Good Pharmacy Practice Guidelines

Guidelines for delivery of Pharmaceutical Services and Care in Community Pharmacy Settings in India

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Indian Pharmaceutical Association

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Practice Guidelines

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The Indian Pharmaceutical Association
Good Pharmacy Practice Guidelines
Documentation Committee

Chairman Brijesh Regal
Chairman, Community Pharmacy Division, (1998-2008)
Indian Pharmaceutical Association, Mumbai
Email: Brijesh@Apothecaries.net

Secretary Raj Vaidya
Email: Pharmhin@Sancharnet.in

Members Ajay Pal Gupta
Ashok Sakhuja
Kul Bhushan Gupta
M P Mittal
Mohinder Bareja
Pankaj Maini
Pritpal Singh
Ravi Narang
Sunil Gadi
Sunil Arora

Guidance Dr. D. B. A. Narayana
Managing Trustee, Delhi Pharmaceutical Trust
P.D. Sheth
Professional Secretary,
WHO-SEARPHARM Forum

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GPP and Pharmaceutical Care are dynamic concepts. To continually improve and update these guidelines – the practitioners are invited to send their feedback and experience to Brijesh@Apothecaries.net or to Pharmhin@Sancharnet.in

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Preamble

Our society is going through a massive change in its health care needs and provisions. Pharmacy itself is a profession in transition. While the profession is changing much more rapidly, now than 5 years ago, there are still too many Pharmacists who are fighting change rather than embracing it. Many in the profession are looking for someone to blame rather than deciding what they can do to move forward.

The profession of pharmacy in India can seize the opportunity and respond to changes in the health care system, in part, by making pharmaceutical care its mission. Pharmaceutical care is an evolutionary and revolutionary way of practicing pharmacy. It requires complete rethinking about how Pharmacists in India have traditionally worked so far. Despite some Pharmacists confusing pharmaceutical care with patient counseling and/or disease state management, pharmaceutical care is far more complex and occurs many more challenges and opportunities. It requires that pharmacists take responsibility for preventing and solving drug related problems and optimizing drug therapy. It does not end when the patient leaves the pharmacy. Assessing (patients understanding of illness and treatment plan), monitoring, documenting care and progress and follow-up care are integral part of providing pharmaceutical care.

Pharmaceutical care requires marketing and management support. While there is no doubt about the market need for pharmaceutical care, there is not a clear market demand for it yet. Patients don't know they need it, doctors aren't sure what it is or if they should like it, and the Government doesn't understand it or isn't convinced that it will really reduce health care costs. It is our job to create this demand for pharmaceutical care and for the mission of pharmacy. We are a profession in search of a savior. We are waiting for someone else to 'sell' our mission. Yet, experience tells us that no one would really care about pharmacy except pharmacists. Therefore, it is up to every pharmacist to market pharmaceutical care.

Notwithstanding our optimism, it is hard to see how pharmacy and its practitioners will survive if they do not embrace the changes we are facing. Merely selling drugs will not keep pharmacists afloat. The absence of even a passing reference to 'Pharmacists' in the country's latest health policy has sent a clear message that simply dispensing drugs has very little value. In fact, some sections of decision makers feel that pharmacists do not provide any value but merely add to the health care costs and should be removed as patient interface. Society does not want to pay for anything that does not lower costs or improve outcomes. Yet, almost all Pharmacists in India continue to merely sell medicines – arguing that they have no time to do anything but selling.

What has happened to the profession of pharmacy? How did we get here? How did we lose sight of what is truly important: the patient? What we do know and understand about the patient's illness and treatment?

Are we behaving morally and ethically as a profession? When patients do not receive important information about their medicine or when their understanding of the illness and treatment is

not assessed, we are putting people at risk. Equally, if not more importantly, do we realize that we are jeopardizing the relevance of our profession to the society.

When we practice pharmacy, are we able to answer these questions? If the answer is no, then we are really getting to the root of the problem. Why don't we know these things?

Good Pharmacy Practice Guidelines aim to set standards for practice of pharmacy as a profession in India. It is also an affirmative statement conveying that we ourselves control our profession's standards, not anyone else.

We essentially and urgently need to establish and respect the conventional relationship between the patient and the pharmacist.

Being professional means that what we do is not solely motivated by financial gains. In fact, the primary motivation should be service to the public. If this appears altruistic, we must realize that altruism is the foundation for professional behavior.

By definition, all professional

i. Render some specialised services to the society
ii. Have a state enforces monopoly of rendering those services in which they engage
iii. Have undergone training with specialised length and content
iv. Offer consistently high and ethical standards of service to the society.

These guidelines aim to provide the framework to meet the last and the most important of the above criteria that has the potential to make pharmacy profession relevant to the society.

We say that pharmaceutical care should be our mission but is it our standard?

Standards play an important part in the measurement of quality of service. GPP guidelines aim to set the standards for pharmacy services to be provided to the society through community pharmacies.

These guidelines have been documented with the understanding and acceptance that the conditions of pharmacy practice may vary between different areas within the country. Not only is there likely to remain a difference in the pharmacy services available in our urban and rural area, the inordinate large number of retail pharmacies in most cities would keep a wide difference in level of the services provided.

It is accepted that even though there are adequate 'qualified' pharmacists, the benefits that accrue from Pharmacists' direct supervision in ensuring the quality of pharmaceutical products and services cannot be realized where there are insufficient number of 'trained' pharmacists. For the foreseeable future, 'trained' qualified pharmacists will continue to be in short supply. 'Qualified pharmacists' will therefore have to take up such responsibilities and duties which are inappropriate to their current level of training. Therefore, there is a real need to organize well-structured continuing education facilities for qualified pharmacists if implementation of GPP guidelines is to be achieved in our country. Timelines for perceptible improvement in the provision of pharmaceutical care across the country would necessarily be dependent upon the provisions made for continuing-education facilities.

A powerful parallel force to raise the standards of practice can result by increasing the awareness of public, government and other healthcare professionals about the services that can be offered by the pharmacists and the benefits that would accrue from the full use of their expertise and knowledge. This increased awareness would serve to raise public expectations and the process is likely to become a major motivating factor for community Pharmacists to upgrade themselves.

However, it will be individual Pharmacists and pharmacies that will have to decide what is the highest level of service that can be provided by them and achieving it will be their professional decision. A certain level of commitment to change will be the essential prerequisite for adoption of these guidelines.

In India, Pharmacists are largely involved in the distribution role. As the number of 'trained' Pharmacists increases, provision of dissimilation of information aimed at improving the outcomes of pharmacy-therapy would be perceptible in the society.

The Drugs and Cosmetics Rules prescribe that the word "Pharmacy" be displayed by those premises which comply with Schedule N (for compounding of medicines). However, the word "Pharmacy" has been used here to progressively describe all retail medicine outlets irrespective of whether they are compounding or not. It is opined that compounding pharmacies be called as such.

The objective of framing and implementing these GPP Guidelines for India is that over the next few years, all pharmacies in India should achieve these standards of practice. It is left up to individual pharmacies how they go about achieving these standards. This has to be through continuous education, training and perseverance of the pharmacists as well as the professional organizations.

Even though it may seem that high level of standards have been set, the time has come for the situation in India to change from a product oriented approach to a patient oriented approach with Pharmaceutical Care the ultimate goal of pharmacy practice. As new medicines are being introduced in India at the global pace our standards of pharmacy practice will have to be set on par with standards of other pharmaceutically evolved countries sooner than later.

These GPP Guidelines are like the North Star in the sky: we may never reach there but that's where we aim to reach. They will show us the way, like the North Star does, when we do not know which way to go.

Brijesh Regal
March 2002
Email:
Brijesh@Apothecaries.net

Definitions

Chief Pharmacist: A "Pharmacist" as described above, with at least one year experience of providing pharmaceutical care to patients.

Client: All persons who come to the pharmacy for obtaining medicines, cosmetics or other products and services.

Community 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 designated primarily for the purpose of providing medicines. The sale or provision of the medicine may either be on the order or prescription of a doctor or "over the counter" by the Pharmacist.

Drug: All chemical or natural substances capable of being used for therapeutic purposes. The expression Drug also includes narcotics, etc.

Medicine: Drugs used for therapeutic purposes. All medicines are drugs but all drugs are not medicines.

Patient: A client who is suffering from an ailment and visits the pharmacy to obtain medication or advice. All patients are clients but all clients may not be patients.

Pharmacy: See Community Pharmacy.

Pharmacy Assistant: A person engaged by a Community Pharmacy, who does not have any formal pharmacy qualifications but has received "on the job" or "in house" training.

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 such as a degree or diploma in pharmacy, and who is registered with the State Pharmacy Council where he is practicing the profession.

Profession: A vocation that meets the following criteria:

1. A state-enforced monopoly of rendering specialised services to society.
2. A control over length and content of the training that is mandatory for the occupational group.
3. An area of work where the society needs and receives consistently high and ethical standards of service.
4. The practitioners have an accepted and enforced code of ethics.

Qualified Pharmacist: A pharmacist who has adequate qualification(s) that make him/her eligible to get registered.

Registered Pharmacist: A Pharmacist who is registered under the Pharmacy Act with the state pharmacy council where he normally practices.

Trained Pharmacist: A Qualified Pharmacist who has adequate training to deliver Pharmaceutical Care.

Good Pharmacy Practices

1. Structure Guidelines

These refer to pharmacy as an organization, and give standards/guidelines for

- 1.1 Facilities
  - 1.1.1 Premises
  - 1.1.2 Furniture and fixtures
  - 1.1.3 Equipment
- 1.2 Personnel
- 1.3 Systems
  - 1.3.1 Quality policy
  - 1.3.2 Service policy
  - 1.3.3 Staff training policy
  - 1.3.4 Complaints policy
  - 1.3.5 Drug Recall policy
  - 1.3.6 Audit policy
  - 1.3.7 Documentation system

Structure guidelines aim to create suitable conditions for the process guidelines.

2. Process guidelines

These refer to the provision of pharmaceutical care and lay down the guidelines for:

- 2.1 Procurement &inventory management
- 2.2 Storage inventory management
- 2.3 Prescription handling
- 2.4 Dispensing
- 2.5 Information for patient
- 2.6 Patient counselling
- 2.7 Health promotion & ill health prevention
- 2.8 Pharmacovigilance
- 2.9 Enhancement of professional role
- 2.10 Professional interactions

1. Structure Guidelines

1.1 Facilities

1.1.1 Premises

The pharmacy should be easily located & identified by the public. Exterior of the pharmacy should be maintained neat and clean. The façade should be clearly marked with the word "PHARMACY" written in English as well as in the local language(s) of the area.

As far as possible, the pharmacy should be conveniently assessable to people using prams or wheel chairs etc. pharmaceutical services and products should be served from an area which is separate from the other activities/services and products. This facilitates the integrity & quality of products, and minimizes the risk of dispensing errors. The Pharmacist should be directly & easily accessible to public for information, counseling, etc.

Purpose:

(i) Patients may feel hesitant or uncomfortable to speak out his/her illness /about his medicine to a pharmacist when he feels he could be overheard by others.

(ii) If the problem/query of the patient needs alone time (10 minutes or more), it needs a place where a patient can sit at ease.

(iii) Demonstration of certain instruments,/diagnostic kits/self-usable devices (for e.g. Training the patient on making an insulin injection, or demonstrating with the help of charts or video would be better done in a secluded and related place.

The pharmacy environment should be clean with minimum dust and should be maintained clean as per pharmacist cleaning schedules and SOPs. It should be free from rodents and pests/ insects and pest control measures should be taken from time to time.

The pharmacy should have a constant supply of energy especially for the refrigerator(s). There should preferably be a provision for drinking water to facilitate drug administration to the patients and for use of the staff.

The pharmacy should have a comfortable environment for ease/comfort of clients and personnel.

The pharmacy should have:

(i) Sufficient pace for clients to stand comfortably at the dispensing counter and if possible for some to sit comfortably while they wait.

(ii) Space for patient information displays, including for information leaflets/ material.

(iii) A separate enclosure described as "counselling Area" for patient counselling, storage of reference resources (e.g. books, internet access etc.) is a fundamental requirement. Counselling 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.

(iv) A compounding pharmacy should also have sufficient additional space for making extemporaneous preparations, besides the necessary equipment for doing so.
(v) Separate waste collection baskets/boxes should be available for the staff and for the clients.

The products 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.

1.1.2 Furniture and fixtures

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 light. Adequate provisions should be available for storing various medicines at prescribed temperature conditions.

The counseling area should be furnished with:

(i) A table.
(ii) Chair for the Pharmacist and a couple of patients
(iii) Cabinet for storing patient medication records (PMRs)

1.1.3 Equipment

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

The counseling area should be equipped with:

(i) Reference material
(ii) Demonstration charts, kits and other demonstration material.
(iii) Patient information leaflets (PILs)
(iv) Some basic instruments for e.g. Sphygmomanometer, glucometer, Snellens chart, stethoscope, etc.
(v) Weight and height scale

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

1. Manage inventory
2. Manage invoicing
3. Generate timely warning for expiring medicines
4. Archive patient medication records

The computer should also be equipped to give demonstrations to the patients and other relevant purposes.

Compounding section of the pharmacy should be equipped as prescribed under Schedule N to the Drugs and Cosmetics Rules. Other equipment, as necessary for operations, should also be available.

1.2 Personnel

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

All staff members including newly recruited staff should be trained as per the staff training policy of the pharmacy.

All activities in the Pharmacy should be carried out as per well documented guidelines and procedures, which should have been framed by the management in consultation with the Chief Pharmacist.

Each staff member should have clearly allotted responsibilities, which must be performed according to documented standard operating procedures.

All personnel in the pharmacy must, at all times, wear a neat apron/ coat. All Pharmacists should additionally wear a badge prominently displaying their name and the word "Pharmacist". Additionally, a recent photograph, qualification certificate and the State Pharmacy Council Registration Certificate may be displayed in clear view of the clients entering the pharmacy.

Due to regular exposure to patients some of whom may be carriers of contagious diseases all pharmacy personnel should wear medically examined and adequately immunized periodically and their health data should be archived.

Pharmacists working in the pharmacy should:

1. Hold at least a Diploma in Pharmacy and preferably a degree in Pharmacy.
2. Be registered as a pharmacist with the Pharmacy council of the state in which he/she is practicing.
3. Have undergone adequate practical training in a community pharmacy.
4. Undergo in house training as per the organisation's staff training policy.
5. Have communication skills & capabilities to give adequate and proper advice to the clients on the appropriate use of medicines, illness, etc. so as to achieve optimal patient compliance.

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

(i) Play a professional role to assess prescriptions.
(ii) Advise the patients on appropriate selection and use of OTC medicines.
(iii) Advise patients on appropriate use of prescribed medicines.
(iv) Check & advice on drug-drug and drug-food interactions.
(v) Be alert for adverse drug reactions.
(vi) Comprehend the client's condition or illness and provide advice on proper use of medication and diet.
(vii) Assess the patient's condition and decide when to refer him/her to the doctor.
(viii) Perform the role of a health care provider and a counsellor.

1.3 Systems

The pharmacy should have well defined and documented systems for each operation carried out in the pharmacy.

1.3.1 Quality Policy

It is a general declaration of the intent of the pharmacy about the level of quality of service and products offered to the public.
Quality goals emanate from the stated quality policy and they are the targets, which are set and which can be in a stipulated period of time. Different quality goals need to be set in the various operational areas of the pharmacy.
It is the responsibility of the Chief Pharmacist to formulate a Quality Policy and set and achieve Quality Goals along with the management and other staff.
The pharmacy should have a quality manual, which 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, distribution of responsibilities, work procedures and instructions that are necessary for achieving the quality goals in day-to-day operations in the pharmacy. The Quality Manual should be accessible to the staff of the pharmacy for their easy reference.
All the activities mentioned in the Quality Manual should be well documented, and it shall be the final responsibility of the Chief Pharmacist to ensure that the pharmacy quality goals are in consonance with the quality policy of the pharmacy.
The Chief 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 a review to further improve the process.

1.3.2 Service Policy

Service policy is a statement of the nature of services provided in the pharmacy and the standards laid down for the provision of those services.
The pharmacy should have a well-documented service policy based on its client servicing goals. Service policy statement should include issues like home delivery of products, the nature and level of attention to be given to clients of
Various kinds (e.g. elderly clients, regular clients, etc.). The service 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, etc. form an important part of the service policy. The manual should also enlist the details of the activities, routines, distribution of responsibilities, work procedures and instructions that are necessary for provision of the services in day to day operations of the pharmacy.

1.3.3 Staff Training Policy

A well-conceived and implemented staff training policy has the potential to determine the future of the pharmacy in the community in which it operates.
Availability of adequate reference resources (books, current periodicals, software, etc.) in the pharmacy is the fundamental requirement of the training process.

Training policy should encompass the needs evolving out of service policy of the pharmacy. The policy should prescribe the content & frequency of the training and the training resources. Training policy 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 policy so that pharmacy personnel can operate in tandem with other healthcare providers on one end and are able to form professional bonds with the clients on the other. Efforts should be made to involve professional representatives of pharmaceutical companies in the trading process.

The policy should prescribe the minimum continuing education levels to be attained by each staff member so that the ultimate goal of pharmacy-provision of Pharmaceutical Care – is achieved.

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

Special emphasis should be laid on training

(i) Pharmacists: in communication & counselling skills, handling of prescriptions & clients, continuing education in illnesses & drugs, latest developments in the field of medicine and pharmacy and general health matters, on "when to refer" to a doctor.

(ii) Pharmacy assistants: in communication skills, salesmanship, handling of prescriptions, dispensing of drugs, procurement & storage of drugs, and "when to refer" to a Pharmacist for counselling.

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

Training process should be well documented and reviewed periodically.

Pharmacists should be encouraged to keep their knowledge up-to –date through scientific literature, textbooks, journal and periodicals, workshops, etc. Networking with pharmacists in other pharmacies should be encouraged.

Management and the Chief Pharmacist shall be responsible to continuously train the human resources available in the pharmacy to ensure maximum benefits to the community.

1.3.4 Complaints policy

The pharmacy should have a complaints policy which should be reviewed from time to time. All complaints-oral or written- must be immediately addressed by the pharmacist, and suitable action be taken to amend the situation.

The complaint, its nature, the erring person's name and the action taken must be documented in a complaint register. The event should be reviewed and evaluated to find the underlying cause(s).

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.

1.3.5 Drug Recall Policy

The Pharmacist should have a well-documented recall policy:

(i) The pharmacy should proactively participate in any state wide or nationwide recall process for any substandard drug. All such records should be initiated upon receiving authentic information and alarms to do so. The initiation, progress and completion of recall should be well documented. Adequate vigilance must be maintained to look out for recall alarms from regulatory sources as well as from pharmaceutical companies.

(ii) In case of any suspicion, the pharmacist should take immediate steps to stop the sale of drug and notify the relevant parties.

(iii) If the pharmacist has a suspicion or a reason to believe that short comings have occurred in the process of delivery of medicines from the pharmacy, immediate effective measures should be initiated to minimise the risk of damage or danger to the patient(s).

1.3.6 Audit Policy

Audits are conducted to check whether the Quality Management Systems are functioning properly, and as per guidelines set forth in the Quality Manual, to see whether the desired objectives of the pharmacy are being achieved. By a Quality Audit, the Chief 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 frequent internal audit and a periodic external audit. Based on the audit reports, steps should be initiated to make necessary improvements.

The internal audit can be conducted by the chief pharmacist along with the senior staff or members of the management team. The staff deployed for internal audit should be adequately trained for the purpose. Audit may be carried out once in six months, or more frequently.

An external audit must be done at least once a year by external auditors, who are competent to do so and are appointed by the management.

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

1.3.7 Documentation system

Documentation is one of the core activities for achieving and maintaining quality. The overall responsibility for documentation rests with the chief pharmacist.

All necessary statutory documents (for 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.

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

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

Some of the necessary documents include:

(i) Protocols

(ii) Standard Working Procedures

(iii) Operation instructions
(iv) Quality Manual
(v) Cleaning and maintenance processes and records
(vi) Complaint records
(vii) Audit records (internal and external)
(viii) Policy documents
(ix) Personal details

In addition, the documents required for the pharmaceutical care process should also be adequately maintained and stored. These documents include:

(i) Patients' health profile
(ii) Patients' medication records
(iii) Records of counselling follow-ups, etc.

2. Process guidelines

The pharmacy should develop and maintain a safe, effective operational and socio-economically acceptable operation system. As far as possible, the chief pharmacist should ensure that medicines and other health care products are readily available in the pharmacy in sufficient quantities. The operational system should be socioeconomically effective so that the pharmacists' financial interests are maintained while providing optimal health and cost benefits to the clients.

2.1 Procurement and inventory management

Vendors and purchasing:

The pharmacist should ensure that the source of supply of medicines and other items meet the standards laid down in the law. Where no regulatory standards have been prescribed the chief pharmacist has the additional responsibility to protect the interest of clients and the pharmacy from being cheated by substandard supplies.

The chief pharmacist should satisfy himself about the reliability and adequacy of the matches deployed by the vendor's chain to ensure that all products have been handled in appropriate storage and transit conditions. Details of the vendors (for e.g. their addresses, contact numbers, names and addresses of their management persons, technical persons and administrative staff, copies of various licenses held by them should be maintained). A written communication regarding the list of authorized representatives of the vendors and their specimen signatures should be maintained and archived. Responsible designated person(s) from the pharmacy should visit the vendor's 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 products. Errors made by the vendors should be brought to the notice as soon as possible and get rectified. All errors made by the vendors, nature of errors, repetition of the same errors, method and time frame of rectification should be documented and reviewed periodically to prevent their recurrence.

The chief pharmacist may consider informing the regulatory authorities in case there are reasons to believe deliberate, dubious activities by the vendors(s).

It is important to store products manufactured by reputed companies. The pharmacist should maintain a 'products list' where all items 'approved' by the pharmacy for stocking are described. This will discourage the non-approved and low quality medicine vendor, who may otherwise try to sell drugs, which may not be of standard quality and/or those which do not have a proven safety profile.

This list may be reviewed and updated as often as necessary. Any new items added to the inventory must be first included in the list after a professional review by the chief pharmacist. Where the pharmacy operations are managed using computers the item must first be entered into the database and then ordered for procurement.

Ideally, the product lists also specify the location of that product in the pharmacy. Adequate cost – effective purchasing methods should be followed which ensures adequate inventories leading to optimal financial gain for the pharmacy. In-house benchmarks for various categories of products should be set for minimum-remaining - shelf –life at the time of procurement.

All products received from vendors should be tallied against their invoice and checked for correctness of quality, price, batch number and expiry date. Any anomalies should be brought to the notice of the supplier /s and suitable rectification got done. All such rectification should be documented and got authenticated by an authorized representative of the vendor.

The purchase records/invoices should be maintained as stipulated under the law.

2.2 Storage

2.2.1 Storage management

A products coming into the pharmacy should initially be quarantined, preferably in the separate area, before they are checked for correctness of quality, batch number, expiry, integrity, etc. after necessary, checks, they should be transferred to their respective storage location.

All drugs should be stored at stipulated temperature areas, protected from excessive light, dust, and humidity. Temperature at various areas should be recorded at predetermined periodicity and daily records should be preserved for a period of 2 years. They may be correlated with the subsequent years' corresponding data to improve arrangements for maintenance of temperatures. The medicines and shelves should be maintained clean and dust free at all times by following cleaning schedules and SOPs. Prescription drugs should be maintained be kept in such a manner that they are out of reach of clients. All the drugs that are to be stored in a 'cold' temperature should be kept in the refrigerator unless the ambient temperature in the area is cold enough.

Drug and dosage form that special care while dispensing (e.g. drugs specified under the schedule X, Narcotic drug and Psychotropic Substances Act and some other CNS drug etc.) should be kept under lock and key. The key for this should be available only with the Pharmacist in-charge at the time. Records of purchase and sales of such medicines should be kept as per legal requirement.

Shelves should be checked at a predetermined periodicity to ensure removal of drugs whose expiry date is approaching. In-house threshold period should be set and followed foe such

retrieval of drugs from the shelves. The near expiry products should be stored separately and disposed of either by returning to the respective vendors or by expending their dispensing. Drugs, 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 client in any case. Expired drugs should be returned to the supplier or destroyed as per in-house procedure at the earliest.

2.2.2 Disposal of unused pharmaceutical products and waste

The unused and unopened pharmaceutical products (non-saleable or expired) lying in the pharmacy should be listed and returned to the respective vendor who would in turn send them back to the manufacturer. However in case this is not possible the same may be disposed off as per the pharmacy’s standard operations procedures in this regard.

2.3 Prescription handling

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

2.3.1 Upon receiving the prescription , the Pharmacist should confirm:

(i) Identity of the client

(ii) Whether the prescription is presented by the client himself or by someone on the client’s behalf.

2.3.2 The client may be politely requested to wait while the pharmacist review the prescription for:

(i) therapeutic aspects (Pharmaceutical 7 pharmacological)

(ii) Appropriate for an individual

(iii) Social, legal & economic aspects

(iv) Legality & completeness of prescription

2.3.3 Prescription should be complete with regard to:

(i) Name of the Doctor, his /her address and registration number.

(ii) Name, address, age, sex of the patient

(iii) Name(s) of the medicine(s), potency, dosage, total amount of the medicines to be supplied.

(iv) Instruction to the patient

(v) Refill information if any

(vi) Prescribed doctors’ usual signature.

Any ambient, confusion, shortcoming or anomalies should be brought to notice of the prescribing doctors.

2.3.4 Correctness of prescribed medicines

The prescription should be checked for:

(i) Dosage: Whether the dosage prescribed is within the standard minimum and maximum dose range.

(ii) Double medication (same drug or different drug with same pharmacotherapeutic effect) concurrently prescribed by the same Doctor or by two or more doctors to the same patients undergoing concurrent treatment by more than one doctor.

(iii) Interaction between the currently prescribed medicines, OTC medicines being taken by the patient & the medicines being taken from any past prescription (records of which may be available in the Patient's Medication Records). Any drug interaction likely the render the therapy ineffective or cause undesirable effects to the patients should be brought to notice of the prescribing doctor.

(iv) Contraindication: age, sex, disease(s), conditions or other characteristics of a patient that may cause certain prescribed medicines to be contraindicated.

(v) History of overuse, under use, or misuse of medicines by the patient.

Any of the above as well as handwriting legibility problem should be brought to the notice of the prescribing Doctors. Any necessary change made by the doctor should be recorded on the prescription, with the words "Changes made over the telephone in consultation with the Dr. (name) at (time) on (date)" and should be signed and stamped by the pharmacist. This exercise necessitates a trust based professional relationship with the prescribing doctor incise of any doubt the prescription should be got suitably amended from the doctor.

2.4 Dispensing

2.4.1 Filling the prescription

The medicine should be removed from the storage area, counted and invoiced. In all cases, final review of prescription and the correctness of dispensed medicines must be personally made by the pharmacist.

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

The medicines should be packed neatly so that their integrity is maintained any medicines requiring special storage condition e.g. cold place (2-8◦C) must be packed in cold packs so that they remain at the stipulated temperature till they are taken from a larger bulk pack then they should be packed in a clean, food grade glass or plastic bottle or in a clean envelop and neatly labeled as provided under the lock.

Appropriate counseling/guidelines must be given for the patient as recommended below under patient information (section 2.5).

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

2.4.2 Extemporaneous preparations

Written standard operating procedures as well as standard formulations should be maintained for commonly made extemporaneous preparation. Proposed adjuvants, their quantities and method of preparation must be written down before any compounding activity is initiated. Each step should be followed methodically and step by step record maintained. Batch numbers of each medicines used for compounding should be recorded. All such preparation should preferably be compounding by the Pharmacist, only under direct supervision of a pharmacist.

Only medicinal quality or better grade ingredient should be used for compounding. The preparation area should be cleaned immediately before and after compounding. All necessary weighing, measuring instrument must be calibrated periodically and records maintained.

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, direction, quantity, a reference (batch) number generated by the pharmacy, 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.

2.5 Information for patient

Pharmacists' fundamental concern is welfare of the client. Clients responsible to make decisions regarding his/her health must be respected at all times. Therefore, the pharmacist must help the client in making well – informed decision about proper use of medicines & other health care products. Pharmacist should support the client in making well – considered decision with regard to self – care.

Whenever a pharmacist has doubt or reasons to believe that it would be in better interest of the client, he/she must advice the client is to see a doctor or another health care provider as soon as possible.

Pharmacist should offer the client sufficient opportunities for personal consultation, and should ensure that are aware of this possibility.

Pharmacist should provide oral as well as written information about various illness, medicines & other health care products, in order to increase the awareness level of the client regarding his illness and his medicines. The goal of consultation is to achieve maximum compliance. As far as possible, delivery of medicines to the client should be supported by written information.

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

(i) Name of the patient

(ii) Name, strength, batch number and expiry of the medicine, in case the medicine has been repacked or cut out from a larger pack

(iii) Dosage and usage instructions

(iv) Date of delivery
(v) Storage instructions
(vi) Name and address of the pharmacy

Dosage and usage information must also be given verbally to the client.
It must be ensured that the information and advice given is correct, clear, explicit, up-to-date and understandable to 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 clients needs and wishes. The attitude of the pharmacist towards the client must guarantee a correct understanding and a sufficient confidence in the information provided.

2.6 Patient Counseling

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

(i) How to take the medications.
(ii) For how long.
(iii) When to take the medicines and whether to take the medicines and whether to take them before, during or after meals, etc
(iv) What foods/beverages/tasks to avoid during the therapy.
(v) What side effects to expect and how to manage them.
(vi) What to do if one or more doses get skipped.
(vii) Any other precautions.

Appropriate discretion should be exercised while discussing the nature of illness, its cause, prognosis (course of the disease), and the expected outcomes of the therapy.
Patients' counseling should ideally be done in the counseling area or where separate area is not available – in such an area of the pharmacy where the conversation is not overheard by others.
As far as possible, oral information given to clients 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 clients, the Chief Pharmacist should devise methods to improve patient compliance.
A list of general and specialized healthcare professionals and facilities (including laboratories) in the locality and the city should be maintained and made available to the clients whenever necessary.

2.6.1 Professional guidance

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

2.6.2 Medication records

The pharmacy should maintain individual Patient Medication Records in a system (manual or computerized) which allows for easy retrieval of patients' health and medication history.
The medication history of patient may be taken depending on the following conditions:

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

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

(i) All medicines taken during the last one year or more (name of the medicine, potency, dose taken, duration for which it was consumed)
(ii) Are there any known allergies or hypersensitivity reactions to any medicine(s)?
(iii) Adverse drug reactions, drug interactions encountered by the patient.
(iv) What medication, if any, was give to manage the reaction.
(v) Id there any dependence on any drug(s) or medicine(s) and does the prescribing doctor know of these?
(vi) Does the patient regularly consume alcoholic beverages, tobacco, tea or coffee (frequency and amount may be recorded).
(vii) Have there been any problems with medicines e.g. difficulty in swallowing etc.
(viii) Professional advice given from time to time.

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.

2.6.3 Patient follow-up

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

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

(i) Patient's general condition and response to therapy.
(ii) General problems, adverse events encountered by the patient.
(iii) Dose and frequency at which medicines have been taken by the patient.
(iv) Missed doses.

Possible causes of non compliance by the patient should be evaluated and the patients counselled accordingly. The pharmacist should keep the patient's doctor updated about all the adverse events reported by or elicited from the patient and the stated or probable reasons for the patient not complying with the prescription/therapy.

2.6.4 Self Care

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

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 doctor if the Pharmacist is unsure of the condition and has a reason to believe that 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. Pharmacy should have written protocols for offering advice for self-medication, offering non-prescription drugs and the information that must be given to the clients in both these cases. The pharmacy should maintain a record of all such patients and advises & medicines given to them.

2.7 Health promotion & ill health prevention

The Chief Pharmacist must keep himself aware of the national policies and various programmes related to health. The pharmacy should proactively participate in health promotion campaigns and programmes 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.

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

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

2.8 Pharmacovigilance

The Pharmacist should be alert to the occurrence of adverse effects (expected or unexpected) to medicines during active conversation with the patient.

These should be recorded in the individual Patient Medication Records. The Pharmacist should give suitable instructions to the patient to reduce the adverse effects in the future, e.g. by advising the patient hw to take the medicine correctly, what other medicines or food to avoid, any activities that the patient should avoid (e.g. not going out in the sun, not driving, etc.), or by consulting the prescribing doctor .

If participating in pharmacovigilence programme the occurrence of adverse event should also be recorded in the programme's prescribed format and forwarded to the coordinating center.

2.9 Enhancement of professional role (Development of professional competence working with other health care providers)

Pharmacists should keep themselves updated about the developments in their 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.

In case of any discrepancy / doubt in the prescription, the Pharmacist should contact the doctor over the telephone without unduly alarming the patient, & in a friendly manner, put forward the query to the doctor.

Before doing so, he must doubly check & ensure 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 doctor.

2.10 Professional interactions (organizing professional meetings for the community's healthcare professionals)

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