Draft

National Good Pharmacy Practice Guidelines

Developed By:

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Foreword

Standards play an important role in the evaluation and accreditation. The society is going through continuous change in its health care needs and expectations. The health care seeking behaviour has shifted from patient's passive role to active participation in therapeutic decision-making. In Nepal pharmacy profession itself is in transition. There is a clear need for this profession to evolve and become visible through its mission and vision for providing cost effective pharmaceutical care and services to the society. For this there has to be a basic level of quality assurance component in every pharmaceutical care and service related establishments.

Realising the need of National Good Pharmacy Practice Standards, work was initiated at the Department of Drug Administration (DDA) during 2003 by conducting workshop and making initial draft with the support of WHO. Then the responsibility to prepare a draft document was given to Nepal Pharmacy Council by the Department of Drug Administration as APW of WHO support.

Nepal Pharmacy Council established by HMG as per the Nepal Pharmacy Council Act 2000 is responsible for setting pharmacy practice standards. The council has mandate to implement such standards and therefore the council took responsibility to draft Good Pharmacy Practice (GPP) guidelines. The guideline was drafted by Nepal Pharmacy Council, then electronic consultation with experts was taken and policy seminar was organised in process of its finalisation as well as development of a realistic national level implementation plan. The activity was co-ordinated by Mr. Keshav Dhoj Joshi Member of Nepal Pharmacy Council and successfully completed by active participation of other members and stakeholders.

A realistic Good Pharmacy Practice standard and checklist as quality assurance tools has been set for Nepal taking in account DDA's earlier work like Standards of Regulatory and Pharmaceutical care 2000, GPP workshop and recommendation 2003, recommendation of the working committee constituted by DDA to develop directives, procedure and determination for enforcing codes on sales and distribution of drugs 2004 having the Co-ordinator Mr. Tirtha Ratna Shakya and representatives Mr. Narayan Prasad Dhakal, Mr. Baburam Humagain, Mr. Paras Mani Baral, Mr. Mrigendra Mehar Shrestha and Mr. Prakash Man Pradhan, as well as Good Pharmacy Practice in Community and Hospital Pharmacy Setting (WHO Technical Report Services No. 885,

1999), Good Pharmacy Practice in Developing Countries, Federation International Pharmaceutical (FIP) 1997 and Indian Pharmaceutical Association GPP document 2002.

The Council has the honour of submitting the draft document to HMG for approval and effective implementation.

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Radha Raman Prasad

Registrar

Nepal Pharmacy Council

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1. Facilities

1.1 Premises

1.1.1 The location of pharmacy should be such that it is easily identified by the public. The neat and clean environment should be maintained at the exterior of the pharmacy. The facade should be clearly marked with the word "PHARMACY", written in English as well as in Nepali.

1.1.2 The pharmacy should be conveniently accessible to people using prams or wheel chairs.

1.1.3 Pharmaceutical services and medicines should be served from an area which is separate from other activities / services and medicines. This facilitates the integrity and quality of service, and minimizes the risk of dispensing errors.

1.1.4 The pharmacist should be directly and easily accessible to public for information and counseling.

1.1.5 The pharmacy environment should be clean with minimum dust and should be maintained clean as per the cleaning schedules and Standard Operating Procedures (SOPs). The pharmacy should be free from rodents and pests/insects and pest control measures should be undertaken from time to time.

1.1.6 Adequate space as recommended by the regulatory authority is necessary, which should be enough for holding shelves of medicines, display counter, counseling area, and sufficient for proper movement of personnel and patients.

1.1.7 The pharmacy should have a telephone service and constant supply of electricity, especially for the refrigerator(s). There should be a provision for drinking water to facilitate medicine administration to the patients and for use of the personnel.

1.1.8 The pharmacy should have:

a. Sufficient place for patients to stand comfortably at the dispensing counter and for some to sit comfortably while they wait.

b. Space for patient information displays, including information leaflets / material.
c. A separate enclosure described as "Counseling Area" for patient counseling, storage of reference resources (e.g. books, internet access) is a fundamental requirement.

1.1.9 Counseling area should be a place where patients can talk freely with the Pharmacist. It should be away from the area otherwise normally accessed by the patients and should preferably be an enclosure with a door which can be closed for further confidentiality. It should be well lighted with comfortable seating for the Pharmacist and the patient/attendant.

1.1.10 A compounding pharmacy should also have sufficient additional space for making extemporaneous preparations, and the necessary equipment for doing so.

1.1.11 Separate waste collection baskets/boxes should be available for the personnel and for the patients.

1.1.12 The pharmacy should be air-conditioned and well ventilated. The medicine storage area should be protected from exposure to excessive light and heat. Ambient temperature in the pharmacy should be maintained within the stipulated range to prevent deterioration of various medicines stored at room temperature conditions.

1.1.13 Pharmacy providing related services such as doctors, clinics, and first aid and dressing services should manage them separately from the pharmacy.

1.2 **Furniture & Fixtures**

1.2.1 The pharmacy should have neat, well-placed shelves with provision for storage of medicines and other items in a neat manner, protected from dust, moisture, excessive heat and light. Adequate provisions should be available for storing various medicines at prescribed temperature conditions.

1.2.2 The counseling area should at least be furnished with
a. A table
b. Chairs for the Pharmacist and a couple of patients.
c. Cabinet for storing Patient Medication Records (PMRs)

1.3 **Equipments**

1.3.1 The pharmacy should be equipped with refrigerated storage facilities (validated from time to time) and should be available for medicines requiring storage at cold temperatures.

1.3.2 The counseling area should be equipped with:

a. Reference material
b. Demonstration charts, kits and other demonstration material
c. Patient information leaflets (PILs)
d. Some basic instruments e.g. sphygmomanometer, glucometer, thermometer and stethoscope.
e. Weight & height scale

1.3.3 The pharmacy should preferably be equipped with computers and appropriate software that can

a. Manage inventory
b. Manage invoicing
c. Generate timely warnings for expiring medicines
d. Archive patient medication records

1.3.4 The computers should also be equipped to give demonstrations to the patients and for maintaining database

1.3.5 Compounding section of the Pharmacy should be equipped with appropriate apparatus required for the preparation.

2. Personnel

2.1 The Pharmacy should be managed under the overall supervision of a Pharmacist, who will have the final responsibility for all the professional activities and operations.

2.2 All personnel including newly recruited personnel should be trained as per the personnel-training program of the pharmacy.

2.3 All activities by the pharmacy personnel should be carried out as per well-documented guidelines and procedures, which should have been developed by the management in consultation with the Pharmacist.

2.4 Each personnel should have clear job description, which should be performed accordingly.

2.5 All personnel in the pharmacy must, at all times, wear a neat apron / coat. All personnel should additionally wear a badge prominently displaying their name and designation.

2.6 All pharmacy personnel should be medically examined and adequately immunized periodically and their health data should be archived.

2.7 Pharmacists working in the pharmacy should:

a. Hold at least a bachelor degree in Pharmacy.
b. Be registered as a Pharmacist with the Nepal Pharmacy Council.
c. Have undergone adequate practical training in a community pharmacy.
d. Have communication skills & capabilities to give adequate and proper advice to the patients on illness and appropriate use of medicines. so as to achieve optimal patient compliance.

2.8 Each Pharmacist working in the pharmacy must be competent enough to:

a. Play a professional role to assess prescriptions.
b. Advise patients on appropriate selection and use of OTC medicines.
c. Advise patients on appropriate use of prescribed medicines.
d. Check and advice on medicine-medicine and medicine-food interactions.
e. Be alert for adverse drug reactions.

f. Comprehend the client's condition or illness and provide advice on proper medication and diet.
g. Assess the patient's condition and decide when to refer him/her to the Doctor.
h. Perform the role of a healthcare provider and a counselor.

2.9 Pharmacy assistant working in the pharmacy should:
a. Hold at least a Diploma in Pharmacy.
b. Be registered as a pharmacy assistant with the Nepal Pharmacy Council.
c. Have undergone adequate practical training in a community pharmacy.
d. Have communication skills

2.10 Professionalist working in the pharmacy should:
a. Hold the qualification as specified by the Drug advisory committee and recognized by that committee.

3. Quality Policy

3.1 Quality Policy (QP) is a general declaration of the intent of the pharmacy about the quality of service and medicines offered to the public. Quality goals emanate from the stated quality policy and they are the targets which are set and which can be measured. These expressly stated targets must be met in a stipulated period of time. Different quality goals need to be set in the various operational areas of pharmacy. It is the responsibility of the management and the pharmacist to formulate a Quality Policy and set and achieve Quality Goals.

3.2 The pharmacy should have a quality manual, which should describe quality policy and quality goals and should state, in detail, the necessary steps to be carried out for fulfillment of the desired quality goals. The manual should also enlist the details of the activities, routines, roles and responsibilities, work procedures and instructions that are necessary for achieving the quality goals in day-to-day operations in the pharmacy.

3.3 The Quality Manual should be accessible to the personnel of the pharmacy for their easy reference.

3.4 All the activities mentioned in the Quality Manual should be well documented, and it shall be the final responsibility of Pharmacist to ensure that the quality goals are in consonance with the quality policy of the pharmacy.

3.5 The Pharmacist should ensure that the quality policy and quality goals are understood, implemented and maintained throughout the operations in the pharmacy. Timely audits should be conducted to check the extent to which the pharmacy meets its quality goals and the outcomes should be documented for review to further improve the processes.

4. Service Strategy

4.1 Service strategy is a statement of the nature of services provided in the pharmacy and the standards laid down for provision of those services.

4.2 The pharmacy should have a well-documented service strategy based on its goals.

4.3 Service strategy statement should include issues like home delivery of medicines, the nature and level of attention to be given to patients of various kinds (e.g. elderly patients, regular patients).

4.4 The service manual, which can be a part of quality manual, should state, in detail, the necessary steps to be carried out for providing each service offered in the pharmacy. Promptness of service, service time and pharmacy operation schedule form an important part of the service policy.

4.5 The manual should also enlist the details of the activities, routines, delegations, work procedures and instructions that are necessary for provision of the services in day to day operations of the pharmacy.

5. Training

5.1 A well conceived and implemented personnel training program has the potential to determine future of the pharmacy in the community in which it operates. Availability of adequate reference resources (books, current periodicals, software) curriculum and training manuals is fundamental requirement of the training process.

5.2 The training program should prescribe the content and frequency of the training and the training resources based on service strategy of the pharmacy. It should ensure that all personnel in the pharmacy are kept abreast of the developments in their fields. Upgrading communication and inter-personal skills should form the core of the training program so that pharmacy personnel can operate in parallel with other healthcare providers on one end and are able to form professional bonds with the patients on the other.

5.3 Efforts should be made to involve professional representatives and appropriate external trainers and resource persons for training.

5.4 The program should prescribe the minimum knowledge to be attained by each personnel to be able to provide better Pharmaceutical Care.

5.5 All pharmacy personnel should be aware of Quality Policy of the pharmacy, and should be conscious about their role of delivering health care to the patients.

5.6 They should be trained and made aware of personal hygiene, as well as the level of hygiene to be maintained in storage and handling of medicines.

5.7 Special emphasis should be laid on training

5.7.1 Pharmacists: in communication and counseling skills, handling of prescriptions and patients, continuing education in illnesses & medicines, latest developments in the field of medicine and pharmacy and general health matters, on "when to refer" to a Doctor.

5.7.2 Pharmacy assistants: in communication skills, salesmanship, handling of prescriptions, dispensing of medicines, procurement and storage of medicines, and "when to refer" to a Pharmacist and Doctor for counseling.

5.8 Other personnel should also receive training as per their job description.

5.9 Procedures for imparting education / training should be well documented, and carried out as per a predetermined schedule

5.10 Training process should be well documented and reviewed periodically.

5.11 Pharmacists should be encouraged to keep their knowledge up-to-date through scientific literature, textbooks, journals, periodicals and workshops. Networking with pharmacists in other pharmacies should be encouraged. Management and Pharmacist shall be responsible to continuously train the personnel available in the pharmacy to ensure maximum benefits to the community.

6 Complaints and Recalls

6.1 Complaint

6.1.1 The pharmacy should have procedure, to receive complaints, which should be reviewed from time to time.

6.1.2 All complaints - oral or written - must be immediately addressed by the Pharmacist, and appropriate action be taken to amend the situation.

6.1.3 The complaint, its nature, the erring persons' name, and the action taken must be documented in a Complaint Register.

6.1.4 The event should be reviewed and evaluated to find the underlying cause(s).

6.1.5 Appropriate steps should be taken to amend the operating procedures or other guidelines so as to prevent the recurrence of the same or similar events.

6.2 Medicine Recall

6.2.1 The pharmacy should have a well-documented recall procedure.

6.2.2 The pharmacy should proactively participate in nationwide recall process for any substandard medicines. All such recalls should be initiated upon receiving authentic information and alarms to do so. The initiation, progress and completion of the recall should be well documented.

6.2.3 In case of any suspicion, the Pharmacist should take immediate steps to stop the sale of the medicine and notify the relevant parties.

6.2.4 If the Pharmacist has a suspicion or a reason to believe that shortcomings have occurred in the process of delivery of medicines from the pharmacy – immediate effective measures should be initiated to minimize the risk of damage or danger to the patient(s).

7 Documentation System

7.1 Documentation is one of the core activities for achieving and maintaining quality. The overall responsibility for documentation rests with the Pharmacist. All necessary statutory documents (e.g. regulatory licenses, registrations, permissions etc.) for operating a pharmacy must be adequately maintained, and should be displayed if required under the law. In all cases they should be easily accessible whenever required.

7.2 All operational documents e.g. purchase invoices, sales invoices and other statutory documents should be maintained and archived as prescribed by the law.

7.3 There should also be adequate control and maintenance of documents that form a part of the pharmacy's quality system.

7.4 Some of the necessary documents include:

a. Quality Manual and policy documents
b. Protocols
c. Standard Operating Procedures
d. Cleaning & maintenance processes & records
e. Training manuals and training records
f. Complaint records
g. Audit records
h. Personnel details and job descriptions
i. Record of narcotics and psychotropics

7.5 In addition, the documents required for the Pharmaceutical Care Process should also be adequately maintained and stored. These documents include:

a. Patients' health profile
b. Patient's medication records
c. Records of counseling follow-ups, etc.

8 Procurement and Inventory Management

8.1 The pharmacy should develop and maintain a safe, effective, operational and socio-economically acceptable procurement and inventory management. As far as possible, the Pharmacist should ensure that medicines and other health care products are readily available in the pharmacy in sufficient quantities.

8.2 **Suppliers and Purchasing:**

8.2.1 The Pharmacist should ensure that the sources of supply of medicines and other items meet the standards laid down by the law. Pharmacist also has the responsibility to protect the interests of the patients and the pharmacy by purchasing the medicines from the authorized sources.

8.2.2 The Pharmacist should satisfy himself about the reliability and adequacy of the measures deployed by the suppliers' chain to ensure that all medicines have been handled in appropriate storage and transit conditions. Details of the suppliers (e.g. their addresses, contact numbers, names and addresses of their management persons, technical persons and administrative personnel, copies of the various licenses held by them) should be maintained.

8.2.3 A written communication regarding the list of authorized representatives of the supplier and their specimen signatures should be obtained and archived. Responsible designated person(s) from the pharmacy should visit the suppliers' premises from time to time for conducting audit of their premises and systems – to the extent they are likely to affect the quality of the medicines. Errors made by the suppliers should be brought to notice as soon as possible and rectified.

8.2.4 All errors made by the suppliers, nature of errors, repetition of same errors, method and time frame of rectification should be documented and reviewed periodically to prevent their recurrence.

8.3 The Pharmacist may consider informing the regulatory authorities in case there are reasons to believe deliberate dubious activities by the supplier(s) and/or if repeated error or malpractice occurs.

8.4 The pharmacy should have written procedure for the selection of the medicines. The pharmacy should maintain "Product List", along with the retail price, where all items approved by the pharmacy for stocking are described.

8.5 A separate list of important medicines including essential and life saving medicines should be prepared.

8.6 The product list should be reviewed and updated as often as necessary. Any new item added to the inventory must first be included in the list after a professional review by the Pharmacist. Where the pharmacy operations are managed using computers – the item must first be entered into the database and then ordered for procurement.

8.7 Ideally, the product list should also specify the location of that product in the pharmacy.

8.8 Adequate cost-effective purchasing methods should be followed which ensures adequate inventories and optimal financial investment for the pharmacy.

8.9 Availability of the listed medicines should be assured. The list should include essential and life saving medicines as per current Nepalese Essential Drug List.

8.10 In-house benchmarks for various categories of medicines should be set for minimum-remaining-shelf -life at the time of procurement.

8.11 All medicines received from suppliers should be tallied against their invoices and checked for correctness of quantity, price, batch number and expiry date. Any anomalies should be brought to the notice of the supplier/s and suitable rectifications should be done. All such rectifications should be documented and get authenticated by an authorized representative of the suppliers.

8.12 The purchase records/invoices should be maintained regularly.

9 Storage

9.1 **Storage management**

9.1.1 All medicines coming into the pharmacy should initially be quarantined, preferably in a separate area, before they are checked for correctness of quantity, batch number, expiry, integrity etc. After necessary checks, they should be transferred to their respective storage locations.

9.1.2 All medicines should be stored at stipulated temperature areas, protected from excessive light, dust, and humidity. Temperatures at the various areas should be recorded at predetermined periodicity and records should be preserved for a period of 2 year. They may be correlated with the subsequent years' corresponding data to improve arrangements for maintenance of temperatures.

9.1.3 The medicines and shelves should be maintained clean and dust free at all times by following cleaning schedules and SOPs. Prescription medicines should be kept in such a manner that they are out of reach of patients.

9.1.4 All the medicines that are to be stored in a 'cold' temperature should be kept in the refrigerator. Special care and arrangement should be made for the medicines which need to be stored at a prescribed temperature

9.1.5 Medicines and dosage forms that need special care while dispensing (e.g. medicines that fall in group Ka.) should be kept under lock and key. The key for this should be available only with the Pharmacist. Records of purchases and sales of such medicines should be kept as per legal requirements.

9.1.6 Shelves should be checked at a predetermined periodicity to ensure removal of medicines whose expiry date is approaching. In-house threshold periods should be set and followed for such retrieval of medicines from the shelves. The near expiry medicines should be stored separately for early disposal. Medicines, which have already expired, should be stored separately in a locked shelf, bearing the label "Expired Goods – Not For Sale". Care should be taken that such goods do not reach the patients in any case. Medicines should not be sold to the patients after the 1st of the labeled expiry month.

9.1.7 Medicines should be sold in such a way that they do not expire during the time period for which the patient is prescribed to take the medication.

9.1.8 Expired and damaged medicines should be returned to the supplier or destroyed as per in-house procedures at the earliest.

9.1.9 The unused and unopened medicines lying in the pharmacy should be listed and returned to the respective suppliers. However in case this is not possible – the same may be disposed off as per the pharmacy's in-house procedures in this regard.

10 Prescription Handling

10.1 Patients must be made to feel attended and comfortable by friendly gestures and ambience as soon as they come into the pharmacy. Communication should be opened in such a way that it encourages the client to convey his / her needs by producing a prescription or by asking for other medicines or advice.

10.2 Upon receiving the prescription, the Pharmacist or person instructed by the pharmacist should confirm:

a. Identity of the client
b. Whether the prescription is presented by the client himself/herself or by someone on the client's behalf.

10.3 The client may be politely requested to wait while the prescription is reviewed for:

a. Therapeutic aspects (Pharmaceutical & pharmacological)
b. Appropriateness for an individual
c. Social, legal and economic aspects
d. Legality and completeness of prescription

10.4 Prescription should be considered as incomplete if any of the following information is missing:

a. Name of the prescriber, his/her address and Council registration number
b. Name, address, age, sex of the patient
c. Name(s) of the medicine(s), potency, dosage, total amount of the medicines to be supplied
d. Instructions to the patient
e. Refill information if any
f. Prescribers' signature and Date

10.5 Any incompleteness, ambiguities, confusions, shortcomings or anomalies in the prescription should be brought to notice of the prescriber.

10.6 Correctness of prescribed medicines:

The prescription should be checked for

a. Dosage regimen: Whether the dosage prescribed is within the standard minimum or maximum dosage range.

b. Double medication (same medicine or different medicine with same pharmacotherapeutic effect) concurrently prescribed by the same prescriber or by two or more prescribers to the same patient .
c. Interactions between the currently prescribed medicines with other medicines being taken by the patient like OTC medicines, medicines from any past prescriptions (record of which may be available in the Patient's Medication Records), vitamins, tonics, or any other herbal medicines. Any medicine interactions likely to render the therapy ineffective or cause undesirable effects to the patient should be brought to notice of the prescriber.
d. Contraindications: Age, sex, disease(s), conditions or other characteristics of a patient that may cause certain prescribed medicines to be contraindicated.
e. History of overuse, under use, or misuse of medicines by the patient.
f. Any of the above as well as handwriting legibility problems should be brought to the notice of the prescriber. Any necessary changes made by the prescriber should be recorded on the prescription, with the words "Changes made over the telephone in consultation with the prescriber (name) at (time) on (date)" and should be signed and stamped by the Pharmacist.

10.6 This exercise necessitates a trust based professional relationship with the prescriber. In case of any doubt, the prescription should be suitably amended from the prescriber.

11 Dispensing

11.1 Filling the Prescriptions:

11.1.1 The medicines should be taken out from the storage area, counted and invoiced. In all cases, final review of prescription and the correctness of dispensed medicines must be made personally by a Pharmacist.

11.1.2 As a final step, the Pharmacist should personally dispense the medicines, at which stage appropriate counseling should be given for the patient.

11.1.3 The prescriptions with Group 'Ka' medicines should be stamped "Prescription Filled" after dispensing the medicines.

11.1.4 The medicines should be packed neatly so that their integrity is maintained. Any medicines requiring special storage conditions, e.g. a cold place (2-8^{o}C) must be packed in cold packs so that they remain at the stipulated temperature till they are stored subsequently. If solid unit dosage forms are taken from a larger bulk pack then they should be packed in a clean, food grade glass or plastic bottles or in a clean envelop and neatly labeled as provided under the law.

11.1.5 Appropriate counseling / guidelines must be given for the patient, as recommended below under Patient Information.

11.1.6 Conscious efforts should be made to ensure that the patients' waiting time is kept at the minimum, while all the necessary steps are carried out systematically. This can be achieved by several management options e.g. by deploying appropriate personnel to patients' ratio.

11.1.7 After filling the prescription, the patient should be provided with a bill in which the batch no, manufactured date and the expiry date of the dispensed medicines should be clearly written.

11.2 Extemporaneous Preparations

11.2.1 Standard operating procedures as well as standard formulations should be maintained for commonly made extemporaneous preparations. Proposed adjuvant, their quantities and the method of preparation must

be written down before any compounding activity is initiated. Each step should be followed methodically and a step by step record maintained. Batch numbers of each medicine used for compounding should be recorded. All such preparations should preferably be compounded by the Pharmacist, or under direct supervision of a Pharmacist.

11.2.2 Only approved grade of ingredients should be used for compounding. The preparation area should be cleaned immediately before and after compounding. All necessary weighing, measuring instruments must be calibrated periodically and records maintained.

11.2.3 After compounding, the product should be transferred to a suitable container and closed securely. The container should be appropriately labeled, stating name of the preparation, date of preparation, name of the patient, directions, quantity, a reference (batch) number generated by the pharmacy, expiry date, storage conditions and name of the pharmacy. These details must be recorded in a register or electronically for suitable reference and retrieval as and when required.

11.2.4 Extemporaneous preparations are meant to be dispensed to a particular patient and should not be prepared for another pharmacy except in special circumstances.

12 Patient Information

12.1 Pharmacists' fundamental concern is welfare of the patient. Patient's responsibility to make decisions regarding his/her health must be respected at all times. Therefore, the Pharmacist must help the client in making well-informed decisions about proper use of medicines and other health care medicines. Pharmacist should support the patient in making well-considered decisions with regard to self-care.

12.2 Whenever a Pharmacist has doubts or reasons to believe that it would be in better interest of the patient, he/she must advice the patient to see a doctor or health care provider as soon as possible.

12.3 Pharmacist should offer the patients sufficient opportunities for personal consultation.

12.4 Pharmacist should provide oral as well as written information about various illnesses, medicines and other health care products, in order to increase the awareness levels of the client regarding his illness and his medicines. The goal of consultation is to achieve maximum compliance.

12.5 As far as possible, delivery of medicine to the client should be supported by written information.

12.6 All dispensed medicines should ideally be provided with a label, which clearly states:

a. Name of the patient, age, sex.
b. Name, strength, batch number and expiry date of the medicine, in case the medicine has been repacked or cut-out from a larger pack.
c. Dosage and usage instructions to the patient Storage instructions.
d. Date of delivery.
e. Name and address of the pharmacy.

12.7 Dosage and usage information must also be given verbally to the patients (e.g. use of dispersible tablets, chewable tablets, inhalers) along with the demonstrations and pictograms where ever required.

12.8 It must be ensured that the information and advice given is correct, clear, explicit, up-to-date and understandable for the client. It should be given in a language and at a level of complexity that is easily understood by the client. Nature and quantity of information and advice, as well as the way these are provided, often need to be suited to the client's needs and wishes. The attitude of the Pharmacists towards the client must guarantee a correct understanding of and a sufficient confidence in the information provided.

13 Patient Counseling

13.1 The Pharmacist must work out strategies to make time to provide professional counseling with regard to use of medicines and health related products, so as to improve the quality of the patient's life. While dispensing, the patient should be explained:

a. How to take the medications
b. For how long
c. When to take the medicines and whether to take them before, during or after meals etc.
d. What foods / beverages / tasks to avoid during the therapy
e. What side effects to expect and how to manage them
f. What to do if one or more doses get skipped
g. Refill information where ever applicable
h. Any other precautions

13.2 Appropriate discretion should be exercised while discussing nature of illness, its cause, prognosis (course of the disease), and the expected outcomes of the therapy.

13.3 Patients' counseling should ideally be done in the Counseling Area or where a separate area is not available - in such an area of the pharmacy where the conversation is not overheard by others.

13.4 As far as possible, oral information given to the patients should be supplemented by additional written information (in the form of Patient Information Leaflets) about their illness and the medicines. To reinforce the understanding and improve compliance, the patient should be asked to explain what has been conveyed. Depending on the local needs and understanding levels of the patients, the Chief Pharmacist should devise methods to improve Patient Compliance.

13.5 A list of general and specialized health care professionals and facilities (including laboratories) in the locality and the city should be maintained and made available to the patients whenever necessary.

13.6 The pharmacy should have the latest version of Essential Drug List and Nepalese National Formulary and other relevant documents about the banned and DDA registered Drugs.

14 Medication records & Patient follow-up

14.1 Medication records

14.1.1 The pharmacy should maintain individual PMR in a system (manual or computerized) which allows for easy retrieval of patients' health and medication history wherever appropriate.

14.1.2 Home delivery of medication should only be done for patients having PMR at the pharmacy.

14.1.3 The medication history of patient may be taken depending on the following conditions:

a. Whether the patient is suffering from a chronic ailment
b. Whether the patient needs to monitor and control certain values or conditions e.g. blood pressure, asthma, cholesterol, blood sugar level etc.

14.1.4 The most generic format for Patient Medication Record should cover the following:

a. All medicines taken during the last one year or more (name of the medicine, potency, dose taken, duration for which consumed)
b. Are there any known allergies or hypersensitivity reactions to any medicine(s)
c. Adverse medicine reactions, medicine interactions encountered by the patient
d. What medication, if any, was given to manage the reaction
e. Is there any dependence on any medicine(s) and does the prescriber know of these?
f. Does the patient regularly consume alcoholic beverages, tobacco, tea or coffee (frequency and amount may be recorded).
g. Have there been any problems with medicines e.g. difficulty in swallowing etc.
h. Professional advice given from time to time

14.1.5 All data and information related to the patients should be stored and maintained in such a way that it remains confidential and is accessible only to the authorized persons. Such data may be shared with other healthcare professionals usually at the specific request of the patient or when it is in the best interest of the patient.

14.2 **Patient follow-up**

14.2.1 Continuity of care is essential to many patients, particularly those with chronic conditions. Pharmacists should track medications taken by such patients and regularly update the patient's medication history as long as the patient is under his/her care. Whenever the Pharmacist has any reason to believe that another healthcare provider would be able to give better treatment to the patient – the patient should be given a referral slip stating the condition of the patient and the medication received by the patient so that the other healthcare provider can be referred. Pharmacist's name and pharmacy contact numbers should be stated on the referral slip so as to facilitate any further inquiries by the other healthcare provider.

14.2.2 Follow up may be accomplished during subsequent visits of the patient or through telephone callbacks for which the patient's consent may be obtained.

14.2.3 The Pharmacist must personally make the follow-up calls or meetings and enquire about:

a. Patient's general condition and response to therapy
b. General problems, adverse events encountered by the patient
c. Dose and frequency at which medicines have been taken by the patient
d. Missed doses

14.2.4 Possible causes of non-compliance by the patient should be evaluated and the patients counseled accordingly. The Pharmacist should keep the prescribers updated about all adverse events reported by or elicited from the patient and the stated or probable reasons for patient not complying with the prescription / therapy.

15. Self Care

15.1 Pharmacy should have a clearly stated health promotion policy under which its Pharmacists should promote self-care by the patients. Programs and campaigns may be conducted to promote healthy life styles and prevention of ill health through appropriate diet, regular exercise, avoiding alcohol, tobacco, excessive tea or coffee etc. Misuse and abuse of medicines and medicines should be particularly reinforced.

15.2 Pharmacist may promote informed self-medication or suggest/offer non-prescription medicines, when preventive measures fail and the patient's condition does not appear to be serious. The patient must be referred to a prescriber if the Pharmacist is unsure of the condition and has a reason to believe that the referral would be in the best interest of the patient. Even when an advice or a non-prescription medication has been given to the patient – he/she must be advised to refer to a Doctor if the symptoms persist beyond three days or whenever the patient feels worse.

15.3 Pharmacy should have written protocols for offering advice for self-medication, offering non-prescription medicines and the information that must be given to the patients in both these cases

16 Health Promotion

16.1 The Pharmacist must keep himself/herself aware of the national policies and various programs related to health. The pharmacy should proactively participate in health promotion campaigns and programs at the local as well as national level. This can be achieved by distributing patient information leaflets, displaying posters and informative material in the pharmacy etc.

16.2 The pharmacy should be in a position to give advice and assistance on some selected topics like diabetes, hypertension, arthritis, AIDS, breastfeeding, use of devices, appropriate usage of medicines etc.

16.3 Personnel involved in such campaigns should necessarily be educated through focused continuing education programs, regular interactions with other healthcare providers and should have practiced communication skills.

17 Enhancement and Development of Professional Role

17.1 Pharmacists should keep themselves updated about the developments in the profession. They should possess excellent communication skills to be able to work closely with other healthcare providers and mutually share the learning. Pharmacists must maintain healthy relationship with other health care professionals.

17.2 In case of any discrepancy/doubt in the prescription, the Pharmacist should contact the prescriber over telephone without unduly alarming the patient, and, put forward the query to the prescriber in a friendly manner. Before doing so, he must doubly check and assure that there is really an error or discrepancy in the prescription, and also work out the alternative/ solution, which can be promptly suggested on inquiry from the prescriber.

17.3 Up-gradation of professional skills and improved understanding between various healthcare professionals in the locality can be achieved through this process

17.4 Pharmacists should make all efforts to deliver pharmaceutical care to his patients. This can be achieved by providing various professional services to the patients.

18 Pharmacovigilance

18.1 The Pharmacist should be alert to the occurrence of adverse effects (expected & unexpected) to medicines during active conversation with the patient. These should be recorded in the individual PMR. The Pharmacist should give suitable instructions to the patient to reduce the adverse effects in the future, e.g. by advising the patient how to take the medicine correctly, what other medicines or foods to avoid, any activities that the patient should avoid (e.g. not going out in the sun, not driving, etc.), or by consulting the prescriber.

18.2 In participating in a pharmacovigilance program the occurrence of an adverse event should also be recorded in the prescribed format and forwarded to the coordinating center.

19. Audit

19.1 Audits are conducted to check whether the pharmacies comply with the quality standards stated in the Quality Manual, to see whether the desired objectives of the pharmacy are being achieved. By a Quality Audit, the Pharmacist can evaluate the different routine processes and the quality systems in the pharmacy, and check whether the systems are functioning as per requirements. This is achieved by a frequent auditing. Based on the audit reports, steps should be initiated to make necessary improvements.

19.2 The Pharmacist along with senior personnel or members of the management team can conduct the internal audit.

19.3 The personnel deployed for internal audit should be adequately trained for the purpose. The internal audit may be carried out once in six months, or more frequently. External experts may be included in the team for internal auditing.

19.4 All audit procedures should be suitably documented. The audit reports should be used to analyze the weaknesses and deficiency in the system so that rectifications are initiated.

20 Definitions

Patient:
A client who is suffering from an ailment and visits the pharmacy to obtain medication or advice.

Medicine:
All chemical or natural substances capable of being used for therapeutic purposes.

Pharmacy:
The area of pharmacy practice in which medicines and other related products are sold or provided directly to the public from a retail outlet designed primarily for the purpose of providing medicines. The sale or provision of the medicine may be either on the order or prescription of a doctor or "over the counter" by the Pharmacist.

Pharmaceutical Care:
The responsible provision of pharmaco-therapy for the purpose of achieving definite outcomes that improve or maintain a patient's quality of life. It is a collaborative process that aims to prevent or identify and solve medicinal product and health related problems.

Pharmacist:
A person with a formal pharmacy qualification with a bachelor degree in pharmacy, and who is registered with the Nepal Pharmacy Council where he is practicing the profession as a pharmacist.

Pharmacy Assistant:
A person who has obtained certificate level in pharmacy (diploma pharmacy), and who is registered with the Nepal Pharmacy Council where he is practicing the profession as a pharmacy assistant.

Expiry Date:
A date fixed for each individual batch specifications for quality of medicines; before which the batch still meets the required standard

Prescriber:
A person in health care who is permitted by law to order drugs that legally require a prescription; includes physicians, physician assistants, dentists. The prescriber is not always a medical doctor but can also be a paramedical worker, such as a medical assistant.

Professionalist:
A person engaged by a Pharmacy, who does not have any formal pharmacy qualification but has acquired the qualification as specified by the drug advisory committee and recognized by the committee.

21 References

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3. Good Pharmacy Practice (GPP) in Developing Countries-Federation International Pharmaceutical (FIP) 1997

4. Good Pharmacy Practice in Community and Hospital Pharmacy Settings, WHO Technical report series No. 885, 1999

5. Good Practice in Donations of Medicines, FIP 1997

6. WHO Guidelines for Drug Donations, 1999

7. Report on Working Committee for directives, procedure and determination for enforcing codes on sales and distribution of drugs, DDA, 2004

ANNEX A

CHECK LIST

For

Quality Audit as per

National Good Pharmacy Practice Guidelines

CHECK LIST
For
Quality Audit as per
National Good Pharmacy Practice Guidelines

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	Yes	No	Comments
1. Facilities:			
1.1 **Premises**			
1.1.1 Is the environment around the pharmacy neat and clean?			
1.1.2 Is the facade marked clearly with the word "PHARMACY", written in English as well as in Nepali?			
1.1.3 Is the pharmacy conveniently accessible to people using prams or wheel chairs?			
1.1.4 Are the pharmaceutical services and medicines served from an area which is separate from other activities / services and medicines?			
1.1.5 Is the pharmacist easily accessible to public for information and counseling?			
1.1.6 Is the environment of the pharmacy clean with minimum dust and maintained as per the cleaning schedules and Standard Operating Procedures (SOPs)?			
1.1.7 Is the pharmacy free from rodents and pests/insects?			
1.1.8 Are the pest control measures undertaken from time to time?			
1.1.9 Does the pharmacy have adequate space as recommended by the regulatory authority?			
1.1.10 Is the space enough for holding shelves of medicines, display counter, counseling area, and sufficient for proper movement of personnel and patients?			
1.1.11 Does the pharmacy have a constant supply of electricity, especially for the refrigerator(s).			

1.1.12	Is there a provision for drinking water to facilitate medicine administration to the patients and for use of the personnel?			
1.1.13	Does the pharmacy have:			
a.	Sufficient place for patients to stand comfortably at the dispensing counter and for some to sit comfortably while they wait?			
b.	Space for patient information displays, including information leaflets / material?			
c.	A separate enclosure described as "Counseling Area" for patient counseling, storage of reference resources (e.g. books, internet access) is a fundamental requirement?			
1.1.14	Does the pharmacy have a separate counseling area away from the area otherwise normally accessed by the patients?			
1.1.15	Is the counseling area enclosed with a door which can be closed for further confidentiality?			
1.1.16	Is it well lighted with comfortable seating for the Pharmacist and the patient/attendant?			
1.1.17	If the pharmacy dispenses extemporaneous preparation does it have enough space to do so?			
1.1.18	Does the pharmacy have separate waste collection baskets /boxes available for the personnel and for the patients?			
1.1.19	Is the medicine storage area protected from exposure to excessive light and heat?			
1.1.20	Is the pharmacy maintained at ambient temperature in the within			

the stipulated range?			
1.1.21 If the Pharmacy provides related services such as doctors, clinics, and first aid and dressing services, are they managed separately from the pharmacy?			
1.2 **Furniture & Fixtures**			
1.2.1 Does the pharmacy have neat, well placed shelves for the provision of storage of medicines and other items in a neat manner?			
1.2.2 Are the medicines protected from dust, moisture, excessive heat and light?			
1.2.3 Are there adequate provisions for storing medicines at prescribed temperature conditions?			
1.2.4 Is the counseling area furnished with			
a. A table?			
b. Chairs for the Pharmacist and a couple of patients?			
c. Cabinet for storing Patient Medication Records (PMRs)?			
1.3 **Equipment**			
1.3.1 Is the pharmacy equipped with refrigerated storage facilities?			
1.3.2 Is this facility validated from time to time?			
1.3.3 Is the counseling area equipped with:			
a. Reference material			
b. Demonstration charts, kits and other demonstration material			
c. Patient information leaflets (PILs)			
d. Some basic instruments e.g. sphygmomanometer, glucometer, Snellens chart, stethoscope			
e. Weight & height scale			
1.3.4 Is the pharmacy equipped with computers and appropriate software?			

1.3.5 Computers are used for			
a. Manage inventory?			
b. Manage invoicing?			
c. Generate timely warnings for expiring medicines?			
d. Archive patient medication records?			
1.3.6 Are the computers equipped to give demonstrations to the patients and for maintaining database?			
1.3.7 Does the pharmacy have it own compounding section?			
1.3.8 Is the compounding section of the Pharmacy equipped with appropriate apparatus required for the preparation?			

2. Personnel			
2.1 Is the Pharmacy managed under the overall supervision of a Pharmacist?			
2.2 Does the Pharmacist/s working in the pharmacy:			
a. Hold at least a bachelor degree in Pharmacy?			
b. Is registered as a Pharmacist with the Nepal Pharmacy Council?			
c. Have undergone adequate practical training in a community pharmacy?			
2.3 Pharmacy assistant working in the pharmacy should:			
a. Hold at least a Diploma in Pharmacy?			
b. Be registered as a pharmacy assistant with the Nepal Pharmacy Council?			
c. Have undergone adequate practical training in a community pharmacy?			
2.4 Are all activities in the Pharmacy carried out as per well-documented guidelines and procedures?			
2.5 Do each personnel have clearly allotted responsibilities?			
2.6 Are these responsibilities performed according to documented SOPs?			
2.7 Do all personnel in the pharmacy wear a neat apron / coat?			
2.8 Do all Pharmacists wear a badge prominently displaying their name and the word "Pharmacist"?			
2.9 Is hiring an employee proceeded by a medical examination?			
2.10 Do all pharmacy personnel undergo medical examination?			
2.11 Do all pharmacy personnel undergo periodic immunization?			
2.12 Is there a system for archiving their health data?			

3. Quality Policy:			
3.1 Does the pharmacy have well documented Quality Policy?			
3.2 Does the pharmacy have a quality manual stating, in detail, the necessary steps to be carried out for fulfillment of the desired quality goals?			
3.3 Does the manual enlist the details of the activities, routines, distribution of responsibilities, work procedures and instructions?			
3.4 Is the Quality Manual accessible to the personnel of the pharmacy for their easy reference?			
3.5 Are all the activities mentioned in the Quality Manual well documented?			
3.6 Is the Quality manual periodically reviewed and updated and the outcomes should be documented for review to further improve the processes?			

4. Service Strategy			
4.1 Does the pharmacy have a well documented service strategy based on its client servicing goals?			
4.2 Does the service strategy statement include issues like home delivery of medicines, the nature and level of attention to be given to patients of various kinds (e.g. elderly patients, regular patients)?			
4.3 Does the pharmacy have its own service manual, stating in detail, the necessary steps to be carried out for providing each service offered in the pharmacy.			

5. Training			
5.1 Are all personnel including newly recruited personnel trained as per the personnel training policy of the pharmacy?			
5.2 Are there adequate reference resources (books, current periodicals, software etc.) curriculum and training manuals for the training process?			
5.3 Are professional representatives and appropriate external trainers and resource persons involved in the training process?			
5.4 Are All pharmacy personnel aware of Quality Policy of the pharmacy?			
5.5 Are they conscious about their role of delivering health care to the patients?			
5.6 Are they trained about personal hygiene, as well as the level of hygiene to be maintained in storage and handling of medicines?			
5.7 Are procedures for imparting education / training well documented, and carried out as per a predetermined schedule?			
5.8 Are training processes well documented and reviewed periodically?			

6. Complaints and Recalls			
6.1 **Complaint**			
6.1.1 Does the pharmacy have written procedure/SOP, to receive complaints?			
6.1.2 Are all complaints immediately addressed by the Pharmacist, and suitable action be taken to amend the situation?			
6.1.3 Is the complaint reviewed and evaluated to find the underlying cause(s)?			
6.1.4 Are appropriate steps taken to amend the operating procedures or other guidelines so as to prevent the recurrence of the same or similar events?			
6.1.5 Is complain, its nature, the erring persons' name, and the action taken documented in a Complaint Register?			
6.2 **Medicine Recall**			
6.2.1 Does the pharmacy have a well-documented recall procedure?			
6.2.2 Does the pharmacy have a well-documented recall procedure?			
6.2.3 Does the pharmacy participate in nationwide recall process for any substandard medicine?			
6.2.4 Are all recalls initiated upon receiving authentic information and alarms to do so?			
6.2.5 Are all the initiation, progress and completion of the recall well documented?			
6.2.6 Are all the initiation, progress and completion of the recall well documented?			

6.2.7	In case of any suspicion, does the Pharmacist take immediate steps to stop the sale of the medicine and notify the relevant parties?			

7. Documentation System:			
7.1 Is there a description of the documentation system? (Responsibility for preparation, revision, storage)			
7.2 Are all necessary statutory documents (e.g. regulatory licenses, registrations, permissions) for operating a pharmacy adequately maintained?			
7.3 Are the documents easily accessible whenever required?			
7.4 Are all the operational documents e.g. purchase invoices, sales invoices and other statutory documents maintained and archived as prescribed by the law?			
7.5 Are there adequate control and maintenance of documents that form a part of the pharmacy's quality system?			
7.6 Are the following documents available in the pharmacy?:			
a. Protocols			
b. Standard Operating Procedures			
c. Quality Manual and policy documents			
d. Cleaning & maintenance processes & records.			
e. Complaint records			
f. Audit records			
g. Personnel details and job descriptions			
h. Record of narcotics and psychotropics			
7.7 Are the documents required for the Pharmaceutical Care Process adequately maintained and stored?			
7.8 Do these documents include:			

a. Patients' health profile			
b. Patient's medication records			
c. Records of counseling follow-ups, etc.			

8. Procurement and Inventory Management			
8.1 Does the pharmacy maintain a safe, effective, operational and socio-economically acceptable procurement and inventory management?			
8.2 Are the medicines checked for their standard, laid down in the law, before they are accepted inside the pharmacy?			
8.3 Are medicines purchased from the authorized sources only?			
8.4 Does the Pharmacist check for the reliability and adequacy of the measures deployed by the suppliers' chain to ensure that all medicines have been handled in appropriate storage and transit conditions?			
8.5 Are the details of the suppliers (e.g. their addresses, contact numbers, names and addresses of their management persons, technical persons and administrative personnel, copies of the various licenses held by them) maintained?			
8.6 Does the pharmacy obtain a written communication regarding the list of authorized representatives of the supplier and their specimen signatures and archived?			
8.7 Does the pharmacy have the provision to send designated person(s) from the pharmacy to visit the suppliers' premises from time to time for conducting audit of their premises and systems – to the extent they are likely to affect the quality of the medicines?			
8.8 Are the errors made by the suppliers			

	brought to the notice as soon as possible and rectified?			
8.9	Are all errors made by the suppliers, nature of errors, and repetition of same errors, method and time frame of rectification documented and reviewed periodically to prevent their recurrence?			
8.10	Does the Pharmacist inform the regulatory authorities in case there are reasons to believe deliberate dubious activities by the supplier(s)?			
8.11	Does the pharmacy have written procedure for the selection of the medicines?			
8.12	Does the pharmacy maintain "Product List", along with the retail price, where all items approved by the pharmacy for stocking are described?			
8.13	Does the pharmacy assure the availability of the listed medicines?			
8.14	Do listed medicines include essential and life saving medicines?			
8.15	Is the list of medication reviewed and updated periodically?			
8.16	Is any new item added to the inventory first included in the list after a professional review by the Pharmacist, before sending for procurement?			
8.17	Does the product list specify the location of that product in the pharmacy?			
8.18	Is there In-house benchmark for various categories of medicines for minimum-remaining-shelf-life at the time of procurement?			
8.19	Are all medicines received from suppliers tallied against their invoices and checked for correctness of quantity, price, batch number and expiry date?			

8.20	Are all errors and rectifications during procurement, documented and get authenticated by an authorized representative of the suppliers?			
8.21	Are all the purchase records/invoices maintained as stipulated under the law?			

9. Storage				
9.1	Are storage area enclosed and locked where required?			
9.2	Is there separate storage area for initial quarantine of all incoming medicines?			
9.3	Are all medicines coming into the pharmacy checked for correctness of quantity, batch number, expiry, integrity before transferring into storage location?			
9.4	Are all medicines stored at stipulated temperature areas, protected from excessive light, dust, and humidity?			
9.5	Are Temperatures at the various areas recorded at predetermined periodicity and daily records preserved for a period of 2 year?			
9.6	Are the medicines and shelves maintained clean and dust free at all times by following cleaning schedules and SOPs?			
9.7	Are Prescription medicines kept in such a manner that they are out of reach of patients?			
9.8	Are all the medicines that are to be stored in a 'cold' temperature kept in the refrigerator?			
9.9	Are medicines and dosage forms that need special care while dispensing			

	(e.g. medicines that fall in group Ka.) kept under lock and key?			
9.10	Is the key for this strictly available only with the Pharmacist?			
9.11	Are Records of purchases and sales of such medicines kept as per legal requirements?			
9.12	Are Shelves checked at a predetermined periodicity to ensure removal of medicines whose expiry date is approaching?			
9.13	Are there any In-house threshold periods for retrieval of medicines from the shelves?			
9.14	Are the near expiry medicines stored separately and disposed off either by returning to the respective suppliers or by expediting their dispensing?			
9.15	Are Medicines, which have already expired, stored separately in a locked shelf, bearing the label "Expired Goods – Not For Sale"?			
9.16	Are the Expired medicines to the supplier or destroyed as per in-house procedures at the earliest?			
9.17	Are the unused and unopened pharmaceutical medicines lying in the pharmacy listed and returned to the respective suppliers?			
9.18	However in case 9.17 is not possible. Is there a provision to dispose off the unused and unopened pharmaceutical medicines as per the pharmacy's in-house procedure?			

10. Prescription Handling			
10.1 Upon receiving the prescription, Does the Pharmacist confirm for:			
a. Identity of the client?			
b. Whether the prescription is presented by the client himself/herself or by someone on the client's behalf?			
10.2 Does the Pharmacist review the prescription for -			
a. Therapeutic aspects (Pharmaceutical & pharmacological)?			
b. Appropriateness for an individual?			
c. Social, legal & economic aspects?			
d. Legality & completeness of prescription?			
10.3 Are the prescriptions checked for			
g. Name of the prescriber, his/her address and Council registration number			
h. Name, address, age, sex of the patient			
i. Name(s) of the medicine(s), potency, dosage, total amount of the			
j. Mdicines to be supplied			
k. Instructions to the patient			
l. Refill information if any			
m. Prescribers' signature			
10.4 Is the prescription should be checked for			
10.4.1.1 Dosage: Whether the dosage prescribed is within the standard minimum or maximum dose range?			
10.4.1.2 Double medication (same medicine or different medicine			
10.4.1.3 with same pharmacotherapeutic effect) concurrently prescribed			

	by the same prescriber or by two or more prescribers to the same patient?			
10.4.1.4	Interactions between the currently prescribed medicines, OTC medicines being taken by the patient and the medicines being taken from any past prescriptions (record of which may be available in the Patient's Medication Records)?			
10.4.1.5	Any medicine interactions likely to render the therapy ineffective or cause undesirable effects to the patient should be brought to notice of the prescriber?			
10.4.1.6	Contraindications: Age, sex, disease(s), conditions or other characteristics of a patient that may cause certain prescribed medicines to be contraindicated?			
10.4.1.7	History of overuse, under use, or misuse of medicines by the patient?			
10.5	Are any necessary changes made by the prescriber recorded on the prescription, with the words "Changes made over the telephone in consultation with the prescriber (name) at (time) on (date)" and signed and stamped by the Pharmacist?			

11. Dispensing				
11.1	Is the final review of prescription and the correctness of dispensed medicines made personally by a Pharmacist?			
11.2	As a final step, does the Pharmacist personally dispense the medicines?			
11.3	Does the pharmacist give appropriate counseling during dispensing?			
11.4	Are the medicines requiring special storage conditions, e.g. a cold place (2-8^{o}C) packed in cold packs?			
11.5	If solid unit dosage forms are taken from a larger bulk pack, are they packed in a clean, food grade glass or plastic bottles or in a clean envelop and neatly labeled as provided under the law.			
11.6	Are appropriate counseling / guidelines given for the patient, as recommended?			
11.7	Are there written standard operating procedures as well as standard formulations commonly made extemporaneous preparations?			
11.8	Proposed adjuvant, their quantities and the method of preparation must be written down before any compounding activity is initiated?			
11.9	Are each step followed methodically and a step by step record maintained?			
11.10	Are Batch numbers of each medicine used for compounding recorded in written?			
11.11	Are all preparations compounded by the Pharmacist, or under direct supervision of a Pharmacist?			

11.12	Are approved grade of ingredients should be used for compounding.			
11.13	Is the preparation area cleaned immediately before and after compounding?			
11.14	Are all necessary weighing, measuring instruments calibrated periodically and records maintained?			
11.15	After compounding, are the product transferred to a suitable container and closed securely.			
11.16	Are The container appropriately labeled, stating name of the preparation, date of preparation, name of the patient, directions, quantity, a reference (batch) number generated by the pharmacy, storage conditions and name of the pharmacy.			
11.17	Are these details recorded in a register or electronically for suitable reference and retrieval as and when required?			
11.18	Are the Extemporaneous preparations dispensed to a particular patient and not be prepared for another pharmacy except in special circumstances?			

ANNEX B

National Good Pharmacy Practice Guidelines

STEPWISE IMPLEMENTATION PLAN

National Good Pharmacy Practice Guidelines

STEPWISE IMPLEMENTATION PLAN

1. **PERSONNEL**
2. **TRAINING**
3. **STANDARDS**
4. **GPP IMPLEMENTATION**

1 PERSONNEL

Aim: all people have access to a qualified pharmacist

Access to pharmaceutical personnel

1.1 In Nepal it is accepted that at present, and for some time to come in most cases, due to insufficient numbers of pharmacists, it is not possible for people in all areas to have direct access to a pharmacist. The level of pharmaceutical service that can be offered will, therefore, largely be determined by location.

1.2 However, the underlying principle that has to be adopted is that all people should have access to an adequate pharmaceutical service.

1.3 In many cases it is perceived that the level of responsibility placed on health workers is disproportionate to the training that they have received. It is assumed that at the primary health care level, the medicines will be relatively simple and few in number. The community health care workers need to be given basic training in how these medicines must be used to ensure that patients are given medicines which are appropriate for the condition/problem being treated, along with accurate instructions.

1.4 As one progresses upwards to the next higher level of health institution, it would be assumed and recommended that a worker with a greater level of training/specialization would be available. In the step-wise approach, this would be represented as follows:

All people should have:

STEP 1 Access to trained drug retailers (professionalists) with appropriate pharmaceutical training

STEP 2 Access to trained drug retailers (professionalists) having follow up training.

STEP 3 Access to a pharmacy assistant with appropriate training

STEP 4 Access to a pharmacy assistant working under the direct supervision of a pharmacist

STEP 5 Direct accesses to a pharmacist

1.5 In the first instance this may represent simply a move up through the levels within the health delivery service, but the recommendation is that each

location offering a particular level of service should attempt to progress to the next higher level of service.

1.6 Governments need to be convinced of the need for, and value of, a quality pharmaceutical service before they will make a commitment to allocating resources to the training of more pharmaceutical personnel, and doing so at a higher level

2 TRAINING

Aim: for the country to be self-sufficient in trained pharmacy personnel

2.1 The requirement is to increase the number of pharmaceutically trained personnel, ultimately pharmacists, as well as to continuously extend and improve the level of training, knowledge and expertise of all pharmaceutical personnel. At each level the training must be appropriate to the level of service provided and medicines used.

2.2 It is recognized that in many smaller countries, sufficient resource person to conduct training may not be available within the country. Depending on the availability of suitably qualified/experienced personnel to carry out the training, in cases where this is not possible, it should be feasible to bring in outside trainers, possibly under inter-government aid programs to develop other trainers.

2.3 Standards and curricula must be established for each level of training to ensure consistency and appropriateness. In time, these standards can be raised to improve the competency and knowledge base of all levels of pharmaceutical workers.

2.4 Protocols should be drawn up for the different services performed as well as medicine use protocols.

STEP 1 Conduct follow up training with appropriate pharmaceutical input

STEP 2 Produce more pharmacy assistant.

STEP 3 Train pharmacy assistant.

STEP 4 Produce more pharmacy graduates.

STEP 5 Provide access to continuing education and professional development for pharmacists and pharmacy assistant.

3. **STANDARDS**

3.1 It is recognized that in most developing countries, pharmaceutical services are virtually exclusively carried out from the institutions or premises at which the worker is based. No attempt has, therefore, been made to include domiciliary services.

3.2 Premises

Aim: that there should be adequate premises from which services are provided.

A. Pharmaceutical services and products should be provided from an area, which is separate from other activities/services and products. The aim is to guarantee the integrity and quality of the product and minimize the risk of dispensing errors.
The requisites here (not ranked in order) are:
Clean, tidy and hygienic conditions
Adequate space
Appropriate conditions for storage, re-packing, dispensing and distribution of medicines, including security
Adequate light
Protection from exposure to excessive light and heat
Refrigeration if required
Availability of equipment appropriate to the tasks carried out (dispensing/compounding/manufacturing)
Access to basic reference texts
Direct access to the public for instruction, counseling.

B. If a clearly defined, separate area for the provision of pharmaceutical services is not available; this should be the first objective. Thereafter, the premises can be upgraded allowing for clearer separation of different activities e.g. dispensing and storage.

C. Premises be appropriate for the level of service provided and personnel involved, e.g. need for running water, benches, light, refrigeration etc.

STEP 1 Secure, isolated area for storage and dispensing

STEP 2 Separate area for storage and dispensing

STEP 3 Provision of quarantive for received medicines

STEP 4 Provision for isolated area for patient counseling

3.3 Dispensing

Aim: to ensure that the right patient receives the appropriate medicine in the correct dose and form

The requisites here (not ranked in order) are:

A The right patient gets the right medicine
B Possible interactions are avoided
C The quality and integrity of the medicine are maintained throughout the indicated shelf life
D Correct and clear instructions are given to the patient to ensure correct and safe use of the medicine, to the optimal benefit of the patient in line with the objective of the treatment.
E The patient is given, at the least, basic information regarding special instructions for use, warnings if applicable, possible adverse/side effects and action to take in the event of certain events occurring.

3.4 Instructions to the patient

Aim: to ensure that the patient knows how and when to take/use the product

STEP 1 Instructions are verbal

STEP 2 Instructions are verbal + hand-written and affixed to the container

STEP 3 Instructions are verbal + printed/typed and affixed to the container

STEP 4 In addition to step 3, verbal counseling is given to the patient

STEP 5 In addition to step 4, supplementary written information is given

STEP 6 GPP is observed.

3.5 Records

Aim: to facilitate patient care and provide an audit trail

STEP 1 A record of all medicines supplied should be kept detailing name of patient, name & strength of medicine, dosage, quantity supplied, date of dispensing
STEP 2 Individual patient medicine records should be maintained in a system, manual or computerized, which allows for easy retrieval of patient information

3.6 Health information, patient counseling & pharmaceutical care

Aim: to promote good health and prevent ill health

A. All personnel should be trained and equipped in terms of literature and support material to give advice on general health matters as well as more specific information and services relating to medicines supplied by them.
B. In terms of the provision of this service the steps would be as follows:

STEP 1 Provide health promotion literature and support materials on general health
STEP 2 Provide basic information and pharmaceutical care

3.7 Self-medication

A. Where pharmacists or other pharmaceutically qualified personnel are involved in self medication and response to symptoms, protocols should be devised to ensure that the advice is accurate and appropriate.

4. GPP Implementation

4.1 Implementation

Aim: to implement a national GPP policy that can be adequately enforced in stepwise.

4.1.1 Not only must be in place, but also it must be adequately enforced.

4.1.2 Stepwise implementation starts from Metropolis and stepwise will be implement in cities, towns and village.

STEP 1 Approval of GPP by the government.

STEP 2 Awareness on GPP to the stakeholders.

STEP 3 Stepwise implementation of various elements of GPP.

Population per Retail Medical Shop

(Sensus 2001; Number of medical shop of 2004)

Zone	District	VDC+Municipality	No. of shops	Population per shop
Mechi	Taplejung	50+0	11	12,322
	Panchthar	41+0	32	6,331
	Ilam	48+1	46	6,148
	Jhapa	47+3	442	1,564
Koshi	Morang	65+1	703	1,200
	Sunsari	49+3	440	1,428
	Dhankuta	35+1	32	5,177
	Sankhuwashabha	33+1	41	3,895
	Bhojpur	63+0	19	10,801
	Terhathum	32+0	19	6,007
Sagarmatha	Solukhumbu	34+0	8	13,485
	Ohaldhunga	56+0	26	6,013
	Khotang	76+0	24	9,676
	Udayapur	44+1	67	4,301
	Saptari	114+1	417	1,385
	Siraha	106+2	331	1,730
Janakpur	Dhanusha	101+1	431	1,594
	Mahottari	76+1	302	1,834
	Saralahi	99+1	377	1,703
	Sindhuli	53+1	49	5,714
	Ramechhap	55+0	18	11,809
	Dolakha	51+1	13	15,750
Bagmati	Sindhupalchok	79+0	39	7,847
	Kavrepalanchok	87+3	125	3,082
	Lalitpur	41+1	359	938
	Bhaktapur	16+2	185	1,226
	Kathmandu	57+2	1872	584
	Nuwakot	61+1	91	3,161
	Rasuwa	18+0	8	5,562
	Dhading	50+0	99	3,419
Narayani	Makawanpur	43+1	127	3,065
	Rautahat	96+1	266	2,057
	Bara	98+1	269	2,071
	Parsa	82+1	394	1,256
	Chitwan	36+2	276	1,705

Gandaki	Gorkha	66+1	88	3,274
	Lamjung	61+0	74	2,397
	Tanahu	44+1	115	2,748
	Syangja	60+2	187	1,695
	Kaski	43+2	439	869
	Manang	13+0	0	-
Dhawalagiri	Parbat	55+0	85	1,859
	Baglung	59+1	170	1,579
	Myagdi	43+0	38	3,036
	Mustang	16+0	2	
Lumbini	Gulmi	79+0	222	1,339
	Palpa	65+1	93	2,880
	Nawalparasi	73+1	210	2,677
	Rupandehi	69+2	522	1,346
	Kapalvastu	77+1	210	2,306
	Arghakhanchi	51+0	137	1,526
Rapti	Pyuthan	52+0	75	2,834
	Rolpa	53+0	44	4,792
	Rukum	45+0	58	3,238
	Salyan	47+0	106	2,019
	Dang	39+2	306	1,513
Bheri	Banke	46+1	370	1,059
	Bardiya	31+1	60	6,395
	Surkhet	50+1	107	2,698
	Dailekh	55+1	10	22,634
	Jajarkot	30+0	9	14,863
Karnali	Dolpa	23+0	6	4,942
	Jumla	30+0	27	3,314
	Kalikot	30+0	5	21,156
	Mugu	24+0	8	5,516
	Humla	27+0	5	8,150
Seti	Bajura	27+0	22	4,942
	Bajhang	47+0	24	6,974
	Achham	75+0	80	2,916
	Doti	50+1	43	4,859
	Kailali	42+2	389	1,596
Mahakali	Kanchanpur	19+1	150	2,539
	Dadeldhura	20+1	32	3,959
	Baitadi	62+1	60	3,919

	Darchula	41+0	17	7,171

Range of Ratio: Population per shop.

Terai: 1059-6395 Hills: 1339-22634 Mountain: 3895-15750

Exception: Kaski- 869; Kathmandu-584; Lalitpur-938

Suggested range of ratio: 2000-5000

Estimated consumption of drug: 8 Billion (In 2000, Rs.6 billion with growth of 18.8%*) (Expenses on medicine approximately Rs. 25. per month per person; For the suggested ratio, sale per shop ranges from Rs. 50,000 to 1,25000, which gives profit, before deducting operating expenses, ranging from Rs. 8000 to 20,000. per month. The chart shows that the numbers of shop are more than required within respect to population.

* A study on consumption and quantification of modern drugs for human use for the fiscal year (1999/2000) conducted for Department of Drug Administration by Pharmaceutical Horizon of Nepal.

Human Resource Production & Need Situation

Minimum number of Pharmacists and Pharmacy Assistants Required in Mahanagarpalika & Upamahanagarpalika : One Pharmacist and One Pharmacy Assistant per pharmacy.
Nagarpalika & District Headquarter: One Pharmacy Assistant per pharmacy.

Requirement

Category & Number	Pharmacy present	Pharmacy expected addition	Pharmacists required	Pharm. Asst. required
Mahanagarpalika (1)	1200	0	1200	1200
Upamahanagarpalika (4)	1100	140	1240	1240
Nagarpalika (53)	4450	570	0	5020
District Headquarter (33)	650	370	0	1020
Total	7400	1080	2440	8480

Human Resource Production Projection

Year	2063-67	2068-72	2073-77	2078-82	Total	% in pharmacy	No. in pharmacy	% of demand
Pharmacist	380	580	600	600	2160	40	864	35.4
Pharmacy Assistant	2210	4000	4000	4000	14210	80	11370	134.1

Pharmacists Production every year

Tribhuvan University:	8-20
Kathmandu University:	30-40
Pokhara University:	30-40
Purbanchal University	0-40
Abroad:	10-50
Total:	78-190

Pharmacy Assistant Production every year

Tribhuvan University:	5-15
CTEVT (21 Institutes):	600-840
Abroad:	0-4

Human resource production projection at the present capacity is not enough to meet the demand of pharmacist but more than required for pharmacy assistant.

Stepwise implementation in terms of years at different location

		Mahanagar Palika	Upamahanagar Palika	Nagar Palika	DHQ
Facility	Premises and other	2	5	10	15
Personnel	Pharmacist	10	20	30	50
	Pharmacy Assistant	5	10	15	30
Quality System	Quality Manual and implementation	5	10	15	30