Guideline for License Holders and Managing Pharmacists on the Provision of Online Dispensing Services in compliance with the Online Dispensing of Medicinal Products to Third Countries from Free Zones and Customs Authorised Warehouses Regulations

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Medical Devices, Pharmaceutical Collaboration and Entrepreneurship Directorate

1. Introduction

This guideline document sets out the regulatory framework governing the online dispensing of medicinal products from Free Zones and Customs Authorised Warehouses in Malta. It applies to licence holders and designated managing pharmacists engaged in the online dispensing of medicinal products from Free Zones and Customs-Authorised Warehouses situated in Malta in terms of Subsidiary Legislation 458.64 (hereunder also 'the Regulations') *Online Dispensing of Medicinal Products to Third Countries from Free Zones and Customs-Authorised Warehouses Regulations*

This document should be read in conjunction with the Regulations, to ensure consistent implementation. While it does not replace or supersede any legal obligations, it provides a framework to support compliance, safeguard public health and protect the integrity of the supply chain. Where uncertainty arises, the Regulations prevail.

The Authority reserves the right, at its sole discretion, to revise or update this guideline document whenever it considers such amendments necessary.

2. Scope

This guideline document is intended to support license holders and designated managing pharmacists in understanding and fulfilling their legal obligations and professional responsibilities. It sets out the criteria governing the licensing, operational standards, sourcing, storage, handling, online dispensing and export of medicinal products intended exclusively for supply to consumers residing in third countries. It also covers standards for good pharmacy (dispensing) practices, data and documentation management, and cybersecurity.

3. Terms, Definitions and Abbreviations

Definitions:

Consumer

An individual residing in a third country who receives medicinal products, in terms of the Regulations.

Customs Authorised Warehouse

A premises or warehouse that has been assessed as suitable and authorised by the Customs Department of the Government of Malta, for the lodging, storage and securing of goods in accordance with Article 2 of the Customs Ordinance, and/or any substituting or supplementing legislation as applicable from time to time.

Dispensing Service

Licensed operation and its associated premises, located in a Free Zone or Customs Authorised Warehouse which processes requests for the dispensing and supply of medicinal products and dispatches such medicinal products via mail, in terms of the Regulations.

Free Zone

Areas or parts of Malta designated for use as free zones in terms of the applicable provisions of the Import Duties Act and of the Union Customs Code or any substituting or supplementing legislation as may be applicable from time to time. [Chapter 337 of the Laws of Malta]

Good Pharmacy (Dispensing) Practice

The standards applicable to the proper sourcing, storage, recordkeeping and dispensing that may, from time to time, in terms of the Regulations.

Licence

A licence issued by the Licensing Authority in accordance with these Regulations to operate an online dispensing service for medicinal products from the Free Zones and Customs Authorised Warehouses to consumers residing in third countries, in terms of the Regulations.

Licensing Authority

The Licensing Authority established by Article 3 of the Medicines Act (Chapter 458 of the Laws of Malta).

License Holder

The holder of the license issued, in terms of the Regulations.

Logo

The logo authorised by the Licensing Authority signifying compliance, in terms of the Regulations.

Managing Pharmacist

Shall be interpreted in accordance with Article 75 of the Medicines Act (Chapter 458 of the Laws of Malta).

Malta Medicines Authority

The Authority established under Article 4 of the Medicines Act (Chapter 458 of the Laws of Malta).

MRA Countries

Third countries which hold a Mutual Recognition Agreement with the European Union, in terms of the Regulations.

Online Dispensing of Medicinal Products

The dispensing of medicinal products to consumers residing in third countries from the premises of a licence holder in accordance with these Regulations and any other applicable law, including any guidelines issued by the Licensing Authority from time to time. [S.L 458.64]

Pharmacist

In accordance with Article 2 of the Medicines Act (Chapter 458 of the Laws of Malta).

Premises

Any physical location or facility, including but not limited to buildings, warehouses, or other structures, located within a Free Zone or Customs Authorised Warehouse in terms of applicable legislation, which is approved by the Licensing Authority for the storage, handling, and dispensing of medicinal products intended for consumers residing in third countries, in terms of the Regulations.

Storefront

A digital platform or website through which prescriptions are received and the dispensing of medicinal products to consumers residing in third countries is facilitated, in terms of the Regulations.

Third Country

Any country outside the European Union or the European Economic Area, in terms of the Regulations.

Abbreviations:

EU: European Union

EEA: European Economic Area

GDP: Good Distribution Practice

GPP: Good Pharmacy Practice

MRA: Mutual Recognition Agreement

WHO: World Health Organisation

S.L: Subsidiary Legislation

4. Specific Guidelines

4.1 General Provision

The online dispensing of medicinal products to third countries from Free Zones and Customs Authorised Warehouses in Malta is a highly regulated activity that requires prior authorisation from the Licensing Authority. No medicinal products may be dispensed from these areas to consumers in third countries unless a valid licence has been issued in accordance with the applicable Regulations.

All online dispensing activities must fully comply with Good Pharmacy (Dispensing) Practices (GPP). Licence holders are responsible for ensuring that medicinal products dispensed meet the required standards of safety, quality, and efficacy.

License holders must ensure that operations comply with applicable data protection, including Regulation EU 2016/679 (GDPR) and the Data Protection Act.

4.2 Licence holder

The license holder bears the legal responsibility for ensuring that medicinal products are dispensed only under lawful conditions, that cross-border supply chains are secure and transparent, and that all activities are duly authorised and appropriately documented in terms of the Regulations.

The obligations set out in the following sections derive from the relevant provisions of Regulations. The obligations must be interpreted in line with the overarching public health objective of protecting consumers and safeguarding the integrity of the regulatory system.

Licence holders must also comply with any other requirements as may be requested by the Licensing Authority in accordance with the Regulations, the Medicines Act and any other applicable law.

4.2.1 Licensing and Operational Governance

All online dispensing activities must operate under a valid license issued by the Licensing Authority. Licence holders are responsible for ensuring that their licence remains valid and that renewal applications are submitted at least three (3) months before expiry.

A managing pharmacist must be formally appointed by the licence holder to effectively fulfil the responsibilities associated with the dispensing of medicinal products and compliance with GPP standards. The licence holder must ensure that the managing pharmacist is granted sufficient authority, independence, and resources to effectively carry out the obligations. In tandem, consumers must be given access and contact details of the managing pharmacist for guidance regarding medicinal products.

The licence holder is ultimately accountable for governance and must ensure operations continuously comply with the provisions of the Regulations, as well as with any other

applicable laws, including those of the destination country.

4.2.2 Product Sourcing and Supply Chain Integrity

To ensure product sourcing complies with regulatory requirements and supply chain integrity is maintained, medicinal products for online dispensing must be sourced from a European Union licensed wholesale dealer who sources from manufacturers or wholesale distributors established in one of the following criteria:

(a) Located within the European Union (EU) and, or European Economic Area (EEA) market, provided that the export of critical medicinal products subject to shortages in the originating EU and, or EEA Member State is prohibited;

(b) Countries forming part of a Mutual Recognition Agreement (MRA), provided that the medicinal product is licensed in that country;

(c) The United Kingdom and any other operator, supplier or country as established by Government notice in the Gazette by the Minister, following consultation with the Licensing Authority;

(d) Suppliers who have procured products manufactured in compliance with Good Manufacturing Practice standards established by a regulatory authority in the EU or EEA market, or a country forming part of a MRA;

(e) Operators licensed by regulatory bodies classified under the World Health Organisation (WHO) Listed Authorities Level 4 strictly for products which would be authorised to be placed on their respective markets.

Medicinal products must be stored in accordance with Good Distribution Practice (GDP) requirements including the use of appropriate environmental controls. Licence holders must also maintain an electronic verification and decommissioning system to authenticate all

medicinal products and ensure that they are dispensed in line with the principles of safety, quality, and regulatory compliance.

Online dispensing is strictly limited to consumers residing in third countries. Licence holders are fully responsible for ensuring that such products meet all the legal, regulatory and quality standards of the destination country. Redistribution or dispensing of any medicinal product within the EU is explicitly prohibited. Medicinal products subject to prohibitions under the Dangerous Drugs Ordinance, or any other applicable legislation and restrictions in the jurisdiction of the country of destination must not be dispensed. Licence holders must also ensure that prescriptions comply with the laws of the destination country. Medicinal products requiring special handling (e.g., vaccines, temperature-sensitive items) and medical devices shall be excluded from online dispensing.

4.2.3 Record Keeping and Documentation

Accurate and complete records are a fundamental legal obligation of license holders. Licence holders must develop and maintain a comprehensive data management plan that ensures full traceability of every medicinal product from its source to its delivery in the country of destination.

Records must be updated on a daily basis, retained securely for a minimum of five (5) years and kept in a format that allows retrieval during inspections. Records must cover the full lifecycle of each medicinal product including sourcing, purchasing, storage, dispensing and prescription details. At a minimum, records must capture the following information: the date of dispensing, product details (name, active ingredient, dosage form, dose, pack size, batch and lot numbers, supplier, expiration date, and storage conditions), the quantity supplied, the registration number of the dispensing pharmacist, the consumer details and country of destination and the prescribing healthcare professional’s details. Prescriptions must be kept in scanned or electronic copy as submitted by the consumer through the website.

4.2.4 Annual Reporting and Financial Transparency

Licence holders are required to submit, on an annual basis, a Special Purpose Assurance Report prepared by a certified auditor or audit firm with expertise in the pharmaceutical sector, together with an audited financial statement. For the purpose of the Special Purpose Assurance Report, the submission date is determined by the financial year end. Where the financial year ends on 31 December, then the Special Purpose Assurance Report needs to be submitted by 1 July of the following year. Where the financial year ends on 30 June, the Special Purpose Assurance Report needs to be submitted by 31 December of the same year. It must verify the annual turnover and validate that all products were sourced and dispensed according to the Regulations. Failure to submit the report or submitting a materially deficient report may lead to warnings, administrative penalties, licence suspension or revocation, and potentially criminal proceedings. The audited financial statement must relate to the preceding financial year and must not be more than two (2) years old at the time of submission. It must include a revenue note clearly identifying the turnover derived from the services provided.

4.2.5 Risk and Quality Management

Licence holders must develop and maintain a risk management plan that is reviewed and updated on an annual basis. The plan must address all relevant risks associated with online dispensing activities, including but not limited to information security, business continuity, professional indemnity, and the dispensing of medicinal products to third countries. The risk management plan must be subject to independent certification by an approved auditor in the Maltese Islands, possessing experience in management systems and regulatory compliance.

Licence holders must also establish a quality management system to ensure that medicinal products are procured solely in accordance with the criteria set out in *section 4.2.2* of these guidelines and the provisions of *Regulation 12 of S.L 458.64,* and that all medicinal products dispensed comply with all relevant legislative, regulatory and quality standards applicable in the third country in respect of the importation of medicinal products by the patient for personal use.

4.2.6 Storefront and Website Requirements

The online storefront is the consumer-facing gateway to the dispensing service and must reflect the highest standards of transparency and safety. Storefront licence holders are required to ensure that the online platforms visibly display the official licensing logo as a mark of legitimacy and verification. The website must provide clear and accessible features for consumers to verify the licensing status of the licence holder, view the contact details of the licence holder and access the consumer support policy, including clear guidance on complaint procedures related to the medicinal product, and any other issues.

Each medicinal product listing must include the product's name, active ingredient, dosage form, pack size, intended use, potential risks, and contraindications. This can be made accessible either directly or via a link to the patient information leaflet. The website must also provide comprehensive usage guidelines and instructions to help consumers authenticate the medicinal product, including guidance on the use of safety features, such as anti-tampering devices, or links to official verification systems provided by national or international regulatory authorities.

Pricing must be fully transparent, including a breakdown of costs such as product price, transportation, and the total price payable. The license number, the name of the Licensing Authority, and the contact details of the Licensing Authority must also be included. Any third-party packaging or labelling must include the authorised logo, the license number, the licence holder's contact information and the official website of the Medicines Authority, thereby confirming the licensing status of the storefront and/or dispensing operation.

All website and associated data relating to online dispensing must be hosted on backup servers physically located within Malta's jurisdiction.

4.3 Managing Pharmacist Obligations

4.3.1 Professional Role and Accountability

The managing pharmacist is responsible for ensuring the lawful and safe dispensing of medicinal products to third countries. This role includes assuming both professional and operational oversight of all dispensing activities, as well as overseeing the safety and compliance of storage carried out by the licence holder. The managing pharmacist must, at all times, ensure adherence to applicable Regulations and recognised standards of Good Pharmacy (Dispensing) Practices (GPP).

4.3.2 Qualifications and Availability

To qualify for appointment, the managing pharmacist must be duly registered with the Pharmacy Council in Malta, hold a valid licence to practice and have at least two (2) years of professional experience in pharmaceutical management or the dispensing of medicinal products. The managing pharmacist must be present and available during all operational hours of the dispensing service. The direct involvement is required to oversee the receipt and processing of prescriptions, to monitor and verify the storage, handling and dispensing of medicinal products, and to address third-country consumer inquiries. In cases of absence, a locum pharmacist must be nominated, with a clear and documented handover, to ensure continuity of service.

4.3.3 Product Procurement and Dispensing Restrictions

A key responsibility of the managing pharmacist is to safeguard the safety, quality and legality of all medicinal products procured and offered for online dispensing. This includes ensuring that all medicinal products offered for online dispensing are procured from a wholesale dealer licensed within the European Union, who source such medicinal products from manufacturers or wholesale distributors in accordance with Section 4.2.2, and shall be supported by the maintenance of robust supplier verification procedures and the proper storage of medicinal products at all times.

The managing pharmacist must also ensure strict compliance with all restrictions on dispensing. No medicinal products may be dispensed or redistributed within the EU supply chain, nor may products be dispensed if they are banned, restricted or unauthorised in the jurisdiction of the country of destination. In this regard, the managing pharmacist must also verify that all medicinal products dispensed for delivery to consumers in a third country comply with the prescription legislation of the country of destination, including prescription validity and authorised quantities. The managing pharmacist must further ensure that all dispensed products are shipped in suitable tertiary outer packaging to preserve the integrity of the medicinal product, and that the accompanying customs documentation clearly designates the contents as "Medicinal Products for Personal Use" in terms of the Regulations.

4.3.4 Data Management and Record-Keeping

The managing pharmacist must exercise professional oversight of the licence holder's data management and record-keeping systems to ensure full compliance in terms of the Regulations. This responsibility includes verifying that a complete data registry is maintained to trace the entire lifecycle of each medicinal product, from its source to its delivery in the country of destination. Records must be updated daily, securely stored for at least five years, and retained in a format that allows immediate retrieval during inspections. The managing pharmacist must also confirm that prescriptions are stored in electronic or scanned form, and that product details such as batch numbers, expiry dates, and dispensing information are accurately recorded. The managing pharmacist must also support compliance with data storage and cybersecurity requirements, ensuring that records and consumer data are hosted on backup servers physically located in Malta and protected with adequate technical safeguards against unauthorised access or tampering.

4.3.5 Risk and Quality Management

The managing pharmacist must play an active role in risk and quality management. The managing pharmacist must contribute to the development and maintenance of the licence holder's risk management plan, which must address information security, business continuity, professional indemnity, and the risks inherent to dispensing to third countries. The managing

pharmacist must also ensure the development and maintenance of documented procedures addressing mitigation measures of the dispensing of counterfeit, unauthorised, or substandard medicinal products through online platforms. In addition, the managing pharmacist must oversee the practical operation of the quality management system in terms of the Regulations, verifying that procurement, storage, and dispensing processes meet the necessary safety, quality, and efficacy standards. The managing pharmacist must also ensure compliance with requirements relating to the storefront and website, including the proper display of the logo, product information transparency, and consumer support features as provided under the Regulations.

4.3.6 Reporting and Licence Maintenance

The managing pharmacist has supporting responsibilities in relation to regulatory reporting and licence maintenance. While the legal duty to submit annual Special Purpose Assurance Reports, audited financial statements, and licence renewal applications rests with the licence holder in terms of the Regulations, the managing pharmacist must ensure that all pharmaceutical records, compliance documentation (Special Purpose Assurance Reports and audited financial statements), and professional verifications are prepared in good time to support these submissions. This includes verifying that the Special Purpose Assurance Report and the financial audit statement are finalised in a timely manner, and that the license renewal application is submitted at least three months before its date of expiry.

4.3.7 Inspections, Audits and Consumer Access

The managing pharmacist must cooperate fully with inspections and audits of licensed premises and online platforms carried out by the Medicines Authority in terms of the Regulations. This includes granting access to premises, records, and systems, answering queries from inspectors, and implementing any corrective actions required. The managing pharmacist must also be directly accessible to consumers for professional advice regarding the safe use of medicinal products, including guidance on risks, contraindications, and safe handling, thereby fulfilling the consumer safety protections in terms of the Regulations.

4.3.8 Other Obligations

The managing pharmacist must comply with any additional obligations that may be imposed by the Licensing Authority under the Regulations, the Medicines Act, or other applicable laws. Through these responsibilities, the managing pharmacist acts as the professional guarantor of compliance, consumer safety, and regulatory integrity within the licensed dispensing operation.

5. References

The Malta Medicines Authority - Online Dispensing to Third Countries for Consultation [https://medicinesauthority.gov.mt/news-details?id=F693FE]

Subsidiary Legislation 458.64: Online Dispensing of Medicinal Products to Third Countries from Free Zones and Customs Authorised Warehouses Regulations

Subsidiary Legislation 458.49: Prescription and Dispensing Requirements Rules Regulations

Medicines Act, Chapter 458 of the Laws of Malta

Health Care Professions Act, Chapter 464 of the Laws of Malta

Malta Free Zone Act, Chapter 598 of the Laws of Malta

Customs Ordinance, Chapter 37 of the Laws of Malta

Import Duties Act, Chapter 337 of the Laws of Malta

This guideline should be read in conjunction with the applicable legislation, as amended from time to time.

6.

Signatures on file

List of Appendices

N/A