

GOOD PHARMACY PRACTICES GUIDE

I. Introduction

Health services are a team effort involving many professions. The pharmacist is a member of this multi-disciplinary team who has a duty and responsibility to improve medicines use to ensure better patient outcomes.

The Good Pharmacy Practices Guide is organized to ensure good quality, safety, and efficacy of all medicines to be delivered to patients. Pharmacists and their assistants have the important function of ensuring that patients understand how their medicines should be taken. It is important that pharmacists reinforce the advice necessary for the proper use of medicines.

Pharmacies should be well organized and comply with all technical requirements, including hygiene for inside and outside, and adequate equipment for all operations to be carried out therein.

In the name of the public health care profession, pharmacists continually improve their level of professional knowledge and skills which are within the code of ethics.

This Good Pharmacy Practices Guide has been revised and reorganized by the Department of Drugs and Food of the Ministry of Health to guide all pharmacists in maintaining and protecting the public health.

II. Suitability of Premises

A. Premises

1. The pharmacy must be separated from residence.
2. The pharmacy must always be clean and tidy both inside (wall, ceiling, and floor) and outside.

3. The pharmacy should be at least 4m x 5m=20m² (do not include warehouse) and depot of pharmacy should be sized at least 4m x 4m=16m².
4. The Label of the pharmacy
 - 4.1. The label should be at least 0.6m x 3.8m.
 - 4.2. The label should have a white surface with blue letters.
 - 4.3. Khmer language should be bigger and above the foreign language (French or English).
 - 4.4. The name of the pharmacist in-charge should be under the name of the pharmacy.
 - 4.5. The address, phone and fax numbers, and email address should be at the bottom of the label.
 - 4.6. The green pharmacy logo should be on the right side of the label.
5. The pharmacy should have sufficient cupboards, including storage and display cupboards, in the proper order complying with technical management.
6. The pharmacy should have a warehouse for storing medicines, materials, and medical devices. The warehouse should meet these requirements:
 - 6.1. The size should be sufficient (at least 3m x 4m) and well ordered to avoid confusing each other.
 - 6.2. There should be sufficient pallets to allow air flow.
 - 6.3. There should be air conditioners, and a daily record should be kept (see annex 1). A recorder should record the temperature after inspection, noting the time, date, signature, and name of the recorder.
 - 6.4. All items should always be completed on stock cards (see annex 2).
7. The pharmacy should be equipped with air conditioners, have adequate light, and have a means of monitoring safety.
8. If the pharmacy has stocked products needing cool chain, such as vaccines, etc., it should have a refrigerator equipped with a thermometer. Daily temperature checks should be done to ensure that the temperature is within

the requirements. This information should be recorded with the time, date, signature, and name of the recorder (see annex 3).

9. If the pharmacy sells special medicines such as narcotics, psychotropics, etc., it should have a special storage cupboard that is always locked and is to be monitored by the pharmacist.
10. The pharmacy should have a fire extinguisher easily reached for use during an emergency.
11. The pharmacy should have sufficient space (table) for counseling between the pharmacist and consumers.
12. The pharmacy should have an emergency exit.
13. No member of the public should be allowed to enter the dispensing area.
14. No sounds should disturb the personnel or clients.
15. The pharmacy should have a security system to guard against theft.
16. Other conditions must be specified so as to protect the safety of the public and people working in the premises, e.g. No smoking, etc.

B. Equipment

The pharmacist and the owner should ensure that the equipment on the premises is adequate and suitable for all the operations to be carried out therein. All equipment should be kept clean and checked for cleanliness prior to each use. Equipment should include:

1. A bench of adequate size with a smooth, stainless, non-corrosive, impervious working top that will be unreactive with any active pharmaceutical ingredient and should be used solely for the purpose of dispensing and counting.
2. A refrigerator unit capable of storing vaccines and other products within a selected temperature range from 2 to 8 degrees Celsius. Daily temperature checks should be done to ensure that the temperature remains within the required range.
 - 2.1 Food and beverages should not be stored in the refrigerator.

III. Pharmacy Management

A. Cleanliness and Hygiene

1. A uniform (white coat) must always be worn by pharmacists and pharmacy staff when on duty. High standards of personal hygiene should be observed.
2. If the pharmacist or pharmacy staff have cuts or abrasions on any exposed part of the skin, these should be covered with a suitable waterproof dressing.
3. Direct contact between the operator's hands and dispensed products should be avoided.
4. Smoking and eating in the pharmacy is prohibited.

B. Received Medicines

For all medicines received from manufacturers, import-export companies, or other pharmacies, the pharmacist and the owner should ensure that:

1. There are appropriate invoices (Annex 4).
2. The invoice should be kept until those medicines expire, even though those medicines may be sold out.
3. All medicines in the pharmacy must bear their vignette on the box or bottle.

C. Storage of Medicines

1. Medicines must normally be stored in the manufacturer's original container. In exceptional cases (the outer package was broken, etc.), it is permitted to store medicines in a different container, but care must be taken to avoid contamination, and all relevant information must be clearly marked on the new container. A report of this transfer must be made, and the broken box or bottle must be kept for the drug inspector.
 - 1.1. Relevant information includes proprietary and generic name, strength, quantity, manufacturer's name, batch number, and expiry date.

2. All medicines must be stored under suitable conditions which are mentioned on the box or bottle, as stipulated by the manufacturer. This includes avoiding exposure to sunlight, moisture, and high temperatures.
3. Medicines for external use should preferably be stored separately from those for internal use. In addition, all medicines should be stored in alphabetical order.
4. Expired or spurious medicines must be kept separately for the drug inspector to destroy.

D. Dispensed Medicines

A pharmacist should undertake all counseling and all activities directly relating to patients.

1. Receipt of Drug Order or Prescription

A pharmacist should review and interpret every drug order or prescription and resolve any problems or ambiguities before it is processed. The pharmacist must ensure that:

- 1.1. The prescription or drug order is not forged or tampered with. If there is suspicion, appropriate interventions with the doctor must be undertaken.
- 1.2. All legal requirements in the prescription have been complied with (see Annex 5).
- 1.3. The medication is indicated for the condition being treated.
- 1.4. The drug regimen such as dosage, frequency, and duration are appropriate.
- 1.5. The prescribed medicine is not prohibited.
- 1.6. There are no double medicines in the therapeutic group for the patient.
- 1.7. For any drug order or prescription that is not clear or may be unacceptable (e. g. A very high dose or being used beyond the labeled indications on the box or bottle), appropriate intervention with

the doctor should be undertaken and documented before processing.

2. Selling antimalarials

- 2.1. Selling all kinds of Artesunate monotherapy is prohibited.
- 2.2. Prior to treatment, diagnostics for malaria should be performed with rapid tests or slides.
- 2.3. All patients should be counseled on the treatment protocol and other relevant health-related messages.
- 2.4. Patients who have deadly illnesses or frequent relapses, as well as children or pregnant women, should be referred to the closest public health services.

3. Interventions from the medical doctor

Any form of intervention from the medical doctor should be documented on the drug order or prescription. Details of the recording should include the following:

- 3.1. The name of the doctor involved, or the clinic assistant if the doctor is unavailable.
- 3.2. The reason(s) clarification was needed.
- 3.3. Name, strength, form, and quantity of medicine.
- 3.4. Date of the intervention.
- 3.5. Name of the pharmacist who did the intervention and his/her signature.

4. Packaging and Labeling

Prior to dispensing medicines, the pharmacist must clarify some information on the label.

4.1. Information on labels

- 4.1.1. Generic name, form, and strength
- 4.1.2. Dosing instructions
- 4.1.3. Name and age of patient
- 4.1.4. Prescription number or identification number

- 4.1.5. Name, address, and telephone number of the pharmacy where the medicine is dispensed.
- 4.1.6. Directions for correct storage
- 4.1.7. Expiry date of the medicine
- 4.1.8. Any special precautions

4.2. Legibility of Labels

All labels should be printed using a computer or typewriter. Avoid scraping or erasing on the label.

4.3. Language and Expression

Words which are easy for the patient to understand and remember should be used, e.g. use "ear" rather than "-otic" or "aural," or "eye" rather than "ophthalmic."

4.4. Dispensing Containers

- 4.4.1. The manufacturer's original container should be used as often as possible in the pharmacy.
- 4.4.2. When necessary, the pharmacy can use a new box or bottle. When repackaging medicines, all information on the original container should be transferred to the new.

4.5. Placement of labels on containers

- 4.5.1. All labels should be firmly attached to the primary container.
- 4.5.2. Care should be taken to ensure that labels are not wrinkled or crooked when placed on containers.

The following information should be made visible:

- Generic name, form and strength
- Storage conditions
- Batch/or Lot number
- Expiry date
- The manufacturer's name

5. Counseling

The pharmacist should actively impart sufficient information to patients about their medicines to ensure that their medicines are used safely and correctly. To perform this task effectively, both oral and written means must be employed in all cases since the use of written means without oral explanation may lead to miscommunication and confusion. Oral counseling without written information can be easily forgotten. The following points must be emphasized to the patients during counseling:

- Drug name and its information
- Drug regimen (dosage, frequency, and duration)
- Special directions for preparation (e.g. fresh boiled and cooled water for reconstitution of powder for suspensions)
- Special direction for administration (e.g. correct use of inhalers) and transdermal patches
- Potential drug-drug or drug-food interactions and other contraindications
- Adverse drug reactions
- Action to be taken in the event of a missed dose
- Proper storage
- Any other information that is particular to the specific patient or drug
- Leaflets must be kept inside the boxes of medicine

E. Dispensing Errors

Errors can take many forms when dispensing medicines to patients. These include dispensing the wrong product, the correct product with the wrong label, the incorrect quantity of product, product diluted with the wrong diluent, expired product, or a product which was meant for another patient.

The most frequent errors are human errors in selection of product and incorrect interpretations of the prescription. To minimize errors, the pharmacist should take measures as described below:

1. Incorrect selection

- Medicine containers should not be grouped according to manufacturer, since these products may be packaged and labeled similarly and thus contribute to selection errors, especially during busy dispensing periods.
- Physically separate or clearly highlight drug containers with similar brand names or products with different strengths but similar packaging.
- Do not allow untrained or inexperienced staff to package or dispense medicines to patients.
- Do not select idiosyncratic personnel to work in the pharmacy

2. Incorrect interpretation

Illegible or ambiguous prescriptions are the main causes for misinterpretations. Hence, the pharmacist must:

- Exercise vigilance when deciphering prescriptions
- Become adept at determining the prescriber's intentions
- Discreetly question the patient during counseling
- If the prescriber's intention remains uncertain, the prescriber must be contacted to determine exactly what is required

3. Control of expiry date

Pharmacists must establish procedures to monitor stocks before they expire or prevent expired stocks from being sold or dispensed. The following measures can be taken:

- Keeping the bin card (paper record or computer system) of the expiry dates of the medicines in stock
- Number coding of expiring stocks (e.g. 3 months before expiry date)
- Regularly checking stocks with respect to their expiry dates
- Expired or deteriorated stocks must be kept separately for drug inspectors to destroy

4. Self-checking procedures

Errors fall into two main categories: interpretation and selection. Hence, the pharmacist must exercise self-discipline to minimize mistakes in dispensing.

Self-checking procedures should include:

- Interpretation: take time to carefully read the prescription in its entirety
- Selection: double check the selection of product
 - When selecting medicines from the shelf
 - When affixing labels – the label should be verified with the original prescription
 - A final check should be done before dispensing medicine to the patient

F. Dispensing Responsibilities

Pharmacists take personal responsibility for every prescription they dispense or for which they supervise the dispense. Hence, all prescription records must bear the code number, signature, and name of the dispenser or pharmacist so that in the event of any error, query, or concern, the pharmacist responsible can be identified. The prescription must be recorded in the logbook or.for pharmacist.

G. Sale of Medicines from a Pharmacy

1. The pharmacy can sell all kinds of medicines including prescription and over the counter (OTC) medicines by or under the supervision of the pharmacist. If the pharmacist is off duty, OTC medicines can be sold by the pharmacist's assistants provided that they have adequate training and up-to-date knowledge of the products they sell. The sale of prescription and OTC medicines "under the supervision of the pharmacist" can be complied with if:
 - The pharmacist's assistants have adequate training in the products they are selling

- The pharmacist is in the pharmacy area
2. All pharmacists and pharmacy staff supplying prescription and OTC medicines should ensure that the medicines supplied are appropriate for the treatment of the person for whom it is intended to be used. Furthermore, appropriate counseling with the patients is very important.
 3. The pharmacy staff who sell OTC medicines should give advice based on the medicine's label.
 4. Pharmacists should handle the sale of prescription medicines intended for use in young children and the elderly.
 5. When two or more medicines with the same therapeutic properties are requested, e. g. Aspirin and Paracetamol, the pharmacist and pharmacy staff should inform the purchaser that they have the same indication.
 6. Pharmacists and pharmacy staff should treat patient issues with confidentiality and sensitivity.
 7. In the following circumstances, pharmacy assistants should always refer patients to the pharmacist:
 - When the medicines requested are for children
 - When there are requests for advice on the treatment of symptoms in infants, young children, or the elderly
 - When there are requests for new prescriptions
 - When there are requests for purchasing more than the usual quantity of medicines or over a prolonged period.

H. Reports of Adverse Reactions to Medicines

When any adverse reactions occur, pharmacists or pharmacy owners should report them to the Cambodia Pharmacovigilance Center of the Department of Drugs and Food (see annex 6).

IV. Code of Ethics for Pharmacists in Charge of Pharmacies

A. A pharmacist should regard the health and safety of each patient to be of primary importance

- Pharmacists should have specialized knowledge about medicines, health-related products, and medicinal and non-medicinal therapies and will use this knowledge to benefit their patients.
- Pharmacists are aware of the limitations of their knowledge and skill and refer patients to appropriate health care professionals when they are unable to meet the needs of their patients.
- Pharmacists accept responsibility to supply prescription and OTC medicines that are of good quality, safety, and efficacy.

B. Pharmacists form a professional relationship with each patient

- Pharmacists respect the professional relationship with the patient and act with honesty, integrity, and compassion.
- Pharmacists should have capacity and skill and take time to determine the patient's health needs to achieve desired outcomes.

C. Pharmacists honour the autonomy, values, and dignity of each patient

- Pharmacists must provide correct and clear information to patients so that patients can make decisions on their health treatment.
- Pharmacists are committed to each patient regardless of rank, race, religion, gender, or age.
- Pharmacists respect the informed decision of competent patients who choose to refuse treatment/services and live at risk.
- Pharmacists respect the dignity of patients with diminished competence and seek to involve them to an appropriate extent in decisions regarding their health.

D. Pharmacists respect and protect the patient's right of confidentiality

- Pharmacists keep confidential all information acquired in the course of professional practice.
- Pharmacists may disclose prescription information for scientific research only if the information will not identify the patient.

- Confidential information is disclosed only in cases where the patient or patient's agent provides consent or where the law demands or where disclosure will protect the patient or other from harm.

E. Pharmacists respect the patient's right to receive pharmacy services

- Pharmacists who are unable to provide prescribed medicines or services to their patients shall take reasonable steps to advise the patients where they can receive the pharmacy services in safety.
- Pharmacists have a duty, through communication and co-ordination, to ensure the continuity of care of patients.

F. Pharmacists observe the law, preserve high professional standards, and uphold the dignity and honour of the profession

- Pharmacists obey the laws, regulations, standards, and code of ethics of pharmacists.
- Pharmacists do not condone breaches of laws, regulations, standards, or codes of ethics of pharmacists, co-workers, or pharmacy owners and report to the authority such breaches, without fear.
- Pharmacists do not seek more than fair and reasonable remuneration for professional services.
- Pharmacists do not accept inducements from medical doctors or suppliers that could reasonably be perceived as affecting the pharmacist's independent professional judgment.
- Pharmacists should promote themselves via methods which uphold the dignity and honour of the profession and which are within the boundaries of law.

G. Pharmacists cooperate with colleagues and other health care professionals so that maximum benefits to patients

- Pharmacists acknowledge the ability of colleagues or other health care professionals to benefit the patient. If appropriate, pharmacists refer their patients to medical doctors.

- Pharmacists ensure that every patient requirement is completed before sending a patient to a physician.

H. Pharmacists participate in the enhancement of the profession of pharmacy

- Pharmacists associate with organizations that strive to improve the profession of pharmacy.
- Pharmacists contribute to the future of the profession by participating willingly and diligently in the education of students and candidates for registration.

I. Pharmacists contribute to the health care system and to societal health needs

- Pharmacists participate actively in upholding the health care system by participating in health policy development and review and revision of health policy.
- Pharmacists support cost-effective therapies.
- Pharmacists participate in programs to educate the public about health.
- Pharmacists foster the advancement of knowledge by supporting appropriate research projects, wherever possible.
- Pharmacists support environmental issues related to pharmacy by promoting the safe keeping of medicines and health care products.

Reference Documents:

1. The Checklist of the Ministry of Health to Evaluate the Premises (Pharmacy and Depot of Pharmacy)
2. Pharmaceutical Society of Singapore "Good Pharmacy Practice Guide" (Version-2009 March)
3. Good Practices in Drug Services in the Kingdom of Cambodia (2006)