



**STANDARDS OF
PHARMACY PRACTICE
FOR WHOLESALE 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

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Forward

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 Wholesale 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 Wholesale 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These standards are a revision of the 2001 version of the standards of pharmacy practice in Uganda that had become outdated because of emerging practice challenges in the pharmacy profession and practice environments.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, Wholesale 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 wholesale 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 eight Parts providing specific standards that should be implemented. Part I presents the guidance on citation of the document for reference purposes.

Part II deals with specific standards for premises and outlines in a practical manner the standards for Location, Appearance, Environment, Waiting area, Dispatch area, Storage area, Administrative area, Security, safety and Stocking. Part III deals with specific standards for equipments and materials that are vital in delivery of community pharmacy services in a wholesale pharmacy. These include Drug handling equipment, cold storage 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 ownership and administration 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. Wholesale 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 wholesale 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 Parts VIII and IX respectively.

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 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 Amanyana Diana, MPS - Secretary
4. Mr Okello Bosco, MPS - Member
5. Mr Mangusho Joseph, MPS - Member
6. Mr Oteba Martin, MPS - Member
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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

**MEMBERS OF THE COUNCIL OF THE
PHARMACEUTICAL SOCIETY OF UGANDA**

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

- 01 Hussein Oria
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- 04 Kitimbo Brenda
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- 09 Oteba Martin
- 10 Lutoti Stephen
- 11 Okello Bosco
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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

PSU : Pharmaceutical society of Uganda

WHO : World Health Organization

PART I:

CITATION AND INTERPRETATIONS

1. Citation: These standards may be cited as “*Standards of pharmacy practice for Wholesale 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 under 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 to end user
- xii. **Whole sale** : Supply of medicine or drug in bulk for redistribution to end users through retailers

PART II

STANDARDS FOR PREMISES

3. SCOPE

All aspects of wholesale pharmacy premises should be well maintained to reflect the professional role of the pharmacist in the delivery of comprehensive pharmaceutical services. A wholesale pharmacy premises should facilitate a safe and effective working environment. The client for wholesale pharmacy services is entitled to expect that any part of the premises from which such services are provided is readily identifiable and maintained. The scope of the standards for wholesale pharmacy premises shall cover the following aspects:

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

4. Standards for location

The location for wholesale pharmacy premises should be suitable for the intended pharmacy operations and should meet the following requirements:

- a) Should be accessible by road.

- b) Where a wholesale pharmacy provides both human and veterinary pharmaceutical services, a physical separation should be provided between the two premises.
- c) Should have ample parking space for offloading and loading of supplies.
- d) Should not be located within a pharmaceutical manufacturing facility.
- e) The precise physical address of the wholesale pharmacy premises should be registered with Council of the Pharmaceutical Society of Uganda.
- f) Any change of location of a wholesale pharmacy should be approved by Council of the Pharmaceutical Society of Uganda.
- g) Where a wholesale pharmacy operates an external store, the store should meet all the standards (a) to (f) above.

5. Standards for construction

- a) A sketch plan showing the layout of the premises should meet the required spatial relationships in the different areas necessary for wholesale pharmacy premises.
- b) 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 size of a wholesale pharmacy should not be less than 25 square meters.

- e) The ceiling should be made of thick material and should not leak.
- f) The premises should be lit adequately.
- g) The design and layout should automatically control direct access to pharmaceuticals to only registered pharmacy personnel.
- h) Internally the wall should be painted with light colors.
- i) The walls should not be filled with medicines adverts that are not acceptable to Council.
- j) The floor should be smooth and free from cracks.
- k) Should ensure that water does not pour into the premises during rain.

6. Standards for Environment

- a) There should be a sanitation plan in place to ensure that the premises including storage, dispatch, administration, waiting area and toilet are cleaned daily at a defined frequency.
- b) The pharmacy premises should have a lockable and dedicated toilet facility with an intact mirror, toiletries and appropriate waste paper bin.
- c) The pharmacy premises should have a hand washing facility 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 and clean 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

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 of wholesale pharmacies clearly placed to be visible from the outside of the premises.
- d) Should conspicuously display the pharmacist practicing certificate and a framed A4 colored photograph of the pharmacist in charge at all times at the reception.

5. Standards for waiting area

- a) Should have an adequate number of comfortable seats.
- b) Should have appropriate pharmacy literature with at least a copy of the most recent Uganda Pharmaceutical Journal.
- c) There should be a feedback mechanism at the waiting area such as a suggestion box.

6. Standards for Administration area

- a) Should have a well furnished office for the pharmacist in charge clearly labeled so.
- b) Offices for non-pharmacist administrators should be clearly cordoned off from storage and dispatch areas.
- c) The administration area should be situated so that the pharmacist has a full view of the pharmacy operations.

7. Standards for dispatch area

- a) No edibles should be brought into this area.
- b) Only approved technical personnel should be in this area with name tags.
- c) Noise levels should be kept to a minimum.
- d) Should meet the minimum conditions for storage.

8. 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 or room 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, 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) Storage facilities/area should be checked at defined intervals for expired or near expiry products.
- l) 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.
- m) All medicines stored and distributed should have their records maintained using an appropriate system that includes but not limited to stock cards or equivalent.
- n) Where a wholesale 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.
- o) 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.

9. Standards for Security

- a) There should be burglar proofing to minimize theft of pharmaceuticals and other items at the premises. The integrity of the doors and windows should be strong enough to barr forced entry.
- b) Where desirable, smoke detectors, alarm systems and CCTV cameras should be placed in the storage and dispatch areas.
- c) Only the pharmacists and personnel approved by him/ her should access the medicines stores and dispatch areas.
- d) All personnel working in the dispatch and stores area should wear name identification badges indicating their professional qualifications or designation.

10. 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 wholesale pharmacy should use wax, kerosene, or any other form of candles for lighting purposes during operations.

PART III**STANDARDS FOR EQUIPMENT AND MATERIALS****11 .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 the delivery of professional services.

The standards are categorized under the following subthemes:

- a) Drug handling equipment
- b) Cold Storage equipment
- c) Reference materials
- d) Records handling
- e) Disposal materials and equipment

12. Standards for drug handling equipment

- a) Pallets used in warehouse stores should be intact and in no decay/rust state.
- b) Warehouse stores should use appropriate shelves for medicines placement.
- c) Warehouse stores should use appropriate metallic ladders or automation where viable.
- d) Where forklifts are used in the store, they shall be of appropriate type.
- e) Appropriate packaging materials should be used for supplying medicines to clients. Packing of medicines should be done using approved secondary packs.

- f) All the packaging materials should be adequately labelled mechanically or electronically to ensure clarity and legibility of the written instructions.
- g) Supply of medicines should be in the manufacturer's secondary pack.

13. Standards for cold storage equipment

The refrigerator should be dedicated for medicines only and regularly cleaned with 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.

14. 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 Wholesale 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

15. Standards for records 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, dispatch 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 back-up 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.

16. 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****17.Scope**

The activity of the wholesale 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 wholesale 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 wholesale Pharmacy shall employ a minimum of one Pharmacist or qualified person 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 wholesale pharmacy shall be determined by the Council from time to time.

These standards are categorized under the following subthemes:

- a) Pharmacist.
- b) Pharmacy technicians
- c) Pharmacy auxiliary staff.
- d) Pharmacy support personnel.
- e) Other human resource activities.
- f) Training and CPDs.

18. 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 wholesale 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 wholesale 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 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 endeavor 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.

19. Standards for Pharmacy Technicians

The pharmacy technicians should be:

- a) Qualified and registered.
- 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.

20. 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.

21. Standards for Pharmacy Support Staff

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, 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.

22. Standards for Other Human Resource Activities

The pharmacy should:

- a) Have a human resource manual that clearly details organizational structure and the process of recruitment, selection, retention, trainings, remuneration and termination.
- b) Issue appointments, contracts and job descriptions to all support staff personnel employed by the pharmacy.
- c) Inform the pharmacist and his/her team immediately of any new staff employed by the pharmacy or any staff that leaves the employment of the pharmacy, or any changes in the staffing of the pharmacy.

23. Standards for training and CPDs

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

- a) Pharmacists and pharmacy support personnel should receive sufficient education and training to enable them to provide competently the professional services being offered.
- b) Continuing professional development is a professional obligation.
- c) 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.
- d) 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.
- e) 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.
- f) All staff should continually review their level of professional knowledge and expertise. They should document an appropriate self-development plan.
- g) Qualifications should be kept current while staffs are working in the pharmacy.
- h) 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 WHOLE SALE PHARMACY PERATIONS

24. Scope

These standards are categorised under the following subthemes:

- a) Procurement
- b) Storage
- c) Distribution
- d) Transport
- e) Professional services
- f) Pharmaceutical waste management

25. Standards for procurement

- a) Wholesale pharmacies should procure medicines from only licensed Pharmaceutical distributors and manufacturers.
- b) The Local Pharmaceutical manufacturers wholesaling medicines should have a distribution point which is not part of the manufacturing facility and fully supervised by a pharmacist other than the ones involved in manufacturing at the facility.
- c) The procurement process of all medicines to be sold in a wholesale Pharmacy should be supervised by the pharmacist in charge.
- d) Final selection of a supplier(s) of medicines in a wholesale Pharmacy should be done in consultation with the pharmacist in charge taking into consideration the drug regulatory quality assurance requirements in Uganda.
- e) The documents used in the procurement of medicines and other

health supplies for every wholesale pharmacy should each be signed by the pharmacist in charge and these documents shall include the Pro-forma Invoice(s), Purchase order form(s), delivery note(s) and Goods received note(s).

- f) All documents used in the procurement of medicines and health supplies for a wholesale Pharmacy should be properly dated, filled, signed, stamped and appropriately filed. The stamp referred to here should be a separate Pharmacist's stamp reserved for this purpose.
- g) All the procurement documents should be kept for a minimum period of one year post the expiry date indicated on the product label.
- h) Only medicines with at least 60% shelf life should be procured by every wholesale Pharmacy unless there is a crisis and the only available product on the market is not past its shelf life.
- i) Procurements of medicines in wholesale pharmacies should be done by both generic and Trade names.

26. Standards for storage

- a) All medicines in a wholesale Pharmacy should be stored at the manufacturer's recommended storage conditions.
- b) Medicines should strictly be kept 15cm above the floor, below the ceiling and off the walls.
- c) Storage areas should be fitted with calibrated hygrometers.
- d) Temperature and relative humidity records should be taken at least twice in a day by a Pharmacy staff delegated by the pharmacist and recorded in Logbook designed for this purpose.
- e) Relevant Standard operating Procedure(s) designed by the responsible pharmacist for the appropriate storage of medicines in a wholesale pharmacy should be well distributed

and displayed.

- f) Storage areas should be adequately secure with appropriate security mechanisms that shall include alarm systems, CCTV cameras, appropriate fire detection and fire fighting equipments.
- g) Medicines requiring cold storage should be kept in a calibrated refrigerator at the manufacturer's recommended temperature. Temperature should be monitored using a calibrated temperature monitoring device and recorded in a separate Temperature Logbook on a daily basis.
- h) There should be a standby power back up system for the refrigerator in case of power supply interruption
- i) Refrigerators should not be packed with non drug items.
- j) Routine Stock taking should be done 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) The Supervising pharmacist should determine which pharmacy staff has access to medicines stores.
- n) The following signs should be prominently displayed within the stores premises: No Smoking, Fire Exit directions, Access to Authorized staff only and others as the council may deem necessary.
- o) The store should be kept clean at all times.
- p) Recommended 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 external stores of a wholesale pharmacy shall be treated

as separate entities and should be supervised by another pharmacist except when it is located within a radius of 500 meters from the wholesale pharmacy.

27. Standards for distribution

- a) Wholesale pharmacies should distribute / sell only to authorized entities in accordance to prevailing laws but not to individual patients or their care taker(s).
- b) Wholesale pharmacies should distribute /sell medicines only on a signed order from the qualified person in charge of an authorized entity and copy of this order should be kept at the pharmacy. A delivery note should be provided by the wholesale pharmacy. This note should be signed and stamped by the responsible pharmacist for the wholesale pharmacy.
- c) All documentation used in distribution should be kept and appropriately maintained.
- d) The person who receives and processes the order from clients in a Wholesale Pharmacy should be qualified and certified by the Council from time to time.
- e) Medicines samples should be clearly labeled ‘Sample not for sale’.

28. Standards for transport

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.

- d) Vessels used in the shipping of medicines in and out of Uganda should be transported under conditions which maintain the quality, safety and efficacy of the medicine(s) being shipped.
- e) No medicines should be sold or supplied from a vehicle in transit.

29. Standards for professional services

- a) The pharmacist in a wholesale pharmacy may provide professional services for which he has been certified by the Council.
- b) The marketing and promotion of pharmaceuticals should be done by a pharmacist or persons certified by the Council.

30. Standards for handling expired, damaged and recalled pharmaceuticals

- a) Expired, unwanted, or otherwise unsuitable medicines should be clearly identified and separated from usable stocks.
- b) There should be a proper record maintained of all unwanted, expired or otherwise unsuitable medicines and other health supplies.
- c) Destruction of unwanted, expired or otherwise unsuitable medicines should be in accordance with the prevailing drug regulations and national guidelines.
- d) There should be a standard operating procedure for handling of product recalls in every wholesale Pharmacy.

PART VI

Standards for Whole sale Pharmacy ownership and Administration

31. 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 service delivery. Wholesale 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.

32. Standards for ownership

The following arrangements shall apply for ownership of wholesale pharmacies:

- a) For sole ownership, a Wholesale 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 wholesale pharmacy, the responsible pharmacist should provide a written notification of intention to change such ownership/name to Council and the drug Authority within a period of not less than 7 working days before change is effected.

33. Standards for administration

- a) There should be a supervising pharmacist for every Wholesale pharmacy
- b) The supervising Pharmacist shall be the Technical director for the Pharmaceutical aspects of the Wholesale 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 Wholesale 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 wholesale 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 WHOLESALE PHARMACIES****34. 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 Wholesale pharmacies, quality assurance should cover all aspects of these standards of pharmacy practice and should include the following:

- a) Each Wholesale 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 Wholesale 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 Wholesale pharmacy level.

- h) Up to date reference materials/literature should be kept.
- i) Standard operating procedures should be available for all operations of the Wholesale pharmacy as required under each of the sections of these standards of practice.

PART VIII**STANDARDS FOR DRESS CODES****35. 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 Wholesale 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 Wholesale 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 Wholesale 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 Wholesale pharmacy.

PART IX

STANDARDS FOR PENALTIES, COMPLAINT HANDLING AND ACTIONS

36: 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.

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PHARMACY HOUSE

