Table of Content

| Preface | 1 |
|--|-----|
| List of Abbreviations | ii |
| Operational definitions | iii |
| Part 1. Introduction | 1 |
| 1.1. Background | 1 |
| 1.2. Objectives of the manual preparation | 3 |
| 1.3. Methodology | 4 |
| 1.4. Scope and Limitations | |
| Part 2. Principles of Good Dispensing | 5 |
| Part 3. Dispensing Environment and Stock Management | 8 |
| 3.1. Dispensing Environment | 8 |
| 3.1.1. Hygiene and Sanitation | 8 |
| 3.1.2. Premises and facilities | 8 |
| 3.2. Stock management | 9 |
| 3.2.1. Acquisition of drugs | 9 |
| 3.2.2. Stock keeping | 10 |
| 3.2.3. Stock rotation | |
| 3.2.4. Arrangement of drugs | 11 |
| 3.2.5.Storage conditions | 12 |
| Part-4: The Dispenser | 15 |
| Part-5: Good Dispensing Process | 17 |
| 5.1. Dispensing procedures | |
| 5.1.1.Dispensing for ambulatory patients | 17 |
| 5.1.2. Dispensing for in-patients | |
| 5.1.3. Veterinary drug dispensing | 24 |
| 5.2 Extemporaneous compounding | 25 |
| 5.2.1. Conditions required for the extemporaneous preparation | |
| 5.2.2. Determination of appropriate formulation | |
| 5.2.3. Compounding drugs | |
| 5.3. Dispensing aids and materials | |
| Part-6: Packaging and labeling drugs for dispensing | |
| 6.1. Packaging of drugs | |
| 6.2. Packaging aids and materials | 32 |
| 6.3. Labeling of drugs | |
| Part 7. Quality assurance of the dispensing practice and dispensed drugs | 36 |
| 7.1. Techniques for Quality Dispensing | |
| 7.2. Process of monitoring the quality of dispensed drugs | 37 |
| Part 8: Drug information | |
| 8.1. Importance of drug information | |
| 8.2. Sources of drug information | |
| 8.3. Dissemination of drug information | |
| Annex 1. Dispensing aid and materials | |
| Annex 2. References for further reading. | |

Preface

Good dispensing of drugs and medical supplies is an important component of rational drug therapy in order to maximize the benefit and minimize the risk to recipients. However, the prevailing dispensing practices in Ethiopia are below the standard in most cases. It is therefore, of utmost importance to prepare this manual that would aid individuals involved in dispensing and improve the quality of their services. The manual may also be useful for other health care professionals and training institutions.

For the preparation of this manual, relevant literature such as text books, health journals, drug bulletins, unpublished studies, legislations & regulations as well as an expertise of pharmacy professionals were used.

The manual contains eight main parts. Part one provides an introduction highlighting aspects of good dispensing, regulations for promoting good dispensing, and the situation of dispensing practices in Ethiopia. Objectives for preparing the manual and a brief methodology section are also included in this part. Part two describes the principles of good dispensing followed by part three that deals with some aspects of the dispensing environment and stock management. Part four briefly describes persons authorized for dispensing (dispenser). Part five deals with good dispensing processes. Details of packaging and labeling of drugs are presented in part six. Part seven describes quality assurance of the dispensing practice and dispensed drugs. Part eight deals with drug information.

Readers are encouraged to refer the references mentioned in annex section for further reading. It is hoped that the manual would enhance the quality of service and inspire confidence to maintain the good image of the pharmacy profession in the eyes of the society.

Drug Administration and Control Authority Addis Ababa, 2005

List of Abbreviations

ADR: Adverse Drug Reaction

BID: Bis IN Die (Latin)-meaning Two Times Daily

DACA: Drug Administration and Control Authority

DRO: Drug Retail Outlet

EDL: Essential Drug List

FIFO: First - In First- Out

FEFO: First-Expired First – Out

LIDE: List of Drugs for Ethiopia

Mitte: Mitte (Latin)-meaning Send

OTC: Over-The- Counter

PO: Per Os (latin)-meaning by mouth

TID: Ter In Die (Latin) - meaning Three Times a Day

Tabs: Tablets

USP: United States Pharmacopoeia

WHO: World Health Organization

Operational definitions

Drug: means any substance or mixture of substances used in the diagnosis, treatment, mitigation or prevention of a disease in man or animal.

Medical supply: means any article that may be used on the inner or outer part of the body for diagnosis or treatment of disease in man or animal.

Prescription: means any order for drug written and signed by a duly licensed or authorized medical practitioner issued to a patient in order to collect drug from dispensing unit.

Prescriber: means any medical practitioner who is licensed or authorized to write prescription.

Dispensing: means to prepare drugs and/or medical supplies and distribute them to their users.

Dispenser: means any person who is licensed or authorized to dispense drugs and/or medical supplies.

Prescription drugs: means drugs which are dispensed with prescription only.

Over-the-counter drugs: means drugs which are dispensed even without prescription.

Oral request: means verbal request of patients or care providers for drugs or medical supplies without presenting a prescription.

Patient: means a person or an animal with ill health

Stock: means the amount of drugs and/or medical supplies available in drug retail outlets.

Repackaging: means packaging of a drug from its original container to another one.

Prepackaging: means repackaging of drugs into usable quantities before they are requested by of patients (users)

Adverse drug reaction: means a noxious and unintended effect of drug that occurs in doses normally used in humans or animals for the diagnosis, prophylaxis or treatment of disease.

Shelf-life: means the length of time a drug product may remain on the shelf, in the original package and under usual environmental conditions and retain an acceptable level of its original potency and overall quality.

Stock solution: means a solution of higher strength of a drug that requires dilution before use

Part 1. Introduction

1.1. Background

Good dispensing practice refers to the delivery of the correct drug and medical supply to the right patient, in the required dosage and quantities, in the package that maintains acceptable potency and quality for the specified period, and clear drug information. The role of such practice in realizing rational drug therapy is enormous, and the contribution of pharmacy professionals in this regard is immense although rational drug therapy requires the concerted efforts of all health care professionals towards that goal

Traditionally, the pharmacists primary responsibility has been the correct dispensing of drugs and maintain the pharmaceutical quality of the drugs dispensed. Nowadays, their role has increased to involve advising the physician and other health professionals about drug therapy, counseling patients about drugs and monitoring drug use. They bridge the gap between the physician and the patient and serve as the gate-keepers of drug supply system. Due to shortage of pharmacists in Ethiopia, however, druggists, Pharmacy technicians, nurses and health assistants are involved in rendering some of the pharmaceutical services, particularly the dispensing of drugs. Whosoever it may be, the dispensing of drugs of proven safety, efficacy and quality with appropriate information at an affordable price is required to maximize the benefit and minimize the risk to the recipient as well as the community at large.

Irrational dispensing practices like any other developing country are not uncommon in Ethiopia. The dispensing of prescription-only drugs at partial doses and even without prescription, poor labeling of the dispensed items, lack of patient counseling, incomplete compiling and recording of prescriptions, and charging patients unreasonably high prices for the dispensed items are some of the practices that reflect an irrational dispensing. The availability of smuggled and counterfeit drugs worsens the situation and complicates the issue of rational use of drugs in Ethiopia.

An appropriate selection and regular supply of affordable drugs that are effective, safe and of good quality are a prerequisite for any operative health care system. The initiation of a list of essential drugs concept was mainly aimed at improving the availability and rational use of drugs. Many countries drafted a list of essential drugs (EDL) based on their needs, and the first list of essential drugs for Ethiopia was published in 1985.

Unfortunately, developing countries confront a lot of problems in their efforts to ensure the availability and rational use of safe and effective drugs. A considerable percentage of population in developing countries has low or no access to essential drugs due to various reasons. On the other hand, the proportion of health budget allocated to drugs in developing countries is greater than that of developed countries. The availability of drugs alone also does not ensure rational prescribing, dispensing or appropriate patient use.

Globally, the World Health Organization (WHO) sets international standards, recommendations and instruments to assure the safety, efficacy and quality of drugs. Each country needs to have a reliable system of drug control to assure whether the drugs entering in to that country meet the acceptable standards of safety, efficacy and quality. The development and implementation of national drug policies is one of the approaches to ensure equitable access to drugs, rational use of drugs, and quality, safety and efficacy of drugs. The latest national drug policy of Ethiopia that was promulgated in 1993 was to ensure that:

- Essential drugs and medical instruments are available in adequate quantities.
- Imported and locally produced drugs meet the required standards and specifications.
- Both foreign and local manufacturers are qualified for a minimum good manufacturing practice requirement.
- The channels of drug importation and wholesale distribution are appropriate.
- Drug use (prescribing, dispensing and patient use) is rational
- There are no professional and ethical malpractices.

The Drug Administration and Control Authority (DACA), which was established by proclamation No. 176/99 is mainly responsible to oversee and coordinate the implementation of the national drug policy of Ethiopia. The dissemination of drug information and public education, establishment of guidelines for inspection and quality control, organization of training workshops on rational use of drugs and preparation of manuals on various aspects related to drugs are some of the activities of the DACA. The legal importation and local production of drugs is based on the comprehensive list of drugs for Ethiopia (LIDE) and essential drugs list for Ethiopia (EDL), which are prepared by strong commitment and coordination of DACA.

Although remarkable positive results are achieved on the objectives of the national drug policy there are still some problems with the supply, distribution, and use of prescription drugs in the country. As part of the strategies to solve these problems, the DACA regularly prepares and distributes educational brochures and manuals (including this manual).

1.2. Objectives of the manual preparation

General objectives

The general objective of this manual is to lay a basis for good dispensing practices in Ethiopia.

Specific objectives

The specific objectives of this manual are to:

- Describe the principles of good dispensing process
- Describe the elements of good dispensing such as stock management, dispensing procedures, record keeping and reporting activity.
- Encourage professionals to prevent ethical and professional malpractices
- Indicate the potential drug information sources

1.3. Methodology

For the preparation of this manual, an accessible literature on good dispensing practices such as text books, journals, drug bulletins, and other relevant materials on the area of drug use were used. Further more, experienced pharmacy professions have been consulted.

1.4. Scope and Limitations

This manual sheds light on important aspects of good dispensing processes so that it can be used by all individuals involved in these processes. The absence of large-scale studies revealing the national trends in drug dispensing processes can be mentioned as a limitation in the preparation of this manual.

Part 2. Principles of Good Dispensing

The rational use of drugs requires that patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community. Rational use of drugs is a complex issue demanding mainly an integrated action of drug prescribers, dispensers and users and/or patients. It may even extend to the level of health administrators and policy makers, for instance, in matters related to the development of a list of essential drugs and improvement of the availability of drugs. Dispensing practice, the duty of dispensers, plays a central role in the provision of rational drug therapy.

Dispensing refers to the process of preparing drugs and distributing them to their users with provision of an appropriate information .It may be based on a prescription or an oral request of users (patients or care providers) depending on the type of drugs to be dispensed. The dispensing process involves the correct interpretation of the prescription or oral request, accurate preparation and labeling of drugs with provision of appropriate information. The drug should be dispensed in a safe and hygienic manner, making sure that the patient or care provider understands and appreciates the value of taking specific drugs for specific indications.

Good dispensing practices ensure that the correct drug is delivered to the right patient, in the required dosage and quantities, with clear instructions, and in package that maintains an acceptable potency and quality of the drug. Dispensing includes all the activities that occur between the time the prescription or oral request of the patient or care provider is presented and the drug or other items are issued to them. This process may take place in health institutions and community drug retail outlets. It is often carried out by pharmacy professionals. No matter where dispensing takes place or who does it, any error or failure in the dispensing process can seriously affect the care of the patient mainly with medical and economical consequences.

Therefore, the dispenser plays a crucial role in the therapeutic process. The quality of dispensing may be determined by the training and supervision the dispenser has received and the drug information available to the dispenser. A shortage of dispensing materials and insufficient dispensing time due to heavy patients load may also have adverse impacts on dispensing.

One good way to reduce the dispensing time and potential errors is to prepackaging and labeling commonly used drugs. Another way to prevent staff from making errors when working under pressure is to organize the work so that more than one individual is involved in the dispensing process for each prescription.

Pharmacist or other health professionals involved in dispensing drugs have a need for drug information in order to keep themselves up to date with developments related to drugs and to provide such information to patients, other health professionals and to the general public. Because of an increasing number and complexity of drugs, the need for up-to-date information is greater than ever. The provision of drug information to physicians and other health care professionals is mainly directed at improving prescribing and drug administration. On the other hand, because counseling of patients on medications is an integral part of the dispensing of a prescription or their oral requests, drug dispensers should be adequately equipped with up-to-date drug information. Lack of knowledge and information by patients about the drugs they take leads to incorrect use which in turn results in loss of efficacy or occurrence of adverse effects.

Communication skill is very important for dispensers dealing with patients or health care professionals to convey relevant drug information effectively and clearly, which can be done verbally and/or in written form. Drug dispensers must have the ability to explain information clearly by the language particularly the patient or care provider can understand and check whether the information is being understood by them.

Finally, an application of the professional code of ethics by pharmacy professionals is an important issue that needs due consideration particularly with respect to confidentiality of patient data, withholding therapeutic interventions and varying cost of drug

Part 3. Dispensing Environment and Stock Management

3.1. Dispensing Environment

3.1.1. Hygiene and Sanitation

The Physical surroundings must be maintained as free of dust and dirt as possible. Although the dispensary must be accessible to patients, care should be taken to locate it in a protected place and not beside, or open to, a road or other area where dust, dirt, and pollution are common.

Maintaining a clean environment requires a regular routine of cleaning shelves and a daily cleaning of floors and working surfaces. There should be a regular schedule for checking, cleaning, and defrosting the refrigerator. Spills should be wiped up immediately, especially if the liquid spilled is sticky, sweet, or attractive to insects and flies. Food and drink must be kept out of the dispensing area, with the refrigerator used strictly for drugs.

Dispensing equipment used for measuring liquids or counting tablets or capsules should be kept clean at all times. For example, uncoated tablets normally leave a layer of powder on any surface they touch, which can easily be transferred to other tablets or capsules counted on the same surface. This is called cross contamination and could be dangerous if the contaminating substance (e.g. aspirin or penicillin) is one to which a patient is sensitive

3.1.2. Premises and facilities

The premises on which a dispensing service is provided would reflect the quality of service and inspire confidence on patients in the nature of pharmaceutical service delivered. Therefore:

Working conditions are recommended to be so arranged as to take into considerations the safety and health of the public and people working on the premises.

- The walls, floors, windows, ceiling, and all other parts of the premises should be as per the requirement set by the regulatory body.
- Rooms (with minimum area specified) are required for dispensing, storing and compounding drugs. Room for compounding is required for pharmacies only.
- Toilet with water supply and drainage system is also a requirement.
- All parts of the premises are recommended to be maintained in an orderly and tidy condition.

The dispensing environment should possess:

- Appropriate temperature
- Sufficient lighting
- Humidity control
- Cold storage facilities
- Adequate shelving to ensure integrity of the stored drugs
- Dispensing table, aids, etc.
- Careful consideration is to be given to the overall security of the dispensary and the stores. Special attention must be paid to controlled drugs and flammables, which must be kept separately from other drugs and be locked properly.

3.2. Stock management

Good stock management facilitates safe and effective dispensing service. To ensure proper stock management, the following elements are important.

3.2.1. Acquisition of drugs

Before drugs and medical supplies are issued from store to dispensing room, store requisition/delivery (issue) form should be filled by the dispenser and duly signed by authorized personnel. It is mandatory that all drugs found in drug retail outlets are obtained or collected from legal sources.

When you receive drugs for dispensing:

- Ensure that there is sufficient storage place
- Prepare and clean the areas for receiving and storing

- Inspect packages for damaged and/or expired products
- Check that all original boxes, tins, or bottles are unopened and are in good condition.

If products are defective:

- Separate the damaged or expired stock from the usable stock
- Refuse to accept the products and note the problem(s) on the delivery note
- Follow your facility's procedure for handling damaged or expired stock.
- Report quality problem to the nearest regulatory body.

If Products are not damaged:

- Fill issue voucher and requisition voucher
- Count the number of units for each product received and compare to issue voucher
- Record received item on receiving voucher, stock card, bin card and computer(if applicable)
- Ensure the expiry date is visibly marked on every package or unit
- Arrange products in the storage area in such a way to facilitate the dispensing of the first to expire by first expiry first out (FEFO) or first in first out (FIFO) procedure.
- Take note of the unit price of each drug and medical supplies and compare it to the previous unit price.

3.2.2. Stock keeping

Drug should be kept with in the dispensary/or store rooms as follows:

- Follow the manufacturer or shippers directions when stocking, and follow labels for storage conditions
- Ensure safe custody of dangerous drugs, dangerous drugs should be stored separately under lock and key
- Place liquid products on the lower shelves or on bottom of stacks
- Store products that require cold storage in appropriate temperature controlled zones.
- Keep high security/high value products in appropriate secured places
- Separate damaged or expired products from the usable stock with out delay and dispose using established disposal procedures

- Always store all products in a manner that facilitates FEFO policy for stock managements.
- Keep veterinary drugs separated from drugs for human use
- Report to appropriate body for redistribution of drugs with near expiry date

3.2.3. Stock rotation

When issuing products, it is important to follow the FEFO and FIFO procedures, which minimize wastage due to product expiry. Therefore:

- Always issue products that will expire first, ensuring they are not too close to or
 past their expiration date. The shelf life remaining should be sufficient for the
 product to be used before the expiry date.
- To facilitate FEFO, place products that may expire first in front of products with a latter expiry date.
- Write expiry dates on stock cards, so that stocks can be used before they expire.
- Supplies with no expiry or manufacture date (e.g. gauze, cotton, etc.) should be stored in the order received and dispensed accordingly.

3.2.4. Arrangement of drugs

The following guidelines are recommended for arrangement of drugs on shelves:

- Shelves should be made of steel or treated wood
- Shelves should be strong and robust

Health institutions and drug retail outlets can use one or a combination of the following commonly used methods of drug arrangement:

- Alphabetical order by generic name
- Pharmacotherapeutic category
- Dosage forms

In arranging drugs, the following points should be considered:

- Each dosage form of drug is arranged in separate and distinct areas
- Sufficient empty space should demarcate one drug or dosage form from another
- Put drugs in dry place protected from direct sun light and heat

- Store liquids in a pallet on the floor or on the lowest shelf
- Do not store anything directly on the floor
- Always store cold-chain items in the refrigerator.

3.2.5. Storage conditions

3.2.5.1. Normal storage condition

Unless special storage conditions are stated, it is vital that drugs be stored in a dry, adequately ventilated shady and cool store room. Efforts should be made to maintain the specified storage conditions with regard to exposure to humidity, sun light, heat, etc. When a product label states "Protect from moisture", store the product in a space with no more than 60% relative humidity. Free air circulation by opening windows, using fans or air conditioners can be considered to reduce the effects of humidity.

Some products are photosensitive and will be damaged if exposed to light.

To protect products from sunlight:

- Shade the windows or use curtains, if they allow the passage of direct sunlight,
- Keep products in cartoon
- Do not store or pack products in sunlight

Heat will also affect many products. It melts ointments and creams and affects other products.

It is important to have thermometers, hygrometer and other equipment in order to regulate the temperature and humidity of storage areas.

3.2.5.2. Cold storage conditions

Cold storage conditions can be maintained by using refrigerators and freezers for products that may be degraded rapidly when kept at room temperature or even at cool places, e.g. vaccines, insulin, etc.

The following guidelines are recommended when using refrigerators and freezers:

 Refrigerators that open on the top are more efficient than vertical ones, because hot air rises while cold air falls

- Store products that are sensitive to freezing or very low temperatures on the upper shelves.
- If there is enough space, place a few plastic bottles of water in the refrigerator. This will help maintain the temperature for a longer period of time if the power is cut off. The temperature ranges for different storage conditions are shown in the following table.

Table 3.1. Terms that relate to storage temperature

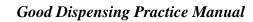
| | Terms used | Applications |
|----|---------------------------------------|---|
| 1. | Store frozen (-20 ^o C | For products, such as certain vaccines, need to be |
| | (4^0F)) | transported within a cold chain. |
| 2. | Store at $2^{0}C - 8^{0} C (36^{0} -$ | For products which are very heat sensitive but must not be |
| | 46 ⁰ F) | frozen. This temperature is appropriate of storing vaccines |
| | | for a short period of time. |
| 3. | Keep cool | For products labeled to be kept between 8 ⁰ -15 ⁰ C (45 ⁰ -59 ⁰ |
| | | F). |
| 4. | Store at room | For products labeled to be kept between 15°-25°C (59°- |
| | temperature | 77^{0} F). |
| 5. | Store at ambient | Store at the surrounding temperature. It means "room |
| | temperature | temperature" or normal storage conditions, i.e. storage in |
| | | a dry, clean, well-ventilated area room temperature |
| | | between $15^{0}-25^{0}$ C ($59^{0}-77^{0}$ F) or up to 30^{0} C, depending |
| | | on climatic conditions |

3.2.5.3. Special storage conditions

Some categories of drugs and supplies require special storage conditions. These include narcotic and psychotropic substances, and combustibles.

Narcotic drugs, psychotropic substances, and their documents should be kept in securely locked rooms or cupboards. The keys should be kept in a secure place and it is preferable that only the chief of pharmacy should have access to them.

Combustibles such as alcohol, ether and other organic solvents must be stored in special or separate rooms. An advisable precautionary measure is to use a small, separate outbuilding as a special store for inflammable supplies, since it virtually guarantees that fire will not spread throughout the store. All stores should be equipped with fire extinguishers. A good alternative to fire extinguishers is represented by wooden or metal buckets filled with sand.



Part-4: The Dispenser

The dispenser is a person who is authorized to dispense drugs and medical supplies to recipients. Depending on the level of dispensaries, pharmacy professionals of varying level of qualification may be licensed for dispensing practices. All licensed private pharmacies, drug shops and rural drug vendor shops are required to work under the technical leadership of registered pharmacists, druggists and pharmacy technicians, respectively, as per the new proclamation. Previously, nurses and health assistants were eligible to obtain a license for and are still working particularly in rural drug vendor shops. Druggists and pharmacy technicians may also work in pharmacies under the supervision of the pharmacist.

The drug outlets within public health institutions are to be managed by appropriately qualified staff: a pharmacist, a druggist, or pharmacy technician- depending on the level of the outlet. For example, the dispensaries in hospital and health centers should be run by pharmacists and druggists, respectively. But due to shortage of pharmacy personnel, nurses and health assistants are allowed to work in the dispensaries of public health institutions as well as in special clinics e.g. Clinics in factories. The dispensing of drugs (except emergency drugs) in ordinary private clinics is, however, illegal. Veterinary drug shops are run by persons with appropriate qualification on veterinary drugs. Besides, pharmacy professionals are also allowed to dispense veterinary drugs.

The responsibility for the correctness and quality of drugs supplied, therefore, lies entirely on the person dispensing them. The dispenser or dispensing team should have knowledge, skills and attitudes to carry out the dispensing process rationally. These include:

- Knowledge about the drugs being dispensed (common use, usual dosage, precautions about the method of use, common side effects, common interactions with other drugs or food, storage condition)
- Good calculation and arithmetic skills
- Skills in assessing the quality of preparations
- Attributes of cleanliness, accuracy and honesty
- Attitudes and skills required to communicate effectively with patients,

•

- Sufficient training according to the level of the health institution and drug retail outlet
- Knowledge about national polices and working guidelines
- Good knowledge of societal norms and cultural values
- Good working relation with other health care professionals
- Good administrative knowledge and skill
- Fair attitude towards patient interest and commercial pressure
- Respect to pharmacy law and professional code of ethics.

Case study 4.1:

Ato Tamiru is a licensed druggist working in his private drug shop. His wife assists him although she is not pharmacy or health care professional. On a day Ato Tamiru was out of the drug shop, she dispensed an expired gentamicin kept on the shelf for a patient. Comment.

Discussion: First of all, allowing non-professionals to dispense drugs is illegal. Secondly, expired drugs should be stored in a separate place and be reported to the concerned regulatory body timely. Dispensing expired drugs is also illegal. It is important to check the expiry date of the stock regularly.

Part-5: Good Dispensing Process

The dispensing of prescriptions involves both interpretation of the prescriber's instructions and the technical knowledge required to carryout these instructions with accuracy and safety to the patient. There are a considerable variety of factors that require close attention in dispensing, and proficiency requires the establishment of a routine system which can be followed safely even under stress. In fact, for OTCs, dispensers may be involved in selection of drugs for their users.

5.1. Dispensing procedures

5.1.1. Dispensing for ambulatory patients

In general there are five major steps to be performed in the dispensing cycle during the dispensing process.

Step 1. Receive and validate prescription or verbal request

- Ask the patient to give his/her name and check the name with that on the prescription.
 If in doubt ask for identification card. Cross checking the name and identity of the patient must also be done when issuing the drugs.
- Check the following information on the prescription.
 - Patients name, sex, age, card number, address
 - Diagnosis (ICD code number)
 - Drug name, strength, dosage form, course of treatment
 - The prescriber name, qualification, signature, registration number
 - Date of the prescription
 - Whether appropriate prescription form is issued or not (e.g. for controlled drugs)
 - Seal of the health institution, if available.
- Verbal request can be done only for OTCs with justification.

Step 2. Understand and interpret prescription

- Carefully read the prescription or validate verbal request
- Check if the prescription is legally and currently written

- Correctly interpret any abbreviations used by the prescriber
- Confirm that the doses prescribed are in the normal range for the patient (noting sex and age)
- Identify common drug- interaction(s)
- Verify inadequately written prescription and make necessary correction with the prescriber's consent.
- Correctly perform any calculations of dose and the quantity to be issued

Step 3. Prepare items for issue

- Select stock container of pre-pack reading the label and cross matching the drug name and strength against the prescription.
- Read the container label at least twice during the dispensing process.
- Do not select the prescribed drugs according to the color or location of container.
- Do not open many stock containers at the same time. This trend will lead to errors and/or expose the drugs to air and eventually leads to deterioration in quality.
- Open and close containers once at a time.
- While counting, pouring or measuring, the following points should be noted:
 - Short and/or over counting should be avoided
 - Clean counting tray and/or spoon used
 - Graduated measuring cylinder and/or flask must be used for measuring liquid reduction. If small volume is to be measured, small measuring cylinder/flask has to be used.
- Appropriate balance should be used
- In dispensing liquids:
 - Must be measured in a clean vessel and should be poured from the stock bottle with the label kept up ward. This avoids damage to the label by any spilled or dripping liquid.
 - Pour the measured liquid preparation into the container/bottle and label it.
 - Provide appropriate bottles with caps for repackaging liquid preparations
 - Dispense liquid preparations in suitable containers

- Do not use patient's own bottle
- Dispense each drug in a different bottle
- In dispensing tablets and capsules:
 - Do not use fingers to count tablets as this can lead to contamination of drugs
 - Use a spoon to put tablets and capsules onto a counting tray
 - Count and put them in a labeled drug container or pack
 - Close stock containers tightly after dispensing
 - Keep the spoon clean at all times
 - Do not keep the spoon inside the container
- Labeling of dispensed drugs should be clear and legible. All drugs should normally be labeled with the following particulars:
 - The drug name (use generic name),
 - Strength (usually in mg)
 - The dose, quantity dispensed and frequency
 - Direction for use in a familiar language
 - Expiry date or use by date
 - The name of the patient
 - Owner name (for veterinary drugs)
 - The name and address of pharmacy
 - Dispensing date
 - Dispenser name and initials
 - Special caution (whenever applicable)

Figure 5.1 shows how of labels can be written for different dosage forms with pictorial illustration for time of administration.

Figure 5.1: Example of labels

or capsules

Recording

LABEL B LABEL A QTTY domycycline 100mp 14 OPEN AND CLOSE HERE ME OF HOSPITAL/CLINIC ele Bu Teaching Warrical TABLETS/GAPSULES poence: Take I tables recetamed 500 mg Morning and everning for I days . to be taken react times daily before/after meals 17-02-95 Patient's Name Absence Man Date 4th January 1995 PAGELITY Label for tablets Pictorial label

THE MIXTURE

Drug name: _______One ______tbs/tsp ______THREE ______TIMES DAILY BEFORE/AFTER

MEALS
Name: ROSEMARY
Date: 18/07/97

Shake the bottle before use
KEEP ALL MEDICINES AWAY FROM CHILDREN'S REACH

Name of Health Centre

Label for liquid preparations

Step 4. Recording, documentation and reporting

There are three different methods that can be used to keep a record of drugs dispensed. These are:-

- When a prescription is retained, the dispensing staff should put initials and annotate the prescription and either files or enters the details into a record book.
- When the prescription is returned to the patient details of the drugs dispensed must be entered into a record book before the items are issued to the patient.

• When computers are used in the dispensing process the computer program should retain the information, which can be recalled to generate summary report.

The following information should be included into the record book and or computer:

- The date, the patient's name, sex, age, name of the owner (for veterinary drugs)
- The drug name, dosage strength and dosage form
- The name, address and qualification of the prescriber
- The date on which the drug was prescribed
- The amount issued and the dispenser's name and initials
- The date of dispensing
- Details of any repeat indications

Documentation and report

- The receipts for requisition, receiving as well as the prescription registration book should be kept properly
- Blank prescription should be kept carefully, only prescribers have access to them.
- Filled prescription should be kept as a receipt. Prescriptions for narcotic and psychotropic substances should be kept for 5 years and other prescriptions for 2 years.
 Thereafter, they should be disposed carefully in the presence of inspectors from the drug regulatory body.
- Regular reports on drug consumption and prescribing pattern from patient prescription registration book should be prepared and report to the concerned drug authority timely.
- Information obtained from prescription registration book could be used for further planning and efficient utilization of resource.
- The report on physical inventory shall be documented.

Step 5. Issue drugs to patient with clear instructions and advice

The prepared, packaged and labeled drug is handed over to the right patient or care provider with appropriate drug information. The information in the form of verbal and/or written instructions should include the following:

How much and how often to take the drug

- When to take the drug (e.g., before or after meals)
- How long the treatment is to last (e.g., why the entire course of an antibiotic treatment must be taken)
- How to take the drug (e.g., with water, chewing or swallowing)
- How to store the drug (e.g., avoid heat, light and dampness)
- Not to share drugs with other persons
- To keep drugs out of reach of children
- One has to demonstrate to the patient on how to administer the dispensed medications in case of inhaled administration and suppository application.
- Patients should also be informed not to stop treatment when side effects occur or in the absence of response with out consulting the prescriber or dispenser..
- Finally, check whether patients have understood the information provided (see figure 5.2)

Figure 5. 2. Communicating with a patient at the dispensary



Source: Managing Drug Supply. MSH/WHO, Kumanian 1997.

5.1.2. Dispensing for in-patients

There are three basic techniques for hospital drug distribution to in- patients:

5.1.2.1. Bulk ward stock order system

In a ward stock system, the pharmacy functions as a ware house and dispense bulk containers on requisition with out reviewing individual drug orders for appropriateness. The main advantage is shorter turn around time between prescribing and administering the drug. The use of stock medications should be minimized, although it is appropriate and desirable for certain situations:

- In life threatening emergency situations, drugs should be kept in patient care areas as a time saving measure.
- High volume, low-cost drugs can be dispensed if there is low risk of medication error.

5.1.2.2. Individual drug order system

The individual drug order system closely resembles dispensing to out patients: a course of therapy is dispensed according to a written prescription for an individual patient. Compared to ward stock distribution the advantages are:

- The pharmacist can review the appropriateness of therapy.
- A patient-specific medication profile can be maintained.
- Pharmacy charges to patients are facilitated.
- Closer control of inventory is possible

5.1.2.3. Unit dose system

The preferred system from a patient care perspective is the unit dose system, in which there is the lowest possibility for error. Commonly a twenty-four-hour supply is provided. It minimizes unnecessary expense if treatment is changed. But it requires that the pharmacy be opened for 24 hours.

5.1.3. Veterinary drug dispensing

Both pre-compounded and compounded drugs are dispensed for animals through their owners by presenting a prescription or based on an oral request. The following should be taken into consideration when veterinary drugs are dispensed:

- Receive and validate prescription or oral request
- Make sure to which type of animal it is prescribed
- Prepare items for issue
- Properly label before being dispensed: When the drug is dispensed according to the veterinarian's order, the product must have a complete, indelible, legible label attached.

A complete label requires the following:

- Name and address of the attending veterinarian;
- Date dispensed;
- Name ,strength, dosage of a drug
- Route and duration of administration
- Identity of animal(s) to be treated
- Owner name and address
- Directions for use:
- Cautionary statements, if needed;
- Slaughter-withdrawal times and /or milk withholding times, if needed.
- Name and address of pharmacy

Additional information that may be included on a label:

- Disease conditions to be treated;
- Expiration date of a drug.
- When compounded drugs are used, appropriate records must be maintained.

5.2 Extemporaneous compounding

An extemporaneous prescription is the type of prescription in which the prescriber selects the drugs, doses and dosage form desired and the pharmacist prepares the medication.

The pharmacist is expected to prepare small quantities of non-sterile products and/or sterile products, including creams, ointments, suppositories, mixtures, suspensions, solutions and/or total potential nutrition, and eye drops. The following should be taken into consideration during extemporaneous compounding of prescriptions.

5.2.1. Conditions required for the extemporaneous preparation

- Identify dosage forms that must be prepared with aseptic techniques in a clean room environment e.g. those instilled, injected or used to irrigate sterile body cavities
- Do not attempt to make extemporaneous compounding in normal dispensary area
- Identify potentially harmful ingredients and products e.g. podophyllin, and ensure they are dealt with safety, including storage and transport

5.2.2. Determination of appropriate formulation

- Select correct formulations for specified products
- Assess formulations used in workplace or use reference sources
- Interpret common terminology and abbreviations, e.g. ingredients, instructions, dosage forms, quantities
- Identify problem formulations, e.g. incorrect proportions, drug instability, vehicle instabilities, inaccuracies, precipitations, compatibilities/incompatibilities.
- Identify what each ingredient is in the formulation- stabilizers, therapeutic agents, preservatives, vehicles, diluents, antioxidants, suspending agents, flavoring agents.
- Follow manufactures' guidelines, or appropriate reference source, for dilution of solutions, suspensions & ointments

5.2.3. Compounding drugs

- Calculate quantities of ingredients & end product to 100% accuracy, and document this
- Produce clear labels for end products, including full patient instructions, expiry dates, storage information and any supplementary advisory labels
- Check each ingredient to ensure it is fit to use, e.g. check expiry date, signs of degradation, store correctly (temperature & protection from light & moisture), stability if packaging already opened. Check whether the ingredient is of pharmaceutical grade.
- Ensure equipment and work area are appropriate, clean & tidy e.g. ointment slab cleaned
- Personnel should be appropriately prepared for aseptic production, e.g. hand washing, appropriate clothing
- Use appropriate compounding technique to prepare product
- Weigh or measure correct quantity of ingredients
- Undertake a visual final check for product, e.g. check for particulate contamination, uniform mixing, aesthetically pleasing products
- Pack each compounded product in container suitable for type, quantity, intended use & storage requirements of product, e.g. protected from light & moisture, container suited to product & use, bottle with dropper dispenser for ear drops.
- Attach labels securely, without obscuring relevant information, e.g. graduations on syringes, poison bottle ribs
- Comply with optimal storage conditions regarding: temperature, light, moisture, type of container, transport of product
- Clean all equipment after use
- Record the details
- Issue items for users with appropriate instruction for use

5.3. Dispensing aids and materials

The following are commonly used dispensing aids and materials (see annex for pictures):

• Triangular tablet counters,

- Capsule counter,
- Pan weighing scales
- Electronic tablet counters.
- Dispensing spoon,
- Measuring cylinder
- Spatula,
- Mortar and pestle
- Balance.

Aids for counting tablets and capsules include triangular tablet counters, capsule counter, spatula, weighing scales and electronic tablet counters.

Triangular Tablet Counter is an equilateral triangle made of wood metal or plastic with raised edges along two sides. Metal or plastic counters preferred because these surfaces can be easily cleaned or washed between uses for different products. The tablets are counted by counting the number of rows of tablets and then pouring them in to the container using a raised edge as a guide.

Capsule counter is a metal tray which consists of 10 rows of grooves. The capsules are poured on to the tray and using a spatula, lined up in the grooves. Each complete row will contain capsules so the number of complete rows multiplied by 10 gives the number of capsules.

Pan Weighing Scales can be particularly useful when counting tablets or capsules during prepackaging. The balance must be free to move, and the pans must be clean, the required number of tablets or capsules is counted and placed on one of the scale pans. Equal quantities or the same tablet or capsule can then be counted by adding to the other scale pan until a balanced positions is reached.

Electronic Tablet Counter is a machine used when prepackaging is done on a large scale in a teaching hospital for both ward and outpatient departments. But is difficult to clean, may not identify damaged tablets and is expensive for drug retail outlets.

Dispensing balance, mortar and pestle, measuring cylinders, etc. are useful aids for compounding drug products.

Dispensing balance is used for weighing ingredients and final drug products. Class A and class B types of balances are commonly used in pharmacies.

Mortar and pestle are used to reduce the size of powders, mix powders, mix powders and liquids, and make emulsions.

For measuring liquids in dispensing, conical and cylindrical measures can be used.

Whichever type of measure is chosen always ensure that:

- The measure is vertical when reading meniscus
- The measure is thoroughly drained
- Select the smallest measure which will hold the desired volume
- Volume should be measured by difference for viscous liquids.

Case study 5.1.

Ato Abebe, pharmacist, has filled some prescriptions for carbimazole on one working day. On the same day a customer, epileptic patient, presented him a prescription for carbamazepine. Glancing at it, Abebe thinks it is carbimazole once again, and that is what he dispensed. The patient went to his physician with complaints of no improvement. Comment on this case.

Discussion: Ato Abebe, the pharmacist, failed to read and understand the prescription correctly. This has led to failure of treatment regimen prescribed for the epileptic patient. Because of the existence of similarity with the names of some drugs, it is important to read and understand the prescribed drugs carefully and correctly.

Case study 5.2.

Woizero Aster went to a drug shop and made verbal request for ampicillin and cough syrup for her 8 years old daughter with complaints of cough and poor appetite. As she did not have enough amount of money, she wanted to purchase only ten capsules of ampicillin and one bottle of cough syrup suspension. The dispenser fulfilled her request. Comment.

Discussion: Woizero Aster made a verbal request for a prescription drug (ampicillin) and an OTC cough syrup. The dispenser should have asked her a prescription at least for ampicillin.

Secondly, dispensing inadequate quantity of ampicillin even with prescription is irrational. Such clients should be referred to authorized prescribers.

Case study 5.3.

An extemporaneous prescription order calls for 200ml of a 1 in 5000ml solution of a drug. A busy pharmacy professional prepared it by taking 5 ml of a 4% w/v stock solution and 195 ml of the appropriate diluent. Comment on the strength of the finished product.

Discussion: A 1 in 5000 ml solution contains 1gm in 5000ml. Two hundred ml of this solution will contain 40mg which is equal to 1ml of a 4% w/v stock solution. The solution prepared by the pharmacy professional is five times stronger than what has been prescribed.

Case study 5.4.

A prescription that calls for atenolol 50 mg. tablets is presented to a pharmacy. The total quantity to be dispensed is not indicated. One Tab. BID po for 4 weeks is written after Sig. All other information is complete. The pharmacy professional dispensed 28 atenolol 50 mg tablets. Comment.

Discussion: The total quantity dispensed is not correct. According to the prescription 56 tablets (2 tablets a day for 4 weeks or 28 days) should be dispensed.

Case study 5.5.

A client presented an ordinary prescription that calls for 20 diazepam 10 mg. and 10 paracetamol 500 mg. tablets to a pharmacy. The pharmacy professional dispensed both drugs with appropriate instructions for use. Comment.

Discussion:Diazepam is a psychotropic drug that should be prescribed by using prescription paper for narcotic and psychotropic drugs. The pharmacy professionals should not dispense such drugs based on ordinary prescriptions or verbal requests.

Part-6: Packaging and labeling drugs for dispensing

6.1. Packaging of drugs

Drugs must be suitably contained, protected and labeled from the time of manufacture until they are used by the patient. The container must maintain the quality, safety and stability of the drug throughout this period.

The selection of packaging for drugs depends on:

- Nature of the drug
- Type of patient
- Dosage form
- Method of administering the drug
- Required shelf-life
- Use, such as for dispensing.

Original containers used by manufacturers are expected to protect drugs for their specified shelf-life. Because original containers may contain large amount of drugs, repackaging of drugs into another container may be necessary in order to dispense drugs for patients. Such repackaging procedure can be done at-the –spot or in advance.

Prepackaging is the process by which the pharmacy transfers a medication manually, or by means of an automated system, from a manufacturer's original commercial container to another type of container in advance(before clients come to drug retail out lets).

The following guidelines are recommended in prepackaging of drugs:

- Prepackaging procedures must comply with laws and regulations.
- The prepackaging operations and area must be clean and separate from other pharmacy activities.
- Only one drug product at a time should be prepackaged in a specific work area. No drug products other than the one being packaged should be present in the immediate
- packaging area. Labels other than those for the product being packaged should not be present in the area.

- Before beginning a prepackaging run, a physical evaluation (color, odor, appearance, and markings) of the drug product being prepackaged should be made to assure product integrity. The bulk container should also be examined for evidence of damage, contamination, and other deleterious effects.
- All prepackaging equipment and systems should be operated and used in accordance
 with the manufacturer's or other established instructions. There should be valid
 justification and authorization by the supervisor for any deviation from those
 instructions on the part of the operator.
- The pharmacist must use available data on the characteristics of all packaging material used to protect the integrity of the drug product. This information should include data on the chemical composition, light transmission, moisture permeability, size, thickness (alone or in laminate), recommended sealing temperature, and storage requirements.
- The beyond-use date applied to prepackaged medications should adhere to USP standards.

An additional trained individual, other than the packaging operator, should verify that the prepackaging system (drug, materials, and machines) is in correct working order and that all procedures have been performed properly

Control records of all packaging operations must be kept according to the guidelines, and include the following information:

- Complete descriptions of the drug, e.g. name, strength, dosage form
- The name of the product's manufacturer and distributor (as applicable)
- Manufacturer's control number (lot number)
- The pharmacy's control number, if different from the manufacturer's

•

- Expiration date of the manufacturer's original container and the beyond-use dating of the prepackaged product
- Number of units prepackaged, total contents delivered per unit, and the date(s) they were prepackaged
- Initials of the operator and the pharmacist responsible for packing of each individual run
- Description of the packaging materials and equipment used.

Upon completion of prepackaging, all unused drug stock, unused labels and finished packages should be removed from the prepackaging area. The packaging equipment should then be completely emptied, cleaned, and inspected before commencing the next prepackaging operation.

All prepackaged drugs should be stored in a temperature and humidity-controlled environment. Prepackaging materials should be stored and used in accordance with the manufacturer's instructions.

The main advantages of prepackaging drugs is that it allows enough time for patient counseling and minimizes dispensing errors resulting from hectic operation due to heavy patient load. Unfortunately, the materials commonly used for repackaging in many drug retail outlets of Ethiopia are ordinary papers and the labeling is incomplete. In such cases, repackaging of drugs is likely to have many disadvantages than advantages.

6.2. Packaging aids and materials

The materials used for repackaging include: glass bottles, plastic bottles, collapsible tubes, paper envelops, plastic envelops, etc (see annex 1 for pictures). The requirements of containers for packaging different dosage forms are indicated in table 6.1. Paper has the least value as the primary packaging material in terms of maintaining the quality, safety and stability of packaged drug

Table 6.1. Requirements for packaging materials.

| Category of packaging* | Package characteristics | Examples |
|--------------------------------|--|--|
| Tablets/capsules | | |
| Desirable | Clean, dry, plastic or glass container with tightly sealing cap or seal | Blister packages, plastic sachets, tightly sealing plastic or glass containers with screw or snap cap |
| Acceptable | Clean, dry container that provides protection from dirt and moisture | zip-lock plastic bags, glycine paper, hinged-lid unsealed boxes, sifter-top boxes, tight-top tins |
| Undesirable | Unclean absorbent paper, cotton, cardboard containers with no provision for closure | Unsealed plastic bags, paper bags, newspaper or other printed paper |
| Liquids (oral and topical) | | |
| Desirable | Clean, dry, light-resistant glass container with tightly sealing cap | Amber or opaque bottle with screw cap |
| Acceptable | Clean, dry plastic or glass container with tight-fitting cap | Glass or plastic bottle with tight- fitting cap |
| Undesirable Liquids (otic and | Unclean paper, cardboard, metallic | Previously used liquid-containing cartons, plastic-lined paper bags, plastic bags |
| ophthalmic) | | |
| Desirable | Clean (preferably sterile), light- resistant glass or plastic container with a dropper incorporated into a tightly sealing cap or a top fitted with dropper with a protective sleeve | Amber dropper bottle, opaque dropper bottle |
| Acceptable | Clean, dry plastic or glass container with tight-fitting cap and a clean plastic/glass dropper (separate) | Glass or plastic bottle with tight- fitting cap, glass |

| | | or plastic dropper with protective container (cardboard, zip- lock, plastic, or paper) |
|------------------|---|---|
| Undesirable | Anything other than above | Anything else |
| Creams/ointments | | |
| Desirable | Clean glass or porcelain wide-mouth jar with tightly fitting lid or collapsible plastic or metal tube | |
| Acceptable | Clean glass or porcelain jar with lid | Glass or porcelain jar |
| Undesirable | Anything other than above | Anything else |

^{*} Desirable: packaging should meet listed requirements for period greater than 30days

Acceptable: packaging should meet listed requirements for up to 30days.

Undesirable: packaging provides no protection from dirt, moisture, or other contaminants, thus permitting rapid deterioration or contamination

6.3. Labeling of drugs

The main functions of a label on a dispensed drug are to uniquely identify the contents of the container and to ensure that patients have clear and concise information about the use of the drug.

Each dispensed drug must be appropriately labeled to comply with legal and professional requirements. Details which must appear on the label of a dispensed drug include:

- The name, strength and dosage form of the preparation
- The quantity
- Instructions for the patient
- The name of the patient or animal type and owner of the animal for veterinary drugs
- Expiry date or use by date
- The date of dispensing
- The name and address of the pharmacy
- Precautions, other advisory labels

If the drug has been prepared extemporaneously, a batch number may be included. For veterinary prescriptions, an additional labeling requirements e.g. "for animal treatment only" is necessary. All labels must be legible, accurate and comprehensible

The labeling of drugs in drug retail outlets of Ethiopia is very disappointing. It is common to see the dispensed drugs without a label, incomplete label, or illegible label. The size of the commonly used paper envelops may not even allow to write the required information on it.

Case study 6.1.

Ato Kebede went to a pharmacy with a prescription for nitroglycerin sublingual tablets. The pharmacy worker repackaged the prescribed number of tablets in paper envelops and dispensed with appropriate instructions for use. Some other day, Ato Kebede consulted the pharmacy professional about decreasing efficacy of the drug dispensed. Comment.

Discussion: Nitroglycerin is volatile drug. It should be packaged in tightly closed containers(bottles). The use of paper envelops for repackaging leads to a reduced efficacy of nitroglycerin, a possible reason for the complaint of Ato Kebede.

Case study 6.2.

The pharmacy professional received a prescription with the following information:

Tabs Ibuprofen 400mg

Mitte 60

One t.i.d.

The pharmacy professional dispensed 60 tablets of ibuprofen 400mg.and wrote a label that the patient should take three tablets daily with or after food. Comment on dosage.

Discussion: The prescription was to take one tablet three times a day. The information on the label is not clear. Accordingly, the patient may take three tablets at a time, which may lead to an occurrence of adverse effects or loss of efficacy. Understanding the meaning of Latin abbreviations that may appear on the prescription papers is important.

Part 7. Quality assurance of the dispensing practice and dispensed drugs

Dispensing practice should mean more than simple issuance of the prescribed or requested items in order to achieve the desired therapeutic goal. The quality and quantity of the dispensed items as well as appropriate drug information mainly determine the success of drug therapy.

The assessment and assurance of the quality of drugs is an integral part of national drug control system, without which, any health service is evidently compromised. Drug control agency of each country has the responsibility for the development of guidelines, norms and administrative regulations for quality surveillance.

In general, the manufacturers and the distributors (including importers, wholesalers and drug retail outlets) are responsible for the quality of drugs they manufacture or distribute. The desired quality of drugs can be achieved by strict adherence to specifications recommended by drug control agency. It is evident that the quality of dispensed drugs can be determined by the quality of dispensing process.

7.1. Techniques for Quality Dispensing

The main aim of quality dispensing is to maintain the quality of the dispensed drugs for their specified shelf-life and ensure appropriate use of the drug by the patientas. An important facet of quality dispensing concerns the packaging and storage of drugs. The techniques that lead to quality dispensing may be accumulated through training and/or experience.

The most useful techniques to ensure quality in dispensing include:

- Maintenance of records on what drugs and products have been issued.
- Maintenance by the pharmacy department of a daily list of drugs in stock to inform
 prescriber which drugs are available thereby ensuring that only these drugs are
 prescribed.

•

•

- A two prescription system whereby two separate prescriptions are written one for drugs available in the pharmacy and one for those that are not but can be ordered which helps to avoid rewriting of prescriptions.
- Adherence to specifications for storage conditions.
- Adherence to specifications for containers for repackaging
- Keep written procedures for compounding
- Dispensing only one prescription at a time
- Avoid dispensing when dizzy, in stress, etc.
- Double checking of the name, dosage form, strength amount to be dispensed as well as the information on the label
- Organize Drug and Therapeutic Committee at health institution level and participate.

7.2. Process of monitoring the quality of dispensed drugs

Quality specifications comprise a set of properly selected standards with associated methods of analysis which are used to assess the integrity of drugs and starting materials. The selection of methods and procedures used in specifications must be based on their utility for the purpose of quality assurance of drugs. The tests may involve simplified tests (basic tests) or sophisticated analytical examinations.

Because sophisticated analytical examinations require special skills and well-equipped laboratories, simplified tests are commonly used in dispensaries for verifying the quality of dispensed drugs. Such tests may usually serve to ascertain the absence of gross degradation, contamination or damage.

Some indicators of quality problems that can be ascertained by simplified test such as physical inspection are show in table 7.1. When a product fails the basic tests, it should not be used until its quality is established by analytical examination. It is important to note that the shelf-life of drugs may be markedly shortened by improper storage conditions. Therefore, the expiry date information of a drug product may not guarantee the quality of it. Any quality problem of drug product should be reported to the concerned body immediately.

Table 7.1. Common quality problem indicators for different pharmaceutical products

| Types of products | Common Problem indicators |
|--|---|
| All products | Broken or tipped packaging (Vials bottles, boxes etc)Missing, incomplete or unreadable label(s) |
| Liquid products | Discoloration, Cloudiness, Sediment, Broken seal on bottle, Cracks in ampoule, bottle or vial, Dampness, or moistures in the packaging, leakage, caking |
| Light sensitive products (such as x-ray films) | Torn or ripped packaging |
| Latex products | Dry, Brittle, Cracked |
| Lubricated latex products | • Sticky packaging, Discolored products or lubricant, Stained packaging, Leakage of the lubricant (moist or damp packaging) |
| Pills (Tablets) | Discoloration, Crumbled pills, Missing pills (form blister pack) Stickiness (especially coated tablets), Unusual smell |
| Injectables | Liquid does not return to suspension after shacking sterile products Torn or ripped packaging, Missing parts, Broken or bent parts Moisture inside the packaging, Stained packaging Particulate matter Growth |
| Capsules | Discoloration, Stickiness, Crushed capsules |
| Tubes | • Sticky tube(s), Leaking contents, Perforation of holes in the tube |
| Foil packs | Perforation(s):- packaging |
| Chemical Reagents | Discoloration |

Part 8: Drug information

8.1. Importance of drug information

Information about drugs is rapidly expanding because of new drug products entering into drug markets and new information about the drugs, which are already in use.

Persons involved in drug dispensing have to make them selves up-to-date with drug information in order to provide this information for patients, other health care professional and to a general public. Pharmacists particularly are in close working relationships with physicians, nurses, dentists and others, where they can give an advice in the following areas:

- Drug choice, e.g. during pregnancy, breast feeding, etc.
- Dose interval and regimen
- Route of administration
- Adverse drug reactions
- Drug interactions(drug-drug, drug-diet, drug-disease interactions)
- Duration of therapy
- Formulations
- Storage
- Cost

All these information are essential for promotion of rational drug therapy through improving prescribing behavior, drug administration and use.

Patients or care providers usually require information on the prescription or over-the-counter drugs in the following areas:

- Type of drug and how it works
- Amount to be taken
- Frequency of administration
- Duration of therapy
- Side effects
- Storage condition

• Other precautions

It is also possible that pharmacists or other professionals involved in drug dispensing may want to write a material on drugs, and consult health administrators and policy makers on matters related to drugs, which requires to have a thorough knowledge on them.

8.2. Sources of drug information

Although basic information about drugs is obtained through training in pharmacy profession, additional knowledge can be gained from various sources. These sources of drug information can be classified into primary, secondary and tertiary.

Primary sources: provide new drug information mainly based on research in journals. Such sources include health journals such as the Ethiopian pharmaceutical Journal, the Ethiopian Medical Journal, the Ethiopian Journal of Health Development, Lancet, and others. It is important to assess the reputability of the journal and time of publication.

Secondary sources: provide reviews of articles that appear in primary sources. Examples include, drug information bulletins, adverse drug reaction bulletin, hospital formularies, etc.

Tertiary sources: include standard reference books such as British National Formulary, basic and clinical pharmacology, dispensing for pharmaceutical students, medical dictionary, etc. The selection of a particular source of information depends on the type of information required. Tertiary sources are used first than secondary or primary sources as they provide a broad overview of particular subject area. It should also be remembered that standard books are published at longer time intervals than journals.

Drug information inquiries that are beyond the ability of drug dispensers can be referred to the drug information centers (DICs). The drug administration and control authority (DACA) has already established seven drug information centers (most of them in Addis Ababa). The main aim of these centers is to provide accurate and precise drug information for health professionals and the general public.

Drug information supplied by the pharmaceutical industries either in the form of leaflets in the packages or via their representatives is being used by many clients. The impact of pharmaceutical industry, which has several channels of influence, is great. Health professionals should develop critical attitudes towards information provided by pharmaceutical industry as their information may be biased.

8.3. Dissemination of drug information

Dissemination of drug information to health care professionals, patients and the general public is an important responsibility of pharmacy professionals. Both verbal and written communication skills may be used for this purpose.

Verbal communication to drug information must be:

- Clear and fluent by understandable language
- Well-organized on important details
- With confidence done by maintaining eye contact during face-to-face communication It is necessary to avoid:
- Emotion
- Negligence
- Medical jargons
- Unnecessary details

Written communication of drug information must be:

- Well-organized
- Readable and clear
- Complete

Drug information may be provided either directly in response to a specific enquiry (reactive type) or that provided other than in response to a specific enquiry (proactive type).

In both types the following approaches may be involved:

- Identifying the enquirer
- Establishing the degree of urgency of the enquiry
- Obtaining the full background information

- Using the most appropriate source of information and
- Delivering the response

Adverse drug reactions reporting system is an area of drug information that has been given little attention yet. Obviously, drugs not only produce the desired effects, but also undesired effects. It is possible that drugs produce initially unanticipated effects (adverse or potentially useful) after their approval for marketing. Such effects can best be identified by pharmacy professionals, physicians, and nurses because of their close proximity with patients. Pharmacy professionals have a moral responsibility to report adverse drug reactions to the concerned body by using a special form designed and distributed for this purpose by DACA.

Case study 8.1.

A male patient that had chlamydial infection and dyspepsia came to a pharmacy with a prescription for tetracycline capsules and an antacid (magnesium hydroxide suspension). Because the dispenser was busy, no instruction about the usage was given to the patient. After two weeks, the patient consulted his physician for no improvement of the chlamydial infection although he was taking both drugs together for the specified duration. Comment.

Discussion: Tetracycline and antacid were prescribed for chlamydial infection and dyspepsia, respectively. Loss of the efficacy of tetracycline was possibly due to its interaction with magnesium hydroxide, which decreases the absorption of tetracycline when taken together. Therefore, instruction on how to take drugs is important for avoiding such type of drug interactions.

Case study 8.2.

Woizero Tigist, who is a pregnant, collected 30 tablets of ferrous sulfate from a drug shop and kept them on her bed. Her 4-year old child ingested half of the tablets at once and suffered seriously as a result of it. Comment.

Discussion: Iron tablets at high dose can be dangerous particularly in children. Keeping such drugs out off reach of children should be emphasized while dispensing them.

Annex 1. Dispensing aid and materials







Erlenmeyer flasks

Beakers

Prescription Bottles





Graduated Cylinders

Conical Graduates



Volumetric Flasks

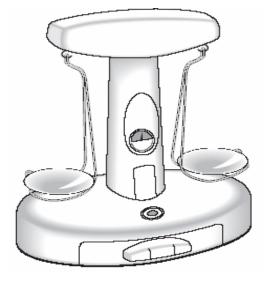




Hypodermic syringes



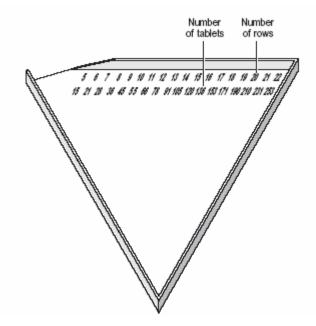
Collapsible ointment tubes



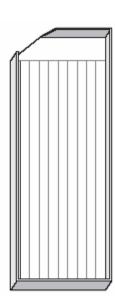
0 0 12 18 24

Class B Dispensing balance

Ointment slap



Counting triangle



Capsule counter

Annex 2. References for further reading

Winfield AT, Richards RME 1990. Pharmaceutical practice 2nd edition, Churchill Livingstone, China.

Laurence DR, Bennett PN 1992. Clinical pharmacology 7th edition, Churchill Livingstone, Edinburgh.

Management Sciences for Health, Managing drug supply 1997. Kumarian press, West Hartford, USA.

Tietze KJ 1997. Clinical skills for pharmacists: a patient focused approach. Mosby, Inc., Philadelphia.

World Health Organization 1997. Quality assurance of pharmaceuticals: a compendium of guidelines and related materials. Geneva, Vol.1

Amanda LE, et al.1999. Intervention research in rational use of drugs. Health policy and planning 14(2):89-102.

Federal Negarit Gazeta of the Federal Democratic Republic of Ethiopia 1999. Drug Administration and Control Proclamation No. 176, Addis Ababa

Federal Ministry of Health, Health Care Financing Secretariat 2002. National base line study on drug supply and use in Ethiopia, Addis Ababa

Abula, T, Ashagrie G 2003. Assessment of drug utilization from prescribers and dispensers perspectives in selected towns of Amhara region, Ethiopia. Ethiopian journal of health development 3:231-237.

Fink JL et al. 2003. Pharmacy law digest 37th edition. Facts and comparisons publishing group, USA.

National association of pharmacy regulatory authorities 2003. Facilities, equipment, supplies, work flow, and facility redesign, Canada. http://www.napra.org/docs/0/95/157/166/180.asp

Abraham G/Giorgis 2004. Drug smuggling and counterfeiting in Ethiopia. Masters Dissertation, University of Bradford, UK.

Pharmacy council of New Zealand 2004. Competence standard 1: Practice pharmacy in a professional manner, pp 1-26

WHO regional office for Africa 2004. Management of drugs at health center level: training manual. World health organization, Brazzaville, pp 1-73.

American Society of Consultant Pharmacists 2005. Guidelines on Prepackaging of Medications,http://www.ascp.com/public/pr/guideline/prepackaging.shtml.

Medical council of Hong Kong 2005. Good dispensing practice manual.http://www.hkma.org/

Abula T, etal. (In press). Assessment of the dispensing practices of drug retail outlets in North West Ethiopia.