Kenya Pharmaceutical Association

Pharmaceutical Excellence

SELF REGULATION STANDARDS

2022

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Contents:

FOREWARD

Kenya Pharmaceutical Association (KPA) is committed to ensuring provision of safe, quality, accessible and affordable health services in collaboration with the Ministry of Health the Pharmacy and Poisons Board and other key stakeholders.

KPA advocates for the establishment of a self-regulation frameworks for the healthcare professions in Kenya. Self-regulation in the pharmacy profession is a progressive tool to enforce high level standards of pharmaceutical care services provision. This is in line with the provisions enshrined in the Bill of Rights of the Constitution of Kenya (2010), in Article 43 (a) which provides that every person has a right to the highest attainable standard of health, which includes the right to health care services, including reproductive health care. Self-regulation will help to ring-fence the practice from charlatans, through clearly laid down networks of pharmacy professionals embracing self-regulation.

There has been a long history of regulation of the professions in many countries, and this has taken many forms from explicit command and control regulation to self-regulation or co-regulation. The overriding objective of professional regulation is generally to protect members of the public who use the services offered by the profession by providing information and ensuring the quality and safety of the healthcare services provided, and to protect the reputation of the profession itself.

Self-regulation typically involves professional associations, voluntarily developing rules or codes of conduct that regulate or guide the behavior, actions and standards of its members in professional practice. Examples of self-regulation instruments include: codes of practice; codes of ethic, service charters, branded networks, clustering/zoning, industry-based accreditation arrangements; quality assurance/audits; and voluntary adoption of standards.

Consumers therefore rely on the professional competence of the service provider to inform them of the options and in some cases to recommend appropriate courses of action. The most important level of “self-governance” of the healthcare profession involves the voluntary, personal commitment by individual professionals to self-regulate by adhering to the tenets of professionalism, and being earnest in upholding the interest of their patients and the public.

The self-regulation standards for KPA is intended to serve as a resource and guide to pharmaceutical technologists practicing pharmacy in both public and private sectors in Kenya with an aim to provide patient-centric services. We believe that these guidelines will be key in enhancing the much needed transformation in pharmacy practice in Kenya.

Eric Gichane
Hon. Secretary General
Kenya Pharmaceutical Association

ACKNOWLEDGEMENT

The National Executive Council of KPA, the committee members on self-regulation standards, have been very committed to the development of this document, researching far and wide on effective self-regulation standards. The Legal services provider for KPA, the legal department of the Pharmacy and Poisons Board (PPB), the PPB secretariat have been key in reviewing the document for coherence and collegiality.

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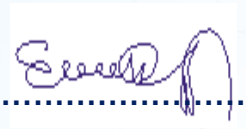

Signed by: ……. on this Date: ……..…25/11/2022……..……

Hon. Eric Sedah, President.
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Hon. Eric Gichane, Secretary General.
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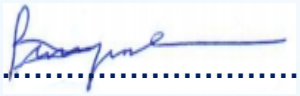
In the presence of;

Hon. Benjamin Mbugua, Board of Trustees Chair.
Kenya Pharmaceutical Association



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INTRODUCTION

The Pharmacy profession encompasses unique knowledge and special skills derived from research, continuous education and training. In Kenya, Pharmacy professionals practice in various capacities in the different fields of the profession. These diverse orientations are key pointers in the actualization of KPA's vision and mission. Pharmaceutical Technologists practice in various capacities and different fields of the profession such as: private and public service sectors, hospital pharmacy, community pharmacy, research, marketing, industrial pharmacy, training, regulatory bodies, parastatal/NGOs, learning institutions, pharmaceutical companies, manufacturing companies etc, where the professionals have consistently offered excellent services to Kenyans since mid-20th Century.

The geographical spread of their practice is widely distributed in all the 47 counties across the country (rural, urban, remote and marginalized areas) enabling the general public access to the highest attainable quality pharmaceutical care as enshrined in our constitution. Pharmaceutical technologists have been in the frontline in the provision of efficient, effective pharmaceutical services that are sustainable, equitable, accessible and affordable, with safe, efficacious and high-quality medicines.

While we appreciate the immense regulatory work done by the Ministry of Health and the Pharmacy and Poisons Board, centered on safe patient care, we acknowledge that there still exist challenges brought about by charlatans, most of whom deal in fraudulent, substandard and falsified commodities and provide unethical service to the public. This lowers public trust, presents safety concerns and raises antimicrobial resistance (AMR).

In this regard, KPA partners with the Ministry of Health, Pharmacy and Poisons Board and other stakeholders in the continuum of pharmacy care, in ensuring sound professional practice is upheld through self-regulation. Self-regulation provides a framework for the professional associations to self-govern their members by way of setting the standards of practice. Kenya Pharmaceutical Association has now developed these standards and attendant client-signaling to address these challenges and discourage "quacks" who compete unfairly for the same consumers with the licensed professionals. Further, a co-branding initiative between PPB and KPA could help the public easily identify safe and reliable pharmacy outlets.

Self-regulation

Self-regulation is an internal initiative by KPA that establishes and enforces standards of education, training and practice. It involves many levels of oversight aimed at guaranteeing the competence of the practitioner and by extension the safety of the patient. Some of the activities that have been and continue to be carried out with skill and rigor include accreditation of medical schools, training and capacity building programs, licensure and certification of professional practice.

Pharmaceutical technologists have purposely chosen to become self-regulating professionals, through KPA. This conscious choice augments the drive to ensure that patient safety remains firmly entrenched at the heart of the pharmacy practice, while addressing the major obstacles for credible self-regulation. This includes providing assurance that those in practice maintain their competence; taking appropriate action once a problem with an individual practitioner has been identified and addressing conflicts of interest as defined by the KPA code of ethics.

Objective

For KPA members, self-regulation focuses on establishment and enforcement of professional pharmacy practice standards, with the aim of delivering quality assured service to the patient. KPA subscribes to the seven (7) inalienable rights of logistics to the patient/client that form the basis of the quality service framework. These rights of logistics are:

1. Right Product; Authentic.
2. Right Condition; Storage and packaging
3. Right Quantities; Proper prescription
4. Right Place: Registered Premises
5. Right Time; Inventory management
6. Right Cost; Ensuring access
7. Right Personnel: Licensed professional

Operationalizing the self-regulations standards is done through development of a network of self-regulated pharmacy professionals

The Network

The KPA branded network of pharmacy professionals is an important first step in addressing the above highlighted issues. For successful brand implementation, quality protocols have been developed, which members abide by. The network brand stands for quality hence boosting client confidence/faith and optimizing member benefits of the common branding. This brand serves the sole purpose of differentiating between the regulated and unregulated pharmacy service provider.

The consumers benefit from the assured quality of product, consistency and therefore predictability of pricing, high quality of service and remedial measures for any complaints. This is done at two levels: at the pharmacy level through its procedures and at the network level through the uniform code of conduct that members subscribe to. The member gets the benefits of peer support for quality improvement, assured product quality due to network-level vetting of the supply chain, consumer confidence in the brand which may translate into increased volumes of sales as clients shift from "quacks" to network pharmacies.

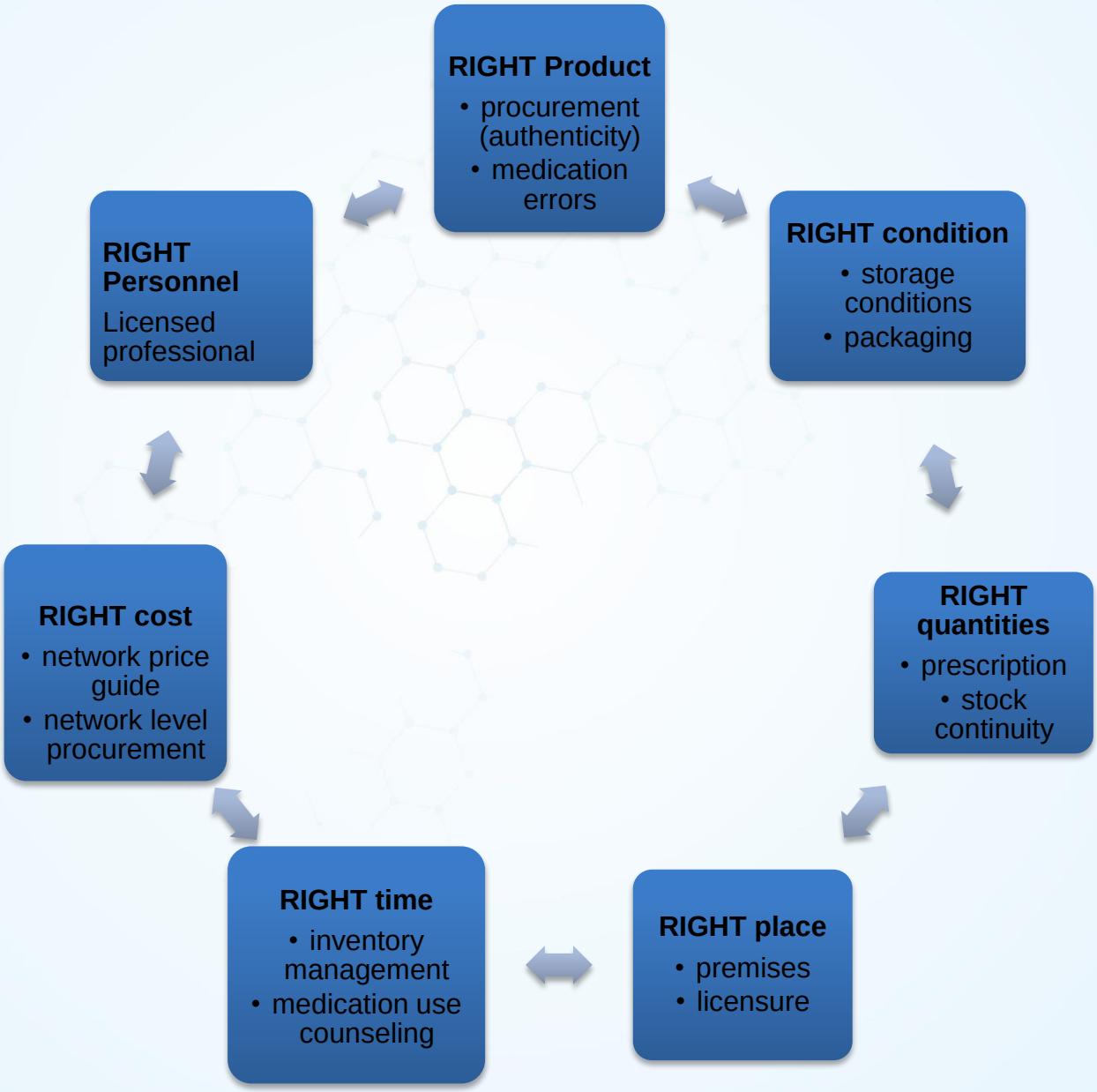
The branded network works through clustering of pharmacies into zones for self-regulation. The clusters work under their respective KPA branches and are responsible for ensuring compliance by all members under the cluster. Non-compliance results in disciplinary action being instituted against the errant member as per the KPA code of ethics. Clusters incorporate members within reasonable geographic proximity so that peer audits and peer support are easy to organize and implement cost effectively.

The role of the KPA branches is to ensure that clusters are carrying out required audits within the zone and across the zones to ensure brand integrity. The branch is responsible for reviewing applications by new members intending to join the network, carrying out pre-entry inspection of members' premises and practice, and making recommendations to the national office. It is also responsible for reviewing cases of non-compliance, supporting non-compliant members to move to fully comply with network standards, and recommending the suspension of network membership of non-compliant members. The branch is additionally charged with the duty of training members and their staff on network standards with the support of the national network office. Dispute resolution where cluster members contest the assessment made by the cluster audit team is handled at branch level and may be escalated to the national network office to carry out an independent audit.

The network's success is anchored on quality care standards that guide self-regulated pharmacy practice. These standards are elaborated in the section below.

1. QUALITY ASSURANCE

Quality assurance is the prevention of quality related problems through planning of activities and processes that work to deliver the product or service in question. The primary purpose of community pharmacy practice is summed up in the Seven "Rights" of Logistics:



2. THE KPA BRANDED NETWORK QUALITY MANAGEMENT SYSTEM

The anticipation of quality challenges that will affect the product (the medicine), the service (the quality of dispensing and medication use-counseling) and the consumption of the product and service (the safe use of the medicine at home) therefore form the key elements of the network's quality assurance concerns and plan.

The network quality management system will therefore work to ensure that the **authentic medical product**, procured from the **correct source** in the most **efficient way**, and having been **stored and later packed** in a manner that **maintains its potency**, is **dispensed correctly** and the **right advice** given to the client on its safe use for **maximum efficacy**

2.1 Network Quality Management System

Supply Chain (NETWORK)	Standard Operating Procedures (PHARMACY)	Quality Audits (PHARMACY & NETWORK)
• Product authenticity • Cost control (where possible)	• Product integrity • Task consistency • Quality of service	• Pre-entry review • Quality improvement • Brand protection

2.1.1 Procurement and Supply Chain

As has been indicated, about 30% of medicines sold in Kenya are reported to be counterfeit by the PPB. Once a counterfeit medicine is in the supply chain, no amount of correct prescribing, storage, dispensing and medication use counseling can remedy its effect- possibly lack of efficacy, and at worst, direct harm from harmful ingredients. This is why product fidelity is at the top of the quality priority in community pharmacy practice. Counterfeit drugs find their way into the market through unethical wholesalers and the procurement of pharmaceuticals from unauthorized sellers such as those that have been referred to locally as "briefcase importers". The harm of counterfeit drugs is not one that can be remedied by good storage, correct prescribing, meticulous dispensing, or great medication use counseling.

Also common in Kenya are medicines that are of locally registered brands but which are meant for restricted use in other countries and are brought in by unauthorized sellers who move from pharmacy to pharmacy (briefcase sellers). Many pharmacy outlets view these as more benign parallel imports and often procure them for their lower prices and larger profit margins. These commodities, however, being imported in a clandestine manner, are not stored in conditions fit for pharmaceuticals for human use. Their probable loss of potency cannot, similarly to the overt counterfeits, be remedied by any measures that may be taken.

Given the grave nature of the quality loss that comes from holding inauthentic stock, the network will seek to seal these loopholes by screening and identifying reputable wholesalers and possibly manufacturers to supply network members, either by billing member pharmacies directly or through central procurement arrangements that may be worked out progressively. The benefits of this arrangement would be twofold- ensuring that the stock held in network pharmacies is authentic and has been handled to the highest of standards for maintenance of quality before delivery, and in allowing the network to negotiate volume discounts. Money saved through this central procurement can go towards or be split between paying for network running costs, improved profit margins for the network members, and lower costs to clients at the pharmacy.

2.1.2 Standard Operating Procedures

Once the correct product is in the pharmacy, it must be stored in a manner that ensures the retention of physical quality and potency, and in keeping with storage rules for medicines as outlined in the Pharmacy and Poisons rules and Narcotics and Psychotropic Substances Act. The storage arrangement needs to be predictable to ensure correct and quick identification of the product during dispensing, and also prevent contamination of medicines or packages of medicines by other medicines and non-medical liquids that could spill. At dispensing, medicines must be properly packaged and labeled and comprehensive and effective medication use counseling given. All persons authorized to do them regardless of experience must do all these processes in a consistent manner. For this reproducibility to happen, there need to be Standard Operating Procedures that describe the way in which to do the process. SOPs set a standard for how a process should be carried out, allow for review of processes for compliance, and are useful also for training and inducting new staff or pre-registration students that may come through the pharmacy and carry out certain processes.

There are certain SOPs that are regarded by the network as crucial and entry into the network will require that applicants have developed written SOPs for these processes and are using them or have adapted network SOPs for this purpose. SOPs should be prepared in a consultative manner between all the persons responsible for the process described in the SOP, they should then be reviewed and authorized by the person in charge of the process, in this case the Superintendent Technologist.

A Standard Operating Procedure (SOP) is a set of **written** instructions that document a **routine or repetitive activity** followed by an organization. The development and use of SOPs are an **integral part** of a **successful quality system** as it provides individuals with the information to perform a job properly, and facilitates **consistency** in the **quality** and **integrity** of a product or service

2.1.3 Creating a Standard Operating Procedure:

SOPs answer the following questions:

What is the task being performed?

Who performs the task?

Where is the task performed?

What is the procedure for the task?

SOPs also have to be approved, signed and dated so that subsequent review dates are agreed upon and are scheduled, and new versions have new dates. They should be written in everyday tense. They should be kept prominently where the task they describe is to be performed and a copy should be kept in a master list of institutional SOP files. An example of a simple SOP is given below.

Title: Standard Operating Procedure for Dispensing Controlled Drugs

No of pages: 1/1 **Procedure No.** PD/06

Version: 1/1 **Date:** 12/1/2014 **Review Date:** 12/1/2015

Objective:

To describe the procedure for the correct dispensing and documentation for controlled drugs in the pharmacy

Responsibility:

The Superintendent Pharmaceutical Technologist

Resources:

Controlled Drugs Register, Prescription

Procedure:

1. The technologist in charge or other designated authorized person reviews and authenticates the original prescription
2. The technologist checks that the doses are appropriate for the age weight and other parameters of the patient
3. The technologist opens the Controlled Drugs cabinet, retrieves the correct quantity of medication, and packs and labels it as provided in the prescription.
4. The technologist makes a record of the prescription in the Controlled Drugs register, balances the ledger for the specific medicine, and signs on the prescription and in the register.
5. The technologist gives the medicine to the patient with medication use counseling as required.
6. The technologist makes a copy of the prescription and files the original prescription in the Controlled Drugs file and a copy in the regular prescription file if other medicines were dispensed as well on the same prescription.
   Note: Controlled Drugs prescriptions are not to be dispensed partially and the original prescription must be retained.

ISSUED BY: **APPROVED BY:**

Sign/Date: **Sign/Date:**

2.2 Quality Audits

A Quality System Audit is the periodic and documented examination and verification of activities, records, and processes of a quality system. The network has developed a quality checklist that is to be used for this. There would be three levels of quality audits:

2.2.1 Self-audit

This is the use of the audit checklist by the network member pharmacy to assess the extent of its own compliance with the network's quality provisions. This is a useful way for the member pharmacy to ensure that its standards continue to be maintained. A non-member intending to apply for membership may also use this to assess their readiness to join the network and what changes they may need to make to meet the network's minimum standards.

2.2.2 Peer audit

This is the review of compliance by a set of peers selected by the cluster, the branch, or the franchise national office. The purpose may be for assessment of applicants for membership, or for review of the compliance status of members and support to these franchisees to improve their quality standards.

2.2.3 External audit

This would be commissioned by the national franchise office at randomly selected member pharmacies to assess compliance of members, branches and the entire franchise network. This may incorporate additional checks beyond the use of the checklist including client and community perception indicators.

Carrying out an effective audit requires a number of things:

1. **Direct Observation**- all quality elements that are observable within the time set aside for a quality audit should be independently observed by the person carrying out the audit.
2. **Good faith**- the Superintendent of the pharmacy being audited should be present, should be the main respondent, and should allow access to staff and allow them to answer questions independently. All required documents should be made available and answers for elements that are not observable- such as whether the Superintendent Technologist is always at the pharmacy whenever the pharmacy is open- should always be completely truthful. The audit team should also present it as a process to encourage quality improvement rather than a negative fault-finding process. It should also be made clear at the beginning of the audit that the results are confidential and only for the use of the network.
3. **Triangulation**- Peer audits should ideally be done by two or three people so as to more easily agree on some of the indicators that require judgment of the enumerator e.g. the floor cleanliness in a rural farming community will be different from that in an urban area and therefore the checklist will ask whether it is "acceptably" clean. These may need to be agreed upon if rated differently by different members of the team.
4. **Feedback**- the member whose pharmacy is being assessed should be given feedback in a timely manner and in a supportive tone that encourages quality improvement and compliance and allows responses from the member themselves to the assessment made.
5. **Appeal system**- the member being assessed should have a reliable and responsive tiered system for registering their disagreement with the results of an

audit at the cluster, branch and national franchise office levels. This enhances the members' confidence in the process and improves its acceptability.

The audit checklist for the network distinguishes 3 categories:

- **Regulatory standards**- these are minimum legal requirements as spelt out in the Pharmacy and Poisons rules under the Pharmacy and Poisons Board in Cap 244 of the Laws of Kenya
- **Network Minimum Standards**- these are additional quality standards that are required for entry into and maintenance of network membership
- **Network Best Practice Standards**- additional network standards that are strongly recommended for the highest level of quality in network pharmacies.

2.3 The Audit Sequence

Every audit, except for self-audit where not feasible, should be done by 2 or 3 persons- this helps with triangulation and contextualization of standards that may require a degree of judgment. The audit sequence is as follows:

1. **Scheduling**- persons being audited should routinely be informed when an audit team will be visiting. This enhances a presumption of good will. The time should be convenient to the member, probably when there is least client traffic at the pharmacy
2. **Introduction**- the audit personnel introduce themselves to the member being audited. It is important to spend some time ice-breaking, familiarizing the member with the confidentiality with which all network audit information is treated, and the positive nature of the exercise.
3. **Overview** of the audit checklist- the interviewers may go over the major sections of the tool and what they will ask, and also inform the member that the exercise will take about an hour of their time.
4. **Actual audit**- going through the questions, taking care to observe and carry out any recommended validation exercises in the checklist fully. This should be done patiently, if clients come to the pharmacy, the audit should be interrupted to allow the member to serve the clients if there is no one standing in for them.
5. **Feedback-** general quick feedback on the areas that are the member is compliant and the areas where compliance could be attained through mechanisms that may be suggested. The member is thanked for the participation and the audit ends.
6. **Closure –** The necessary corrective action will be taken in line with the Code of Ethics

3. PERSONNEL AND LICENSURE

3.1 NETWORK PERSONNEL AND LICENSURE STANDARDS

REGULATORY STANDARDS	NETWORK MINIMUM STANDARDS	NETWORK BEST PRACTICE STANDARDS
Pharmacy registered by the PPB Superintendent Pharmaceutical Technologist enrolled by the PPB. Superintendent Technologist has valid practicing licence Superintendent presides over only one pharmacy outlet Only pharmacists and pharmaceutical technologists dispense PoM medicines Technologists and pharmacists undergo continuous professional development recognized by the KPA	Network pharmacy has written job descriptions document that identifies the roles of various cadres of staff This should form part of the induction for any new persons coming to work in the pharmacy. Network pharmacy employees are trained in network standards and requirements and are assessed and retrained as necessary. All regulated professionals are duly qualified and in good standing.	Network pharmacy has only pharmaceutical technologists and pharmacists handling any medicines

3.2 RATIONALE

The licensure of professionals working in the pharmacy bars those who do not meet this standard from providing these services and attempts to raise the quality of services consumers receive as a result. There are two in-built quality control measures: first the basic qualifications for licensure are met through education and pre-licensing examination. Secondly, the renewal of licences and the requirement of continuous professional development for this renewal incentivizes keeping up with current knowledge and skills in the profession to the benefit of the consumer. Display of licences builds confidence by providing proof of adherence to the above.

Standard Operating Procedures provide a written commitment by the pharmacy to adhere to specific tasks being carried out only by authorized cadres. This adherence improves the quality of service offered to the client because it limits grave medication errors that may originate in the pharmacy because of inadequate training and experience of unauthorized persons carrying out tasks.

Training and systematic induction of new employees or students ensures that standards are maintained in spite of turnover of personnel and mistakes do not occur because new people are unfamiliar with the network standards. In addition to the standards, trainees must understand the importance of the franchise and of maintenance of franchise compliance and membership.

3.3 COMPLIANCE

The verifiable quality elements from this section are a required minimum for network entry- either as provided for under regulatory standards of the PPB or network minimum quality standards. The licensure elements are fairly straightforward. Additional tips for compliance are in the box below:

- Require current licenses for recruitment of pharmaceutical technologists and pharmacists. Consider paying for license renewals as a business expense.
- Plan in advance for CPD throughout the year- while taking advantage of ad hoc opportunities as well. Have a quarterly target of CPD points.
- Write out a role definitions describing scope of tasks, integrate these into employee contracts to prevent performance of unauthorized tasks.
- Prepare an induction package for new employees and students consisting of network quality documents- manual, checklist, SOPs; and verify that these have been reviewed
- Internally audit the processes involved

4. PREMISES

4.1 PHARMACY SET-UP

4.1.1 NETWORK STANDARDS FOR PHARMACY SET UP

REGULATORY STANDARDS	NETWORK MINIMUM STANDARDS	NETWORK BEST PRACTICE STANDARDS
POM medicines section is separate from the rest of the pharmacy and lockable	Pharmacy displays network affiliation, and opening and closing hours clearly	Network pharmacy has prominent signage showing the name of the pharmacy
The premises are secure- the doors, windows and other openings are set up to prevent entry and access to medicines when the pharmacy is closed	The premises are well lit and well ventilated in all areas	Medication use counseling area is available that has auditory privacy
	Safe drinking water is available in the pharmacy, and served in hygienic containers	Pharmacy has disability-friendly access
	There is a provision for seating for clients who may be weak or unable to stand when waiting	

4.1.2 RATIONALE

Pharmacy premises need to be secure to prevent unauthorized access to medicines- when medicines are stolen from the pharmacy they may be stored and used unsafely; break ins may also target medicines that are addictive such as benzodiazepines and other psychotropic drugs, or those that may be used as raw materials for illegal drugs such as pseudoephedrine. Separation of the POM section from the rest of the pharmacy is also prescribed to restrict access to these medicines to authorized persons only.

The set-up of the pharmacy should be friendly and welcoming; shelving and displays should allow quick access to medicines for efficient dispensing. Lighting is important for the correct identification of medicines during dispensing to prevent medication errors. The pharmacy should also be well ventilated and should be a healthy environment for the employees. Lighting and ventilation, in addition to the supply of safe drinking water is also provided for under the Factories and Other Places of Work Act of the laws of Kenya and a pharmacy as a work place is expected to comply. Patients who need to start taking the medication they have bought immediately may also need drinking water. Drinking quality water is also essential for reconstitution of powders for oral suspension.

Good comprehensive signage that is clear shows the pharmacy name and network affiliation; and the clear display of opening and closing hours enhances confidence and predictability of services that clients can expect.

Medication use counseling also often involves the conveying of private patient information either by the patient or the pharmacy staff. It is important that this is done in a way that is not embarrassing and that enhances the confidence of the client- the client may not listen keenly enough to instructions, may be hurried, may fail to ask important questions, and incorrect use of medicines may result. Auditory privacy is therefore recommended to allow for confidential and comprehensive medication use counseling.

4.1.3 COMPLIANCE

- Design interior of pharmacy with legal requirements in mind
- Burglar proof- windows, doors and other openings
- Use network colours for bold singular signage- understand local authority requirements for signage
- Make maximum use of natural lighting, add additional lights to dispensing rooms if necessary; energy saving bulbs may cut down costs
- Open windows, fans may be used to ensure air movement
- Invest in a water filtration system for drinking water to keep costs low or a dispenser for bottled water if preferred, or other source of potable water
- Use recyclable disposable paper cups/tumblers if effective cleaning may be challenging; for reusable glasses, ensure good cleaning with hypochlorite before washing with soap for good hygiene
- Use pharmacy consultation room for medication use counseling for cases where additional privacy is needed if a private dispensing booth cannot be provided

4.2 CLEANLINESS AND TIDINESS OF THE PHARMACY

4.2.1 NETWORK STANDARDS FOR CLEANLINESS AND TIDINESS

REGULATORY STANDARDS	NETWORK MINIMUM STANDARDS	NETWORK BEST PRACTICE STANDARDS
Pharmacy has running water and a sink Floors and Walls are clean	Pharmacy floor is clean and free of visible dirt at all times Walls are clean and dry and free of water seepage, dust and dirt Shelf surfaces are clean and free from dust	Non-medical business of the pharmacy is separate from the pharmacy items The staff have a hand washbasin with soap Hand disinfectant is available in the dispensing area and used before handling medicines during dispensing There is a SOP for infection control displayed in the pharmacy

4.2.2 RATIONALE

Hand washing and disinfection prevents the transmission of infections to patients through contamination of medicines and medicine packages through handling. Staff come into contact with germs from surfaces, shaking hands, and from being infected themselves. While most common infectious agents will die rapidly on dry surfaces, many viruses, cysts and spores will survive and even light contamination carries a risk transmission to patients.

The pharmacy must be free of leaks through the roof and walls since this can damage medicines causing losses and mould growth that may cause risk to staff and patients.

Cleanliness and tidiness also promote a positive impression of the pharmacy when clients walk into it and build confidence in the product and services offered. Separation of any non-pharmacy business from pharmaceuticals enhances a professional image of the pharmacy.

4.2.3 COMPLIANCE

- Incorporate design requirements of the pharmacy as outlined by PPB inspectors
- Prepare and display SOP on infection control, lead by example in adhering strictly to it and forming the habit of hand washing/ disinfection among pharmacy employees
- Arrange for routine cleaning, scheduled cleaning/dusting of surfaces should be on a roster and confirmed by being signed; frequency may depend on the extent of exposure to dust. This may be subject to its own SOP.
- Where feasible, protect medicines on display shelves using sliding glass doors to reduce contact with dust
- Hand disinfectant may be made locally in the pharmacy if preferred by using ethanol and glycerin

5. COMMODITY MANAGEMENT

5.1 PROCUREMENT AND STORAGE OF MEDICAL COMMODITIES

5.1.1 NETWORK STANDARDS

REGULATORY STANDARDS	NETWORK MINIMUM STANDARDS	NETWORK BEST PRACTICE STANDARDS
Pharmacy only stocks registered brands of medicines and other medical commodities	A refrigerator is maintained for refrigerable medicines	Suppliers are vetted and prequalified by the network
Pharmacy only buys from registered and licensed wholesalers and distributors	No items other than medicines are kept in the fridge	Pharmacy only procures medicines from prequalified suppliers
Pharmacy keeps a file of all purchases of medicines	A thermometer is kept in the fridge and a temperature-monitoring log is kept to track fridge temperatures	Medicines are arranged in order of expiry to facilitate FEFO (first-to-expire-first out) and FIFO (first in, first out)
Medicines are stored in such a manner as prescribed to maintain their integrity and potency	SOP is written and displayed of the process for storage and handling of refrigerable medicines	SOP is written and displayed for the receiving, checking and storage/arrangement of medicines
Controlled drugs are kept in a locked cabinet clearly marked	SOP is written and displayed for the handling and dispensing of controlled drugs	Pharmacy has stocks of all medicines on the network's essential list in stock at all times
A register is maintained for controlled drugs and is kept current at all times	Medicines in the pharmacy are protected from excessive light and heat	

5.1.2 RATIONALE

The stocking of only registered brands of medicines whose quality at entry has been ascertained by the PPB is important for ensuring a minimum standard of quality of the commodity. The procurement of these medicines only from vetted wholesalers with a high level of ethical conduct and the additional motivation of staying on the network's list of approved wholesalers further works to prevent the intrusion of counterfeit medicines into the supply chain for network pharmacies. This assures the quality of the product that is sold at network pharmacies to enhance trust of both prescribers and consumers. Purchases of medicines are supposed to have a clear paper trail that allows audit and traceability of medicines. Being able to trace medicines is critical for medicine safety- such as the ability to recall medicines that may have had problems that failed to be detected at manufacture and during storage through the distribution process.

Controlled drugs are so classified because of the potential for abuse and the fact that they may have a monetary value in illegal markets that surpasses their direct value in the pharmacy. This way, they can be subject to unauthorized procurement and disposal in the pharmacy and this makes the profession's custodial role over them ever the more important. Abuse of this role also therefore carries considerable legal penalty.

Proper storage of medicines requires that they retain their potency and appearance by being protected from excessive heat and light, and are easily and quickly retrievable because of orderly arrangement. Most drugs maintain their stated shelf life below 30 degrees Celcius, refrigerable medicines must be kept between 2 and 8 degrees Celcius. Arranging medicines using the FEFO (and FIFO- first in, first out- for same expiry) method ensures that:

- losses of medicines to expiry are limited,
- inadvertent dispensing of expired medicines is prevented,
- medicines get out at the earliest opportunity to take care of possible forays outside the acceptable temperature range within the supply chain,
- and also ensures that this happens at the time of arranging the medication rather than during retrieval for dispensing when this might not be meticulously observed

Medicines found in the retail pharmacy that need refrigeration most commonly have to be kept between 2 and 8 degrees Celcius with the requirement that they should never be frozen. Freezing and thawing may interfere with the physical integrity of some medicines such as insulin and this may interfere with efficacy. Prolonged exposure to temperatures outside this rate would also have the same effect. This is the reason temperature monitoring for medicine fridges is recommended. Too much variation in temperature caused by frequent opening and closing of the fridge should be avoided such when non-medical items of more frequent use such as food are kept in the fridge. This also causes the risk of cross-contamination.

5.1.3 COMPLIANCE

- Use licensed and reputable wholesalers; if the network vets and recommends wholesalers, these should be exclusively used
- Keep designated file for all delivery notes for all medicines procured
- Prepare and ensure all staff are familiar with SOPs for ordering, receiving, and storing medicines
- Shade windows that could cause excess heat in the pharmacy
- Set aside and mark as such the refrigerator for medicines only

5.2 INVENTORY MANAGEMENT

5.2.1 NETWORK STANDARDS

REGULATORY STANDARDS	NETWORK MINIMUM STANDARDS	NETWORK BEST PRACTICE STANDARDS
Pharmacy keeps a record of all medicines bought Pharmacy sets aside damaged, expired, or returned medicines and ensures their destruction	Pharmacy avoids stock-outs of essential medicines by forecasting and planning A reorder system (manual or electronic) is maintained to highlight medicines in need of reorder A quarantine box or cabinet is clearly marked for storage of medicines to be disposed of	Pharmacy stays in good financial standing to ensure ability to promptly restock SOP for safe disposal of pharmaceuticals is in place A copy of the National Guidelines for Safe Disposal of Pharmaceutical Waste

5.2.2 RATIONALE

Records of medicines procured and the source is a legal requirement and an important quality assurance measure since it facilitates the ability to trace medicines back to the source for pharmacovigilance purposes such as in case of adverse drug events or recalls from post-market surveillance by regulatory bodies, a manufacturer or a distributor.

Stock-outs undermine consumer confidence in the pharmacy and can contribute to the start of a vicious cycle that causes loss of sales and collapse of a pharmacy from a business standpoint. It also undermines the brand of the network and as such franchisees that cannot keep adequate stocks may have their membership suspended until they can regain the financial standing required for maintenance of stocks.

Waste pharmaceuticals- damaged, expired, or otherwise unusable medicines- can be a danger in the dispensing room where they may be mistaken for valid medicines and erroneously dispensed, in the household where they might be used, and in the environment where they may harm people directly, harm living organisms by exposure or contaminate water sources. They must therefore be stored safely in the pharmacy and destroyed in accordance with guidelines of the PPB.

5.2.3 COMPLIANCE

- File delivery notes as part of the SOP for receiving procured medicines (batch numbers may be annotated against the stocks procured in manual systems or recorded in electronic inventory management systems)
- Carry out accurate forecasting by anticipating consumption
- Limit varieties of brands of some medicines stocked so that not too much money is tied up in the same medicines leading to stock-outs of others. The originator brand and a few price-distributed generics suffice for most pharmacies' needs
- Set reorder levels based on consumption- either in electronic inventory management systems or on the shelf for manual systems. This enables the person dispensing a medicine to check if a medicine should be reordered.
- Keep a reorder book at a designated place so that no items are missed because it could not be found- instruct all dispensing staff in its use and have an reorder schedule and a provision for emergency orders either by pre-paying or having a credit facility to ensure non-failure
- Set a quarantine box for medicines to be disposed of, keep a record of all medicines taken into quarantine and when they are destroyed.
- Obtain a copy or print a downloaded copy of the National Guideline for Safe Disposal of Pharmaceutical Waste

6. DISPENSING AND MEDICATION SAFETY

6.1 DISPENSING, PRESCRIPTIONS, AND MEDICATION ERRORS

6.1.1 NETWORK STANDARDS

REGULATORY STANDARDS	NETWORK MINIMUM STANDARDS	NETWORK BEST PRACTICE STANDARDS
Pharmacy has reference materials adequate for correct dispensing	The pharmacy has adequate supplies of dispensing equipment such as tablet counters, and spatulas and these are used for hygienic handling of loose tablets and capsules	Network has price guidelines that are adhered to by member pharmacies
Medicines are labeled comprehensively with details of the patient, the pharmacy, the medicine, the usage instructions and cautions	Liquid medicines re-bottled in the pharmacy are kept in light-resistant bottles that are kept in a clean and hygienic manner in the pharmacy	Pharmacies routinely label medicines comprehensively to prevent errors
Prescription medicines should only be given on valid original prescription	Solid dosage forms are packed in well-sealed good quality envelopes that are opaque	Medication use counseling is done thoroughly and in accordance with a complete checklist
A record of all prescriptions is kept in the pharmacy	There is a clear SOP printed/written, displayed and used for dispensing of medicines	Pharmacy has a copy of National Pharmacovigilance Guidelines
Prescriptions are filed and kept in the pharmacy for a period of at least two years	SOP for prescription handling- either integrated in the dispensing SOP or on its own	Staff are familiar with national ADR reporting guidelines
	Pharmacy routinely consults with prescribers when mediation errors are noted	Pharmacy has ADR reporting forms that are used and logged
		SOP for ADR reporting
		Pharmacy has a system to recording medication errors
		Reference books are not more than 3 editions behind current edition

6.1.2 RATIONALE

Dispensing is the final step in the delivery of quality pharmaceutical products and services. Good dispensing requires that an assessment is made of the prescription as to its validity and that it is free from prescribing errors such as drug-drug interactions, incorrect dosing, frequency, or duration of treatment. In case of suspected medication errors, or any lack of clarity on a prescription, immediate contact with the prescriber should be made. Network pharmacies should therefore have a means to contact prescribers, and a mechanism for recording prescription errors. Drug reference books are important for confirming suspected errors, for checking for possible adverse drug reactions, and checking for complete medication use counseling information for unfamiliar medicines. All these improve the safety of patients and enhance quality in this way.

Once a prescription is cleared for dispensing, good dispensing equipment protects the patient from contamination of the medicine and the person dispensing from being unnecessarily exposed to medicines. Packing the medicines properly also preserves its potency and limits its contamination after being taken away by the client. Complete labeling helps prevent medication errors that may arise from administration of the medicine at home due to a misinterpretation of the dose, frequency, or even the patient for whom the medicine is meant. The pharmacy details allow reporting of adverse drug events (ADEs) and reactions (ADR) by patients. Clear labeling is therefore required under the Pharmacy and Poisons Rules.

A prescription being dispensed should be serialized, dated and signed by the person dispensing and quantities dispensed noted. This allows the tracking of dispensed prescriptions, and facilitates filing and recording in the prescription book as required by law. The issuance of refills on old prescriptions is also made easier.

Provisions of the PPB guide current pricing of pharmaceuticals. The network may implement a network formulary with a price guide for the items. This helps with consistency within the network and predictability of costs for prescribers and patients.

Patients should be advised comprehensively about their medicines- this improves compliance to treatment and prevents errors in administration of medicine that may affect efficacy of the patient’s treatment- both leading to positive treatment outcomes.

Adverse drug reactions are unwanted effects of medications that may range from being uncomfortable to being dangerous or even fatal. Suspected adverse drug reactions should be reported to the PPB’s national pharmacovigilance unit by the filling and submission of ADR reporting forms. ADR reporting improves patient safety by contributing more information to risk-benefit analysis at prescribing, to the preparedness of health workers for possible ADRs when medicines are given, and helping patients to know more and therefore be more ready to accept harmless ADRs.

6.1.3 COMPLIANCE

- Obtain reference materials from the association and source more recent editions with newer drugs and possible changes in usage and labeling recommendations
- Buy printed adhesive labels and order printed envelopes where feasible for a more professional image. Smaller pharmacies can have a label ink-stamp made for stamping on envelopes and wide adhesive tapes for labeling
- Have a clear SOP for dispensing and handling of prescriptions.
- Make a stamp for dispensed prescriptions for serializing, noting that the prescription was signed, quantities dispensed, and the date
- Set aside space for storing prescription files beforehand and store prescriptions in an orderly manner
- Make routine the filling of the prescription book and set a deadline when prescription book has to be current such as at the end of the day or at the close of the week.
- Have a good stock to minimize partially filled prescriptions; note on partially filled prescriptions the extent to which they have been dispensed and take a copy either by scanning, photocopying or photography for the pharmacy's prescription record
- Obtain dispensing equipment such as tablet counters and spatulas from professional associations, pharmaceutical companies, or by buying them; train all new staff in using them
- Buy packaging material- e.g. bottles, envelopes, and ensure that they are well stored in marked cabinets
- Have a pharmacy phone that staff can use to get in touch with prescribers, do not rely on personal phones only for this purpose; build staff confidence to raise important suspected medication errors with prescribers clearly
- Prepare a medication use-counseling checklist and familiarize staff with it. Have internal quality assurance for medication use counseling by peer audit or self-audit using the checklist
- Obtain pharmacovigilance guidelines from the KPA or the PPB; make copies of ADR reporting forms and familiarize staff with their use

7. QUALITY ASSURANCE MONITORING PLAN

Quality Assurance seeks to prevent quality related problems by anticipating them and putting in place mechanisms to avoid them. The main challenges looked at through this manual and the QA mechanisms for preventing them can be summarized sequentially thus:

1. **Non-genuine product:** sourcing, network vetting of wholesalers and distributors
2. **Loss of product integrity:** storage, refrigeration, arrangement in the pharmacy,
3. **Medication errors (Prescribing):** references, phone lines, competence
4. **Medication errors (Dispensing):** references, arrangement, documentation, labeling, task distribution, competence
5. **Medication errors (Patient):** medication use counseling checklist, labeling

All these are underpinned by:

- **Standard Operating Procedures**
- **Training, Induction and Continuous Professional Development**
- **System Audits**

The responsibility for QA at the network franchise pharmacy falls upon the Superintendent Pharmaceutical Technologist. Beyond the pharmacy, this duty for ensuring compliance falls upon the cluster leaders and the KPA branch officials of the network.

Because of their preventive nature, QA systems must be continually checked for adherence to standards set within them and this should be proactive and scheduled rather than reactive and triggered by an incident arising from non-compliance. The frequency of QA checks should be a balance between not being so frequent as to be cause fatigue, and fail to be done comprehensively and carefully on the one hand, and not being so infrequent that standards are allowed to possibly fall long enough for an incident, known or unknown, to occur.

The degree of compliance must also be quantifiable so that progress can be measured for each of the major areas that the quality policy concerns itself with, and benchmarks can be set and shared, and peer-to-peer comparisons made for ranking, sharing of experiences and learning. For this purpose, the Quality Standards Checklist prioritizes certain verifiable elements from the quality manual and provides a scoring system for them- in this way turns a complex set of qualitative concerns into a simple quantitative measurement.

The following schedule is proposed for QA monitoring through Quality System Audits:

7.1 National Evaluation:

The national office may contract an external evaluator or use trained members of the association from other branches to carry out an audit of randomly selected pharmacies in all the branches in the network. This is to be done each year before an annual forum for the network that may be set to coincide with the KPA's annual scientific conference. The main metrics to be considered by the national evaluation in addition to any others that the national franchise office may decide will be-

- The average % of compliance of network members in each of the categories (regulatory, network-minimum, network- best practice) overall and by branch
- The % concordance between evaluation scores, self-audit scores, and cluster scores for the same pharmacies
- % compliance by quality standards area (sections of audit checklist)

In addition to direct audits at the selected pharmacies, the evaluators may obtain copies of audits from individual pharmacies, clusters, and branches for analyses and comparisons. The national audit will help the network in a number of ways:

- Allow comparisons of compliance across the branches
- Enable identification of training areas or focus areas for continuous professional development (nationally and at branch level) by identifying quality areas in which incomplete compliance is most common.
- Allows review of network level procedures and the network quality standards checklist categories

The national level is also responsible for resolution of appeals by members who have appealed cluster level and branch level audit results especially if the result would cause the pharmacy to be de-franchised. The national office will then constitute a team, perhaps from neighbouring branches, to review the case.

7.2 Branch Clusters Audit:

Every branch should ensure that every cluster of network pharmacies is audited. It is recommended that his is done every six months. This is done by checking cluster audit records and by randomly selecting a few pharmacies in each cluster (more than 15% of cluster pharmacies) and carrying out a parallel QA audit at or near the time of the cluster audit for the same pharmacies. The primary reason is to countercheck that the cluster's audits are consistent with their own findings and are as objective as possible.

Branches are also responsible for taking up remedial measures for pharmacies that are non-compliant, and where no progress is made, recommend to the national office the temporary suspension of the franchise network membership of the member.

7.3 Cluster Member Audit:

Clusters should carry out audits of all their members every quarter. Audits should be carried out by at least 2 or 3 members who may be selected by any random method. These should be scheduled to ensure that there is a gap of about 3 months between audits for individual pharmacies, and members are able to distribute audit tasks evenly so none is overburdened.

7.4 Member Self Audit:

Every member pharmacy should carry out a self-audit every month. This should be documented and filed, and should be made available to the cluster, branch or national office whenever requested. The member should also check that they are improving from audit to audit and not slackening in standards.

Every member pharmacy is expected to have a QA file in which all filled audit checklists are filed. This file should be made available to peer and other quality audit personnel at the time of every audit.

7.5 POST-AUDIT PROCESS

At the end of any external (non-self) audit exercise, the persons carrying out the audit should provide immediate summary feedback to the member pharmacy being audited in a friendly, respectful and positive way and emphasize the confidentiality by which the audit results are held by the network.

The audit team should do the audit first in pencil, each auditor on a separate audit checklist but listing the name(s) of the other auditor(s) in the team. After the audit and summary feedback, the auditors should review their results together and discuss their results standard by standard where they do not concur on the scoring. Once explanations have been shared, they should agree on the scoring for each of these and reflect this on the checklists used. They should then write in the final scores in ink. The copies of the filled audit checklist should be signed by the auditors and the Superintendent Pharmaceutical Technologist and one copy should be filed in the pharmacy's QA file and another copy taken by the auditors either for the cluster, branch or national file.

In future, the network may develop a digital or possible online information management system for these audit results- in such cases, the results should be uploaded into such systems within a short time after completion of the audit and should be accessible to the members who were audited.

7.6 NON-COMPLIANCE MEASURES

The failure to comply fully with the quality standards during an audit as supposed to set in motion a series of predictable events so that there is no perception in arbitrariness in the mechanisms for maintaining quality in the network.

The National Network office will set benchmarks for various actions but the 2 primary outcomes of an audit would be:

1. Full compliance- this is where there is complete compliance with regulatory and network minimum standards and either full or partial compliance with network best practice standards.
2. Non-compliance- this is failure to conform to some regulatory or network minimum standards.

For simple non-compliance (where the pharmacy's standards lapses can be corrected fairly quickly), a Quality Improvement Action Plan should be discussed with the Superintendent. This is a list of **SHORT, CLEAR, TIME-BOUND** actions that should be taken by the pharmacy to come into full compliance. These should be written in bullet format in the "Comments" section of the checklist, with more paper added and signed at the end if necessary.

For egregious non-compliance- such as crucial regulatory failures (especially acts of commission of regulatory nature such as the stocking of counterfeit medication and other such instances as may be judged by the national network office and listed for network members)- the auditors have a duty to protect the network and if this happens at cluster level, the branch should receive this information and copy of the audit within 72 hours.

The branch will then contact the member and the national office. A decision should then be taken as to whether on whether to undertake measures to bring the member into full compliance or to suspend their membership of the network for a given duration. Suspension from membership may entail administrative steps relating to the withdrawal of group guarantees given to a member perhaps for procurement, withdrawal of the group branding and removal of signage from the pharmacy, and other measures to protect the brand and the other network members.

Suspended members should continue to be supported and encouraged to come back into full compliance and rejoin the network.

8. QUALITY PROFESSIONAL PRACTICE STANDARDS

KPA endeavors to progressively develop specific practice standards for Pharmaceutical Technologists operating in all areas of practice that include; community practice, hospital practice, industrial and regulatory practice, among others.

8.1 QUALITY CARE STANDARDS IN COMMUNITY PHARMACY PRACTICE

Community or retail pharmacy is a crucial level whereby the pharmacy profession interacts with its consumers directly and delivers the product to the user in a way that can enhance safety, and effectiveness, and promote trust in the profession. The International Pharmaceutical Federation's Community Pharmacy section outlines the 3 main stages of Quality Care Standards for community pharmacies.

Stage 1 constitutes the essential minimum requirements for Community pharmacy:

COMMUNITY PHARMACY QUALITY CARE STANDARDS- Stage 1

Setting of the Pharmacy:

Appearance of the pharmacy

Accessibility of the pharmacy

Window dressing

Dispensing Area/ consultation area

Staffing

Handling of Stock and Preparation of Medicines:

Purchasing of stock

Storage of stock

Maintenance of quality of stock

Availability of Standard Operating Procedures

Documentation of extemporaneous preparations

Storage of raw materials

Provision of Prescription Medicines:

Prescription receipt and Patient identification

Prescription checking

Provision of information on the use of medications

Dispensing of Medications

Supply of Non-Prescription Medicines for Self-Care:

Advice on the selection and use of medicines

Responding to minor ailments

COMMUNITY PHARMACY QUALITY CARE STANDARDS- Stage I (continued)

Interaction with patients:

Communication skills (verbal and non-verbal messages)

Provision of advice on the safe use of medicines and on the management of disease conditions

Promotion of good health

Provision of written information (labels, leaflets)

Documentation Systems:

Patient medication profiles

Formulary systems

Policies and standard operating procedures

Documentation of interventions

Source: International Pharmaceutical Federation,

Community Pharmacy Working Group Report, 2005

These minimum standards are comprehensively covered in this manual and the most important verifiable elements are highlighted in the Quality Audit checklist of the network. They should also form part of the training and induction processes for pharmacy staff coming into the network and be covered as far as possible in Standard Operating Procedures of the network pharmacies.

Stage II quality care standards also deal with very important elements many of which fall under the supervision of the Superintendent of the pharmacy. The areas listed under this section are also covered in this manual especially those that the network foresees the membership as taking part in routinely and for which network standards need to be set and monitored.

COMMUNITY PHARMACY QUALITY CARE STANDARDS- Stage II

Equipment:

Cleanliness and good state

Routine maintenance and validity

Availability of refrigerator, counting devices, and other dispensing equipment

Reference drug information systems (e.g. pharmacopoeia)

Health Promotion Activities:

Distribution of leaflets

Display of health promotion advertisements

Participation in health promotion campaigns

Diagnostics:

Provision of diagnostic tests

Documentation of diagnostic tests carried out

Pharmacotherapy Monitoring

Development of pharmaceutical care plans

Patient monitoring

Identification of medication-related problems

Interaction with prescribers

Research and professional development

Participation in research projects

Participation in Continuing Professional Development activities

Audit

Development of quality manuals for the pharmacy system

Running audit exercises for services provided (self-audit)

Source: International Pharmaceutical Federation,

Community Pharmacy Working Group Report, 2005

The third stage of Community Pharmacy quality standards consists of specific domains under these areas:

- Domiciliary services

- Online services
- Pre-registration training
- Para-pharmaceuticals
- Customer perceptions (external audit)

Some of these fall outside the scope of this manual since the KPA does not at this time see them as being part of routine services for membership- such as domiciliary and online services. These may be covered in subsequent versions of the manual as they become more commonplace and network standards are defined for them. Pre-registration training falls under the Pharmacy and Poisons Board and linkages to community pharmacies as practicum centres would be based on standards set by the PPB for this purpose. Para-pharmaceuticals and their handling in the pharmacy is covered in this manual. Customer perceptions and other means of external audit are covered in the section under Monitoring and Evaluation and are the responsibility of the national network offices.

8.1.1 KPA's Branded Network Quality Standards Areas

Adapting international community pharmacy standards for the Kenyan setting, the network has focused on the Stage I quality care standards, and incorporated major applicable elements from Stage II and Stage III standards.

KPA NETWORK QUALITY CARE STANDARDS

Licensure and Personnel:

Registration and Licenses

Personnel, Roles and Training

Premises:

Pharmacy set-up: signage, opening hours, security, lighting, ventilation, dispensing area, and medication-use counseling area

Cleanliness and Tidiness: cleanliness, arrangement of items, hygiene

Commodity management:

Selection and traceability of commodities

Storage of medicines- protection from light, heat, arrangement, refrigeration, controlled drugs

Inventory management- documentation, stock continuity, quarantine and disposal

Dispensing and Medication Safety

Dispensing- drug references, pricing, packaging, labeling, medication use counseling

Prescription handling- checking, documentation, prescription storage

Adverse Drug Reactions monitoring- references, forms and procedures

Medication errors- procedures and log

All these elements are underpinned by Standard Operating Procedures

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Kenya Pharmaceutical Association

Pharmaceutical Excellence

SELF REGULATION STANDARDS

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