

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

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### 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?**

The principal laws and regulations regulating the import, wholesale distribution, retail sale and export of therapeutic products in Norway distinguish between medicinal products/biological products and medical devices, and are harmonised with European Union legislation through the European Economic Area (EEA) Agreement. The Norwegian Medical Products Agency (NOMA), subordinate to the Ministry of Health and Care Services, serves as the primary supervisory authority for all categories of medicinal products. NOMA handles approvals, permits, inspections and pharmacovigilance throughout the supply chain, with requirements for good marketing practice (GMP)/good distribution practice (GDP) and quality assurance.

For medicinal products, the Medicinal Products Directive (2001/83/EC) is transposed into Norwegian law through the Medicinal Products Act and associated regulations, governing the manufacture, import, marketing and export of medicinal products and biological products, including the Regulation on the Manufacture and Import of Medicinal Products and the Regulation on Wholesale Distribution of Medicinal Products. The Norwegian Pharmacy Act and the Pharmacy Regulation further regulate the sale and dispensing of medicinal products by pharmacies.

For veterinary medical products, Regulation (EU) 2019/6 on veterinary medical products is implemented in Norway through Chapter Ia of the Medicinal Products Act and supplementary Norwegian regulations, including the Regulation on Medicinal Products for Animals.

For medical devices, Norwegian rules are harmonised with EU law through Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR), both of which are incorporated into Norwegian law through the Medical Devices Act and the Regulation on Medical Devices.

**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 are attached 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?**

Therapeutic products are classified for regulatory purposes according to specific criteria that determine their legal status, marketing conditions and distribution requirements.

For medicinal products, the prescription status is regulated in Chapter 7 of the Medicinal Products Regulation, which sets out detailed rules on when a medicinal product is prescription only and how it is classified. The prescription status of a medicinal product is determined during the marketing authorisation process, which is required before market entry. The competent authority involved depends on the authorisation route: for nationally authorised, mutual recognition or decentralised procedures, NOMA is the decision-maker, while for centrally authorised products, classification is set at the EU/EEA level and applies uniformly across EU/EEA Member States. Classification depends on factors such as toxicity, risk of misuse or dependence, the need for medical supervision and clinical experience. Prescription-only medicines are divided into groups A, B and C, reflecting decreasing degrees of control and dependence risk (Medicinal Products Regulation Section 7-3). Non-prescription medicines fall under category F, with some in group CF, where specific strengths, package sizes or forms are exempt from the need for a prescription. Classification directly affects trade and distribution: prescription medicines may only be dispensed by authorised pharmacies and are subject to strict advertising restrictions, while certain over-the-counter (OTC) medicines may be sold outside pharmacies under the medicines outside pharmacies (*Legemidler Utenom Apotek* or LUA) scheme, which permits the retail sale of a limited range of non-prescription medicines by food retailers and other approved outlets.

Medical devices are classified by risk in accordance with the MDR, as implemented through the Norwegian Regulation on Medical Devices, based on their intended use. Manufacturers assign the appropriate class from I (low risk) to IIa, IIb and III (higher risk), which determines the conformity assessment procedure applicable and whether a notified body must be involved. In vitro diagnostic devices follow a similar regime under the IVDR, involving classes A to D. Only after a successful conformity assessment and CE marking may a device be legally placed on the EU/EEA market.

## 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?**

Engaging in the wholesale distribution of medicinal products in Norway requires a wholesale distribution authorisation from NOMA. This authorisation grants the right to purchase, store, distribute, export and otherwise handle medicinal products at the wholesale level. Companies holding an equivalent authorisation from another EU/EEA country may operate in Norway within the scope of the authorisation. EU/EEA manufacturers must notify NOMA before commencing distribution, while EU/EEA wholesalers are encouraged to do so. Wholesale distribution is regulated by the Regulations on Wholesale Distribution of Medicinal Products, which require compliance with the EU Good Distribution Practice (GDP) guidelines. Other key requirements include obligations related to supply continuity, emergency preparedness, qualified personnel and standards for premises and equipment.

The wholesale distribution of medical devices does not require a separate wholesale authorisation from NOMA. These activities are regulated by the Norwegian Medical Devices Regulations implementing the MDR and IVDR. Distributors must register with NOMA when importing certain classes of devices and ensure key compliance measures are in place, including proper storage,

traceability and cooperation with manufacturers.

**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?**

Owning and operating a pharmacy in Norway requires two licences from NOMA, pursuant to Section 1-4 of the Norwegian Pharmacy Act. First, entities must obtain a pharmacy ownership licence by demonstrating sufficient financial capacity and scale to ensure professional operations. Second, a pharmacy operations licence is required for a pharmacist serving as the responsible manager. In addition, all pharmacies have a delivery obligation for medicinal products that must be compounded for individual customers and must, therefore, either have their own manufacturing authorisation or a supply agreement with a compounding producer (or both). Prescription-only medicinal products may only be dispensed from authorised pharmacies, which are required to meet statutory requirements on premises, internal controls, qualified staff, quality systems and advertising restrictions.

Pursuant to Section 42 of the Norwegian Pharmacy Regulation, online pharmacies must also register with NOMA and display the EU common logo that links to NOMA's information page on the sale of medicines over the internet. They must also comply with all of the pharmacy regulations, including quality preservation during transportation, recipient authentication via the e-prescription system, traceability to delivery and consumer guidance on storage and use with access to advice from a pharmacist.

Certain food retailers may sell a limited range of OTC medicines listed by NOMA if they comply with the Regulation on the sale of certain non-prescription medicines outside pharmacies (LUA), with key requirements including internal controls, a designated responsible person, proper storage and reporting to NOMA. Online sales under the LUA scheme require prior notification to NOMA and the display of the EU common logo on each webpage that is linked to NOMA's information page and register of authorised sellers.

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

Online sales of therapeutic products must in principle follow the same rules as those for physical pharmacies (see Question 4 above), supplemented by specific requirements for distance and internet sales under the Pharmacy Regulations Section 42 (pharmacies) and LUA Regulation Section 10a (foodstuff retailers selling OTC products under the LUA scheme). Key requirements include NOMA notification, EU common logo display on every webpage that is linked to NOMA's register, e-prescription authentication for the sale of prescription-only medicines and a prohibition on online sales of all non-prescription medicines to persons under 18 years of age. Sales via social media or third-party marketplace platforms are prohibited.

**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)?**

Imports of medicinal products to Norway are regulated by the Norwegian Medicines Act Section 13 and the Regulation on Manufacturing and Import of Medicinal Products (Chapter III). NOMA is the competent authority, and the Norwegian Customs Authority enforces border controls, including risk-based inspections and the seizure of non-compliant consignments.

Under the Regulation on Manufacturing and Import of Medicinal Products Section 3-1, EU/EEA-based manufacturers, wholesalers and pharmacies may import medicines without a separate licence if their establishment authorisation covers imports. Imports from third countries require NOMA authorisation, compliance with GMP and GDP standards, batch certification by a qualified person and, where applicable, batch testing. In principle, medicinal products must have a marketing authorisation, except for certain limited cases, such as named-patient supply, clinical trials and emergencies.

Medical devices generally do not require an import licence. Importers must be EU/EEA established and comply with the MDR or IVDR, as implemented in the Norwegian Regulation on Medical Devices, including in regard to CE marking, proper labelling, unique device identification (UDI) traceability, post-market surveillance and registration.

The Norwegian Customs Authority applies risk-based border controls and may seize or destroy non-compliant products. Most therapeutic products, including both medicinal products and medical devices, enter duty free under Norwegian customs rules.

**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?**

Section 3-2 of the Norwegian Regulation on the Manufacture and Import of Medicinal Products permits consumers to import medicines for personal use under strict conditions, distinguishing between medicines carried upon entry and postal shipments from the EU/EEA.

Upon entry, private individuals may bring a reasonable quantity of medicines equivalent to a maximum of one year's supply from EU/EEA countries or three months' supply from third countries, provided they can document to the authorities that the medicines were lawfully acquired in the country of purchase and are for personal use.

For postal shipments from the EU/EEA, individuals over the age of 18 may import non-prescription medicines equivalent to a maximum of three months' supply within any three-month period. The shipment requires documentation confirming the seller's right to sell and export the medicines, along with Norwegian marketing authorisation. Prescription medicines and all shipments from third countries are prohibited, with the Norwegian prescription status determining eligibility even if it differs from that of the country of origin.

For medical devices, unlike medicinal products, no special import restrictions apply.

Regardless of the product category, a 25 per cent value-added tax (VAT) applies to all online purchases of therapeutic products. However, for personal imports when physically entering Norway, goods up to NOK 6,000 may be imported without VAT. No customs duties apply.

The Norwegian Customs Authority may seize and destroy both prescription and non-prescription

medicines that have been imported unlawfully.

**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?**

Foreign suppliers are prohibited from shipping prescription medicines directly to patients in Norway via e-commerce or mail order. Only pharmacies holding a Norwegian pharmacy licence issued by NOMA may dispense prescription medicines directly to patients. Individuals aged 18 and above may, however, within a three-month period, import up to a three-month supply of non-prescription (OTC) medicines from the EU/EEA for personal use pursuant to Section 3-2 of the Regulation on the Manufacture and Import of Medicinal Products (see answer to Question 7 above). Such private imports of non-prescription medicines are only permitted provided that the importer can document to the authorities that:

- the medicines are for personal use and were lawfully obtained in the country of purchase,
- the shipment is accompanied by documentation evidencing that the seller is legally authorised to sell and export the medicines in question,
- the medicines have marketing authorisation in Norway, and
- the importer is above the age of 18.

Medical devices may generally be sold and shipped directly to consumers by EU/EEA-established suppliers through e-commerce or mail order, provided they meet all of the requirements set out in the Norwegian Regulation on Medical Devices and the MDR or IVDR. Key obligations include CE marking, Norwegian labelling and instructions for use, UDI traceability and the availability of the EU declaration of conformity.

**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?**

Parallel importation of medicinal products from the EU/EEA is permitted in Norway under stringent conditions designed to protect public health, product quality and traceability. Businesses must obtain a specific parallel import marketing authorisation (MA(PI)) from NOMA pursuant to Section 3-24 of the Medicinal Products Regulations. Approval requires the product to benefit from valid authorisation in another EU/EEA country and to compete with an equivalent product authorised in Norway.

For medical devices, parallel trade is governed by the MDR, as implemented in Norway. Importers and distributors must verify CE conformity, provide Norwegian labelling and instructions for use, maintain UDI traceability and perform post-market surveillance.

Intellectual property rights generally do not impede parallel imports from the EU/EEA due to the exhaustion of intellectual property rights upon the first lawful sale within the EU/EEA. Importers must notify the marketing authorisation holder (and the European Medicines Agency for centrally authorised products) and, for patent-protected medicines imported from Bulgaria, Estonia, Croatia, Latvia, Lithuania, Poland, Romania, Slovakia, Slovenia, the Czech Republic or Hungary, the patent holder or holder of the supplementary protection certificate must receive one month's advance notice, pursuant to Section 3-25 of the Medicinal Products Regulations. Any intellectual property disputes are resolved through the courts.

Re-labelling and re-packaging are permitted, but they are strictly regulated to ensure product quality, safety and traceability. Parallel importers conducting these operations must secure a manufacturing authorisation, while repackaging firms must be EU/EEA established, with their national authorisation documented in the MA(PI) application. Underlying foreign text is acceptable if securely over-stickered with non-transparent Norwegian labels. Applications require mock-ups of clean and final packaging, plus inner packaging samples, with NOMA approving the design and text content.

## 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 export of therapeutic products from Norway requires a wholesale licence from NOMA, as per Section 2 of the Regulation on Wholesale Distribution of Medicinal Products. While the licensing does not impose general quantitative restrictions, exports remain subject to the delivery obligation set out in Section 4 of the Regulation on Wholesale Distribution of Medicinal Products, requiring the supply to the Norwegian market within 24 to 48 hours.

NOMA may impose restrictions on sales and delivery, including exports, under Section 15 of the Regulation on Wholesale Distribution of Medicinal Products, if there is risk to medicinal product supply in Norway, with restricted products listed publicly on NOMA's website. Additionally, under Section 16, NOMA may impose further restrictions specifically on parallel exports where there is an imminent risk of a supply shortage.

**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?**

Under Norwegian law, there is no dedicated central 'export-only' or 'dual-labelling' authorisation permitting the manufacture and export of therapeutic products (medicinal products) that have not been approved for domestic marketing purposes. Instead, such activities are permissible under existing manufacturing or wholesale distribution authorisations, subject to the relevant GMP and GDP requirements being met.

## 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 Norwegian Medicines Regulations Section 3-29 to 3-56 set out detailed requirements for the labelling, serialisation and traceability of therapeutic products prior to their circulation on the Norwegian market, implementing the EU rules set out in the Medicinal Products Directive (2001/83/EC). Labelling must be provided in Norwegian on both the outer and immediate packaging, in accordance with the approved Summary of Product Characteristics (SmPC). Mock-

ups must be submitted to NOMA for review and approval before the product is placed on the market.

The labelling must include key information, such as the product name, strength, pharmaceutical form, active substances, batch number, expiry date, storage conditions, marketing authorisation number, Nordic article number, mandatory warnings, disposal instructions and the product name and strength in Braille on the outer packaging.

Prescription medicines must also comply with the safety feature requirements set out in the EU Falsified Medicines Directive (Directive 2011/62/EU), including the need for a 2D DataMatrix code with a unique identifier (Global Trade Item Number (GTIN), serial number, batch number and expiry date) and an anti-tampering device.

For medical devices, UDI obligations apply under the MDR. The UDI system must be implemented for all medical devices except custom-made devices and devices used in performance studies. In addition, manufacturers must complete conformity assessment procedures and demonstrate compliance with the applicable essential requirements before affixing the CE mark, which should not be applied to non-compliant devices.

## 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?**

Norwegian legislation contains several mechanisms that, while not trade measures, substantially influence the pricing, distribution and availability of therapeutic products.

For prescription medicines for humans, NOMA must approve a maximum pharmacy purchase price (AIP) and retail price (AUP) before marketing can take place. Prices are based on international reference pricing, calculated as the average of the three lowest market prices in a selection of EU/EEA reference countries. When patent protection expires and equivalent generics or biosimilars enter the market, the step-price system establishes defined step price reductions compared with the maximum price within each group to encourage competition, and pharmacies must offer at least one product at the step (reduced) price within each group.

Reimbursement is governed by the Regulation on Reimbursement of Medicines. Under the Blue Prescription Scheme, the National Insurance Scheme covers all or part of the patient cost for eligible medicines, contingent on the documented clinical benefit and cost effectiveness.

Medicines used in hospitals are procured through competitive tenders organised by Sykehusinnkjøp HF (the national agency responsible for centralised hospital procurement), pursuant to the Public Procurement Act. Such tenders largely determine which medicines are available in hospitals and may influence market shares among competing suppliers.

Finally, under Section 4 of the Regulation on Wholesale Distribution of Medicinal Products, marketing authorisation holders and wholesalers are required to ensure the continuous supply of medicinal products and to notify NOMA in case of shortages or foreseeable supply disruptions.

## 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?**

In Norway, NOMA enforces the trade and distribution rules for therapeutic products under the Medicinal Products Act.

Inspections are generally announced two to four weeks in advance, accompanied by a prior request for documentation, although unannounced visits are carried out when necessary. Inspectors may enter all licensed premises, obtain documents, samples and information, interview staff, tour facilities, review records and take photographs. They are bound by statutory confidentiality obligations.

Observations are documented and form the basis of a report, usually issued within one month. The report classifies deviations and triggers the notice of an order to remedy under Section 28. Deadlines vary depending on severity; critical issues are addressed immediately with evidence provided within about one month. Major issues are normally closed within roughly 75 days from the last inspection day. Other issues are addressed within about six months. Companies must submit documentation and proof of implementation, and for major or other issues, companies must create and update an action plan using NOMA's template. Within approximately 90 days of the last inspection day, NOMA also decides on GDP or GMP certification and issues certificates once any critical and major issues are satisfactorily closed.

If non-compliance persists, NOMA may impose coercive fines until the situation is corrected and, in serious cases, withdraw all or part of a licence. Criminal liability applies in parallel. Intentional or negligent breaches may be prosecuted under the Medicinal Products Act Section 31 and are punishable by fines or up to three months' imprisonment.

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

A significant recent policy development in Norway that may affect the regulation and distribution of therapeutic products is the introduction of tendering (procurement) for selected prescription-only (blue prescription) medicines. Following a parliamentary decision in 2023, NOMA, in cooperation with the Norwegian Directorate of Health and Sykehusinnkjøp HF, has established a permanent tender scheme for certain patented medicines where at least two therapeutically equivalent alternatives exist. This reform aims to improve the cost efficiency of publicly reimbursed medicines and broaden patient access to innovative therapies without increasing state healthcare expenditure. While it does not directly restrict the trade in or cross-border movement of medicinal products, the tender system may indirectly influence market dynamics and product availability by concentrating the demand on certain suppliers.

The EU's pharmaceutical reform, politically agreed between the Parliament and the Council in December 2025, will also drive major changes to Norwegian regulations once it is incorporated into the EEA Agreement and transposed into Norwegian law. Among other things, in regard to the trade and distribution of therapeutic products, the reform strengthens supply chain security by imposing additional obligations on both marketing authorisation holders and distributors, as well as on national authorities, particularly measures against medicine shortages, including risk assessments and notification duties.