LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

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

These guidelines offer guidance on how to complete the application form for authorisation to wholesale distribute medicines within the EU/EEA.

In the following, an authorisation for wholesale distribution of medicines within the EU/EEA will be referred to as a wholesale dealer's authorisation.

For information on general requirements and guidelines for application for a company authorisation, please see Guidelines on 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"*) and the GDP guidelines.

These guidelines firstly provide general guidance on applications for wholesale dealer's authorisations and then offer guidance on the application form and how to complete each of the application form's annexes.

The application must be submitted with a detailed cover letter or cover email, describing the reason for the application, and must contain relevant additional material. Please send the application by email to virksomhedstilladelse@dkma.dk according to our Guidelines on requirements and deadlines for applications for company authorisations.

General guidance on applications for wholesale dealer's authorisations

The application form for authorisation of wholesale distribution of medicines is divided into three annexes:

Annex 1: Wholesale distribution of medicines between countries within the EU/EEA
Annex 2: Contract acceptors
Annex 3: Responsible manager

In the following sections, you can find information on how to complete the application form.

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

2. GDP responsibility
Overall, a wholesale dealer cannot disclaim responsibility (GDP responsibility) pursuant to the Danish GDP executive order 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 responsibility” to ensure that the owned medicinal products are store according to the GDP rules, regardless of where the medicines are stored.

3. Receipt, storage and supply of medicinal products

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

1) Wholesale dealers with own stock holding, which will appear from the wholesale dealer's authorisation with the activity "2.2 Holding". Only wholesale dealers authorised to have a stock holding can store medicinal products; this applies even to small packages.
2) Wholesale dealers without own stock holding, who have outsourced the receipt, storage and supply of medicinal products to a wholesaler with own stock holding (e.g. a consignment warehouse). Wholesale dealers without own stock holdings of medicinal products are responsible for ensuring that their wholesaler is storing the medicines in compliance with the GDP executive order. An audit of the wholesaler must be made to ensure compliance with the rules. A wholesale dealer without own stock holding is comparable with an order processing unit, which owns the medicinal products stored at the wholesaler, see item 4. Contract wholesale distribution is described in item 5.

4. Purchase and sale of medicinal products

Wholesale dealers 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 dealer's authorisation because purchase and sale of medicinal products are defined as wholesale dealing 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 pay for an external audit. Wholesalers storing medicinal products for the order processing unit must be listed in Annex 2 of the order processing unit's wholesale dealer's authorisation (does not apply to foreign contract acceptors, see current practice).
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 Danish GDP executive order. An order processing unit selling the medicinal products immediately after they were purchased has no contract acceptors listed in Annex 2.

5. Wholesale distribution outsourced to contract acceptor

Receipt, storage and supply of medicinal products can be outsourced in accordance with section 33 of the Danish GDP executive order. Outsourcing of wholesale distribution requires that a contract is entered into between the companies, typically termed a technical agreement. 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.

6. Wholesalers must not receive medicines from non-EU/EEA countries (third countries)

A wholesale dealer's authorisation does not permit the receipt (importation) of medicines from non-EU/EEA countries (third countries). Please note that the MRA countries Australia, Canada, Japan, New Zealand and Switzerland are also third countries. A wholesaler in Denmark is only permitted to receive medicines from either Denmark or other EU/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 EU/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 and in the GMP executive order.

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 dealer's authorisation.

8. A wholesale dealer's authorisation exclusively covers finished, manufactured medicines
A wholesale dealer's authorisation is granted only for wholesale dealing of finished medicinal products that are batch certified (released) by a manufacturer. A wholesale dealer is not permitted to purchase, sell, receive, store or supply non-released medicines without holding a manufacturer's and importer's authorisation ("MIA").

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 by wholesale. If a company is to handle intermediate products, it must obtain an MIA.

10. Simultaneous manufacture and wholesale distribution
A manufacturer's and importer's authorisation also permits wholesale dealing of the medicines batch certified (released) by the company itself. If a manufacturer wishes to wholesale distribute medicines of "others" that are not released by the manufacturer itself, the manufacturer must hold a wholesale dealer's authorisation in parallel with the MIA.

11. Storage of own self-manufactured medicines
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 dealer's 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 other EU country manufactures and batch certifies (releases) the medicines. Medicines released by a parent, affiliated or subsidiary company are considered as medicines belonging to "others". If the Danish subsidiary wishes to wholesale deal these medicines, these medicines belong to others because they have been released at another address.

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 dealer's authorisation for this purpose.

13. Name or address changes
If a company changes name or address, an application to change the wholesale dealer's authorisation must be submitted, see Guidelines on requirements and deadlines for applications for company authorisations. When a company changes name, it is sufficient to fill in and submit the first page of the application form as well as a confirmation that other matters in the company remain unchanged. In case of address changes, the new address should be entered in Annex 1 and be submitted together with the first page.

14. Special requirements for application to change an authorisation
Where changes of activities are concerned, all fields of the relevant Annex 1 must be completed (all tick marks must be put). If changes only involve one site, it is enough to complete Annex 1 for the site in question. The front page must always be completed.
When applying to change contract acceptors (Annex 2) or the responsible manager (Annex 3), it is sufficient to fill in and submit the first page of the application form and the relevant annex(es). It is sufficient to indicate the new companies or new persons to be added. If a company wishes to delete a contract acceptor from an Annex 2, all other remaining companies must be stated in Annex 2.

15. Special requirements for application to renew a wholesale dealer's authorisation
For renewal applications, the company must submit a fully completed application form with completed front page and all required information (however, not the contracts, audit reports, regulatory approvals of already approved contract acceptors). Annex 1 must be completed for all relevant sites, and all contract acceptors and the responsible manager must be indicated in the relevant annexes. Please note that as of 1 September 2012, the Danish Medicines Agency issues company authorisations without expiry date. Consequently, only companies holding a wholesale dealer's authorisation issued before 1 September 2012 should apply for renewal in future. The next time the authorisation is renewed, it will be renewed without expiry date.

16. Termination of wholesale dealer's authorisation
If a wholesale dealer's authorisation is to be terminated, the Danish Medicines Agency must be informed in writing indicating the requested date for termination of the authorisation. A company applying for termination of an authorisation will normally be contacted by an inspector who, in connection with a close-down inspection, will ensure that complaints and withdrawal handling are adequately dealt with. If the company continues to have GDP responsibilities for medicines in the form of complaints and withdrawal handling, the wholesale dealer's authorisation cannot be terminated until the GDP responsibilities end. Instead, the company must submit a variation application indicating that all wholesale dealing activities are terminated except "2.5.1 Complaints and withdrawal handling only". As soon as the company is no longer obliged to carry out these activities, the company must ask the Danish Medicines Agency in writing to effect an absolute termination of the wholesale dealer's authorisation.

17. Before submission of the application
The company must be ready for inspection at the time of application, i.e. the company must have fully implemented the applicable GDP legislation, entailing that storage areas etc. must be suitably equipped, temperature monitoring installed based on temperature mapping, documentation and procedures must be established and the company must have sufficient staff.

The application form step-by-step

The following sections describe how to complete Annex 1-3 of the application form. The format for wholesale dealer's authorisations, 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

Quality assurance responsible person
The company must have a quality responsible person who is to ensure that the activities carried out comply with the provisions of the Danish GDP executive order. The quality responsible person must be at the company regularly to an adequate extent with due consideration to the company's activities. The name, title, telephone number and email address of the quality responsible manager is to be stated on the first page. The quality responsible person is not stated on the issued wholesale dealer's authorisation, but since the information forms part of the information forming the basis for the issuance of a wholesale dealer's authorisation, the Danish Medicines Agency must be informed in writing in case of change of the quality responsible person. Please send the information to virksomhedstilladelse@dkma.dk

General remarks on 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. Specify the address of the relevant site at the top of Annex 1. In Annex 1, only the wholesale dealing 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 only in Annex 2.

Annex 1
The activities of Annex 1 fall into three parts:
1. Medicinal products
2. Wholesale distribution activities
3. Medicinal products with additional requirements

1. Medicinal products
In part 1, please specify the types of medicines which the company is responsible for distributing by wholesale. 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 to a third party.

2. Wholesale distribution activities
In part 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. Only physical receipt and supply can be contracted out to a third party.

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 withdrawal handling are included in the activities 2.1-2.5. Companies only carrying out complaints and withdrawal handling for medicinal products can apply for the activity "2.5.1 Complaints and withdrawal handling 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 medicinal product samples to doctors on behalf of another company, which is the MAH/representative for a given medicinal product. Companies that want to perform this activity under a contract for an MAH/representative must indicate this in the application form under item "2.5.2 Distribution of medicinal product samples to doctors on behalf of another company".

3. Medicinal products with additional requirements
Some medicinal products have additional handling requirements. If a wholesale dealer carries out activities with these medicinal products, it must be indicated under part 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.

Annex 2

Annex 2 is used to indicate the contract acceptors that the company uses for receipt, storage and/or supply of medicinal products that have been outsourced according to section 33 of the Danish GDP executive order. The contract acceptor's name and main address must be indicated, also in case the activities are carried out at a site under this main address. When the contract acceptor's main address has been approved, the wholesale dealer may outsource activities to all the approved sites of this wholesale dealer, 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 indicated in Annex 2. The list of contract acceptors can also be attached as a file.

When submitting an application to add a new contract acceptor to the wholesale dealer's authorisation, the contract acceptor must be indicated in Annex 2, and the following documentation must be attached to the application:

- A valid wholesale dealer's authorisation for the contract acceptor covering the concerned addresses and activities
- Audit opinion based on an audit performed of the contract acceptor, which must have taken place within the past two to three years. It must appear from the audit opinion whether the contract acceptor is estimated to comply with the GDP rules.
- First page of the contract concluded (or any other page which lists the names and addresses of the contract giver and contract acceptor) and a page from the contract with the signatures of all relevant parties (i.e. representative of contract giver and representative of contract acceptor).

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 from the company's wholesale dealer's authorisation under Annex 2. However, foreign contract acceptors are not included on a wholesale dealer's authorisation, but a foreign contract acceptor must still be approved by the Danish Medicines Agency before it can be used.

Annex 3
In Annex 3, the applicant must indicate who the company's responsible manager is. The title of the responsible manager must be stated in Danish and English.
Please note that doctors, dentists and proprietary pharmacists are legally bound to apply to the Danish Medicines Agency for permission to establish a relationship with or run a pharmaceutical company, cf. section 3(2) of the Danish Pharmacy Act., see Doctors, dentists and proprietary pharmacists associated with a pharmaceutical company
Please also note that according to section 8A of the Danish Veterinarian Act, veterinarians are not permitted to be associated with a company handling veterinary medicines, unless the Danish Veterinary and Food Administration has granted an exemption. More information in Danish is available here Veterinarians' financial independence of pharmaceutical companies

Additional material to the application
When a wholesale dealer's authorisation is applied for, an organisation chart and SMF must be submitted with the application. When an application to change or renew an existing authorisation is submitted, it is only necessary to attach an organisation chart and SMF if these documents have changed significantly. 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.

Sanctions
Pursuant to section 39 of the Danish Medicines Act, wholesale distribution etc. of medicinal products may only take place upon 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 withdrawn 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 released will most likely be withdrawn.

Exemptions from applying for a wholesale dealer's authorisation
Exemption from section 39(1) and (2) of the Danish Medicines Act applies to the following:
1. Hospital wards which only perform additive service
2. Hospital wards which only perform simple labelling and preparation of registered radiopharmaceuticals
3. Companies authorised by the Danish Medicines Agency to order medicine for life rafts, etc.

4. Companies that exclusively pass on orders for medicinal products or carry out other activities are not subject to the GDP rules. However, please note that companies acting as a broker of medicinal products must be registered as a broker. Read more on our website under brokering

If you are unsure about whether your company falls under item 4 above, you are advised to contact the Danish Medicines Agency.

If you have any questions to these guidelines, please contact Company Authorisations on telephone +45 4488 9779 or by email to virksomhedstilladelse@dkma.dk

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