Guideline for the Application for a Licence for Online Dispensing to Third Countries from Free Zones and Customs Authorised Warehouses

1. Introduction

The Malta Medicines Authority is introducing an application form for the licencing of online dispensing of medicinal products to third countries from designated Free Zones and Customs-Authorised Warehouses. This initiative forms part of a broader strategic framework aimed at strengthening regulatory oversight and to ensuring compliance with the Subsidiary Legislation 458.64 (hereunder also 'the Regulations') *Online Dispensing of Medicinal Products to Third Countries from Free Zones and Customs Authorised Warehouses Regulations* in relation to the online dispensing, export, storage, and handling of medicinal products from authorised zones, within the Maltese Islands.

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

Any requests for clarification regarding the contents of this guideline document may be addressed to the Malta Medicines Authority by email at: collaboration.medicinesauthority@gov.mt.

2. Scope

The purpose of this guideline document is to outline the regulatory requirements and procedures when submitting an application to the Malta Medicines Authority for the granting of a licence to dispense medicinal products online to third countries from designated Free Zones or Customs Authorised Warehouses. The provisions outlined herein are to be interpreted and applied in accordance with the *Online Dispensing of Medicinal Products to Third Countries from Free Zones and Customs-Authorised Warehouses Regulations,* and any other applicable legislation.

3. Terms, Definitions and Abbreviations

Definitions:

Applicant

An individual or an entity who intends to provide services related to the online dispensing of medicinal products to third countries from free zones or customs-authorised warehouses, and who submits the licence application form, MT-ODF01, to the Authority in terms of the Regulations, and upon approval and adherence to all regulatory requirements and the provision of all complete information and documentation , the applicant is recognised as a licence holder.

Authorised Contact Person

If different from the applicant, the authorised contact person is the individual formally designated by the proposed licence holder for official communication with the Authority, including correspondence, submission of documents and receipt of notifications, in relation to the licence application.

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

Licenced 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]

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.

Licence Holder

The holder of the licence issued 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).

Medicines Authority

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

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]

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, 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.

Source of Wealth

The origin of the overall wealth of the ultimate beneficial owner, derived from lawful economic activity or activities, such as employment, business, investment, or inheritance, and as may be required to be demonstrated in accordance with applicable anti-money laundering and counter-terrorism financing legislation, including the Prevention of Money Laundering Act (Chapter 373 of the Laws of Malta), on a risk-based and proportionate basis.

Source of Funds

The origin of the particular funds utilised or intended to be utilised in relation to the online dispensing operations, as derived from an identifiable activity, transaction, or event, and as may be required to be demonstrated in accordance with applicable anti-money laundering and counter-terrorism financing legislation, including the Prevention of Money Laundering Act (Chapter 373 of the Laws of Malta), on a risk-based and proportionate basis.

Site Master File

A document describing the pharmaceutical activities undertaken at a licensed site, including the organisational structure, key personnel, quality management systems, premises, equipment, and procedures relevant to the storage, handling, and dispensing of medicinal products.

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.

Website URL

The Website Uniform Resource Locator which signifies the address of a unique resource on the internet, in terms of the Regulations.

Abbreviations:

e-form: Electronic Form

GDPR: General Data Protection Regulation

MBR: Malta Business Registry

ODL: Online Dispensing Licence

URL: Uniform Resource Locator

S.L: Subsidiary Legislation

4. Specific Guidelines

4.1 Application for a Licence

An application for a licence to dispense medicinal products online to third countries from Free Zones and Customs Authorised Warehouses may be submitted by an applicant who fulfils the applicable requirements established under Subsidiary Legislation 458.64. Applications may be submitted either by first-time applicants or by existing licence holders applying for the renewal of their licence or for an extension of the scope of authorised online dispensing activities, in accordance with the applicable regulatory framework. Applicants are required to submit a completed application form together with all relevant supporting documentation, ensuring that such information is accurate and complete in line with the requirements established by the Malta Medicines Authority.

For the avoidance of doubt, the Online Dispensing Licence authorises the storage, handling, and dispatch of medicinal products solely for export to consumers residing in third countries. Medicinal products covered by this licence shall not be released for free circulation in Malta or in the European Union, notwithstanding any possibilities for such release under the applicable customs procedures governing Free Zones or Customs-Authorised Warehouses, unless declared otherwise by the Superintendent of Public Health.

Any release for free circulation would fall outside the scope of this licence and may result in regulatory action, without prejudice to any action by the competent customs authorities.

4.2 General Provisions for Licence Application

4.2.1 Application Form Title

The application form related to this guideline document is *MT-ODF01 - Application for a Licence for Online Dispensing to Third Countries from Free Zones and Customs-Authorised Warehouses*, which may be accessed from the Malta Medicines Authority website through the following link: https://medicinesauthority.gov.mt/pharmaceuticalcollaborationandentrepreneurship

4.2.2 E-Form

The application *MT-ODF01* is an e-form which must be completed electronically using the designated fields. Handwritten application forms will not be accepted. A signed and scanned copy of the completed e-form, together with all required supporting documentation, must be submitted by email to collaboration.medicinesauthority@gov.mt.

4.2.3 Official Languages

The official languages of Malta are Maltese and English. All application forms and supporting documentation submitted as part of the registration process must be completed in either Maltese or English. Where supporting documentation is in a language other than Maltese or English, a certified translation must be provided.

4.2.4 Acknowledgment

Upon receipt of the submitted application form, the Authority will issue a formal acknowledgment of submission. This acknowledgment does not imply acceptance of the application's completeness.

Following an initial regulatory screening to verify administrative and technical completeness, a unique application reference number will be assigned and communicated to the applicant. The assigned reference number will serve as the official identifier in all subsequent correspondence with the Authority concerning the online dispensing licence application process.

Should the application be identified as incomplete, the Authority will place it in an 'Incomplete' status for a period of sixty (60) calendar days. The applicant will be notified in writing of the deficiencies identified and will be required to submit, within a defined period, the outstanding information and/or supporting documentation necessary to render the application complete and eligible for further assessment.

Failure to submit a complete and satisfactory resubmission within the stipulated period will result in the closure of the application. In such cases, the application will be deemed withdrawn and rejected. Any further consideration of the matter will require the submission of a new application, which shall be assessed as a new and independent application in accordance with the applicable regulatory requirements, fees, and procedural provisions.

Subject to the foregoing provisions, where following the conduct of an inspection of the licenced premises and/or online platform for the purpose of verifying compliance in terms of the Regulations, deficiencies and/or non-conformities are identified, the Authority will place the application in an 'Incomplete' status for a period of sixty (60) calendar days. The applicant will be notified in writing of the deficiencies and non-conformities identified during the inspection and will be required to submit, within the defined period, all outstanding information, corrective actions, and/or supporting documentation necessary to remedy such deficiencies and render the application assessment as complete and eligible for further regulatory assessment. Failure to fully address the identified deficiencies and to submit a complete and satisfactory response within the stipulated period, will result in the termination of the application process. In such circumstances, the application will be deemed withdrawn and rejected, in such cases the applicant will be informed giving reasons for refusal of application. Any further consideration of the matter will require the submission of a new application, which shall be assessed as a new and independent application in accordance with the applicable regulatory requirements, fees, and procedural provisions.

4.2.5 Licence Validity

Upon successful completion of the application review process, the applicant will be issued an Online Dispensing Licence to Third Countries from Free Zones and Customs-Authorised Warehouses by the Licensing Authority, which is valid for one (1) year from the date of issuance.

4.2.6 Application Fees

All applications must be accompanied by payment of the prescribed application fee. An application will not be processed unless the relevant fee is paid. The current fee schedule is available on the Malta Medicines Authority website at https://medicinesauthority.gov.mt/pharmaceuticalcollaborationandentrepreneurshipor may be obtained by contacting the Authority at collaboration.medicinesauthority@gov.mt**.**

Payment must be made in accordance with the payment instructions provided by the Authority. Proof of payment must be submitted with the application form as specified in Section 4.4.

4.3 Filling of the Application Form

Applicants are required to complete only those sections of the application form that are relevant to the specific service(s) intended to be provided.

The application form is structured as follows:

- Section A: Application Introduction
- Section B: Information on Licence Holder
- Section C: Information on Premises within Free Zones and Customs-Authorised Warehouses
- Section D: Information on Online Storefront
- Section E: Information on the Managing Pharmacist
- Section F: Declaration of Licence Holder
- Malta Medicines Authority Declaration for Form Submission
- Data Protection Consent Statement
- Annex 1 – Documents to be attached to Application
- Annex 2 – Managing Pharmacist Declaration Form

4.3.1 Section A: Application Introduction

Section A captures general information relating to the application form to be submitted to the Malta Medicines Authority for authorisation to conduct online dispensing of medicinal products to third countries. This section is divided into two sub-sections:

4.3.1.1 Category of Application

The applicant must indicate the category of application being submitted by selecting one of the following options:

i. First-time Application: Submitted by an applicant seeking authorisation for the first time under the applicable national regulatory framework in terms of the Regulations.

ii. Renewal Application: Submitted by an applicant seeking renewal of an existing authorisation prior to its expiry, in accordance with applicable legislative and procedural requirements.

For a Renewal Application, the applicant must provide the:

i. Original Application Reference Number, as previously issued by the Malta Medicines Authority, in the prescribed format: MT-ODF01-AA_____/_____.

ii. Original Licence Reference Number, as previously issued by the Malta Medicines Authority, in the prescribed format: MT-ODL-[D/OS/DOS]_____/_____.

4.3.2 Section B: Information on Licence Holder

Section B requires the applicant to provide details of the licence holder applying to undertake online dispensing services, in accordance with the applicable regulatory requirements.

4.3.2.1 Particulars of Licence Holder

Where the applicant is a natural person, full contact details must be provided.

Where the applicant is a legal entity, the contact details provided must correspond with those registered with the Malta Business Registry (MBR).

It is the responsibility of the applicant to notify the Malta Medicines Authority in a timely manner of any changes to any details.

4.3.2.2 Particulars of the Authorised Contact Person for the Proposed Licence Holder

Where different from the particulars provided under Section 4.3.2.1, the applicant must provide the Full Name, Official designation, Contact number, Residential address, and Email address of the individual designated as the primary contact person for all licence-related matters.

4.3.3 Section C: Information on Premises in Free Zones and Customs Authorised Warehouses

In accordance with the Regulations, the applicant must provide details of the premises from which dispensing activities of medicinal products to third countries will be conducted.

The following particulars must be provided in the application form:

- ***Premises Location*****:** indication of whether the premises are a Customs Authorised Warehouse or situated within a designated Free Zone in terms of the applicable legislation.

- ***Entity Name*****:** the full registered name of the entity operating within the Free Zone or Customs Authorised Warehouse, as registered with the MBR.

- ***Registered Office Address*****:** the exact and complete physical address of the office, as registered with the MBR.

- ***Physical Premises Address*****:** the exact and complete physical address of the physical premises, including any unit or warehouse identification, Free Zone designation, and exact postal code.

- ***Premises Contact Person*****:** the full name, official position, contact number, and email address of the person designated as the primary contact responsible for the premises.

4.3.4 Section D: Information on Online Storefront

Section D captures the details of the online storefront used for online dispensing operations. This section is subdivided into the following three subsections:

4.3.4.1 Website Details

The applicant must provide the proposed Uniform Resource Locator (URL) of the online storefront, along with the full address(es) of the physical location(s) where the website will be hosted and where the backup server infrastructure for data operations is located.

4.3.4.2 Details of Website Developer

The applicant must specify whether the website developer is an individual or an entity. If an entity, provide the name of the entity, the Company Registration Number, and the corresponding details of the entity's legal and judicial representative.

4.3.4.3 Website Service

The applicant must describe clearly and in detail the services offered through the online platform, particularly with reference to the online dispensing of medicinal products. The description should include, at minimum:

- The types of medicinal products to be dispensed (e.g., prescription-only medicines, over-the-counter products);
- The geographical scope of services (target third countries or regions);
- Payment and delivery methods;
- Customer service and complaint handling procedures;
- Procedures for ensuring patient safety and appropriate use of medicinal products.

In this section, the applicant is required to provide a detailed account of the procedures established for the verification and handling of prescriptions, such as the:

- Verifying the formal completeness of prescriptions received from consumers in third countries;
- Identifying that prescriptions are issued by appropriately qualified and licensed prescribers;

- Handling prescriptions in different languages or formats;
- Ensuring that all dispensing and warehousing activities carried out within the jurisdiction of Malta are fully compliant with the relevant and applicable Maltese pharmaceutical legislation;
- Refusing to dispense where prescriptions are incomplete, fraudulent, or not suitable for dispensing;
- Maintaining records of all prescriptions received and dispensed.

4.3.5 Section E: Managing Pharmacist General Information

The applicant must provide the particulars of the designated Managing Pharmacist, who shall be accountable for all operations related to the online dispensing of medicinal products to third countries in terms of the Regulations**.**

4.3.6 Section F: Declaration of Licence Holder

Section F must be completed and signed by the applicant, confirming that all the information provided in the application form is true, complete, and accurate. By signing the declaration, the applicant agrees to pay all applicable fees and contributions, acknowledges full awareness of and commitment to comply with the obligations arising under relevant laws, regulations, and licence conditions, and accepts that the licence will remain subject to all standard provisions applicable to Online Dispensing Licence for Third Countries Free Zone and Customs-Authorised Warehouse, including any future amendments. The applicant confirms that appropriate systems are in place to safeguard consumer safety and to ensure the protection of personal data in compliance with applicable data protection, the GDPR and pharmaceutical legislation. False, misleading, or incomplete information may result in regulatory action, including the refusal, suspension, or revocation of the licence in terms of the Regulations.

4.3.7 Malta Medicines Authority Declaration for Form Submission

The applicant must sign the Malta Medicines Authority declaration, confirming that all the information provided in the application form is true, accurate, and complete. The applicant is required to notify the Malta Medicines Authority without delay of any changes to the details provided in the application form or its annexes.

4.3.8 Data Protection Consent Statement

The applicant submitting the application hereby provides consent to the Authority for the processing of all personal data disclosed within this application form. By ticking the appropriate box in the relevant section, the applicant acknowledges that the personal data relates to the applicant and consents to its processing in accordance with the provisions of the General Data Protection Regulation (GDPR).

4.4 Submission of Supporting Documentation

The applicant must submit, where applicable, the supporting documentation specified in Annex 1 and Annex 2, together with the completed application form. This documentation includes:

- Completed Managing Pharmacist Declaration Form, where the applicant intends to provide online dispensing services;
- Curriculum Vitae of the proposed Managing Pharmacist;
- Valid Police Conduct Certificate for the Licence Holder, issued no earlier than one (1) month preceding the application date;
- Site Master File, including an organisational chart with names, designations, and, if applicable, the functional scale of relevant personnel;
- Certified and notarised list of shareholders, reflecting the current ownership structure of the entity. The list must include, for each shareholder: (i) the full legal name of the individual or legal entity; (ii) the type and class of shares held**;** (iii) the percentage of shares held; (iv) the date of acquisition of the shares; (v) nationality and country of residence, in the case of natural persons; (vi**)** jurisdiction of incorporation and company registration number, in the case of legal entities; and **(**vii) details of the ultimate beneficial owner(s), where applicable, including their full legal name(s), percentage of beneficial interest, and relevant identification particulars. The shareholders list shall document the Source of Funds and Source of Wealth for all recorded shareholders;
- Site Plan of the Free Zone or Customs Authorised Warehouse;
- Declaration confirming that the premises are located within a Free Zone as established under the customs legislation, or within a facility designated and approved as a Customs Authorised Warehouse area by the competent customs authority;
- Valid Company Registration Certificate issued by the MBR, dated no earlier than three (3) months prior to the application date;
- Declaration listing all pharmacists authorised to perform online dispensing activities, including their full name and professional registration numbers, assigned

responsibilities, and confirmation of adequate training in online dispensing pharmacy systems, patient confidentiality, and applicable regulatory requirements. Declarations must be kept up-to-date, and revised in the event of any change in authorised personnel;

- Quality management system plan, relevant to the storage, handling, and dispensing of medicinal products, including refrigeration units, security systems, and dispensing equipment;

- Description of equipment and control facilities, including workflow diagrams and procedures for receiving, storing, and dispatching medicinal products**;**

- Description of premises layout and operation activities,

- Anti-counterfeit, unauthorized, or substandard medicinal products plan or procedures, with confirmation that these procedures will be fully in place;

- Compliance plan for good pharmacy practice, including a commitment to implement the necessary procedures for the storage, handling, and dispensing of medicinal products within the premises;

- Data management plan that ensures full traceability of each medicinal product from the point of source to destination, including details pertaining to the original manufacturer;

- Declaration confirming that the hosting of the website and of the services where the data related to the online dispensing operations are stored, complies with applicable data protection, cybersecurity requirements, and the GDPR;

- A covering letter confirming that the designated contact person is authorised to communicate with the Authority, receive the licence, and/or perform any other activities on behalf of the proposed licence holder, but is expressly not authorised to sign any documentation on behalf of the proposed licence holder;

- Proof of Payment of the applicable application fee. This document will be subject to verification by the Finance and Corporate Services Unit of the Malta Medicines Authority, which shall confirm receipt of the corresponding funds.

All additional documentation relevant to the provision of online dispensing services to third countries from Free Zones and Customs-Authorised Warehouses must be made available to the Malta Medicines Authority upon request.

For an application form to be duly considered, all relevant sections of the application form must be completed in full and accurately, in accordance with this guideline document. Sections that are not applicable to the service being applied for shall be clearly marked as "N/A".

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

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

7. Appendices

MT ODF01 – Application for a Licence for Online Dispensing to Third Countries from Free Zones and Customs-Authorised Warehouses