

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

A company which handles medicines or intermediates must be authorised by the Danish Health and Medicines Authority under section 39 of the Danish Medicines Act (a section 39 authorisation). Further details are given under "Types of section 39 authorisations".

A company brokering medicinal products between two parties which does not itself carry out the activities of wholesale distribution must register with the Danish Health and Medicines Authority pursuant to section 41B(1) of the Danish Medicines Act. Further details are given under "Types of company registrations".

A company manufacturing, importing, distributing (receiving, storing and supplying) active substances intended to be used in the manufacturing of medicinal products for human use must register with the Danish Health and Medicines Authority pursuant to section 50A(1) of the Danish Medicines Act. Further details are given under "Types of company registrations".

Types of section 39 authorisations

In practice, the Danish Health and Medicines Authority grants three types of section 39 authorisations; they are:

- *MIA (manufacturer's and importer's authorisation for medicines and intermediate products)*
Issued for medicines for either human or veterinary use. If a company manufactures and imports medicines for both human and veterinary use, it must hold two MIAs.
- *Wholesale dealer's authorisation (authorisation for wholesale distribution of medicines within the EU/EEA)*
Issued collectively for medicines for human and veterinary use and exclusively covers wholesale distribution (purchase, sale, receipt, storage and supply) of medicines batch certified (released) by a manufacturer within the EU/EEA.
- *Retail authorisation (authorisation to retail sell medicines that are not exclusively reserved for pharmacies)*
Issued for retail sale of either over-the-counter medicines (including smoking cessation products), smoking cessation products only, v-marked medicines, medicinal gases or medicines for production animals.

Please be aware 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.

Which activities require a section 39 authorisation?

The handling of medicines covers the activities related to manufacturing, importing, exporting, storing, selling, distributing, dispensing, splitting and packing medicines or intermediate products as well as selling medicines by retail to the end-user. Companies which have outsourced the physical handling of medicines on a contractual basis to a contract acceptor, but have the overall responsibility for the contract acceptor's compliance with the GMP and GDP rules, must also hold a section 39 authorisation. It will appear from the section 39 authorisation if the company does not physically handle medicines at its address.

Types of company registrations

There are two types of company registrations:

- *Brokers of medicinal products (Registration as a broker of medicinal products).*
Companies are required to register if they broker medicinal products for human and veterinary use with a marketing authorisation within EU/EEA.
- *API manufacturers, importers and distributors (Registration as manufacturer, importer and distributor of active substances for manufacturing of medicinal products for human use).*

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. The list is sorted based on the first manufacturing stage through to the stage when the medicines are dispensed to end-users or supplied to retailers

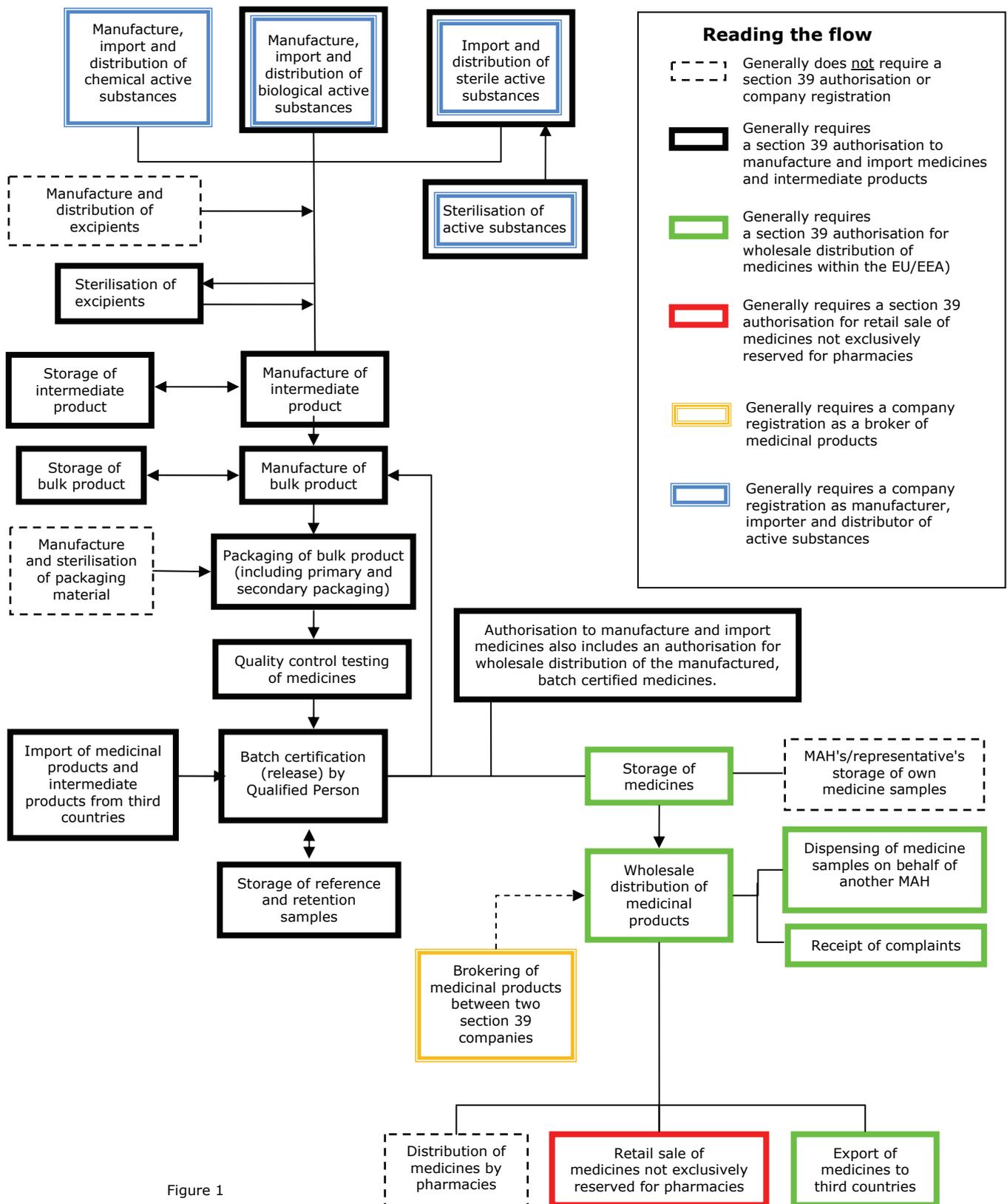


Figure 1 explained**Manufacture, import and distribution of chemical active substances (API)**

The manufacture, import and distribution of chemical active substances require a company registration, but generally not a section 39 authorisation. Please note that the manufacturing of active substances is subject to compliance with Good Manufacturing Practises (GMP), cf. *"The Rules Governing Medicinal Products in the European Union, Volume 4 Part II, Good manufacturing practice (GMP) Guidelines"* (EU GMP guidelines). Import refers to importation of medicines from a third country (countries outside the EU/EEA). Distribution covers distribution, receipt, storage and supply within the EU/EEA.

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

The manufacture, import and distribution of biological active substances require both a company registration and an MIA because a biological active substance is considered an API as well as an intermediate product.

Import and distribution of sterile active substances (API)

The import and distribution of sterile active substances require both a company registration and an MIA because a sterile active substance is considered an API as well as an intermediate product.

Sterilisation of active substances

Sterilisation of active substances requires both a company authorisation and an MIA. Once an API is sterile, it is considered an intermediate product. A sterile API is therefore considered an API as well as an intermediate product.

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.

Manufacture of intermediate products

Manufacture of intermediate products with one or several active substances requires an MIA. In this context, an intermediate product means a partly processed product that is to undergo further manufacturing stages. Once an active substance is mixed with an excipient, it becomes an intermediate product.

Storage of intermediate product

Storage of intermediate products with one or several active substances requires an MIA.

Manufacture of bulk product

The manufacture of bulk products requires an MIA. In this context, a bulk product 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.

Packaging of bulk product (including primary and secondary packaging)

The packaging of bulk products requires an MIA. Packaging includes all processing stages, including filling and labelling, which a bulk product has to undergo in order to become a finished medicinal product. 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.
- 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 are examples of activities that require an MIA, in practice for secondary packaging.

Manufacture and sterilisation of packaging material

Generally, the manufacture of packaging materials 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). This means that a 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 company physically receiving the medicines from a third country (the importer) is responsible for batch certification (release) of the medicinal products or intermediate products before further distribution within the EU/EEA. Therefore, the import of medicines is considered a manufacturing activity. 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.

Batch certification by Qualified Person

Batch certification (release) requires an MIA. Batch certification must take place within the EU/EEA, and once the medicine has been batch certified, they are considered batch certified for release to the EU/EEA market. Therefore, medicines are not to be batch certified again when sent from one EU/EEA country to another. In practice, the company must apply for an MIA to the Danish Health and Medicines Authority for the authorisation of at least one Qualified Person.

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 the samples. If a company wants to cease the manufacture of medicines, the company must maintain its MIA for as long as the manufacturer is obliged to store 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 Danish GMP executive order on manufacture and importation of medicinal products and intermediate products further specifies that reference samples of medicines 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 the company has itself manufactured (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 an address other than the one indicated on the MIA, the company must have a wholesale dealer's authorisation covering the storage address in question.

Storage of medicines

Storage of finished medicinal products requires a wholesale dealer's authorisation. Storage of the company's own manufactured medicines is covered by the company's MIA. If a company stores products that it has not itself manufactured at its own address, it must apply for a wholesale dealer's authorisation in addition to its MIA. This equally applies if a Danish branch stores medicines manufactured and batch certified (released) by a parent company abroad.

Storing of medicine samples by the MAH or his representative

The marketing authorisation holder (MAH) or his representative has the right to store own medicine samples. The Danish Health and Medicines Authority 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 his representative stores their medicine samples at another company, they must ensure that the company has a wholesale dealer's authorisation for storing the medicines.

Wholesale distribution of medicinal products

Wholesale distribution (or wholesale dealing) means the activities associated with the 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 wholesale dealer's authorisation is required to wholesale deal medicines which the company has not itself manufactured.

Note that the definition of wholesale distribution changed as of 1 January 2013 to also cover purchase and sale. Prior to this date, only the physical handling of medicinal products was the pivotal element for the concept of wholesale distribution of medicinal products.

Please be aware 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.

Receipt of complaints

The handling of product defects, complaints and withdrawals of medicines are covered by both the MIA and the wholesale dealer's authorisation. Companies exclusively engaged in the handling of approaches or investigations of complaints and withdrawal of defective products must hold a wholesale dealer's authorisation. Generally, a wholesale dealer's authorisation is not required if the company only receives information about product defects, complaints and withdrawals 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.

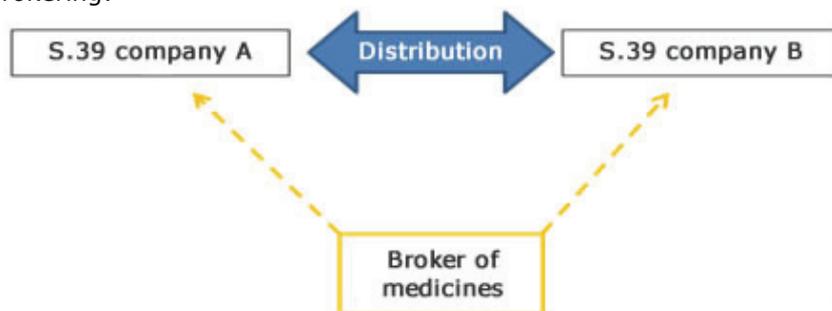
Dispensing of medicine samples on behalf of another MAH

A wholesale dealer's authorisation is required to dispense medicine samples on behalf of another MAH according to the Danish executive order on distribution of samples of medicinal products.

Brokering of medicinal products

Companies are required to register their activities of buying and selling (brokering) of medicines not involving the activities of wholesale distribution (purchase, sale, receipt, storage and supply, etc.). Thus, brokering does not include the physical handling of medicinal products, but consists of negotiating independently and on behalf of another legal or natural person. Registration is required for the brokering of medicines for human and veterinary use with a marketing authorisation within the EU/EEA. Thus, brokers of magistral medicinal products, medicines for non-clinical trials and clinical trials, medicated feed and inactivated and non-inactivated immunological veterinary medicines 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.

Brokering:



Distribution of medicines by 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 Health and Medicines Authority under [Over-the-counter medicines](#).

Export of medicines to third countries

Export of medicines to third countries requires a wholesale dealer's authorisation.

More information about section 39 authorisations

Further information about application for the different types of section 39 authorisations is available under

1. [Application for authorisation to manufacture and import medicines and intermediates](#)
2. [Application for authorisation to wholesale distribute medicines within the EU/EEA](#)
3. [Sale of medicine outside pharmacies](#)

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

Version: Section 39-activities-02