

## TRADE AND DISTRIBUTION OF THERAPEUTIC PRODUCTS (PHARMACEUTICALS/BIOLOGICS AND MEDICAL DEVICES)

**Author(s):** Camilla Appelgren, Emmie Montgomery, Michaela Fischerström and Alexander Mild

**Firm:** Mannheimer Swartling

[camilla.appelgren@msa.se](mailto:camilla.appelgren@msa.se); [emmie.montgomery@msa.se](mailto:emmie.montgomery@msa.se); [michaela.fischerstrom@msa.se](mailto:michaela.fischerstrom@msa.se);  
[alexander.mild@msa.se](mailto:alexander.mild@msa.se)

## REGULATORY FRAMEWORK AND COMPETENT AUTHORITIES

**1. What are the principal statutes, regulations and competent authorities that govern the import, wholesale distribution, retail sale and export of therapeutic products (ie, for pharmaceuticals/biologics and medical devices, noting any separate or overlapping regimes)? In the case of a federal state, what is the division of powers between the federal government and the states?**

Trade in therapeutic products in Sweden is regulated by both European Union law and national legislation. Medicinal products are regulated at EU level primarily through Directive 2001/83/EC and Regulation (EC) No 726/2004. At national level, the Medicinal Products Act (*läkemedelslagen*, 2015:315) establishes the overall framework for requirements applicable to medicinal products, including requirements relating to marketing authorisation, manufacture, import and marketing. The Act on Trade in Medicinal Products (*lag om handel med läkemedel*, 2009:366) constitutes the main legislation governing trade in medicinal products.

With regard to medical devices, Regulation (EU) 2017/745 (Medical Device Regulation or MDR) and Regulation (EU) 2017/746 (In Vitro Diagnostics Regulation or IVDR) are directly applicable in Sweden. These regulations are supplemented by national legislation, such as the Act with Supplementary Rules to the EU Regulations on Medical Devices (*lag med kompletterande bestämmelser till EUs förordningar om medicintekniska produkter*, 2021:600) and the Regulation with Supplementary Provisions to the EU Regulations on Medical Devices (*förordning med kompletterande bestämmelser till EUs förordningar om medicintekniska produkter*, 2021:631).

The competent authorities are:

- the Swedish Medical Products Agency (*Läkemedelsverket*) (MPA) – the competent regulatory authority for therapeutic products;
- the Dental and Pharmaceutical Benefits Agency (*Tandvårds- och läkemedelsförmånsverket* or TLV) – responsible for pricing and reimbursement of medicinal products and certain medical devices;
- the Swedish eHealth Agency (*E-hälsomyndigheten*) – responsible for central digital pharmaceutical services in Sweden; and
- the Swedish Customs Service (*Tullverket*) – which monitors and controls the flow of goods into and out of Sweden.

**2. How are therapeutic products classified for regulatory purposes (eg, prescription only, over the counter, hospital use, risk classes for devices, etc) and what legal consequences attach to each classification with respect to trade and distribution? In particular, is the**

**conclusion of a premarket review and approval process required by a competent authority?**

Under the Medicinal Products Act, no medicinal product may be placed on the Swedish market without obtaining a marketing authorisation from the MPA or the European Commission (through the centralised procedure).

Medicinal products are classified as prescription-only (Rx) or non-prescription over-the-counter (OTC) products and the classification determines whether the product may be sold without a prescription. Rx medicinal products can either be dispensed by an outpatient pharmacy or administered at a hospital (hospital use). While this does not constitute a separate classification, it affects the distribution chain in practice (see Question 13).

Under the Act on Trade in Medicinal Products, the wholesale distribution of medicinal products, irrespective of their classification, requires authorisation from the MPA.

Medical devices are subject to a conformity assessment and CE marking by the legal manufacturer, according to the MDR/IVDR requirements. There is no requirement for premarket authorisation by a regulatory body, instead it is the legal manufacturer that has the main responsibility to ensure that its devices comply with all of the applicable requirements under the MDR/IVDR and the national implementing legislation before the products are placed on the Swedish market.

Medical devices are divided into different risk classes under the MDR/IVDR framework, where generally products in higher risk classes require the involvement (review and certification) of a notified body before affixing the CE mark and placing the device on the market. Once properly CE marked, devices may be freely marketed throughout the EU.

No authorisation is required for trading in medical devices in Sweden, but certain economic operators (such as legal manufacturers, authorised representatives and certain importers and distributors) seated in Sweden must register with the MPA. From 28 May 2026, registration shall (with certain exceptions) take place via the EUDAMED database instead of the MPA's national register.

**LICENSING, AUTHORISATIONS AND DISTRIBUTION CHANNELS**

**3. Which licences, authorisations, registrations or other official permissions are required for businesses to engage in the wholesale distribution of therapeutic products, and what key conditions (such as good distribution practices, facility standards, personnel-related requirements and insurance or financial guarantees) are attached to them?**

In order to engage in the wholesale trade in medicinal products in Sweden, a wholesale distribution authorisation or manufacturing authorisation is required in any country in the EU or European Economic Area (EEA). Key conditions include, among other things, adhering to the Good Distribution Practice requirements, having suitable premises and a responsible person with overall responsibility for all wholesale activity and compliance with all of the applicable rules, submitting information to the eHealth Agency and the MPA, documenting the handling of medicinal products so that they can be traced, meeting the requirements on product safety and quality and exercising self-monitoring.

As mentioned above, no official authorisation is required for trading in medical devices in Sweden, but certain economic operators must register themselves and their products according to the requirements provided in the MDR/IVDR and the national implementing legislation (see Question 2).

**4. Are there distinct licensing or notification requirements for businesses that provide therapeutic products directly to consumers (including community pharmacies, internet pharmacies or other retailers), and what key conditions are attached to them?**

Medicinal products:

- The retail sale of medicinal products to consumers may only be conducted by pharmacies that have been granted authorisation by the MPA. Basic requirements for such operations include having premises staffed by a pharmacist during opening hours, having suitable premises that protect consumer privacy, employing a responsible pharmacist, submitting information to the eHealth Agency and the MPA, exercising self-monitoring and providing individual and manufacturer-independent information and advice on medicinal products, the substitution of medicinal products, medicinal product use and self-care to consumers, as well as ensuring that the information and advice is only provided by staff with sufficient competence for the task.
- Certain non-prescription medicinal products may be sold at points of sale other than pharmacies. The MPA decides which medicinal products may be sold based on factors such as suitability for self-care, the occurrence of serious adverse effects and suitability with regard to patient safety and public health. A business operator wishing to sell such medicinal products must notify the MPA.
- For certain medicinal products, eg, traditional herbal medicinal products, the regulations governing the retail sale of non-prescription medicinal products outside pharmacies do not apply and such products may be sold without any notification to the MPA.

For medical devices, there are no specific licencing or notification requirements in order to provide products directly to customers (other than that certain economic operators need to register, as described in the response to Question 2.)

**5. What rules govern the sale of therapeutic products to consumers over the internet (including social media and marketplace platforms)?**

In addition to what has been described above (Question 4), business operators conducting sales of medicinal products over the internet must also display on their website the contact details of the MPA and a hyperlink to the website, in accordance with Article 85c.4 of Directive 2001/83/EC, as well as clearly display the EU common logo. They must also ensure that the medicinal products meet the national requirements on authorisation in the EEA Member State where the sale is made.

For sales via social media and the like, it is also important to take into account the rules that apply to the marketing of medicinal products. Please see below for information on the general marketing rules. In addition to these rules, the Medicinal Products Act contains specific rules on marketing medicinal products.

As to the marketing/sale of medical devices over the internet, there is no specific national legislation in Sweden. In addition to the obligations provided in the MDR/IVDR (such as Article 6 and 7 concerning distance sales and claims), the general marketing rules found in the Marketing Act (2008:486) (*Marknadsföringslagen*) apply to all forms of marketing activities directed towards the Swedish market, regardless of the sector and product categories. The Marketing Act stipulates, for eg, that all marketing must be in line with ‘good marketing practice’, that marketing must not be aggressive or misleading and that all marketing claims must be substantiated.

Additionally, the sale of medical devices directly to consumers must comply with the applicable general consumer legislation in Sweden. In this regard, the general requirements of the Distance and Off-Premises Contracts Act apply to the distance selling of products (including medical

devices) directly to consumers, eg, over the internet. The Distance and Off-Premises Contracts Act requires, for example, that clear and comprehensive information must be provided to consumers before a contract is concluded, including the main characteristics of the products, as well as information on the right of withdrawal, right to complain, delivery and payment.

## IMPORT

### **6. What requirements are set as part of the import control framework for therapeutic products (eg, import licences, product registration or listing prerequisites, customs classification, tariff rates, national or regional exemptions and routine or risk-based border inspections)?**

To import medicinal products from a country outside the EEA, either a manufacturing authorisation for medicinal products or a special import authorisation for medicinal products is required. Such authorisations are issued by the MPA. For parallel importation of medicinal products from an EEA country, the parallel import rules described in the response to Question 9 apply.

Medical devices, by contrast, do not as a main rule require any specific authorisation for import but must comply with the requirements set out in the MDR/IVDR and Swedish implementing legislation before being placed on the Swedish market, including Swedish language labelling requirements. As mentioned above, importers must also register in accordance with the requirements set out in the MDR/IVDR, currently with the MPA (to be replaced by EUDAMED registration when applicable), see Question 2 above.

Customs classification and tariff treatment follow EU and Swedish regulations. Within the EU, the principle of free movement applies, meaning that custom fees are generally not applicable and controls are more limited when products are imported from another Member State. There are, however, certain restrictions on free movement, as each Member State has the right to stop the movement of goods in certain cases for environmental, health and safety reasons. An example of goods that may pose such risks is narcotics. In regard to imports into Sweden from countries outside the EU, they are generally subject to custom fees and more extensive controls.

### **7. To what extent may consumers import therapeutic products for personal use (whether by taking the products across the border or receiving them by post), and what quantitative limits, prescription requirements, customs declarations, duties or other restrictions apply?**

Private individuals travelling into Sweden may bring medicinal products with them for personal use. One must be able to demonstrate that the medicinal product is for personal use, for example through the provision of a prescription or medical certificate. When travelling from a country within the EEA, one may bring a year's supply, and when travelling from a country outside the EEA, one may bring a three-month supply. Special restrictions apply to narcotic-classified medicinal products.

Through postal deliveries, private individuals may only receive medicinal products:

- from another EU/EEA country;
- for a maximum of one year's supply;
- that are for private use;
- that are not classified as narcotics or doping substances;
- that are approved both in Sweden and in the country from which they are being sent;

- that are prescribed by an authorised prescriber within the EU/EEA (this requirement applies if the medicinal product is prescription only in Sweden and/or in the country of dispatch); and
- that are purchased from a pharmacy or equivalent.

For medical devices, there is no specific regulation for consumer imports, but the Swedish Customs Authority may stop suspected goods (eg, regarding inadequate product safety) at the border.

**8. Are foreign suppliers allowed to ship therapeutic products directly to consumers via e-commerce or mail order, and what local presence, platform registration, verification or labelling obligations – if any – must they satisfy?**

In regard to the Swedish market, only those who have obtained authorisation from the MPA may conduct retail trade in medicinal products to consumers. This means that operators established in Sweden must be authorised by the MPA in order to conduct retail trade direct to consumers.

Swedish consumers may order medicinal products from operators in other countries within the EEA. Distance selling within the EEA is primarily regulated in Article 85c of Directive 2001/83/EC, which in Sweden is implemented through the Act on Trade in Medicinal Products and the MPA's regulations. These regulations require, inter alia, that the operator is authorised or licensed to supply medicinal products to the public, including at a distance, in accordance with national legislation in the Member State in which that person is established, and that the medicinal product in question is approved for sale in the country of destination.

Swedish consumers are prohibited from receiving medicinal products from countries outside the EEA.

As provided above, in addition to the obligations provided in the MDR/IVDR, general marketing rules and consumer legislation must be considered when providing medical devices directly to consumers in Sweden. The Distance and Off-Premises Contracts Act applies to distance selling (eg, online, mail order or by telephone) of medical devices directly to consumers. See further Question 5 above.

**9. How is the parallel importation (ie, of products licensed and sold in other jurisdictions) of therapeutic products by businesses regulated, particularly with respect to intellectual property rights, product re-labelling or re-packaging and requirements to maintain the product's original quality, safety and traceability?**

To sell parallel-imported medicinal products, authorisation from the MPA is required. For an application for authorisation to sell a parallel-imported medicinal product to be granted, the following requirements must be fulfilled:

- the directly imported human medicinal product is approved for sale in Sweden when the application is received by the MPA;
- the parallel-imported human medicinal product is approved for sale in the country of export;
- the country of export is a Member State within the EEA; and
- the parallel-imported human medicinal product is sufficiently similar to the directly imported human medicinal product (the active substance is always the same, but certain differences in the excipients may occur).

Medicinal products approved under the centralised procedure may instead be parallel distributed. This type of activity is handled by the European Medicines Agency (EMA).

Labelling shall be designed in accordance with the MPA's general rules on labelling and package leaflets, and the following additional requirements apply:

- The medicinal product container and outer packaging shall be labelled with the name and address of the manufacturer, the parallel importer and the re-packager. Instead of the manufacturer's name and address, a relevant group designation may be stated.
- If the parallel-imported human medicinal product differs in any respect from the directly imported human medicinal product, the outer packaging shall be labelled with text informing the consumer of this.

No special authorisation is required for the parallel importation of medical devices. Instead, the goods are subject to the EU rules on free movement and as long as the products and involved economic operators comply with the requirements set out in the MDR/IVDR and Swedish implementing legislation (including Swedish language labelling requirements) they may be placed on the Swedish market without the need to meet any supplementary regulatory requirements.

## EXPORT

### **10. Are there quantitative quotas, permits or other measures that restrict or condition the export of therapeutic products (for example, to mitigate shortages or address public health emergencies), and how are such measures administered and enforced?**

The availability of medicinal products in Sweden is ensured through requirements on supply rather than prohibitions on export. Those who conduct the wholesale distribution of medicinal products must deliver the medicinal products covered by the authorisation to pharmacies as soon as possible.

The Swedish government has appointed an inquiry to review what measures are needed to create a more secure supply of medicinal products, both in everyday situations and in crisis situations. The inquiry is due to submit proposals for necessary legislative amendments, but the inquiry has not yet been concluded.

Neither are there any general export prohibitions for medical devices. A practical example of a temporary prohibition, however, is the restrictions imposed during the Covid-19 pandemic on exports from the EU of various medical protective equipment.

### **11. Is there any form of 'export-only' or 'dual-labelling' authorisation that permits the manufacture and export of therapeutic products not approved for domestic marketing and, if so, what standards, labelling or record-keeping obligations apply?**

In order to manufacture medicinal products in Sweden, a manufacturing authorisation from the Swedish MPA is required. Authorisation is required regardless of whether the medicinal product is intended solely for export, and manufacturing must always be carried out in accordance with good manufacturing practice. There is no specific manufacturing authorisation for medicinal products intended for export. Further, export of medicinal products constitutes wholesale distribution and requires a wholesale distribution authorisation.

There are no export-only licences or authorisations for medical devices under Swedish law. The MDR/IVDR and supplementary Swedish legislation regulates the providing of devices on the Swedish market. In accordance with the provisions set out in the MDR/IVDR, Swedish registered manufacturers and authorised representatives may apply for a certificate of free sale from the MPA, which states that the operator has its registered place of business in Sweden and that the device in question bearing the CE marking, in accordance with the MDR/IVDR, may be marketed in the EU.

In some cases, the importing country requires such a certificate. A certificate of free sale is not required if the device does not leave the EU/EEA.

## **LABELLING, TRACEABILITY AND PRODUCT INFORMATION**

### **12. What local-language labelling, patient information, unique device identification, serialisation, anti-counterfeiting or traceability requirements must be met before imported therapeutic products may circulate domestically or before therapeutic products may be exported?**

The outer packaging and medicinal product container must be labelled with the information specified in the MPA's regulations, including the name, strength, form, etc, of the medicinal product. A package leaflet designed in accordance with the medicinal product's summary of product characteristics must also accompany the medicinal product. The labelling and package leaflet must be written in Swedish. However, the labelling and package leaflet may be written in several languages, provided that the information is the same in all of the languages used. The requirements also apply to parallel imported medicinal products (see Question 9). Prescription-only (and certain non-prescription) medicinal products must (with certain exceptions) be provided with security features in the form of a unique identifier and an anti-tampering device.

A wholesaler is required to verify the authenticity of and decommission the unique identifier of medicinal products that it intends to distribute outside of the EU.

The labelling, information and traceability requirements in relation to medical devices placed on the Swedish market follows the requirements provided in the MDR/IVDR, including that the labelling shall include identification details of the legal manufacturer, that the product shall be accompanied with the safety and performance information necessary for the safe and effective use of the device (including instructions for use (IFU)), be CE marked and contain the relevant unique device identification (UDI) marking. According to local language requirements, the information must, in general, be provided in Swedish.

## **PRICING, REIMBURSEMENT AND MARKET ACCESS**

### **13. Are there any price control, reimbursement, public procurement or stock/supply-related obligations that (while not trade measures per se) materially influence the distribution channels or availability of therapeutic products?**

In Sweden, healthcare is part of the social security system and, thus, is mainly organised, structured and provided in the public domain. The offering of healthcare is primarily managed at a regional level by the regional authorities (ie, the regions (*regioner*)), who establish the specific frameworks and guidelines for the offering of healthcare services within their geographical areas, including what services and products are covered.

For medicinal products subject to a prescription, the marketing authorisation holder may apply to the TLV for the medicinal product to be included in the pharmaceutical benefits scheme (the so-called 'high-cost threshold'). The high-cost threshold limits how much patients pay for their reimbursed medicinal products each year. The TLV makes decisions and simultaneously determines the purchase and sales price for medicinal products. In practice, medicinal products are then primarily financed through the regions.

Medicinal products to be administered in hospitals are usually procured by the regions through public procurement. The TLV may also be involved in these processes and make assessments in terms of a product's cost effectiveness.

The practical consequence of this arrangement is that effective market entry for medicinal products often requires some form of collaboration with the TLV and/or the regions.

The TLV is also responsible for determining whether a medical device shall be included in the reimbursement scheme, and the pricing and reimbursement of such products. However, the Swedish reimbursement scheme for medical devices is limited to certain medical device consumables (the administration of pharmaceuticals, the self-monitoring of pharmaceutical levels and stoma products for patients). For medical devices that are not covered by the Swedish reimbursement scheme but are to be procured by the Swedish regions, the TLV performs health economic assessments to provide the regions with the best possible basis for their decisions.

## **ENFORCEMENT, COMPLIANCE AND RECENT DEVELOPMENTS**

### **14. What investigative powers, sanctions and remedial measures (administrative, civil or criminal) are available to regulators when they detect non-compliance with trade and distribution rules for therapeutic products, and how are these powers used in practice?**

The Medicinal Products Act and the Act on Trade in Medicinal Products contain criminal sanctions for serious violations, including related to unauthorised manufacturing, wholesale distribution or the retail sale of medicinal products.

The Marketing Practices Act provides for several remedies or sanctions depending on the nature of the violation. Possible sanctions include a prohibitive injunction subject to fines, market disruption fees and third-party damages.

As provided above, the MPA is the competent supervisory authority that oversees the MDR/IVDR and the supplementary Swedish requirements. As such, the Medical Product's Agency has the right to require documentation and information, conduct announced and unannounced inspections, take samples and, in urgent cases, confiscate or destroy dangerous products. The available sanctions and remedies include (depending on the nature and severity of the non-compliance) injunctions combined with conditional fines (*vite*), administrative fines (*sanktionsavgift*) of up to SEK 100m, a market ban and criminal liability. In our experience, the MPA generally adopts a pragmatic approach and tries to cooperate with economic operators to correct non-compliance, rather than imposing stringent sanctions (depending on the circumstances and the severity of the non-compliance). The MPA's enforcement actions typically begin with investigations/inspections, the issuance of warnings and requirements to take corrective actions, and if the economic operator fails to comply or if there is intentional misconduct leading to significant risk or harm, more stringent actions will be considered.

### **15. Is there any recent case law, legislative or policy developments, noteworthy enforcement trends or anticipated reforms that may significantly alter the regulation of trade, distribution or cross-border movement of therapeutic products in the future?**

N/A