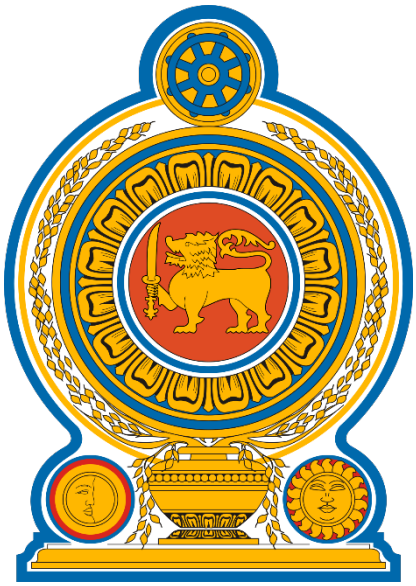
NMRA
NATIONAL MEDICINES REGULATORY AUTHORITY



Pharmacy Regulatory Division

GUIDELINE ON GOOD PHARMACY PRACTICE (GPP)

NATIONAL MEDICINE REGULATORY AUTHORITY
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GUIDELINE ON GOOD PHARMACY PRACTICE (GPP)

Contents

1. INTRODUCTION

The objective of framing and implementing these GPP Guidelines for Sri Lanka is that over the next few years, all pharmacies in Sri Lanka should achieve standards of practice laid down in this document. It is the commitment of individual pharmacies how they achieve 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 has been set, the time has come for the situation in Sri Lanka to change from a product oriented approach to a patient oriented approach with Pharmaceutical Care the ultimate goal of pharmacy practice.

2. PURPOSE

In order to ensure the maintaining of high standards of quality assurance and the integrity of the practices followed in community pharmacy set up, and to promote uniformity in licensing of retail sale of products regulated under NMRA Act, the following Guidelines on Good Pharmacy Practice (GPP) for Medicinal Products has been adopted.

3. SCOPE

The standards set out herein apply to medicines and other products regulated under NMRA Act. At the time of issue, this document reflected the current state of the art. It is not intended to be a barrier to technical innovation or the pursuit of excellence or to place any restraint upon the development of new concepts or new technologies, which have been validated and provide a level of Quality Assurance and integrity of the distribution processes at least equivalent to those set out in this Guide.

4. STRUCTURE GUIDELINES

4.1 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 Sinhala and Tamil language(s) of Sri Lanka.
- The pharmacy should be conveniently assessable to differently able people.
- 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.
- The pharmacy environment should be clean with minimum dust and should be maintained clean as per the cleaning schedules and Standard Operation Procedure (SOPs).
- It should be free from rodents and pests/ insects and pest control measures should be taken. 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 customers and personnel.
- The pharmacy should have a separate enclosure described as “counselling Area” for patient counselling, storage of reference resources (e.g. books, internet access etc.).
- Counselling area should be a place where patients can talk freely with the pharmacist.
- There should be a sufficient additional space for making extemporaneous preparations, besides the necessary equipment for doing so.
- Separate waste collection baskets/boxes should be available for the staff and for the customers.
- The products storage area should be protected from exposure to excessive light and heat.
- Temperature in the pharmacy should be maintained within the stipulated (Refrigerator 2 C to 8C and Room temperature) to prevent deterioration of medicines.

4.2 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:

1. A table.
2. Chair for the Pharmacist and a couple of patients
3. Cabinet for storing patient medicines use records

4.3 Equipment

The pharmacy should be equipped with refrigerated storage facilities with continuous temperature monitoring (validated periodically) and should be available for products requiring storage at cold temperature.
The counseling area should be equipped with:

1. Reference material
2. Patient information leaflets (PILs)
3. 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 medicines use records

4.4 Personnel

- The Community Pharmacy should be managed under the overall supervision of a pharmacist known as the "responsible 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 "responsible pharmacist".
- Each staff member should have clearly assigned 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".
- The license issued by the NMRA to sell medicines by retail and registration certificate(s) of the pharmacist(s) should be displayed in a prominent place in the pharmacy in clear view of the customers entering the pharmacy.
- Additionally, a recent photograph and the qualification certificate may be displayed.
- All pharmacy personnel should have been adequately immunized and should be medically examined periodically and, their health data should be available for inspection.
- Each Pharmacist working in the pharmacy must be competent enough to:
  - Play a professional role to assess prescriptions.
  - Advise the patients on appropriate selection and use of OTC medicines.
  - Advise patients on appropriate use of prescribed medicines.
  - Check & advice on drug-drug and drug-food interactions.
  - Be alert for adverse drug reactions.
  - Comprehend the customer's condition or illness and provide advice on proper use of medication and diet.
  - Assess the patient's condition and decide when to refer him/her to the prescriber.
  - Perform the role of a health care provider and a counsellor.

4.5 Systems

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

4.6 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.
- It is the responsibility of the "responsible pharmacist" to formulate a Quality Policy and set and achieve Quality Goals along with the management and other staff.
- Quality goals derive 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.
- 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
- The "responsible 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.

4.7 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 customer servicing goals.
- Service policy statement should include issues like home delivery of products, the nature and level of attention to be given to customers of various kinds (e.g. elderly customers, regular customers, etc.). The service manual should state, in detail, the necessary steps to be carried out for providing each service offered in the pharmacy.

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

4.8 Staff Training Policy

Availability of adequate reference resources (books, current periodicals, software, etc.) in the pharmacy is the fundamental requirement of the training process.

Training

- 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.
- 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 customers. 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.
- Availability of adequate reference resources (books, current periodicals, software, etc.) in the pharmacy is the fundamental requirement of the training process.

Training process should be well documented and reviewed periodically.
Management and the "responsible pharmacist" shall be responsible to continuously train the human resources available in the pharmacy to ensure maximum benefits to the community.

4.9 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.

4.10 Medicine Recall Policy

The "responsible pharmacist" should have a well-documented recall policy:
The pharmacy should proactively participate in any nationwide recall process for any substandard medicine. All such records should be initiated upon receiving authentic information to do so. The initiation, progress and completion of recall should be well documented. Adequate vigilance must be maintained to look out for recalls from NMRA as well as from pharmaceutical companies.
In case of any suspicion, the pharmacist should take immediate steps to stop the sale of that medicine and notify the relevant parties.

4.11 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 "responsible pharmacist" can evaluate the different routine processes and the quality systems in the pharmacy, and check whether the systems are functioning as per requirements.

4.12 Documentation system

Documentation is one of the core activities for achieving and maintaining quality. The overall responsibility for documentation rests with the "responsible pharmacist".
All necessary statutory documents (for e.g. regulatory licenses, registrations, 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, etc should be maintained and be available for inspection.

Prescription registers and Dangerous Drug Registers should be maintained as per relevant regulations and be available for inspection.
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:

- Protocols
- Standard Operation Procedures
- Operation instructions
- Quality Manual
- Cleaning and maintenance processes and records
- Complaint records
- Audit records
- Policy documents
- Personal details

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

- Patients' medicine use records
- Records of counselling follow-ups.
- Prescription registers
- Dangerous Drug Registers

5. PROCESS GUIDLINES

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

5.1 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.
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The "responsible pharmacist" should satisfy himself about the reliability of 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.
The "responsible pharmacist" may consider informing the regulatory authorities in case there are reasons to believe deliberate, dubious activities by the vendors(s).

The pharmacist should maintain a 'products list' where all items 'approved' by the pharmacy for stocking are described.
This list may be reviewed and updated as often as necessary.
Ideally, the product lists specify the location of that product in the pharmacy.
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.

5.2 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 medicines should be maintained be kept in such a manner that they are out of reach of customers. All the drugs that are to be stored in a 'cold' temperature should be kept in the refrigerator.
- Medicines and dosage form that special care while dispensing (e.g. schedule 111 medicines.) 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.
- Medicines, which have already expired, should be stored separately in a locked shelf. Bearing the label "Expired Goods Not for Sale". Care should be taken that such goods do not reach the customer in any case. Expired drugs should be returned to the supplier or inform about the details of the stocks of expired products in order to destroy them as per NMRA regulations.

5.3Disposal 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 following the "Guideline on procedure for expired products".

5.4 Prescription handling

Customers 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 encourages the customer to convey his/her needs by producing a prescription or by asking for other products or advice.

5.4.1 Upon receiving the prescription, the Pharmacist should confirm:

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

5.4.2 The customer may be politely requested to wait while the pharmacist review the prescription.

5.4.3 Prescription should be complete with regard to:

a. Name of the prescriber, his /her address and registration number.
b. Name, address, age, sex of the patient
c. Name(s) of the medicine(s), potency, dosage, total amount of the medicines to be supplied.

d. Instruction to the patient
e. Refill information if any
f. Prescribed prescribers' usual signature.

- Any ambient, confusion, shortcoming or anomalies should be brought to notice of the prescriber.

5.4.4 Correctness of prescribed medicines

The prescription should be checked for:

a. Dosage: Whether the dosage prescribed is within the standard minimum and maximum dose range.
b. Double medication (same drug or different drug with same phar/.maco therapeutic effect) concurrently prescribed.
c. 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 medicine use records). Any drug interaction likely the render the therapy ineffective or cause undesirable effects to the patients should be brought to notice of the prescriber.
d. Contraindication: age, sex, disease(s), conditions or other characteristics of a patient that may cause certain prescribed medicines to be contraindicated.
e. History of overuse, under use, or misuse of medicines by the patient.

- Any of the above as well as handwriting legibility problem should be brought to the notice of the prescriber.
- Any necessary change made by the prescriber 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.

5.5 Dispensing

5.5.1 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.

5.6Extemporaneous 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, and 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.

5.7 Information for patient

- The pharmacist must help the customer in making well – informed decision about proper use of medicines & other health care products. Pharmacist should support the customer 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 customer, he/she must advice the customer is to see a prescriber or another health care provider as soon as possible.
- Pharmacist should offer the customer sufficient opportunities for personal consultation, and should ensure that are aware of this possibility.
- Pharmacist should provide oral as well as written information (from one of the local languages requested by the customer) about various illness, medicines & other health care products, in order to increase the awareness level of the customer regarding his illness and his medicines. The goal of consultation is to achieve maximum compliance. As far as possible, delivery of medicines to the customer 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
  VII. The statement “For External Use Only” for medicines used topically
  VIII. The statement “Shake before Use” for relevant liquid formulations.
- Dosage and usage information must also be given verbally to the customer.
- It must be ensured that the information and advice given is correct, clear, explicit, up-to-date and understandable to the customer. It should be given in a language and at a level of complexity that is easily understood by the customer nature and quantity of information and advice, as well as the way these are provided, often need to be suited to the customer needs and wishes. The attitude of the pharmacist towards the customer must guarantee a correct understanding and a sufficient confidence in the information provided.

5.8 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 customers 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 customers, 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 customers whenever necessary.

5.9Professional guidance

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

5.10 Medication records

- The pharmacy shall maintain individual Patient medicine use 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 from 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.
  III. The most generic format for patient medicine use record should cover the following:
  IV. All medicines taken during the last one year or more (name of the medicine, potency, dose taken, duration for which it was consumed)
  V. Are there any known allergies or hypersensitivity reactions to any medicine(s)?
  VI. Adverse drug reactions, drug interactions encountered by the patient.
  VII. What medication, if any, was given to manage the reaction.
  VIII. Is there any dependence on any drug(s) or medicine(s) and does the prescriber know of these?
  IX. Does the patient regularly consume alcoholic beverages and tobacco (frequency and amount may be recorded)
  X. Have there been any problems with medicines e.g. difficulty in swallowing etc.
  XI. Professional advice given from time to time.
- All data and information related to the patients shall 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.

5.11 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.
- 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 noncompliance by the patient should be evaluated and the patients council accordingly. The pharmacist should keep the patient's prescriber 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.

5.12 Self Care

Pharmacy should have a clearly stated health promotion policy and Pharmacists should promote self-care by customers. Programs 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.

5.13 Health promotion & ill health prevention

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

5.14 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 medicine use records. The Pharmacist should give suitable instructions to the patient to reduce the adverse effects in the future, e.g. by advising the patient how to take the medicine correctly, what other medicines or 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 prescriber.
- Such adverse effects should be informed to the pharmacovigilance Division of NMRA as per relevant guidelines and regulations on pharmacovigilance.

5.15 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 prescriber over the telephone without unduly alarming the patient, & in a friendly manner, put forward the query to the prescriber.
- 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 prescriber.

5.16 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.

6. FEED BACK

Staff and customers may provide feedback about this document by emailing info@nmra.gov.lk.

7. APPROVAL AND REVIEW DETAILS

	Title	SIGNATURE	Date
Prepared by			
Reviewed By			
Authorized By			

Next Review Date	