STANDARDS OF PHARMACY PRACTICE FOR RETAIL PHARMACIES IN UGANDA

(Under S.21 (1) (3) of The Pharmacy and Drugs Act, Cap 280, Laws of Uganda, Edition 2000)

The Council of The Pharmaceutical Society Of Uganda

September 2014

Table of Contents

Forward by President PSU

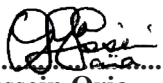
Pharmacists are health professionals who are the experts on medicines. Pharmacists are also given the responsibility to help people to maintain good health, to avoid ill health and, where medication is appropriate, to promote the rational use of medicines and to assist patients to acquire, and gain maximum therapeutic benefit from, their medicines. The role of the pharmacist is continuing to develop and this has necessitated the development of new standards of practice to meet these changes.
The standards for Retail pharmacy practice in Uganda are made as subsidiary legislation Under Section 21 subsections (1) & (3) OF The Pharmacy and drugs Act, Cap 280, Laws of Uganda, Edition 2000.

Acting within the provisions of the law as cited above, these standards are intended to help "**secure the highest practicable standards in the practice of pharmacy"** at Retail pharmacy settings which is the legal mandate of the council of the Pharmaceutical Society of Uganda.

I would like to acknowledge the efforts of the standards committee, council members and all the members of the pharmaceutical society for working so hard to ensure that these standards are put in place with the consultation of several stakeholders within the pharmaceutical sector.

These standards are a revision of the 2001 version of the standards of pharmacy practice in Uganda that had become outdated because of emerging practice challenges in the pharmacy profession and practice environments. Together with other initiatives of the council like support supervision exercises, issuance of certificates of practice, capacity building of pharmacy auxiliary staffs, Pharmacy self inspection programs, I strongly believe the standard of practice will be improved to the benefit of the public being served.

I encourage every pharmacist, pharmacy technician, Retail pharmacy owner and every pharmacy stakeholder to obtain copy, read and apply the provisions of these standards of practice as stated in line with existing legal frameworks governing medicines supply and distribution in Uganda for the good of the communities we serve.



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Hussein Oria

President, Pharmaceutical Society of Uganda

PREFACE

Following a series of consultations with key stakeholders within the pharmaceutical sector, I am glad to present to you this comprehensive document that deals with retail pharmacy practice issues in Uganda.

The standards of Pharmacy practice for retail pharmacies in Uganda have been developed to include key aspects of delivery of quality and comprehensive pharmaceutical services at community pharmacy level.

The standards are presented in Nine Parts providing specific standards that should be implemented.

Part I of these standards deals with the guidance on citation and interpretation of key terms that are used within these standards.

Part II deals with specific standards for premises and outlines in a practical manner the standards for Location, Appearance, Environment, Waiting area, Dispensing area, Storage area, Administrative area, Security and Stocking.

Part III deals with specific standards for equipments and materials that are vital in delivery of community pharmacy services. These include Dispensing equipment, Professional services equipment, Cold Storage equipment, Reference materials, Records handling, Disposal materials and equipment.

Part IV provides for standards on human resources. These standards are categorized under the six subthemes: Pharmacist, Pharmacy technicians, Pharmacy auxiliary staff, Pharmacy support personnel, other human resource activities, Training and CPDs.

Part V provides for standards for services**.** These are categorized under the following subthemes: Procurement**,** Storage**,** Distribution**,** Transport**,** Professional services **and** Pharmaceutical waste management

Standards for Pharmacy owners and management are presented in Part VI. These standards are to ensure that the pharmacy is organized in such a way that its services and processes contribute to the highest quality of pharmaceutical care. Retail Pharmacy ownership and management should comply with both the existing statutory requirements and professional standards to facilitate a conducive environment for professional practice

and safeguard the health of the public.

With regard to retail pharmacies, quality assurance should cover all aspects of these standards of pharmacy practice. The specific standards on quality assurance are presented in Part VII. This is followed by standards for dressing and penalties presented in chapters VIII and IX respectively.

In the development of this standards of practice, reference was made to the FIP statement of professional standards and codes of ethics for pharmacists, and established standards for pharmacy practice in East African region, West Africa, South Africa, UK, Australia and Ireland.

It is the desired hope of the standards committee and the Council of the Pharmaceutical Society of Uganda, that you find this document helpful in your practice and service delivery as pharmaceutical stakeholder.

FOR GOD AND MY COUNTRY

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Stephen Lutoti

Chairperson, PSU Standards Committee

ACKNOWLEDGMENT

I would like to thank members of the standards committee for the work well done as assigned by the council of the Pharmaceutical society of Uganda. The following was the composition of the standards committee that made it possible to review the existing standards and come up with this document :

1. Mr Stephen Lutoti, MPS - Chairperson
2. Mr Lukwago Mohammed, MPS - Vice Chairperson
3. Ms Amanya Diana, MPS - Secretary
4. Mr Okello Bosco, MPS - member
5. Mr Mangusho Joseph, MPS - Member
6. Mr Oteba Martin, MPS - Member
7. Mr. Benjamin Mwesigye, MPS - Member
8. Ms. Stella Nanyonga, MPS - Member
9. Mr. Brian Bagyenda, MPS - Member
10. Ms Kitimbo Brenda Claire, MPS - member and PSU Treasurer
11. Mr Obicho John, MPS - Member

The following members of the Pharmaceutical society are also acknowledged for the contributions they put in the initial development of these standards:, Ekau David, Mwigo John Banobere , Edwin Bossa , Robert B.D Otto and Brian Arinaitwe.

On behalf of the council, I would also like to acknowledge the contribution of pharmacy owners, pharmacists, National drug Authority, Pharmacy technicians/Dispensers, Pharmacist interns, student associations like MUPSA and all the stakeholders who took part in the consultative process during the development of these standards of practice.

Finally, I thank the council of PSU for the guidance and support provided to the secretariat and the committee work that has enabled the completion of these standards.

Yours faithfully,

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Samuel Opio
Secretary, Council Pharmaceutical Society of Uganda

COMPOSITION OF COUNCIL OF PHARMACEUTICAL SOCIETY OF UGANDA

The following is the council of PSU that spearheaded the development of these standards of retail pharmacy practice in Uganda:

01 Hussein Oria

02 Roshan Ismail

03 Opio Samuel

04 Kitimbo Brenda

05 Otim Francis

06 Gilbert Ohairwe

07 Kiiza Alfred

08 Prof. Richard Odoi

09 Oteba Martin

10 Lutoti Stephen

11 Okello Bosco

12 Lyeni Masereka

IMPORTANT ABBREVIATIONS /ACRONYMS

ADR : Adverse drug reaction

cGMP : Current Good manufacturing practices

C.O.P : Certificate of practice

CPD : Continuous professional development

FEFO: First expiry First Out

FIFO: First in First out

FIP : International Pharmaceutical Federation

MOH : Ministry of Health

MPS : Member of the Pharmaceutical society of Uganda

NDA : National Drug Authority

PAS : Pharmacy Auxilliary staff

PSU : Pharmaceutical society of Uganda

S.O.P : Standard operating procedure

WHO : World Health Organization

PART I:
CITATION AND INTERPRETATIONS

1. Citation: This standards may be cited as "*Standards of pharmacy practice for retail pharmacies in Uganda, Edition 2014"*

2. Interpretations

In these Standards, unless the context otherwise requires:

i. **Council** : Means Council of the Pharmaceutical Society of Uganda

ii. **Dispensing** : carries same meaning as provided in the National Drug policy and Authority Act, Cap 206

iii. **Drug** : Means drug as defined in the National Drug policy and Authority Act, Cap 206

iv. **Health professional:** Means any person who is registered as a Pharmacist, Medical practitioner, Dentist, Veterinary surgeon, Veterinary assistant, nurse, midwife or Allied health professional as defined in existing legislations.

v. **Member :** Means fully subscribed member of PSU as per provisions of The Pharmacy and Drugs Act

vi. **Pharmacist** : Means Registered pharmacist under Pharmacy and drugs Act, Cap 280

vii. **Pharmacy auxiliary staff:** means any person working under supervision of and assists the registered pharmacist in retail pharmacy

viii. **Pharmacy practice:** means areas of practice of a pharmacist recognized by International Pharmaceutical Federation and/ or The World Health Organization and approved by the council

ix. **Prescription**: carries same meaning as in the National Drug policy and Authority Act, Cap 206

x. **Restricted drug :** carries same meaning as defined in the National Drug policy and Authority Act, Cap 206

xi. **Retail** : supply or dispensing medicine or drug to end user

PART II
STANDARDS FOR PREMISES

3. Scope of standards for premises

Retail pharmacy premises should reflect the professional character of pharmacy and facilitate the delivery of quality and comprehensive pharmaceutical services by the pharmacist without compromising his or her professional judgment. The premises should be designed and maintained to meet the patient rights and needs. The scope of the standards for retail pharmacy premises covers the following aspects:

a) Location
b) Construction
c) Appearance
d) Environment
e) Waiting area
f) Dispensing area
g) Storage area
h) Administrative area
i) Security
j) Stocking

4. Standards for location

The location of a retail pharmacy should be suitable for the intended pharmacy operations.

a) Where a retail pharmacy provides both human and veterinary pharmaceutical services, a physical separation should be provided between the two premises.

b) Where a retail pharmacy is located in a medical centre, clinic or hospital, the pharmacy shall be a fully-fledged directorate headed by a pharmacist.

c) The precise physical address of the retail pharmacy should be registered with the Council of the Pharmaceutical Society of Uganda.

d) Any change of location of a retail pharmacy should be approved by the Council of the Pharmaceutical Society of Uganda.

5. Standards for construction

a) A sketch plan showing the layout of the premises of a retail pharmacy should meet the required spatial relationships in the different areas necessary for retail pharmacy premises.

b) Retail pharmacy premises should be permanent in nature, well laid out and designed so as to allow easy and clear flow of activities.

c) The design and layout of the pharmacy should permit a logical flow of work, effective communication and supervision and ensure effective cleaning and maintenance and should minimize the risk of errors, cross-contamination and anything else which would have an adverse effect on the quality of products.

d) The minimum size of a retail pharmacy should be 20 square meters.

e) The premises should be well fitted with adequate utilities and ventilations.

f) All ceilings should be thick and of good material so as to transmit no or minimal heat from the roof and should not have falling debris.

g) Internally the pharmacy should be painted with light colors.

h) The premises should be free of medicines adverts UNLESS as authorised by Council. Authorised materials to be used as adverts in the pharmacy are those vetted and approved by NDA.

i) The premises should be lit adequately.

j) The design and layout should automatically control direct access to pharmaceuticals to only registered pharmacy personnel.

k) Entrances to pharmacy premises, consultation room and treatment room should be sufficiently wide to allow easy entry and exit of wheel chairs and push chairs.

6. Standards for Environment

a) There should be a sanitation plan in place to ensure that the premises including storage, dispensing, waiting area, consultation room and toilet facilities are cleaned daily at a defined frequency.

b) The pharmacy premises should have a dedicated toilet facility with an intact mirror, toiletries and appropriate waste paper bin.

c) The pharmacy premises should have a hand washing sink in good working condition with soap, clean water, and clean hand drying towels/electric hand drier.

d) The external environment of the pharmacy should be tidy, clean and free of overlying rubbish within its perimeter and entrance area.

e) There should be SOPs for cleaning the premises and cleaning log in place.

f) Dedicated persons should be officially assigned to handle housekeeping duties on a day to day basis or as appropriate.

g) All parts of the pharmacy premises should be smoke free with NO SMOKING status label in a visible area to the public.

h) Noise levels in the pharmacy should be kept minimum to avoid distraction.

i) All parts of the premises should be well ventilated and with adequate lighting.

7. Standards for Appearance of premises

The appearance of the pharmacy should reflect the professional character of pharmacy.

a) All parts of the premises should be kept clean, tidy and in a state of good order and repair.

b) There should be a clearly visible sign post affixed to the premises measuring not less than 0.5 to 2 metres in any direction with name of the pharmacy, physical and postal address, Telephone contacts, and opening hours of the pharmacy. The telephone contact referred to here is a fixed landline.

c) Should have the standard symbol for retail pharmacy approved by council and clearly placed to be visible from the outside of the premises**.**

d) Should conspicuously display the pharmacist's Certificate of practice bearing his/her photograph and a framed A4 colored photograph of the pharmacist in charge at all times at the reception.

8. Standards for waiting area

a) Should have an adequate number of comfortable seats.

b) Should have a water dispenser and at all times with disposable cups.

c) Be in proximity to consulting area and dispensing area.

d) Should have appropriate pharmacy literature with at least a copy of the most recent Uganda Pharmaceutical Journal.

e) There should be a feedback mechanism at the waiting area such as a suggestion box.

9. Standards for consultation area

a) There should be a fully furnished consultation office for the pharmacist in charge and clearly labelled so.

b) Should have an examination bed for professional services that require examining the patient.

c) Should be equipped with all the stated professional services equipment as required to offer the professional services for which Council of PSU certification has been provided.

10. Standards for dispensing area

a) No edibles should be allowed into this area.

b) Only approved technical personnel should have access in this area.

c) A roster of the approved technical personnel should be pinned up and visible to clients**.**

d) Dispensing surface should be made of such material that is impermeable and easy to clean.

e) The dispensing area should be of adequate size not less than four (4) square metres.

f) A clear working surface area of not less than 70cm by 1 metre should be provided for each person responsible for dispensing.

g) The height of the dispensing counters should not be more than 1 metre high.

h) The dispensing areas should be kept clean, uncluttered and maintained in good order.

i) The dispensing area should have a suitable range of equipment as specified under the standards for equipment.

j) Appropriate reference materials should be available within the dispensary as specified under standards for reference materials.

k) Should have an approved thermometer placed appropriately and temperature records taken every 4 hours. These records should be signed by the pharmacist in charge and filed.

l) Should have minimum 2 chairs for pharmacy staff and a chair for the pharmacist.

11. Standards for Storage area

a) Drugs and sundries should be kept strictly at least 15 cm above the floor**.**

b) Shelving should be constructed from smooth, washable and impermeable materials which are easy to maintain in a hygienic condition.

c) Drugs or any devices that require cold storage should be kept in approved medicines refrigerators**.**

d) Medicine refrigerators or any devices used for cold storage should be assessed for proper functioning every six months by a standards certifying body recommended by Council.

e) Medicines should be stored at temperatures and humidity recommended by the manufacturer of a given product**.**

f) Uninterrupted power supply mechanisms should be in place where cold chain products are stocked.

g) All Narcotics and psychotropic substances under international control should be kept in a secure and lockable cabinet accessible only with the permission of the pharmacist in charge. They should be stored under a double lock system with the pharmacist holding the keys to one of the locks.

h) Should be kept clean at all times free from contaminants including but not limited to dust, a rubbish, rodents, pests and chemicals.

i) Should have appropriate calibrated temperature and humidity monitoring devices and the daily records including time of reading, maximum and minimum readings should be entered in the log checked and approved by the Pharmacist.

j) Should have certified functional fire detection and fire fighting equipment e.g. fire extinguisher.

k) There should be a designated lockable area for storage of all expired, damaged and rejected products clearly labelled and the keys should be kept by the pharmacist only**.**

l) All medicines stored and distributed should have their records maintained using an appropriate system that includes but not limited to stock cards or equivalent system.

m) Where a retail pharmacy has an external store, such a store shall be treated as an independent store within close proximity of not more than 500 meters for the pharmacist in charge to supervise it and should meet all the minimum standards above.

n) Any external store located at distance of more than 500 meters from the pharmacy should be supervised by a named registered pharmacist other than the pharmacist in charge unless he or she is authorized by the Council.

12. Standards for Security

a) Where a retail pharmacy is located within another approved business like a supermarket, it should be clearly separated and ceiling to floor partitioned from the rest of the business with a lockable access.

b) There should be burglar proofing to minimize theft of pharmaceuticals and other items at the premises. Door and windows should be strong to barr break ins.

c) Where desirable, smoke detectors, alarm systems and CCTV cameras should be placed in the storage and dispensing areas.

d) Only the pharmacists and personnel approved by him/ her should access the medicines stores and dispensing areas.

e) All personnel working in the dispensing and stores area should wear name identification badges indicating their professional qualifications.

13. Standards for Safety

a) Appropriate protective gear should be provided to stores personnel.

b) Approved First aid boxes should be available at the premises.

c) Premises should be fitted with fire / emergency exit direction with status labels.

d) Electrical equipment and installations should be safe, properly installed and maintained regularly. There should be no loosely trailing wires across floors, work surfaces or sinks.

e) Health and safety Standard Operating Procedures should be available and duly approved by the pharmacist.

f) No retail pharmacy should use wax, kerosene, or any other form of candles for lighting purposes during operations.

PART III

STANDARDS FOR EQUIPMENT AND MATERIALS

14. Scope

Equipment should be located, adapted and maintained to suit the professional operations carried out in the pharmacy. The suitability, accessibility, maintenance and cleaning of equipment should be ensured to prevent any adverse impact on the quality, safety and efficacy of pharmaceutical products and delivery of professional services. The standards for equipment are categorized under the following subthemes:

a) Dispensing equipment.

b) Professional services equipment.

c) Cold Storage equipment.

d) Reference materials.

e) Records handling.

f) Disposal materials and equipment.

15. Standards for dispensing equipment

a) Counting trays and spatulas should be available, cleaned regularly and cleaning records maintained. Where applicable, dedicated trays should be available for selected drugs categories like sulphur drugs, beta lactams, highly potent drugs. There should be a color coding system to identify them.

b) Appropriate packaging materials should be used for supplying medicines to clients. Repackaging of medicines should be done using approved secondary packs.

c) All the packaging materials should be adequately labelled mechanically or electronically to ensure clarity and legibility of the written instructions.

d) Calibrated weight and height scales and equipment should be

available.

e) The premises should have a dedicated phone line in the dispensing area.

16. Standards for professional services equipment and materials

a) There should be appropriate disease monitoring equipment that includes Blood pressure machine, stethoscope, glucometers, clinical thermometer, peak flow meters among others.

b) Appropriate hand sanitizers, sterile gloves, rapid diagnostic test kits/strips, gloves, disinfectants, injection syringes, sterile & non sterile cotton wool as a minimum should be available.

c) Where compounding, reconstitution, measurement is required, Mortars & pestles, graduated and calibrated cylinders should be used.

17. Standards for cold storage equipment

The refrigerator should be dedicated for medicines only and regularly cleaned with cleaning records properly maintained.

a) An appropriate medicines refrigerator for cold storage should be available with a fridge thermometer.

b) Temperature logbooks in an approved format should be used to record temperatures.

c) There should be an appropriate alternative cold storage provision such as cold chain box to keep medicines during cleaning of the refrigerator, in instances of power shut down and transportation.

18. Standards for reference materials

Copies of the following literature should be available in the pharmacist's office:

a) Latest available edition of Uganda National Formulary,

b) British National Formulary for both adults and children.

c) Latest edition of Uganda Pharmaceutical Journal.

d) A medical dictionary.

e) Latest version of the Uganda Retail Pharmacy Standards.

f) Latest version of Uganda Pharmacy Atlas.

g) Latest version of Uganda Health Directory.

h) Latest edition of clinical pharmacology textbook.

i) Side effect and adverse reaction hand book

j) Drug interaction hand book

k) Other statutory documents

19. Standards for record handling

a) There should be a policy in place to facilitate management of records in the pharmacy.

b) The pharmacy should maintain records that include medicine Order forms, Local Purchase Order forms, Invitation for Quotations, Invitation for Proposals, Invitation for Bids, Goods Received Notes, Delivery Notes, Temperature logbooks and Stock Cards used in conducting business at the pharmacy.

c) The records relating to medicines should be kept for not less than 5 years. However, the manner and duration of storage should be such that it provides sufficient audit trail in the event of product complaints and to facilitate research.

d) Attendance records, dispensing logs, patient records and regulatory records should not be destroyed for purposes of research, investigations and follow up for future references.

e) Where electronic systems are used there should be adequate

controls on access to allow only authorized persons and a backup system should be available.

f) A separate file should be appropriately maintained on site for PSU/NDA Regulatory records and should be available upon request.

20. Standards for disposal materials and equipment

a) There should be segregated waste bins for biohazard waste, hazardous waste and nonhazardous labelled in three colors red, yellow and black respectively. For sharps (bio-hazardous waste), a sharps container should be available.

b) Records should be maintained for disposal of bio-hazardous and hazardous waste and never destroyed.

PART IV

STANDARDS FOR HUMAN RESOURCES IN RETAIL PHARMACIES

21. Scope and Rationale

The activity of the retail pharmacy is the professional activity of the pharmacist in charge and under him/her staff should ensure that they possess, maintain, update and display competence and accountability in patient management. The provision of retail pharmacy services is critically linked to having adequate number of individuals who possess the relevant skills to ensure a high level of competency and pharmaceutical service delivery.

A retail Pharmacy shall employ a minimum of one Pharmacist and qualified persons certified by the Council other than the responsible pharmacist for the purpose of technical management of medicines under his/her supervision. However, the number of pharmacists/ such other qualified persons required in a retail pharmacy shall be determined by the Council from time to time.

These standards are categorized under the following subthemes:

i. Pharmacist.

ii. Pharmacy technicians.

iii. Pharmacy auxiliary staff.

iv. Pharmacy support personnel.

v. Other human resource activities.

vi. Training and CPDs.

22. Standards for pharmacist(s)

The pharmacist in-charge should ensure that:

a) He/she is a registered pharmacist and a fully subscribed member of the Pharmaceutical Society of Uganda (PSU).

b) He/she is accountable for all professional activities of the pharmacy.

c) He/she is responsible for prohibiting any individuals from unduly influencing, directing, controlling or supervising any professional activities of the Retail Pharmacy.

d) He/she oversees the recruitment and training of pharmacy technicians/pharmacy auxiliary staff employed therein.

e) Any pharmacy auxiliary staff operating in the pharmacy is duly qualified to do so.

f) This standard and any other regulation governing the practice of pharmacy in Uganda are adhered to.

g) All personnel employed are adequately and distinctly identified referencing name and role which is clear to the public.

h) All personnel operating within the pharmacy have clearly defined roles and responsibilities with a proper reporting structure.

i) Staffs undergo continuous professional development by participating in in-house and external CPD/E sessions. Each staff should have appropriate documentation in which the various trainings are captured.

j) All members of the retail Pharmacy team possess and maintain adequate competence in professionally carrying out their assigned duties in compliance with pharmaceutical legal requirements.

k) He/she regularly monitors all activities in the pharmacy and has delegated arrangements in his /her absence, whereby the documentation that such actions have been carried out are verified by him/her.

l) Information disseminated to the patient, patient attendant, his/her care taker or public is accurate, relevant, precise and unbiased.

m) He/she does not conduct him/herself in a way that discredits the noble profession of pharmacy and shall endeavour to uphold the PSU Pharmacist code of conduct at all times.

n) He/she complies with the PSU membership pledge and upholds the Pharmacists oath as administered by the training institutions.

23. Standards for pharmacy technicians

The pharmacy technicians should be:

a) Qualified and registered to practice as pharmacy technician in Uganda.

b) Familiar with and not exceed his/her limitations.

c) Given a written job description outlining the areas of responsibility.

d) Readily identifiable to the public through use of uniforms and name tags with titles, clearly marked.

e) Regularly assessed by the Supervising pharmacist through observation, oral and written assessments to ensure that their competency is maintained.

24. Standards for Pharmacy auxiliary staff

The pharmacy auxiliary staff should be:

a) Qualified and registered by their respective health professional bodies.

b) Familiar with and not exceed his/her limitations.

c) Given a written job description outlining the areas of responsibility.

d) Readily identifiable to the public through use of uniforms and name tags with titles, clearly marked.

e) Regularly assessed by the Supervising pharmacist through observation, oral and written assessments to ensure that their competency is maintained.

f) Sit the PSU PAS competency test offered every 3 years and should pass it for them to be allowed to work in the Pharmacies.

25. Standards for pharmacy support personnel

Any other employees of the pharmacy apart from pharmacists, pharmacy technicians and/or any health personnel certified by PSU to assist pharmacists are support staff. They include: cashiers, warehouse/store clerks, drivers, cleaners, porters etc. They should:

a) Be competent to carry out work duties assigned to them.

b) Not seek to unduly influence, direct, control or interfere with the professional activities of the pharmacy.

c) Receive the prescribed in service training to enable them execute their duties.

d) The staff should be regularly assessed by the supervising pharmacist through observation, oral and written assessments to ensure that their competency is maintained.

26. Standards for training and CPDs

a) Training should be sufficient to enable staff to provide a comprehensive and effective pharmaceutical service.

b) Pharmacists and pharmacy support personnel should receive sufficient education and training to enable them to provide competently the professional services being offered.

c) Continuing professional development is a professional obligation.
d) Continuing education and training will include attending courses, symposia, congresses, scientific and professional meetings, participating in distance learning, workplace learning experience and reading scientific journals and reviews.
e) Professional learning or training activities which are of relevance to pharmacy practice should be documented so that the pharmacist's portfolio of learning activities is kept up to date on a permanent basis as per PSU guidelines.
f) The pharmacy should maintain a staff development program and training plan which ensures that staffs are properly trained in areas relevant to their identified needs and to the current and the future work plans of the pharmacy.
g) All staff should continually review their level of professional knowledge and expertise. They should document an appropriate self-development plan.
h) Qualifications should be kept current while staffs are working in the pharmacy.
i) In the event of an error being committed at the time of providing the pharmaceutical service, an appropriate retraining program should be conducted as a corrective action measure by the pharmacist or PSU as applicable.

PART V

STANDARDS FOR SERVICES

27. Scope

These are categorized under the following subthemes:

a) Procurement

b) Storage

c) Distribution

d) Transport

e) Professional services

f) Pharmaceutical waste management

28. Standards for procurement

a) Retail pharmacies should procure medicines only from licensed wholesalers and importers.

b) Procurement from manufacturers directly should only be done where the existing importers/distributors do not stock that medicine.

c) The procurement process of all medicines should be handled and supervised by a pharmacist.

d) Final selection of supplier(s) of medicines should be done by the pharmacist in accordance with a defined pre-qualification check list highlighting the following:

   i. Storage conditions of the facility

   ii. Legal and regulatory standing

   iii. presence of qualified persons

   iv. authenticity of the product sources

v. In the case of importers, registration status of the products and cGMP approvals of the manufacturers.

vi. Pricing considerations.

e) All purchases should be done through formal Order book, / LPOs signed off by the pharmacist.

f) All purchases should be received by formal delivery notes clearly detailing; the product generic name, Brand name, quantity, batch Number, expiry date and other technical specifications like strength, dosage form etc. All documents used per procurement should be properly dated, filled, signed, stamped with the pharmacist's stamp bearing the name and registration number and filed in a box file.

g) All these documents should be kept in good condition and locked in file cabinet accessible only by the responsible pharmacist. They should be kept for a minimum period of one year post expiry.

29. Standards for storage

a) Medicines should be stored at the manufacturer's recommended temperature and environmental conditions.

b) Medicines should strictly be kept 15cm above the floor, below the ceiling and off the wall.

c) Storage areas should be fitted with calibrated environmental monitoring devices such as hygrometers.

d) Temperature records should be taken 4 hourly by the Stores Head delegated by the pharmacist and recorded in a certified Temperature Logbook. Records should be signed off by the responsible pharmacist daily and records kept securely by the pharmacist for a period of at least three years.

e) Storage area should have safety measures in place for example smoke detectors, alarm systems, CCTV cameras, fire extinguishers and security guards.

f) Medicines requiring cold storage should be kept in an approved refrigerator at the manufacturer's recommended temperature. Temperature here should be monitored using an approved temperature monitoring device and recorded in a separate approved Temperature Logbook.

g) There should be a standby power back up system for the refrigerator in case of power supply interruption.

h) Refrigerators should not be packed with non-drug items.

i) Preferably suitable software should be used for stock management.

j) Stock taking should be done on a monthly basis under the pharmacist's supervision.

k) Up to date stock cards should be used to track medicines stock.

l) Stock rotation should follow FEFO/FIFO basis.

m) All staff having access to the store should be authorized by the Supervising pharmacist and their names should be displayed at the stores entrance.

n) The following notices should be prominently displayed within the stores premises: No Smoking and No Unauthorized Persons.

o) Any liquid, soaps or detergents used in cleaning of medicines stores should be approved by the pharmacist.

p) Pest and rodent control measures should be in place and may include a steel/aluminum wire mesh from the inside of the stores, insect trap light installed at the main stores entrance, mouse trap placed in the stores, etc.

q) All documentation on storage should be kept within the premises.

r) All external stores are treated as separate entities subject to all the standards herein.

30. Standards for distribution

a) Retail pharmacies should distribute/sell only to individual clients/patients/ their caretakers.

b) Retail pharmacies may sell medicines to other retail pharmacies only where there is an LPO presented and in which case the LPO has been signed and stamped by the Pharmacist In-Charge of the purchasing premises. All PoMs should be sold only on receipt of a valid prescription.

c) An appropriate system should be used to capture all required patient records regarding PoMs and OTCs issued.

d) All documentation used in distribution should be kept within the premises.

31. Standards for handling and transportation of medicines

The transportation and containment of medicines should not pose any risk to the quality of the medicines.

a) The storage condition of the medicine should be maintained during transportation and containment for example insulin should be transported under cold storage.

b) The pharmacy should have appropriate transportation/ containment vessels to cater for the different storage conditions of the medicines that they stock.

c) Where non medicines are transported within the same transport vessel with the medicines, they should not pose any risk to the quality of the medicines.

32. Standards for professional services

In general, the provision of professional services offered should ensure that:

a) A schedule of services availed at the Pharmacy should be available. The services may include: drug consultation, B.P monitoring, glucose monitoring, immunization

and vaccination services, contraceptive services, hypercholestereamia checks, BMI checks, malaria, pregnancy tests, HIV checks, drug administration, nutritional advice, smoke cessation, addiction cessation, patient monitoring and pharmaceutical care among others.

b) Job aids should be available to provide a quick reference for the Pharmacy staff on the services being provided

c) The pharmacist should continuously update himself/herself on new developments in regard to the services being offered through attending regular trainings, self reading etcetera.

d) Appropriate documentation should be available to capture the various professional services provided. These include: patient bio data, medical, social and drug history, drug allergies and hypersensitivities, diagnosis, current treatment regimen etcetera

e) Pharmacies offering professional services should have appropriate equipment and instruments to avail these services and the pharmacist should be certified by PSU to provide them.

f) An incident book should be available for documenting all incidents such as dispensing errors and these should be further analyzed and evaluated with a view of reducing them for example dosing error, drug error, formulation error etc.

g) Regular review meetings should be held in regard to the services being offered at the Pharmacies for purposes of monitoring outcomes and making improvements.

h) The pharmacy should have the Pharmacy Initiated Treatment book.

33. Standards for provision of Pharmaceutical Care

In pharmaceutical care, the pharmacist takes responsibility for optimizing all of a patient's drug therapy, regardless of the

source (prescription, non-prescription or traditional medicines), to achieve better patient outcomes and to improve the quality of each patient's life. This should occur with the patient's/ care taker's cooperation and may involve cooperation with the patient's other health care providers. The pharmacist offering pharmaceutical care in a retail pharmacy should ensure that:

a) The patient's condition(s) and category lies within his/ her competency as accredited by PSU before initiating pharmaceutical care on the patient(s);

b) He/she develops and documents a care / intervention plan for the patient(s).

c) The most optimal therapy is given to the patient.

d) A fair and reasonable professional fee is charged from each patient for each pharmaceutical care round made. Any communication cost or other cost needed or met for optimizing the pharmaceutical care should be charged to the patient differently from the other charges.

e) The professional fees structure shall be as prescribed in the standards for payment and remuneration of pharmacists.

f) Not make more than three rounds of care attempts on a condition which does not improve. Referrals are made in writing.

34. Standards for disease screening and monitoring therapeutic outcomes

a) The scope of disease screening and the pharmacist providing such services shall be as approved by council of PSU.

b) A pharmacy providing disease screening and monitoring of therapeutic outcomes should have appropriate testing facilities.

c) A pharmacist in a retail pharmacy with clinical interest may request or carry out relevant investigations on some disease states in his/ her client (s), document the results and give advice or agree on a care plan with the client(s).

d) Where necessary and based on one's specialization, a pharmacist in a retail pharmacy should carry out monitoring of therapeutic outcomes of patient(s) that require care of a pharmacist especially in patients on long term therapies.

e) A pharmacist carrying out therapeutic drug monitoring on patients should keep a record of such professional service(s) and share the outcomes with the patient's lead health care provider.

35. Standards for providing information or advice on pharmaceuticals and disease state(s).

a) A Pharmacist in a retail pharmacy should provide accurate, relevant, precise and unbiased information to all clients and/ or their care takers.

b) No misleading or exaggerated claims shall be made for any medicinal product.

c) Where necessary, the pharmacist should document the pieces of information or advice given.

d) Where the Pharmacist has a concern about a prescribed drug, he or she should contact the prescriber for clarification about the prescription before dispensing. Where the pharmacist reasonably believes that the prescribed drug is inappropriate to the patient, he/she may refuse to dispense it. In such an instance, the pharmacist shall issue a rejection note attached to the prescription explaining the reasons for rejection.

e) A reference to the rejection shall be made on the prescription in red indelible ink.

36. Standards for rational dispensing of therapies

a) A pharmacist in a retail pharmacy should ensure that there is rational dispensing of all therapies whether prescribed or not.

b) Classified drugs categorized as pharmacy only medicines should not be dispensed without the pharmacist's

authorization.

c) The Pharmacist who recommends and initiates therapies in a retail pharmacy should not dispense his/her recommendation unless in the case of emergencies or unavailability of other qualified staff in the pharmacy premises.

d) A pharmacist should only delegate those tasks that he/she is sure can be undertaken satisfactorily by another staff member in the pharmacy.

e) An appropriate dispensing log book should be well maintained in the pharmacy and should be readily available for inspection by relevant authorities from time to time.

f) A drug or medicine likely to cause addiction or other form of abuse should not be supplied when there is reason to suppose that it is required for such purpose.

g) Drugs should not be supplied to any person when there is reason to suppose that such drugs are destined for illicit channels or will be misused.

h) The materials for packing dispensed medicines should be appropriate to maintain the quality, safe and efficacy of medicines.

i) Labelling of dispensed products should be clear and legible.

j) Dispensed medicines should bear the necessary cautionary and advisory labels.

k) A pharmacist should ensure that the patient or their care taker understands the information and advice given well enough to ensure safe and effective use of the medicine.

37. Standards for offering new services in a retail Pharmacy

Any pharmacist who provides a new service should ensure that:

a) He/ she has the necessary expertise to provide a safe and comprehensive service

b) Other staff in the pharmacy have been trained to perform

the required duties effectively.

c) The new service has been approved by the Council.

38. Standards for pharmaceutical waste management

Pharmaceutical waste shall include but not limited to: unused medicines, expired drugs, used drug receptacles like bottles, vials, boxes and used sundries.

a) Retail pharmacies should establish a mechanism of informing clients to return expired drugs, unused medicines, used drug receptacles (bottles, vials, boxes etc) to the pharmacy premises.

b) Pharmaceutical waste should be clearly identified and separated from usable stock.

c) The pharmacist should ensure that all the existing legal and professional requirements with respect to the disposal of pharmaceutical waste are met.

d) The pharmacist should ensure that the relevant documentation is completed and complies with legal and professional requirements.

PART VI

Standards for Pharmacy ownership and management

39.Rationale

These standards are to ensure that the pharmacy is organized in such a way that its services and processes contribute to the highest quality of pharmaceutical care. Retail Pharmacy ownership and management shall comply with both the existing statutory requirements and professional standards to facilitate a conducive environment for professional practice and safeguard the health of the public.

40. Standards for pharmacy ownership

The following arrangements shall apply for ownership of retail pharmacies:

a) For sole ownership, a Retail pharmacy shall be owned by a registered pharmacist(s).

b) In case of a partnership or company with other person(s) other than registered pharmacists, the responsible pharmacist should hold a percentage of the total shares as shall be agreed among the parties.

c) In case of a nonprofit making body, one of the board member/ director should be a registered pharmacist in Uganda.

d) The name of the Pharmacy, irrespective of the language used should reflect the professional character of the Pharmacy profession.

e) In the event of a change in ownership and/or name of the retail pharmacy, the responsible pharmacist should provide a written notification of intention to change such ownership/name to Council and drug Authority within a period of not less than 7 working days before change is effected.

41. Standards for administration in retail pharmacies

a) There should be a supervising pharmacist for every retail pharmacy

b) The supervising Pharmacist shall be the Technical director for the Pharmaceutical aspects of the retail pharmacy and SHOULD :

i. Endeavour that the members of the board of the body corporate/ senior management of the pharmacy are aware of and understand the responsibilities of Pharmacists.

ii. Retain overall professional accountability for the pharmaceutical aspects of the retail pharmacy at all times.

iii. Retain overall access to the Pharmacy premises where medicines are stored and supplied from at all times.

c) Management meetings of the pharmacy should be held regularly with the full participation of the pharmacist and minutes of such meetings should be properly kept.

d) Management should ensure that all relevant PSU regulations, standards and guidelines governing pharmacy practice are complied with at all times.

e) An up to date duty roster should be maintained within the premises.

f) There should be an attendance register for all the pharmacy staff.

g) There should be a human resource manual for every retail pharmacy that clearly details the process of staff recruitment, selection, retention, development and disengagement.

h) All aspects of administration as highlighted in these standards of practice should be complied with.

PART VII

STANDARDS FOR QUALITY ASSURANCE IN RETAIL PHARMACIES

42. Aspects of Quality assurance in a retail Pharmacy

Quality assurance is a wide-ranging concept covering all matters that individually or collectively influence the quality of the service and the product. With regard to retail pharmacies, quality assurance should cover all aspects of these standards of pharmacy practice and should include the following:

a) Each retail pharmacy should have a quality management manual which clearly stipulates the quality objectives of the pharmacy and provides the necessary systems and mechanisms to ensure that they are continuously monitored and improved upon.

b) A quality policy should be available and prominently displayed in an area where both the personnel and the public can easily see.

c) Self inspection using PSU checklists should be done at least once every 6 months by the responsible Pharmacist.

d) A feedback mechanism should be in place to handle patient complaints.

e) Routine sampling and physical checks should be carried out on medicines held in stock.

f) There should be documented procedures to ensure that medicines held in stock at a retail pharmacy are continuously monitored to guard against their deterioration.

g) There should be a documented procedure to detect and report adverse drug reactions, cases of drug resistance at a retail pharmacy level.

h) Up to date reference materials/literature should be kept.

i) Standard operating procedures should be available for all operations of the retail pharmacy as required under each of the sections of these standards of practice.

PART VIII

STANDARDS FOR DRESS CODES

43. Dress code

The importance of personal appearance of the pharmacy personnel should not be underestimated as the image of the profession is reflected, in part, by its members. The following dress code shall apply to pharmacists and pharmacy auxiliary staffs in retail pharmacy settings:

a) An appropriate company uniform should be worn by all staff of the retail pharmacy when in the pharmacy premises during the time of operation.

b) Name tags / IDs should be worn at all times.

c) All clothing is should be clean and ironed.

d) Staff should have neat, clean and well groomed hair.

e) The beards, moustaches and nails where maintained should be neat, clean and well groomed not to impair confidence in the staff providing services in retail pharmacy.

f) Only clean shoes with non-skid soles and of reasonable heel height can be worn in the pharmacy.

g) Cosmetics should be used in moderation.

h) Adequate measures should be taken to maintain good personal and dental hygiene for a neat and clean appearance.

i) Dress that is not acceptable at any time in the retail pharmacy includes hats, caps, bandanas, baggies, sagging bottoms, shorts, mid-drifts or low cut tops, backless clothing, tank tops, spaghetti strap tops, cut-off shirts, pajamas, halters , tube tops , sweat pants, sweat shirts, running or jogging suits, athletic shoes, slippers , flip-flop sandals and dark sunglasses.

j) Obscene phrases, words, letterings or drawings on the body or clothing are not accepted in a retail pharmacy.

PART IX

STANDARDS FOR PENALTIES, COMPLAINT HANDING AND ACTIONS

44: **Penalties, complaint handling and actions**

The responsibilities defined in the standards SHOULD be complied with at all times. Any violation of the provisions of these standards shall result in any one or more of the following actions by the Council:

a) Verbal warning and advice.

b) Written warning and advice.

c) Recommendation for re-training on the specific area of deficiency.

d) Withdrawal of the Pharmacists' Certificate of practice .

e) Refusal to issue Certificate of Practice.

f) Withdrawal of the registered retail pharmacy symbol.

g) Black-listing for non-compliance to PSU standards.

h) Publication within the newsprints and media.

i) Referral to the Disciplinary Committee of the Pharmacy Board or any other relevant professional body for further action.

j) Notification for further action by the Police or any other enforcement agency.

k) The actions from c to g shall be for not more than 12 months.

Pharmaceutical Society Of Uganda
Plot 1847, Ntinda Kyambogo
P.O. Box 3774, Kampala-Uganda
Email: psupc@psu.or.ug
Website:www.psu.or.ug
Tel: +256 312 266 993, +256 414 340 385