



**REPUBLIC OF KENYA MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD**

**GUIDELINES FOR DIGITAL PHARMACY SERVICES IN
KENYA**

2026 EDITION

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PRA/TRA/GUD/ 075	Guidelines for Digital Pharmacy Services in Kenya	Revision No. 02	Effective Date: 2026 Review Date: 2029
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ACKNOWLEDGMENTS

The Pharmacy and Poisons Board (PPB) wishes to express its sincere appreciation to all individuals and institutions whose commitment, expertise, and valuable contributions made the development of the Digital Pharmacy Practice Guideline possible.

The Board extends special gratitude to **Jhpiego** Kenya, through the **xxxx Project**, for their generous financial support and technical assistance throughout the development and review of this guideline.

The PPB also acknowledges the significant contributions of technical expert authors, reviewers, and contributors, whose knowledge and dedication were instrumental in shaping the content and ensuring the quality and relevance of this document.

The Board is grateful to representatives from the Ministry of Health (MOH), members of various technical committees, digital health and pharmacy practice experts, and stakeholders drawn from diverse sectors of healthcare and pharmaceutical practice, who actively participated in the consultative process, research, and compilation of this guideline.

Special recognition is extended to key stakeholders, including professional associations such as the Pharmaceutical Society of Kenya (PSK) and the Kenya Pharmaceutical Association (KPA), pharmacy establishments, the pharmaceutical industry, digital health innovators, and practicing professionals, whose insights and feedback greatly enriched this guideline.

Finally, the Board acknowledges and appreciates the dedication, coordination, and tireless efforts of PPB staff in facilitating the development, review, and publication of this guideline.

FOREWORD

The Pharmacy and Poisons Board (PPB) is the National Regulatory Authority (NRA) established under the Pharmacy and Poisons Act, Chapter 244, Laws of Kenya. The Board is mandated to protect and promote public health by regulating the practice of pharmacy and ensuring that pharmaceutical services in Kenya meet the highest standards of quality, safety, efficacy, and cost-effectiveness.

In fulfilling this mandate, the PPB is committed to advancing pharmacy practice in line with globally accepted standards and evolving healthcare needs. This is consistent with Article 43(1)(a) of the Constitution of Kenya, which guarantees every individual the right to the highest attainable standard of health, including access to healthcare services.

The healthcare landscape is rapidly transforming, driven by advancements in digital technologies, increasing demand for accessible healthcare services, and the need for more patient-centered care models. Digital health innovations—including telepharmacy, electronic prescribing, and digital health records—are redefining how pharmaceutical services are delivered, accessed, and managed. These developments present both opportunities and responsibilities for the pharmacy profession to adapt and maintain high standards of practice.

Recognizing these changes, the Pharmacy and Poisons Board has developed the **Digital Pharmacy Practice Guidelines** to provide a comprehensive framework for the safe, effective, and ethical implementation of digital pharmacy services in Kenya. This guideline has been developed through a consultative process involving key stakeholders, technical experts, and practitioners across the health and pharmaceutical sectors.

The guideline is intended to guide pharmacy professionals, healthcare institutions, digital health providers, and other stakeholders on the standards, requirements, and best practices for delivering digital pharmacy services. It emphasizes the integration of technology with professional practice while safeguarding patient safety, data privacy, and regulatory compliance.

The Board believes that the successful implementation of digital pharmacy services will enhance access to quality pharmaceutical care, improve health outcomes, and contribute significantly to the achievement of national health goals and universal health coverage.

A competent, adaptable, and ethically grounded pharmaceutical workforce remains central to this transformation. The PPB therefore calls upon all stakeholders to embrace this guideline and work collaboratively towards strengthening digital pharmacy practice in Kenya.

Thank you.

CHAIRMAN

PHARMACY AND POISONS BOARD

For Public Participation

PREAMBLE

The second revision of the Guidelines for Digital Pharmacy Services in Kenya has been undertaken in response to the rapidly evolving landscape of digital health and pharmaceutical practice. Since the release of the previous edition, there has been increased adoption of digital technologies in healthcare, including telepharmacy, electronic prescribing, digital health platforms, and integrated health information systems, all of which continue to transform the delivery of pharmaceutical services.

While these advancements have improved access to medicines, enhanced efficiency, and strengthened patient-centered care, they have also introduced emerging challenges related to patient safety, data privacy and protection, medicine quality, and regulatory oversight. Furthermore, the growth of digital platforms and innovations in healthcare delivery has necessitated the continuous review and strengthening of regulatory frameworks to ensure safe, ethical, and accountable practice.

This second revision builds upon the foundation established in the earlier edition and incorporates insights from stakeholder consultations, regulatory experience, and evolving national and international best practices. It reflects the need to align digital pharmacy services with Kenya's health priorities, including Universal Health Coverage (UHC), as well as with applicable legal, regulatory, and technological developments.

In developing this revised guideline, consideration was given to the changing scope of pharmacy practice, the increasing integration of digital systems in healthcare, and the need to enhance regulatory clarity and enforcement mechanisms. The revision process included situational analysis, stakeholder engagement, and benchmarking against global standards to ensure that the guideline remains relevant, practical, and responsive to current and future needs.

This guideline provides an updated and comprehensive framework covering governance and licensing, digital system and technology requirements, prescription management, clinical safety, data protection, service delivery standards, supply chain management, ethical practice, and quality assurance. It is intended to guide pharmacy professionals, digital health providers, healthcare institutions, and other stakeholders involved in the delivery of digital pharmacy services.

It is anticipated that the implementation of this revised guideline will strengthen regulatory oversight, promote standardization, enhance patient safety, and support innovation in pharmaceutical service delivery. Ultimately, it will contribute to improved health outcomes and the advancement of Kenya's healthcare system.

The Pharmacy and Poisons Board calls upon all stakeholders to embrace and implement this guideline and to work collaboratively towards ensuring that digital pharmacy services in Kenya are delivered safely, responsibly, and in accordance with the highest standards of professional practice.

CHIEF EXECUTIVE OFFICER

PHARMACY AND POISONS BOARD

ABBREVIATIONS

ADR	Adverse Drug Reaction
API	Application Programming Interface
CDSS	Clinical Decision Support System
EHR	Electronic Health Record
EMR	Electronic Medical Record
e-Prescription	Electronic Prescription
FIP	International Pharmaceutical Federation
GDPR	General Data Protection Regulation (<i>if applicable</i>)
HSC	Health Safety Code
ICT	Information and Communication Technology
IT	Information Technology
KPA	Kenya Pharmaceutical Association
MOH	Ministry of Health
OTC	Over-the-Counter
PPB	Pharmacy and Poisons Board
PSK	Pharmaceutical Society of Kenya
QMS	Quality Management System
QR Code	Quick Response Code
SOP	Standard Operating Procedure
UHC	Universal Health Coverage
WHO	World Health Organization

DEFINITIONS AND KEY TERMS

For the purpose of this guideline, the following terms shall have the meanings assigned to them below:

Adverse Drug Reaction (ADR): A noxious and unintended response to a medicinal product that occurs at doses normally used in humans for prophylaxis, diagnosis, or therapy.

Audit Trail: A secure, chronological record that provides documentary evidence of all system activities, user actions, and transactions to ensure traceability and accountability.

Clinical Decision Support System (CDSS): A digital tool that provides healthcare professionals with patient-specific assessments or recommendations to aid clinical decision-making.

Controlled Medicines: Medicines that are regulated under national laws due to their potential for abuse, dependence, or misuse, and are subject to additional restrictions in prescribing, dispensing, and monitoring.

Digital Pharmacy: A pharmacy service that utilizes digital platforms, including web-based or mobile applications, to deliver pharmaceutical services such as dispensing, consultation, and patient support.

Digital Pharmacy Platform: A software-based system, including websites or mobile applications, used to provide digital pharmacy services and facilitate interactions between patients, pharmacists, and other stakeholders.

Electronic Prescription (E-Prescription): A prescription generated, transmitted, and stored in digital form, which contains all required information for dispensing medicines.

Health Safety Code: A unique verification identifier issued by the regulatory authority to confirm the legitimacy and registration status of a digital pharmacy service.

Interoperability: The ability of different digital health systems and applications to communicate, exchange, and interpret shared data accurately and effectively.

Licensed Pharmacy Premises: A physical location that has been approved and licensed by the regulatory authority to operate as a pharmacy.

Pharmacovigilance: The science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other medicine-related problems.

Prescription Validation: The process of verifying the authenticity, completeness, and clinical appropriateness of a prescription before dispensing.

Superintendent Pharmacist: A licensed pharmacist designated as responsible for the overall management, compliance, and professional oversight of a pharmacy, including digital operations.

Telepharmacy: The provision of pharmaceutical care and services through telecommunications and digital technologies to patients at a distance.

Traceability: The ability to track the movement and history of a medicinal product throughout the supply chain, from procurement to delivery to the patient.

Unique Identifier: A distinct code or number assigned to a prescription, patient, medicine, or transaction to ensure accurate identification and tracking within a system.

Verification System: A mechanism that enables users, regulators, or stakeholders to confirm the authenticity and registration status of a digital pharmacy service or product.

For Public Participation

CHAPTER 1

INTRODUCTION AND LEGAL FRAMEWORK

1.1. Background

The global healthcare landscape is undergoing a significant transformation driven by rapid advancements in digital technologies. Digital health innovations—including telemedicine, electronic health records, mobile health applications, and e-prescribing systems—are increasingly being integrated into healthcare systems to improve access, efficiency, and quality of care (World Health Organization [WHO], 2019)¹. These technologies have been particularly instrumental in expanding healthcare access to underserved and remote populations, strengthening health system resilience, and supporting continuity of care.

Within this broader digital health ecosystem, pharmacy practice has also evolved to incorporate digital platforms for the delivery of pharmaceutical services. Digital pharmacy services, including online dispensing, telepharmacy, and electronic prescription management, enable patients to access medicines and professional pharmaceutical care remotely. These services enhance convenience, support medication adherence, and facilitate timely communication between patients and healthcare providers (International Pharmaceutical Federation [FIP], 2021)².

At the national level, the adoption of digital pharmacy services is aligned with ongoing efforts to modernize healthcare delivery, improve access to essential medicines, and strengthen health system efficiency. In Kenya, the increasing use of digital platforms in healthcare delivery reflects broader national priorities in digital transformation and universal health coverage. However, the rapid growth of digital pharmacy services has also introduced new regulatory challenges, including risks related to patient safety, data privacy, quality of medicines, and the proliferation of unregulated online pharmacies.

Without appropriate regulatory oversight, digital platforms may facilitate the distribution of counterfeit, substandard, or inappropriate medicines, posing significant risks to public health (WHO, 2011)³. Additionally, the lack of standardized frameworks may lead to inconsistent practices, reduced accountability, and compromised quality of pharmaceutical care.

In response to these developments, there is a need for a comprehensive regulatory framework to guide the safe, effective, and ethical delivery of digital pharmacy services. This guideline has been developed to provide clear standards and requirements that ensure patient safety, promote responsible use of

¹ World Health Organization (WHO). (2019). *WHO guideline: Recommendations on digital interventions for health system strengthening*.

² International Pharmaceutical Federation (FIP). (2021). *FIP statement of policy: Digital health*.

³ World Health Organization (WHO). (2011). *Safety and security on the internet: Challenges and advances in member states*.

medicines, and support the integration of digital technologies into pharmacy practice within a regulated and accountable environment.

1.2. Rationale for Digital Pharmacy Services

Digital pharmacy services present significant opportunities to enhance healthcare delivery by improving access to pharmaceutical care, increasing efficiency, and supporting patient-centered services. Through the use of digital platforms, patients can access medicines and professional pharmaceutical services remotely, thereby reducing geographical and logistical barriers to care. This is particularly important in underserved and remote settings where access to licensed pharmacy services may be limited (World Health Organization [WHO], 2019)⁴.

The integration of digital technologies into pharmacy practice also contributes to improved medication safety and quality of care. Electronic prescription systems, clinical decision support tools, and digital patient records enable better monitoring of therapy, reduce medication errors, and support evidence-based clinical decision-making (International Pharmaceutical Federation [FIP], 2021)⁵. In addition, digital platforms facilitate real-time pharmacovigilance reporting, strengthen supply chain transparency, and enhance the tracking and traceability of medicines.

Furthermore, digital pharmacy services support broader public health objectives by enabling health education, promoting rational use of medicines, and improving adherence to treatment through patient engagement tools and follow-up mechanisms. These systems can also enhance coordination between healthcare providers, thereby improving continuity of care.

Despite these benefits, the rapid expansion of digital pharmacy services presents significant risks if not adequately regulated. These include the potential for the distribution of counterfeit or substandard medicines, inappropriate prescribing and dispensing practices, breaches of patient data privacy, and the emergence of unlicensed or illegal online pharmacies (WHO, 2011)⁶. Additionally, digital platforms may introduce challenges related to accountability, professional oversight, and the integrity of pharmaceutical services if clear regulatory controls are not established.

⁴ World Health Organization (WHO). (2019). *WHO guideline: Recommendations on digital interventions for health system strengthening*.

⁵ International Pharmaceutical Federation (FIP). (2021). *FIP statement of policy: Digital health*.

⁶ World Health Organization (WHO). (2011). *Safety and security on the internet: Challenges and advances in member states*.

The absence of standardized regulatory frameworks may lead to inconsistent practices, compromised patient safety, and erosion of public trust in digital health services. Therefore, there is a need for clear, comprehensive, and enforceable guidelines to ensure that digital pharmacy services are delivered in a safe, ethical, and accountable manner, while maximizing their potential to improve healthcare outcomes.

1.3. Rationale for Revision

The Pharmacy and Poisons Board previously issued guidelines for internet pharmacy services to regulate the provision of pharmaceutical services through online platforms and to ensure patient safety and compliance with applicable laws. These guidelines provided a foundational framework for the registration, licensing, and operation of internet-based pharmacy services in Kenya.

However, since the publication of the previous guideline, there have been significant advancements in digital health technologies and a rapid expansion in the scope and complexity of digital pharmacy services. The emergence of integrated digital health platforms, electronic prescribing systems, telepharmacy services, mobile health applications, and interoperable health information systems has transformed the delivery of pharmaceutical care.

In addition, evolving models of service delivery—including platform-based services, third-party integrations, pharmacy chains, and digital marketplaces—have introduced new operational and regulatory challenges. These developments have highlighted the need for enhanced regulatory clarity, strengthened governance mechanisms, and more comprehensive oversight of digital pharmacy activities.

Furthermore, increased adoption of digital health solutions has raised critical concerns related to patient safety, data protection, cybersecurity, medicine quality, and the proliferation of unregulated or illegal online pharmacy services. These risks necessitate updated regulatory controls to safeguard public health and maintain the integrity of pharmaceutical services.

This revision has therefore been undertaken to:

- Expand the scope of regulation from internet pharmacy services to comprehensive digital pharmacy services
- Align the guideline with current technological developments and evolving models of care
- Strengthen governance, regulatory oversight, and enforcement mechanisms
- Address emerging risks related to patient safety, data privacy, and medicine quality
- Ensure consistency with national health priorities, legal frameworks, and international best practices

This revised guideline builds upon the foundation of the previous version while providing a more robust, comprehensive, and forward-looking regulatory framework to support safe, effective, and accountable digital pharmacy practice in Kenya.

1.4. Purpose of the Guideline

The purpose of this guideline is to provide a comprehensive regulatory framework for the establishment, operation, and oversight of digital pharmacy services in Kenya.

This guideline is intended to:

- a) Ensure the safe, effective, and quality delivery of pharmaceutical services through digital platforms, consistent with national regulatory and professional standards
- b) Protect patients and the public from risks associated with unregulated, unsafe, or unethical digital pharmacy practices, including the supply of substandard or falsified health products
- c) Establish clear requirements for the registration, licensing, and operation of digital pharmacy services
- d) Promote accountability, transparency, and professional responsibility in the delivery of digital pharmaceutical services
- e) Support the integration of digital technologies into pharmacy practice while maintaining clinical governance, patient safety, and data protection
- f) Strengthen regulatory oversight, monitoring, and enforcement mechanisms for digital pharmacy services
- g) Provide guidance to pharmacy professionals, digital health providers, and other stakeholders on standards, requirements, and best practices for digital pharmacy operations
- h) Facilitate innovation in pharmaceutical service delivery while ensuring compliance with applicable legal, regulatory, and ethical standards

1.5. Scope of Application

This guideline applies to all entities involved in the provision, facilitation, or support of digital pharmacy services in Kenya.

The guideline is applicable to:

- a) Licensed pharmacy premises operating digital pharmacy platforms
- b) Online and internet-based pharmacy service providers
- c) Telepharmacy service providers offering remote pharmaceutical care
- d) Digital health platforms providing or facilitating access to pharmaceutical services
- e) Pharmacy chains, networks, or platform-based service models offering digital pharmacy services
- f) Third-party service providers supporting digital pharmacy operations, including technology providers, hosting services, payment platforms, and logistics partners

1.5.1. This guideline covers all activities conducted through digital platforms related to the delivery of pharmaceutical services, including but not limited to:

- a) Electronic prescription generation, transmission, validation, and management
- b) Online dispensing, sale, and supply of health products and technologies
- c) Telepharmacy services and digital consultation

- d) Digital self-care support and over-the-counter (OTC) medicine management
- e) Pharmacovigilance and post-market surveillance activities
- f) Digital record keeping, documentation, and reporting
- g) Integration with national health systems, regulatory systems, and other digital health platforms
- h) Supply chain management, delivery, and last-mile logistics associated with digital pharmacy services
- i) Advertisement, promotion, and public engagement related to digital pharmacy services
- j) Data protection, privacy, cybersecurity, and system integrity

This guideline shall apply to all digital pharmacy services regardless of the technology platform used, and shall be implemented in conjunction with applicable national laws, regulations, and professional standards governing pharmacy practice and digital health.

1.6. Legal and Regulatory Framework

Digital pharmacy services in Kenya shall operate within the framework of applicable national laws, regulations, and professional standards governing pharmacy practice, health services, digital health, and electronic transactions. This framework ensures that digital pharmacy operations are conducted in a lawful, ethical, and accountable manner, while safeguarding public health, patient safety, and the integrity of pharmaceutical services.

1.6.1. Regulatory Authority and Mandate

The Pharmacy and Poisons Board (PPB) is the National Medicines Regulatory Authority established under the **Pharmacy and Poisons Act, Cap 244, Laws of Kenya**. The Board is mandated to regulate the profession of pharmacy and the manufacture, trade, and distribution of medicines and health products and technologies.

Pursuant to Cap 244 and its subsidiary legislation, the Board is responsible for:

- a) Licensing and registration of pharmacy premises, including digital pharmacy services
- b) Regulation of the practice of pharmacy and professional conduct of pharmacists and pharmaceutical technologists
- c) Inspection and supervision of pharmacy premises, digital platforms, and related operations
- d) Enforcement of compliance with applicable laws, regulations, and guidelines
- e) Protection of public health by ensuring the safety, quality, and efficacy of medicines

In the context of digital pharmacy services, this mandate extends to the regulation of all pharmaceutical activities conducted through digital platforms, ensuring that such services meet the same standards of care, accountability, and professional oversight as traditional pharmacy practice.

1.6.2. Applicable Laws and Regulations

Digital pharmacy services shall comply with all applicable National laws and regulatory instruments, including but not limited to:

- a) **The Constitution of Kenya (2010)**⁷, particularly Article 43(1)(a), which guarantees the right to the highest attainable standard of health
- b) **Pharmacy and Poisons Act, Cap 244**⁸, and its subsidiary legislation, governing pharmacy practice and control of medicines
- c) **Pharmacy and Poisons (Amendment) Rules, 2022**⁹, which provide for the licensing and regulation of online pharmacies
- d) **Data Protection Act, 2019**¹⁰, governing the collection, processing, storage, and protection of personal data
- e) **Computer Misuse and Cybercrimes Act, 2018**¹¹, addressing cybersecurity and protection of digital systems
- f) **Health Act, 2017**¹², providing the overarching framework for health services in Kenya
- g) **Digital Health Act, 2023** which establishes the legal and institutional framework for digital health, including governance, standards, and regulation of digital health services, systems and platforms.
- h) Applicable policies and standards issued by relevant authorities, including those relating to digital health, information systems, and health data governance

Compliance with these laws ensures that digital pharmacy services operate within established legal boundaries, uphold patient rights, and maintain data privacy, security, and professional accountability.

1.6.3. Scope of Digital Pharmacy Regulation

The regulation of digital pharmacy services encompasses all pharmaceutical activities conducted through digital platforms, including but not limited to:

- a) Electronic prescription generation, transmission, validation, and management

⁷ Republic of Kenya. (2010). *The Constitution of Kenya*.

⁸ Republic of Kenya. (2022). *Pharmacy and Poisons Act (Cap. 244)*.

⁹ Republic of Kenya. (2022). *Pharmacy and Poisons (Amendment) Rules*.

¹⁰ Republic of Kenya. (2019). *Data Protection Act*.

¹¹ Republic of Kenya. (2018). *Computer Misuse and Cybercrimes Act*.

¹² Republic of Kenya. (2017). *Health Act*.

- b) Online dispensing, sale, and supply of medicines and health products and technologies
 - c) Telepharmacy services and remote pharmaceutical consultation
 - d) Digital self-care support and over-the-counter (OTC) medicine management
 - e) Pharmacovigilance and post-market surveillance activities
 - f) Integration with national health information systems and regulatory databases
 - g) Digital record keeping, reporting, and audit processes
 - h) Use of digital systems for clinical decision support and medication safety
- 1.6.3.1. Regulatory oversight aims to ensure that these activities are conducted in a manner that:
- a) Safeguards public health and patient safety
 - b) Maintains the quality, safety, and efficacy of medicines
 - c) Ensures professional accountability and ethical practice
 - d) Promotes secure, interoperable, and reliable digital health systems

This guideline is aligned with international best practices, including guidance from the World Health Organization¹³ and the International Pharmaceutical Federation¹⁴, which emphasize the safe and regulated integration of digital technologies into healthcare systems.

¹³ World Health Organization (WHO). (2019). *Recommendations on digital interventions for health system strengthening*.

¹⁴ International Pharmaceutical Federation (FIP). (2021). *FIP statement of policy: Digital health*.

CHAPTER 2

GOVERNANCE, REGULATORY OVERSIGHT AND ENFORCEMENT

Standard

Digital pharmacy services in Kenya including third-party providers shall operate under a structured governance and enforcement framework that ensures compliance with National regulatory requirements.

Description

This standard establishes the governance, regulatory oversight, and enforcement framework for digital pharmacy services in Kenya. It ensures that all digital pharmacy operations are legally registered, appropriately licensed, professionally supervised, and compliant with national regulatory requirements. The standard emphasizes accountability, transparency, and patient safety through structured oversight mechanisms, monitoring systems, and enforcement provisions. It also defines responsibilities for operators, including management of third-party service providers, reporting obligations, and adherence to professional and ethical standards to safeguard public health in digital pharmaceutical service delivery.

2.1. Registration of digital and internet pharmacy services

- 2.1.1. All pharmacies intending to provide pharmaceutical services or sell Health Products and Technologies (HPTs) online to the general public shall be registered with the Board. No person or pharmacy shall operate a digital pharmacy without explicit Board authorisation.
- 2.1.2. Every digital pharmacy platform must be linked to a licensed physical pharmacy premises with a permanent physical address duly registered and licensed by the Board; the digital platform shall operate under the authority of that licensed premises.
- 2.1.3. Digital pharmacies shall be owned and operated only by persons legally authorised to conduct pharmacy business:
 - a) a licensed pharmacist or pharmaceutical technologist who is the lawful owner; or
 - b) a body corporate operating under the professional oversight of a superintendent pharmacist or pharmaceutical technologist registered and licensed by the Board.
- 2.1.4. Information required for Registration shall include ownership details, system specifications, scope of services, the URL or electronic address of the platform, category of linked pharmacy as approved under Good Pharmacy Practice (GPP), and contact telephone details.
- 2.1.5. Registered platforms shall maintain accurate, up-to-date information with the Board and shall conspicuously display the Board's Health Safety Code on every web page offering HPTs for sale.

2.2. Licensing

- 2.2.1. Digital pharmacy services shall operate only upon valid licensing issued by the Pharmacy and Poisons Board (the Board) and shall comply with all applicable regulatory, technical and professional standards.
- 2.2.2. Licenses shall be renewable annually, subject to continued compliance.

2.3. Human Resource

- 2.3.1. A licensed superintendent pharmacist or pharmaceutical technologist shall be appointed and shall be responsible for oversight of digital pharmacy operations, compliance with regulatory and professional requirements, clinical services, dispensing practices and system use.
- 2.3.2. Digital pharmacy services shall employ qualified, licensed personnel with competencies appropriate to the services provided and shall maintain records of qualifications and licensure.
- 2.3.3. Continuous professional development relevant to digital and clinical practice shall be maintained.

2.4. Notification of changes

- 2.4.1. The superintendent shall notify the Board of any changes in to the digital pharmacy platform, linked premises, contact details, or any other changes as required under Cap 244 within 14 working Days.
- 2.4.2. Notification procedures and timelines shall be specified by the Board.

2.5. Inspection and Supervision

- 2.5.1. Digital pharmacies shall be subject to inspection and supervision by the Board. Inspections may be remote or on-site.
- 2.5.2. Operators shall provide access to systems, records, facilities and linked physical premises during inspections.

2.6. Monitoring and Reporting

- 2.6.1. Digital pharmacy systems shall enable continuous monitoring of prescribing, dispensing and other health care encounters.
- 2.6.2. The systems shall support detection of non-compliant or high-risk conduct.
- 2.6.3. Digital pharmacy systems shall support detection of non-compliant or high-risk activities, including inappropriate prescribing, dispensing, unauthorized access, or suspicious patterns through automated alerts and monitoring tools.
- 2.6.4. Operators shall submit operational, clinical and compliance reports to the Board within prescribed timelines.
- 2.6.5. Reports must be accurate, complete and verifiable.

2.7. Regulation of Third-Party Service Providers & Pharmacy Chains

- 2.7.1. Digital pharmacy services may engage third-party service providers or operate under chain or network models, provided such arrangements comply with all applicable regulatory and professional requirements.
- 2.7.2. The licensed digital pharmacy operator shall remain fully responsible and accountable for all services delivered through third-party providers, partner pharmacies, or chain structures.
- 2.7.3. Third-party service providers shall not independently provide pharmaceutical services.
- 2.7.4. All pharmacy chains operating digital pharmacy services shall have a designated superintendent pharmacist or pharmaceutical technologist specifically responsible for the oversight of all digital pharmacy services.
- 2.7.5. The superintendent pharmacist shall retain direct professional control over dispensing, clinical decisions, and compliance, and such responsibility shall not be delegated to third-party providers.

2.8. Penalties and Sanctions

- 2.8.1. Violations shall attract appropriate penalties or sanctions proportionate to the severity and impact of non-compliance.
- 2.8.2. Sanctions may include fines, suspension, revocation, and other remedial measures provided by law. The Board shall specify types and levels of penalties and maintain a register of enforcement actions.
- 2.8.3. The Board may suspend operations in cases of non-compliance, risk to public health, or violation of regulatory requirements. Grounds for suspension shall be communicated.
- 2.8.4. Licenses may be revoked in cases of serious or repeated non-compliance. Grounds for Revocation decisions shall be communicated.

2.9. Appeals and Review Mechanisms

- 2.9.1. Operators shall have the right to appeal Board decisions to the Registrar of PPF.
- 2.9.2. Procedures for appeals should be clearly documented and communicated.

2.10. Transitional registration

- 2.10.1. All existing internet pharmacies shall apply for registration and authorisation within timelines specified by the Board and must cease operations if not authorised by the deadline.
- 2.10.2. Implementation guidance: The Board shall publish transitional arrangements.
- 2.10.3. Digital pharmacy systems shall retain auditable records of transactions, prescriptions, communications and enforcement actions for periods

prescribed by the Board and make them available to authorised inspectors.

For Public Participation

CHAPTER 3

DIGITAL SYSTEM AND TECHNOLOGY REQUIREMENTS

Standard

Digital pharmacy systems shall operate within a robust, secure, and interoperable digital infrastructure that ensures compliance with national digital health, regulatory, and data protection requirements, and supports safe, reliable, and patient-centered delivery of pharmaceutical services.

Description

This standard defines the technical, functional, and system requirements for digital pharmacy platforms to ensure the secure, reliable, interoperable, and patient-centered delivery of pharmaceutical services. It establishes minimum expectations for system architecture, data integrity, interoperability, cybersecurity, and clinical safety within digital environments. The standard emphasizes the use of robust digital infrastructure to support safe prescribing, dispensing, communication, and reporting, while ensuring protection of patient data, continuity of care, and compliance with national digital health and regulatory frameworks.

3.1. Digital Pharmacy System Architecture

- 3.1.1. Digital pharmacy systems shall be fit-for-purpose, reliable, and capable of supporting all core pharmacy functions, including prescription processing, dispensing, and record management.
- 3.1.2. Systems shall ensure data accuracy, integrity, and consistency across all operations.
- 3.1.3. Systems shall support real-time or near real-time processing of transactions and data updates.
- 3.1.4. Systems shall maintain comprehensive audit trails for all system activities and transactions.
- 3.1.5. Systems shall include built-in controls to detect and prevent errors, unauthorized access, and system misuse.

3.2. System Integration and Compatibility

- 3.2.1. The system should be able to by interoperability be able to fetch client identification and share health records to the national core digital health services, as set by the DHA interoperability standards.
- 3.2.2. Systems shall be capable of secure data exchange with external systems by deploying encryption for all data in transit and at rest.

- 3.2.3. Systems shall ensure interoperability using standardized data formats and protocols as will be prescribed from time to time by the DHA and ICT Authority.
- 3.2.4. Integration shall not compromise data security, integrity, or system performance.

3.3. Platform Identity and Verification

- 3.3.1. Digital pharmacy platforms shall clearly display identifying information of the licensed pharmacy fetched from the Kenya health facility registry
- 3.3.2. The platform shall provide details of the physical premises, licensing status, and responsible personnel.
- 3.3.3. Platforms shall maintain consistency between digital identity and registered physical pharmacy identity.
- 3.3.4. Users shall be able to verify that the platform is legitimate and authorized by the regulatory authority by checking the PPB registry.
- 3.3.5. Digital pharmacy platforms shall display a valid health safety code issued by the regulatory authority.
- 3.3.6. The health safety code shall be visible on all relevant pages of the platform.
- 3.3.7. Systems shall allow users to verify the authenticity and registration status of the pharmacy via the PPB portal.
- 3.3.8. Mechanisms shall be in place to prevent misuse or falsification of verification credentials and sanctions for this

3.4. Public Information Disclosure

- 3.4.1. Digital pharmacy platforms shall provide clear and accessible information on services offered.
- 3.4.2. Policies related to privacy, data protection, complaints handling, and returns/refunds shall be publicly available
- 3.4.3. Information provided shall be accurate, up-to-date, and easily understandable.
- 3.4.4. Platforms shall disclose terms and conditions governing the use of services.
- 3.4.5. The platform shall adhere to the Electronic Record and Data Management Standards as prescribed by the ICT authority.

3.5. Patient Communication and Access to Services

- 3.5.1. Digital pharmacy systems shall enable secure and reliable communication between patients and pharmacy personnel.
- 3.5.2. Patients shall have access to professional advice and consultation services through the platform.
- 3.5.3. Communication channels shall ensure confidentiality, privacy and data protection.
- 3.5.4. Systems shall ensure timely response to patient inquiries and service requests.

3.5.5. System shall have turn around information on resolution of patient queries

3.6. Electronic or Digital Prescription Format

- 3.6.1. Digital pharmacy systems shall support standardized electronic or digital prescription formats compliant with National regulatory requirements.
- 3.6.2. The system should have capacity to support digitized paper prescriptions
- 3.6.3. Prescriptions shall include complete patient, prescriber, and medicine information, including dosage, strength, route, and duration.
- 3.6.4. Valid Prescriptions shall be securely stored in the system.
- 3.6.5. Systems shall ensure that prescriptions are tamper-proof and protected from unauthorized modification.
- 3.6.6. The system shall ensure digitized /electronic prescriptions adhere to the ICT authority electronic Records and data management standards
- 3.6.7. Each prescription shall be assigned a unique and traceable identifier within the system.
- 3.6.8. The unique identifier shall be :
 - a) Unique: No two entities share the same ID
 - b) Non-Intelligence (Minimal Meaning): avoid encoding sensitive information e.g. hypertensive, HIV status
 - c) Persistence: ID stays the same for life especially for prescription
 - d) Scalability: can support millions of records
 - e) Interoperability: work across the national core digital services to ensure they form part of the Shared Health Record (SHR).
- 3.6.9. The identifier shall enable tracking of the prescription throughout its lifecycle, including validation, dispensing, and record keeping.
- 3.6.10. Systems shall ensure that prescription identifiers are secure and cannot be duplicated or altered.
- 3.6.11. The unique identifier will adhere to a global standard as defined by the DHA.

3.7. Prescription Authentication and Validation

- 3.7.1. All prescriptions shall be authenticated to confirm the identity and licensing status of the prescriber through the Kenya Workforce Registry.
- 3.7.2. Systems shall verify that prescriptions are legitimate and issued within the scope of professional practice.
- 3.7.3. Prescriptions shall be validated for completeness, accuracy, and clinical appropriateness before dispensing.
- 3.7.4. Digital pharmacy systems shall detect and prevent duplicate dispensing of the same prescription.
- 3.7.5. Systems shall flag attempts to process multiple prescriptions for the same medicine and patient within inappropriate timeframes.
- 3.7.6. Mechanisms shall be in place to prevent intentional or unintentional reuse of prescriptions.

3.8. Clinical Safety Framework in Digital Systems

- 3.8.1. Digital pharmacy platforms shall establish a clinical governance framework to ensure safe and appropriate use of medicines.
- 3.8.2. Clinical processes shall be supervised by a licensed pharmacist responsible for patient safety.
- 3.8.3. Systems shall support clinical review and decision-making prior to dispensing.
- 3.8.4. Mechanisms shall be in place to ensure accountability for clinical decisions made through the platform.
- 3.8.5. Systems shall have inbuilt controls to minimize medication errors during prescribing, dispensing, and administration stages.
- 3.8.6. Systems shall flag high-risk medicines and dosing errors.
- 3.8.7. Systems shall ensure appropriate checks for patient-specific factors such as age, allergies, and comorbidities.

3.9. Clinical Decision Support Systems (CDSS)

- 3.9.1. Systems shall detect and alert for potential drug-drug interactions prior to dispensing.
- 3.9.2. Interaction alerts shall be based on reliable and up-to-date clinical data sources.
- 3.9.3. The system CDSS shall have access to drug database with the following information:
 - a) Drug-drug interactions
 - b) Drug-allergy interactions
 - c) Contraindications
 - d) Dose ranges (adult/paediatric)
 - e) Pregnancy/lactation safety
- 3.9.4. The CDSS shall adhere to common CDSS rules such as:
 - a) safety alerts such as: allergies, drug-drug interactions),
 - b) dose checking such as Weight-based dosing for paediatrics), Renal/hepatic dose adjustment
 - c) Guideline-Based Recommendations such as Standard Treatment Guidelines (STGs), Kenya Essential Medicines List (KEML)
 - d) Contraindications such as in Pregnancy, case where Comorbidities exist
- 3.9.5. Systems shall identify and alert for patient-specific allergies and contraindications and prevent the dispensing of medicines that pose significant risk to the patient.
- 3.9.6. Systems shall provide alerts for inappropriate dosing, including overdosing and underdosing, based on patient-specific parameters.
- 3.9.7. The system should be able to fetch patient key information from the SHR
- 3.9.8. Systems shall include mechanisms to prevent and detect medication errors throughout the medication use process and shall maintain records of such errors, including corrective and preventive actions, to support continuous quality improvement.

3.10. Information Exchange and Interoperability

- 3.10.1. Digital pharmacy systems shall adhere to the Kenya health interoperability standards in order to communicate with national digital health systems to support continuity of care.
- 3.10.2. Systems shall enable secure exchange of patient and prescription data with authorized health platforms.
- 3.10.3. Interoperability ensures data consistency, accuracy, and timeliness across systems.
- 3.10.4. Digital pharmacy systems shall integrate with regulatory authority systems for licensing, verification, and reporting.
- 3.10.5. Systems shall support real-time or periodic reporting of regulatory data as required.
- 3.10.6. Integration shall enable verification of pharmacy and prescriber credentials.
- 3.10.7. Digital pharmacy systems shall support interoperability with national pharmacovigilance systems and enable the reporting and timely transmission of adverse drug reactions (ADRs) and other safety concerns.
- 3.10.8. All data exchanges shall be conducted using secure and standardized communication protocols via the national super highway, ensuring the confidentiality, integrity, and authenticity of transmitted data and preventing unauthorized access or interception during transmission.

3.11. Data Security, Privacy and Cybersecurity

- 3.11.1. Digital pharmacy systems shall comply with applicable data protection and privacy laws.
- 3.11.2. Personal and health data shall be processed lawfully, fairly, and transparently.
- 3.11.3. Systems shall ensure protection of patient confidentiality at all times.
- 3.11.4. Patient and system data shall be encrypted at rest, in transit and when in storage and encryption methods shall meet industry best practice security standards.
- 3.11.5. The system shall restrict access to authorized users only by implementing user authentication and role-based access control mechanisms for effective user management.
- 3.11.6. Data shall be stored securely and protected from loss, damage, or unauthorized access in accordance with DHA regulations, with systems maintaining regular backups and ensuring data retention complies with applicable regulatory requirements and policies.
- 3.11.7. The system shall adhere to cybersecurity standards prescribed by the ICT Authority, implementing measures to identify, assess, and mitigate cybersecurity risks, protect against malware, hacking, and unauthorized access, and undergo regular security assessments.

- 3.11.8. Systems shall include mechanisms for detecting, reporting, documenting, and investigating security incidents, including data breaches and system outages.
- 3.11.9. All data breaches and outages shall be reported to the relevant regulatory authorities within prescribed timelines in accordance with the Digital Health Act and Data Protection Act.
- 3.11.10. Third-party systems integrated with digital pharmacy platforms shall comply with applicable security and regulatory requirements, with data shared securely protected and controlled, and third-party access restricted and continuously monitored.

3.12. Hardware requirements

- 3.12.1. Digital pharmacy systems shall be supported industry best practice minimum hardware specifications
- 3.12.2. The hardware should be able to provide reliability, scalability and safety
- 3.12.3. Systems hardware shall be capable of handling expected workload and user demand.
- 3.12.4. Implementation Guidance
- 3.12.5. Systems should use validated and regularly maintained hardware and software components.

3.13. Software requirements

- 3.13.1. the system software should be able to support interoperability.
- 3.13.2. The software should be able for purposes of terminology consume from the Kenya National Health Terminology Services for clinical and pharmaceutical terminologies
- 3.13.3. The software should be able to support structured prescription, ensuring mandatory data elements are collected and digital signature support.
- 3.13.4. The system software should support easy usability on the user interface with simple workflows
- 3.13.5. The system software may be able to support on and offline capability
- 3.13.6. The system software should be able to support:
 - a) Maintenance Updates to cover Security, Bug fixes and Performance
 - b) Improvement Updates to cover Features and Compatibility
 - c) Critical Updates to cover Emergency fixes and major upgrade

3.14. Risk Management for System Failure

- 3.14.1. Systems shall include measures to manage and mitigate risks associated with system failures, i.e a business continuity plan to ensure health care provision continues
- 3.14.2. The system developers will ensure there are established back up policies and data recovery procedures

- 3.14.3. Critical functions shall be protected against unexpected downtime or disruptions.
- 3.14.4. Systems shall implement develop back up policies and data recovery procedures.
- 3.14.5. Data shall be recoverable in the event of system failure will be subjected to integrity tests.
- 3.14.6. Systems shall be capable of scaling to accommodate increased demand.
- 3.14.7. Systems shall ensure consistent performance and minimal downtime.
- 3.14.8. The system shall have established thresholds for latency, throughput and error rate to inform scalability.

3.15. Digital Health Care Encounters

- 3.15.1. Digital pharmacy systems shall maintain complete, accurate, and time-stamped records of all health care encounters.
- 3.15.2. Health care encounters records shall include prescription processing, dispensing, modifications, user access, and system activities.
- 3.15.3. Records shall be secure, tamper-evident, and protected from unauthorized alteration or deletion.
- 3.15.4. Systems shall ensure that health care encounters records are readily retrievable for review and inspection.

3.16. Regulatory and Operational Reporting

- 3.16.1. Digital pharmacy systems shall support generation of accurate and timely reports for regulatory and operational purposes for all prescribed report as guided by the DHA..
- 3.16.2. Systems shall provide reports on dispensing activities, prescriptions processed, controlled medicines, and other required indicators.
- 3.16.3. Reports shall be complete, verifiable, and available for inspection by the regulatory authority.
- 3.16.4. Systems shall support periodic and on-demand reporting as required by the regulator.
- 3.16.5. System shall have inbuilt alerts for prompt reporting of concerns of public health or as per guided by the national health surveillance systems

3.17. Pharmacovigilance and Post-Market Surveillance

- 3.17.1. Digital pharmacy systems shall support the identification, documentation, and reporting of suspected adverse drug reactions (ADRs) in accordance with regulatory requirements.
- 3.17.2. Digital pharmacy platforms shall provide an interface for reporting adverse drug events by the general public, integrated with the Pharmacy and Poisons Board (PPB) reporting system.
- 3.17.3. Systems shall facilitate the dissemination of safety alerts and warnings related to medicines.

3.17.4. Integration with national pharmacovigilance systems shall be implemented to enable secure and reliable data exchange with relevant regulatory authorities.

For Public Participation

CHAPTER 4

SERVICE DELIVERY REQUIREMENTS

Standard

Digital pharmacy services in Kenya shall deliver safe, effective, and patient-centered pharmaceutical care that meets the same clinical, ethical, and professional standards as in-person practice, and complies with National regulatory and professional standards.

Description

This standard outlines the requirements for the safe, effective, and patient-centered delivery of pharmaceutical services through digital pharmacy platforms. It establishes minimum standards for prescription handling, dispensing, patient counselling, telepharmacy services, and professional responsibilities. The standard emphasizes clinical appropriateness, patient safety, ethical practice, and accountability in all digital pharmacy interactions. It ensures that digital service delivery maintains the same level of quality and care as in-person pharmacy services while supporting appropriate referral, self-care, and documentation practices.

4.1. Prescription handling and validation

- 4.1.1. All prescriptions shall be reviewed and validated for completeness, authenticity, validity, origin, and clinical appropriateness prior to dispensing.
- 4.1.2. All prescriptions for medicines shall be assessed to identify potential misuse or inappropriate use.
- 4.1.3. The following products are prohibited from online access to clients:
 - a) Schedule IV, or controlled medicines, including but not limited to Benzodiazepines (diazepam, lorazepam), certain opioids (tramadol, codeine).
 - b) Products that require direct administration or observation by health care worker.
 - c) Products that require therapeutic drug monitoring, including but not limited to Digoxin, phenytoin, aminophylline, lithium, vancomycin, and carbamazepine.
 - d) Medication(s) that require clients to be in health care facility, including general anesthetics (e.g., propofol), thrombolytics (e.g., alteplase), chemotherapy regimens, and medications used in emergency care (e.g., adrenaline in advanced life support settings)
- 4.1.4. The system shall have inbuilt thresholds to detect and prevent misuse, abuse, or overuse of medicines.

4.2. Dispensing Standards

- 4.2.1. HPTs shall be dispensed strictly in accordance with validated prescriptions and applicable professional and regulatory standards.
- 4.2.2. Dispensing processes shall ensure the correct HPTs, strength, dosage, quantity, labelling, and patient instructions.
- 4.2.3. Patient-specific clinical factors, including age, allergies, comorbidities, and potential contraindications or interactions, shall be verified prior to dispensing.

4.3. Patient Counselling and Education

- 4.3.1. Digital pharmacy platforms shall incorporate structured approaches to collect relevant patient-reported information during virtual consultations to support safe medication use and appropriate advice.
- 4.3.2. Clients shall receive adequate counselling and information on the use of prescription and OTC HPTs.
- 4.3.3. Counselling shall be delivered through appropriate secure digital channels (e.g., video, audio, or messaging), ensuring patient privacy and understanding through confirmation or feedback mechanisms where appropriate.
- 4.3.4. Counselling shall include dosage, administration, precautions, side effects, and storage instructions as per the nature of the HPT.
- 4.3.5. Information provided shall be clear, accurate, and appropriate to the patient's needs.
- 4.3.6. Digital platforms shall provide written, audio, or video counselling materials.

4.4. Digital Pharmacy Consultation

- 4.4.1. Telepharmacy services shall be limited to authorized pharmaceutical services delivered remotely.
- 4.4.2. Remote consultations shall be conducted in a manner that ensures patient safety, confidentiality, and professional integrity.
- 4.4.3. Consultations shall meet the same standard of care as in-person services.
- 4.4.4. The approved scope of practice by the Board shall be adhered to when providing digital counselling and telepharmacy, ensuring compliance with regulatory and professional practice standards.
- 4.4.5. Sufficient information shall be obtained from the prescription or the client to support informed pharmaceutical care decision making.
- 4.4.6. All telepharmacy interactions shall be documented accurately and securely.

4.5. Referral Protocols

- 4.5.1. Digital pharmacy services shall incorporate clear mechanisms to identify cases requiring referral to appropriate healthcare providers, including the recognition of danger signs and high-risk conditions.
- 4.5.2. Clients shall be referred when conditions fall outside the scope of digital pharmacy services, self-care, or present potential risks.
- 4.5.3. Clear referral pathways shall be established, implemented, and effectively communicated to clients, particularly for urgent or high-risk situations, in accordance with approved protocols.

4.6. Digital Self-Care and OTC HPTs Management

- 4.6.1. Digital pharmacy services shall implement a structured digital self-care and OTC medicine management framework for minor ailments.
- 4.6.2. Self-care services shall be limited to conditions appropriate for non-prescription management, as per the Good Pharmacy Practice (GPP) Guidelines.
- 4.6.3. The right Over-the-counter (OTC) HPTs shall be supplied to right indications in accordance to self-care guidelines.
- 4.6.4. Measures shall be in place to prevent inappropriate, excessive, or unsafe use of OTC medicines.

4.7. Record Keeping and Documentation

- 4.7.1. Digital pharmacy systems shall maintain comprehensive and secure records of prescriptions, dispensing activities, consultations, and transactions.
- 4.7.2. Records shall include patient information, medicines supplied, consultation details, advice provided, and relevant outcomes.
- 4.7.3. Documentation shall be retained and accessible for the period specified by applicable regulatory and legal requirements.
- 4.7.4. Audit trails shall be maintained to capture all activities related to records and transactions, ensuring traceability and accountability, and shall be protected from modification or deletion.
- 4.7.5. Records shall be readily accessible to authorized personnel and regulatory authorities, with appropriate access controls to safeguard patient privacy and data security.

4.8. Professional Responsibilities and Ethics

- 4.8.1. Patient confidentiality and privacy shall be maintained at all times in digital pharmacy practice.
- 4.8.2. Ethical guidelines and codes of conduct shall be integrated into digital pharmacy practice.
- 4.8.3. Where there is conflicts of interest, it shall be identified and appropriately managed.
- 4.8.4. Digital pharmacy services shall be delivered within the scope of professional competence and applicable regulatory requirements.

- 4.8.5. Communication with clients and use of client data shall be strictly limited to healthcare purposes.
- 4.8.6. Client data collected during digital pharmacy services shall not be shared with third parties without prior informed consent, except where there is court order.
- 4.8.7. Safe and accurate dispensing practices shall be maintained at all times, without shortcuts.
- 4.8.8. The quality of care in digital pharmacy services shall be equivalent to that of in-person services.
- 4.8.9. Communication shall be clear, professional, and adapted to the client's level of understanding, with appropriate confirmation of comprehension.
- 4.8.10. Comprehensive documentation shall be maintained for all client interactions.
- 4.8.11. Professional boundaries shall be maintained in all digital interactions.
- 4.8.12. Continuous professional development shall be undertaken to remain current with digital pharmacy practices and emerging standards.

For Public Participation

CHAPTER 5

HPT DELIVERY AND LOGISTICS MANAGEMENT

Standard

Digital pharmacy services shall ensure the safe, secure, and efficient handling, storage, and delivery of health products and technologies, in accordance with National regulatory and quality standards

Description

This standard establishes the requirements for the safe, secure, and efficient handling, storage, and delivery of health products and technologies (HPTs) within digital pharmacy services. It ensures full traceability, product integrity, patient confidentiality, and accountability throughout the supply chain—from dispensing to final delivery or return. The standard emphasizes robust logistics systems, appropriate packaging, cold chain management, and regulatory compliance, while ensuring that delivery processes maintain quality, safety, and continuity of care.

5.1. HPT Traceability and Track-and-Trace Systems

- 5.1.1. Systems shall enable end-to-end traceability of medicines from dispensing through delivery and receipt by patient.
- 5.1.2. Systems shall take adequate steps to ensure that the delivery mechanism used is secure and that medicines are delivered to the intended user promptly, safely, and in a condition appropriate for use.
- 5.1.3. Records shall be maintained for dispensing, and delivery details. These records may be subject to audit/inspection
- 5.1.4. Systems shall support identification, return and management of recalled, defective or undelivered medicines.

5.2. Delivery and Last-Mile Logistics

- 5.2.1. Medicines shall be delivered in a manner that ensures safety, quality, and integrity of products.
- 5.2.2. Delivery processes shall ensure timely and accurate delivery to the intended recipient. Delivery systems shall maintain confidentiality of patient information.
- 5.2.3. All dispensed HPTs shall have a mandatory inner and outer (shipping) packaging for purpose of delivery.
- 5.2.4. Labels must be clear, legible, indelible, and preferably printed.

a) Secondary Packaging (Medicine Container Label)

The secondary packaging label shall contain the full dispensing information necessary to ensure the safe and effective use of the medicine by the patient. The label shall include:

- a) Generic name of the HPT
- b) Strength and dosage form
- c) Directions for use
- d) Frequency and duration of therapy
- e) Total quantity supplied
- f) Patient name
- g) Date of dispensing
- h) Expiry date or use-by date
- i) Name and address of the dispensing pharmacy
- j) Special precautions

The label shall be clear, legible, indelible, and securely attached to the medicine container.

b) Outer/shipping Packaging (Outer Delivery Package)

The outer (shipping) packaging used for transport or delivery shall protect the confidentiality of the patient and the contents of the package.

The outer package shall include only the minimum information required for delivery, such as:

- a) Name of the recipient
- b) Delivery address and contact information
- c) Name and contact details of the dispensing pharmacy
- d) Delivery **tracking number or reference code** where applicable, which will also be shared with the client.

The secondary packaging shall not display the name of the medicine, medical condition, prescription details, or other sensitive health information.

The packaging shall be tamper-evident and designed to maintain the integrity, safety, and stability of the medicine during transportation.

5.3. Cold Chain Management

5.3.1. Medicines requiring temperature control shall be packaged and transported under appropriate cold chain conditions.

5.3.2. Systems shall ensure continuous monitoring of temperature during transport.

5.3.3. Thermolabile products shall be delivered through express delivery and shall not remain in transit for more than 8 hours.

5.3.4. Deviations from required conditions shall be detected and addressed promptly.

5.4. Packaging and Tamper-Evident Systems

5.4.1. Medicines shall be packaged to ensure protection from damage, contamination, and environmental exposure during transit.

5.4.2. Packaging shall be tamper-evident to detect unauthorized access.

5.4.3. Packaging shall include appropriate labeling and instructions bearing in mind confidentiality.

5.5. Patient Identity Verification

- 5.5.1. Systems shall ensure that medicines are delivered to the correct patient or authorized recipient.
- 5.5.2. Identity verification shall be conducted prior to handover of medicines.
- 5.5.3. Unauthorized receipt of medicines shall be prevented.

5.6. Delivery Audit Trails

- 5.6.1. Systems shall maintain records of all delivery activities and transactions.
- 5.6.2. Delivery records shall include date, time, route including any stops, recipient details, and delivery status.
- 5.6.3. Records shall support traceability and accountability of delivery processes.

5.7. Recall and Reverse Logistics Systems

- 5.7.1. Systems shall support identification and retrieval of HPTs subject to recall or failed delivery.
- 5.7.2. Reverse logistics processes shall enable return, quarantine and safe handling of recalled or undelivered HPTs.
- 5.7.3. Patients shall be informed promptly in the event of product recalls.

5.8. Regulation of Third-Party Logistics Providers

- 5.8.1. Third-party logistics providers shall comply with prescribed regulatory and quality standards, which shall include the following:
- 5.8.2. For short distances (up to 100 km), designated motorcycle riders may be used to transport medicines, provided they are equipped with a lockable delivery box and are able to maintain the required conditions of safety, integrity, and product quality during transit. For transport over longer distances, medicines shall be conveyed only through transporters licensed by the Board and compliant with all applicable storage, handling, and security requirements.
- 5.8.3. The roles and responsibilities of third-party providers shall be clearly defined and documented, with overall liability remaining with the digital pharmacy. Systems shall ensure that third-party providers maintain product integrity and patient confidentiality.

5.9. Environmental and Pharmaceutical Waste Management

- 5.9.1. All digital pharmacies shall display to the public a clear return and refund policy
- 5.9.2. All returned HPTs shall be quarantined, assessed for suitability and integrity, based upon which they may be restocked for sale or scheduled for disposal in accordance with regulatory requirements.

- 5.9.3. Digital pharmacies whose operations may lead to generation of medical waste shall provide procedures for managing medical waste from the patients
- 5.9.4. Hazardous pharmaceutical waste shall be handled and disposed of in accordance with safety and environmental regulations.
- 5.9.5. Systems shall ensure that hazardous materials do not pose risk to public health or the environment.

For Public Participation

CHAPTER 6

ADVERTISEMENT AND PROMOTION OF HEALTH PRODUCTS AND TECHNOLOGIES (HPTs)

Standard

Digital pharmacy services shall ensure that all advertisements and promotions of health products and technologies are conducted in compliance with National regulatory requirements and ethical standards.

Description

This standard establishes the regulatory and ethical framework governing the advertisement and promotion of health products and technologies within digital pharmacy platforms. It ensures that all promotional activities are compliant with national regulations, scientifically accurate, and aligned with principles of rational medicine use. The standard aims to protect public health by preventing misinformation, unethical marketing practices, and inappropriate demand generation, while promoting transparency, accountability, and professional integrity in digital pharmaceutical communication.

6.1 General Regulatory Requirements for Advertisement

- 6.1.1. No person or entity shall advertise any health product or technology on a digital platform without prior written approval from the Board.
- 6.1.2. Only HPTs officially registered or listed by the Board may be promoted or advertised through any digital media, including social media channels.
- 6.1.3. Advertisements must be detailed, balanced, factual, informative, up-to-date, and strictly consistent with the approved product registration information.
- 6.1.4. All claims, descriptions, and comparisons should be substantiated by current scientific data (generally not older than five years).
- 6.1.5. All content relating to HPTs in the Digital Pharmacy platform must exclusively use the generic name, International Non-proprietary Name (INN), or chemical name.
- 6.1.6. The display of branded names and product images is strictly prohibited.
- 6.1.7. Approved patient information including indication, side effects, contraindications and patient safety and indicative prices must be stated.

6.2 Digital Platform Structure and Access

- 6.2.1. Digital pharmacies must maintain two strictly segregated interfaces: a public-facing portal for the general public and a restricted-access portal for Healthcare Professionals (HCPs).
- 6.2.1 The public landing page shall be restricted to General Sales (GS) health products and pharmacy services. It shall not reference, list, or display named Prescription Only Medicines (POMs).

- 6.2.2 The HCP interface must be securely gated, clearly labeled "For Healthcare Professionals Only," and may contain technical and scientific product information consistent with approved pharmacological literature.

6.3 Promotion of Over-the-Counter (OTC) Medicines

- 6.3.1. The promotion of OTC medicines shall strictly align with approved indications and safe-use guidelines.
- 6.3.2. Promotional content must include adequate instructions for proper use, necessary precautions, and usage limitations. Platforms should integrate patient education materials alongside promotional content.
- 6.3.3. Promotions shall not encourage irrational, excessive, or unnecessary consumption of medicines. Digital systems must incorporate safeguards to monitor and prevent inappropriate purchasing patterns.
- 6.3.4. Consistent with general requirements, OTC promotional content must use the generic name, INN, or chemical name. Product images and branded names are prohibited unless approved by the Board for advertisements.

6.4 Restrictions on Prescription Only Medicines (POMs)

- 6.4.1. Direct-to-Consumer Advertising (DTCA) of POMs is strictly prohibited across all digital platforms.
- 6.4.2. On public-facing pages, digital pharmacies may only list the generic name/INN/chemical name, approved indication, and indicative price of a POM. Digital pharmacies are prohibited from using any visual representation (images or graphics) of POM products.
- 6.4.3. The promotion of off-label or unregistered indications is prohibited.
- 6.4.4. Digital pharmacies may advertise services related to POMs (e.g., online prescription routing, refill reminders, chronic disease management support) provided they do not reference specific medication brands.

6.5 Influencer and Third-Party Regulations

- 6.5.1. Endorsements or recommendations by celebrities, social media influencers, or high-profile organizations that may drive irrational consumption of health products due to their social status are prohibited.
- 6.5.2. The use of actual healthcare workers, or individuals portraying healthcare workers, to promote specific medicines to the general public is prohibited.
- 6.5.3. Digital pharmacy operators bear ultimate legal and regulatory accountability for any HPT information or misinformation published on webpages, apps, social media handles, or portals they own, operate, or influence.

6.6 Demand Generation and Responsible Public Engagement

- 6.6.1. Engagement activities must promote rational medicine use and appropriate healthcare-seeking behavior.

- 6.6.2. General statements regarding human health, wellness, or diseases are permitted, provided no specific product or brand is referenced.
- 6.6.3. Operators are encouraged to highlight their digital pharmacy services (e.g., medication synchronization, adherence packaging, 24/7 pharmacist consultations, telehealth integrations, and secure home delivery).
- 6.6.4. Advertisements shall not exploit superstitions, induce fear, or cause undue public distress.
- 6.6.5. Content must not exaggerate the severity of a medical condition or suggest that a user's health will deteriorate if a specific product is not consumed.
- 6.6.6. Consumer incentives, including bonus offers, free samples, competitions, and discounts, designed to induce the unnecessary purchase of medicines are prohibited.
- 6.6.7. Absolute claims and superlatives such as "magic," "miracle," "most effective," or "100% safe" (implying an absence of side effects) are forbidden.
- 6.6.8. Highlighting "special offers" or flash sales on medicine prices is prohibited.
- 6.6.9. The use of medical representatives, digital bots, or automated algorithms to make unsolicited requests to HCPs or patients to use specific products is prohibited.

6.7 Ethical Awareness Campaigns and Demand generation

- 6.7.1. Public engagement must align with national health priorities, focusing on disease prevention and rational medicine use.
- 6.7.2. Platforms may participate in global health observances (e.g., "World Diabetes Day") using factual, educational statements without referencing specific brands.
- 6.7.3. Public education information must be scientifically accurate, factual, and strictly informative rather than persuasive.

6.8 Data Privacy and Targeted Advertising

- 6.8.1. Digital pharmacies shall not use programmatic advertising, tracking cookies, or targeted algorithms that exploit a user's sensitive health data, search history, or past purchases to push specific health products.
- 6.8.2. Retargeting campaigns (showing ads to users based on their previous browsing behavior on the pharmacy platform) for any medicines are prohibited.

6.9 Direct Digital Marketing

- 6.9.1. Direct marketing communications via SMS, email, WhatsApp, or app push notifications must require explicit, documented opt-in consent from the user.
- 6.9.2. Direct communications shall strictly be limited to General Sales products or general pharmacy services, and shall not include promotional content for Prescription Only Medicines.
- 6.9.3. All direct marketing messages must include a clear, easily accessible, and functional opt-out or unsubscribe mechanism.

6.10 Patient Testimonials and User Reviews

- 6.10.1. The publication, moderation, or use of patient testimonials, star ratings, or user reviews related to the efficacy, side effects, or performance of specific health products is prohibited, as they may constitute unsubstantiated medical claims.
- 6.10.2. Reviews regarding the general service of the digital pharmacy (e.g., delivery speed, customer service) are permitted, provided they do not mention specific HPTs.
- 6.10.3. Public reviews must be moderated before publication/posting on the website

6.11 Search Engine Marketing and Affiliate Programs

- 6.11.1. Bidding on search engine keywords related to specific Prescription Only Medicines for the purpose of directing public traffic to a digital pharmacy portal is prohibited.
- 6.11.2. The use of affiliate marketing programs, where unverified third-party websites or individuals receive financial compensation or commission for directing consumer traffic to specific HPTs on the digital platform, is prohibited.

6.12 Misinformation Reporting and Digital Oversight

- 6.12.1. Digital pharmacies must provide visible, easily accessible mechanisms (e.g., embedded reporting links directed to the PPB) for users to flag false or misleading advertisements.
- 6.12.2. Platforms are required to investigate complaints, report misleading information to the Board, and provide supporting evidence, including digital logs and screenshots.

CHAPTER 7

QUALITY ASSURANCE

Standard

Digital pharmacy services shall implement and maintain a robust quality assurance framework that ensures continuous compliance with regulatory and professional standards.

Description

This standard establishes the framework for quality assurance in digital pharmacy services to ensure consistent delivery of safe, effective, and high-quality pharmaceutical care. It defines the requirements for implementing a structured quality management system, conducting internal audits, monitoring performance, and promoting continuous quality improvement. The standard emphasizes accountability, data-driven decision-making, patient safety, and compliance with regulatory and professional standards across all aspects of digital pharmacy operations

7.1. Quality Assurance Framework

The digital pharmacy shall:

7.1.1. Establish and maintain a documented QA framework that:

- a) Ensures compliance with regulatory, professional, and operational standards.
- b) Covers systems, service delivery, logistics, and IT.

7.1.2. Clearly define, document, and communicate quality management roles and responsibilities.

7.1.3. Integrate QA policies and procedures into daily operations.

7.2. Internal Quality Audits, Monitoring and Review

7.2.1. The superintendent shall ensure internal audits and quality reviews are conducted at least quarterly.

7.2.2. The QA program shall review, at a minimum:

- a) Personnel qualifications, staffing, and training.
- b) Communication systems with prescribers and patients.
- c) Systems for receiving and processing prescriptions.
- d) Prescription processing, dispensing, and patient counselling.
- e) Systems for dispensing and managing patient medication records.
- f) Packaging, transportation, and delivery of medicines and other HPTs.
- g) Documentation and record management.
- h) Performance and validation of IT systems and equipment.
- i) Security and confidentiality of patient information.
- j) Accuracy of information on the digital pharmacy platform.
- k) Customer feedback and complaint management.
- l) Pharmacovigilance records and reports.

- 7.2.3. Systems shall support continuous monitoring of operations, performance, and compliance.
- 7.2.4. Audit findings, schedules, reports, and corrective actions (CAPA) shall be documented, implemented promptly, and maintained.
- 7.2.5. Audit records shall be made available to PPB inspectors upon request.

7.3. Performance Indicators and Benchmarking

The digital pharmacy shall:

- 7.3.1. Define and monitor KPIs on service quality, safety, efficiency, and patient outcomes (e.g., dispensing accuracy, response times, delivery performance, complaints, satisfaction).
- 7.3.2. Use performance data to evaluate effectiveness and identify improvements.
- 7.3.3. Benchmark performance against regulatory standards, best practices, and internal historical data where applicable.

7.4. Customer Feedback and Complaint Management

The digital pharmacy shall

- 7.4.1. Provide accessible mechanisms for clients to submit feedback and complaints.
- 7.4.2. Log, investigate, and resolve all complaints within defined timeframes.
- 7.4.3. Analyse feedback and complaints to identify trends, systemic issues, and improvement opportunities, and document resulting actions.

7.5. Continuous Quality Improvement (CQI)

The digital pharmacy shall

- 7.5.1. Implement formal CQI processes using audit results, KPIs, benchmarking, and patient feedback.
- 7.5.2. Maintain quality improvement plans with objectives, responsibilities, timelines, and success measures; review them regularly.
- 7.5.3. Ensure systems support ongoing evaluation and enhancement of services and IT platforms.
- 7.5.4. Provide staff training and capacity building to support QA and CQI activities.

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ANNEX I: REVISION HISTORY

Revision No.	Date	Prepared by	Section(s) Revised	Description of Change
01	2023	Pharmacy and Poisons Board (PPB)	Entire document	Initial guidelines developed focusing on internet pharmacy services , including registration, licensing, dispensing, delivery, record keeping, and basic ICT requirements.
02	2026	Pharmacy and Poisons Board (PPB)	Chapters 1–7 (Entire document revised and expanded)	Comprehensive revision and expansion from internet pharmacy to full digital pharmacy services framework . Key changes include: • Expansion of scope to include telepharmacy, digital platforms, interoperability, and integrated digital health systems • Introduction of new structured chapters, including: • Governance, Regulatory Oversight and Enforcement • Digital System and Technology Requirements • Service Delivery Requirements • HPT Delivery and Logistics Management • Advertisement and Promotion of HPTs • Quality Assurance and Continuous Improvement • Strengthening of regulatory oversight, licensing, and enforcement mechanisms • Inclusion of clinical safety frameworks, CDSS, and prescription validation systems • Introduction of data protection, cybersecurity, and interoperability requirements • Establishment of ethical digital marketing and advertisement controls • Integration of quality assurance systems, KPIs, audits, and CQI frameworks • Enhanced provisions for pharmacovigilance, traceability, and logistics management This revision aligns the guideline with current digital health advancements, national priorities

				(UHC), and international best practices, ensuring a comprehensive, patient-centered, and technology-enabled regulatory framework.
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