



# Guidelines on activities subject to a section 39 authorisation or a company registration

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## Introduction

Any company manufacturing, importing, exporting, storing, procuring, distributing, dispensing, splitting or packaging medicinal products or intermediate products must obtain authorisation from the Danish Medicines Agency according to section 39(1) and (2) of the Danish Medicines Act (a section 39 authorisation).

Any company manufacturing, importing and distributing active substances (API) intended to be used in the manufacturing of marketed medicinal products for human or veterinary use must register with the Danish Medicines Agency pursuant to section 50A(1) of the Danish Medicines Act or article 95 in Regulation (EU) 2019/6 on veterinary medicinal products (API registration).

Any company brokering medicinal products for human use between two parties which does not itself carry out the activities of wholesale distribution must register with the Danish Medicines Agency pursuant to section 41B(1) of the Danish Medicines Act (broker's registration).

Any company storing, distributing and importing substances with anabolic, anti-infectious, antiparasitic, anti-inflammatory, hormonal, narcotic or psychotropic properties and that may be used in animals, hereinafter referred to as certain substances, must obtain the Danish Medicines Agency's authorisation under Section 39(1) of the Danish Medicines Act (Section 39 authorisation). Certain substances may not be used in the manufacture of medicinal products and should therefore not be confused with API or medicinal products.

Definitions of medicinal product, intermediate product, active substance and excipient are available in section 2 of the Danish Medicines Act. The definition of manufacturing and wholesale dealing activities etc. are available in the executive order on the manufacture and import of medicinal products and intermediate products as well as the executive order on distribution of medicinal products.

## Types of section 39 authorisation

In practice, the Danish Medicines Agency grants four types of section 39 authorisation:

- **MIA (Manufacturing and Importation Authorisation for medicines and intermediate products)**  
Issued for complete or partial manufacture, import and/or analysis of intermediate products and medicinal products. The authorisation includes wholesale distribution of own finished and released medicinal products from site of production.
- **WDA (Wholesale Distribution Authorisation for wholesale distribution of medicines within the EU/EEA)**  
Issued for purchase, sale, receipt, storage and/or supply of finished medicinal products, batch certified (released) by a manufacturer within the EU/EEA. Wholesale distribution only covers trading between companies and not dispensing to end-users.
- **Wholesale distributor authorisation for the wholesale distribution of certain substances.**  
Issued for the receipt, purchase, sale, storage and/or supply and import of certain substances from third countries. The wholesale distributor authorisation shall also apply to products in which one or more of certain substances are incorporated as a constituent. Wholesale distribution covers only distribution between wholesale distributors of certain substances and the sale of of certain substances to retailers.
- **Retail authorisation (authorisation to retail sell medicines not exclusively reserved for pharmacies)**  
Issued for the retail sale of medicines not exclusively reserved for pharmacies to end-users. A distinction is made between over-the-counter medicines for both human and veterinary use, sealed medicine chests, medicinal gases and medicines for production animals.

Please note that a section 39 authorisation does not take into account whether or not the company is the marketing authorisation holder of the medicines the company is authorised to handle. A section 39 authorisation is issued to the company and describes the activities performed by the company.

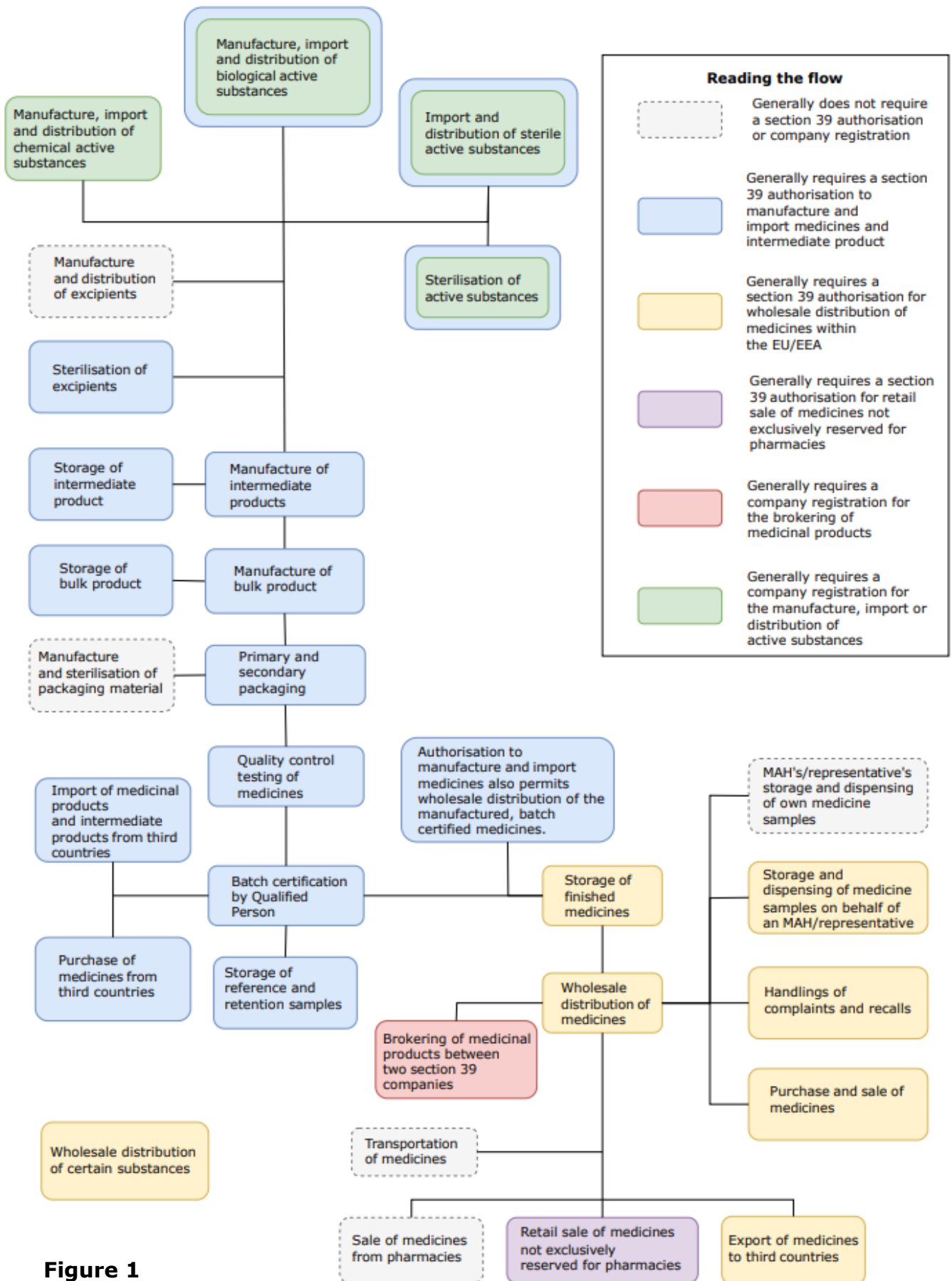


## **Types of company registrations**

In practice, there are two types of company registration:

- *Registration as manufacturer, importer and distributor of active substances*  
Registration is required for the manufacture, import and distribution of APIs intended for use in the manufacturing of medicinal products for human or veterinary use covered by a marketing authorisation.
- *Registration as a broker of medicinal products*  
Registration is required for companies brokering medicinal products for human use with a marketing authorisation within the EU/EEA.

Examples of activities subject to a section 39 authorisation or company registration are given below. Please note that this list is not exhaustive but only indicative - there may be exceptions from the below requirements for a section 39 authorisation or company registration.



**Figure 1**

## Figure 1 explained

### Manufacture, import and distribution of chemical active substances (API)

The manufacture, import and distribution of chemical non-sterile APIs require a company registration, but generally not a section 39 authorisation. Import covers import from countries outside the EU/EEA (third countries), whereas distribution covers procurement, receipt, storage and supply within the EU/EEA.

### Manufacture, import and distribution of biological active substances (API)

The manufacture, import and distribution of biological APIs require both a company registration and an MIA because a biological API is considered both an API and an intermediate product.

### Import and distribution of sterile active substances (API)

The import and distribution of sterile APIs require both a company registration and an MIA because a sterile API is considered both an API and an intermediate product.

### Sterilisation of active substances

Sterilisation of an API requires both a company registration and an MIA because an API is considered an intermediate product once it is sterile. A sterile API is therefore considered an API as well as an intermediate product.

### Overview of the requirements to a section 39 authorisation and API registration in connection with the manufacture and import of APIs

The table below provides an overview of MIA, API registration, inspection and written confirmation in connection with the manufacture, import or distribution of various types of API.

Type of API	Manufacture or import requires an MIA	Manufacture, import or distribution requires API registration	Ongoing inspection by DKMA	Import requires written confirmation
Biological API (H/V) to medicine without MA	yes	no	yes	no
Biological API (H) to medicine with MA	yes	yes	yes	yes
Biological API (V) to medicine with MA	yes	yes	yes	no
Chemical API (H/V) to medicine without MA	no	no	voluntary	no
Chemical API (H) to medicine with MA	no	yes	yes	yes
Chemical API (V) to medicine with MA	no	yes	yes	no
Chemical sterile API (H/V) to medicine without MA	yes	no	yes	no
Chemical sterile API (H) to medicine with MA	yes	yes	yes	yes
Chemical sterile API (V) to medicine with MA	yes	yes	yes	no

Table 1. Overview of MIA, API registration, inspection and written confirmation for API  
V = veterinary use, H = human use, MA = Marketing authorisation



### **Manufacture and distribution of excipients**

Generally, the manufacture of excipients requires neither a section 39 authorisation nor a company registration. Excipients are used to manufacture a finished medicinal product, but are not the active substance contained in the medicine.

### **Sterilisation of excipients**

Sterilisation of excipients requires an MIA, because the excipient is used in a sterile medicinal product.

### **Manufacture of intermediate products**

The manufacture of intermediate products with one or several APIs requires an MIA. An intermediate product is a mixture of active substances and excipients intended for further processing into a medicinal product. Once an API is mixed with an excipient, it becomes an intermediate product.

### **Storage of intermediate product**

Storage of intermediate products requires an MIA.

Please note that all components released for the manufacture of a medicinal product are considered to be an intermediate. Therefore it requires an MIA for storage of the released raw materials and packaging components, if these components are not released before the manufacturing of the medicinal product.

### **Manufacture of bulk product**

The manufacture of bulk products requires an MIA. In this context, bulk means a product that has completed all processing stages up to, but not including, final packaging.

### **Storage of bulk product**

Storage of bulk products requires an MIA.

### **Primary and secondary packaging**

Primary and secondary packaging requires an MIA. Packaging includes all processing stages, including filling and labelling, which a bulk product has to undergo in order to become a medicinal product in its final packaging. There are two stages of packaging; primary and secondary packaging:

- Primary packaging is the packaging process where the bulk product is enveloped by a packaging material in direct contact with the bulk product - e.g. filling tablets into tablet bottles or blister packs, filling injection fluid into ampoules etc.
- Secondary packaging is the packaging process where the packaging material is not in contact with the bulk product - e.g. the packaging of blister cards in cartons, labelling of ampoules, vials, etc.

Repackaging of medicinal products also requires an MIA, regardless of whether it is the primary or secondary packaging that is being repackaged. The replacement of a package leaflet or additional labelling also requires an MIA, in practice for secondary packaging.

### **Manufacture and sterilisation of packaging material**

Generally, the manufacture of packaging material does not require a section 39 authorisation, regardless of whether the packaging material is intended for sterile or non-sterile medicines. The responsibility to ensure that the packaging material complies with the requirements of, for example, a marketing authorisation lies with the manufacturer's Qualified Person who releases the finished medicine (batch certification). The manufacturer of packaging material is likely to be audited by the pharmaceutical manufacturers, which the packaging material is supplied to, but the manufacturer of packaging material will not be inspected by drug regulatory authorities.

### **Quality control testing of medicines**

The testing of finished medicinal products requires an MIA. Therefore, analytical laboratories that test finished medicinal products must hold an MIA. Companies that exclusively test medicines are not required to have a Qualified Person.

### **Import of medicinal products and intermediate products from third countries**

The import of medicinal products or intermediate products from third countries requires an MIA because the import of medicines is considered a manufacturing activity. Import can be divided into two parts; physical receipt of medicines from third countries and batch release of imported medicines. Companies physically receiving medicines from third countries (the importer) are responsible for batch certification (release) of the medicinal products or intermediate products before further distribution within the EU/EEA. The release may be handled by another company than the importer, for example if company A buys another company B to handle the physical receipt while company A handles the release. In such cases, both companies must have an MIA, because both companies perform manufacturing activities in connection with the import.



If a company releases medicines within the EU/EEA and then sends them to a third country, the medicines must be batch certified (released) again if they are imported into the EU/EEA again.

### **Purchase of medicines in a third country**

Purchase of medicines from companies in a third country intended for the EU/EEA market, including medicines for compassionate use, requires an MIA. This also applies to medicines physically located in the EU/EEA. Purchase from the MRA countries Australia, Canada, Israel, Japan, New Zealand, Switzerland, and USA also requires an MIA because these countries are also third countries.

Storage of medicines owned by a company in a third country requires an MIA. The reason is that medicines sold by a company from a third country must be released for the EU/EEA market after the ownership has been passed to the EU/EEA company. Consequently, the medicines are not released for the EU/EEA market until this last release has taken place.

### **Batch certification by Qualified Person**

Batch certification (release) requires an MIA. Batch certification must be handled by a Qualified Person within the EU/EEA, and once the medicines have been batch certified, they are considered batch certified for release to the EU/EEA market. This means that the medicines do not have to be released again if they are distributed within the EU/EEA.

### **Storage of reference and retention samples**

Storage of reference and retention samples is part of the manufacturing process and therefore requires an MIA. A site address, which is exclusively authorised for wholesale distribution of medicines, cannot take over the responsibility for storing these samples. If a company wants to cease the manufacture of medicines, the company must maintain its MIA for as long as the manufacturer is responsible for the storage of reference and retention samples.

Pursuant to Annex 19, items 7.1 and 8.1 in the EU GMP rules, reference samples must be stored at the manufacturer of the original product and retention samples should be stored at the site where the Qualified Person released the product. Section 26 of the GMP executive order and Annex 19, 3.1 and 3.2 in the EU GMP rules further specifies that reference samples of the medicine must be stored for at least one year after the expiry date. Reference samples of an API used in the finished product must be stored for at least two years after manufacture of the medicine.

### **Authorisation to manufacture and import medicines also permits wholesale distribution of the manufactured, batch certified medicines**

An MIA also authorises wholesale distribution of the medicines which the company has itself manufactured and released (own manufactured medicines). However, the right to distribute the manufactured medicines by wholesale only covers the site address holding the MIA. If the company wishes to store its products at other addresses than the ones indicated on the MIA, the company must have a WDA covering the storage addresses in question.

### **Storage of finished medicines**

Storage of finished medicinal products which have been batch certified (released) by a Qualified Person within the EU/EEA requires a WDA. Storage of medicines manufactured by the company itself or released at its own address is covered by the company's MIA, but only from the address where the production takes place. If a manufacturer releases medicinal products at one address and then transports them to another storage address, that other address must have a wholesale distribution authorisation, as this is the storage of finished medicinal products released at another site.

If a company stores products that the company does not manufacture or release at its own address, it must hold a WDA in addition to its MIA. This also applies if a Danish branch stores medicines manufactured and batch certified (released) by a parent company abroad.

### **Wholesale distribution of medicines**

Wholesale distribution (or wholesale dealing) means the activities associated with the procurement, purchase, sale, receipt, storage or supply of medicines within the EU/EEA as well as the export of medicines to third countries. Wholesale distribution of medicines manufactured by the company itself is covered by the company's MIA. A WDA is required to wholesale deal medicines, which the company has not itself manufactured. Please note that when medicines are received from other EU/EEA countries, they must be accompanied by a control report from the company responsible for having released the medicine.

### **MAH's/representative's storage and dispensing of own medicine samples**

The marketing authorisation holder (MAH) or his representative may store and dispense own medicine samples.





The Danish Medicines Agency trusts that the MAH or his representative stores the medicine samples in compliance with the storage conditions applicable to the medicinal product in question. If the MAH or representative outsources the storage and dispensing of their samples of medicinal products for human use to another company, the MAH/representative must make sure that the company has a WDA covering storage and dispensing of medicine samples. It is not permitted to store and dispense samples of medicinal products for veterinary use in contract.

### **Storage and dispensing of medicine samples on behalf of an MAH/representative**

A WDA is required to store and dispense samples of medicinal products for human use on behalf of an MAH or his representative. It is not permitted to store and dispense samples of medicinal products for veterinary use in contract.

### **Handling of complaints and recalls**

The handling of product defects, complaints and recalls of medicines are covered by both the MIA and the WDA and is part of the general GMP and GDP responsibilities. Companies exclusively engaged in the handling of investigations of complaints and recalls of defective products must hold a WDA. Generally, a WDA is not required if the company only receives information about product defects, complaints and recalls for the purpose of forwarding it immediately to another company as the responsibility to ensure that the information is redistributed lies with the company that is to process the information.

### **Purchase and sale of medicines**

Purchase of finished medicines in the EU/EEA requires a WDA. As regards the purchase of medicines in a third country, please see the section above "Purchase of medicines in a third country".

Wholesalers exclusively engaging in the purchase and sale of medicinal products can be divided into two types:

- 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. The order processing unit 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 WDA (does not apply to foreign contract acceptors, see current practice).
- 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* (typically on the same day) after they were purchased. These order processing units are not GDP responsible for the medicinal products, because in practice the order processing unit does not own the medicinal products (for a longer period of time), while they are stored at wholesalers. The order processing unit's GDP tasks are only to ensure that they are dealing with authorised companies and complying with the requirements for documentation of purchase and sale. An order processing unit selling the medicinal products immediately after they were purchased has no contract acceptors listed in Annex 2 and has no obligation to enter into a contract\* with or conduct an audit of the wholesalers that they purchase from and sell to.

\*) This refers only to the requirement for a contract according to section 35 of the executive order on distribution of medicinal products and not any other legal requirements for a contract.

### **Wholesale distribution of certain substances**

Wholesale distribution refers to activities related to the purchase, sale, receipt, storage or supply of certain substances within the EU/EEA. Wholesale distribution covers only the sale of certain substances and products in which one or more of certain substances are constituents to companies which resell them to other companies. That is to say, companies wishing to retail certain substances to the end-user should not be in possession of an authorisation. However, retailers of certain substances in Denmark may only purchase certain substances from Danish wholesale distributors with a section 39 authorisation.

Please note that certain substances must not be used in the manufacture of medicinal products and should therefore not be confused with API or medicinal products.

In Denmark, the Danish Medicines Agency requires companies importing certain substances from third countries to have a wholesale distribution authorisation. This also applies to retailers and end-users of certain substances.

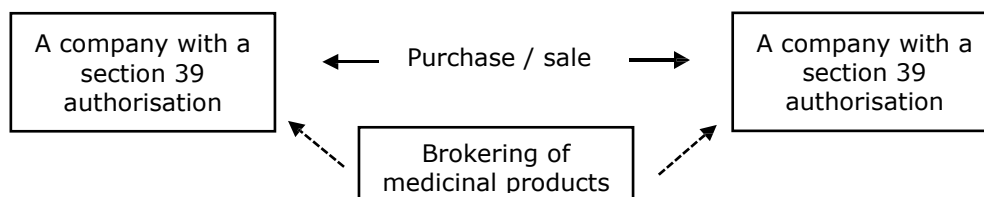
Please note that when receiving certain substances from companies in other countries, it must be demonstrated that the company in that country complies with national legislation.





## Brokering of medicinal products

A broker's registration is required when a company engages in the buying and selling of medicines for human use, but is not involved in wholesale dealing activities (e.g. purchase, sale, receipt, storage and supply). Brokering does not include physical handling of medicinal products, but consists of dealing independently and on behalf of another legal or natural person. Registration is not required when dealing on behalf of a separate legal entity, e.g. a parent company or the like. Registration is required for the brokering of medicines for human use with a marketing authorisation within the EU/EEA. Brokers of magistral medicinal products and medicines for non-clinical trials and clinical trials, are not subject to registration. A section 39 authorisation is not required for the routing or arranging of orders between two section 39 companies, as long as no GDP activities take place at the broker.



## Transportation of medicines

A transportation provider that only transports medicinal products does not need a section 39 authorisation. Nor is a section 39 authorisation required if the medicinal products are not transported directly from A to B, but are carried e.g. via a transportation hub and stored for a short period (for example during the weekend). Any unpacking or repacking of the medicinal product during transportation must not take place. The supplying wholesale distributor is responsible for ensuring that the medicinal products are transported in compliance with the GDP rules. Thus, the supplying wholesale distributor must ensure that the medicinal products are protected against breakage, adulteration and theft, and that temperature conditions are maintained within acceptable limits during transport. The supplying wholesale distributor must also ensure that own carriers and/or the transportation provider used comply with this practice. The requirements applying to transportation are described in chapter 9 of [guidelines on good distribution practice of medicinal products for human use](#) and chapter 10 of [implementing regulation \(EU\) 2021/1248 on good distribution practices for veterinary medicinal products](#).

## Sale of medicines from pharmacies

Pharmacies are not covered by the requirement for a section 39 authorisation, but are - by virtue of their pharmacy licence - authorised to sell medicines by retail.

## Retail sale of medicines

Retail sale of medicines that are not exclusively reserved for pharmacies requires a retail authorisation. The list of medicines not exclusively reserved for pharmacies can be found on the website of the Danish Medicines Agency under [Over-the-counter medicines](#)

## Export of medicines to third countries

Export of medicines to third countries requires a WDA. However, export of medicinal products manufactured by your own company is included in the MIA.

## Use of medicinal products, intermediate products and certain substances in medical devices

Where medicinal products, intermediate products and certain substances are used in the manufacture of medical devices, those products are also covered by the pharmaceutical legislation until or during the manufacture of the medical device itself. The finished medical device may also fall within the scope of legislation on the wholesale distribution of certain substances if the finished medical device contains certain substances.



## More information about section 39 authorisations and company registrations

More information about application for the different types of section 39 authorisation:

1. [Application for authorisation to manufacture and import medicines and intermediates](#)
2. [Application for authorisation to wholesale distribute medicines within the EU/EEA](#)
3. [Application for authorisation of retail distribution of OTC medicines](#)

More information about the different types of company registration is available under

1. [Registration as manufacturer, importer and distributor of active substances \(APIs\)](#)
2. [Registration as a broker of medicinal products](#)

More information on the general requirements and deadlines for applications for manufacture, wholesale and retail authorisations is available under [Requirements and deadlines for applications for company authorisations](#).

If you have questions to these guidelines, please contact [virksomhedstilladelse@dkma.dk](mailto:virksomhedstilladelse@dkma.dk)

## Change log

Date	Version	Changes
30-05-2022	06	<p>Update related to the entry into force of Regulation (EU) 2019/6 on veterinary medicinal products:</p> <ul style="list-style-type: none"><li>- API for use in veterinary medicinal products with a marketing authorisation requires a API registration</li><li>- Wholesale distribution of certain substances requires a wholesale distribution authorisation</li><li>- The brokering registration is required only for medicinal products for human use</li><li>- The sections on samples of medicinal products are updated in relation to the fact that it is no longer permitted to store and dispense samples of medicinal products for veterinary use in contract</li></ul> <p>Other changes:</p> <p>It is clarified that a manufacturing authorisation only includes wholesale distribution of its own manufactured and released medicinal products from the site where the manufacture takes place.</p> <p>The "Overall" section just before Explanation to Figure 1 has been removed.</p> <p>The section "Storage of intermediate product" is updated regarding the practice that all components released for GMP production are considered as intermediates.</p> <p>Israel and the United States have been added to the list of MRA countries.</p> <p>New section on the rules for medicinal products, intermediates and certain substances used in medical devices.</p> <p>In addition, general update with linguistic clarifications, updated references as well as insertion of table of contents and change log.</p>