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Taqsima B

L.N. 191 of 2025

MEDICINES ACT
(CAP. 458)

Online Dispensing of Medicinal Products to Third Countries from Free Zones and Customs Authorised Warehouses Regulations, 2025

IN EXERCISE of the powers conferred by article 106 of the Medicines Act, the Minister responsible for public health, in consultation with the Licensing Authority, has made the following regulations:-

Citation, scope, applicability and commencement.

1. (1) The title of these regulations is the Online Dispensing of Medicinal Products to Third Countries from Free Zones and Customs Authorised Warehouse Regulations, 2025.

(2) The scope of these regulations is to govern the sourcing, storage, handling, online dispensing, and export of medicinal products from Free Zones and Customs Authorised Warehouses in Malta to consumers residing in third countries. They establish licensing, operational, and compliance requirements to ensure the safety, quality, and traceability of such medicinal products.

(3) These regulations shall apply to the sourcing, storage, handling, online dispensing, and export of medicinal products from the Free Zones or Customs Authorised Warehouses in Malta, for the purpose of sale to consumers residing in third countries.

(4) These regulations shall come into force on such date or dates as the Minister responsible for public health may by notice in the Gazette establish and different dates may be so established for different provisions and, or purposes of these regulations.

Interpretation.

2. In these regulations, unless the context otherwise requires:

"Act" means the Medicines Act; Cap. 458.

"consumer" means an individual residing in a third country who receives medicinal products in accordance with these regulations;

"Customs Authorised Warehouse" means any authorised government warehouse for lodging, storage and securing of goods in accordance with article 2 of the Customs Ordinance, Cap. 37.

and in accordance with the applicable procedures under Article 240 of the Union Customs Code, as may be applicable from time to time;

"dispensing service" means a 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 products via mail in accordance with these regulations;

"EEA market" means the internal market comprising the Member States of the European Union together with the EEA EFTA States, namely Iceland, Liechtenstein, and Norway, as established under the Agreement on the European Economic Area, within which the free movement of goods, persons, services, and capital is ensured.

"EU market" means the internal market comprising the Member States of the European Union, within which the free movement of goods, persons, services, and capital is guaranteed under the Treaty on the Functioning of the European Union and relevant Union legislation.

"European Union licensed wholesale distributor" means any wholesale dealer licensed in accordance with Title III of the Act, the provisions of any regulation or rules made thereunder, and any applicable European Union law governing such licences;

Cap. 598.

"Free Zone" shall have the same meaning as assigned to it in the Malta Free Zones Act;

"Good Manufacturing Practice" means that part of quality assurance which ensures that products are consistently produced, imported and controlled in accordance with the quality standards appropriate to their intended use and in accordance with these regulations;

"Good Pharmacy (Dispensing) Practice" means the standards applicable to the proper sourcing, storage, record-keeping and dispensing that may, from time to time, be issued by means of regulations under the Act;

"Licensing Authority" means the Licensing Authority established by article 3 of the Act;

"licence" means 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;

"logo" means the logo authorised by the Licensing Authority signifying compliance with these regulations and any other applicable law;

"managing pharmacist" shall be interpreted in accordance with article 75 of the Act;

"Medicines Authority" means the Medicines Authority established by article 4 of the Act;

"medicinal products" shall have the same meaning as assigned to it in the Act;

"Minister" shall have the same meaning as assigned to it in the Act;

"MRA countries" means those third countries which hold a Mutual Recognition Agreement with the European Union;

"Regulation (EU) 2016/679" means the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation);

"online dispensing of medicinal products" means 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;

"premises" means 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;

"registered pharmacist" shall be interpreted in accordance with article 13 of the Health Care Professions Act; Cap. 464.

"Special Purpose Assurance Report" means a formal, independent report prepared and signed by a certified auditor or

audit firm;

"third country" means any country outside the European Union or the European Economic Area;

"WHO Listed Authorities Level 4" means regulatory bodies recognised by the World Health Organization for meeting rigorous safety and quality standards;

"website" means a digital platform or website through which prescriptions are received and the dispensing of medicinal products to consumers residing in third countries is facilitated;

"website URL" means the Website Uniform Resource Locator which signifies the address of a unique resource on the internet.

Online dispensing licence and regulatory standards.

3. (1) No person shall engage in the dispensing of medicinal products from the Free Zones and Customs Authorised Warehouses in Malta to consumers residing in third countries, unless they hold a valid licence issued by the Licensing Authority in accordance with the provisions of these regulations.

(2) The online dispensing of medicinal products under this regulation shall be conducted in accordance with recognised standards of Good Pharmacy (Dispensing) Practices. Licence holders shall ensure that all medicinal products dispensed meet high standards of safety, quality, and efficacy as stipulated in these regulations.

(3) The licence holder shall bear full responsibility for all activities carried out under these regulations, including compliance with any applicable regulatory requirements in the country of destination.

Application for an online dispensing licence.

4. (1) An application for a licence in accordance with these regulations shall be submitted to the Licensing Authority and shall include the following information:

(a) the name and address of the applicant;

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

(c) the equipment and control facilities as may be required by these regulations, under the Act and any other applicable law;

(d) the name of the managing pharmacist responsible for overseeing dispensing operations and ensuring compliance with good dispensing practices as outlined by, or under these regulations.

(e) a detailed plan outlining the quality management system that shall 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 shall be fully in place prior to the commencement of operations;

(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 data management plan that ensures full traceability of each medicinal product from point of source to country of destination in accordance with these regulations;

(i) the address of the hosting location of the website and of the servers where the data related to the online dispensing operations shall be stored, including confirmation that the hosting complies with cybersecurity requirements;

(j) any other information, documentation or evidence as may be requested by the Licensing Authority in accordance with these regulations, under the Act and any other applicable law.

(2) Upon submission of the application, an application fee in accordance with the First Schedule shall be payable to the Medicines Authority.

(3) For the purposes of these regulations, any notice may be served electronically at the email address provided by the applicant to the Licensing Authority. Such service shall, unless otherwise provided in these regulations, be deemed duly served if delivered to the most recent residential or email address furnished by the applicant, provided that proof of delivery is available:

Provided that proof of delivery may include, but shall not

be limited to, a delivery receipt, server log entry, acknowledgment of receipt from the recipient, or confirmation generated by a registered electronic delivery system.

Processing of personal data conducted by the Licensing Authority. Cap. 586.

5. (1) The processing of personal data conducted by the Licensing Authority for the purposes of these regulation shall fully comply with Regulation (EU) 2016/679 and the Data Protection Act including the regulations made thereunder and the fundamental rights and freedoms of the data subjects.

(2) The Licensing Authority, acting in its capacity of a controller in terms of Article 4(7) of Regulation (EU) 2016/679 shall perform the relevant processing operations which are strictly necessary for the purposes of these regulations.

(3) The controller, taking into account the nature, scope, context and purposes of processing as well as the risks of varying likelihood and severity for the rights and freedoms of the data subjects, shall implement appropriate technical and organisational measures, in an effective manner and to integrate the necessary safeguards into the processing, in order to protect the rights of the data subjects and to ensure a level of security appropriate to the risk.

(4) For the purpose of ensuring and to be able to demonstrate that the processing of data is performed in accordance with the provisions of Regulation (EU) 2016/679, the controller shall implement the appropriate data protection policies, which policies shall be periodically reviewed and updated where necessary.

(5) The controller shall ensure that the physical and, or electronic access to personal data processed for the purposes of these regulations shall be strictly granted to personnel authorised by the controller.

(6) The data protection officer designated by the controller in terms of Article 37(1)(a) of Regulation (EU) 2016/679 shall be consulted properly and in a timely manner on all issues in relation to the protection of personal data processed for the purposes of these regulations.

Operational requirements.

6. All licensed holders are required to:

(a) follow applicable Good Pharmacy (Dispensing) Practice standards;

(b) ensure that medicinal products are sourced solely from operators listed in regulation 12.

(c) ensure the proper storage of medicinal products, maintaining environmental controls, including monitoring for temperature and humidity in compliance with any applicable law and, or regulations.

(d) maintain a traceable record for all received and dispensed medicinal products:

Provided that such records are to be updated on a daily basis.

(e) comply with the requirements relating to the website and, or the logo, including the proper display of the authorised 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;

(f) 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 present;

(g) any other requirements as may be requested by the Licensing Authority in accordance with these regulations, the Act and any other applicable law.

Obligations of the licence holder.

7. The licence holder shall:

(a) ensure continuous compliance with all licence conditions and shall conduct activities and operations in full compliance with the provisions of these regulations and any other applicable law;

(b) appoint a managing pharmacist who shall:

(i) be a registered pharmacist in accordance with the Health Care Professions Act; Cap. 464.

(ii) hold a valid licence to practice as a pharmacist;

(iii) possess a minimum of two (2) years professional experience in pharmaceutical management or the dispensing of medicinal products;

(c) ensure that the managing pharmacist is granted sufficient authority and resources to effectively carry out the responsibilities associated with the dispensing of medicinal products and adherence with Good Pharmacy (Dispensing) Practice standards;

(d) 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:

Provided that the plan shall comply with these regulations and any applicable guidelines issued by the Licensing Authority and shall also be certified by an approved auditor in the Maltese Islands;

(e) ensure that all medicinal products dispensed, fully 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;

Cap. 101.

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

(g) ensure compliance with all standards and requirements for the website as may be issued by means of regulations under the Act or any other applicable law;

(h) ensure that, in the event of the absence of the managing pharmacist, a *locum* pharmacist is present to perform the duties of the managing pharmacist;

(i) comply with any other requirements as may be requested by the Licensing Authority in accordance with these regulations, the Act and any other applicable law;

(j) comply with the provisions of these regulations, the Act and any other applicable law.

Obligations of the managing pharmacist.

8. 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 dispensing service to oversee dispensing practices and address any third-country consumer inquiries;

(c) ensure that, in the event of his absence, a locum pharmacist is nominated to perform the duties of the managing

pharmacist;

(d) comply with any other requirements as may be requested by the Licensing Authority in accordance with these regulations, the Act and any other applicable laws;

(e) comply with the provisions of these regulations, the Act and any other applicable law.

Renewal of licence.

9. (1) Any licence issued in accordance with these regulations shall, be valid for a period of one (1) year from the date of issuance.

(2) Applications for the renewal of a licence shall be submitted at least three (3) months prior to the expiration of the licence.

(3) The Licensing Authority shall have the right to reject renewal applications if compliance standards are not satisfied.

Refusal to grant or renew licence.

10. (1) The Licensing Authority may refuse to grant or renew a licence in accordance with these regulations on any of the following grounds:

(a) where the applicant has failed to meet all or any of the requirements established in these regulations during the application stage;

(b) where the Licensing Authority has reasonable grounds to believe that the medicinal products to be dispensed do not meet established safety and quality standards, as prescribed by relevant health authorities;

(c) where the applicant or the managing pharmacist nominated by the applicant has previously been found to be in violation of any of the provisions of these regulations and the Act;

(d) where the applicant lacks the necessary facilities, equipment, personnel or managing pharmacist to ensure safe and effective storage, handling, and dispensing of medicinal products in conformity with these regulations, the Act and any applicable law;

(e) where the applicant has engaged in any act of misrepresentation, deceit, or fraudulent conduct related to the application process or the operation of the licensed premises;

(f) where the granting or renewal of the licence would

pose a significant risk to public health or safety, considering the potential consequences of the online dispensing activities;

(g) where the applicant has failed to demonstrate technical capacity, operational capability, or financial resources necessary for the lawful, safe and effective online dispensing services;

(h) for any other reason that would normally be a valid reason for the refusal or renewal of the licence, including criminal convictions and regulatory actions;

(i) for any other reason which the Licensing Authority deems appropriate in accordance with these regulations, the Act, or any other applicable law.

(2) In the event of a refusal to grant or renew a licence, the Licensing Authority shall provide written notice to the applicant, specifying the grounds for such refusal and any applicable rights to appeal the decision.

(3) The applicant shall have the right to request a review of the decision to refuse, grant or renew the licence, in accordance with the procedures established in these regulations.

Right of appeal.

Cap. 490.

11. Decisions in accordance with these regulations shall be subject to a right of appeal before the Administrative Review Tribunal established in terms of article 5(1) of the Administrative Justice Act by not later than twenty (20) days from the service of the decision, wherein the person aggrieved by the said decision shall specify the reasons on the basis of which the said decision of the Director should be cancelled or modified:

Provided that the decision shall become immediately applicable and enforceable and shall remain applicable throughout the term of appeal until final judgement by the Administrative Review Tribunal, unless such decision is reversed by the said Tribunal and, or the Court of Appeal or cancelled or modified by the Director:

Provided further that any party, who feels aggrieved by a decision of the Tribunal, may on a point of law, appeal to the Court of Appeal in accordance with article 22 of the Administrative Justice Act.

Cap. 490.

Procurement standards.

12. The managing pharmacist shall ensure that medicinal products offered for online dispensing in accordance with these regulations shall be sourced from a European Union licensed wholesale dealer who sources them from manufacturers or wholesale distributors established in one of the following:

(a) the EU and, or 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) MRA countries, provided that the medicinal product is licensed in that country forming part of the Mutual Recognition Agreement;

(c) suppliers who have procured products manufactured in compliance with Good Manufacturing Practice standards established by a regulatory authority listed in paragraphs (a) and (b).

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

(e) the United Kingdom and any other operator, supplier or country as established by Government notice in the Gazette by the Minister after consultation with the Licensing Authority.

Quality assurance and traceability.

13. (1) The licence holder shall establish and maintain a quality management system to ensure that medicinal products are procured solely in accordance with the provisions of regulation 12. Furthermore, the licence holder shall ensure that each medicinal product dispensed complies with the safety, quality, and efficacy standards specified in the authorisation of the product in the country of origin, without exception:

Provided that, for the purpose of this regulation, "authorisation" means an authorisation equivalent to, or substantially similar to, a marketing authorisation as defined in accordance with Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency.

(2) The licence holder shall ensure that there is full traceability of all medicinal products purchased, stored and dispensed in accordance with these regulations, which shall, at a minimum include records and documentation in relation to:

(a) prescriptions, including consumer’s details, country of prescription, prescribing healthcare professional’s information, and prescription dates:

Provided that a scanned or electronic copy of the

prescription as provided by the consumer through the website shall suffice;

(b) product name, active ingredient, dosage form, dose, pack size, batch and lot numbers, supplier, expiration date, and storage conditions;

(c) purchasing, storage, and dispensing of a medicinal product, including date of dispensing and the registration number of the dispensing pharmacist;

(d) any other information, as may from time to time, be established by the Licensing Authority in accordance with regulation 20(3).

Internet marketing and safety information.

14. (1) All licence holders shall prominently display the logo on their website as a verification of legitimacy.

(2) The website shall allow customers to:

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

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

(c) access the consumer support policy of the licence holder, including information on how to contact the licence holder in the event of complaints related to the medicinal product, and any other issues;

(d) any other information as may from time to time be established by the Licensing Authority in accordance with regulation 20(3).

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

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

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

(e) the licence number, name of the Licencing Authority and the contact details for the Licencing Authority;

(f) any other information, as may from time to time, be established by the Licencing Authority in accordance with regulation 20(3).

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

Consumer safety protections.

15. (1) Licence holders shall offer consumers access and contact details of the managing pharmacist for guidance regarding medicinal products.

(2) An electronic verification and decommissioning system shall be maintained to ensure adherence to the principles of safety, quality, and regulatory compliance.

(3) The dispensed medicinal product shall be delivered to consumers in third countries in suitable tertiary outer packaging that is properly labelled and that preserves the integrity of the medicinal product, including its primary and secondary packaging. The contents of each package shall be accurately declared on the relevant customs documentation as may be required from time to time and shall be designated as "Medicinal Products for Personal Use".

(4) The Licensing Authority shall not be held responsible for any infringements or breaches committed by the licence holder in failing to adhere to the consumer’s country of destination’s laws and regulations.

(5) The licence holder shall ensure that all medicinal products dispensed for delivery to consumers in a third country comply with the legislation regulating prescription applicable in the country of destination. In particular, the licence holder shall observe the following requirements:

(a) the quantity and form of the medicinal product shall be consistent with the specific prescription requirements established by the regulatory authorities of the country of destination;

(b) in jurisdictions where a general prescription may be accepted for a full supply, the licence holder shall adhere to local practices to ensure compliance;

(c) the period of validity of the prescription shall also conform to the regulations of the country of destination, ensuring that prescriptions are honoured only within the authorised time frame.

Dispensing and export controls.

16. (1) Medicinal products procured in accordance with these regulations shall only be dispensed to consumers residing in third countries.

(2) The licence holder shall be entirely responsible for ensuring that all dispensed medicinal products comply with these regulations and ensure that all medicinal products dispensed, fully 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.

(3) Licence holders shall:

(a) prohibit the redistribution or dispensing of any medicinal product in their supply within the European Union;

(b) not dispense any medicinal product which is banned or otherwise subject to restrictions in the jurisdiction of the country of destination.

(c) comply with any other requirements as may be requested by the Licensing Authority in accordance with these regulations, the Act and any other applicable laws.

Documentation, record-keeping and reporting.

17. (1) Licence holders shall maintain detailed transaction records and prescriptions for each medicinal product dispensed, which shall be kept for a minimum period of five (5) years which shall as a minimum include:

(a) the date of dispensing, the product details, the quantity supplied, the batch, lot numbers and registration number of dispensing pharmacist;

(b) the consumer’s details and the country of destination;

(c) comply with any other requirements as may be requested by the Licensing Authority in accordance with these regulations, the Act and any other applicable laws.

(2) Every licence holder shall, on an annual basis and at their own expense, submit to the Licensing Authority the following documents:

(a) a Special Purpose Assurance Report prepared by an independent auditor, duly warranted by the Accountancy Board, and possessing expertise in the pharmaceutical field; and

(b) an audited financial statement relating to the preceding financial year, which shall not, in any case, be more than two (2) years. The financial statements shall include a revenue note that clearly identifies the turnover derived from dispensing services, the online store-front or both.

(3) The Special Purpose Assurance Report shall be submitted not later than the first (1) of July of each year, covering the preceding financial year and shall include the following:

(a) verification of the total annual turnover of the licence holder for the reporting period, commencing on the 1st of July and ending on the 30th June of each calendar year;

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

(4) (a) Failure to submit the Special Purpose Assurance Report within the timeframe in sub-regulation (3), or submission of a report found to be materially deficient, shall constitute a breach of these regulations.

(b) In response to any such breach, the Licensing Authority may impose one or more of the following measures:

(i) issuance of a warning or notice of deficiency.

(ii) administrative penalties as referred to in regulation 21.

(iii) suspension or revocation of the licence holder’s licence.

(iv) the institution of criminal proceedings.

(5) (a) The Licensing Authority reserves the right to audit the licence holder's operations to verify the accuracy of the submitted Special Purpose Assurance Report.

(b) Licence holders shall grant full access to relevant records and documentation upon request by the Licensing Authority or its authorised representatives.

Inspections and compliance monitoring.

18. (1) The Licensing Authority is vested with the authority to conduct periodic inspections of licensed premises and online platforms to verify compliance with these regulations, the Act and any applicable legislation. For the purpose of executing these duties more effectively, the Licensing Authority may appoint officers and, or engage experts to provide assistance.

(2) The Licensing Authority may, if it has reasonable suspicion to believe that any licence holder is acting in breach of any of the provisions of these regulations may:

(a) suspend or revoke the licence;

(b) seize the non-compliant medicinal products;

(c) order any person to undertake any action or refrain to undertake any action to comply with the provisions of these regulations;

(d) impose any conditions in relation to the licence holder and, or the managing pharmacist; and, or

(e) initiate the special procedure as established in article 100 of the Act.

Data storage requirements.

19. (1) All websites operated under these regulations, along with their related data and content, shall be required to store such data on servers physically located within the jurisdiction of Malta.

(2) Non-compliance with sub-regulation (1) may result in administrative penalties as referred to in these regulations, as well as the suspension or revocation of the licence.

Powers of the Licensing Authority.

20. (1) The Licensing Authority shall possess all powers and functions as established in the Act and shall have the right to delegate any of these powers and functions to another public authority to facilitate compliance with the provisions of these regulations.

(2) The Licensing Authority shall also be empowered to issue guidelines to further define and regulate the provisions of these

regulations. Such guidelines shall be binding on any person to whom they are addressed, including the licence holder and the managing pharmacist.

(3) The Licensing Authority shall have the power to request such information, documents, data, or records as it may deem necessary for the proper exercise of its functions and for ensuring compliance with the provisions of these regulations.

Administrative penalties and proceedings.

21. (1) When the Licensing Authority has reasonable cause to believe that:

(a) an offence against the regulations has been committed by any person; and

(b) having regard to the previous conduct of the person concerned, it would be appropriate to impose an administrative penalty under this regulation, the Licensing Authority may cause a notice in writing in accordance with sub-regulation (2) in the appropriate form to be served on such person.

(2) A notice as provided for in sub-regulation (1) shall specify:

(a) the date and nature of the offence;

(b) a summary of the facts upon which the allegation that an offence has been committed is based, this being sufficient for the purpose of fully and fairly informing the person of the allegation against him;

(c) any other matter, not being related to previous convictions, that the Licensing Authority considers relevant in the given circumstances, for the imposition of an administrative penalty, including any precautionary suspension of the licence that is issued in accordance with these regulations; and

(d) the amount of the administrative penalty due, which amount shall be decided in accordance with the severity of the case and the previous conduct of the person concerned:

Provided that the administrative penalty imposed shall not exceed the amount of twenty-three thousand, two hundred and ninety-three euro and seventy-three cents (€23,293.73):

Provided further that in addition to the administrative penalty as imposed under this paragraph, the Licensing Authority may also order the suspension or revocation of the

licence:

Provided further that in any event, the Licensing Authority shall have the option to issue a warning instead of an administrative penalty, if it considers that in the interests of fairness and equity, depending on the circumstances of the case, it is preferable to do so.

(3) Any person on whom a notice under sub-regulation (2) is served may, within thirty (30) days after such service, by notice in writing in the appropriate form served on the Licensing Authority, require that proceedings in respect of the alleged offence shall be dealt with by the court, in which case the provisions of sub-regulation (7) shall apply.

(4) Any person on whom a notice under sub-regulation (2) is served may by notice in writing served on the Licensing Authority:

(a) admit the offence; and

(b) pay the amount of the administrative penalty to the Medicines Authority within thirty (30) days after the notice of the penalty is served upon him or after such subsequent period as the Licensing Authority may determine.

(5) The administrative penalty imposed under sub-regulation (2)(d) shall be due as a civil debt enforceable by the competent court of civil jurisdiction in favour of the Government and the declaration by the person on whom the administrative penalty is imposed, that he admits the charge shall constitute an executive title for the purposes of article 253 of the Code of Organization and Civil Procedure.

Cap. 12.

(6) Without prejudice to any other provision of these regulations or of any other law, where an offence has been admitted under this regulation, no charge may be brought in respect of the offence against any person by whom it has been admitted, unless such person fails to effect payment within the time limit provided in the notice.

(7) In the case that a person on whom a notice under sub-regulations (1) and (2), either does not admit the offence within thirty (30) days from the service of the notice, or chooses to proceed with the proceedings mentioned under sub-regulation (3), the Licensing Authority shall institute proceedings or cause proceedings to be instituted before the Court in respect of the alleged offence:

Provided that where the licence holder is not habitually resident or established in Malta, such person shall be deemed to have

submitted to the jurisdiction of the Courts and tribunals of Malta in respect of any matter arising under or in connection with these regulations, and service effected in accordance with this regulation shall be deemed valid and binding.

Offences and punishments.

22. Any person who:

(a) assaults, hinders, obstructs, molests or interferes, or attempts to assault, hinder, obstruct, resist or wilfully obstructs any authorised official of the Medicines Authority, in the execution of their duties in accordance with these regulations;

(b) refuses or fails to comply with any order or direction lawfully made or given under these regulations;

(c) without reasonable cause fails to:

(i) provide the requested information to an authorised official of the Medicines Authority; or

(ii) produce anything required to be produced in accordance with these regulations;

(d) fails to allow a search or inspection in accordance with these regulations;

(e) prevents or attempts to prevent another person from complying with any orders or directions or from answering any questions, or producing anything or allowing a search or inspection; or

(f) for the purpose of obtaining any licence or permit, or for the purported compliance with any requirement to provide any information under these regulations, provides information which he knows to be false in a material fact or recklessly provides information which is false in a material fact, shall be guilty of an offence and shall be liable on conviction, to a fine (*multa*) of not less than one thousand euro (€1,000), but not exceeding ten thousand euro (€10,000).

Fines (*multi*) and punishment.

23. Unless otherwise provided in these regulations, any person who breaches any provision of these regulations shall be guilty of an offence and shall on conviction, be subject to a fine (*multa*) of not less than five thousand euro (€5,000), but not exceeding fifty thousand euro (€50,000), or to imprisonment for a term not exceeding two (2) years, or to both such fine and imprisonment.

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Consequential amendment. Cap. 490.

24. In the Second Schedule to the Administrative Justice Act immediately after the last item of the subsidiary legislation there shall be added the following new item:

"Online Dispensing of Medicinal Products to Third Countries from Free Zones and Customs Authorised Warehouses Regulations, S.L. 458.64, Superior/Inferior Competence".

FIRST SCHEDULE

Fees payable for the issuing or annual renewal of an online dispensing licence (regulation 4)

(a) Applicants for the issuance of an online dispensing licence shall pay the following fees:

(i) Dispensing services only: thirty-five thousand euro (€35,000);

(ii) Website only: thirty-five thousand euro (€35,000);

(iii) Both dispensing services and a Website: fifty-two thousand and five hundred euro (€52,500):

Provided that upon submission of the application, the applicant shall pay:

(iv) the sum of fifteen thousand euro (€15,000) in the case of an application under sub-paragraph (i) or (ii); or

(v) the sum of twenty thousand euro (€20,000) in the case of an application under sub-paragraph (iii);

and the balance shall become due and payable following confirmation by the Licensing Authority that the application is complete and meets the necessary requirements and shall be settled in full prior to the issuance of the licence(s).

The application fee covers the first year of operation, and no additional annual licensing fee shall be due for the first year.

(b) (i) Starting from the second year of operation, a licence holder shall be required to pay an annual licensing fee, in accordance with the applicable turnover tiers outlined in the Second Schedule (Part I).

(ii) The annual licensing fee shall be determined based on the licensee's annual turnover and the nature of the services provided, which shall fall under one of the following categories:

- Dispensing Services Only;
- Online Website Only;
- Both Dispensing and Online Website;

(iii) If a license is granted after the start of the calendar year, the annual fee shall be calculated on a *pro rata* basis, based on the number of full months remaining in the year.

(c) The *pro rata* amount shall be determined by dividing the applicable annual licensing fee by twelve (12) months and multiplying it by the number of remaining months in the calendar year.

(d) Any licence issued after the fifteenth day of a month shall be considered as having commenced in the following month for fee calculation purposes.

(e) (i) Inspection and audit fees shall be payable to the Medicines Authority as required under these regulations, in accordance with the fee structure provided in the Second Schedule (Part II).

(ii) The licence holder shall not be liable for inspection or audit fees unless an inspection or audit has been duly conducted.

SECOND SCHEDULE
(Part I)

Annual Licence Fee	**From** **€**	**To** **€**	**Dispensing services only** **€**	**Online Storefront only** **€**	**Dispensing and Online storefront** **€**
Turnover Tier 1	-	5,000,000	35,000	35,000	52,500
Turnover Tier 2	5,000,000	10,000,000	55,000	55,000	82,500
Turnover Tier 3	10,000,000	15,000,000	72,500	72,500	108,750
Turnover Tier 4	15,000,000	20,000,000	87,500	87,500	131,250
Turnover Tier 5	20,000,000	25,000,000	100,000	100,000	150,000
Turnover Tier 6	25,000,000	30,000,000	110,000	110,000	165,000

Turnover Tier 7	30,000,000	35,000,000	117,500	117,500	176,250
Turnover Tier 8	35,000,000	40,000,000	122,500	122,500	183,750
Turnover Tier 9	40,000,000	45,000,000	125,000	125,000	187,500
Turnover Tier 10	45,000,000	50,000,000	125,000	125,000	187,500

(Part II)

Audit and Inspection Fees:	
Audit Fee	160 Euro per hour (minimum chargeable is 5,000 Euro)
Inspection Fee	160 Euro per hour (minimum chargeable is 5,000 Euro)

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