LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

Guidelines on applications for authorisation to wholesale distribute certain substances within the EEA

Table of Content

1 Introduction

This guide describes how to apply for authorisation for wholesale distribution of substances that have anabolic, anti-infectious, antiparasitic, anti-inflammatory, hormonal, euphoric or psychotropic properties (hereinafter *certain substances*) that may be used in animals.

Certain substances may not be administered or used in animals. Therefore, *certain substances* should not be confused with API used in the manufacture of medicinal products.
Authorisation requirements were introduced by the Veterinary Medicinal Products Regulation and are regulated in section 93 of the Danish Medicines Act.

The authorisation will be named as a wholesale distribution authorisation for medicinal products, but will be granted for *certain substances* only. If the company has activities with medicinal products as well, then two wholesale distribution authorisations will be issued.

For applications for wholesale distribution of *certain substances*, a specific form must be used, which can be found on the website.

For information on general requirements and guidelines for applying for company authorisations, see Requirements and deadlines for applications for company authorisations. For information on which activities require a company authorisation under section 39 of the Danish Medicines Act or a company registration pursuant to section 50a of the Danish Medicines Act, see Guidelines on activities subject to a section 39 authorisation or a company registration.

For requirements for the distribution of *certain substances* see Regulation (EU) 2019/6 on veterinary medicinal products, Implementing regulation (EU) 2021/1248 on good distribution practice for veterinary medicinal products and the Danish Medicines Act. Article 2(6)(a) of the veterinary regulation states that the rules for the wholesale distribution of medicinal products also apply to *certain substances*. *Certain substances* will not appear specifically in the articles on wholesale distribution of medicinal products, but the rules will apply anyway.

Please note that the rules for *certain substances* also apply to products containing one or more of the substances covered as a constituent.

This guide starts with a section providing general information and subsequently you can find information on the completion of the application form and guidance for submitting an application, including the documentation to be provided with the application.

Please submit your application electronically to virksomhedstilladelse@dkma.dk.

2 General information

2.1 Establishment of company

In order for a company to apply for a wholesale distribution authorisation, the company must have a physical address in Denmark where the wholesale distribution activities take place. The Danish Medicines Agency must be able to carry out inspections at any given time at the address indicated on the wholesale distribution authorisation.
There must be consistency between the wholesaling site where the wholesale distribution activities occur and the wholesale distribution authorisation granted. Therefore, no wholesale distribution authorisation can be issued to:

- Companies that use c/o addresses without being physically present at the address.
- Companies that rent an office, but where the company actually operates from another country or another location in Denmark, and the office is therefore empty.

2.2 Wholesale distribution of *certain substances*

Wholesale distribution of *certain substances* is defined as any activity consisting of buying, selling, receiving, storing and supplying *certain substances* within the EEA, as well as exporting *certain substances* to countries outside the EEA (third countries).
Companies that purchase, sell, receive, store or supply *certain substances*, or are simply responsible for compliance with GDP rules at other wholesale distributors of *certain substances* (contractee), must have a wholesale distribution authorisation for *certain substances*.
The manufacture of *certain substances* is not independently regulated by the pharmaceutical rules, but the sale of the substances to wholesale distributors and retailers requires a wholesale distribution authorisation.

2.3 Retail distribution of *certain substances*

Retail distribution of *certain substances* is defined as the sale and supply of *certain substances* to the end user. This does not require a permit.
Retailers may only purchase *certain substances* from Danish companies with a wholesale distribution authorisation, while sales may be made to both Danish and foreign end-users. When selling abroad, it is the retailers responsibility to ensure that the recipient country allows sales from Denmark.
In the past, there was a registration system in which also retailers had to report their activities to the Danish Medicines Agency. The registration system was abolished with the introduction of the veterinary regulation's wholesale authorisation requirement.

2.4 End-users of *certain substances*

End-users must purchase *certain substances* from a retailer in Denmark. It is illegal to possess *certain substances* if they have been purchased by a dealer outside Denmark, and it is illegal to use or possess legally purchased *certain substances* for the purpose of their use in animals. The ban ensures that only authorised veterinary medicinal products are used on animals. Section 93(6) of the Danish Medicines Act contains an exemption for the use of *certain substances* in accordance with the Animal Testing Act.

2.5 GDP Responsibility

In general, as a wholesale distributor of *certain substances*, you cannot disclaim the responsibility (GDP responsibility) you have under the Veterinary Regulation for the substances you handle, regardless of whether you buy, sell, receive, import, store or supply *certain substances*.

2.6 Receipt, storage and delivery of *certain substances*

Wholesale distributors receiving, storing and supplying *certain substances* can be divided into two types:

1) Wholesale distributors with their own warehouse, which will be stated in the wholesale distribution authorisation for *certain substances* with activity '2.2 Storage'. Only wholesale distributors of *certain substances* authorised for storage are allowed to store *certain substances*.
2) Wholesalers without their own warehouse who have outsourced the receipt, storage and supply of *certain substances* to a wholesaler with warehouse (e.g. a consignment warehouse). Wholesale distributors without storage of *certain substances* are responsible for ensuring that their contract acceptor is storing the certain substances in accordance with GDP rules. Compliance shall be ensured by audits of the wholesaler. Wholesale distribution according to contract is described in more detail in section 2.7.

2.7 Outsourcing

Receipt, including import, storage and supply of *certain substances*, may be outsourced to companies with a wholesale distribution authorisation covering *certain substances*.
The rules on outsourcing are described in Chapter 8 of Regulation (EU) 2021/1248. Outsourcing of wholesale distribution requires a contract between the companies. Please note that it is not possible to outsource the GDP responsibility; this responsibility always rests with the contract giver which owns the substances.
The contract giver is responsible for assessing whether the contract acceptor is competent to carry out the required work and to ensure, by means of the contract and audits, that the principles and guidelines of good distribution practice are complied with.

2.7.1 Audits of contract acceptors

During an audit, the company must make sure that the contract acceptor is audited on the basis of the activities/products and any special requirements that the company wishes to outsource. The contract acceptor must be audited before the contract acceptor can be used and the conclusion of the audit carried out must be included in the application for approval of the contract acceptor.
The Danish Medicines Agency expects the following from an audit to approve a contract acceptor:

- The audit must have been carried out in the last 12 months.
- The contract acceptor must have followed up on deviations from the audit and the audit for the relevant areas must be completed before submission of the application. Documentation for this must be readily available during inspections.
- The company must carry out a risk assessment for when the next audit is to be carried out (the expectation from the Danish Medicines Agency is no later than 1 year after the contract acceptor first has been used). The risk assessment must be readily available during inspections.

It is possible to use an external auditor to audit the contract acceptor. In this case, the Danish Medicines Agency expects the following:

- The responsible person for the contract giver must document to have reviewed the audit report in order to ensure that it is adequate for the activities to be contracted out, including any special requirements, for example regarding receipt and supply.
- The company must ensure that the external auditor is independent of the contract acceptor and does not have any conflict of interest including financial interests or any other significant affiliation with the audited contract acceptor.
- It must be documented that the external auditor has relevant expertise and experience with auditing.

The company must be able to document the above during inspections.

2.8 Import of *certain substances* from outside the EEA (third countries)

Unlike import of medicinal products, *certain substances* may be imported on the basis of a wholesale distribution authorisation for *certain substances*, provided that the activity "import of substances from third countries" under point 2.5 is authorised on the authorisation. It is the Danish Medicines Agency's assesment that the veterinary regulation does not prevent the importation of *certain substances* from third countries even if it does not regulate it. The Danish Medicines Agency has therefore decided that the activity must appear on the wholesale distribution authorisation if the substances are to be wholesale distributed in Denmark. The Danish Medicines Agency requires the wholesale distributor to ensure that the supplier can lawfully distribute the substances from the country concerned prior to import. Upon receipt, the general rules of reception control apply.

2.9 Inactive activities

A wholesale distribution authorisation must be up-to-date in relation to a company's current activities. When a company no longer has activities, the authorisation must be terminated, see section 4.6. In the case of a shorter period during which all activities are inactive, the company may contact the Danish Medicines Agency in order to maintain the authorisation. The Danish Medicines Agency's general view is that there can be no more than 6 months without activities. When the Danish Medicines Agency receives the company's arguments in favour of maintaining the authorisation, a specific assessment of the current situation will be made.

2.10 The company's responsible person

The responsible person (RP) is the person appointed by the company to ensure that the company complies with applicable rules of good distribution practice. There are no specific education requirements for the RP in Denmark, but the RP must be qualified for the tasks he or she is to perform. The RP must acquire the necessary competence, e.g. through courses, seminars, meetings and the like. It is expected that the RP will keep up to date with the latest legislation in the area. The RP can delegate tasks to others, but not the responsibility.

It is not a requirement that the RP resides in Denmark, but it is a requirement that the person can read and understand the Danish national legislation and thus keep up to date with it. The RP must be at the company regularly and to an adequate extent, considering the activity in the company.

A company can have several RPs. If a company chooses to share responsibility between several RPs, the responsibilities must be clearly divided between the RPs.

3 Completion of the application form

The following sets out guidelines for completing the application form.

Wholesale distribution authorisations for *certain substances* are issued in the same EU format as wholesale distribution authorisations for medicinal products. This is because authorisations are required to be transferred to the European database EudraGMDP, and this can only be done by using the same format as for medicinal products. Therefore, the activities on the application form for *certain substances* do not have consecutive numbers, as only relevant sections from the above format are included in this application form.

The application form for wholesale distribution authorisation is divided into an introduction and 3 annexes:

Introductory pages:	Type of application, company details and signature
Annex 1:	Substance groups and activities at the wholesale distributors own address
Annex 2:	Contract acceptors
Annex 3:	Responsible Person (RP)

The general guidelines for completing the application form are set out below.

3.1 The Introductory Pages

In the introductory pages, the applicant must first specify what the application is about, i.e. whether it is a new application, a change to an existing authorisation or the termination of an existing authorisation. In addition, it must be stated when the company wants the new authorisation or termination to apply from. Please note that authorisations cannot be issued or terminated retrospectively.
As it is often necessary to elaborate on the reason for the application, there is room in the following section to describe the application in free text.

When providing company information, the associated OMS LOC ID must be provided for each site, and for the company's head office, OMS ORG ID must also be indicated. OMS (Organisation Management Service) is EMA's business register of pharmaceutical companies. The company is generally assigned an ORG ID, while each site is assigned a specific LOC ID. The company is responsible for ensuring that the information in this register is correct and for applying to EMA for change of information, e.g. in case of change of name or change of address. This must be applied for and approved before the application for a company authorisation is submitted. New companies must apply to EMA for registration in OMS, which must also be done before applying to the Danish Medicines Agency. See information about OMS and how to apply for changes to the register here.

In the last paragraph, the company must sign the application. The Danish Medicines Agency does not have specific requirements for who in the company must sign the application.

3.2 Completion of Annex 1

Please note that Annex 1 is specific to each site. An Annex 1 must therefore be filled in for each of the company's sites that have GDP activities with *certain substances*. The address of the site concerned shall be indicated at the top of Annex 1.

Annex 1 lists only the wholesale distribution activities carried out at the company's own address. Activities which are not carried out at the company's own address, but are carried out only at the premises of the contract acceptor shall not be listed in Annex 1, but only in Annex 2.

The activities listed in Annex 1 are divided into three sections:

- Substance groups
- Wholesale distribution activities
- Products with additional requirements

And at the end of the annex there is room to specify the activities.

3.2.1 Substance groups

This section lists the groups of substances for which the company is wholesale distributing.

3.2.2 Wholesale distribution activities

This section lists the activities that the company carries out at its own address. The storage and export to third countries involve the physical handling of the substances, and only these activities can be outsourced. Buying and selling does not involve physical handling of the substances and cannot be outsourced.

Please note that "2.2 Holding" includes the physical receipt and delivery of substances unless stated otherwise. For authorisations issued before 1 November 2024, the activities 2.1 and 2.3 were twofold, i.e. the activities included both the physical handling of receipt and/or delivery and also the purchase and/or sale of the substances. This is no longer the case as "2.1 Procurement" and "2.3 Supply" do not involve physical handling of the substances anymore.

Examples of how a company should fill in the application form are given below, depending on whether they store *certain substances* themselves or if this is outsourced.

Example 1
A company which exclusively buys and sells *certain substances* where storage has been outsourced must complete Annex 1 and Annex 2 as illustrated below (in Danish):

2	**Engrosforhandlingsaktiviteter** *Wholesale distribution operations*	
☒	2.1	Køb *Procurement*
☐	2.2	Lagerhold *Holding*
☒	2.3	Salg *Supply*

Kontrakttagere *Contracting-out* **ANNEX 2**

Navn og adresse *Name and address*	**Angiv aktuelt punkt** *Specify paragraph* (2.2/2.4) *(Skal udfyldes / must be completed)*
	Aktivitet
Navn på kontrakttager Adresse Postnummer og by Land	2.2 Lagerhold

Example 2
A company buying, storing and selling *certain substances* shall complete the form as follows:

2	**Engrosforhandlingsaktiviteter** *Wholesale distribution operations*	
☒	2.1	Køb *Procurement*
☒	2.2	Lagerhold *Holding*
☒	2.3	Salg *Supply*

Handling of complaints and recalls is included in the activities 2.1-2.4, and this activity cannot be outsourced.

3.2.3 Products with additional requirements

Some substances have additional requirements for handling. A wholesale distributor operating with these substances shall indicate this here. The activities must also be selected by companies that are not responsible for the physical handling of the substances themselves.

In item 3.2, the company shall indicate whether they have products that require low-temperature storage. Activity 3.2.1 must be selected for products which must be stored between 2–8 °C. If the company has products which must be stored at temperatures lower than this, activity 3.2.2 must be selected and the temperatures must be indicated in the corresponding free text field.

In section 3.3 Other products there is no pre-filled proposals on the application form, but the company has the opportunity to indicate something in free text under this point.

3.2.4 Clarifications

At the end of Annex 1, it is possible to provide comments if necessary. The field should be used if some of the selected activities should be elaborated.

3.3 Completion of Annex 2

Annex 2 lists the contract acceptors used for storage of *certain substances*. A contract acceptor must be listed with the name and main address, even if the activities are carried out at another of the contract acceptors sites. Once a contract acceptor has been approved with the main address, the wholesale distributor may outsource activities to all approved sites at that wholesale distributor, provided that the address is covered by the contract and that an audit has been carried out at the address. Please note that only the activities "2.2 Holding" and "2.4 Exports to third countries" can be outsourced. The activities to be carried out by the contract acceptor should be listed in Annex 2.

The company may not use a contract acceptor until it has been approved by the Danish Medicines Agency. When we approve a contract holder, this will appear in the company's wholesale distribution authorisation under Annex 2. This applies to both Danish and foreign contract acceptors.

3.4 Completion of Annex 3

Annex 3 specifies the responsible person (RP). The title of the responsible person must be indicated in Danish and in English.

If a company chooses to share responsibility between several RPs, then the responsibilities must be clearly divided between the RPs. This should be described in the section for describing the application in the introductory pages of the application form.

Annex 3 previously stated the company's responsible management person. This is changed to the RP from January 1, 2023.

4 Submission and requirements for applications

For information on general requirements and guidelines for applying for company authorisations, see Requirements and deadlines for applications for company authorisations. In this guide you can get information about how the application is submitted, processing times including the concept of clock stop, electronic issuance and validity of the authorisation, as well as fees. Please note that if a company has both a wholesale distribution authorisation for medicinal products and a wholesale distribution authorisation for *certain substances*, only one fee per site must be paid.

In Requirements and deadlines for applications for company authorisations, you can also see what the Danish Medicines Agency expects from the company before submitting the application for the three types of applications for a company authorisation:

1. Application for a new company authorisation (first application)
2. Application for change of an existing company authorisation
3. Termination of an existing company authorisation

Please note that the company must be ready for inspection at the time of application, i.e. the company must have implemented current GDP legislation, including that the storage area, etc. must be fully completed and arranged, temperature monitoring must be installed on the basis of temperature mapping, documentation and procedures must be established, and the company must have sufficient staff.

There may be different requirements for the documentation to be provided with the application form depending on the type of application submitted. The specific requirements for documentation when applying for a wholesale distribution authorisation are described below.

Please note that for changes to wholesale distribution authorisations issued before November 1, 2024, a completed Annex 1 must be submitted for all sites regardless of what the application relates to or what is listed below. A completed annex 2 must also be submitted in this case. This is due to the changes to the format for the authorisation.

For authorisations issued before January 1, 2023, Annex 3 should always be filled in, since the responsible person is given here instead of the responsible management person.

Application for termination of an authorisation is exempted as no new authorisation is issued.

4.1 Application for a new authorisation

When applying for a new wholesale distribution authorisation, the full application form must be completed and, in addition, the organisation chart, an overview of the buildings and a list of substances for each substance group handled by the company must be included. If the company uses a contract acceptor, documentation must be submitted to approve the contract acceptor.

The following must therefore be submitted:

- Application form
- Organisation chart
- Overview of buildings
- List of substances for each group of substances handled by the establishment
- Documentation for the approval of contract acceptor, if applicable. See section 4.4

4.2 Change of name or address

If a company wishes to change its name or address, a change to the wholesale distribution authorisation must be applied for. When changing the name of the company, it is sufficient to submit the introductory pages of the application form together with a confirmation that other conditions in the company are unchanged. In case of change of address, Annex 1 for the new address must be filled in with the introductory pages.
The organisation chart and the overview of the buildings shall be attached only if there are significant changes to the documents.

4.3 Change of substance groups or activities (Annex 1)

In case of changes to substance groups or activities, Annex 1 must be completed (all boxes must be filled in). When adding a new substance group, a list of substances in the new substance group must be included. If there are only changes to one site, it is sufficient to fill in Annex 1 for that site and state in the application that the change affects this site only. In addition, the introductory pages must always be filled in.

4.4 Change of contract acceptors (Annex 2)

When applying for a new contract acceptor, it is sufficient to complete the introductory pages of the application form and Annex 2. All contract acceptors of the company must be listed in Annex 2 both new contract acceptors as well as contract acceptors who have already been approved and are still to be used. The list of contract acceptors may also be attached as an appendix.

The following supporting documents must also be submitted together with the application form:

- A valid wholesale distribution authorisation for the contract acceptor, covering the addresses and activities in question;
- The front page of the contract (or any other page showing the names and addresses of the contract acceptor and contract giver) as well as the page of the contract with the signatures of all relevant parties (i.e. the representative of the contract acceptor and the representative of the contract giver) as well as the date.
- Conclusion from the audit report based on audits of the contract acceptor, which must have been carried out within the last 12 months. It has to be specified in the conclusion which legislation was applied during the audit and whether the contract acceptor complies with the GDP rules. It must also state where and when the audit was carried out. Where an external auditor is used, a declaration from the contract givers responsible person (RP) shall be submitted for the following:
    - The audit report has been reviewed by the responsible person, who has ensured that the audit covers the activities to be outsourced, including any special requirements e.g. for reception and delivery.
    - The contract giver has ensured that the external auditor is independent from the contract acceptor and does not have conflicts of interest, including financial interests or any other significant affiliation with the audited contract acceptor.
    - The contract giver has ensured that the external auditor has relevant skills and experience in auditing.
    - The contract giver has prepared a risk assessment for when the next audit of the contractor is to be carried out.

4.5 Change of responsible person (Annex 3)

When applying for change of responsible person, it is sufficient to complete the introductory pages of the application form and Annex 3.

The responsible person should be approved on the wholesale distribution authorisation on the day he or she takes over responsibility as responsible person. However, the Danish Medicines Agency considers it timely if the application for change is submitted on the same day.

4.6 Termination of a wholesale distribution authorisation

If a wholesale distributor wishes to terminate its wholesale distribution authorisation, the applicant shall complete the initial pages of the application form and indicate the desired date of entry into force. In the description of application section, the plan for termination of activities should be described.

5 Additional information

5.1 Sanction options

According to Section 39 of the Danish Medicines Act, wholesale distribution of *certain substances*, etc. may only take place with authorisation from the Danish Medicines Agency. The Agency checks compliance with the Danish Medicines Act, the Veterinary Regulation and in acts adopted pursuant thereto. All changes to the authorisation must be approved by the Danish Medicines Agency before they are put into practice. If that is not followed, it may have consequences for the authorisation. In addition, the Agency may report violations of the Danish Medicines Act to the police.

5.2 Contact

Questions for this guide can be directed to the Authorisations & Security of Supply section at virksomhedstilladelser@dkma.dk.

5.3 Change log

Date	Version	Change
17-01-2025	Guide-VS-01	New section 2.1 Establishment of company. New section 2.10 on responsible person (RP), including the possibility of more than one RP. Section 3.4 on the completion of Annex 3 has been updated accordingly. Update of section 3.2.2. on activities in relation to receipt and delivery which are no longer part of activities 2.1 and 2.3 on the authorisation, respectively. Now these activities are covered by "2.2 Holding". Update of section 3.2.3 on substances with additional requirements in relation to the modification of this section in the format. Update of section 3.3 on completion of Annex 2 in relation to the fact that only "2.2 Holding" and "2.4 Export to third countries" can be outsourced. A new box in section 4 regarding information to be included in an application. Update of section 4.4 on the content of a submitted conclusion of an audit report. Update of section 4.5 on what the Danish Medicines Agency considers to be a timely application for a new responsible person.
12-03-2024	Guide-VS-00	A new guide.