promossa s-sostenibbiltà tal-industrija lokali tal-kannabis billi tnaqqas il-pressjoni finanzjarja permezz ta' miżuri ta' sostenn fir-rigward tal-ħlas ta' kontribuzzjonijiet għar-riċerka u l-edukazzjoni u l-applikazzjoni ta' drittijiet annwali;

simplifikata u jitħaffef il-proċess ta' manutenzjoni tal-applikazzjonijiet u tiġdid tal-liċenzji, permezz tal-użu ta' sistema ta' tiġdid darba biss minflok tiġdid iterattiv, u permezz tal-introduzzjoni ta' rotta fast-track sabiex tapplika għal ċerti tibdiliet fil-liċenzja;

mħeġġa l-kooperazzjoni bejn l-operaturi lokali tal-kannabis billi toħloq fluss ta' liċenzja għal faċilitajiet li jiffukaw fuq l-ittestjar tal-kannabis għal skopijiet mediċinali u ta' riċerka;

żgurati riżorsi suffiċjenti għall-operazzjonijiet ta' produzzjoni u attivatijiet ta' riċerka siguri u regolati sew, permezz li jiġu introdotti drittijiet għall-ipproċessar tal-liċenzji li jsostnu l-operati regolatorji.

5. Sezzjonijiet konklużivi

Dawn ir-regolamenti emendatorji għandhom jidħlu fis-seħħ mal-pubblikazzjoni tagħhom fil-Gazzetta tal-Gvern.

Għal aktar informazzjoni jekk jogħġbok ikkuntattja: cannabis.medicinesauthority@gov.mt/legal.medicinesauthority@gov.mt

N.B. Dawn in-Noti mhumiex maħsuba bħala deskrizzjoni eżawrjenti tal-istrument legali, lanqas bħala sostitut tiegħu jew bħala supplement leġislattiv għalih. Dawn in-Noti ma jiddikjarawx li huma interpretazzjoni awtorevoli tal-leġiżlazzjoni.

Il-5 ta' Settembru, 2025

No. 1396

MEDICINES AUTHORITY

Explanatory Notes[1]

1. Introduction

Title of legislation	Production of Cannabis for Medicinal and Research Purposes (Amendment) Regulations, 2025 the "amending regulations")
Regulated activity	Production of cannabis for medicinal and research purposes
Responsible entity	Medicines Authority

2. Summary and background

In April 2018, Malta enacted the legislative measures to permit the production and ancillary activities of cannabis for medicinal and research purposes under The Production of Cannabis for Medicinal and Research Purposes Act (Cap. 578). This was followed by the enactment of the subsidiary legislation the "Production of Cannabis for Medicinal and Research Purposes (Fees) Regulations" (hereinafter referred to as the "principal regulations"), which primarily allowed the Regulatory Authority (the Medicines Authority) to receive regulatory fees, research fees and contributions.

The rationale of the amending regulations is centred on: ensuring good governance and transparency, enhancing sustainability of the local cannabis industry, streamlining the application and licence maintenance process, promoting synergies between local operators and safeguarding sufficient resources for safe, secure and regulated production and research operations.

3. Overview of the structure of the instrument

- The amending regulations consist of five (5) regulations as follows:
- Regulation 1: Citation;

- Regulation 2: Amends regulation 2 of the principal regulations;

- Regulation 3: Amends regulation 3 of the principal regulations;

- Regulation 4: Amends regulation 4 of the principal regulations;

- Regulation 5: Amends the Schedule to the principal regulations.

4. Commentary

The objectives of the amending regulations are to:

ensure clarity by defining legal terms and explaining the different types of inspections for GMP (Good Manufacturing Practice) certification;

promote the long-term success of the local cannabis industry by easing the financial pressure through supportive measures in relation to the payment of research and education contributions and the application of annual fees;

make the application and licence renewal process quicker and simpler, a one-time renewal system instead of iterative renewals, and by introducing a fast-track route to apply for certain licence changes;

encourage cooperation between local cannabis operators by creating a licence stream for facilities that focus on testing cannabis for medicinal and research purposes;

secure sufficient resources for safe and properly regulated production and research activities by introducing licence processing fees that sustain regulatory operations.

5. Concluding Sections

The amending regulations shall come into force upon their publication in the Government Gazette.

For further information please contact: cannabis.medicinesauthority@gov.mt/legal.medicinesauthority@gov.mt

N.B. These Explanatory Notes are not intended to be an exhaustive description of the instrument nor a substitute thereof or a legislative supplement to it. These Notes do not purport to be an authoritative ruling on the interpretation of the legislation.

5th September, 2025

No. 1397

MEDICINES AUTHORITY

Explanatory Notes
(for the purposes of article 3(2)(c) of Chapter 512 of the Laws of Malta)

1. Introduction

Title of Legal Notice	A Legal Notice entitled Online Dispensing of Medicinal Products to Third Countries from Free Zones and Customs Authorised Warehouses Regulations, 2025 (the "Regulations").
Activity to be regulated	The activities to be regulated are those related to the online dispensing and export of medicinal products from Malta's Free Zones and Customs Authorised Warehouses to consumers residing in third countries. This involves activities undertaken by licence holders, managing pharmacists, wholesale distributors, and third-country consumers. The Regulations provide for comprehensive oversight of the entire supply chain from sourcing through to final delivery, including website operations, quality management systems, data protection, and consumer safety measures.
Entity that prepared the legislation	Malta Medicines Authority within the Ministry for Health.

2. Summary and background

2.1 Aims & Objectives of the Legislation

2.2 Importance of Regulations

The need for proper regulation of online pharmaceutical dispensing to third countries has been identified as a priority for Malta's economic development and pharmaceutical sector growth. The creation of this regulatory framework supports Malta's positioning as a leading jurisdiction for regulated pharmaceutical distribution services.

Malta has committed itself to establishing a comprehensive legal framework for cross-border pharmaceutical activities that maintains the highest standards of safety, quality, and regulatory compliance while enabling legitimate commercial opportunities.

Furthermore, these Regulations support Malta's broader objectives to develop its pharmaceutical and life sciences sectors while maintaining strict regulatory oversight. The framework ensures compliance with international pharmaceutical standards and respects the regulatory sovereignty of destination countries.

The Regulations are deemed important to honour Malta's commitments to international pharmaceutical trade standards and to contribute to the safeguarding of consumer health in third countries while supporting Malta's economic development objectives.

The Regulations will provide the necessary national legislation to support Malta's pharmaceutical export activities while ensuring full compliance with EU pharmaceutical regulations and international best practices.

There could be an increased number of operators as a result of a clear legal framework on obligations and the creation of a level playing field. The increased predictability and resulting protection offered to investments brought about by the proposed legislation will encourage industry development in Malta's Free Zones and Customs Authorised Warehouses.

There is also a clear need to establish comprehensive oversight to better control this emerging sector. Through these Regulations, the Licensing Authority gains comprehensive inspection and enforcement powers, including the ability to conduct audits, seize non-compliant products, and impose administrative penalties.

2.3 Public Consultation

The Malta Medicines Authority launched a consultation process with stakeholders in relation to the Online Dispensing of Medicinal Products to Third Countries from Free Zones and Customs Warehouses with a stakeholders meeting held on 14 February 2025. The consultation aimed to present and discuss a proposed strategic framework for the exportation, storage, handling, and online dispensing of medicinal products from designated zones in Maltese Islands. Key areas of focus included the online dispensing licencing approach, procurement standards, professional operational requirements and compliance, patient safety, quality assurance standards, the online dispensing platform, and regulatory obligations. This initiative reflects the Authority's ongoing commitment to transparency, regulatory clarity, and stakeholder inclusion in shaping future pharmaceutical regulatory policy in Malta.

Stakeholders were informed of the consultation via official email communications sent by the Medicines Authority on 6 and 11 February 2025, in tandem with announcement on the Medicines Authority website on 6 February 2025 (link). These communications included a registration link, consultation meeting details (date, time, and venue), and a summary document outlining key salient points for discussion (Appendix 1). Stakeholders requiring further clarification after the consultation meeting were invited to request a follow-up in-person meeting through the same communication channels. Stakeholders were invited to forward their feedback and queries via email at communications.medicinesauthority@gov.mt until 31 March 2025.

3. Overview of the Structure of the Instrument

The Regulations consist of 23 regulations and 2 schedules.

Regulation 1 establishes the citation, scope, and applicability. Regulations 2 through 22 establish the comprehensive regulatory framework. Regulation 23 provides for consequential amendments to the Administrative Justice Act.

Regulations 3 through 11 establish the licensing framework including application requirements, data protection compliance, operational standards, licence holder obligations, managing pharmacist responsibilities, licence renewal procedures, refusal grounds, and appeal rights.

Regulations 12 through 16 establish operational requirements including procurement standards, quality assurance and traceability, internet marketing requirements, consumer safety protections, and dispensing and export controls.

Regulations 17 through 22 establish enforcement and compliance mechanisms including documentation and reporting requirements, inspection powers, data storage requirements, Licensing Authority powers, administrative penalties, and criminal offences.

The First Schedule establishes application fees, and the Second Schedule establishes annual licensing fees based on turnover tiers and audit/inspection fee structures.

4. Commentary on Regulations

Regulation 1: Establishes the title, scope, and applicability of the Regulations. The scope specifically covers sourcing, storage, handling, online dispensing, and export of medicinal products from Free Zones and Customs Authorised Warehouses to consumers in third countries. Includes provision for phased implementation dates as determined by the Minister through Government Gazette notice.

Regulation 2: Establishes comprehensive definitions including key terms such as "consumer" (individual in third country), "dispensing service" (licensed operation in Free Zone/Customs Authorised Warehouse), "EEA market," "EU market," "European Union licensed wholesale distributor," "managing pharmacist," "MRA countries," "online dispensing of medicinal products," "Special Purpose Assurance Report," "third country," "WHO Listed Authorities Level 4," and "website URL." These definitions ensure consistent interpretation throughout the regulatory framework.

Regulation 3: Establishes the fundamental licensing requirement prohibiting online dispensing operations without a valid licence. Sets baseline standards requiring compliance with Good Pharmacy (Dispensing) Practice and places full responsibility on licence holders for all activities including destination country regulatory compliance.

Regulation 4: Establishes comprehensive application requirements including: applicant identification, website URL and premises addresses, equipment and control facilities, managing pharmacist designation, quality management system plans, anti-counterfeiting procedures, Good Pharmacy Practice compliance approach, data management and traceability plans, website hosting and cybersecurity details, and additional documentation as requested. Establishes application fees per First Schedule and electronic service provisions with proof of delivery requirements.

Regulation 5: Establishes data protection compliance requirements under GDPR and Data Protection Act. Designates the Licensing Authority as controller with obligations for technical and organizational measures, data protection policies, access controls, and data protection officer involvement. Ensures fundamental rights protection and appropriate security levels.

Regulation 6: Establishes operational requirements including: Good Pharmacy Practice compliance, sourcing restrictions per regulation 12, proper storage with environmental controls, daily traceable record maintenance, logo and website compliance, continuous pharmacist presence (managing or locum), and additional Licensing Authority requirements.

Regulation 7: Establishes comprehensive licence holder obligations including: continuous compliance maintenance, managing pharmacist appointment with specific qualifications (registered pharmacist, valid practice licence, minimum 2 years' experience), sufficient authority and resources for managing pharmacist, annual risk management plan updates with auditor certification, destination country compliance, prohibited product restrictions per Dangerous Drugs Ordinance, website compliance, locum pharmacist arrangements, and additional regulatory compliance requirements.

Regulation 8: Establishes managing pharmacist obligations including: oversight of storage and dispensing activities with Good Pharmacy Practice compliance, availability during operational hours for oversight and consumer inquiries, locum pharmacist nomination during absence, and comprehensive regulatory compliance obligations.

Regulation 9: Establishes licence validity of one year from issuance, renewal application requirements at least three months prior to expiration, and Licensing Authority discretion to reject renewals based on compliance standards.

Regulation 10: Establishes comprehensive grounds for licence refusal including: failure to meet regulatory requirements, safety and quality concerns, previous violations, inadequate facilities/personnel/managing pharmacist, misrepresentation or fraudulent conduct, public health risks, insufficient technical/operational/financial capacity, criminal convictions and regulatory actions, and other appropriate reasons. Provides for written notice with grounds and appeal rights.

Regulation 11: Establishes appeal procedures through Administrative Review Tribunal within twenty days of decision service, with Court of Appeal rights on points of law. Decisions remain enforceable during appeals unless reversed by Tribunal or Court of Appeal.

Regulation 12: Establishes strict procurement standards limiting sourcing to European Union licensed wholesale dealers sourcing from: EU/EEA markets (with prohibition on critical medicines subject to shortages), MRA countries (for licensed products), GMP-compliant suppliers from approved jurisdictions, WHO Level 4 licensed operators (for market-authorized products), United Kingdom, and other operators/countries established by Minister through Government Gazette notice.

Regulation 13: Establishes quality assurance and traceability requirements including: quality management systems ensuring regulation 12 compliance, product compliance with origin country authorization standards (equivalent to marketing authorization per Regulation EC 726/2004), and comprehensive traceability records covering prescriptions (consumer details, country, prescriber information), product details (name, ingredients, batch numbers, supplier, expiration, storage), dispensing records (dates, pharmacist registration numbers), and additional information as established by Licensing Authority.

Regulation 14: Establishes internet marketing and safety information requirements including: mandatory logo display for legitimacy verification, customer access to licence verification, contact details, consumer support policies, comprehensive product listings with safety information, authenticity verification instructions, transparent pricing with component breakdowns, licence and authority information display, and packaging labelling with licence numbers and authority website access.

Regulation 15: Establishes consumer safety protections including: managing pharmacist access for guidance, electronic verification and decommissioning systems, suitable tertiary packaging preserving product integrity with proper customs documentation as "Medicinal Products for Personal Use," Licensing Authority limitation of liability for licence holder

breaches, and destination country prescription compliance including quantity/form consistency, local practice adherence, and prescription validity period compliance.

Regulation 16: Establishes dispensing and export controls limiting dispensing to third-country consumers only, requiring full destination country compliance for personal use importation, prohibiting EU redistribution, restricting banned products in destination jurisdictions, and ensuring additional regulatory compliance.

Regulation 17: Establishes comprehensive documentation, record-keeping, and reporting requirements including: minimum five-year retention of detailed transaction records and prescriptions (dispensing dates, product details, quantities, batch numbers, pharmacist registration, consumer details, destination countries), annual submissions of Special Purpose Assurance Reports by independent auditors with pharmaceutical expertise and audited financial statements identifying dispensing turnover, Special Purpose Assurance Report submission by July 1st covering preceding financial year with turnover verification and sourcing compliance verification, breach consequences including warnings, administrative penalties, licence suspension/revocation, and criminal proceedings, and Licensing Authority audit rights with full access requirements.

Regulation 18: Establishes inspection and compliance monitoring powers including: periodic inspection authority for premises and online platforms with officer appointment and expert engagement capabilities, enforcement measures for reasonable breach suspicion including licence suspension/revocation, non-compliant product seizure, compliance orders, licence/pharmacist conditions, and special procedures under Medicines Act article 100.

Regulation 19: Establishes mandatory data storage requirements within Malta jurisdiction for all websites, related data, and content, with penalties including administrative penalties and licence suspension/revocation for non-compliance.

Regulation 20: Establishes comprehensive Licensing Authority powers including: full Medicines Act authority, delegation rights to other public authorities, and authority to issue binding guidelines for licence holders and managing pharmacists.

Regulation 21: Establishes detailed administrative penalty procedures including: written notice requirements specifying offence dates/nature, fact summaries, relevant circumstances, penalty amounts up to €23,293.73, court proceeding options within thirty days, admission and payment options within thirty days, civil debt enforcement provisions, and jurisdiction submission requirements for non-Malta residents.

Regulation 22: Establishes specific criminal offences for: assaulting/obstructing/interfering with authorized officials, refusing compliance with lawful orders, failing to provide requested information or produce required items, preventing inspections, preventing others' compliance, and providing false information for licences or compliance, with fines of €1,000-€10,000.

Regulation 23: Establishes general penalties for any regulatory breach with fines of €5,000-€50,000, imprisonment up to two years, or both.

Regulation 24: Amends the Administrative Justice Act Second Schedule to include these Regulations within Administrative Review Tribunal jurisdiction.

First Schedule: Establishes comprehensive fee structure including: application fees of €35,000 for single services (dispensing only or website only) and €52,500 for combined services, staged payment with €15,000/€20,000 initial payments and balance due upon application completion confirmation, first-year coverage with no additional annual fees, subsequent annual licensing fees based on turnover tiers, pro rata calculations for mid-year licences, and separate inspection/audit fees as required.

Second Schedule: Establishes detailed annual licensing fee structure with ten turnover tiers ranging from under €5 million to €45-50 million, with fees scaling from €35,000 to €187,500 depending on turnover and service type (dispensing only, website only, or combined), pro rata calculations for partial years, and audit/inspection fees of €160 per hour with €5,000 minimum charges.

5. Concluding Section

The Regulations will permit Malta to establish itself as a leading jurisdiction for regulated cross-border pharmaceutical

distribution while maintaining the highest standards of safety, quality, and regulatory compliance. The comprehensive framework ensures protection of consumer health in third countries while enabling legitimate commercial opportunities for Malta-based operators.

The Regulations provide a modern legal framework that permits effective oversight of online pharmaceutical dispensing activities while supporting Malta's economic development objectives in the pharmaceutical and life sciences sectors. The framework includes robust enforcement mechanisms, comprehensive quality assurance requirements, and strong consumer protection measures.

The ultimate aim of the Regulations is to provide a comprehensive regulatory framework that ensures the highest standards of pharmaceutical quality and safety while enabling Malta to capture economic opportunities in the growing cross-border pharmaceutical distribution market. The detailed provisions ensure full traceability, proper professional oversight, and compliance with international pharmaceutical standards.

The Regulations shall come into force on such date as the Minister may establish by notice published in the Government Gazette, allowing for phased implementation as necessary to ensure industry readiness and regulatory compliance.

N.B. This Explanatory Note is not intended to be an exhaustive description of the instrument nor a substitute thereof or a legislative supplement to it. This Note does not purport to be an authoritative ruling on the interpretation of the legislation.

5th September, 2025

User Guidelines

Introduction of Online Dispensing of Medicinal Products to Third Countries from Free Zones and Customs Authorised Warehouses Regulations, 2025 under the Medicines Act (Cap. 458 of the Laws of Malta)

1. Introduction

The primary objective of the Online Dispensing of Medicinal Products to Third Countries from Free Zones and Customs Authorised Warehouses Regulations, 2025 (hereunder referred to as 'the Regulations') is to establish a comprehensive legal and regulatory framework governing the online dispensing, export and supply of medicinal products from Free Zones or Customs Authorised Warehouses in Malta to consumers residing in third countries.

These regulations are designed to ensure that all medicinal products dispensed via online channels in Malta meet established applicable standards. They strengthen the responsibilities of the licence holder and the respective managing pharmacist, while ensuring compliance with applicable requirements related to the dispensing and export of medicinal products.

Furthermore, the regulatory framework provides clear legal requirements for obtaining and maintaining a licence, obligations for the licence holder and managing pharmacist, requirements related to the sourcing and procurement of the medicinal products to be supplied to third countries consumers, good pharmacy (dispensing) practices, data requirements and cybersecurity measures to ensure safety and supply chain integrity.

A new Legal Notice will be issued in this respect. This new legislation will establish Malta's first regulatory framework for online dispensing for third country consumers, ensuring the controlled distribution of medicinal products through these digital platforms.

2. Purpose and Background

The Regulations were enacted under Article 106 of the Medicines Act (Cap. 458) in terms of the powers of the Minister to legislate for the sale and supply of medicinal products from Malta, following consultation with the Licensing Authority. The purpose is to ensure a robust mechanism for the online sale and supply of medicinal products from authorised dispensing services and websites operating within Malta's Free Zones and Customs Authorised Warehouses to consumers in third countries outside the EU.

These Regulations reflect Malta's strong commitment to fostering a regulated and export-oriented pharmaceutical sector, aligning with broader policy goals that prioritise both economic growth and public health safeguards. Central objectives include regulating the supply and export of medicinal products to consumers in third countries, ensuring robust traceability and transparency in all online dispensing activities and implementing a licensing framework that is proportionate to the scale and financial turnover of operations.

Additionally, the Regulations place a significant emphasis on reinforcing data protection, cybersecurity and prescription control mechanisms. By establishing this comprehensive regulatory instrument, Malta aims to strike a careful balance between encouraging economic opportunity and maintaining rigorous regulatory oversight, thereby strengthening its reputation as a reliable and forward-looking jurisdiction for pharmaceutical operations.

3. Commentary on the Regulations

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

The new legislation will be entitled Online Dispensing of Medicinal Products to Third Countries from Free Zones and Customs Authorised Warehouses Regulations and will be issued as a subsidiary legislation under the Medicines Act (Cap. 458 of the Laws of Malta) and in the English language.

Below one may find an overview of provisions in the new set of regulations governing online dispensing of medicinal products:

Regulation No. of New Legal Notice	**Meaning and Obligations [Commentary]**
1	This provides that the Online Dispensing of Medicinal Products to Third Countries from Free Zones and Customs Authorised Warehouses Regulations govern the sourcing, storage, handling, online dispensing, and export of medicinal products from Malta's Free Zones and Customs Warehouses to consumers in third countries.
2	This caters for the definitions to be used throughout the regulations. Therefore, regulation 2 establishes the terminology to be applied throughout the new regulations. It is important that these definitions are familiarised with before proceeding to read and assess the other provisions of these regulations.
3	The purpose of regulation 3 is to explain that to operate an online service that supplies medicinal products from Malta's Free Zones or Customs Authorised Warehouses to consumers residing outside the EU or EEA (often referred to as third countries), a licence is required. This licence is issued by the Licensing Authority. It further specifies that the dispensing of medicinal products through the online platform is carried out in accordance with recognised standards of good pharmacy (dispensing) practices. The licence holder remains fully responsible for all activities conducted under these regulations, including compliance with any applicable regulatory requirements in the country of destination.
4	This regulation provides that an application must be submitted to the Licensing Authority and must include details such as the applicant's identity, website, dispensing location, required equipment and the responsible managing pharmacist. The application must outline systems for quality management, traceability, data security and measures to prevent counterfeit, unauthorised or substandard products. Compliance with good pharmacy (dispensing) practice must be demonstrated. Applicable fees, including annual fees, will be payable in terms of the First Schedule to these regulations. Electronic service provisions are established with proof of delivery requirements.
5	Regulation 5 provides legal requirements in relation to data protection compliance under GDPR and the Data Protection Act. The Licensing Authority acts as controller with obligations for technical and organizational measures, data protection policies, access controls, and data protection officer involvement. This ensures fundamental rights protection and appropriate security levels for all personal data processed under these regulations.

6	Regulation 6 provides legal requirements in relation to the operations of the licence holder. Licensed holders must adhere to recognised Good Pharmacy (Dispensing) Practice standards and source medicinal products only from operators listed in regulation 12. Proper storage of medicinal products, maintaining environmental controls, including monitoring for temperature and humidity in compliance with any applicable law and regulations must be maintained. Traceable records of all received and dispensed medicinal products must be maintained and updated on a daily basis. The authorised logo confirming the licensing status must be clearly displayed on the online storefront and, where applicable, on packaging or labelling. A managing pharmacist, or a locum in their absence, must always be present during all operational hours of the online dispensing service. The Licensing Authority may impose additional requirements as needed under relevant laws and regulations.
7	Regulation 7 is very important as it outlines the obligations and duties of the licence holder. The licence holder is responsible for maintaining 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. A managing pharmacist must be appointed, holding valid registration and a minimum of two years' experience in pharmaceutical management or dispensing. The managing pharmacist must be 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. A risk management plan that addresses relevant risks, including those related to information security, business, indemnity, and dispensing medicinal products to third countries must be developed and annually updated. 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. The licence holder shall 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. Products prohibited under the Dangerous Drugs Ordinance or any other applicable law must not be sourced, dispensed or sold. The licence holder must comply with all standards and requirements for the website as may be issued by means of regulations under the Act or any other applicable law and 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. The licence holder shall 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.
8	This regulation provides for the Managing Pharmacist Obligations. The managing pharmacist is 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. The managing pharmacist shall be available during all operational hours of the dispensing service to oversee dispensing practices and address any third-country consumer inquiries. The managing pharmacist shall ensure that, in the event of his absence, a locum pharmacist is nominated to perform the duties of the managing pharmacist. The managing pharmacist must 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 and comply with the provisions of these regulations, the Act and any other applicable law.
9	This regulation stipulates that a licence issued under these regulations is valid for a period of one (1) year from the date of issuance. Applications for the renewal of a licence must be submitted at least three (3) months prior to the expiration of the licence. The Licensing Authority shall have the right to reject renewal applications if compliance standards are not satisfied.
10	This regulation deals with the refusal to renew or grant a licence. The Licensing Authority may refuse to grant or renew a licence if the applicant has failed to meet all or any of the requirements established in these regulations during the application stage, if 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, or if 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. Licences may also be refused if 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. 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 is also grounds for refusal. Additionally, licences may be denied if 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, where the applicant has failed to demonstrate technical capacity, operational capability, or financial resources necessary for the lawful, safe and effective online dispensing services, or 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, or for any other reason which the Licensing Authority deems appropriate in accordance with these regulations, the Act, or any other applicable law. 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. 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 laid out in these regulations.
11	This regulation deals with the right of appeal. 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. 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. 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.
12	This regulation provides that the managing pharmacist shall ensure that all 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: 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; MRA countries, provided that the medicinal product is licensed in that country forming part of the Mutual Recognition Agreement; suppliers who have procured products manufactured in compliance with Good Manufacturing Practice standards established by a regulatory authority listed in sub-regulation 12 (1)(a) and (1)(b); 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; 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.
13	This regulation provides for quality assurance and traceability. The licence holder must implement 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. For the purpose of this regulation, "authorisation" means an authorisation equivalent to, or substantially similar to, a marketing authorisation as defined in accordance with EU 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. 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: prescriptions, including consumer's details, country of prescription, prescribing healthcare professional's information, and prescription dates (a scanned or electronic copy of the prescription as provided by the consumer through the website shall suffice); product name, active ingredient, dosage form, dose, pack size, batch and lot numbers, supplier, expiration date, and storage conditions; purchasing, storage, and dispensing of a medicinal product, including date of dispensing and the registration number of the dispensing pharmacist; and any other information as may from time

14	This regulation provides for the requirements related to internet marketing and the safety information. All licence holders shall prominently display the logo on their website as a verification of legitimacy. The website shall allow customers to verify the licensing status of the licence holder; view the contact details of the licence holder; 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; and any other information as may from time to time be established by the Licencing Authority in accordance with regulation 18(2). Each online medicinal product listing on the website shall as a minimum include: the product name, active ingredient, dosage form, pack size and intended use, or a link to the patient information leaflet; the potential risks, contraindications, and necessary usage guidelines, or a link to the patient information leaflet; instructions for consumers to verify the authenticity of the medicinal product being sold, including, 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; the 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; the licence number, name of the Licencing Authority and the contact details for the Licencing Authority; and any other information as may from time to time be established by the Licencing Authority in accordance with regulation 18(2). 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 holders.
15	This regulation deals with consumer safety protections. Licence holders shall offer consumers access and contact details of the managing pharmacist for guidance regarding medicinal products. An electronic verification and decommissioning system shall be maintained to ensure adherence to the principles of safety, quality, and regulatory compliance. 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". 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. 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: 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; in jurisdictions where a general prescription may be accepted for a full supply, the licence holder shall adhere to local practices to ensure compliance; 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.
16	This regulation deals with dispensing and export controls. Medicinal products procured in accordance with these regulations shall only be dispensed to consumers residing in third countries. 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. Licence holders shall: prohibit the redistribution or dispensing of any medicinal product in their supply within the European Union; not dispense any medicinal product which is banned or otherwise subject to restrictions in the jurisdiction of the country of destination; and comply with any other requirements as may be requested by the Licensing Authority in accordance with these regulations, the Act and
17	This regulation deals with the documentation, record-keeping and reporting. Licence holders are required to maintain detailed transaction records and prescriptions for each medicinal product dispensed for a minimum of five (5) years. These records must include: the date of dispensing, product details, quantity supplied, batch and lot numbers, and the registration number of the dispensing pharmacist; the consumer's details and the country of destination; and any other information as may be requested by the Licensing Authority in accordance with these regulations,

	the Act and any other applicable laws. Every licence holder shall, on an annual basis and at their own expense, submit to the Licensing Authority: a Special Purpose Assurance Report prepared by an independent auditor duly warranted by the Accountancy Board and possessing expertise in the pharmaceutical field; and an audited financial statement relating to the preceding financial year, which in no case shall be older than two (2) years. The financial statements shall include a revenue note that clearly identifies the turnover derived from dispensing services, the online storefront, or both. The Special Purpose Assurance Report shall be submitted no later than the first (1) of July of each year, covering the preceding financial year and shall include the following: 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; verification that all medicinal products handled by the licence holder during the reporting period were sourced and dispensed in accordance with these regulations. Failure to submit the Special Purpose Assurance Report within the timeframe or submission of a report found to be materially deficient, shall constitute a breach of these regulations. In response to any such breach, the Licensing Authority may impose one or more of the following measures: issuance of a warning or notice of deficiency; administrative penalties as referred to in regulation 21; suspension or revocation of the licence holder's licence; or the institution of criminal proceedings. The Licensing Authority reserves the right to audit the licence holder's operations to verify the accuracy of the submitted Special Purpose Assurance Report. Licence holders shall grant full access to relevant records and documentation upon request by the Licensing Authority or its authorised representatives.
18	This regulation deals with inspections and compliance monitoring. 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. 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: suspend or revoke the licence; and/or seize the non-compliant medicinal products; and/or order any person to undertake any action or refrain to undertake any action to comply with the provisions of these regulations; and/or impose any conditions in relation to the licence holder and/or the managing pharmacist; and/or initiate the special procedure as outlined in article 100 of the Act.
19	This regulation deals with data storage requirements. 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. Non-compliance with regulation 19(1) may result in administrative penalties as referred to in these regulations, as well as the suspension or revocation of the licence.
20	This regulation deals with the powers of the Licensing Authority. The Licensing Authority shall possess all powers and functions as set out 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. 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.
21	This regulation deals with administrative penalties and proceedings. When the Licensing Authority has reasonable cause to believe that an offence against these regulations has been committed by any person and having regard to the previous conduct of the person concerned, it would be appropriate to impose an administrative penalty, the Licensing Authority may cause a notice in writing to be served on such person. The notice shall specify: the date and nature of the offence; a summary of the facts upon which the allegation is based; any other matter that the Licensing Authority considers relevant for the imposition of an administrative penalty, including any precautionary suspension of the licence; and the amount of the administrative penalty due, which shall be decided in accordance with the severity of the case and the previous conduct of the person concerned. The administrative penalty imposed in no case exceed the amount of twenty-three thousand, two hundred and ninety-three euro and seventy-three cents (€23,293.73). In addition to the administrative penalties, the Licensing Authority may also order the suspension or revocation of the licence. The Licensing Authority shall have the option to give a warning instead of an administrative penalty, if it considers that in the interests of fairness and equity, it is preferable to do so. Any person on whom a notice is served may, within thirty (30) days after such service, require that proceedings in respect of the alleged offence shall be dealt with by the court. Any person who does not want court proceedings may admit the offence and pay the administrative penalty within thirty (30) days. The administrative penalty shall be due as a civil debt enforceable by the competent court. Where an offence has been admitted, no charge may be brought against any person by whom it has been admitted.

	If a person does not admit the offence within thirty (30) days or chooses to proceed with court proceedings, the Licensing Authority shall institute proceedings before the court. Service of the notice may be made electronically to the electronic mail address indicated to the Licensing Authority by the person charged with the offence.
22	This regulation deals with offences and punishments. Any person who: assaults, hinders, obstructs, molests or interferes with any authorised official of the Medicines Authority in the execution of their duties; refuses or fails to comply with any order or direction lawfully made under these regulations; without reasonable cause fails to provide requested information or produce anything required under these regulations; fails to allow a search or inspection; prevents another person from complying with orders or directions; or provides false information for the purpose of obtaining any licence or permit, 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).
23	This regulation deals with fines (multi) and punishment. 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) and 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.
24	This regulation deals with consequential amendments. 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.___, Superior/Inferior Competence".
First Schedule	This Schedule provides for the application fees to be paid by the applicant. Applicants seeking an online dispensing licence must pay a set fee depending on whether they are applying for: Dispensing services only (€35,000); A website only (€35,000); Both dispensing services and a website (€52,500). An initial portion of the fee is payable upon application (€15,000 for single services, €20,000 for combined services), with the remaining balance due once the Licensing Authority confirms that the application is complete and meets all regulatory requirements. The full fee must be settled before the licence is issued. This application fee covers the first year of operation, with no separate renewal fee due for that year. Note: For the full list of applicable fees and specific amounts, it is strongly recommended to consult the detailed Schedules to these regulations.
Second Schedule	From the second year of operation, licence holders are required to pay an annual licensing fee, which is determined based on the licence holder'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. The applicable fee is calculated based on defined turnover tiers ranging from €35,000 to €187,500 depending on turnover levels from under €5 million to €45-50 million annually. For licences issued after the start of the calendar year, the annual fee is calculated on a pro rata basis. Licences issued after the 15th of any month are considered to commence the following month for this purpose. Licence holders are liable for audit and inspection fees only if such procedures are conducted. These are charged at €160 per hour, subject to a minimum charge of €5,000. Note: For the full list of applicable fees, turnover bands, and specific amounts, it is strongly recommended to consult the detailed Schedules to these regulations.

4. Concluding Remarks

It is to be noted that the applicable stakeholders and users should be fully aware of the new regulations coming into force. It is advisable that when stakeholders are unsure about their legal obligations, they consult a lawyer, accountant or auditor (as applicable), particularly in relation to the requirements and obligations of the licence holder and the managing pharmacist and the applicable fees that will be levied as per the First Schedule and the Second Schedule to the regulations.

Should more information be required, the Malta Medicines Authority is to be contacted on +356 2343 9000.

Address:

Malta Medicines Authority, Malta Life Sciences Park, San Gwann SGN 3000

N.B: The User Guidelines contained within this document are solely intended to serve as guidelines and should not be construed as legislation. This document should not be considered as an exhaustive description of the instrument nor a substitute thereof or a legislative supplement to it. The Guidelines do not purport to be an authoritative ruling on the interpretation of the legislation. Please refer to the related legislation for a more comprehensive understanding.