Online Dispensing of Medicinal Products to Third Countries from Free Zones and Customs Warehouses

Scope

This framework covers the entry, storage, handling, online dispensing, and export of medicinal products from the Free Zones and Customs Warehouses in Malta, for the purpose of sale to consumers in third countries. The online dispensing of medicinal products from Free Zones or Customs Warehouses in Malta to third countries shall be conducted in accordance with recognised standards of good pharmacy (dispensing) practices. Licence holders engaged in online dispensing must ensure that all medicinal products dispensed meet high standards of safety, quality, and efficacy.

Glossary

"Consumer" for the purpose of these regulations means an individual in a third country who receives medicinal products in accordance with these regulations.

"Customs Warehouses" means any government warehouse provided by the Government for lodging goods.

"Dispensing Service" means a licensed operation and its associated premises, located in a Free Zone or Customs Warehouse, which processes requests for the dispensing of medicinal products and dispatches such products via mail.

"Free Zones" means an area of Malta designated as a Free Zone in accordance with the provisions of Article 3 of the Malta Free Zones Act.

"Good Pharmacy (Dispensing) Practice" refers to standards applicable to the proper sourcing, storage, record-keeping and dispensing that may from time to time be issued by or under these regulations, the Act and any applicable European Union law governing such licences.

"International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) " means the organisation that brings together regulatory authorities and the pharmaceutical industry to discuss and develop guidelines for the quality, safety, and efficacy of medicines.

"Licence" means a licence issued by the Licensing Authority to operate an online dispensing service for medicinal products from the Free Zones and Customs Warehouses to consumers in third countries.

"Logo" means the logo authorised by the Licensing Authority signifying compliance with applicable regulation.

"Medicinal products" shall have the meaning assigned under the Act.

"Online Dispensing of Medicinal Products" means the dispensing of medicinal products to consumers in third countries through electronic means.

DRAFT

"Premises" means any physical location or facility, including but not limited to buildings, warehouses, or other structures, located within a Free Zone or Customs Warehouse, which is approved by the Licensing Authority for the storage, handling, and dispensing of medicinal products intended for consumers in third countries.

"Third countries" means any country outside the European Union or European Economic Area.

"Website" means a digital platform or website, licenced under these regulations, which receives prescriptions and facilitates the supply of medicinal products to patients in third countries via the online dispensing pharmacy operated licence holder.

Salient Points

Online Dispensing Licence

1. A licence issued by the Licensing Authority is required to operate an online dispensing platform of medicinal products from the Free Zones and Customs Warehouses to consumers in third countries.

2. Licences issued are valid for a period of 1 year. Applications for renewal of licences shall be submitted at least 3 months before the expiry of the licence, with updated documentation confirming ongoing compliance with relevant regulations.

3. The licence holder shall be required to comply with all regulations for medicinal products in addition to the Freeport Act, the Customs Ordinance and any other applicable legislation.

4. The Application for an online dispensing licence shall include:

   (a) the name and address of the applicant.

   (b) the address of the website URL, and/or the premises located within a Free Zone or Customs Warehouse intended for the dispensing of medicinal products to third countries.

   (c) the equipment and control facilities as may be required.

   (d) the name of the managing pharmacist responsible for overseeing dispensing operations and ensuring compliance with good dispensing practices.

   (e) a detailed plan outlining the quality management system that will be implemented to ensure the safety, authenticity, and efficacy of medicinal products, with a commitment to full implementation upon licensure.

   (f) documented procedures, or a plan for their development, to prevent the dispensing of counterfeit, unauthorised, or substandard medicinal products through online platforms, with confirmation that these procedures will be in place prior to commencing operations.

DRAFT

(g) an outline of the applicant's approach to complying with Good Pharmacy (Dispensing) Practice, including a commitment to implement the necessary procedures for the storage, handling, and dispensing of medicinal products within the premises, prior to operation.

(h) a plan for maintaining records for each medicinal product dispensed online, including details of the original manufacturer, with a commitment to implement traceable record-keeping systems upon commencement of dispensing operations.

Operational Requirements

1. Licence holders are required to:

a) follow Good Pharmacy (Dispensing) Practice for storage and handling of medicinal products.

b) ensure that medicinal products are sourced solely from authorised operators (refer to *Procurement standards*).

c) ensure the proper storage of medicinal products, including monitoring for temperature and humidity.

d) maintain an updated daily traceable record for all received and dispensed medicinal products ensuring there is full traceability of all medicinal products stored and dispensed in relation to:

i. prescriptions, including consumer's details, country of dispensing, prescribing healthcare professional's information, and prescription dates.

ii. product name, active ingredient, dosage form, dose, pack size, batch and lot numbers, supplier, expiration date, and storage conditions.

iii. purchasing, storage, and dispensing of a medicinal product.

All transaction records and prescriptions to be kept for a minimum period of 5 years.

e) ensure that all medicinal products dispensed online fully comply with all relevant legislative, regulatory, and quality standards applicable in the third-country destination.

f) not source, dispense, or sell any medicinal product or item prohibited by the Dangerous Drugs Ordinance or any other applicable legislation.

g) comply with the requirements for the Website and the Logo, including the proper display of the authorised verification logo on the online storefront and/or on the third-party packaging or labelling of dispensed products, thereby confirming the licencing status of the shopfront and/or dispensing operation.

DRAFT

h) develop and annually update a risk management plan that addresses relevant risks, including those related to information security, business, indemnity, and dispensing medicinal products to third countries. The plan must comply with relevant regulations and must be certified by an approved auditor in the Maltese Islands.

i) Every licence holder shall, on an annual basis and at their own expense, submit to the Licensing Authority a report prepared by an independent auditor, duly warranted by the Accountancy Board, who must possess expertise in the pharmaceutical field. The report shall be submitted no later than the thirty first (31) of March of each year, covering the preceding financial year and shall include the following:

   i. verification of the licence holder's total annual turnover for the reporting period.

   ii. confirmation that the licence holder has complied with the requirements of the General Data Protection Regulation or any applicable equivalent data protection legislation, and evidence of adherence to data protection policies, including but not limited to, secure processing, storage, and handling of personal data.

   iii. verification that all products handled by the licence holder during the reporting period were sourced and dispensed in accordance with these regulations.

j) appoint a Managing Pharmacist in possession of a minimum of two (2) years professional experience in pharmaceutical management or the dispensing of medicinal products.

k) ensure that during all operational hours of the online dispensing service, a Managing Pharmacist or, in the absence of a Managing Pharmacist, a locum pharmacist is always in attendance.

2. The Managing Pharmacist shall:

   (a) be responsible for the oversight, safety, and compliance of the storage and dispensing activities carried out by the licence holder with particular emphasis on the compliance to Good Pharmacy (Dispensing) Practice standards.

   (b) be available during all operational hours of the online dispensing service to oversee dispensing practices and address any third-country consumer inquiries.

   (c) ensure that, in the event of their absence, a locum pharmacist is nominated to perform the duties of the Managing Pharmacist in their absence.

Procurement Standards

1. Medicinal products offered for online dispensing shall be procured from:

   (a) European Union Licensed Wholesale distributors for medicinal products authorised to be placed on the EU/EEA market, provided that the export of critical

DRAFT

medicinal products subject to shortages in the originating EU/EEA Member State is prohibited.

(b) Operators licenced by ICH stringent regulatory authorities, coming from the EU, EEA, UK, USA, Canada, Japan, Singapore, Switzerland, Australia, and New Zealand, strictly for products which would be authorised for markets within the ICH countries.

(c) Suppliers who have procured products manufactured in compliance with Good Manufacturing Practice standards.

(d) Operators licensed by regulatory bodies classified under the WHO Listed Authorities as Level 4 strictly for products which would be authorised for their respective markets.

Online Dispensing Platform and Patient Safety

1. All licence holders shall prominently display the Logo assigned to the Online Dispensing of Medicinal Products to Third Countries from Free Zones and Customs Warehouses on their website as a verification of legitimacy.

2. The website shall include a facility that allows patients to:

   (a) verify the licensing status of the licence holder.

   (b) view the contact details of the licence holder.

   (c) access the patient support policy of the licence holder, including information on how to contact the licence holder or managing pharmacist.

3. Each online medicinal product listing on the website shall as a minimum include:

   (a) product name, active ingredient, dosage form, pack size and intended use, or a link to the patient information leaflet.

   (b) potential risks, contraindications, and necessary usage guidelines, or a link to the patient information leaflet.

   (c) instructions for consumers to verify the authenticity of the medicinal product being sold. This shall include, where applicable, guidance on how to use safety features (such as anti-tampering devices), or access links to official verification systems, including those provided by national or international regulatory authorities.

   (d) pricing details, which shall be provided in a manner that ensures full transparency to the consumer, clearly outlining the individual price components such as product cost, transport fees, and the corresponding cost for each, as well as the total price payable.

DRAFT

(e) licence number, name of licencing authority and the contact details for the licencing authority.

4. For each dispensed product delivered in a package, the licence holder shall include on or within the package the licence number, the contact information of the dispensing operator and the official website of the Authority that provides access to the official list of licensed operators.

Inspections and Compliance Monitoring

1. The licence holders shall be subject to periodic inspections of licensed premises and online platforms to verify compliance with relevant regulations to safeguard patient safety.

DRAFT