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 main legislation related to medicinal products is European Union Directive 2001/83/EC, as amended, which was transposed into Maltese law as the Medicines Act (Chapter 458 of the Laws of Malta), together with its subsidiary legislation, including regulations on the manufacture and importation (S.L. 458.36), wholesale distribution and brokering (S.L. 458.37) and labelling and packaging (S.L. 458.33) of medicinal products.

The EU's Medical Device Regulation (EU) 2017/745 applies directly to medical devices and the Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices applies to those types of devices. These rules are supported by local legislation, specifically the Medical Devices and In Vitro Diagnostic Medical Devices Provision on the Maltese Market Regulations (S.L. 458.59).

The Malta Medicines Authority is the competent authority that governs the import, manufacture, wholesale distribution, retail sale and export of medicinal products and medical devices, including the designation and supervision of notified bodies for the carrying out of medical device conformity assessments. The Superintendent of Public Health (the 'Licensing Authority') is responsible for:

- granting marketing authorisations;
- processing individual requests (both for medicinal products by certified prescribers and for use in public and private hospitals);
- authorising controlled substances; and
- issuing wholesale and pharmacy licences.

As Malta is a unitary state, all regulatory powers are centralised at the national level, with no division between federal and state governments.

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?

In Malta, all medicinal products are dispensed from pharmacies only. The Licensing Authority determines during the marketing authorisation process whether products require a prescription, based on criteria, including:

- potential danger posed when used without medical supervision;
- the risk of widespread incorrect use;
- substances requiring further investigation; or
- products normally administered by injection.

Medical devices are classified into risk classes (I/IIa/IIb/III for medical devices; A/B/C/D for in vitro diagnostic medical devices (IVDs)), based on their intended use and inherent risks, determining the level of conformity assessment required.

The premarket review and approval process is mandatory for all therapeutic products. The Malta Medicines Authority assesses medicinal product applications and recommends them to the Licensing Authority, who issues marketing authorisations. Medical devices require CE marking, following the conclusion of the appropriate conformity assessment.

The classification given to a medical device will determine its:

- dispensing requirements (prescription, pharmacy supervision or hospital only);
- conformity assessment levels;
- wholesale licensing and good distribution practice (GDP) compliance obligations;
- advertising restrictions; and
- import/export requirements, including record keeping (a minimum of five years for wholesale transactions).

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 Malta, a wholesale dealer's licence is required to trade in medicinal products. The Malta Medicines Authority must be satisfied that the applicant has suitable premises, installations and equipment for the proper conservation and distribution of such products. Distributors must follow GDP guidelines, maintain a quality control system and keep records of all transactions for at least five years.

Every licensed wholesale dealer must appoint a responsible person (a pharmacist registered with the Pharmacy Council) who ensures the company's compliance with the licence conditions and GDP requirements. Wholesalers must only obtain supplies from and supply to appropriately authorised persons and must have emergency plans in place to deal with product recalls.

In regard to manufacturers, each product batch must be released by a qualified person permanently at the manufacturer's disposal.

Businesses distributing medical devices must:

- comply with the Medical Devices and In Vitro Diagnostic Medical Devices Provision on the Maltese Market Regulations (SL 458.59);
- obtain authorisation from the Malta Medicines Authority;

- employ a medical device registered person in Malta;
- register the relevant medical devices in the national database;
- ensure accurate CE marking and carry out conformity assessments;
- maintain traceability; and
- participate in post-market surveillance and vigilance activities.

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?

Businesses providing therapeutic products directly to consumers in Malta must hold specific licences under the Medicines Act (Chapter 458 of the Laws of Malta).

A pharmacy licence is required to sell medicinal products in a retail context. Key conditions include:

- a managing pharmacist must be present during the premise's opening hours;
- the premises must meet specified standards of cleanliness, access and product protection;
- pharmacies must comply with specific geo-demographic criteria;
- only licenced pharmacists may dispense prescribed products; and
- prescriptions must be retained for three months, with the dispensing details recorded.

Malta does not permit the operation of dedicated internet pharmacies. The requirement for physical dispensing by a licenced pharmacist effectively prohibits the online sale of medicinal products by Malta-based suppliers.

Businesses distributing medical devices must comply with S.L. 458.59, obtain authorisation from the Malta Medicines Authority, employ a registered person in Malta, register medical devices in the national database, ensure accurate CE marking and the carrying out of conformity assessments, maintain traceability and participate in post-market surveillance. Medical devices face fewer direct-to-consumer restrictions than medicinal products.

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

Malta does not permit the operation of internet pharmacies or the online sale of medicinal products by Malta-based suppliers, including through social media and marketplace platforms. Physical dispensing by a licenced pharmacist is required.

All medicinal product sales must be conducted through the regulated pharmaceutical supply chain, with the appropriate licences and GDP compliance. Advertising prescription-only medicines to the public is prohibited, and the unauthorised sale of such products constitutes an offence under the Medicines Act.

Maltese consumers may purchase products from EU-based internet pharmacies that display the common EU market logo, are registered with their national authority and comply with the applicable distance selling legislation.

Medical devices are not subject to pharmacy-only restrictions. Distributors may sell medical devices online provided they obtain authorisation from the Malta Medicines Authority, employ a registered person in Malta, register medical devices in the national database, ensure accurate CE marking and the completion of conformity assessments, maintain traceability and participate in post-market surveillance.

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 from non-EU/European Economic Area (EEA) countries require a manufacturer's/importer's licence, with a qualified person permanently available and each batch must undergo a full qualitative and quantitative analysis, according to EU-equivalent good manufacturing practice (GMP) standards. All medicinal products require a valid marketing authorisation before importation.

Parallel imports from EU/EEA Member States require both a wholesale dealer's licence and a parallel import licence, granted only where both products hold valid marketing authorisations and are therapeutically equivalent. For medical devices, importers must obtain authorisation from the Malta Medicines Authority, employ a registered person in Malta, register such devices in the national database, ensure accurate CE marking and the carry out conformity assessments and maintain product traceability.

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?

Maltese law does not contain specific provisions relating to the importation of therapeutic products by consumers for personal use. Generally, importing medicinal products from outside the EU/EEA requires a manufacturer's licence.

However, the personal importation of small quantities for strictly personal medical use may be tolerated where the quantities are minimal, prescription medicines are accompanied by a valid prescription and the importation is not for commercial purposes.

Importation of such products from EU Member States benefits from free movement principles, allowing purchases from regulated EU pharmacies, including those operating online. Third-country imports of unauthorised products may require guidance from the Malta Medicines Authority on compassionate grounds. Consumer importation of CE-marked medical devices is generally less restricted. Customs declarations, tariffs and value-added tax (VAT) are applied according to EU customs law.

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 cannot routinely ship medicinal products directly to Maltese consumers via e-commerce platforms or mail order. No person shall place a medicinal product on the market in

Malta unless in possession of a marketing authorisation from the Licensing Authority, and importation from countries outside the EU/EEA requires a manufacturer's licence. Direct commercial supply bypasses the licenced pharmaceutical supply chain required under the Medicines Act.

However, Maltese consumers may purchase medicinal products from properly regulated internet pharmacies established in other EU Member States that comply with EU requirements, namely those that display the common EU logo and those sites that are registered with their national competent authority. Such purchases fall under the EU's free movement principles, rather than being deemed to be commercial importation.

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?

The parallel importation of medicinal products requires both a wholesale dealer's licence and a parallel import licence under S.L. 458.40. Licences are granted only where both the Maltese-market and source-country products hold valid marketing authorisations and are therapeutically equivalent.

The EU principle of exhaustion of intellectual property rights applies, permitting parallel trade once products are lawfully placed on the market. Any re-packaging and re-labelling must comply with the Maltese requirements without adversely affecting the product's condition, and the marketing authorisation holder must be notified before any re-packaged products are marketed. Parallel importers must comply with the GDP obligations, maintain full traceability and keep all transaction records for at least five years.

For medical devices, re-labelling and re-packaging are governed by Regulation (EU) 2017/745. Distributors or importers carrying out such activities must indicate their details on the device, maintain a quality management system and submit a notified body certificate to the Malta Medicines Authority at least 28 days before making the device available. The EU principle of exhaustion of intellectual property rights applies in this context as well.

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?

Malta does not operate any quantitative export quotas for therapeutic products. As an EU Member State, Malta is bound by the principle of free movement of goods. While the Licensing Authority has broad regulatory powers over medicinal products under the Medicines Act, the legislation does not expressly provide for any export-specific prohibitions or quota-based controls.

The principal mechanism affecting export availability arises from statutory continuity of supply obligations. Wholesale dealers, marketing authorisation holders and distributors must ensure appropriate and continued supplies to meet patient needs in Malta, which may constrain exports in situations where they would jeopardise domestic availability. Manufacturers must also notify the competent authority at least six months in advance of any anticipated supply interruption that could result in serious harm to patients or public health.

During public health emergencies, the Licensing Authority may exercise exceptional powers to temporarily authorise the distribution of unauthorised medicinal products or impose special conditions on the supply of such products. Malta is also bound to implement any EU-level export authorisation schemes imposed during exceptional circumstances.

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?

Maltese law requires medicinal products to be covered by a marketing authorisation for domestic distribution. However, an express exception exists for products intended solely for export to third countries. Where medicinal products are stored in Malta but not distributed domestically, or are wholesaled exclusively for export, only a valid wholesale dealer's licence is required, no Maltese or EU marketing authorisation is necessary.

Export-only medicinal products remain fully subject to EU GMP requirements. The Licensing Authority may conduct inspections to verify compliance with the EU's GMP and GDP obligations for all authorised premises, regardless of whether the products are placed on the Maltese market.

When wholesaling to third countries, wholesalers must ensure the recipients are authorised under the destination country's laws to receive such products. Standard GDP documentation requirements apply, including records of the supply date, product details, quantities, batch numbers and information on the supplier's/consignee's identity.

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?

Medicinal product labelling must comply with S.L. 458.33, transposing EU Directive 2001/83/EC. All particulars must be legible, comprehensible, indelible and in Maltese or English. Prescription-only and certain at-risk non-prescription products require the adoption of specific safety features (unique identifier and anti-tampering device), as per the framework set by the EU's Falsified Medicines Directive.

Where safety features are removed or replaced, equivalent features must be applied under GMP supervision. Advanced therapy medicinal products are subject to enhanced traceability requirements. Parallel importers must indicate the relevant licence numbers on the packaging and maintain traceability records.

Medical device labelling must be in Maltese or English and must include the manufacturer's details, product identification, batch/serial number, expiry date, storage conditions, warnings and essential safety information, as required under Regulation (EU) 2017/745.

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?

While Malta does not impose statutory price controls on medicinal products, reimbursement structures, public procurement mechanisms and supply obligations materially influence distribution channels and product availability. Malta operates a publicly funded healthcare system, where access to medicines is determined by medical diagnoses or financial need.

Medicinal products supplied through the national healthcare service are centrally procured through the Central Procurement of Supplies Unit (CPSU) and provided free to eligible patients via a formulary-based system. Multi-year framework agreements with pharmaceutical suppliers determine which products are available within the public healthcare system. Only medicinal products included in the Government Formulary List are routinely procured and dispensed through public healthcare facilities. Non-formulary medicines may be accessed through exceptional or named-patient procedures.

Products not listed in reimbursement schedules have limited distribution in the public sector, with patients bearing the costs out of their own pocket through the private retail pharmacy market, where prices are commercially determined. The Licensing Authority may grant exceptional permission for the supply of unauthorised medicinal products where no suitable registered alternative is available. The unique identifier system may be extended to any medical product subject to a prescription or reimbursement for the purposes of reimbursement or pharmacovigilance.

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?

Under the Medicines Act (Chapter 458 of the Laws of Malta), the Licensing Authority regulates the trade, distribution and supply of therapeutic products, with the Malta Medicines Authority providing technical assistance. The Licensing Authority has investigative powers to conduct unannounced inspections of premises that are involved in the manufacture, importation, wholesale distribution, brokering, storage or supply of medicinal products.

The Licensing Authority may also suspend, revoke or vary wholesale dealer's licences or marketing authorisations for non-compliance with the GDP, GMP or other regulatory requirements. For advertising breaches, compliance orders may be issued requiring the cessation of such activities and corrective action.

An administrative penalty procedure allows fines of up to approximately €23,500 for minor offences, in situations where compliance is achieved within 21 days. Serious offences, including unlicensed activities and product falsification, are punishable by fines up to approximately €116,500 and/or imprisonment for up to two years. The courts may also order licence revocation or suspension upon conviction.

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?

There has been limited recent national case law in Malta fundamentally altering the regulation of the trade, distribution or cross-border movement of therapeutic products.

At EU level, proposed reforms to the EU pharmaceutical legislation aim to improve the availability and accessibility of medicinal products, including in smaller Member States. Once finalised, these reforms are expected to influence Maltese law. Malta continues to implement the EU Medical Devices Regulation.

Enforcement activity currently prioritises: supply chain integrity (GMP/GDP compliance); the prevention of falsified and counterfeit products; and licensing and inspection controls.

Looking ahead, Malta is expected to continue aligning its regulatory framework with EU-level initiatives addressing digitalisation, supply chain resilience and emerging healthcare technologies.