a PDF file (scanned and preferably in OCR format) by email to virksomhedstilladelse@dkma.dk.

3. Acknowledgement of receipt

The Danish Medicines Agency confirms receipt of the registration form. The receipt will include a registration number. This registration number will appear on the list of brokers of medicinal products which is published on the website of the Danish Medicines Agency.

4. Inspection
The Danish Medicines Agency has the right to inspect brokers of medicinal products.

5. Changes to the registration
Any changes to the registration submitted to the Danish Medicines Agency must be notified to the Danish Medicines Agency without undue delay. Changes are notified by filling out the registration form as described under section 2.

6. Termination of registration
If a company having registered as a broker of medicinal products wishes to stop its brokering activities, it must notify the Danish Medicines Agency in writing in order to terminate the registration.

7. Fees
The registration fee is determined by the Ministry of Health and in the Danish Executive Order on Fees Payable for Medicinal Products.

A fee is payable for first-time registrations, relocation to a new address or expansion to cover several, geographically separated addresses. One fee is charged for each site (geographical locality) where brokering of medicinal products takes place. The registration fee is a one-off fee, which is charged on receipt of a registration request. In addition, an annual fee/control fee is charged in the first quarter every year. However, no annual fee/control fee is payable in the year when the registration fee for first-time registration is paid.

An annual fee/control fee is charged for each of the sites that the company has registered with the Danish Medicines Agency. No registration fee is charged for changes not involving address changes.

The registration fee/annual fee may be adjusted on 1 January every year.

Version: Guidelines-Registration of brokers of medicinal products-02

Last updated August 2016