LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

Guidelines on applications for authorisation to wholesale distribute medicines within the EEA

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1. Introduction

These guidelines offer guidance on how to the apply for authorisation to wholesale distribute medicines within the EEA.

In the following, an authorisation for wholesale distribution of medicines within the EEA will be referred to as a wholesale distribution authorisation (WDA).

For information on general requirements and guidelines for application for a company authorisation, please see Requirements and deadlines for applications for company authorisations.
For information about which activities require a company authorisation pursuant to section 39 of the Danish Medicines Act, or a company registration pursuant to sections 41(b) or 50(a) of the Danish Medicines Act, please see Guidelines on activities subject to a section 39 authorisation or company registration.

For information on the requirements for distribution of medicinal products, see the Danish executive order on the distribution of medicinal products (Danish title: *"Bekendtgørelse om distribution af lægemidler"*), Guidelines on Good Distribution Practice for medicinal products for human use, Regulation (EU) 2019/6 on veterinary medicinal products and Implementing regulation (EU) 2021/1248 on good distribution practice for veterinary medicinal products. The Danish Medicines Agency also have a Q&A about GDP.

These guidelines firstly provide general information about wholesale distribution and then offer guidance on the application form and the submission of application including which documentation should be submitted with the application.

Please send the application by email to virksomhedstilladelse@dkma.dk according to Requirements and deadlines for applications for company authorisations.

2. General information on wholesale distribution

2.1 Wholesale distribution

Wholesale distribution means any activity associated with the purchase, sale, receipt, storage and supply of finished medicinal products within the EEA as well as the export of finished medicinal products to countries outside the EEA (third countries).
Companies that purchase, sell, receive, store or supply medicines, or merely have the responsibility to ensure that another wholesale distributor (contract acceptor) complies with the GDP rules, must hold a wholesale distribution authorisation. On the receipt of medicines from other EEA countries than Denmark, the company must ensure that the medicines are accompanied by a control report or similar documentation.

2.2 GDP responsibility

Overall, a wholesale distributor cannot disclaim responsibility (GDP responsibility) pursuant to the Danish GDP executive order and the regulation on veterinary medicinal products for the medicinal products handled, whether the medicines are purchased, sold, received, stored or supplied. In relation to GDP responsibility, ownership of the medicines plays a key role because ownership entails a responsibility to ensure that the owned medicinal products are stored according to the GDP rules, regardless of where the medicines are stored.

2.3 Receipt, storage and supply of medicinal products

Wholesale distributors receiving, storing and supplying medicinal products can be divided into two types:

1) Wholesale distributors with storage, which will appear from the wholesale distribution authorisation with the activity ”2.2 Holding”. Only wholesale distributors authorised to have storage can store medicinal products; this applies even to a few packages.
2) Wholesale distributors without storage, who have outsourced the receipt, storage and supply

of medicinal products to a wholesaler with storage (e.g. a consignment warehouse). Wholesale distributors without storage of medicinal products are responsible for ensuring that their contract acceptor is storing the medicines in compliance with the GDP rules. An audit of the wholesaler must be made to ensure compliance with the rules. A wholesale distributor without storage is comparable to an order processing unit, which owns the medicinal products stored at another wholesaler, see section 2.4. Wholesale distribution according to contract is described in section 2.5.

2.4 Purchase and sale of medicinal products

Wholesale distributors only engaging in the purchase and sale of medicinal products and not in the receipt, storage or supply of the purchased/sold medicines are also called order processing units. An order processing unit must hold a wholesale distribution authorisation because purchase and sale of medicinal products are defined as wholesale distribution activities. There are two types of order processing units:

1) Order processing units which own medicinal products for a longer period of time and which are therefore GDP responsible for their medicinal products while they are stored at wholesalers. In this case, the wholesaler is a contract acceptor of the order processing unit that enters into contracts with all wholesalers storing the order processing unit's medicinal products, and audits must be conducted of the wholesalers. The order processing unit may use an external auditor. Wholesalers storing medicinal products for the order processing unit must be listed in Annex 2 of the order processing unit's wholesale distribution authorisation.
2) Order processing units which do not own the medicinal products for a longer period of time, i.e. the order processing unit sells the medicines immediately after they were purchased. These order processing units are not GDP responsible for the medicinal products, because they are not stored by a wholesaler while being owned by the order processing unit. The order processing unit's GDP tasks are only to ensure that they are dealing with authorised companies and that they comply with the requirements for documentation laid down in the GDP rules. An order processing unit selling the medicinal products immediately after they were purchased has no contract acceptors listed in Annex 2.

2.5 Outsourcing

Receipt, storage and supply of medicinal products can be outsourced in accordance with section 35 of the Danish GDP executive order. For veterinary medicinal products outsourced activities are described in chapter 8 in implementing 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 medicinal products.
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.

2.5.1 Audit 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 for an audit for approval of 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.

2.6 Wholesalers must not receive medicines from non-EEA countries (third countries)

A wholesale distribution authorisation does not permit the receipt (importation) of medicines from non-EEA countries (third countries). Please note that the MRA countries Australia, Canada, Israel, Japan, New Zealand, Switzerland and USA are also third countries. A wholesaler in Denmark is only permitted to receive medicines from either Denmark or other EEA countries.
Only companies authorised to manufacture medicines and having the relevant activities for import are allowed to import medicines from third countries. Medicines that are imported from third countries must generally be reanalysed and must always be batch certified (released) by a Qualified Person (QP) authorised by the Danish Medicines Agency (contrary to medicines imported from other EEA countries).
You can read more about the importation and release of medicines in our Guidelines on applications for authorisation to manufacture and import medicines and intermediates.

2.7 Export (supply) of medicines to third countries

Even though wholesalers in Denmark are not permitted to import medicines from third countries, the company can obtain authorisation to export (supply) medicines to third countries, provided that the activity ”2.4 Export to third countries” has been approved on the company's wholesale distribution authorisation.

2.8 A wholesale distribution authorisation exclusively covers finished, released medicines

A wholesale distribution authorisation is granted only for wholesale distribution of finished medicinal products that are batch certified (released) by a manufacturer. A wholesale distributor is not permitted to purchase, sell, receive, store or supply non-released medicines without holding a manufacturing and importation authorisation (MIA).

2.9 Wholesalers must not handle intermediate products

Wholesale distribution of medicines only involves the activities of receiving, storing and/or distributing finished, released (batch certified) medicines that are ready for sale or use in clinical trials. A wholesaler is not authorised to sell intermediate products. If a company is to handle intermediate products, it must obtain an MIA.

2.10 Simultaneous manufacture and wholesale distribution

A manufacturing and importation authorisation also permits wholesale distribution of the medicines batch certified (released) by the company itself. If a manufacturer wishes to wholesale distribute medicines that are not released by the manufacturer itself, the manufacturer must hold a wholesale distribution authorisation in parallel with the MIA.

2.11 A manufacturers storage of own medicinal products

In situations where a Danish manufacturer releases medicines at site A (which holds an MIA) and wishes to store these medicines at site B (which does not hold an MIA), site B must obtain a wholesale distribution authorisation before being permitted to store medicines for site A - even if both sites belong to the same company.
This also applies if a company's parent, affiliated or subsidiary company located at another address or in another EU country manufactures and batch certifies (releases) the medicines. Medicines released by a parent, affiliated or subsidiary company are considered as medicines belonging to another manufacturer. If the Danish subsidiary wishes to wholesale distribute these medicines, it requires a wholesale distribution authorisation since the medicinal product has been released at another address.

2.12 Samples of medicines

Companies which are the marketing authorisation holder (MAH) or representative may, in capacity as MAH/representative, store and supply samples of medicines and do not need to have a wholesale distribution authorisation for this purpose.
A MAH/representative can outsource the storage and dispensing of medicinal samples for human medicinal products to another company. The contract acceptor must have a wholesale distribution authorisation which include storage and dispensing of medicinal samples for human medicinal products on behalf of another company, see section 3.2.2. It is not permitted to outsource the storage and dispensing of medicinal samples for veterinary medicinal products.

2.13 Inactive activities

A wholesale distribution authorisation shall be up-to-date in relation to a company's current activities. In exceptional cases, there may be a need for a company to have activities on the authorisation that are inactive. An example could be a company that performs activities in contract for others and would like to offer an activity to their customers, but do not have a current customer for the activity. It is a prerequisite that the company has other active activities on the authorisation and that procedures, premises, equipment and training of personnel are maintained for all activities on the authorisation, including inactive activities.

It is not permitted to hold an authorisation consisting exclusively of inactive activities. When a company no longer has activities, the authorisation must be discontinued, see point 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 position is that there can be a maximum of 6 months without any activity. When the Danish Medicines Agency receives the company's argument for the wish to maintain the authorisation, a specific assessment of the current situation will be made.

3 Completion of the application form

The following sections describe how to complete the application form. The format for wholesale distribution authorisation, and thus the application form, reflects the common EU format published by the European Medicines Agency (EMA) in Compilation of Community Procedures on Inspections and Exchange of Information. Details of the various activities of the authorisation can be found in 'Interpretation of the Union format for a wholesale distribution authorisation (medicinal products for human use)', which can be found on pages 205-208 of the aforementioned EMA document.

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:	Wholesale distribution of medicinal products between countries within the EEA
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 change to apply. Please note that authorisations cannot be issued retrospectively.
Since it is often necessary to clarify what the application relates to, there is room in the following section to describe the application in free text.

When specifying company information for each site, the associated OMS LOC ID must be provided, and for the company's head office also OMS ORG ID must be indicated. OMS (Organisation Management

Service) is the 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 to apply to the EMA for modification of the information, e.g. when the company is moving or changing name. This must be applied for and approved before the application for a wholesale distribution authorisation is submitted. New companies must apply to the EMA for registration in OMS, which must also be done before submitting an application to the Danish Medicines Agency. See information about the 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 as to who in the company must sign the application.

3.2 Completion of Annex 1

Please note that Annex 1 is site-specific. Therefore, Annex 1 must be completed for each of the company's sites that wholesale distribute medicines. The address of the relevant site should be specified at the top of Annex 1, and it should be stated if the medicines at the site are for human and/or veterinary use.
In Annex 1, only the wholesale distribution activities carried out at the company's own address are indicated. Activities that are not carried out at the company's own address but only by a contract acceptor are not to be indicated in Annex 1, but in Annex 2.

The activities of Annex 1 fall into three parts:

1. Medicinal products
2. Wholesale distribution activities
3. Medicinal products with additional requirements

And at the end of the annex there is room for specifications of the activities.

3.2.1 Section 1. Medicinal Products

In section 1, please specify the types of medicines which the company is responsible for wholesale distributing. The activities do not involve the physical handling of products, but solely the GDP responsibility for the type of medicine, and therefore 1.x cannot be outsourced.

3.2.2 Section 2. Wholesale distribution activities

In section 2, please provide the activities performed by the company at its own address. The activities of receiving, storing, supplying and exporting to third countries involve physical handling of medicines. Therefore, only these activities can be outsourced to a third party. The activities of purchasing and selling do not involve physical handling of the medicines and cannot be contracted out. Please note that the activities "2.1. Procurement" and "2.3 Supply" are split in two parts on the Danish WDA. "2.1 Procurement" is used for receipt and buying medicinal products, and "2.3 Supply" is used for describing the activities selling and supplying medicinal products. Only physical receipt and supply can be contracted out.

Below is given an example on how the company should fill in the application depending on whether they store medicines themselves or if storage is outsourced.

Example 1:
If a company exclusively purchases and sells medicines, but has contracted out its storing and supplying activities, Annexes 1 and 2 must be filled out as illustrated below:

2	**Engrosforhandlingsaktiviteter** *Wholesale distribution activities*	
☒	2.1	Modtagelse og/eller køb *Procurement*
☐	2.2	Lagerhold *Holding*
☒	2.3	Levering og/eller salg *Supply*

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

Navn og adresse *Name and address*	**Angiv aktuelt punkt** *Specify paragraph* (2.1/2.2/2.3/2.4/2.5) *(Skal udfyldes)*
	Aktivitet
Navn på kontrakttager (Virksomhed)	2.1 Modtagelse
Adresse	2.2 Lagerhold
Postnummer og By	2.3 Levering

Example 2:
If a company receives, stores and supplies medicines, the form is to be filled out as follows:

2	**Engrosforhandlingsaktiviteter** *Wholesale distribution activities*	
☒	2.1	Modtagelse og/eller køb *Procurement*
☒	2.2	Lagerhold *Holding*
☒	2.3	Levering og/eller salg *Supply*

Complaints and recall handling are included in the activities 2.1-2.4. Companies only carrying out complaints and recall handling for medicinal products can apply for the activity "2.5 Other Activities: Handling of complaints and recalls only" in the application form. The activity does not involve the physical handling of medicines, but solely the GDP responsibility for complaints handling, and therefore this activity cannot be outsourced to a third party.

A company may be granted special authorisation to distribute samples of human medicinal products to doctors on behalf of the MAH/representative for a given medicinal product. Companies that want to perform this activity under a contract for a MAH/representative must indicate this in the application form under item "2.5 Other activities: Dispensing of medicinal samples of human medicinal products according to contract".

3.2.3 Section 3. Medicinal products with additional requirements

Some medicines have additional requirements. A wholesale distributor engaged in activities with these medicinal products shall indicate this by the relevant types of medicinal products under Section 3.
Item "3.4 Other products" has pre-filled proposals on the application form; frozen medicinal products, investigational medicinal products and homeopathic products, but the company also has the possibility to indicate something in free text.

3.2.3 Clarifying remarks

At the end of Annex 1, it is possible to add comments as necessary. Use this field if some of the selected activities need further elaboration.

3.3 Completion of Annex 2

Annex 2 is used to list the contract acceptors that the company uses for receipt, storage and/or supply of medicinal products. The contract acceptor's name and main address must be indicated, also in case the activities are carried out at another of the contract acceptors sites. When the contract acceptor's main address has been approved, the wholesale distributor may outsource activities to all the approved sites of

this wholesale distributor, provided that the address is covered by the contract and that an audit has been made at the address. Please note that only the following activities can be outsourced ”2.1 Procurement”, ”2.2 Holding”, ”2.3 Supply” and ”2.4 Export to third countries”. The activities to be carried out by the contract acceptor should be listed in Annex 2.

The company must not use a contract acceptor, before it has been authorised by the Danish Medicines Agency. When we approve a contract acceptor, it will appear on the company's wholesale distribution authorisation in Annex 2. This is the case for both Danish and foreign contract acceptors.

3.4 Completion of Annex 3

In Annex 3, the applicant must indicate who the company's responsible person is. The title of the responsible person must be stated in Danish and English.

Annex 3 previously stated the company’s responsible management person. This is changed to the responsible person 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 on how the application is submitted, processing times including the concept of clock stop, electronic issuance and validity of the authorisations, as well as fees.
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 company authorisation applications:

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 completed and furnished, temperature monitoring must be installed on the basis of temperature mapping, documentation and procedures must be established, and the company must have sufficient personnel.

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

Please note that for changes to wholesale distribution authorisations issued before January 28, 2022, a completed Annex 1 must be submitted for all sites regardless of what the application relates to or what is listed below. This is because a new distinction is made between human and veterinary medicinal products.

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. If the company has foreign contract acceptors, then Annex 2 must also be filled in, as they are to be mentioned on the authorisation.

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

4.1 Application for new authorisation

When applying for a new wholesale distribution authorisation, the full application form must be completed and the organisation chart and an overview of the buildings must be provided. If the company uses a contract acceptor to handle the medicinal products, the documentation for approval of the contract acceptor must be submitted as well.
New order processing units must also submit an overview of the product flow and cash flow coupled with time: when are products purchased and sold seen in relation to when the products are moved.

The following should therefore be submitted:
- Application form
- Organisation chart
- Overview of buildings
- Documentation for the approval of contract acceptor, if applicable. See section 4.4
- If order processing unit: Overview of product flow and cash flow

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 company's name, it is sufficient to submit the introductory pages of the application form together with a confirmation that other conditions in the company remain unchanged. In case of change of address, Annex 1 for the new address must be filled in together with the introductory pages.
The organisation chart and overview of buildings shall be attached only if there are significant changes to the documents.

4.3 Change of activities (Annex 1)

For changes to activities, complete the relevant Annex 1 (all boxes must be filled in). If there are only changes to one site, it is sufficient to complete 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 (Annex 2), it is sufficient to fill in the introductory pages of the application form and Annex 2. All contract acceptors of the company must be listed in Annex 2 both the new contract acceptor and 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 concerned
- Front page of the contract entered into (or any other page which lists the names and addresses of the contract giver and the contract acceptor) and a page from the contract with the signatures of all relevant parties (i.e. representative of the contract giver and representative of the contract acceptor) as well as the date.
- Conclusion from the audit report based on the audit of the contract acceptor, which must have been carried out within the last 12 months. It must be clear whether the contract acceptor is assessed to comply with the GDP rules. When an external auditor has been used, a declaration from the contract giver's responsible person must be submitted. The declaration shall state that:
    - 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 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.
    - The contract giver has ensured that the external auditor has relevant expertise and experience with auditing.
    - The contract giver has carried out a risk assessment for when the next audit of the contract acceptor is to be carried out.

When applying for a foreign contract acceptor to be added to Annex 2 on an authorisation and this contract acceptor has previously been approved by the Danish Medicines Agency when these were not listed on the authorisation, please submit documentation of the approval. This may be in the form of an email with the approval. When submitting this, it is not necessary to include the above-mentioned documents in order to have the contract acceptor added to the authorisation.

4.5 Change of responsible person (Annex 3)

When applying for a change of responsible person (Annex 3), it is sufficient to fill in the introductory pages of the application form and Annex 3.

4.6 Termination of wholesale distribution authorisation

If a wholesale distributor wishes to withdraw its wholesale distribution authorisation, the applicant shall fill in the introductory pages of the application form and indicate the desired date of entry into force. In the case of such a request for the termination of a wholesale distribution authorisation, the company will be contacted by a medicines inspector, who will ensure that, where appropriate, the handling of complaints and recalls will continue to be handled.
If the company continues to have GDP responsibility for medicinal products in the form of handling complaints and recalls, the wholesale distribution authorisation cannot be terminated before the company no longer has GDP responsibility. Instead, the company must submit an application for change stating that all wholesale distribution activities are suspended except "Handling of complaints and recalls only". As soon as the company is no longer obligated to such tasks, the company must apply for the authorisation to be terminated.

5 Further information

5.1 Sanctions

Pursuant to section 39 of the Danish Medicines Act, wholesale distribution etc. of medicinal products may only take place with authorisation from the Danish Medicines Agency. The Danish Medicines Agency can prohibit any distribution and dispensing of a medicinal product and order that a product be recalled from the market if the company does not hold a valid section 39 authorisation. All changes must be approved by the Danish Medicines Agency before implementation. If approval has not been obtained, any medicinal products distributed will most likely be recalled.

5.2 Contact

If you have any questions to this guide, please contact Authorisations and Security of Supply at virksomhedstilladelse@dkma.dk.

5.3 Change Log

Date	Version	Change
01-12-2022	Guide-GDP-10	New link to the Danish Medicines Agency's Q&A about GDP. New section, 2.5.1, about audits of contract acceptors, including the Danish Medicines Agency's expectation of an audit and the use of external consultants for audits. Update of section 2.12 on samples with information about the rules for outsourcing activities with samples. Section 3.2.2 has been updated with this as well. Update of section 3.3 on completing Annex 2. It now states that foreign contractors are also listed on the authorisation. Update of the general information in section 4 about annex 3. Update of section 4.4 on what must be included when a new contract acceptor is to be approved. The responsible person is now listed in Annex 3 instead of the responsible management person. Relevant sections are updated with this.

13-12-2021	Guide-GDP-09	General update of the guide i.e. the setup and the reference to the new regulation of veterinary medicinal products. Elaboration of the contract givers responsibility concerning audit of contract acceptor. New section about inactive activities. Update of section on completion of application i.e. with reference to EMA's new document on the WDA-format "Interpretation of the Union format for a wholesale distribution authorisation" and a new section on completions of the introductory pages of the application including OMS IDs. Frozen medicinal products is mentioned regarding item 3.4 Other products. New section: 4 Submission and requirements for applications. Section about application to renew a wholesale distribution authorisation has been deleted. Updated reference to legislation about health care professionals affiliation to medicinal companies and addition of proscribing pharmacists to this section. Deleted section Exemptions from applying for a wholesale distribution authorisation. Addition of change log.