

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, please refer to Guidelines on activities subject to a section 39 authorisation.

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*").

These guidelines firstly provide general guidance on the form to apply for a wholesale dealer's authorisation and then offer guidance on 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.

General guidance on the application form

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

- Annex A.1: Wholesale distribution of medicines between countries within the EU/EEA
- Annex A.2: Contracting-out
- Annex A.3: Responsible manager

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

1. Wholesale distribution

Wholesale distribution (or wholesale dealing) means the activities associated with the receipt, storage and supply of finished medicinal products within the EU/EEA as well as the export of finished medicinal products to third countries. Companies that receive, store or supply medicines or merely have the responsibility to ensure that another company (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. Please be aware that the definition of wholesale distribution changed on 1 January 2013 by the implementation of directive 2011/62/EU on falsified medicinal products. As of 1 January 2013, the concept of wholesale distribution also covers the purchase and sale of medicinal products.

2. 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. The moment the medicines have been released by a manufacturer, the wholesale dealer considers them as belonging to "others".

3. Simultaneous manufacture and wholesale distribution

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

4. 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 applies correspondingly 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.

5. Stock holding outsourced to contract acceptor

Stock holding of medicines can be contracted out pursuant to section 27 of the GDP executive order, and the contract signed between the companies according to this provision is termed a technical agreement. If a company outsources all activities, including the responsibility for ensuring that the medicines are stored in compliance with the GDP rules, the company is no longer contract giver according to section 27 of the GDP executive order. Instead, the companies have entered into a commercial agreement, which is not to be indicated on the wholesale dealer's authorisation.

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

An authorisation for wholesale distribution granted pursuant to section 39(1) of the Danish Medicines Act does not permit the importation (receipt) 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 pursuant to section 39(1) of the Danish Medicines Act 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 Health and Medicines Authority (contrary to medicines imported from other EU/EEA countries). You can read more about the importation of medicines in section 34 of 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.

8. 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.

9. 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.

10. Special requirements for application to change an authorisation

Where changes of activities are concerned, all fields of the relevant Annex A.1 must be completed (all tick marks must be put). If changes only involve one site, it is enough to complete the relevant Annex for the site in question. The front page must also be completed.

When applying to change contract acceptors (Annex A.2) or the responsible manager (Annex A.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 A.2, all other remaining companies must be stated in the relevant Annex A.2.

11. 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 A.1 must be completed for all relevant sites, and all contract acceptors and the responsible manager must be indicated in the relevant annexes. Please be aware that as of 1 September 2012, the Danish Health and Medicines Authority does not issue authorisations with an expiry date. Consequently, only companies that still hold an authorisation with an expiry date must apply for a renewal.

12. Termination of authorisation

If an authorisation is to be terminated, the company will normally be contacted by an inspector who, in connection with a close-down inspection, will ensure that complaints and withdrawal handling is adequately dealt with.

If the company continues to have GDP responsibilities for medicines, it must still hold a section 39 authorisation for a given time frame. If this is the case, the company wishing to terminate a wholesale dealer's authorisation must therefore first submit an application to change the authorisation, notifying the Danish Health and Medicines Authority that all wholesale dealing activities are being stopped. The Danish Health and Medicines Authority will then issue an altered wholesale dealer's authorisation from which it appears that the company exclusively handles complaints and withdrawal handling at the address. As soon as the company is no longer obliged to carry out these activities, the company must inform the Danish Health and Medicines Authority to effect an absolute termination of the wholesale dealer's authorisation.

13. 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, and that documentation and procedures must be established.

The application form step-by-step

The following sections describe how to complete Annex A.1-A.3 of the application form.

Please note that the appearance of the application form has changed significantly. We have changed the application form for the Danish wholesale dealer's authorisation to reflect the common European format published by the European Medicines Agency (EMA).

QA 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.

General remarks on Annex A.1

Please be aware that Annex A.1 is site-specific. Therefore, Annex A.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 A.1.

In Annex A.1, only the wholesale dealing activities carried out at the company's own address are indicated. Activities that are only carried out by a contract acceptor are not to be indicated in Annex A.1, but only in Annex A.2.

Annex A.1

The activities of Annex A.1 fall into three parts.

1. A.1 – Wholesale distribution of medicinal products.
2. A.2 – Wholesale distribution activities.
3. A.3 – Medicinal products with additional requirements

A.1 – Wholesale distribution of medicinal products.

Please specify the product types 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 product type, and A.1.1.x therefore cannot be outsourced to a third party.

A.2 – Wholesale distribution activities.

Please provide the activities performed by the company. As of 1 January 2013, companies purchasing and selling medicinal products must also hold a wholesale dealer's authorisation. This new practice was implemented in conjunction with the implementation of directive 2011/62/EU on falsified medicinal product. Please note that companies which today do not hold a wholesale dealer's authorisation, but engage in the buying and selling of medicinal products do not need to apply for authorisation of this activity until after 1 January 2013.

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 buying and selling cannot be contracted out.

Item A.2.1. is called '*Procurement*', and item A.2.3 is called '*Supply*'. Only physical receipt and supply can be contracted out to a third party.

Example 1:

If a company exclusively buys and sells products, but has contracted out its storing activities, including receipt and supply, the form is to be filled out as illustrated below, and the activities that have been contracted out are to be indicated under Annex 2 as A.2.1 (Procurement), A.2.2 (Holding), A.2.3 (Supply).

A.2	Engrosforhandlingsaktiviteter <i>Wholesale distribution activities</i>
<input checked="" type="checkbox"/>	A.2.1 Modtagelse og/eller køb <i>Procurement</i>
<input type="checkbox"/>	A.2.2 Lagerhold <i>Holding</i>
<input checked="" type="checkbox"/>	A.2.3 Levering og/eller salg <i>Supply</i>

Kontrakttagere *Contracting-out*
ANNEX A.2

Navn og adresse <i>Name and address</i>	Angiv aktuelt punkt <i>Specify paragraph</i> (A.2.1/A.2.2/A.2.3 / A.2.4 / A.2.5) <i>(Skal udfyldes)</i>
	<i>Aktiviteter</i>
Virksomhedsnavn på kontraktager	A.2.1 Modtagelse
Adresse	A.2.2 Lagerhold
Postnummer og by	A.2.3 Levering

Example 2:

If a company stores medicinal products, the form is to be filled out as follows:

A.2	Engrosforhandlingsaktiviteter <i>Wholesale distribution activities</i>	
<input checked="" type="checkbox"/>	A.2.1	Modtagelse og/eller køb <i>Procurement</i>
<input checked="" type="checkbox"/>	A.2.2	Lagerhold <i> Holding</i>
<input checked="" type="checkbox"/>	A.2.3	Levering og/eller salg <i>Supply</i>

Please note that companies which are the MAH or representative may, in capacity as MAH/representative, store samples of medicines and therefore are not required to hold a wholesale dealer's authorisation.

A company may be granted special authorisation to supply samples of medicines to doctors on behalf of another company which is the MAH/representative of a given product. Companies that want to perform this activity under a contract for a MAH/representative must indicate this in the application form under item 'A.2.5 Other activities'.

Complaints and withdrawal handling are included in the activities A.1.1-A.1.3. If a company carries out no other activities than complaints and withdrawal handling, this can be applied for under item 'A.2.5 Other activities' in the application form. The activity does not involve the physical handling of medicines, but solely the GDP responsibility for complaints handling, and this activity therefore cannot be outsourced to a third party.

A.3 – Medicinal products with additional requirements

Some medicinal products may have additional handling requirements. The medicinal products with additional handling requirements which the Danish Health and Medicines Authority wants to be informed of are indicated here in the application form. If the company carries out activities with these medicinal products, it must be indicated here.

Notes

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

Annex A.2:

Annex A.2 is used to indicate all contract acceptors that the company uses for wholesale distribution according to section 27 of the GDP executive order. Please be aware that only the activities in A.2.1 (Procurement), A.2.2 (Holding), A.2.3 (Supply) and A.2.4 (Export to third countries) can be outsourced to a third party.

Application for authorisation of new contract acceptor

When submitting an application to add a stock holding on a wholesale dealer's authorisation, the company must indicate the name and address of the company with which the company has signed a contract on wholesale dealing activities. Indicate the areas within A.2.1, A.2.2, A.2.3 and A.2.4 to be carried out by a contract acceptor. The list of contract acceptors can also be attached as a file. Companies must enclose the following documentation for new contract acceptors to be included on the authorisation:

- A valid wholesale dealer's authorisation 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
- 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 stock holding before it has been authorised by the Danish Health and Medicines Authority. When we approve a stock holding, it will appear from the company's wholesale dealer's authorisation under Annex A.2. However, foreign stock holdings are not included on a wholesale dealer's authorisation, but a foreign stock holding must still be approved by the Danish Health and Medicines Authority before it can be used.

Annex A.3

In Annex A.3, the applicant must indicate who the company's responsible manager is. State the title of the responsible manager in Danish and English.

Please be aware 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.

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. Further 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.

Sanctions

Pursuant to the Danish Medicines Act, wholesale distribution etc. of medicinal products may only take place upon authorisation from the Danish Health and Medicines Authority, which has the legal authority to prohibit any distribution and dispensing of a medicinal product and to 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 Health and Medicines Authority before implementation. If approval has not taken place, any products released will most likely be withdrawn.

Exemptions from applying for a company 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 Health and Medicines Authority to order medicine for life rafts, etc.
4. Companies that exclusively pass on orders for medicinal products to another company, pay for or collect payment for medicinal products, and which are therefore not subject to the rules on good manufacturing and distribution practice (GMP/GDP). As of 1 January 2013 this no longer applies with the implementation of directive 2011/62/EU on falsified medicinal product. We kindly refer you to the website of the Danish Health and Medicines Authority for more information about this.

With reference to item 4 above, please note that a company must hold a company authorisation if it handles, distributes or partakes in the conduct of tasks described in the GDP executive order. For example, outsourcing of a medicine stock to another company does not exempt your company from obtaining an authorisation. If a company only engages in complaints about and withdrawals of medicines, a company authorisation is also required.

Companies that are unsure about whether they fall under item 4 above are advised to contact the Danish Health and Medicines Authority.