



REPUBLIC OF KENYA
MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD

GUIDELINES ON INTERNET PHARMACY SERVICES IN KENYA

JANUARY 2022

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Abbreviations and Acronyms

CDs	Controlled Drugs
EV-SSL	Extended Validation SSL certificate
GPP	Good Pharmacy Practice
ISO	International Organization for Standardization
IT	Information Technology
PIL	Patient Information Leaflet
PPB	Pharmacy and Poisons Board

Glossary of Terms

The definitions given below apply to the terms as used in this document. They may have different meanings in other contexts.

“Internet Pharmacy” means a registered pharmacy which offers to sell or supply medicines (or other pharmaceutical products) and/or provides other professional services over the internet, or makes arrangements for the supply of such products or provision of such services over the internet

“Registered pharmacist” means a person whose name is entered in the register of pharmacists in Kenya.

“Enrolled pharmaceutical technologist” means a pharmaceutical technologist whose name appears on the roll of pharmaceutical technologists in Kenya.

“Superintendent” means any person who is a manager and controls the business and is overall in charge of ensuring compliance.

“Premises” means the fixed portion of any building, structure or vessel leased, used, or controlled by the licensee in the conduct of the pharmacy business registered by the Board at the address for which the registration was issued under section 23 of the Pharmacy and Poisons Act and includes all those areas where medicinal products are, or are intended to be, sold or supplied, prepared, dispensed, compounded or stored.

“Registered premises” means premises registered in accordance with section 23 of the Pharmacy and Poisons Act, and where a valid certificate for registration is available.

“registered pharmacy” means any retail pharmacy premises and shall include, in cases where e-pharmacy or an online pharmacy practice has been licensed, the premises where the practice is domiciled.

A **“pharmacy”** is the premises upon which a pharmacy business is conducted and it includes:

- (a) the portion of the premises where goods of any kind are for sale; and

(b) a professional service room.

The definition of a pharmacy does not include premises located in a public hospital controlled by a public health organization.

“Pharmacy Business” is where the dispensing and compounding of prescriptions for any substance specified as a Part 1 poison in the Poisons List proclaimed under the Pharmacy and Poisons Act occurs.

“Professional services” means pharmaceutical services provided in accordance with approved professional qualifications and as licensed by the Board. A separate room within registered premises may be considered and approved for such services.

“Medical Product” means medicines, vaccines, blood and blood products and medical devices, including in-vitro diagnostics, food supplements, cosmetics, radiopharmaceuticals, cells, tissues and organs, complementary and alternative medicines and borderline products.

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Summary

PPB has developed a guideline on internet pharmacy services to enhance safety and provide greater assurances to the public regarding the provision of internet pharmacy services from registered pharmacy premises in Kenya. The guidance in this document is expected of owners and superintendents of registered pharmacy premises in Kenya to meet in the provision of internet pharmacy services.

This guideline takes into account of all aspects of the legal framework around medicines and pharmacy practice under CAP 244 Laws of Kenya.

Scope

The scope will include all medical products and health technologies offered for sale or sold through electronic means. This includes the internet and mobile applications.

Background

An internet pharmacy service should not be a substitute for a face to face consultation with a pharmacist or other appropriate healthcare professional, but when used safely and appropriately, online access to medicines and healthcare advice can offer benefits to patients.

A registered pharmacy which offers to sell or supply medicines (or other pharmaceutical products) and/or provides other professional services over the internet, or makes arrangements for the supply of such products or provision of such services over the internet must comply with this guideline.

This document expands on the principles of pharmacy practice to explain the pharmacists and pharmaceutical technologists' professional responsibilities when selling and supplying medicines via the internet.

Requirements for Internet Pharmacy Services in Kenya

1. Registration of Internet pharmacy services

- 1.1. Pharmaceutical services provided to the public via the internet include amongst other things, the dispensing of prescriptions, the sale of medicines and the provision of information on website pages.
- 1.2. All pharmacies in Kenya intending to sell medicines online to the general public need to be registered with PPB and be on the list of registered online retail sellers in Kenya. They also need to display on every page of their website offering medicines for sale, the Health safety code provided by the PPB.
- 1.3. A pharmacy offering internet services must meet the following:
 - 1.3.1. There must be pharmacy premises, from where the sale and supply of medicines and medical products takes place, that meet the requirements and are duly registered by PPB.
 - 1.3.2. A person carrying on an internet pharmacy business shall be taken to be a person lawfully conducting such a business, that is, a qualified pharmacist or pharmaceutical technologist owner or if the pharmacy is owned by a 'body corporate' (for example a company) a superintendent pharmacist or pharmaceutical technologist
 - 1.3.3. Any individual buying medicines online can check if the website is legitimately registered and will be able to check the Health safety code for verification.

2. Documentation

- 2.1. The pharmacy procedures must be documented in writing and/or electronic form. The pharmacy procedures and records must be available at the premises for inspection by the:
 - 1.3.4. superintendent,
 - 1.3.5. authorized pharmacy staff, and
 - 1.3.6. PPB inspectors

- 2.2. Appropriate records must be kept for everything
- 2.3. The person carrying on the pharmacy business must ensure the pharmacy records are preserved for a period of not less than five years commencing on:
 - 2.3.1. in the case of a record in electronic form, the day on which it is created
 - 2.3.2. in the case of a written record, the last day to which the record relates.
- 2.4. The person carrying on the pharmacy business should ensure that there is an in-built mechanism:
 - 2.4.1. To alert and thereby restrict excessive/multiple orders of medicines.
 - 2.4.2. To ensure Prescriptions for Controlled Drugs (CDs) **are not** be supplied via the internet.

3. Dispensing

- 3.1. Patients are entitled to expect the same quality of pharmaceutical care irrespective of whether the service is provided on-line or face-to-face on the pharmacy premises.
- 3.2. When selling or supplying medicines via the internet, the pharmacist or pharmaceutical technologist must:
 - 3.2.1. Ensure that advice is available to all prospective purchasers of medicines and vitamin and mineral supplements. This is in addition to and/or to supplement the information contained in the PIL (Patient Information Leaflet);
 - 3.2.2. Establish that the intended user is the person requesting the product: sufficient information about the patient and the condition(s) being treated must be obtained;
 - 3.2.3. Assess the suitability and safety of the product for the intended user and ensure that it is appropriate for the reported indication;

- 3.2.4. Provide appropriate counseling or advice on the safe and effective use of the product to be supplied. The patient should be provided with a contact telephone number on which they can access appropriate information and advice from a suitably trained professional;
- 3.2.5. Be aware of the potential abuse of some medicines and other products. The pharmacist or pharmaceutical technologist must have measures in place to identify requests for large quantities of a product, or abnormally frequent requests and thereupon refuse to make a supply where there are reasonable grounds for suspecting misuse and/or abuse;
- 3.2.6. Advise the patient to consult a local pharmacy or other appropriate healthcare professional whenever a request for a medicine or the symptoms described indicate that the patient's best interests would be served by a face-to-face consultation;
- 3.2.7. Inform the patient of the identity of the pharmacist or pharmaceutical technologist assuming professional responsibility for the supply of medicines.
- 3.2.8. Verify the authenticity and validity of the prescription;

4. Information and advice

- 4.1. Patients are entitled to expect the same quality of pharmaceutical care irrespective of whether the service is provided on-line or face-to-face on the pharmacy premises.
- 4.2. When providing internet pharmacy services, the pharmacist or pharmaceutical technologist must ensure that:
 - 4.2.1. Generic healthcare advice (i.e. not specific to the patient) provided on pharmacy websites is accurate, up-to-date and presented in a professional manner;

- 4.2.2. All information relating to specific products complies with the marketing authorization, the patient information leaflet (PIL) and relevant legislative requirements;
- 4.2.3. Information relating to medicines includes all relevant details of contraindications and side-effects;
- 4.2.4. Product recommendations are given only in respect of individual patients;
- 4.2.5. Any advertising or publicity complies with relevant legislation. Promotional material the pharmacist authorizes, or for which he is responsible, must be accurate and honest and must not abuse the trust, or exploit the lack of knowledge, of the public;
- 4.2.6. Any advice and/or written information is provided to the patient in English or Swahili.

5. Delivering of medicines

- 5.1. When delivering medicines, the pharmacist or pharmaceutical technologist must:
 - 5.1.1. 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;
 - 5.1.2. Ensure the integrity of cold chain and safe transportation of liquid or other vulnerable packaging;
 - 5.1.3. Ensure medicines are packed, transported and delivered in such a way that their integrity, quality and effectiveness are preserved. Care must be exercised with thermo-labile products;
 - 5.1.4. Ensure that the delivery mechanism used provides a verifiable audit trail for the medicine from the initial request for a medicine through to its delivery to the patient, or its return to the pharmacy in the event of a delivery failure;
 - 5.1.5. Ensure that delivery mechanisms safeguard confidential information about the individual patient's medication.

6. Record keeping

- 6.1. The pharmacist or pharmaceutical technologist must maintain records about online consultations and medicines supplied which are sufficient to guard against risks of abuse or misuse. A verifiable audit trail from the initial request for a medicine through to its delivery to the patient must exist.
- 6.2. A pharmacist or pharmaceutical technologist providing internet pharmacy services must maintain records of:
 - 6.2.1. The identity of customers (i.e. name and address) who have been supplied with medicines via the internet;
 - 6.2.2. Details of the medicines requested and supplied;
 - 6.2.3. Details of any consultation with the patient or prescriber, interventions made and/or advice given;
 - 6.2.4. The information upon which decisions to supply were made;
 - 6.2.5. The identity of the pharmacist or pharmaceutical technologist who has assumed professional responsibility for supply of a medicine following an online request to purchase;
 - 6.2.6. All relevant records must be maintained for a period of not less than 5 years.

7. Security and confidentiality

- 7.1. The confidentiality and integrity of all patient information is protected to the standard specified by the International Organization for Standardization (ISO) in ISO/ IEC 27001:2005 and should adhere to the Data Protection Act of Kenya.
- 7.2. All patient data transmissions are encrypted to prevent the possibility of the internet service provider or any other unauthorized party accessing patient information either accidentally or deliberately;
- 7.3. Patient information is backed up daily and kept in a secure, fire-proof system.

- 7.4. Any requests for information on a patient's medicines must only be made by either the patient or an agent acting on his behalf and be fully verifiable.

8. Website requirements

- 8.1. Patients must be able to easily identify who is operating an internet site from a registered pharmacy premises.
- 8.2. Pharmacy websites must clearly and conspicuously display:
 - 8.2.1. The name of the pharmacy owner and/or superintendent pharmacist or pharmaceutical technologist;
 - 8.2.2. The address of the registered pharmacy premises at which the business is conducted, as well as, the premises registration number, email address and telephone number;
 - 8.2.3. Information about how to confirm the registration status of the pharmacy and pharmacist or pharmaceutical technologist;
 - 8.2.4. Details of how to make a complaint about the online services provided;
 - 8.2.5. The Health safety code;
 - 8.2.6. An Extended Validation SSL (EV-SSL) certificate indicating to users that the website is secure and encrypted in terms of an individual entering any sensitive information.

9. Technology Equipment and Software

- 9.1. The pharmacy must have validated and fit-for-purpose technology equipment and software needed to provide online pharmacy services. Examples include dispensing systems, labeling equipment and mobile devices used for remote access.
- 9.2. There must be plans on how to manage the risk of IT equipment and software failure and disruptions.

- 9.3. IT equipment must:
 - 9.3.1. Meet the latest security specifications and the security of data should be protected when it is in transit, by either wired or wireless networks;
 - 9.3.2. Be calibrated, maintained and serviced regularly in line with the developer's specifications.
- 9.4. Software and operating systems must:
 - 9.4.1. be robust enough to handle the volume of work
 - 9.4.2. have control systems built in to help manage risk, such as alarms or alerts for:
 - a) Orders for controlled medicines;
 - b) Suspicious, excessive or multiple orders of medicine;
 - 9.4.3. keep records of all decisions made, and dispensing records for all medicines and medical products.

10. Quality Assurance

- 10.1. The management must make regular audits of the following:
 - 10.4.1. Personnel: Staffing levels, skills and training gaps,
 - 10.4.2. Communication systems between staff, prescribers, other healthcare workers, patients and clients,
 - 10.4.3. Quality of professional services,
 - 10.4.4. systems and procedures for receiving prescriptions,
 - 10.4.5. systems and procedures for dispensing prescriptions,
 - 10.4.6. systems and procedures for secure posting and delivering medicines and other products,
 - 10.4.7. documentation and records
 - 10.4.8. Validation of IT equipment and software,
 - 10.4.9. security and confidentiality,
 - 10.4.10. Information on the website,
 - 10.4.11. Customer complaints and feedback.

10.2. Audit schedules and reports must be availed to the PPB inspectors when required.

11. Validity of Licenses

The licenses issued for internet pharmacy shall expire on the 31st day of December of the year it is issued but will be subject to renewal

12. Suspension or Revocation of Internet Pharmacy License

The Board has the power to revoke the online pharmacy license if it has been closed or if the conditions under which the license was issued are no longer being met.

13. Closure of Internet Pharmacy Services

13.1. The Board must be notified when a licensed establishment operating an online pharmacy is to cease operations and close.

13.2. Where a pharmacy is closed for any reason for a period longer than three months, the Board must be notified.

13.3. The closure of a pharmacy and ceasing to have a financial interest in the pharmacy business should be notified in writing to the Board, within 14 days of closure.

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