

A REPORT ON

Good Pharmacy Practice Training Manual for Community Pharmacists in SEA Region

Compiled by:

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1. Introduction

The concept of GPP was introduced by the **FIP (International Pharmaceutical Federation)** by adopting GPP Guidelines in 1993. These Guidelines are recommended as a set of professional goals in the interest of the patients or clients in the pharmacy. These guidelines were developed as a reference to be used by national pharmaceutical organizations, governments, and international pharmaceutical organizations to set up nationally accepted standards of Good Pharmacy Practice.

The WHO Technical Committee has made similar recommendations based on the FIP's GPP guidelines. The Guidelines were endorsed by WHO in 1997.

Many countries across the world today have framed their own Guidelines for GPP based on FIP Guidelines.

The workshops on Good Pharmacy Practice conducted in **Bangkok (Thailand/ June 2007) and Yogyakarta (Indonesia/ August 2008)** are testimony to the considerable awareness about GPP amongst the national pharmacy associations of the countries of the South East Asia Region (SEAR).

Most of the SEAR countries now have their own GPP Guidelines that are based on FIP Guidelines. These have been made suitable for the practical situation or status of pharmacy practice in these countries. Though the guidelines are in place, implementation of the same is important to ensure that the pharmacy practice is professionalized and also to maximize the health benefits to the community. The SEAR countries have been making efforts for the spread and practice of GPP by pharmacy profession. However, the countries lack in the following:

- i. Systematic awareness and implementation of the GPP Guidelines amongst community pharmacies in the country.
- ii. A Implementation-friendly GPP Training Manual, and subsequent systematic training programmes for GPP awareness, education, and implementation among pharmacies
- iii. Concrete measures to assess GPP implementation.

The success in devising and implementing the above tasks is hindered by a range of problems and difficulties. Some of these common to SEAR countries are:

- i. **Lack of awareness:** Lack of awareness amongst the Government authorities, other health care providers and the public about the need and importance of Pharmacists and about Good Pharmacy Practice.
- ii. **Ineffective implementation of drug laws:** Lack of effective implementation of Drug Laws, viz. ensuring presence of pharmacist all the time while dispensing prescription medicines, ensuring sale of prescription medicines only against the prescription of a qualified doctor, etc.
- iii. **Dispensing doctors:** Dispensing of medicines by doctors, thus competing with pharmacies who often find it difficult to survive.
- iv. **Non-pharmacist owners:** Most of the pharmacies are owned by non-pharmacists. There is a lack of awareness and initiative amongst them about the importance of the role of the pharmacist in health care, and the professional role and services which a pharmacy can offer its clients. Presently, most pharmacies in the region are product oriented, and not patient oriented.
- v. **Curricular deficiencies:** Pharmacists are not well trained & equipped during their curriculum to be professional community pharmacists. Some of the countries do not have a proper framework of curriculum, while some have a 2 year Diploma as the minimum qualification to be a pharmacist
- vi. **Lack of CPD:** There is limited Continuing Professional Development (CPD) facility for pharmacists. However, in many countries it is on a voluntary basis for pharmacists and not mandatory for registration etc.
- vii. CPD is not linked to accreditation
- viii. Other healthcare professionals hold pharmacists in low esteem
- ix. National governments do not often recognize them as health care providers
- x. Peers in the profession look down upon them as they are not degree holders
- xi. Pharmacists themselves lack motivation as their position in society is considered as traders
- xii. Remuneration not linked to their professional standing
- xiii. Their professional associations do not consider them as full fledged members

2. GPP Training Manual

The GPP Training Manual aims at guiding the community pharmacists about Good Pharmacy Practice, its implementation and the role of community pharmacists in the same, with the understanding and acceptance that the conditions of pharmacy practice are likely to vary between different SEAR countries.

The manual is divided into following sections for ease of understanding:

A. Awareness of the GPP Concept:

It is very important that community pharmacists, owners, as well as the staff of the pharmacy are made aware and understand various aspects of GPP. Proper information and training them in these aspects will help in creating the awareness and motivation to implement and follow GPP in their pharmacy, and its subsequent advantages.

What is GPP?

Good Pharmacy Practice or GPP is the foundation on which the working in a pharmacy can be based, and which can give the best outcomes in delivery of medicines, service and care of the patient. While the basic concepts of Pharmaceutical Care and GPP are largely identical, it can be said that GPP is the way to implement Pharmaceutical Care. The main requirements of GPP are

- GPP requires that a pharmacist's first concern in all settings is the welfare of patients
- GPP requires that the core of the pharmacy activity is the supply of medication and other healthcare products of assured quality, appropriate information and advice for the patient, and monitoring the effects of use.
- GPP requires that an integral part of the pharmacist's contribution is the promotion of rational and economic prescribing and of appropriate use of medicines
- GPP requires that the objective of each element of pharmacy service is relevant to the patient, is clearly defined and is effectively communicated to all those involved.

Applying Good Pharmacy Practice:

GPP involves 4 main groups of activities namely:

- a) Activities associated with the promotion of good health, of the avoidance of ill health and the achievement of health objectives.
- b) Activities associated with the supply and the use of medicines and of items for the administration of medicines or for other aspects of treatment.
- c) Activities associated with self care, including advice about and where appropriate, the supply of a medicine or other treatment for symptoms of ailments that tend themselves to self treatment.
- d) Activities associated with influencing the prescribing and use of medicines.

What are the benefits of GPP for a pharmacy?

Implementing GPP will assist in instilling a proper system for performance of various activities in the pharmacy. This will not only assist in achieving the organization's goals but also project a professional image of the pharmacy.

It will thus assist the pharmacy in:

- Increasing speed and efficiency in every activity
- Increasing staff performance and accountability
- Reducing dispensing errors
- Increasing professional services/activities
- Improving client satisfaction & increase clientele
- Increasing profits

What are the benefits of GPP for Pharmacists?

Being part of the team which implements GPP gives pharmacists an opportunity to:

- streamline their activities and delegate work systematically
- utilize and display their professional skills
- interact professionally with clients
- Improve their image as professionals amongst the public as well as other health care providers, and the various authorities.
- Prove their worth/ importance in a pharmacy.

Responsibilities for GPP implementation in the country are with the various stakeholders:

- i. National Pharmacy Associations
- ii. Associations of Chemists/Pharmacies
- iii. Academic Bodies
- iv. Regulatory Bodies
- v. Pharmacy owners
- vi. Community Pharmacists

B. SOPs : Standard Operating Procedures :

A SOP specifies in **writing**:

- **What** should be done
- **When** it should be done
- **Where** it should be done, and
- By **whom** it should be done

It is important that the Pharmacy should write out its own SOPs for different activities in the Pharmacy. SOPs could be written for any activity in the pharmacy, and a beginning could be made by writing SOPs for important/crucial activities, and gradually written out for other activities. Staff should be guided in understanding the SOPs, and carry out their activities as per the SOPs for best outcomes. Respective pharmacy staff should have easy access to the relevant SOPs whenever they need them for easy reference. SOPs should be reviewed and updated from time to time. SOPs should also be used as a useful tool for training of new staff/recruits.

C. Implementing Drug Laws in the Pharmacy:

Owners, pharmacists, and pharmacy staff need to be well versed with the drug laws of their respective country, relating to retail pharmacy.

It is mandatory to follow drug laws, and is an integral part of GPP.

The drug laws need to be followed in the true spirit.

- The pharmacy must conform to the laws in terms of the minimum area requirements and location.
- Prescription medicines must be dispensed only under the supervision of a Qualified Pharmacist.
- The drug licenses of the pharmacy must be displayed prominently in the premises for easy viewing of the clients. The certificate (and preferably the photographs) of the Pharmacist/s under whose supervision dispensing of medicines goes on at the pharmacy must also be displayed prominently for easy viewing of the public entering the pharmacy.
- Prescription medicines should be strictly sold only against the prescription of a qualified doctor, only after checking the prescription for legality and authenticity.
- Pharmacies are not allowed to stock physician samples, and medicines for Government supply.
- The dispensing (sale) of medicines must be done against a proper cash memo/bill, containing all the relevant details :
 - Name, address, contact details, drug license numbers, sales tax numbers of the pharmacy (These must be pre-printed)
 - Name and address of the prescriber, and of the patient.
 - Name of the medicine, name of manufacturer, quantity, batch no., expiry date, cost.
 - Signature of the pharmacist under whose supervision the sale was done.
- Non-prescription (or OTC) medicines may be sold without a prescription, but it is advisable that the pharmacist discusses the need for the medicine, and its proper use with the client.
- Extra precautions need to be taken in procurement, storage, handling and dispensing of narcotic/psychotropic medicines.
- Proper records of purchase and sale of all the medicines in the pharmacy must be maintained, along with the source, date, and product details, and be available on

request for scrutiny. Any other records which need to be maintained under the law should also be maintained. These must be safely kept in the pharmacy for periods as specified under the law.

- Telephonic orders, internet pharmacy, door delivery: It is important to dispense prescription medications by the pharmacy only on seeing a valid prescriptions. After dispensing a prescription, it needs to be stamped with a “Dispensed” stamp and signed and dated, so that it is not used repeatedly.
- Efforts should be made by the pharmacy to educate the public about specific/relevant drug laws, and encouraged not to pressurize the pharmacy not to break the laws, mainly the need to produce a proper prescription when purchasing “prescription medicines”. This will assist the pharmacy to function more professionally.

D. Pharmacy Location, Exterior, Access:

The pharmacy should be easy to locate, identify and access by clients. The exterior look of the facade, the windows, and the displays should be neat and well maintained and should give it a look of a pharmacy. The pharmacy should be easily accessible to clients, including the disabled/those using wheelchairs/prams.

E. Pharmacy Interior, Furniture and Fixtures:

- i. The pharmacy premises have sufficient space for storage of medicines, space for standing and movement of staff and clients. Different areas in the pharmacy are clearly demarcated /separated, and labeled with suitable, easily visible and legible signboards.
- ii. The furniture and fixtures should be adequate, and adapted to the use of the pharmacy activities and storage of medicines. They should be placed systematically in such a way that areas don't look cluttered, and allow for easy movement of staff. They are maintained neat and clean from time to time.
- iii. The pharmacy is preferably fitted with air conditioners of suitable capacity and maintained in good condition. The air conditioning equipment is maintained and validated from time to time to maintain a cool temperature below 25 deg C – to

- serve the purpose of proper storage conditions for the medicines as well as for the comfort of the staff and clients.
- iv. The premises must be maintained free from pests and rodents, with time to time pest control measures, which should be documented.
 - v. The storage conditions of the pharmacy should be as per specified temperature and humidity, and free from dust. Medicines requiring refrigeration should be stored in the refrigerator, to maintain the cold chain
 - vi. Adequate safety precautions – viz : from fire, pilferage and burglary must be taken, and reviewed from time to time.
 - vii. The premises should be maintained neat and clean. Adequate cleaning procedures must be in place, and the cleaning done must be documented.
 - viii. Time to time maintenance of the premises, fixtures and furniture must be done from time to time, and records of this maintained.

F. Personnel:

- i. The pharmacy must hire adequate personnel/staff to man the pharmacy.
- ii. Existing staff should be acquainted with the upgraded/renewed policies and procedures from time to time.
- iii. New staff should be given induction training, and this should be documented
- iv. All staff should undergo periodic training on various aspects, and records of this maintained.
- v. The pharmacy should wear the pharmacy uniform or apron while on duty. The attire of the staff should be neat and clean, and appropriate for a pharmacy. Pharmacists on duty should be easily identifiable by the public by way of a name badge/plate worn by the Pharmacist/s.
- vi. Staff should be allotted tasks and responsibilities to take care of the various activities in the pharmacy.
- vii. The pharmacists should have overall responsibility of the medicines related activities in the pharmacy. Wherever possible, certain, routine activities can be done by non-pharmacist personnel, with due supervision of pharmacists.

G. Procurement & Inventory Control:

- i. The pharmacy should have written down SOPs for procurement and inventory control.
- ii. The pharmacy must have a master list of medicines to be procured and stocked in the pharmacy, along with a master list of authorized suppliers/wholesalers.
- iii. It is important to keep in stock for supply all the medicines which are generally prescribed by doctors in the neighborhood. The pharmacy should arrange to supply those which are not in stock in a reasonable time, so as to satisfy the needs of the clients.
- iv. Procurement will be based on average daily/weekly requirements. The person looking after procurement/inventory will have to be alert for increased/reduced requirements based on movements of company medical representatives in the neighborhood, special promotions drives, and variations in seasonal requirements, or increases because of epidemics, etc.
- v. It is important to purchase medicines only from authorized suppliers, and against a proper invoice/cash memo to avoid the entry to counterfeits, sub-standard or spurious medicines.
- vi. Time to time vendor audit must be done to ensure that proper systems are followed by the suppliers in stocking and dispatch of medicines.
- vii. Due care should be taken when placing orders from these suppliers, to ensure that there is no overstocking or under stocking
- viii. Medicines received from the authorized suppliers should be initially stocked separately in a "Quarantine Area". Here, they should be carefully checked for any visible defects/signs of pilferage/damages, etc, and tallied against the cash memo for correct product, batch number, expiry date, quantity and price. Only after this check, they should be stored in their respective storage places, ready for sale.
- ix. It should be ensured that medicines requiring cold chain be received in cold conditions.
- x. Which brand to order?
- xi. Random checks should be carried out on the stocks on the shelves, to check whether stocks tally with inventory/computer stocks.

H. Storage & Stock Management:

- i. The pharmacy shelf and counter arrangements should be such that prescription medicines are stored safely away from the direct reach/access of clients. OTC medicines may be stored in locations or a separate area where the clients may have direct access to them.
- ii. Care should be taken to stock medicines away from direct light or heat. Care should be taken not to stock medicines on the floor.
- iii. Due care should be taken to stock the medicines in a neat and orderly fashion, systematically. Storing may be done as per convenience of the pharmacy staff – in shelves, cupboards, drawers. Arrangement of medicines can be as per convenience of the staff - company wise, or dosage form wise or therapeutic category wise, or alphabetically. This, is to ensure that the pharmacy looks orderly, and also make it easy for staff to retrieve the medicines easily and quickly whenever required
- iv. Stocks and the shelves should be wiped /cleaned from time to time to keep them neat and free from dust. Such cleaning records should be maintained.
- v. Due care should be taken to follow FEFO (First Expiry First Out), during storage.
- vi. The storage temperatures and humidity should be recorded /documented from time to time and corrective measures taken if necessary.
- vii. Medicines/products requiring cold temperature (2 – 8deg C) should not be left out for more than a few minutes, and should be immediately transferred to the pharmacy refrigerator. Due care should be taken to ensure that the refrigerator is in good working condition. Consumables/beverages like juices, energy drinks, etc should not be stored in the refrigerator along with medicines. They must be kept in a separate refrigerator. Adequate procedures should be followed of regular defrosting, cleaning and maintenance of the refrigerator. Records of this should be maintained.
- viii. Stocks should be periodically checked for near expiry/expired medicines, and retrieved from the shelves and stored separately.
- ix. Spoilt/damaged/expired goods should be stored away from the medicines for sale, in a separate, shelf/cupboard/carton, carrying on it a clearly legible label,

“EXPIRED/SPOILT MEDICINES, NOT FOR SALE. These should be disposed off from time to time as per procedures laid down in the law.

- x. If the pharmacy stocks a medicines belonging to the narcotics category, the same should be stored separately, under lock and key. The key should be with the person in charge. Extra precautions should be taken in handling and dispensing of these medicines.
- xi. If the pharmacy stocks veterinary products if stocked by the pharmacy should be stored in a separately demarcated area/shelf, adequately labeled :“Veterinary Medicine – Not For Human Use”
- xii. If the pharmacy stocks any insecticides and pesticides, they should be kept in a separate cupboard/shelf, preferably away from medicines. The shelf/cupboard should be prominently labeled as “Insecticides – Not for consumption”.

I. Good Dispensing Practices :

Dispensing is the core activity of the pharmacy, and it is important for the pharmacy to have proper systems in place along with proper documentation:

- i. A good dispensing environment, free from distractions assists in carrying out dispensing accurately and efficiently.
 - The prescription counter should be demarcated and easily identifiable & accessible to clients.
 - The dispensing area should be clean, organized, have sufficient space for standing and easy movement of pharmacy staff, be at a controlled temperature and humidity for comfort of staff. Medicines should be systematically organized in the shelves so that they are quickly selected by the staff.
 - There should preferably be a waiting area for clients to wait while their prescriptions are filled /dispensed. This should have comfortable chairs/sofa for seating.
 - The atmosphere and attitude of the staff should be serious, to ensure full concentration on the handling of prescriptions, free from distractions. Conversations not related to the pharmacy work,, loose talk, loud music,

watching television by the staff should be discouraged. Barriers, noise and distractions which can affect dispensing should be identified, and eliminated/reduced to minimum.

- ii. The pharmacy should have SOPs for various aspects and steps in dispensing, and these should be accessible to all pharmacy staff.
- iii. There should be sufficient number of staff to cater to the clients. Clients entering the Pharmacy should be promptly attended to with due respect and concern, and his/her needs verified. They should be made to feel attended promptly and be made comfortable by positive body language, gestures and welcome by the pharmacy staff.
- iv. Prescriptions should be scrutinized /verified for authenticity/legality, legibility, completeness and correctness. Any doubts in the prescription should be clarified with the prescriber.
- v. Due care should be taken in reading and checking the prescription. The staff should be alert, and concentrate on the prescription at hand. He/she should use her professional skills/experience in assessing the prescription. Medicines should be correctly removed from the shelves as per the requirements. Separate containers may be used to segregate medicines of individual patients, to avoid mix-up.
- vi. A system of double checking should be followed, to ensure that the right medicines have been removed. Double checking could be done at the time of billing. One of these activities should be done by the pharmacist, or supervised by the Pharmacist. The cash memo should be signed by the Pharmacist after verification.
- vii. Medicines should then be neatly packed, in presentable/hygienic bags/packets/envelopes. Those requiring storage in cold conditions (2 – 8 deg C) should be packed in cold packs before handing over to the client, and instructed to store such products in a refrigerator.
- viii. Packaged medicines should be handed over to the client, after confirming his/her identity.
- ix. Patient instructions should be provided during any of the dispensing steps above.

- x. The pharmacy staff should be made aware of various possible dispensing errors, and due care and training should be given to avoid any such errors.

J. Patient Information:

- i. **Patient Instructions:** The dispensing task of the pharmacy is not complete unless proper instructions are given to the patient knows about proper use of his medications. Improper information on medicines increases the chances of improper use and low compliance. Sufficient time should be made available by the Pharmacist/s to give at least the basic instructions to the client about proper use of the medication. This includes:
 - a) Which medications have been prescribed, and for what purpose.
 - b) What quantities to take, at what times, and for how long.
 - c) How to take the medication/device properly
 - d) What precautions/care to be taken, , any foods/beverages to avoid, while on medication
 - e) What side effects to expect, and what is to be done in case of side effects
 - f) How to store the medicines

Patient instructions can be in the form of:

- a) Oral information
 - b) Written information/instructions: ancillary labels, patient package insert (PPIs), Patient Information Leaflets (PILs), fact cards, etc.
 - c) Support material – charts, demos, pictorial/video
- ii. **Patient Information:** The pharmacy can be a source of patient education, health promotion. The pharmacy can prepare/stock different kinds of educational materials (viz: PILs, Fact Cards, booklets, videos, charts, etc. o different diseases/illnesses, on safe use medicines, etc., and counsel patients on these as per their needs.
 - iii. **Patient Care Area (PCA):** The patient instructions may be given at the dispensing counter, or preferably in a separately designated patient care/counseling area. A separate patient care area allows privacy, better interaction, and maintains confidentiality.

PCA should be equipped with:

- a. Sufficient chairs and a table for pharmacist and patient/client/s to seat comfortably.
- b. Reference material/books
- c. Devices for demo e.g. insulins, asthma
- d. Weighing machine, height chart, glucometer, sphygmomanometer, etc.

In case the pharmacy is too small to have a separate PCA, a make-shift place in the pharmacy can be isolated on need basis where the pharmacist and patient can talk in confidentiality.

K. Rational Use of Medicines (RUM) :

All pharmacists must be trained in the different aspects of RUM. Further, it is the responsibility of the Pharmacist to promote RUM in the community, through :

- i. Proper care in medicine procurement and maintaining proper inventories.
- ii. Providing information and education to other health care providers
- iii. Educating the public on proper and safe use medicines. While recommending OTC medications, pharmacists must ensure that they consider various aspects of RUM in doing so.

L. Policies and Procedures:

Pharmacies must have written down policies and procedures for various aspects and activities in the pharmacy. These could be the following:

- i. The pharmacy should have a Quality Policy, and it should be prominently displayed in the pharmacy for the public to see.
- ii. The pharmacy should have a Quality Manual, and which is accessible to key persons. Various activities in the pharmacy must be followed as pr the Quality Manual.

- iii. The pharmacy must have documented policies and procedures for :
 - a) Medicines returned by clients
 - b) Product recall,
 - c) Receiving and handling suggestions and complaints from clients
 - d) Handling dispensing errors
 - e) Disposal of waste and unused medicines
 - f) Protocols for providing advice/counseling to clients/patients, and protocols for advice on self medication and recommending OTC medicines

Further, there should be a procedure to document all of the above as and when they take place, and maintain the documentation records systematically.

M. Professional Services/Value Added Services:

Besides the basic duties of dispensing and providing sufficient patient information/instructions to clients, pharmacists can provide additional professional services for health promotion (prevention of ill health), such as .:

- i. Health Checks: Pharmacists can do blood pressure checks, blood glucose checks, height, weight checks and calculation of BMI, waist to hip ratio.
- ii. Conduct awareness or screening camps from time to time for awareness, or early detection of various conditions/illnesses like asthma, diabetes, obesity, hypertension, hyperlipidemia, osteoporosis, etc. Provide advice on vaccinations for children, pregnant ladies, travelers.
- iii. Provide counseling services on various illnesses/diseases
- iv. Demonstrate use of devices for asthma, insulin use, etc. to clients
- v. Recommending OTC medicines to clients, and referring them to other health care professionals.
- vi. Maintain PMRs (Patient Medication Records)

Proper records of these activities should be maintained.

N. Professional Activities:

- i. Pharmacists must update their professional knowledge of diseases and medicines by reading/referencing, attending CPD programmes on a regular basis. Sufficient time should be allotted /spared for such enhancement of knowledge.
- ii. Pharmacists should involve themselves in raise the levels of the public awareness about proper use of medicines through campaigns.
- iii. Pharmacovigilance – Pharmacies should be a part of the Pharmacovigilance programme in the country, and detect and report adverse reactions that they come across in their pharmacy.
- iv. Pharmacies should take part in Accreditation exercise for pharmacies, and seek to upgrade their pharmacy