TW
HEL
016

CHRISTIAN RELIEF & DEVELOPMENT ASSOCIATION

Training Programme on Rational Use and Essential Drug Management

Manual on Drug Supply Management For Peripheral Health Workers

CCRDA

Prepared & Conducted by:-
Drug Administration and Control Development
December 11 - 13, 1997
Wabi Shebele Hotel, Awassa

Table of Content

Page

FORWARD ii

INTRODUCTION 1

Chapter I

Drug Supply Management 4

Major functions of Drug Supply System 4

Drug Selection 5

Drug Quantification 11

Drug Procurement 25

Drug Distribution 32

Drug Use 45

Annex I - Drug defect reporting form 55

Annex II- Storage temperature and environment 56

References 57

CCRDA

FORWARD

The government of Ethiopia has a primary concern of providing adequate and comprehensive preventive and curative health services to all sectors of its population with priority to the most under served rural inhabitants at the cost that the country can afford.

Provision of such health services requires continuous availability of essential drugs of proven quality, safety, efficacy and acceptability at an affordable price and their rational use.
To ensure this the Ethiopian National Drug Policy was developed in 1993 with the following as its main objectives: the continuous availability of drugs and their rational use.

However, the delivery of health service in our country is affected by shortage of needed drugs. Although it is commonly attempted to minimise the shortage by only making more drugs available the economic and effective utilisation of drugs are not given due attention. This has added to the existing problems of financial constraints.

Therefore, the available meager resource should be used efficiently through improved drug supply management.

Hence health professionals need to update and improve their knowledge and skills in the management of Drug Supply in order to be able to carry out their duties effectively. Health institutions differ from one another in managing drug supply and have no references. They do not even have a working manual on the drug supply management.

Therefore, it is a high time to develop a manual on drug supply management to enable Pharmacy technicians, Nurses and Health Assistants, engaged in procuring, storage and dispensing of drugs of health center and health station, discharge their responsibilities.

The ultimate goal of the manual is to realize uniformity among institutions and to improve their managerial capability and thereby to improve availability of needed drugs and to promote their rational use.

It is expected that unreserved efforts shall be put in the rational implementation of this manual at Health center and Health station as well as training institutions.

The manual is subject to revision, comments and constructive critism will be welcome.

Drug Administration and
Control Department
Minister of Health
Addis Ababa, Ethiopia
December 1996

CCRDA

INTRODUCTION

The most prevalent health problems of the country are communicable diseases and diseases emanating from malnutrition, etc. which are preventable and treatable with essential drugs.

Continuous availability of essential drugs of proven quality, safety, efficacy and acceptability at affordable prices, compounded by rational use is indispensable for rendering effective preventive and curative health services.

However, the health service of the country is negatively affected by shortage and excessive wastage of drugs and medical supplies as the result of failure to wisely use the meager resources due to poor drug supply management.

☞ ***The common problems identified in drug supply management include the following:***

- Drugs are not selected on the basis of local needs. Usually, they are rather selected by single section and/or individual.
- Most health institutions do not have their own list of drugs.
- Drug requirements are determined without using appropriate information/data. It is usually done:
  - based on simple past experience
  - by only reviewing previous requisitions
  - based on short-term reactions to crises such as epidemic out break
  - based on subjective impression of needed quantity
  - many times on arbitrary notion.
- Drug procurement is carried out in an unplanned way, and without considering lead time, etc.
- Absence of and failure to observe adherence to procurement time-table.
- Poor follow-up of requisition status.
- Poor storage system which result in the damage and deterioration of drugs before their expiry date.

CCRDA

- Minimal or non-existent Record-keeping and stock control. Where record-keeping systems exist, they often vary from one health institution to another.

- The available drugs are not used rationally. Irrational prescribing and dispensing practices are becoming more common.

    - Inadequate prescription and patient request review by dispensers.

    - Mislabelling, inadequate packaging, and dispensing in inappropriate containers and unhygienic conditions.

    - Poor patient counselling and communication with the prescriber.

    - Poor prescription (filled and blank) handling, recording and reporting.

    - Labelling and provision of pertinent information to patients during dispensing are over looked.

- Many patients fail to take the medication in accordance with medical instruction.

- Many patients take prescription drugs without medical advice. e.g. Antibiotics

- Many patients handle and dispose drugs inappropriately.

- Health professionals are not involved in the preparation of drug budget proposal and most of them even do not know the drug budget of their health institutions and hence, fail to record expenditures.

☞ ***The problems enumerated above have resulted in:***

- Availability of drug products which are not needed and above the level of capacity of health institutions.

- Chronic and wide-spread shortage of highly needed drugs.

- Over-stock of unwanted as well as needed drugs.

- Distortion of distribution as those institutions who over estimate their drug requirements will take the share of others.

CCRDA

- Irrational budgetary constraints as the result of wastage due to expiration, deterioration, obsolescence and annual drug budget/funds are tied up with over-stocked items.

- Occurrence of drug related hazards such as developing of bacterial resistance, serious adverse effects, emergence of incurable health problems.

- Poor forecasting of drug budget for the coming year and poor utilization and control of drug budget over year.

The above problems are believed to be attributable mainly to lack of knowledge and skills on Drug supply management, lack of manuals on Drug supply management, absence of continuous supervision, follow-up, etc.

Recognizing these problems, the Drug Administration and Control Department, Ministry of Health, has been organizing a training programmes on Drug Supply Management for Health professionals from all Regions and as an extension to this a manual on drug supply management is prepared.

The manual consists of the major functions of drug supply which are:

- Drug Selection
- Drug Quantification
- Drug Procurement
- Drug Distribution
- Drug Use.
- Drug Quality Assurance

The manual describes certain processes and procedures that are helpful to manage drugs in cost-effective ways. It also helps to develop an understanding of the procedures for managing drug supply.

The manual is intended for Health centers and Health stations, whose pharmacy units are led by pharmacy technicians, nurses and health assistants.

The manual could also be used as a supplement for teaching institutions.

CCRDA

Chapter I

Drug Supply Management

Drug supply management can be defined as a process of planning, implementing and controllingthe implementation of the major functions of drug supply system as planned and required standards.

Major functions of the Drug Supply System

The major functions of the drug supply system are:

- Drug selection
- Drug quantification
- Drug procurement
- Drug distribution
- Drug use and
- Drug quality assurance

They are inter-linked to each other and form cyclic process and quality assurance is required from drug selection to use and hence will not be discussed separately.

CCRDA

Illustrative example of

Summary and Analysis of health problems/diagnosis

Table 1

Name of Health Institution Jimma Health Center

Region 4 Zone Jimma Town Jimma Woreda _____

ICD Code No.	Diagnosis	Number of Cases by Age & Sex						Total				
		Under 5			Above 5							
		M	F	Total	M	F	Total	M	F	Total	%	C%
	Infectious & Parasitic disease											
002.0	Typhoid	500	300	800	800	700	1500	1300	1000	2300	10.95	10.95
001	Pul. TB	120	150	250	300	200	500	420	350	770	3.7	14.65
090.7	Syphilis	1	10	11	30	20	50	31	30	61	0.29	14.94
098.5	Gonorrhoea	-	-	-	100	80	180	100	80	180	0.87	15.81
120.1	Ascariasis	100	200	300	150	50	200	250	250	500	2.38	18.19
016.0	Amoebiasis	-	-	-	300	200	500	300	200	500	2.38	20.57
037.0	Malaria											
	- Severity 1	500	400	900	300	600	900	800	1000	1800	2.9	23.47
	- Severity 2	200	100	300	150	200	350	350	300	650	3.10	26.57
090.0	Pneumonia											
	- Severity 1	500	300	800	500	400	900	1000	700	1700	8.10	34.67
	- Severity 2	200	250	450	300	100	400	500	350	850	4.077	38.74
	:	:	:	:	:	:	:	:	:	:	:	:
	:	:	:	:	:	:	:	:	:	:	:	:
	Total	*4	*4	*8	*7	*6	*13	*11	*10	*21		100

Key: * In thousands M = Male F = Female C = Cumulative

CCRDA

DRUG SELECTION

Drug selection - is a process of deciding the type of needed drug products for the prevalent diseases.

Objective of drug selection

To determine the type of needed drug products for the prevalent diseases.

Basic steps and criteria in Drug Selection

1. **Establish Drug Selection committee with an appropriate representation**

   Drugs should be selected by a committee, composed of prescribers, dispenser and other concerned health personnel.

   In health institutions staffed with one type of health professionals (e.g. Nurses, or health assistants) drug selection should be done by a committee composed of these professionals.

2. **Determine the prevalent health problems and patient characteristics**

   Health problems encountered should be recorded using the morbidity registration book/format of Ministry of Health. One can also use Patient Prescription Registration Book for obtaining reliable morbidity data.

   The recorded health problems should be summarised and analyzed by age, sex, severity, frequency and ranged using percentage as shown below.

CCRDA

Illustrative example of

Summary and Analysis of health problems/diagnosis

Table 1

Name of Health Institution Jimma Health Center

Region 4 Zone Jimma Town Jimma Woreda _____

ICD Code No.	Diagnosis	Number of Cases by Age & Sex						Total				
		Under 5			Above 5							
		M	F	Total	M	F	Total	M	F	Total	%	C%
	Infectious & Parasitic disease											
002.0	Typhoid	500	300	800	800	700	1500	1300	1000	2300	10.95	10.95
001	Pul TB	120	150	250	300	200	500	420	350	770	3.7	14.65
090.7	Syphilis	1	10	11	30	20	50	31	30	61	0.29	14.94
098.5	Gonorrhoea	-	-	-	100	80	180	100	80	180	0.87	15.81
120.1	Ascariasis	100	200	300	150	50	200	250	250	500	2.38	18.19
016.0	Amoebiasis	-	-	-	300	200	500	300	200	500	2.38	20.57
037.0	Malaria											
	- Severity 1	500	400	900	300	600	900	800	1000	1800	2.9	23.47
	- Severity 2	200	100	300	150	200	350	350	300	650	3.10	26.57
090.0	Pneumonia											
	- Severity 1	500	300	800	500	400	900	1000	700	1700	8.10	34.67
	- Severity 2	200	250	450	300	100	400	500	350	850	4.077	38.74
	:	:	:	:	:	:	:	:	:	:	:	:
	:	:	:	:	:	:	:	:	:	:	:	:
	Total	*4	*4	*8	*7	*6	*13	*11	*10	*21		100

Key: * In thousands M = Male F = Female C = Cumulative

CCRDA

3. **Decide which health problems may be treated at the level of drug selection**

Determine the level of health care unit by determining the level of training of health personnel involved in prescribing and dispensing, etc. and the available diagnostic facilities such as laboratory.

The type of health service that can be provided at each level should be decided according to the diagnostic facilities and prescribing capacity. The curative, preventive and other services that can be provided at a given level of health institution are:

- complete treatment E.g. Amoebiasis at health station level
- initial treatment E.g. Epilepsy at health center level
- follow up treatment E.g. TB at health station/center level
- repeat visit such as injection, dressing, etc. and
- preventive health service E.g. Vaccination, contraception.

4. **Choose the drugs to be used for the health problems**

Select the drugs needed for each health problem using the following criteria.

⇒ Select:

- only drug products which are in the national list of drugs and list of essential drugs for Ethiopia.
- drug products in their generic name or international Non-proprietary names (INN).
- drug products with widest possible coverage of the prevailing health problems.
- only those dosage forms for each drug which are necessary.
- only those drug products for which proper storage could be assured.

⇒ Consider Cost when selecting drugs. Cost comparison between /among drugs should include the total cost of treatment and not only the unit cost of drug(s).

⇒ Select combination drug products if the following advantages are met:

- clinical documentation justifies the concomitant use of more than one drugs;
- the therapeutic effect is greater than the sum of the effect of each;
- the cost of the combination product is less than the sum of individual products;
- compliance is improved;
- sufficient drug ratios are provided to allow dosage adjustments satisfactory for the majority of the population.

CCRDA

⇒ When two or more drugs seem similar in the above respect select:

- the most widely used drug for longer period of time
- drug which offers better patient compliance
- drug product which is locally available

5. **Structure the list of drug products**

The end result of drug selection is list of drugs which should be structured Pharmaco-therapeutically and/or alphabetically

E.g. The National list of drugs is structured as such

The prepared list of drugs need to be further categorized by level importance as shown below.

All the drugs included in the list will not be equally important and hence they should be categorized by level of importance into three categories as discussed below:

(V) Vital - drugs which are potentially life saving (very essential), and which are of major importance in basic health services especially vaccines.
E.g.: Anti-malarial, Vaccines, ORS, etc.

(E) Essential drugs - Drugs which are effective against less life threatening, but nevertheless significant health problems.
E.g.: Certain antibiotics, Anti-inflammatory

(N) Normal usage (Less essential)- these are drugs; used for minor or self-limiting health problems or which have a high cost for small extra effectiveness.
E.g. : Cough syrup, Antacid tablet or suspension.

Such classification should be decided primarily on the basis of the health impact of individual drugs. This type of classification helps in setting priorities for drug purchasing and stock-keeping.

CCRDA

Table 2. **Illustrative example of Structuring of the list of drugs by level of importance.**

Ther. cat. Cod	Name, Strength and dosage form of drugs	Level of Importance		
		V	E	N
GL000	Gastro -intestinal Drugs			
GL100	Antacids			
1	Al(OH)3 + Mg trisilicate tablet	-	E	-
2	Al(OH)3 + Mg trisilicate suspension	-	E	-
GI 200	Anti-spasmodics/spesmolytics			
1	Atropine sulphate 1 mg/ml	-	E	-
2	Hyoscine HBr 0.4 mg/ml injection	V	-	-
3	Hyoscine Butylbromide 10 mg tablet	-	E	-

Key: V - Vital, E - Essential, N - Normal usage
Ther. Cat. Cod -Therapeutic Category Code

6. **Introduce the list of drugs**

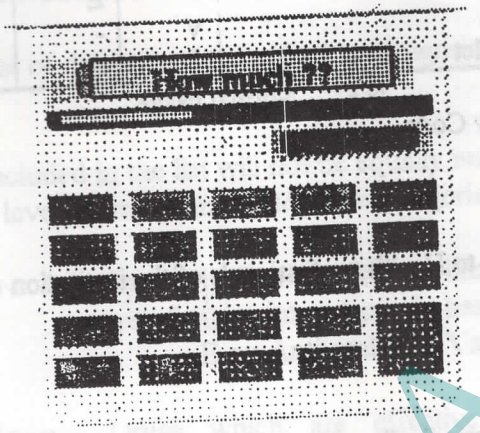
The list of drugs should be introduced to Health professionals of the institution and other concerned bodies.

7. **Up-date the list of drugs**

The list of drugs should be reviewed periodically. Any addition into and deletion from the list should be on the basis of selection criteria.

CCRDA

DRUG QUANTIFICATION



GCRDA

Essential points to note:

Proper drug quantification avoids;

- over-stock
- stock-out and
- shortage of drugs

DRUG QUANTIFICATION

Quantification - is a process of determining the amount of drug products required.

Objective of drug quantification

To determine the right amount of drug products required.

Selection of an appropriate method(s) of Quantification

The most commonly used methods of quantification are:

a) Morbidity method
b) Adjusted consumption method

Select an appropriate method(s) of quantification that suits to your health institution.

When to use each method of quantification

Each method may be more appropriate if any of the following conditions apply

	a) Morbidity Method		b) Adjusted Consumption
1	Available consumption data are incomplete or unreliable	1	The health facility is adequately funded
2	Prescribing pattern are not cost effective and systematic improvement is required	2	The health facility has acceptable patterns of prescribing
3	The drug budget is unlikely to be sufficient to meet estimated requirements	3	The health facility has adequate and uninterrupted drug supply
4	The health facilities or services are new or expanding or contracting rapidly so that consumption is not reliable.	4	The health facility has reasonably good stock management and has complete and accurate consumption data and stock out information.
		5	The health facility has a low level of wastage and losses.

CCRDA

I. Basic Steps in Morbidity method of Quantification

This method uses morbidity data and average standard treatment schedule to calculate the amount of drug products required.

Estimating quantities of drugs required using morbidity method includes the following steps:

Step -1. Use Average Standard Treatment Schedules

Average standard treatment schedule is the average quantity of a drug per course of treatment.

Average treatment schedules are valid if they represent the average treatment which shall actually be used clinically.

The average treatment schedule to be used should include the following information;

- the name of the health problem and ICD code No. of the diagnosis. It should also includes severity of the disease,
- the patient's Age (under 5 and above 5), sex.
- the generic name, strength, dosage form of each drug to be used for the treatment
- the average dose, number of doses/day, number of days these doses are to be given /duration/.
- the total average quantity of each drug used for a standard, course of treatment.

CCRDA

Table 3. Illustrative Example of Average Standard treatment schedule for quantification purpose.

ICD	Diagnosis	Generic, Strength and dosage form	Dose	No. of doses per day	No. of days (duration)	Amount per course of treatment
016.0	Parasitic Diseases Amoebiasis - Adult	Metronidazole 250 mg capsule	3 caps	3	5	45 caps
	- Child	- Metronidazole 250 mg capsule or - Metronidazole 125mg/5ml susp.	1 caps or 10ml	2 or 2	3 or 3	6 caps or 60 ml

Step -2. **Estimate number of treatment episodes for each health problem**

A treatment episode is a patient contact for which a standard course of drug treatment is required.

The quality and reliability of the morbidity data is very important. If the morbidity data are seriously incomplete then the drug estimate may be dangerously inadequate or inappropriate.

To estimate the number of treatment episodes do the following activities:

Obtain the total number of patient contact by diagnosis

- Reorganize the diagnosis according to the health problems defined in the average standard treatments.
- Within health problems, breakdown the number of patient contacts as necessary by age, sex and severity.
- Determine the proportion of contacts for which a standard treatment is required.

All patient contacts /visits/ may not give rise to a treatment episode as may not require a standard course of drug treatment.

GCRDA

Illustrative Example

If the number of treatment episodes for Amoebiasis treated annually by a given health center was 1000, of which 60% were adults and all cases were treated with metronidazole oral preparation the quantity of metronidazole can be calculated as shown below.

Table 5.

ICD Code	Diagnosis	a) No. of treatment episodes	b) Quantity per Average standard treatment	c) Total quantity of the drug (a x c)
016.0	Ameobiasis - Adults	1000x60% = 600	Metronidazole 250mg capsule 3x3x5 = 45 caps	45x600 = 27000 caps
	- Children	1000x40% = 400	Metronidazole 125mg/ 5ml of 60ml or, Metronidazole 250mg caps. 1x2x3 = 6 caps	400 bottle of 60ml or 6x400=2400 caps.
	Total			29400 caps. or 27000 caps + 400 bottle of 60ml

b. **Calculate the total quantity of each drug**

Where a drug is indicated for more than one standard treatments, add the quantities required for each one to obtain the total quantity of each drug by re-organizing the quantities in Step 3 "a" by the drug to be quantified.

CCRDA

Step 4. **Estimate the cost of the drug quantities required**

After calculating the total number of packs of each drug required the next step is to estimate the total cost of the drug using the following formula and then add up the total cost of all drugs.

Total cost of each drug = No. of packs required x Price per pack

Step - 5 **Prepare Annual Drug Budget**

Preparing Annual Drug Budget requires:

- Adding up the estimated cost of all drugs required
- Estimating the cost for procurement (e.g. transportation, perdiem)
- Estimating the cost required for preparing/printing drug requisition format, stock record card, Patient Prescription Registration Book, Prescription paper, Consumption reporting formats, etc.

The estimated Annual Drug Budget for effective Drug Supply will be the sum of all costs indicated above.

The prepared Annual Drug Budget should be discussed by the staff of the health institution before it is submitted for approval to concerned body.

Step -6. **Reconcile drug quantifies to budget**

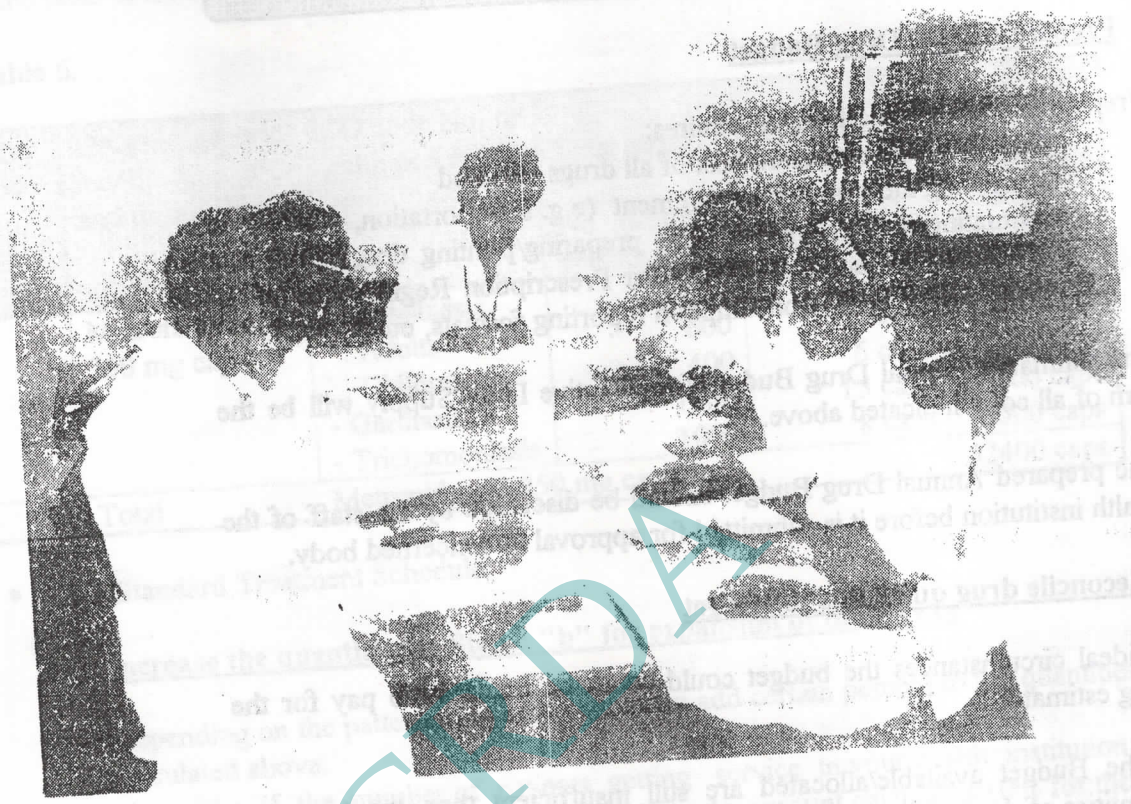
In ideal circumstances the budget could be made available to pay for the drug estimated.

If the Budget available/allocated are still insufficient then the type and quantities of drugs required must be reviewed and reduced to bring the total ordered quantities within the budget limit.

Use VEN system to reconcile budget and need and reduce less essential drugs first and most, and cut the most essential (Vital) drugs least and only as a last sort.

A logical approach should set rational priorities for these reduction to ensure that the most needed items are bought first.

CCRDA



Committee Reconciling need to budget in one health station.

CCRDA

Basic steps in Adjusted consumption method:

This method uses past consumption of the drugs selected to calculate the total amount of drugs required.

Basic step for Adjusted consumption method:

Step -1. Select the period for which the consumption is to be calculated

The simplest and most practical period for which to calculate consumption is one year, so that the morbidity variations of all seasons are covered. If data are available, use the long period data as it can improve the reliability of the results.

Step -2. Calculate the consumption of drugs required

The consumption of each drug can be obtained from:

Patient Prescription Registration Book which is more reliable and give the actual drug consumption and
Stock record card. In this case the consumption is calculated by:

- Adding up all the quantities issued or
- Using the following formula;

Recorded consumption =	Opening stock +	Drug received -	Closing stock

Step -3. Adjust for avoidable wastage and losses

Avoidable wastage, which are mainly due to poor stock management, poor storage, careless handling, expiration, theft, etc. should be adjusted by avoiding their causes. Such an adjustment of avoidable wastage can be done using the following formula;

Consumption Adjusted for avoidable wastage	=	Recorded consumption	-	Avoidable wastage

CCRDA

Step -4. Adjust consumption data for stock-out if necessary

If a drug has been out of stock for part of a period, then the consumption recorded applies only to that part of time when the drug was in the stock.

If the period for which consumption is being calculated is for one year and if the given drug was out of stock for 3 months of the year, then the observed consumption covers only 9 months.

In practice, stock-out up to one month may be ignored because they are not likely to have a significant effect on the estimated drug requirement, as the last issued drugs may be available in the dispensary.

For stock-outs longer than 30 days /a month and not more than 3 months an adjustment should be made using the formula given below.

$$\text{Consumption Adjusted for stock-out} = \text{Recorded consumption} \times \frac{\text{Period in calculation (in days/ weeks/months)}}{\text{period in stock (in days/weeks/months)}}$$

CCRDA

Table 7. **Illustrative example for calculation of consumption**

Stock Record Card

Name of Health Institution TEDA - Health Centre
Name of the item Metronidazole 250 mg capsule — Maximum stock level ____
Re-order " " ____
Unit of issue capsule — Minimum " " ____
Site - Store — Average month consume 2000

Date 96	Document No. (model 19 or 22)	Issued to or received from	Received	Issued	Balance	Remark
1 January	Inventory	Opening stock			4000	
1 January	03258	Dispensary		2000	2000	
2 Feb.	06742	Reg.H. Bureau	6000		8000	
25 Feb.	06758	Dispensary		2000	6000	
20 March	03260	Dispensary		2000	4000	
25 March	Ref.2678/3/9	Expired/dispose		2000	2000	
20 April	03261	Dispensary		2000	0	
30 April	07782	Reg. H.Bureau	6000		6000	
20 May	03262	Dispensary		2000	2000	2000 stolen
25 June	03263	Dispensary		2000	0	
20 Oct.	07783	Reg. H.Bureau	10000		10000	
21 Oct.	03265	Dispensary		2000	8000	
25 Nov.	03266	Dispensary		2000	6000	
26 Dec.	03268	Dispensary		2000	4000	

Given

a) Recorded consumption (+ wastage) = 22000 metronidazole 250 mg. capsule

b) Stock out period = From Jun. 26 - Oct. 19;1993 but the 10,000 tablet taken from store as of Jun. 25 can serve for one month and hence the actual stock-out period is 3 month.

c) Amount of metronidazol 250 mg = 4,000 capsule capsule stolen and expired.

The adjusted consumption is calculated as follow.

1) Consumption adjusted for avoidable wastage = (22,000 - 4,000) capsule.
= 18,000 capsule

2) Consumption adjust for stock out period = $18{,}000 \times \frac{12}{9} = 24{,}000$ capsule

3) Adjusted consumption for avoidable wastage = 240000 capsule of metronidazol 250mg

CCRDA

Step. 5. Increase for service expansion to the quantity obtained in step 4.

Depending on the pattern of service expansion add certain percentage to the calculated quantity above.

Step 6. Convert the quantity obtained in step 5 to the required number of order pack

Calculate the required number of order pack using the formula shown below

$$\text{No. of order pack} = \frac{\text{Quantity calculated}}{\text{Pack size required}}$$

Step 7. Estimate the cost of drug quantities required

Estimate the total cost of drug quantities required using the following formula;

$$\text{Total cost of each drug} = \text{No. of order pack} \times \text{Unit price per pack}$$

After estimating the cost of all drugs required add up the costs of all drugs.

Step -8. Prepare Annual Drug Budget

Do the same as discussed under morbidity method of quantification.

Step -9. Reconcile Drug quantities to budget/fund

Do the same as discussed under morbidity method of quantification.

CCRDA

III. **Combination of morbidity and consumption method**

As it can be seen above neither of the two method is better than the other; They simple suit different conditions. Each method has its own shortcomings.

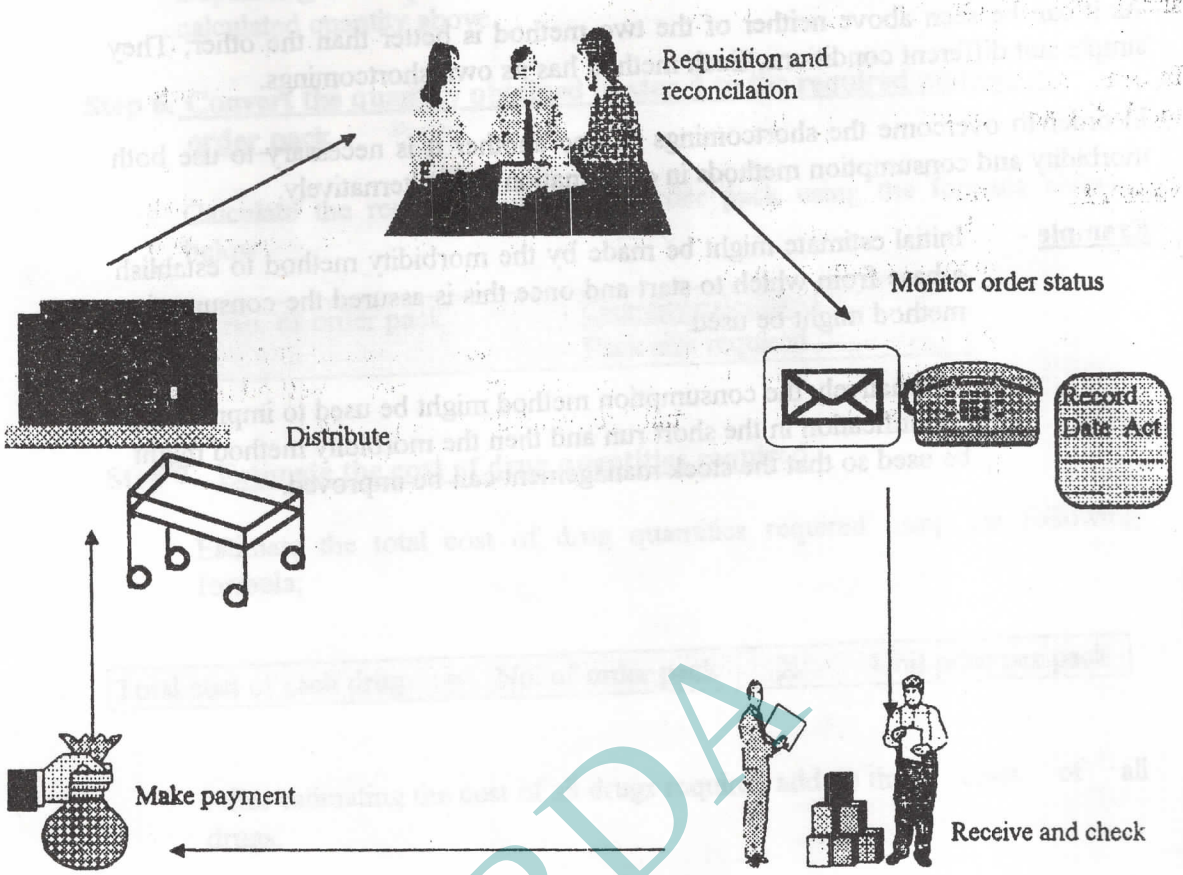
In order to overcome the shortcomings of one another it is necessary to use both morbidity and consumption methods in combination and alternatively.

Example - Initial estimate might be made by the morbidity method to establish a base from which to start and once this is assured the consumption method might be used.

- Alternatively the consumption method might be used to improve the quantification in the short run and then the morbidity method might be used so that the stock management can be improved.

CCRDA

DRUG PROCUREMENT



CCRDA

Essential points to note:

- Appropriate procurement requires the acquisition of drug products:
  - of the right quality
  - in the right quantity
  - at the right price
  - at the right time and
  - from the right source

Drug Procurement

Procurement is the process of acquiring drug products through purchase, manufacture and donation

Objective of Drug Procurement

In drug procurement the objective is to satisfy the drug need of health institutions and/or patients.

In order to satisfy the drug need of health institution and/or patients the product:

- has to be the Right quality
- has to be the Right Quantity
- has to be Supplied at the Right time
- has to be purchased at the Right price
- has to be from the Right source

Major Activities of Procurement

1. **Identify What To Procure**

   Generally, review the selected drugs each time you begin the procurement process. Select more of the essential drugs

2. **Determine how much to Procure**

   Approaches that can be used in determining the quantities needed are discussed in detail under quantification. Undertake this exercise every year using the data and information available and determine the amount to be procured each time.

3. **Reconcile Needs & Funds**

   Estimate the cost of the quantity of drugs to be procured.
   The estimated quantity of drug needs may exceed the available drug budget of the health facility. If this happen in your exercise, reduce the type and quantity of drugs systematically. Omit the less essential items and give emphasis to life-saving and then to essential items.

CCRDA

4 Determine when to Buy

Prepare procurement time-table which indicates the date each activity has to be performed. The time-table will also help you for self-monitoring and follow up of the order status.

In proper procurement planning consider factors like lead-time, demand fluctuations ... etc. which have impact on determining the time of purchase.

lead-time: The time between the date the drug requisition is initiated and the date the drugs so purchased/procured are received.

If the lead-time is long, initiate your drug requisition as early as possible to avoid delay.

Note that:

In any procurement it is very important to know the lead-time to execute drug procurement timely. Failure to consider lead-time in drug procurement results in unexpected shortage of drugs.

5. Locate & Select suppliers

Since most of the health institutions obtain drugs and medical supplies from one government source, PHARMID, locating and selecting of suppliers may not be that more relevant.

6. Prepare Drug Requisition

The drug requisition to be sent to the immediate supplier, should be prepared in triplicate. The following is the standard Drug Requisition Form that can be used at each level of the health care system.

CCRDA

Table 8.

DRUG REQUISITION FORM

Name of Health Institution _____
Region _____ Zone __ Woreda _____ Town _____ Tel. _____ P.O.Box _____
Annual Drug Budget in Birr_____ Balance at the time of request in Birr_____
Supply period from _____ to _____

Code No.	Description (Name, strength, dosage form)	Unit	Monthly consum-ption	Quantity in stock	Quan. requested	Quant. supplied *	Unit cost *	Total Cost *

Total estimated cost of the requested items in Birr _____

Requested by _____ Approved by _____
Signature _____ Signature _____
Date _____ Date _____

N.B.: This form is to be filled in triplicate of which the original is sent to the supplier. The 2nd copy is to be sent to the archive of the institution and the 3rd copy remains filed in the pharmacy section.

* For supplier use only.

CCRDA

7. **Make follow up of the Drug Requisition Status**

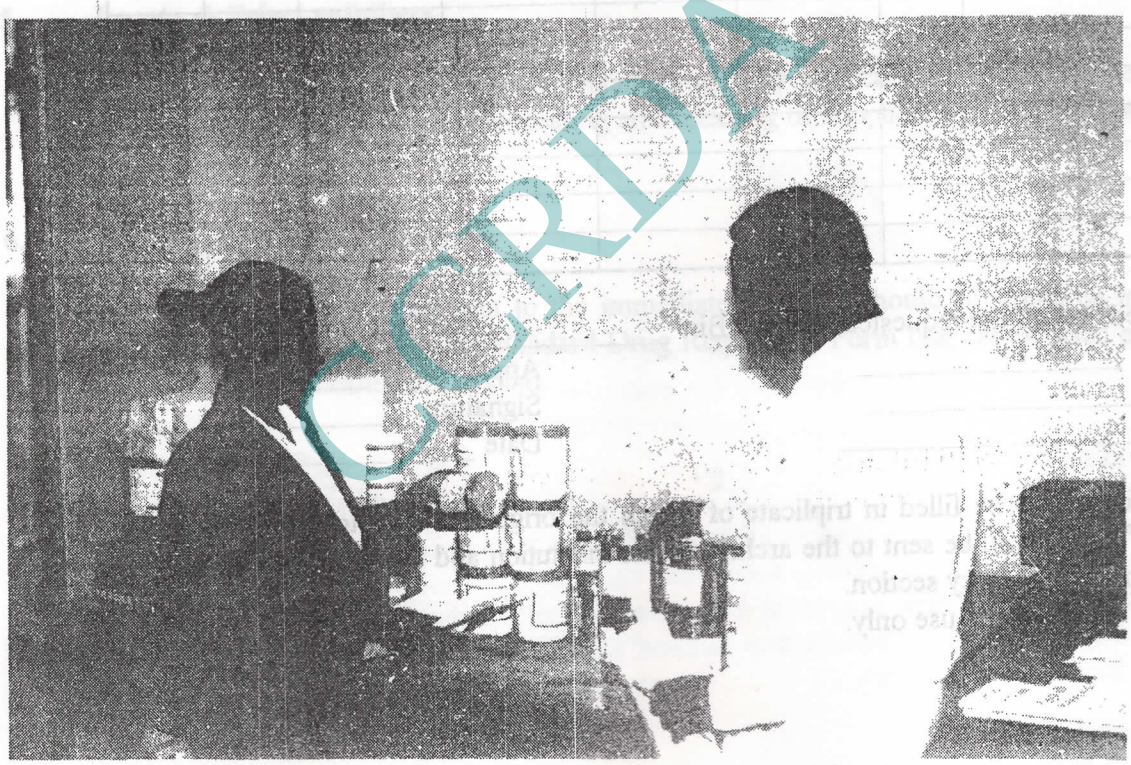
Send your drug request based on standard Drug Requisition. Once the drug request is placed, the progress of the request must be closely monitored. Keep records of the date on which the requisition is prepared, approved, sent to supplier, supplies received in order to react when there is unnecessary delay.

8. **Receive & check Drugs**

As soon as the drug requested from supplier arrive:

- check the type and quantities received against that the drug requisition and invoice.
- Check for the quality, packaging, shelf-life and labelling of the product to verify whether they meets the required standard.
- Report any discrepancy in quantity or quality problem to the supplier using the following format.

The quality problem should also be reported to the Drug Administration and Control Dept, MOH, using Drug Product Defect Reporting format (See Annex I) with a copy to the Regional states Health Bureau.


GCRDA

Undertaking physical Inspection when receiving Drugs.

Table 9. **Discrepancy Reporting Form**

Name of Health Institution _____
Region _____ Zone _____ Woreda _____ Town _____ Tel._____ P.O.Box _____
Supplier _____

Ser No	Description (Name, strength, dosage form)	Unit	Batch No.	Expiry date	Manufacturer	Country	Quantity			Reason for difference
							on invoice	Actual received	Affected *	

Reported by _____ Reviewed by _____
Signature _____ Signature _____
Date _____ Date _____
Action taken and by whom _____

Name _____ Sign. _____ Date _____

N.B.: This is to be prepared in Triplicate of which the 1st copy is sent to the supplier, 2nd copy to the archive and the 3rd copy remains filed in the pharmacy section.

* Quantity affected includes quantity of drugs damaged, missed, expired, mislabelled, etc.

CCRDA

9. **Up-date the balance of Drug Budget**

Once the purchased drugs and inventory control format are received subtract the cost of them from the previous balance in order to know the current status of the Drug Budget.

Table 10. Illustrative Example

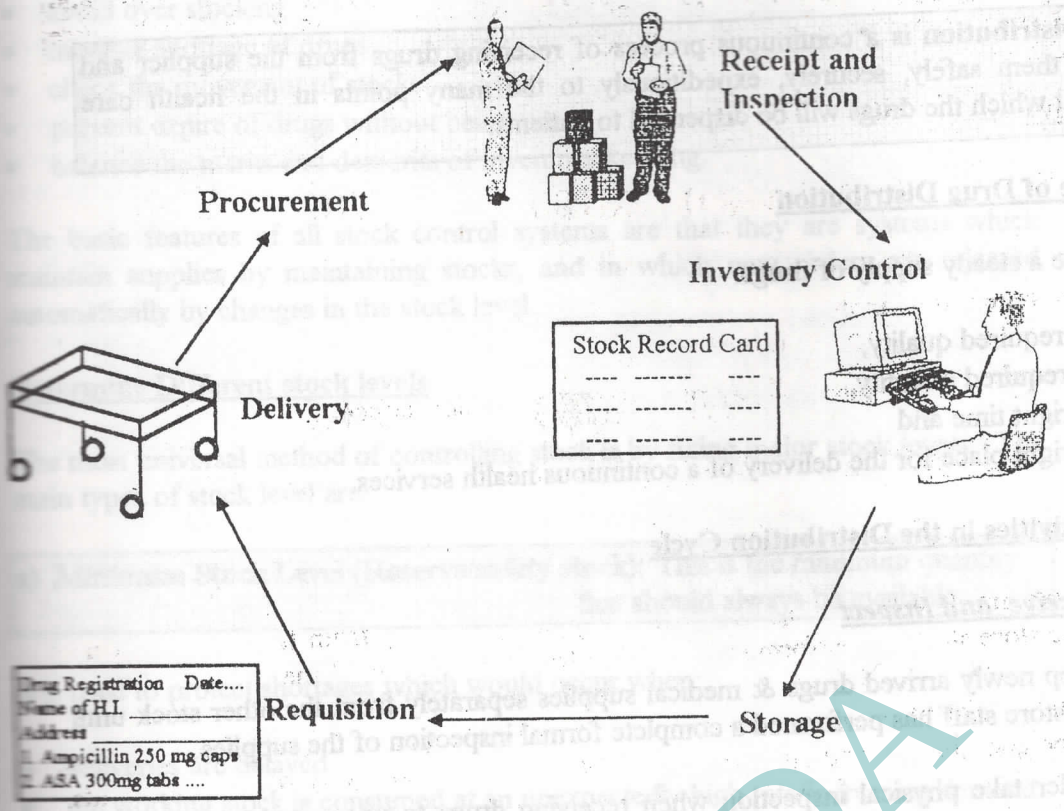
Name of the institution : Sheromeda Health Center Address: Addis Ababa
Budget year: 1988 E.C./FY

Date E.C	Description	Document No.	Amount in Birr		Balance (Birr)	Remark
			Allocated	Expended		
01/11/87	Annual drug budget:					
	. for drugs	Let. No.288/4/87	75,000		75,000	
	. transportation	Let. No.288/4/87	1,000		76,000	
	. printing of formats	Let. No.288/4/87	4,000		80,000	
01/12/87	Printing of formats	Inv.No.02732		4,000	76,000	
01/01/88	Drug purchased from Reg. 14 H.B	Inv.No.49837		10,000	66,000	
01/01/88	Transportation	Inv.No.0032		200	65,800	
04/04/88	Drug purchased from Reg. 14 H.B	Inv. No.67720		15,000	50,800	
04/04/88	Transportation	Inv.No.0096		200	50,600	
10/07/88	Drug purchased from Reg. 14 H.B	Inv. No.92437		30,000	20,600	
10/07/88	Transportation	Inv.No.0120		400	20,200	
15/10/88	Drug purchased from Reg. 14 H.B	Inv. No.92457		20,000	200	
15/10/88	Transportation	Inv.No.0224		200	0	

Summarize and Report the value of drugs and medical supplies purchased monthly, uarterly and annually to the concerned body.

CCRDA

DRUG DISTRIBUTION



Essential Points to note:

- Proper storage ensures quality, safety and efficacy of drugs before expiration
- Inventory control prevents under and over stock of drugs.

CCRDA

DRUG DISTRIBUTION

Drug Distribution is a continuous process of receiving drugs from the supplier and moving them safely, securely, expeditiously to the many points in the health care system at which the drugs will be dispensed to patients.

Objective of Drug Distribution

To provide a steady supply of drugs:

- of the required quality,
- in the required quantity,
- at the right time and
- in the right place for the delivery of a continuous health services.

Major Activities in the Distribution Cycle

1. ***Receive and Inspect***

   Keep newly arrived drugs & medical supplies separately from the other stock until the store staff has performed a complete formal inspection of the supplies.

   Under take physical inspection when receiving drugs to uncover damage, defect, type and quantity and other deviations from the requisition and other requirements.

   Report any discrepancy related to drug quality, type and quantity using the discrepancy reporting format discussed under procurement (See page 30).

   Report any discrepancy related to drug quality requirements to the supplier and Drug Administration and Control Department with a copy to Regional state Health Bureau.

2 ***Perform Inventory Control***

   Inventory is the stock on hand at any given time. It is like money in the bank

   Inventory control is the maintaining of stock properly at all levels and at all times. It is a process of controlling of inventory volume and movement in order to ensure that the obtained drugs have reached to the final consumer correctly.

CCRDA

Inventory control helps to:

- maintain appropriate stock
- avoid over stocking
- monitor shortage of drugs
- check the movement of stocks
- prevent expire of drugs without being used
- balance the merits and demerits of inventory keeping.

The basic features of all stock control systems are that they are systems which maintain supplies by maintaining stocks, and in which new orders are released automatically by changes in the stock level.

Determine Different stock levels

The most universal method of controlling stock is by fixing major stock levels. The main types of stock level are:

a) Minimum Stock Level (Reserve/safety stock): This is the minimum quantity that should always be available.

It is used to protect shortages which would occur when:

- deliveries are delayed
- the working stock is consumed at an unexpectedly high rate/increasing demand.

Reserve stocks should increase with the lead time, since there is a great risk of shortages with longer lead times.

i.e. reserve stocks are determined by the lead time.

b) Reorder Stock Level: This is the level of stock at which new orders should be placed to replenish the supplier or the stock at which an order is initiated

i.e. it is also the stock necessary to cover the lead time

- Reorder before you are short of items.
- Calculate the time between ordering & receiving the supply
- Work out how much you use of each item during that period
- Add this amount to your reserve stock & this gives your re-order level.

ECRDA

c) **Maximum Stock Level:** This is the maximum amount of drug items you are allowed to keep in the store at any item. It helps to determine the order quantity each time an order is placed.

These levels must be reviewed periodically.

Illustrative example of how to calculate stock levels

Assume that:

- you may order drugs every month,
- the average quantity you use is 13 units per month,
- the time between your requisition and actual delivery is about one month,
- and even sometimes nothing may be delivered at all.

For this reason you should always maintain a safety stock of about one month.

When should you order and how much?

You have to order when your stock is just below the level that you need for the delivery time(one month) and a safety stock (also one month). This "re-order level" can be fixed once you know your average consumption per month. In our example it is 13 +13 units = 26 units. This figure should be written on the stock record card, as it will not change.

So, every time your stock level is just below 26 units, you have to order new stock. In our example you will have to order for one month again, that is 13 units, in general you may order up to the maximum level 26+13=39 units. You should never have more than 39 units in stock.

The maximum level is the re-order level plus the quantity to be ordered in a given period (e.g. one month). In our example that would be 26+13=39 unit. You should never have more than 39 units in stock.

To fix each of the above indicated stock levels Consumption data, the period interval for ordering, & the lead time should be known through good management & experience

b. Inventory control techniques

The basic management tool for inventory control are:

- Stock Record Cards
- Bin Cards.

CCRDA

Stock Record Card

A stock record card must exist for each item. The essential content of a stock record card is illustrated below.

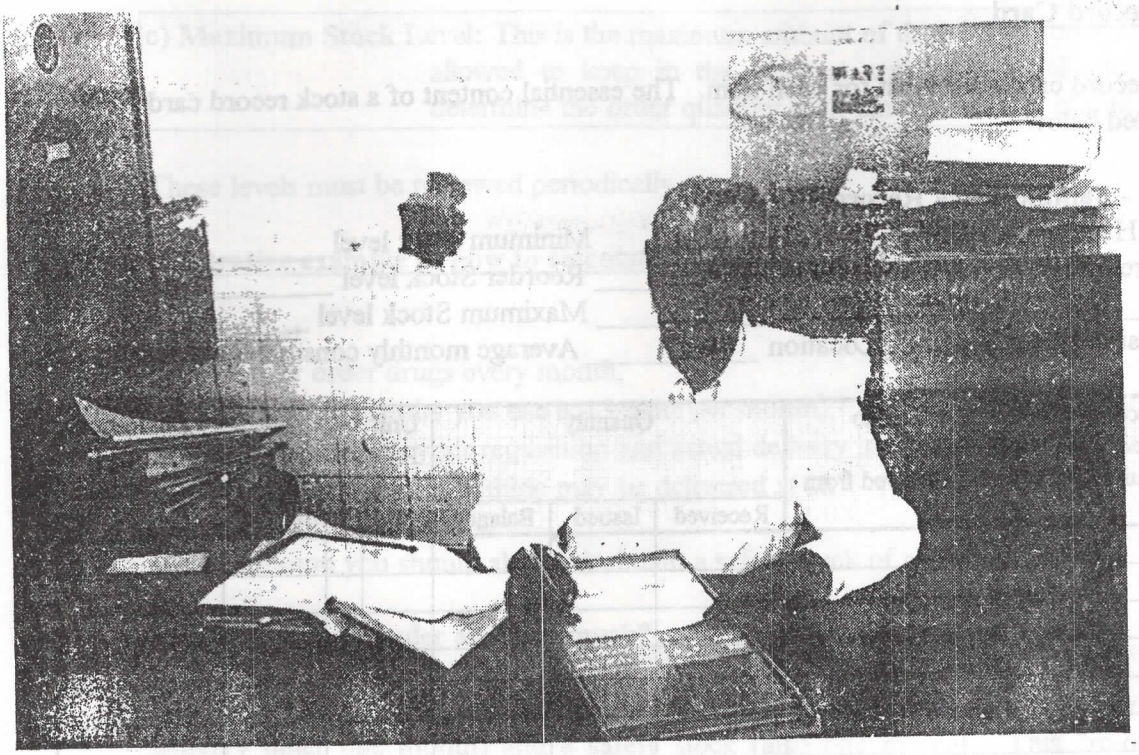
Table 11 - Sample Stock Record Card

Name of Health Institution _____ Minimum stock level _____
Name, strength & dosage form of item _____ Reorder Stock level _____
_____ Maximum Stock level _____
Unit of issue _____ Location _____ Average monthly consumption __

Date	Document No. (receiving or issuing form NO:)	Issued to or received from	Quantity			Unit Price		Expiry Date	Remark
			Received	Issued	Balance	Birr	C		

N.B.: Stock record card should be updated and filled by other than a store keeper. Monthly issuance should be summarized and indicated.

GCRDA



Use and updating of Stock Record Card.

Importance of stock record card

It is used:

- as the basis for requisition & issuing of drugs & medical supplies.
- to know the fluctuation of price of drugs, useful for budget allocation by reconciling drugs budget with the consumption reports necessary for procurement.
- to control shelf-life of drugs.

Bin Cards These cards remain with each lot of supplies and show issues, receipts, balance, expiry dates.

The purpose of Bin Cards is to provide:

- an easy reference on stock levels-they show you quickly how much you have in stock
- an easy reference on expiry dates with in the store rooms.

Based on the above purpose, bin cards should be kept in a store room and filled by a store keeper.

CCRDA

Table 12. Sample Bin Card.

Name of Health Institution _____
Name, strength & dosage form of drug _____
_____
Unit of issue _____

Date	Document No. (receiving or issuing form No)	Received from or Issued to	Quantity			Unit Price		Expiry Date	Remark
			Received	Issued	Balance	Birr	C		

3. ***Storage***

Proper Storage practice is the safe keeping of supplies awaiting dispatch and maintaining the intended quality of drugs until it ultimately reaches the consumer.

Drugs need to be protected from:

- moisture
- sunlight
- heat
- physical damage
- dirt



Drug.

Undertake regular physical Inspection on drugs and medical supplies in store and dispensary.

a. **Appropriate Store**

Proper storage of drugs require well designed store, of adequate size with good ventilation, secured window and doors, etc.

CCRDA

Ventilation

The store should be designed in such a way that there is adequate fresh air circulation (ventilation).

Good air circulation maximizes shelf-life of pharmaceuticals & improves working conditions. Ceiling fans provide a practical alternative; where they are not adequate forced ventilation through the roof is recommended.

Security

The windows should be wide with wire mesh to prevent entry of pests. The windows should be high enough so as not to be blocked by shelves and the store should have lockable door.

Shelving

Proper positioning of shelves promotes both air circulation & movement of stock. Allowing two feets free distance between shelves from rows & walls usually assures adequate circulation.

b. **Storage Condition**

There are:

i. **Normal Storage**

Unless special storage conditions are stated, it is vital that drugs be stored in a dry adequately ventilated, shady and cool condition.

ii. **Special storage conditions**

Vaccines, Narcotic drugs & Psychotropic substances, poisons and combustibles require special storage conditions.

* **Storage of controlled substance**

Narcotic drugs & psychotropic substances and poison and their documents should be kept in secure locking cupboards. The keys should be kept in a secure place and preferably that only the chief of the pharmacy unit should have access to them.

CCRDA

Storage of combustible and corrosive substances

Combustibles such as alcohol, ether, and other organic solvents must be stored separately from other drugs.

All stores should be equipped with fire extinguishers. A good alternative to fire extinguishers is represented by wooden or metal buckets filled with sand, since sand readily smoothers a fire.

Cold Storage

Vaccines, sera (e.g. Anti-A, Anti-B, Anti-D) biological (Insulins) and blood products need to be kept in refrigerator regardless of climate.

Control the temperature of refrigerator regularly in order to maintain the cold storage of vaccines, sera and biological so that internal temperatures could be monitored daily. This could be done by taping temperature recording chart to refrigerator doors.

Maintaining the cold chain

"Cold Chain" is a system of freezes, refrigerators, dry ice and other device to maintain uniform temperature from production to the point of administration of drug product.

Transport vaccines, sera and biologicals to regional, district, health institutions or to special vaccination centers. For this, the cold chain refers to: the storage & shipping of vaccines and other biological products submitted to "cold chain" conditions.

At peripheral facilities, vaccines can be stored in cold storage units in the room in which they are administered.

In addition to adequate storage conditions for biological products and vaccines the distribution system must also have the necessary cold storage boxes or ice boxes for transport between facilities and to immunization sites.

CCRDS

Table 13. Temperature requirements for vaccine storage.

Vaccine	Level	Health center/station	Transport
	Maximum storage time	up to one week	up to one week
Measles oral polio DPT Tetanus Toxoid BCG		+4°c to + 8°c	

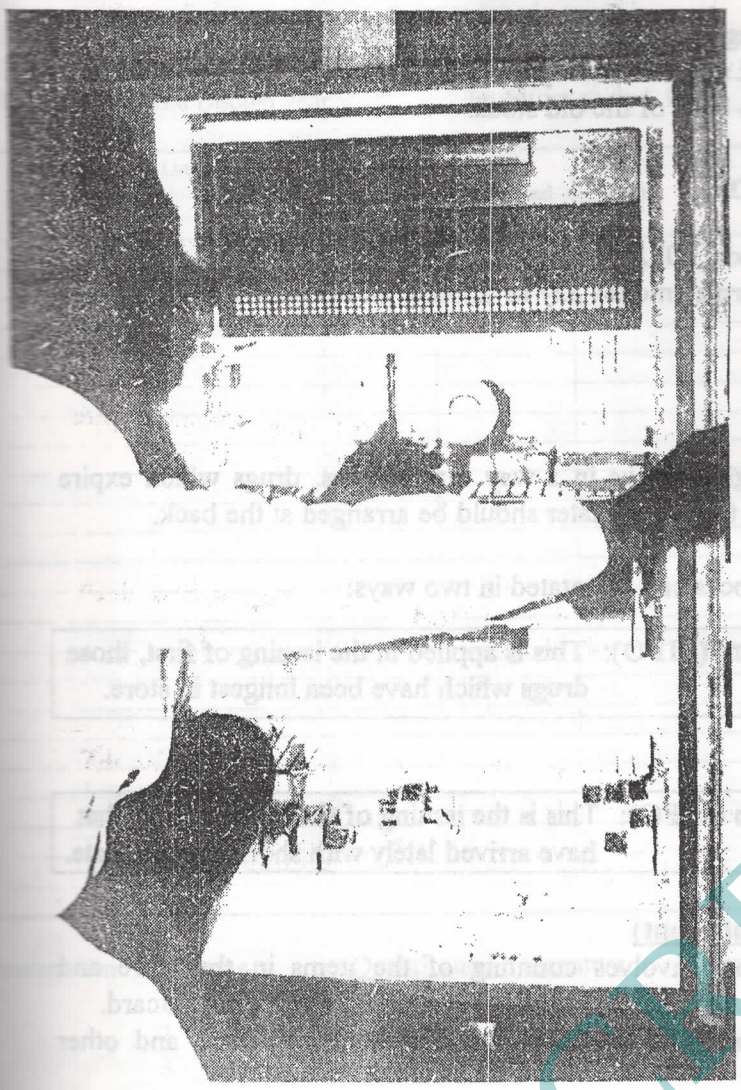
Note: Never freeze DPT or tetanus (which both freeze at temperatures below -3°c).

List of other drug products which require cold storage:

- TAT injection
- Insulins injection
- Anti-A injection
- Anti-B injection
- Anti-D injection
- Blood products

For explanation of specific storage condition see annex II.

CCRDA



Regulating temperature of a Refrigerator in Region 14 Health Bureau.

CCRDA

iii. Stock Keeping

To use the resources effectively select drugs that are given priority, and should be stocked properly using VEN system (See page 9).

iv. Arrangement of Drugs

Arranging drugs properly enables to control shelf-life and simplify accessibility.

Even though the most commonly used arrangements are:

i) Pharmacologic - Therapeutic order
ii) Alphabetic order and
iii) Pharmaceutics order (by dosage form) the most preferred method of arrangement is the pharmaco-therapeutic arrangement for it [illegible] a frame of reference with which health professionals can [illegible].

When the newly arrived drugs have shorter expire date place them in front of the old stock not at the back and when the newly arrived drugs have longer or the same expiry date place them at the back of the old stock.

d. **Issuing of Drugs from Store**

Use a special form (E.g. Model 20) for requesting of supplies from store.
Issue items using issuing forms (model 22) to another health unit or to divisions within the health institution.

e. **Stock Rotation**

Stock rotation means arranging stocks in a way that ensures, drugs which expire early are issued first. Those that expire later should be arranged at the back.

Based on this explanation stocks can be rotated in two ways:

i) **First-in-First-out system (FIFO):** This is applied in the issuing of first, those drugs which have been longest in store.

ii) **Last-in First-out system (LIFO):** This is the issuing of first, those drugs that have arrived lately with shorter expiry date.

4. **Physical inventory (Physical count)**

Physical inventory in a store involves counting of the items in the store and comparing the quantity with the balance in the Stock Record Card and Bin card.
It should also include counting of the item in the dispensary unit(s) and other sections.
Inventory taking should accomplish several purposes, including to:

- know the balance and consumption of drugs and medical supplies and this simplifies "What" and "How much" to request.
- identify surplus, expired and obsolete (outdated) stock;
- promote periodic evaluation of storage conditions and the adequacy of storage facilities, lay out and stock arrangement.

The physical inventory (stock-taking, stock verification, audit) is most commonly done on annual basis. Service stops for a few days while stock clerk/responsible personnel and store keepers count all supply items, identify discrepancies, and reconcile the stock record cards. Physical inventory taking is carried out using inventory sheet. See next page for Sample inventory Sheet.

ECHDA

Table 14. Drugs and Medical Supplies Inventory Sheet

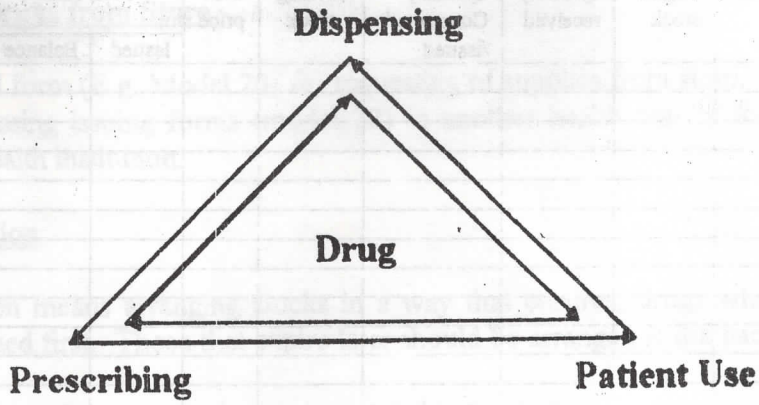
Name of Health Institution _____
Region _____ Zone _____ Town _____ Woreda ____ Tel. _____ P.O.Box _____
Inventory for the Budget year _____ Inventory period from _____ to _____.

Ser No	Description of the Item	Unit	Begn. stock	Quantity received	Quantity Consumed /issued	Ending stock	Unit price	Total Price		Stock out period	Remark
								Issued	Balance		

Inventory done by: Name Qualification Signature Date Approved by: Name _____
1. _____ _____ _____ _____ Qual. _____
2. _____ _____ _____ _____ Sign _____
3. _____ _____ _____ _____ Date _____

CCRDA

Drug Use



CCRDA

Essential points to note:

Rational Drug Use:

- improve patient compliance
- prevents unnecessary exposure to side effects
- reduce treatment expenditure.

Drug Use

Drug Use - is a process of prescribing, dispensing and patient use.

Objectives of Rational Drug Use

To promote safe, effective and cost-effective use of drugs.
Drug use is promoted by:

- rational prescribing practice
- rational dispensing practice and
- appropriate patient use.

Rational Prescribing

Rational drug prescribing requires that the prescriber:

- Makes an accurate diagnosis,
- Decides whether the diagnosis require drug treatment or not,
- Selects the best drug from those available,
- Prescribes the drug in an adequate dose, for sufficient length of time according to standard norms of treatment ,
- follows correct prescription writing and
- Advising/counseling patients.

Appropriate patient use - is adherence to medical advice and taking medicines as directed as well as handling drugs properly.

Role of Dispensers in Promoting Rational Drug Use

Pharmacy technicians, Nurses and health assistants involved in dispensing shall promote rational prescribing, dispensing and patient use by practizing the following:

I. Storing drugs in the dispensary

Once the drugs are in the store, the next step is to keep the needed drugs in the dispensary in the following procedure.

- store drugs securely and properly,
- arrange drugs following an appropriate methods of arrangement preferably pahrmaco-therapeutically,

CCRDA

- label the drugs in the dispensary in such a way that facilitate their ready accessibility,
- use First-in-First-out (FIFO) or List-in-First-Out (LIFO) stock-rotation to use the stock within their expiry-date.
- undertake regular physical inspection on stocked items to check the quality, storage condition, shelf-life and balance.

2. Good Dispensing Practice

Pharmacy technicians, Nurses and Health Assistants, as a dispenser, should follow the following steps of good dispensing practice.

Step 1. Interpreting

Review and confirm prescription:

The dispenser should:

- be certain of the drug product requested
- check if the prescription is legibly and correctly written. S/he should make sure that the prescriber has written.
  - patient's name, sex, age, address, card No.
  - the diagnosis or ICD code No. when necessary.
  - drug's name, strength, dosage form, dose, duration of administration
  - his/her full name, qualification, reg. No., signature, date, etc. correctly.
- check for incompatibility, drug interaction, dosage, direction for use, etc.
- verify incorrectly written prescription with prescribers and make necessary correction with the consent of the prescriber.

Step 2. Retrieval

The dispenser should:

- read the label on the drug container carefully
- counter check the drug against the request
- read the label at least three times during the dispensing process.
  - when picking out from shelf
  - during preparing/processing and
  - during returning the product to the shelf.

CCRDA

Step 3. **Formulating (counting, pouring and measuring)**

Careful countering, pouring and measuring is indispensable in dispensing of pre-manufactured drug products.

While counting, pouring and measuring:

- Take care of short or over count
- Use clean counting tray or spoon for counting
- Use graduated measuring cylinder or flask for measuring liquid medication
- Use small volume measuring cylinder/flask for measuring small volume liquids.

Step 4. **Processing and Labeling**

Label the appropriate containers properly and the label should contain:

- drug's name, strength, dosage form, quantity
- patient's full name
- direction for use
- the name, level and address of the dispensing institution.

And it should be neatly written and carefully displayed .

Step 5. **Delivery of the prepared drug(s)**

- Issue the properly packaged and labeled drug products to patients with clear written and verbal instruction.
- Demonstrate on how to administer the dispensed drugs.
  e.g. - Inhaler Administration
  - Suppository application
- Counsel patients on how to take their medication, about their illness, precautions to be taken etc.

Counseling - is a form of exchanging of ideas and opinions between the dispenser and the patient rather than a unilateral dispensing of information by the dispenser.

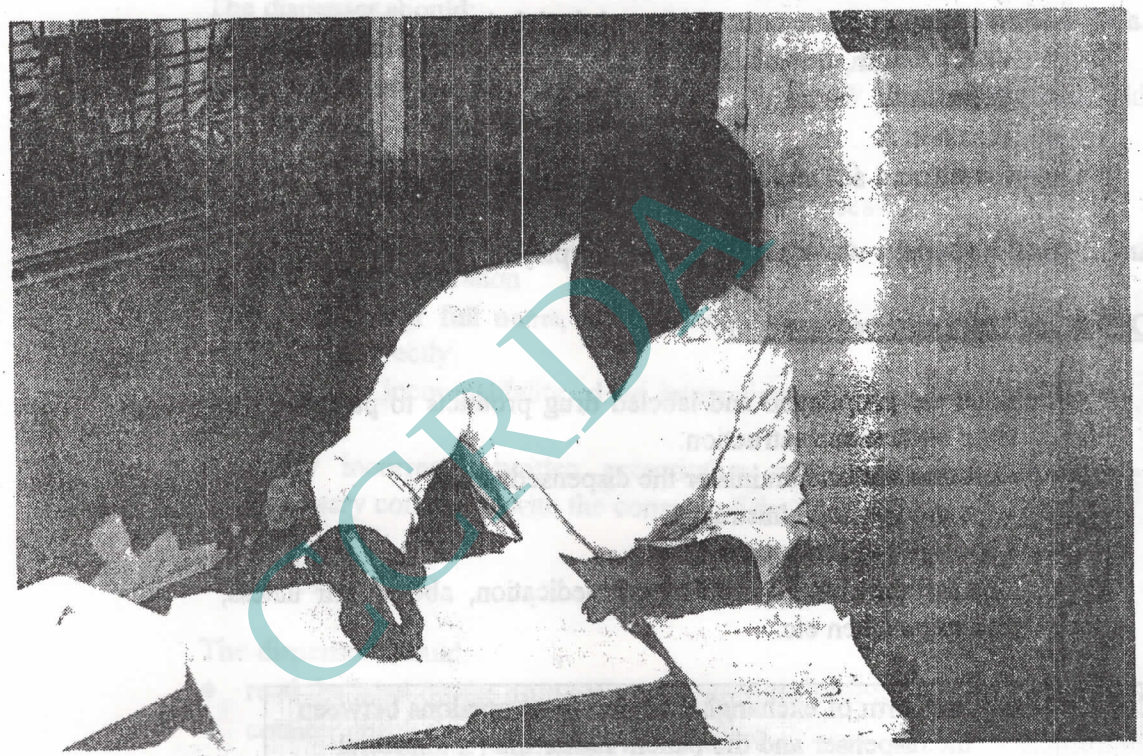
Dispense Narcotic and Psychotropic Drugs using their own prescription paper.

Do not dispense Narcotic and Psychotropic Drugs using other Drugs prescription paper.

CCRDA

3. Recording, documentation and Reporting

- Keep Blank prescription paper carefully in the pharmacy section of the health institution.
- Prescribers should keep prescription paper like their personal cheque.
- Filled prescription papers are the receipt of the pharmacy section of the institution and they should be kept filed in the pharmacy section.
    - filled prescriptions of Narcotics and Psychotropic drugs should be kept for 5 years and other drugs for 2 years.
    - they should be disposed carefully in the presence of MOH inspector.
- Register filled prescription in a Patient Prescription Registration Book.
- Register filled Prescription of Narcotic and Psychotropic Drugs on a separate Patent Prescription Registration Book



CCRDA

Registration of filled Prescription on Patient Prescription Registration book.

Keep Patient prescription Registration Book, receiving and issuing vouchers and other related documents properly.

Descriptions of Patient Prescription Registration Book

Patient Prescription Registration Book could have several variables. Commonly used variables and the formats of the book is illustrated below.

Table 15. Patient Prescription Registration Book.

Ser No.	Date	Patient's				Diagnosis	Treatment (name,strength, dosage form, dose of drug, duration)	Write "F" for free or "P" for paying patients		Unit price		Write "N" for new or "R" for repeat	Source	Remark
		Name	Card No.	Age	Sex			F/P	Rece.No. free let No.	Birr	C			

Remark : Write the name, strength, dosage form and quantity of not dispensed drugs on the remark column.
: Write Rece.No. = Receipt number for paying patient
: Write Free let No. = Free letter number for free patient

FDRE

◊ Review and summarize Patient Prescription Registration Book regularly to:

- calculate actual drug consumption
- determine drug budget: once the consumption is known it is possible to determine drug budget i.e. reconciliation of drugs budget with needs.
- determine the prevalent diseases.
- select drugs - based on the prevalent diseases it is possible to select drugs & hence to prepare list of drugs of the health institutions.
- assess drug utilization to know whether prescribing practice rational or irrational.
- give a clear picture of fast moving drugs in terms of consumption.
- strengthen controlling system: Because there will be counter balancing activity of the issued drugs against filled prescriptions.



Reviewing Patient Prescription Registration Book in one health institution.

CCRDA

Prepare and Report Drug Consumption and Revenue

a. Prepare and Report Drug consumption

The closing link in the drug supply system of health institution is the flow of consumption information back to the concerned supplier and Regional Government Health Bureau.

Prepare regular reports on drug consumption, prevalent health problems/morbidity data and, prescribing pattern from Patient Prescription Registration Book and submit the report to the appropriate body.

If adequate inventory records are kept, the generation of consumption reports should be an easy process.

Health institution should report their annual drug consumption to the concerned supplier using the format shown bellow (Page III).

CCRDA

Table 16. Annual Drug Consumption Reporting Form

Name of Health Institution _____

Region _____ Zone _____ Town _____ Woreda _____

Consumption reporting period from ____ to ____ 19 ____.

Ser No	Description	Unit	Quantity				Balance in stock the end of the year	Value in Birr		Remark
			In stock at the beg. of the year	Received in the year	Total made available	Consu-med in the year		Cons-umed	Balance	

Reported by _____

Signature _____

Date _____

Approved by _____

Signature _____

Date _____

EDRD

Revenue Recording and Reporting

Keep records of revenue generated from the sale of drugs as well as cost of drugs issued freely on weekly, monthly, quarterly and annual basis on a Revenue Recording table as shown below.

Table 17. **Illustrative table for Recording Cost of Drugs Dispensed**

Name of Health Institution Addis Zemen Health Center

Region 3 Zone S. Gondar Town A. Zemen Woreda Kemkem

Ser No	Date/week month	No. of	Cost of sold Drugs	Free patients No.	Cost of drug issue	Total	
						No. of patient	Cost of Drugs
1	1-7/04/87	250	1250.00	100	500	350	1750.00
2	8-14/04/87	300	1570.00	150	800	450	2020.00

Prepare monthly, quarterly and annual report of costs of drugs sold and issued freely from the above table.

Patient and Community Education

Give health education to patients and to community at large to promote rational use of drugs.

The health education may include:

- proper administration of drug
- the good and bad effects of medication
- proper storage of drug
- the merit and demerits of self medication
- precaution, etc.

Patient education

Use the resources and facilities of the health institution to educate patients.

- Give health education on drugs while the patients are waiting for health service.
- Educate patients individually or in group while dispensing drugs.

  Example: Patient counseling service
- Educate patient by displaying posters on wall of the health institution.

Community Education

Community education can be given through:

- mass media such as Radio, Local News Paper
- mass gathering - such as EDIR

CCRDA

Annex I

Drug Defect Reporting Form

Date Reported _____
Date received _____
(of the report)

1. Generic name, Trade name, Strength. Dosage form, Pack size _____

_____

2. Batch number _____

3. Manufacturer _____ Address _____

4. Date purchased/procured _____

5. Source of Product _____

6. Name & Address of Procurement agency _____

7. Name & Address of health facility _____

8. Defects Noted or suspected _____

_____

Reported by :
Name _____
Profession _____
Signature _____

Return to: Drug Administration and Control Department
Ministry of Health
Box 1234, Addis Ababa

ECRDA

Annex II. **Storage temperature and environment**

"... in a dry place"	Relative humidity less than 5%
"... protect from heat"	Not more than 30° c
"... at room temperature"	15 to 30° c
"... in a cool place"	8 to 15° c
"... in a cold place"	temperature not exceeding 8° c
"... in a refrigerator"	0 to 6° c
"... in a deep freezer"	-20 to 0° c

CCRDA

References

1. Managing Drug Supply, Management Science for health, 1989 Edition.
2. Estimating Drug Requirement A Practical Manual, ADDV,WHO 1990 Edition.
3. WHO Expert Committee on Specifications for Pharmaceutical Preparation. 29th Report, WHO, 1984.
4. The Use of Essential Drugs, 3rd report of WHO Expert Committee 1988.
5. Guidelines on the storage of Essential Drugs in Eastern and Southern AFRICA, A Manual for storekeepers, WHO IFPMA, 1991.
6. Uganda Essential Drugs Manual 1st edition 1986.
7. Guidelines for Evaluating an Essential Drugs Programme WHO, DAP/85-8.
8. Financing Essential Drugs : Report of A WHO Workshop Harare Zimbabwe, 14-18 March. 1988.
9. Training course on Drug Quantification Methodologies WHO/DAP 90.9. Bangkok, Thailand.
10. Counterfeit Drugs Report of a Joint WHO/IFPMA workshop 1-3 April 1992.
11. Guidelines for Developing National Drug Policies, WHO, 1988.
12. Management of drug purchasing, storage and distribution, Manual for developing countries, second revised edition by Gerd Dorner, etal, and FIP industrial pharmacists section. 1986.

CCRDA

DRUG INFORMATION

(This is prepared for Nurses and Health Assistants in the training programme organized by CRDA)

CCRDA

By: Asmie Menkir

Drug Administration
and Control Department
Ministry of Health
Addis Ababa, Ethiopia
March 1997

DRUG INFORMATION

I. Introduction

Drug information is the procedure of developing, transferring communicating of factual and sufficiently comprehensive knowledge (written, verbal) on a drug/drug products, dosage form, and its application in therapeutics, to prescribers and consumers.

For the safe, effective, and proper use of drugs, relevant and reliable drug information should be available. This should be undertaken on a continuos basis with periodic monitoring of the activity and impact. The complexity of the task of providing objective Drug information to health professionals and the consumer requires the joint efforts of multi-disciplinary professionals.

Government, pharmaceutical industries, professional organizations, teaching institutions, the medical and pharmaceutical journals, the mass media, the prescriber and the dispenser need to take the responsibility of disseminating objective drug information among themselves and above all to the consumer.

Non compliance to drug therapy is widespread and it is mainly attributable to lack of knowledge and of proper information. The patient thinks that the prescriber gives a prescription routinely, sometimes without a proper examination; the dispenser fails to provide the instructions needed on the package; most patients stop taking the drug(s) when they feel better; some try another prescriber to see if he prescribes the same drugs; and so on. The economic cost of non compliance is also to be considered as an important issue. This calls upon health care providers to fulfill their responsibility for providing information among themselves and also to patients. It is also recommended that information on the utilization of drugs be included in health education programme of the public.

CORDA

Learning Objectives

At the end of the session the participants should be able to:

1. Summarize the need for Drug information.
2. Identify the different levels by which drug information is needed.
3. List down the types of Drug information needed.
4. Demonstrate the means of Disseminating Drug information.

II. Why Do We Need Drug Information ?

A medicinal product must be accompanied by appropriate information. The quality of information accompanying the drug is as important as the quality of the active substance.

In the absence of objective drug information a drug is only a chemical of which its benefit or harm is not known. At times a very safe drug could cause severe harm to health or even be fatal if not accompanied by appropriate information on how, when, how much and for how long it should be taken.

Drug: Chemical(s) + Information

So the need for Drug Information are:

- to promote rational prescribing, Good dispensing practice and appropriate patient use.
- to increase patient compliance
- to promote better care and treatment of patients
- to select the needed drugs
- to facilitate the distribution and storage of drugs.

In this respect, the provision of information on Drugs has a considerable effect on the following activities:

- selection of effective, safe and quality drugs
- procurement of drugs
- distribution and storage of drugs
- use of drugs.

III. Who Needs Drug Information ?

Provision of information about drugs is a prerequisite at all health care levels to ensure their proper utilization and promote rational prescribing. These levels include:

- regulatory authorities;
- physicians;
- pharmacists;
- nurses;
- health assistants and the
- consumer.

CCRDA

The extent to which each type of information is required at different levels varies. A distinction need to be made between the information to be given to prescribers, dispensers and that to be given to patients and the public.

IV. Types of Drug Informations

The types of information required can be classified as:

- ***Chemical***: Description of chemical nature
- ***Pharmaceutical:*** Information on excipients, available dosage forms, strength, storage conditions and shelf-life, pack sizes, legal category (narcotic drug, prescription or non prescription), and name and address of manufacturers.
- ***Pharmacological:*** Brief description of pharmacological effects and mechanism of action.
- ***Clinical:*** Information on indications, contraindications, precautions, side effects, drug interactions, dosage regimen, over dosage.
- ***Economic:*** Information on cost of drugs, (total cost of full course of treatment).

1. Drug Information for Health Professionals

a) For Prescribers*:

The use of any drug without adequate knowledge may be dangerous, but the inclusion of sufficient and concise information with each product should allow the prescriber to achieve optimum effects while minimizing harmful effects.

Prescribers need:

- information that can help them to choose between different treatments;
- detailed information about a particular treatment once it has been selected;
- information on what to tell their patients about treatment including drug therapy.

To choose between different treatments, prescribers need information on:

- effectiveness i.e., does the drug improve the patient's health

*Prescriber: A general term given for health professionals who are practising the act of prescribing drugs to patients. This includes Physicians, Nurses, Health officers and Health assistants

CORDA

- medical indication i.e., is the drug optimally effective in the given circumstances?
- safety
- cost of drugs for the full course of treatment.

It is logical to give the information in the order in which the user needs it, as follows:

- the non-proprietary (generic name) ;
- the therapeutic class of the drug ;
- its pharmacological effects and mechanism of action;
- clinical information i.e. uses, contraindications, precautions, warnings, adverse effects, drug interactions, dosage regimen, over dosage.
- pharmaceutical information: i.e. recommended dosage forms, storage conditions, pack size, legal category, etc.

b) **For Dispensers*.**

The dispensers decides which drug to give to the patient who presents a prescription from the prescriber or forwards his own complaints. To be able to do so, the dispenser needs information about:

- the mode of action of the drug(s) used;
- the potential good and bad effects;
- the factors that influence drug activity and how they relate to patient life style.

c) For the patient

Information to consumers should be presented clearly and simply. When the drug is dispensed, the patient needs information on:

- how to take the drug;
- how to store the drug;
- how it is expected to help;
- how to recognize problems;
- what to do about them.

CCRDA

* Dispenser is a general term given for health professionals who are practising the act of dispensing drugs to patients. This include Pharmacists, Pharmacy technicians, Druggists, Nurses & Health assistants.

Guide to minimum information needed to enable patients to make treatment with a prescribed drug effective and safe.

1. To know how to take the drug;	1.1 To take a specific dose	1.1.1 Amount of drug per tablet or other dosage form 1.1.2 Average dose and dose range, adult 1.1.3 Average dose and dose range, child
	1.2 To take a dose in a specific manner	1.2.1 Manner directed by dosage form or drug
	1.3 To take a dose at specific times	1.3.1 Clock time 1.3.2 Time since last dose 1.3.3 Time since or until food intake 1.3.4 Duration of treatment
2. To know how to store the drug;	2.1 To store it properly	2.1.1 Storage conditions
	2.2 To recognize the time at which the medicine becomes subpotent	2.2.2 Expiry date 2.2.3 Potential consequence of non-compliance
3. To know how the drug is expected to help;	3.1 To recall the basic facts about the complaint	3.1.1 Disease or symptoms to be affected 3.1.2 Potential consequence of compliance 3.1.3 Potential consequence of non-compliance
	3.2 To recognise the desired effect and act upon its absence	3.2.1 Events showing effect 3.2.2 Time at which to expect effect 3.2.3 Direction for follow-up if there is effect

CDRA

If patients are expected to take their medicines, they must be given information as better information may result in better care.

Information that dispensers should consider important for patients includes the:

- action to be taken in the event of a missed dose.
- action to be taken in the event of suspected or confirmed pregnancy.
- aim of the treatment - will it cure or relieve my symptoms ?
- discarding of unused medicine beyond a specific expiry date.
- dosage or amount to be used.
- duration of treatment
- expected side-effects which may be reduced by appropriate action by the patient (e.g. reduction of gastric irritation caused by some non-steriodal anti-inflammatory drugs by administration after food).
- frequency and correct times of administration or use (administrative schedule)
- intended use and expected action, and advice in the event of no apparent effect.
- medicines, food or activities the patient has to avoid during treatment.
- storage of medication.

The above information need to be communicated verbally and in writing.

CCRDA

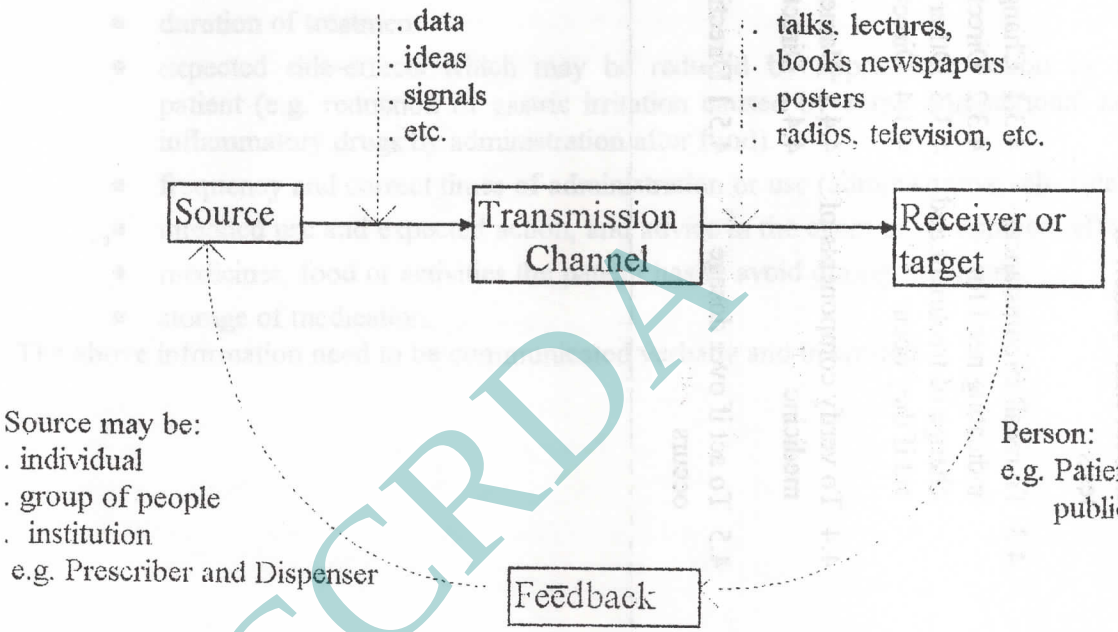
4.2 To recall that certain unwanted effects can only be detected by clinical examination or tests	4.2.1 Unwanted effects that the patient can not observe 4.2.2 Direction for detection of such effects
4.3 To recall circumstances indicating need for change of treatment, and act if they occur	4.3.1 Change in the patient's state 4.3.2 Direction for follow-up of change 4.3.3 Other drug added to therapy 4.3.4 Direction for follow-up of drug addition
4.4 To verify components of medicine	4.4.1 Name of drug and "active" excipient 4.4.2 Direction for follow-up of "action"
4.5 To act if over dosage occurs	4.5.1 Direction for follow-up of occurrence

CCRDA

V. Means of Disseminating Drug Information

Information is fact or a set of facts, and its exchange results in mutual understanding between participants. Thus, it is only when the meaning of a message is understood in the same way by both participants that one can say effective communication has taken place. Communication is the act of meaningful exchange of information.

The flow of drug information follows the same mechanism as that of general information with the :



A feedback being given back for improvement in the next transmission.

Information on drugs may be disseminated to health professionals and the public in a number of ways;

a) **Interpersonal channels** - such as face-to-face communication, community distribution, home visits, training, group discussions, and counseling are generally best for giving credibility to messages, providing information, and teaching complex skills that need two-way communication between the individual and a credible source of information. Interpersonal communication may be verbal and non-verbal. Oral information has to be simple and clear. Non-verbal clues, if we observe them will help us in making contact with other people. As we communicate we are likely to be able to tell from the other person's face how our message is being received: whether our ideas, views, questions, etc. are being listened to, understood, agreed with, etc. We can observe when we might need to repeat or rephrase something, withdraw, etc.

CCRDA

as receivers (listeners) we will need to be aware of using behaviours which show interest; eye contact; nodding; appropriate facial expression; turning towards the speaker; leaning forward if seated, etc. We will be sending signals about ourselves whether we are aware of it or not; how we dress; stand, sit, walk, etc. will all tell others about us. So awareness of what messages we might want to give and how we give them will be important.

Print Channels: Pamphlets, flyers, posters, labels, leaflets, Bulletin, newsletter, formularies, and treatment guidelines are generally considered best for providing a timely reminder of key communication messages. Pamphlets and other graphic materials distributed at the individual or home level can provide complex information in a digestible form, so that the target audience can use that information when it most needs it. Audio visual materials - such as videos, slide tape shows, and flip charts-visually portray key messages during interpersonal communication sessions.

Written materials reinforce verbal information and result in an increase in patient compliance. However, written information is helpful only if it can be understood by the patient.

The label and leaflets are the most important written drug information channels to patients.

Labeling: The labeling of drugs is concerned with the communication of information. The dispenser should preferably check with the patient to ensure that the directions for use are properly understood, and reinforced where necessary by the opportunity for verbal interactive response. Where essential additional information cannot be included on a label, it may be supplied in the form of a leaflet. The label should contain at least the following:

- name and strength of the drug
- dose
- caution
- expiry date

Labeling has three important components that need due consideration-cautionary and advisory warnings, directions, and design of labels.

1. Cautionary and advisory warnings:

Example:
- Do not take milk, iron preparations or indigestion remedies at the same time of day as this medicine.
- This may colour the urine or stool
- Warning: causes drowsiness which may persist the next day. If affected, do not drive or operate machinery. Avoid alcoholic drink.

CCRDA

2. **Directions:**

Make sure that patients are aware of the directions for use.

Written instructions should primarily be regarded as a back-up to the oral counseling.

Example: Suppository:- Empty bowls (if necessary)
- Remove any wrapping from the suppository
- Gently, but firmly, insert the suppository tapered end first in to the rectum
- Wash hands.

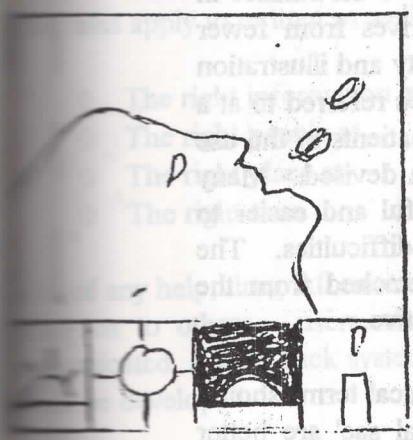
3. **Design of Labels:**

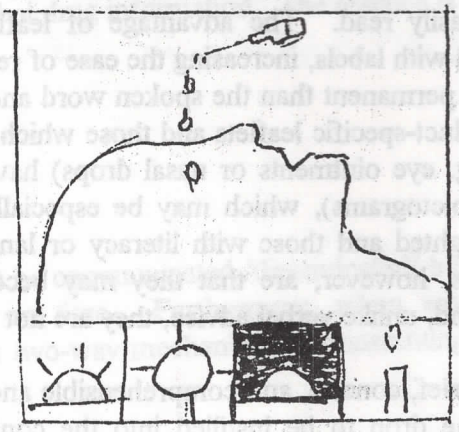
Labels should be clear and readable:

- ◊ keep the letter quality, do not use unnecessary markings or letter style
- ◊ use appropriate colours and black on white paper.
- ◊ use if possible bold type surface for emphasizing, use underscoring for headings only.
- ◊ use lower cases with capitals where appropriate capital may be useful.
  e.g. "ONE to be taken THREE times a day"
- ◊ use pictures to show the quantity to be taken, the period and/or how to apply the medication (see figure 1)

CCRDA

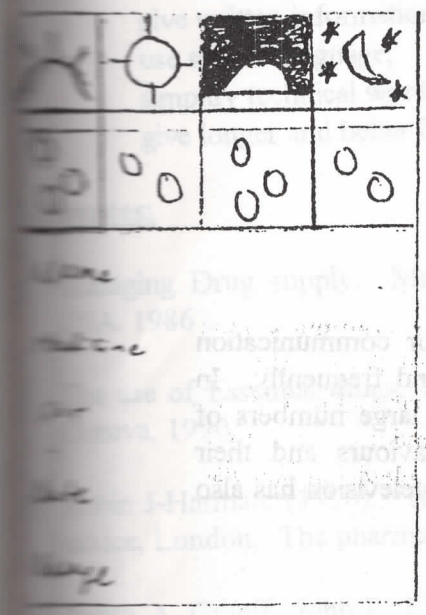
Figure 1:

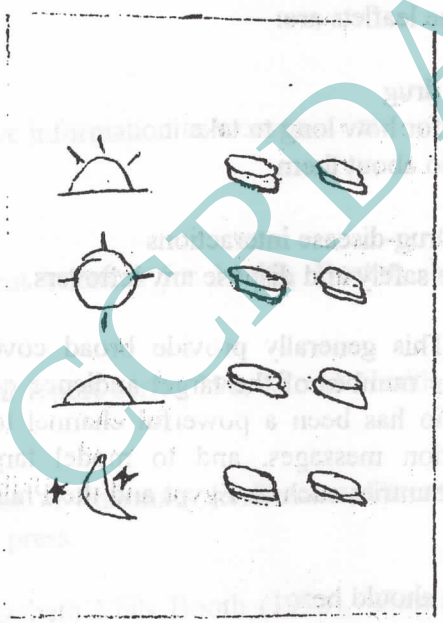




Take 2 tablets 4 times a day

• Put 2 drops in eye 4 times a day





Take 3 tablets in the morning, 2 at midday, 2 in the evening, and 1 at night.

• Take 2 tablets 4 times a day

CCRDA

Leaflets: Leaflets play important part in the communication of information which is too detailed to include on the medicine label. The physical dimensions of many medicine containers are insufficient to allow the necessary information to be affixed to the surface in a print size which can be easily read. The advantage of leaflets derives from fewer constraints on space compared with labels, increasing the ease of readability and illustration potential. They are also more permanent than the spoken word and can be referred to at a later date by the patient. Product-specific leaflets and those which help patients in the use of particular preparations (e.g. eye ointments or nasal drops) have been devised. Many leaflets include illustrations (pictograms), which may be especially helpful and easier to comprehend by the poorly sighted and those with literacy or language difficulties. The main disadvantages of leaflets, however, are that they may become detached from the product to which they apply and, unlike verbal advice, they are not interactive.

The information needs to be brief, concise, and comprehensible and technical terms should be avoided. Phrases like 'one drop to be instilled into the conjunctival sac' are better replaced by 'put one drop in each eye'.

The information covered in the leaflets are:

- Name and strength of the drug
- When and how to take it, for how long to take it
- Side effects and what to do about them
- Precautions
- Drug-Drug, Drug-food, Drug-disease interactions
- How to store the medicine safely and dispose any leftovers.

c) **Broadcast Channels:** This generally provide broad coverage for communication messages, reaching a large number of the target audience quickly and frequently. In developing countries, radio has been a powerful channel to reach large numbers of people with communication messages, and to model target behaviours and their consequences. In some countries such as Egypt and the Philippines, television has also played an important role.

An effective drug information should be:

- clear
- concise
- complete
- convincing
- capable of being used.

CCRDA

these the five 'Cs'.

These rules apply to written as well as verbal drug information. The essence is to see that:

- The right information gets to
- The right people at
- The right place at
- The right time.

For the best of any help, drug information must be communicated /disseminated/ transmitted, i.e. passed on to others - users of drugs on time. Furthermore, when any message is communicated, a feed back system i.e. a two-way mechanism of transmitting information should be developed.

To best communicate important drug information to patients:

- give written information;
- use simple language;
- simplify technical words;
- give longer and better illustrative information to women, ... etc.

References:

Managing Drug supply. Management sciences for health, Boston, Massachusetts, USA. 1986

The use of Essential drugs. Technical report series 796, World Health Organization, Geneva, 1990.

Robin J-Harman, (1990), Hand Book of Pharmacy health-care, Diseases and patient advice, London, The pharmaceutical press.

Judith A. Graeff, John P. Elder, Elizabeth Mills Booth (1993), Communication for health and Behaviour change: A Developing country perspective 1st edition. San Francisco, Jossey - Boss Publishers.

CCRDA

RATIONAL USE OF NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES

BY
TEYIB ABDULKADIR
PHARMACY DEPARTMENT, MOH

CCRDA

RATIONAL USE OF NARCOTIC DRUGS & PSYCHOTROPIC SUBSTANCES

Problems on Rational Use of NPS

1. Availability
2. Prescribing pattern
3. Dispensing pattern
4. USE

Availability

The supply is not adequately assured:

a). Identification of national needs
b). Retailers have become reluctant to stock certain drugs because of the extra storage and record keeping requirements
c). Types of drugs which as a minimum must be available for medical use is not specified
d). Studies envisaging the monitoring of trends in the prescribing and consumption is not available.

Prescribing pattern

a). Patients are not adequately treated either initially or for adequate periods of time.
   - appropriate treatment strategies
   - excessive concern about dependence
   - inadequate accessibility to health care and/or limited availability of drugs.

b). Prescribers are not provided with adequate information on proper drug prescribing & use.
c). Difficulty in pain assessment
d). These drugs are sometimes prescribed for long periods of time with out periodic reevaluation of the need for continuation.
e). Prescriptions are made by practitioners who are not fully aware of the pharmacological properties/Incorrect choice of drug, dosage or duration of administration.
f). Indiscriminate Prescribing/Non-therapeutic Rx. 'Pill for every ill'.

Dispensing

a). In adequate control of prescriptions and psychotropic substances
b). Health professionals are not provided with adequate information
c). Fear of inspection ==> Reluctant to stock
d). Cumbersome handling and record procedures
e). Drug utilization data is not organized

CORDA

f). Information on drug use (consumption/stock is not available ==> No report.

g). Diversion to illicit market and/or dispensed with out prescriptions.

4. *USE*

a). Patients are ignorant of the action of these drugs and of the dangers involved in not taking them as ordered or mixing them with alcohol or other agents.

b). Patients are not well informed about the dose of the drug and any possible reaction with other drugs or alcohol.

c). Drugs are not prescribed on official prescriptions

d). Cheating by abusers.

e). Precaution for combination products, eg. Librax

g). Attitudes influence the prescriber - patient relationship. These include fear, denial, hostility, rationalization and demand.

h). The society attaches stigma to mental illness.

Suggested course of action

1. On the basis of needs, the narcotic and psychotropic substance which as a minimum must be available for medical use must be specified.

2. Professionals should work out agreed guidelines for improving prescription and dispensing practices.

3. Conduct or initiate, studies envisaging the monitoring of trends in the prescribing and consumption of these drugs and on their rational use.

4. Regulate the free distribution of samples of narcotic drugs and psychotropic substances.

Why Monitor the use of Narcotic Drugs and Psychotropic Substances ?

- It is only after careful record keeping of drugs that irregularities and especially diversions from licit to illicit use, can be detected.

- It is important to follow and survey doctors' prescribing and pharmacists' dispensing habits.

- Drug consumption studies can also be used to know the quantity

CCRDA

of drugs used at national, whole sale, hospital, pharmacy and health centre level as well as in self medication.

It is therefore important for many country to develop an effective system for monitoring utilization of drugs.

Drug utilization measurement

As a technical unit of measurement in drug utilization studies the WHO recommends the Defined Daily Dose (DDD) to be used.

"The defined daily dose is the assumed average dose per day for the drug to be used on its main indication in adults."

- The DDD is given as the number of tablets, amps, etc.

- Figures should preferably be presented either as DDD per 100 beds (within hospital drug utilization is presented) i.e. the average proportion of subjects within a community who might be treated with a certain drug, on any given day.

- Hospital drug statistics expressed in DDD/100 bed days may correspondingly give an estimate of frequency of drug use.

CCRDA

Control Activities of Narcotic Drugs and Psychotropic Substances

I. Introduction

The history of the human race has also been a history of drug use. Since earliest times, herbs, roots, bark, leaves and plants have been used to relieve pain and help control disease. In and of itself, the use of drugs does not constitute an evil; drugs, properly administered, have been a medical blessing. Unfortunately, certain drugs also initially produce enticing side effects, such as a feeling of euphoria, a sense of feeling good, elation, serenity and power. What began as something of a recreational activity evolved in time into a problem of dependence and abuse.

Expansion and development of international transport and trade in modern times have effectively reduced distances between countries. Plants and drugs that were formerly of local significance have become familiar and available in other parts of the world, enabling drug traffickers to become one of the most serious international crimes.

It has become generally accepted that the production, sale and consumption of drugs should be controlled by Governments, and the reasons for the establishment of a world wide system of control over drugs and other dangerous substances have been humanitarian and social. The aim of drug control system is to restrict use to medical and scientific requirements.

Abuse of drugs has detrimentally affected individual consumers and the societies in which they live. With varying effects and extent, abuse of drugs can cause very serious physical, psychological, emotional, behavioral, social and financial problems for individuals. It can also result in poor performance at school and at work, as well as in strained and perhaps unsuccessful interpersonal relations, especially within a family setting.

As it is mentioned in the aforesaid paragraphs the abuse and traffic of drugs have many consequences to the individual, community and a nation as a whole. Thus, it is important to given priority to the control of drugs. The establishment of effective and efficient monitoring systems is an important element in controlling the diversion of narcotic drugs and psychotropic substances from licit to illicit markets. Further more, every effort must be made by all interested states to suppress the illicit cultivation of narcotic plants and the illicit production of narcotic drugs and psychotropic

CCRDA

substances.

II. Learning Objectives

The general objective of this paper is to introduce the general elements of drug control activities of Ministry of Health. Efforts was also made to stress on the general ways and mechanisms of proper use of narcotic drugs and psychchotropic substances within different premises. Furthermore, the aim of this presentation is, to aware professionals about the ill effects of drugs and thus, would contribute their part in the rational prescribing, dispensing and use of these controlled drugs.

III. Instruments of control

The world wide control of drugs is based on the international treaties concluded between 1912 and 1988 with the aim of ensuring that the controlled drugs are used exclusively for medical and scientific purposes. The operation of the international system is based, in turn, on national control by individual states within the limits of their Jurisdiction. To comply with the provisions of the treaties, parties are obliged to adopt appropriate legislation, introduce necessary administrative and enforcement measures and cooperate with the international drug control organs, as well as with other countries.

The earlier treaties were summed up, revised and strengthened by the Single Convention On Narcotic Drugs, 1961, and the 1972 Protocol Amending this Convention. The resulting convention, as amended, provides for strict controls of cultivation of the Opium poppy, the coca bush and the cannabis plant as well as their products. it also regulates the use of a considerable number of opiate like dependence producing substances, synthesized by scientific methods and manufactured industrially. The convention stresses the need for treatment, rehabilitation and social integration measures, and emphasizes prevention, drug information and education activities.

The convention on Psychotropic Substances, 1971, extends the international drug control system into new areas of psychoactive substances, such as central nervous system stimulants (e.g. amphetamines), sedative-hypnotic (e.g., barbiturates) and hallucinogens (e.g., LSD and mescaline). The controlled substances are subjected to varying degrees of control in trade, manufacture, distribution and use depending on the balance between therapeutic usefulness and risk of dependence-production and degree of public health and social problems of abuse. There are special provisions for treatment, rehabilitation and social reintegration of abusers, and for prevention.

The United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988, is designed to hit drug traffickers where it hurts them most: by depriving them of ill gotten financial gains and freedom of movement. One of the innovative provisions of the 34 article convention concerns the tracing, freezing and confiscation of proceeds and property derived from drug trafficking. To that effect, courts are improved to make available or to seize bank, financial or commercial records. Bank secrecy cannot be invoked in such cases. In addition to providing for the criminalization of drug trafficking offenses, the 1988 convention bars all havens to drug traffickers, particularly through its provisions for: extradition of major drug traffickers; mutual legal assistance between states on drug related investigations; and the transfer or proceedings for criminal prosecution.

Ethiopia is a party to the Single Convention on Narcotic Drugs, 1961 and the 1971 Convention on Psychotropic Substances. In accordance with the stipulations of the conventions the Ministry of Health, Pharmacy Department is a central body to exercise all control measures to reduce the supply and demand for drugs and there by limit the use of drugs to exclusively medical and scientific purposes.

The principal laws under which Narcotic Drugs and Psychotropic Substances regulated in Ethiopia are:-

a. The Penal Code of 1956;
b. The Pharmacy Regulation of 1964.

The basis of general drug control legislation is the Pharmacy Regulation of the 1964, which regulates the supply of pharmaceutical products at all stages, including registration, manufacture, import, export, storage, quality control and distribution.

IV. Drugs under International Control

The stated general purpose of the conventions is that the parties shall limit, subject to a few special provisions, by appropriate measures, the production, manufacture, export, import, distribution and stocks of, trade in, and use and possession of controlled substances to medical and scientific purposes.

In December 1993 the United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances listed ***22 precursor chemicals,*** the Single Convention listed ***131 narcotic drugs*** where as the Psychotropic Substances Convention controlled ***105 psychotropic substances,*** in the last two cases divided into four schedules associated with varying

CCRDA

levels of control. It should be pointed out, however, that the sets of schedules in the two conventions correspond to different levels of control. While there is a certain broad parallelism between the controls exercised by the conventions, there are also significant differences in detail; a simplified description is therefore given below for each convention.

The placing of a substance in a particular schedule depends on the balance between its therapeutic usefulness and its abuse potential. The substances most strictly controlled have little therapeutic application; they are mainly used, if at all, in scientific research, and are further more liable to heavy abuse. In contrast, the list strictly controlled substances have wide therapeutic use and more limited abuse potential.

A. The Single Convention

Schedule I. This is the major schedule; it lists all substances in the opiate, cocaine and cannabis groups and subjects them to all the specified controls of the Convention. Fentanyl, Methadone, Morphine and Pethidine, listed in this schedule, are included in the National List of Drugs for Ethiopia.

Schedule II. In general, this includes the drugs more commonly used for medical purposes and needing less strict control because of the smaller risk of abuse. The important differences, as compared with schedule I, are that the controls of trade and distribution are less strict. Medical prescriptions are required for schedule II drugs. Codeine, listed in this schedule, is included in the National List of Drugs for Ethiopia.

Schedule III. This includes preparations containing as ingredients schedule II drugs in lower concentrations and in controlled proportions, as well as preparations that have been found by WHO not to be liable to abuse, that cannot produce ill effects, and from which the controlled drug is not readily recoverable.

Schedule IV. This includes a few drugs regarded as having particularly dangerous properties but very limited therapeutic use, and in respect of which the parties may totally prohibit production, manufacture, export, import, trade or possession, the main exception to the prohibition being use in research under their control.

CCRDA

B. The Psychotropic Substance Convention

Schedule I. This includes the hallucinogen group LSD, DMT, Psilocybin, etc. which are drugs of a dangerous nature posing a serious risk to public health, and a doubtful, if any, therapeutic use. Controls over these drugs are of the strictest nature, and include special provisions for very firm controls to limit their use chiefly to research.

Schedule II. This contains stimulant sympathomimetic drugs of the amphetamine type, of very limited therapeutic usefulness, but also certain narcotic analgesics such as phencyclidine, which is of no human therapeutic usefulness. These are all drugs known to be highly addictive, and the controls over them are generally the same as for schedule I but without the special control measures prescribed in the provisions of the convention.

Schedule III. This includes those fast medium acting barbiturates that have been seriously abused, although they are therapeutically useful. The requirements are similar to those for drugs in schedule I and II, but there is no requirement for import and export authorization and for full statistics of production and use, etc., for submission to the United Nations. Pentazocine and Pentobarbital, listed in this schedule, are included in the National List of Drugs for Ethiopia.

Schedule IV. This includes a variety of hypnotic, tranquillizing and analgesics that have marked addictive properties, but widely used therapeutically although, in number of countries, some of them are not so used. Bromazepam, Chlordiazepoxide, Clonazepam, Diazepam, Medazepam, Oxazepam, Phenobarbital and Temazepam, list in this schedule, are included in the National List of Drugs for Ethiopia.

V. Drugs under National Control

In view of the fact that the number of narcotic drugs and psychotropic substances has been steadily increasing during the past few years, and seems certain to continue increasing, it is important to limit the number of narcotic drugs and psychotropic substances to be used nationally. This would ensure that only narcotic drugs and psychotropic substances which are necessary for medical care of the population and research are put on the market. Accordingly, Ethiopia has included the very important and essential narcotic drugs and psychotropic substances in the National List of Drugs for Ethiopia.

CCRDA

Narcotic Drugs and Psychotropic Substances internationally controlled and that are approved for use and included in the National List of Drugs for Ethiopia are:

a) Narcotics

1. Codeine
2. Fentanyl
3. Methadone
4. Morphine
5. Pethidine

b) Psychotropic Substances

1. Bromazepam
2. Chlordiazepoxide
3. Clonazepam
4. Diazepam
5. Medazepam
6. Oxazepam
7. Pentazocine
8. Pentobarbital
9. Phenobarbital
10. Temazepam

VI. Ministry of Health as a Regulatory Authority

As it is stated in the aforesaid paragraphs, Ethiopia is a party to the Single Convention on Narcotic Drugs, 1961 and the 1971 Convention on Psychotropic Substances. In accordance with the stipulations of the conventions the Ministry of Health, Pharmacy Department is a central body to exercise all control measures to reduce the supply and demand for drugs and there by limit the use of drugs to exclusively medical and scientific research purposes.

Since parties to the conventions must subject the manufacture of, trade in & distribution of substances annexed to the 1961 and 1971 conventions to a license or other similar control measures by establishing a special administration, pursuant to the provisions of treaties on narcotic drugs and psychotropic substances the Ministry of Health had established a Division for the control of Narcotic Drugs and Psychotropic Substances under the Pharmacy Department.

The Division has the responsibility to endeavor to ensure a balance between demand for and supply of narcotic drugs and psychotropic substances for medical and scientific purposes, a matter of recent concern to the international community. Moreover, the Division, in cooperation with the police force and customs administration, is to endeavor to prevent illicit drug cultivation, production, manufacture, traffic and use.

The Division is also working closely with the Regional Health Bureaus. The Regional Health Bureaus are responsible to follow up and control the distribution, handling, prescribing, dispensing of narcotic drugs and psychotropic substances within their respective regions.

CERDA

VII. Proper use of Narcotic Drugs and Psychotropic Substances

There is evidence that the supply of narcotic drugs and psychotropic substances is not always adequately assured in every country. The identification of national needs and the assurance of an adequate supply of essential drugs are a first priority in any system of health care. At the same time, overuse and misuse of narcotic drugs and psychotropic substances should be avoided.

In some countries there are indications that most prescriptions for narcotic drugs and psychotropic substances are made by medical practitioners who may not be fully aware of their properties and potential for misuse and abuse. In addition, these drugs are sometimes prescribed, without thorough evaluation and diagnosis, to a large population of patients for long periods of time without periodic re-evaluation of the need for their continuation.

The rational use of narcotic drugs and psychotropic substances is frequently hindered by incomplete and often inaccurate data. National health authorities, academic institutions, health professional organizations and others often do not provide adequate information on proper drug use to health professionals.

In some countries, national or international controls unintentional affect the supply and distribution of narcotic drugs and psychotropic substances, thereby indirectly affecting the availability of these drugs for legitimate medical purposes. In some cases, retail outlets have become reluctant to stock certain drugs because of the extra record keeping imposed by national authorities. This has led to serious problems in availability of these drugs. This has led to serious problems in availability of these drugs. This kind of restricted availability can have dire consequences for the proper treatment of serious medical problems and such consequences should not be overlooked.

A. *Manufacture, Import & Export*

None of the nationally controlled drugs are manufactured locally. Ethiopian Pharmaceutical manufacturing is compounding;

- codeine phosphate in the form of tablet and syrup and
- phenobarbitone in the form of tablet

Narcotic drugs are imported only thorough government agency and is used in health institutions. On the other hand psychotropic substances are imported through private and government agencies. None Governmental Organizations are also allowed to import psychotropic substances for medical use.

CCDA

Importation of such substances require separate import authorization certificate on established forms for each import whether it consists one or more substances.

Import authorization certificate must state the generic name the quantity, the dosage form the name and address of both exporter and importer, and the period within which the import must be effected. The export authorization must also state the number and date of the import authorization as well as the issuing authority. When the importation has been effected, the export authorization must be returned with an endorsement certifying the amount actually imported.

Ethiopia doesn't export any of the internationally controlled drugs.

B. *Distribution*

The International Treaties and the Pharmacy Regulation of 1964 require all persons and enterprises engaged in the manufacture, trade and distribution of the controlled substances to be licensed, and the establishments and premises where such activities take place to be controlled through inspections. Where ever possible, the wholesale and retail distribution of drugs should therefore be restricted to those persons and enterprises having adequate storage facilities at their disposal.

Narcotic drugs are used in hospitals and health centers under medical doctor supervision. While psychotropic substances are dispensed through health institutions, pharmacies and drug shops. The Ministry has prepared and distributed different forms which are useful for distribution within and outside of the Institution.

Since, control of the national distribution network is an obvious prerequisite the Ministry has prepared a serially numbered and accountable prescriptions papers in duplicate.

The Division has taken measures to ensure that prescriptions for these substances are issued in accordance with sound medical practice and subject to such regulation as will protect the public health and welfare by preparing serially numbered and accountable prescriptions and guide lines directing a well-founded general safety precaution for their use.

C. *Prescription and Dispensing against Prescription*

As already emphasized, the basic goal of the convention is to limit the use of narcotic drugs and psychotropic substances to medical and scientific purposes; the great

CCRDA

physician. In view of the liability of these substances to produce dependence and abuse, this is well founded general safety precaution for their use.

Rational for preparing standard and uniform narcotic drugs and psychotropic substances prescription papers:-

- The prescription papers prepared and used by most health institutions were different and didn't have full information and lack proper procedures.

- Some health institutions had some of their prescription papers printed and some of them were prepared on pieces of papers and yet they were not used properly.

- In some health institutions, prescription papers were found thrown else where, and as a result of this improper handling, any health worker or other non-professionals could prescribe the desired drug and could possibly get whatever drugs they want freely from the health institutions or through purchasing from others.

- The prescription papers which were used in the health institution didn't have serial numbers. Care was not taken in handling. Since the dangerous drugs were not sorted out and recorded, it was difficult to follow up and control.

- It has been revealed that, in some health centers and clinics there was no use of prescription papers at all. So drugs were prescribed on the patients card. In case the patient's card was lost, it was difficult to know the type & the amount of drug given.

The Ministry of Health on the basis of its responsibility to maintain the health of the society, is making effort to prevent and/or avoid the problems of health due to abuse of dangerous drugs prior to their being spread. In order to special printed prescription papers. This is believed to be one of the solutions to the prevailing problems pertaining the improper prescribing of narcotic drugs and psychotropic substances.

This guideline has been issued, so that the use of the newly prepared prescription papers for narcotic and psychotropic drugs, in various health institutions should be performed in proper manner and be able to guide in the same manner of performance. Aware of this, each relevant health institution is required to make maximum effort to carry out the responsibility vested on properly.

CGRDA

The main aim of printing of these prescription papers is in line with the action on **"LIMITING NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES FOR LEGITIMATE USE ONLY"** and to assure their rational utilization in the legally operational health institutions. Besides to this the introduction of the prescription papers homogenizes, the now messy prescribing practice throughout the country.

Therefore the following responsibilities are vested on the prescriber, pharmacist and nurse.

The prescriber;
The following are very important points to be borne in the mind of the prescriber:

- Treat prescription pads like a personal check book.
- Before you prescribe be sure that, it is the right prescription pad.
- Don't prescribe more than one Narcotic Drug or Psychotropic Substance on a single prescription paper.
- Fill everything that the prescription requests to.
- Make your prescription clear, legible, complete & signed
- Handout original prescriptions to the patient but leave the copy undetached.
- Return unused prescriptions pads to the Nurse.
- Don't detach erroneous prescription papers from the pad
- Be alert of drug abusers.

The Pharmacist should;
- procure enough quantities of the prescription papers at all times.
- not dispense illegible, incomplete and unsigned prescriptions.
- supervise the appropriate usage of the prescription papers.
- keep records, compile and report to the Pharmacy Department (MInistry of Health).
- disseminate information, guidelines ... etc. to the staff through appropriate media.

CCRDA

The Nurse should;

- store optimum quantities of the pads.
- provide adequate security to the pads.
- submit prescription pads to the prescriber & collect the pads at the beginning and at the ending of the working hours.
- keep necessary records, compile and report to the pharmacy section of the health institution.
- report any theft or misuse to the pharmacy section.

D. Records and Reporting

According to the International Treaties and the Pharmacy Regulation of 1964 records of the movement and handling of the controlled substances should be kept in the whole area of manufacture, whole sale and retail trade, and in scientific and research institutions.

Thus the quantities imported, distributed, disposed and kept in stock must be clearly recorded for all substances under control.

The records kept and the reports furnished to the Ministry of Health must be at least sufficiently detailed to enable the Ministry to provide the International Narcotics Control Board with estimates of the total annual requirements of each controlled substance, and later with statistical data on the actual manufacture, international trade and consumption.

The Ministry of Health requires reports from each organization such as from Importers.distributors every quarter, from retail Pharmacies twice a year ... etc.

E. Inspection

Both conventions and the Pharmacy Regulation of 1964 require parties to exert formal control over persons and enterprises engaged in the manufacture, trade (including international trade) and distribution of controlled substances.

All persons carrying on or engaged in these activities must be controlled under license, state enterprises like hospitals, health centers, etc... are exempted from such licensing.

CCRDA

Both conventions and the Pharmacy Regulation of 19 require that all persons who obtain licenses or are otherwi authorized in accordance with the control measures that th impose "shall have adequate qualifications for the effecti and faithful execution of such (relevant) laws a regulations".

VIII. Major Achievements

The Division was established in 1986 since then, th Division has contributed in limiting Narcotics a Psychotropic Substances for medical and scientific purpose by avoiding all possible loop-holes for abuse.

The major achievements include:

- organizing the control mechanisms to achieve a natio equilibrium between demand for and supply of narco drugs for licit purposes and to prevent their diversi to illicit channels. For the purpose of contr guidelines, regulations and different reporting forms ha been prepared and distributed.

- aware of the psychoactive properties of these drug their addiction liability and their potential for misu and abuse the Ministry has prepared serially numbere accountable prescription papers for narcotic drugs a psychotropic substances, aimed at providing data t improve drug prescribing and drug consumption.

- import authorization certificate had been prepared t avoid drug diversion and to control imports of drugs.

- organizing a national committee to establish coordinati between different law enforcement and Ministries whi have role in the control of substance abuse has be tried.

- facilitating treatment for drug abusers in cooperati with police and psychiatry hospital.

The above mentioned achievements being the major ones th Division is expecting to promote prevention, treatment a rehabilitation further.

IX. Problems Encountered

1. Full picture of the nature and extent of the proble which may usefully assist in guiding program develop and mobilizing resources and ensuring their best use, not investigated.

CCRDA

2. Exchange of information between responsible agencies and the Ministry of Health is limited. Due to this the trend in drug abuse and illicit trafficking is not well known. As a result this our reports to United Nations don't show the full picture of the problem to attain international assistance.

3. The reports on the movement of drugs stocked by retail outlets, non-governmental relief organizations and health institutions are not established on regular basis despite our effort to extend directives and guidelines instructing to report at least twice a year.

4. The penal measures for trafficking offence is not updated in accordance with international national situation. Due to this, drug traffickers are using our airline and our capital city as a transit point.

5. Treatment, after-care and rehabilitation for drug addicts is not developed.

6. The society is not well aware of drugs and the ill-effects associated with drug abuse and illicit trafficking.

X. Future Plan of the Division

1. Undertake epidemiological survey to determine drug abuse patterns in special groups and environment such as schools, work places, major cities and towns; in respect of each type of drug of abuse, the connection (if any) that exists between drug addiction and a variety of social, economic and cultural factors.

2. For all levels of educational institution the development of drug abuse prevention curricula and instructional materials, taking into account cultural values and traditions an emphasizing the benefits of a healthy drug free life-style.

3. Review the national law and practice to ensure that illicit drug production, supply and trafficking offenses are punishable by adequate measures.

4. Developing and maintaining a comprehensive treatment, after care, rehabilitation and social reintegration for drug addicts.

5. Establishing inter ministerial committee to develop coordination, information exchange, to link together all activities related to drug abuse, to mobilize resources and ensure their best use. The committee should be

GCEDA

established by law so as to define its authori requirements, responsibility and organizatio structure.

6. Create public awareness thorough media disseminat information on the hazards associated with drug abuse illicit trafficking.

Reference

1. The United Nation and Drug Abuse Control (United Nati publication, Sale No. E.92.I.31).
2. Declaration of the International Conference on Drug Ab and Illicit Trafficking and Comprehens Multidisciplinary Outline of Future Activities in D Abuse Control (United Nations publication, Sales E.88.XI.1).
3. Rexed R. & Edmondson K., Guidelines for the Control Narcotic and Psychotropic Substances, WHO, Geneva, 19

CCRDA

Annual Reports of Psychotropic Substances

Movement

Name of Reporting Health Institution ..... Address .....

These Reports relate to the calander year 19.....

Artistic Printing Enterprise/1997

S. N.	Psychotropic Substance	Strength	Dosage Form	Balance as at December 31, 19.....	Quantity purchased during the year	Purchased from	Consumption during the year	Stock as at December 31, 19.....

CCRDA

Remark:

Report on the following Psychotropic Substanes is required.

a) Bromazepam
b) Chlordiazepoxide
c) Clonazepam
d. Diazepam
e. Mcdazepam
f. Oxazepam
g) Pentazocine
h) Pentobarbital
i) Phenobarbitone
j. Temazepam
k) Others if present

Annual Report of Narcotic Drug and Psychotropic Substance

Prescriptions Movement

Name of Reporting Health Institution ..... Address .....

These reportsrelate to the calander year 19 .....

Artistic Printing Enterprise /1937

Type of prescription	PURCHASED			CONSUMPTION		BALANCE	
	Quantity in pad	Serial No. From.....To.....	Invoice No.	Quantity in pad	Serial No. From .....To.....	Quan ity in pad	Serial No. From.....To.....

CCRDA

Remark:

— This form should be completed and sent every year to the Pharmacy Department
— Report should be made at the end of December of each year

የኢትዮጵያ ሽግግር መንግሥት
በሐሪዋ የመድኃኒት ፖሊሲ

NATIONAL DRUG POLICY

OF THE

TRANSITIONAL GOVERNMENT OF ETHIOPIA

ግንቦት 1986

Nov. 1993

አርቲስቲክ ማተሚያ ቤት
ARTISTIC PRINTERS

CRDA

10.6 Appropriate means shall be designed to ensure that drug researchers receive rewards and patent rights for their research findings.

11. Drug Pricing

The government shall make all efforts to make sure that the public gets drugs which are within its means.

12. National, Regional and International Relations

12.1 National, regional and international relations shall be established with the aim of strengthening and expanding the sector.

12.2 Due attention shall be given to the implementation of conventions on narcotics, psychotropic drugs, radio-active pharmaceuticals and poisons, which the country is signatory to.

13. Policy Enforcement

Relevant laws, regulations and rules shall be instituted to enforce the policy.

CCRDA

CONTENT

ገጽ

Page

1. መግቢያ 1

2. የፖሊሲው ዓላማ 5

3. አጠቃላይ ፖሊሲ 6

4. አጠቃላይ ሥልቶች 8

5. INTRODUCTION 18

6. OBJECTIVES OF THE POLICY 22

7. GENERAL POLICY 23

8. GENERAL STRATEGIES 25

9. Traditional Drugs

9.1 Attention shall be given to strengthening the sector through research and development. Research priorities shall be given to those traditional drugs which are in wide use.

9.2 Favourable conditions shall be created for the application of traditional drugs ascertained to be safe and effective for treatment. Private participation in the field shall be encouraged.

10. Research and Development

10.1 Favourable conditions shall be created for the introduction of appropriate technology and know-how to vitalize the drug sector. The government shall provide appropriate incentives and support to those engaged in such activities.

10.2 Appropriate means shall be instituted to strengthen the drug sector through research and development. Research and development activities shall be conducted at drug manufacturing plants, compounding laboratories, training and research institutions, etc.

10.3 An independent research centre shall be established to carry out drug research and development.

10.4 Research and studies shall be undertaken on procurement methods, stock management, distribution, use of drugs, etc. in order to strengthen the pharmaceutical service's quality and competence at all levels.

CRDA

8.Drug Use

8.1 A list shall be prepared to show prescription and non-prescription drugs.

8.2 A standard prescription form to be used all over the country shall be instituted and its usage shall be controlled.

8.3 Health practitioners shall be advised and encouraged to prescribe drugs in their generic names.

8.4 Drug dispensing shall be undertaken and closely monitored by licensed professionals. Licensed professionals and enterprises shall be monitored and controlled to ensure that they comply with the rules of drug dispensing.

8.5 A pharmacist shall have the right to dispense generic drugs as substitutes for prescribed brand names.

8.6 Appropriate education, promotion, counselling, etc. shall be offered in every possible way to raise public awareness about drug use.

CCRDA

የኢትዮጵያ ሽግግር መንግሥት

ብሔራዊ የመድኃኒት ፖሊሲ

መግቢያ

በአሁኑ ወቅት ኢትዮጵያ በኢኮኖሚ ዕድገትና በሕዝብ የኑሮ ደረጃ በዓለም በጣም ዝቅተኛ ናቸው ተብለው ከሚታወቁት ሀገሮች አንዷ ናት። ለዚህ ሁኔታ መሠረታዊው ምክንያት ለዘመናት በሀገሪቱ ሠፍኖ የነበረው ኋላቀር ሥርዓት ሲሆን፣ ባለፉት ዓመታት ተከስተው የነበሩት ሰው ሰራሽና የተፈጥሮ አደጋዎች ከፍተኛ አስተዋጽዖ አድርገዋል። በጤናና በመድኃኒት ዘርፉ የሚታዩትም አበይት ችግሮች የነዚህ ጥምር ውጤት ነፀብራቅ ናቸው።

የመድኃኒት ዘርፉ አደረጃጀት፣ አመራርና የአገልግሎት ሥርዓት ሲመረመር ጎልተው የሚታዩት አጠቃላይ ድክመቶች ከሰፊው ሕዝብ ፍላጎትና አቅም ጋር ያለመገናዘብና ለመስኩ ሊውል የሚችለውን ውስን ሃብት አግባብ ባለው፣ በተቀላጠፈና ውጤታማ በሆነ መንገድ አለመጠቀም ናቸው።

በዘውድ አገዛዝ ዘመን ለመዘርጋት ከተሞከረው የጤና አገልግሎት አኳያ የግሉን ዘርፍ ያሳተፈ የመድኃኒት አቅርቦትና አገልግሎት ተዘርግቶ ነበር። ይህንንም ሥርዓት ለማስተዳደር አንዳንድ ሕጎችና ደንቦች በተበታተነ መልክ ወጥተዋል። በዘመኑ እነዚህን ሕጎችና ደንቦች በተግባር ከማዋል ችግር በተጨማሪ፣ መሰኩ ካስመዘገባቸው መጎልበትና መዳበር እንዲሁም ሀገሪቱ ካሳየችው መጠነኛ ዘመናዊነት ጋር ሕጎቹ በየጊዜው እየተሻሻሉ ባለመምጣታቸው ከወቅቱ ሁኔታ ጋር በሚፈለገው ደረጃ ሊጣጣሙ አልቻሉም።

ደርግ የመንግሥት ሥልጣንን ከያዘ በኋላ "የመሠረተ ጤና ክብካቤ ሥልት" የሃገሪቱ የጤና አገልግሎት የሚመራበት መመሪያ ሆኖ እንዲሠራበት ቢደረግም በዚህ ሥልት ከተጠቀሰው የመድኃኒት ጉዳይና በ1977 በተነደፈው የ10 ዓመት ፕሮግራም ውስጥ ከተጠቆሙ ነጥቦች ሌላ መድኃኒትነክ ፖሊሲ፣ ሕግ ወይም ደንብ አልወጣም። በወቅቱ የተደረገ እንቅስቃሴ ቢኖር በመድኃኒት ዘርፍ የግል ባለሃብቶችን ተሳትፎ በማዳከም የመንግሥትን ድርሻ ለማጎልበት የተደረገው ጥረት ነው። በሌላ በኩል ከፍተኛውን የመንግሥት ትኩረት የሳበው ጦርነት ስለነበር ለሕዝብ የሚቀርበው መድኃኒት በዓይነትና በመጠን እየቀነሰ በመምጣቱ ከሌሎች የተፈጥሮ ችግሮች ጋር እየተዳመረ የጤና ችግሩን እንዲባባስ አድርጎታል።

ሰፊው የኢትዮጵያ ሕዝብ የሚያጋጥሙትን የጤና ችግሮች ለመከላከልም ሆነ ለማከም ባብዛኛው የሚጠቀመው በሀገረሰብ መድኃኒቶች መሆኑ እየታወቀ የሀገረሰብ መድኃኒቶች ደህንነታቸውና ፈዋሽነታቸው በጥናት እየተረጋገጠ በስፋት ሥራ ላይ የሚውልበት መንገድ ለመፈለግ የተደረገው ጥረት በጣም አነስተኛ ነው። የነበረውም አነስተኛ የምርምር አቅም በመድኃኒት ዘርፍ የሚታዩትን ተጨባጭ ችግሮች በመፍታት፣ በተለይም ጎብረታሰቡ በስፋት የሚጠቀምባቸው የሀገረሰብ መድኃኒቶች ደህንነትና ፈዋሽነት በማረጋገጥ ላይ ያተኮረ አልነበረም።

በአቅርቦት ረገድ በሀገር ውስጥ ዘመናዊ መድኃኒትን የማምረት አቅም እንዲጎለብት የተደረገው ጥረት አነስተኛ ነው። ከውጭ ሀገር ተገዝተው የሚመጡትም መድኃኒቶች አገዛዝና ከፍፍል የተዛባና ፍትሀዊነት የጎደለው በመሆኑ አብዛኛው የገጠር ሕዝብ በዘመናዊ መድኃኒት የመጠቀም ዕድል አላገኘም። ከዚህም በተጨማሪ የመድኃኒትን አስተዳደርና ቁጥጥር ሥርዓት በተጠናከረ መልኩ ተግባራዊ አለመሆኑ በከምችት አያያዝና በሥርጭት ሂደት ከፍተኛ ብክነት ታይቷል። የመድኃኒት ደህንነት፣ ፈዋሽነትና ጥራት ለማረጋገጥ ያለው አስተዳደራዊና ቴክኒካዊ አቅም ዝቅተኛ ከመሆኑም በላይ በናርኮቲክስና በሳይኮትሮፒክ መድኃኒቶችና መርዞች የሚደረገው ቁጥጥር የተዳከመ ነው።

materials on drugs shall be produced and distributed to practitioners in the field.

6.3 Drug promotion shall be carried out by trained professionals who have appropriate registration. Mass media promotion shall also be monitored and controlled.

6.4 Control shall be exercised to ensure that free medical samples are not offered for sale, but distributed to appropriate health professionals.

7. Trading Agencies and Scientific Bureaus

7.1 Manufacturers shall be allowed to set up scientific bureaus for the purpose of promoting and the dissemination of scientific information about drugs. However, regulations for their establishment and control, shall be instituted to regularize their functions. These functions shall be managed by competent professionals in the field.

7.2 It will be permissible to operate as representative agent of drugs manufacturers and suppliers, however such undertakings must be run by licensed professionals. The same shall apply for commission agencies.

CRDA

5. Manpower Training and Utilization

5.1 Formal pharmaceutical trainings shall be based on the requirements and health needs of the country. Strategies shall be devised to upgrade professionals who are in service.

5.2 Appropriate strategies shall be designed for the local training of biomedical technologists.

5.3 Professionals in the sector shall receive on the job training and continuing education.

5.4 Conducive situations shall be created so as to engage trained manpower in the best possible service of the public.

5.5 Trainers and beneficiary groups shall collaborate and coordinate in the training and utilization of manpower.

5.6 Various incentives and conducive career structures for professionals shall be instituted in accordance with the characteristics of the job and post.

6. Drug Information and Promotion

6.1 The content and distribution of drug information to health professionals and the public shall be subject to monitoring and control.

6.2 Current and accurate information and reference

የመድኃኒት አገልግሎት ከኅብረተሰቡ ሁኔታ፣ ሥነልቦናዊ ዝግጅትና አቅም ጋር የተገናዘበ መሆን ሲገባው የመድኃኒት አስተዛዘዝ፣ መድኃኒት ለሕሙማን የሚደል ተግባር፣ የፍጆታ መረጃ አሰባሰብና አቅርቦት፣ እንዲሁም የመድኃኒት መረጃ አቀራረብና የማስተዋወቅ ተግባር የተዛባ ስለሆነ ሕሙማን መድኃኒትን እራሳቸው የሚያዙበትና የሚጠቀሙበት ሁኔታ የገነነበትና ተጠቃሚውን ለጉዳት የሚያጋልጥ እየሆነ መጥቷል።

በጤና አገልግሎት ተቋሞች ውስጥ የሚገኙት መዛሪያዎች በአንድ በኩል የአገልግሎት ጊዜያቸውን ጨርሰው የወላለቁ፣ ከምርት ገበያ የተገለሉና ለጥገናም ሆነ ለተከላ ችግር የፈጠሩ ሲሆኑ በሌላ በኩል ደግሞ በየደረጃው ካለው የቴክኖሎጂ ሁኔታ የአመራርና የሥራ አፈጻጸም ብቃትና ጥራት ዝቅተኛነት ጋር በመዳመር የአያያዝና የአጠቃቀም ችግር ተፈጥሯል።

ከዚህ ሁኔታም በመነሳት ኢትዮጵያ የምትመራበትን የሽግግር ወቅት ቻርተርና በዚሁ ቻርተር መሠረት የወጣውን የኢኮኖሚ ፖሊሲ ተመርኩዞ የወጣው የጤና ፖሊሲ አካል የሆነና የመድኃኒትን ልዩ ልዩ ገጽታዎች ፈር ለማስያዝ የሚያስችል የመድኃኒት ፖሊሲ ግውጣት መሠረታዊና ቅድሚያ የሚሰጠው ተግባር ነው።

የኢትዮጵያ የሽግግር መንግሥት፣

1. ጤና ለሕዝብ የተደላደለ ሕይወትና ምርታማነት መሠረት መሆኑንና፣ መድኃኒትም በጤና አገልግሎት ውስጥ ያለውን ድርሻ በመገንዘብ፣

2. የመድኃኒት አግልግሎት ለዜጎች በሙሉ ፍትሀዊ በሆነ መንገድ መዳረስ እንዳለበት በማመንና፣ ይህንንም በተግባር ለመተርጎም የመድኃኒት አግልግሎት በሁሉም መልኩ ኅብረተሰቡን የሚያሳትፍ

CCRDA

በነፃ ገበያ ኢኮኖሚ ሥርዓት ላይ የተመሠረተና፣ ላይ.ማከል በየክልል አስተዳደር ሊዘረጋ እንደሚገባው በማመን፣

3. ሀገሪቱ ካላት አነስተኛ አቅም ለመድኃኒት የምታውለው ወጭ ከፍተኛ መሆኑን በመመልከት፣

4. አብዛኛው መድኃኒት ከውጭ ሀገር ስለሚመጣ ሊኖር የሚ ችለውን አዎንታዊና አሉታዊ ገጽታ ከግምት ውስጥ በማስገባት በሕዝብ ጤና ላይ ጉዳት እንዳይደርስ የተጠናከረ የመድኃኒት አስተዳደርና ቁጥጥር አስፈላጊነት በማጤን፣

5. የመደኃኒት ፖሊሲ ባለመኖሩ በመድኃኒት ማምረት፣ ማስመጣት፣ ማከፋፈልና አጠቃቀም፣ ሥራ ዘርፍና እንዲሁም በሀገሪሰብ መድኃኒት አጠቃቀም ላይ ያሳደረውን ተጽዕኖ በመገንዘብ፣

የአብዛኛውን ጎብረተሰብ ጥቅም የሚጠብቅ፣ ራስን በራስ መርዳት ላይ ያተኮረ፣ ለዚህም ተግባር የሚያስፈልጉትን የእንቅስቃሴ፣ የመዋቅር፣ የተሳትፎና የቁጥጥር ሥርዓት የሚጠቁም የመድኃኒት ፖሊሲ አውጥቷል።

በዚህ ፖሊሲ መድኃኒት ማለት፣

የሰውንና የእንሰሳትን ጤና ለመጠበቅ (ለመመርመር፣ ለማከም ወይም በሽታን ለማስታገስ ወይም ለመከላከል) የሚያገለግል ማንኛውም ንጥረ ነገር ወይም የንጥረ ነገሮች ውህድ ወይም የሕክምና መሣሪያዎችና የሕክምና መገልገያዎች ሲሆን፣ መርዘኞችን ናርኮቲክና ሣይኮትሮፒክ ዝግጅቶችን፣ ኬሚካሎችን፣ ደምና የደም ተዋጽኦችን፣ ቫክሲኖችን፣ ሴራዎችን፣ ጨረር አፍላቂ መድኃኒቶችን፣ መድኃኒትነክ ኮስሞቲኮችንና የሳኒታሪ ዝግጅቶችን ይጨምራል።

4.6 The policy enforcing body shall act in collaboration with concerned organizations to ensure that drugs are available to the public at their legal prices.

4.7 Qualified inspectors shall be assigned to enforce laws and regulations issued to implement the policy.

4.8 Rules and regulations governing the clinical trial of drugs shall be issued.

4.9 Laws and regulations shall be instituted and enforced governing the supply, stock management, distribution, use and disposal of narcotic and psychotropic drugs.

4.10 A national committee consisting of different organizations shall be set up to carry out a coordinated control on narcotics and psychotropic drugs on the basis of international conventions.

4.11 Lists of radio-active pharmaceuticals, poisons and chemicals shall be issued along with guidelines about their handling, distribution, use, disposal and compensation for damage.

4.12 Registration, classification and licensing of professionals in the sector shall be carried out by the appropriate body.

4.13 Any drug manufacturing, import, wholesale and retail enterprise, as well as manufacturers of drug related cosmetics and drug quality control laboratories, can only be established under license from the policy enforcing body. The undertaking shall also be operated under the technical responsibility of a licensed professional only.

CRDA

the level of the health institution and retail enterprise.

3.5 Public health institutions and pharmacies within them shall be given priority by the government owned drug distribution system.

4. Drug Administration and Control

4.1 The National Drugs Advisory Committee shall evaluate the safety, efficacy, quality, price and other vital information about drugs and register them before they are marketed.

4.2 Registration certificates shall be issued for drugs that meet the required standards. Drugs already on the market shall also be subject to periodic evaluation and registration.

4.3 Drug quality standards shall be set. Government operated quality control laboratories will be established both centrally and regionally.

4.4 Drug samples for quality control shall be collected from manufacturing plants, distribution outlets, retailers, etc. and substandard products shall be withdrawn from the market.

4.5 An appropriate system shall be devised for the collection of new information about the harmful and beneficial effects of drugs from health professionals as well as patients. After the relevant data are compiled and analyzed, the findings shall be publicized at national and international level.

CCRDA

የፖሊሲው ዓላማ

1. የሀገሪቱን የመሠረታዊ መድኃኒት ፍላጎት ማሟላት፣ ሥርጭትንና አጠቃቀምን ሥርዓት ማስያዝ፣

2. ሕዝቡ ባለው አቅም መድኃኒት ለማግኘት እንዲችል ሁኔታዎችን ማመቻቸት፣

3. የመድኃኒትን ደህንነት፣ ፈዋሽነትና ጥራት ማረጋገጥ፣

4. በሀገር ውስጥ የመድኃኒት ማምረትንና በሂደትም ወደ ውጭ ገበያ የማቅረብ አቅም ማዳበር፣

5. የመድኃኒት ባለሙያዎች ሥልጠና፣ የመድኃኒት ምርምርና ስርፀት ማስፋፋት፣

6. የሀገረሰብ መድኃኒቶች ደህንነታቸውና ፈዋሽነታቸው እየተረጋገጠ ከመደበኛ ጤና አገልግሎት ጋር ተዛምደው ሥራ ላይ የሚውሉበትን መንገድ መቀየስ፣

አጠቃላይ ፖሊሲ

1. የአገሪቱን የጤና ችግሮችና አቅም መሠረት በማድረግ ለጤና አገልግሎት የሚውሉ መድኃኒቶችን ዓይነት መወሰን፤

2. መንግሥት ካለበት የሕዝብ ጤንነት የመጠበቅ ኃላፊነት አኳያ መሠረታዊ መድኃኒቶችን ማቅረብ፤

3. ለሀገረሰብ መድኃኒት አስፈላጊውን ትኩረት በመስጠትና ጠቃሚውን ከጎጂው በጥናትና በምርምር በመለየት ደረጃ በደረጃ ከዘመናዊ ሕክምና ጋር የሚጎዳኝበትን መንገድ ማመቻቸት፤

4. ከመድኃኒት ምርት ጋር ቀጥተኛ ግንኙነት ያላቸውን ጥሬ ዕቃዎችና ማሸጊያዎች ለማምረት ልዩ ትኩረት ለሚሰጡ የመንግሥት፣ ም ሆኑ የግል ኢንዱስትሪዎች ማትጊያ መስጠት፤

5. መሠረታዊ መድኃኒቶችን ለሚያመርቱና እንዲሁም የምርት ውጤታቸውን በፅንስ ሰም ገበያ ላይ ለሚያውሉ አምራቾች ልዩ ማትጊያ መስጠት፤

6. የግል ባለሀብቶች መድኃኒት በማምረት በማስመጣትና በማከፋፈል ሥራ ላይ እንዲሳተፉ ሁኔታዎችን ማመቻቸት፤

7. አስተማማኝ የሆነ የመድኃኒት አስተዳደርና ቁጥጥር በየደረጃው መዘርጋት፤ በተለይም የመድኃኒትን ደህንነት፤ ፈዋሽነትና ጥራት፤ ለማረጋገጥ የሚያስችል አቅም መገንባት፤

way that it does not weaken local drug manufacturing. On the other hand the necessary precaution will be taken to avoid monopolistic tendencies by local manufacturers.

2.10 Import of drugs, in the form of international aid or as part of health related programmes, shall be on the basis of national need and in accordance with the pharmaceutical laws of the country.

3. Stock Management and Distribution

3.1 Specifications for the establishment of storage facilities which are suitable for proper stock management and pertinent to the climatic conditions of the locality shall be issued. The availability of storage facilities which meet the required standards at points of entry and distribution shall be ensured.

3.2 The movement of drugs from ports and distribution points shall be given priority and an efficient transport services shall be provided for timely delivery to consumers.

3.3 Every distribution network shall be subject to strict drug inventory control, supervision and data exchange in order to forecast drug demands, to prevent wastage and avoid shortage of drugs.

3.4 Distribution of drugs shall be carried out in accordance to a standard list of drugs appropriate for

CRDA

9. Devise a programme for the training of professionals able to contribute to solving the health problems of the country as required and create conditions for the application and development of their skills.

10. Conduct a coordinated research on modern and traditional drugs attuned to the country's problems and capacity and strive for the application of their results.

11. Create favourable conditions for the transfer and further development of appropriate technology and modern know-how that could assist in meeting the drug needs of the country.

12. Create favourable conditions for the export of local products.

13. Make the necessary efforts to deter the illegal manufacturing, distribution and consumption of narcotics and psychotropic drugs.

14. Strengthen National and International relations to help develop and expand the pharmaceutical sector and give due attention to the implementation of international obligations.

CCRDA

ምርቶቻቸውን በፅንስ ስም ዝቦ ላይ ለማራመድ ከጣንያዎች አስፈላጊውን ድጋፍ በመስጠት ያበረታታል።

2.3 የመድኃኒት ቅመማ (ኮምፓውንዲንግ) በሆስፒታሎች፣ በመድኃኒት ቤቶችና በመድኃኒት ቅመማ ላብራቶሪዎች አስፈላጊውን ጥራትና ደረጃ በጠበቀ ሁኔታ በፋርማሲስቶች እንዲካሄድ ይደረጋል።

2.4 ከአምራቾችና ከአቅራቢዎች ተጽዕኖ ነፃ የሆነ ድርጅት መንግሥት በማዕከልና በክልል አዋቅሮ የመድኃኒት ግዥንና የማከፋፈሉን ተግባር እንዲከናወን ያደርጋል።

2.5 የሀገር ውስጥ የመድኃኒት ግዢና ማከፋፈል ተግባር በየክልሎች በሚቋቋሙት የመድኃኒት ማከፋፈያ አውታሮች ይከናወናል።

2.6 የመንግሥት የመድኃኒት አቅራቢ ድርጅት(ቶች) ደህንነታቸው፣ ፈዋሽነታቸውና ጥራታቸው አስተማማኝ የሆኑና ዋጋቸው ከሕዝቡ የመግዛት አቅም ጋር ተመጣጣኝ የሆኑ በፅንስ ስም የሚጠሩ መሠረታዊ መድኃኒቶችን እንዲያቀርቡ ሁኔታዎች ይመቻቹላቸዋል።

2.7 በመንግሥት ይሁን በግል አቅራቢዎች የሚከናወን ግዥ አመች ሆኖ በሚገኝ የግዥ ሥልት ይካሄዳል።

2.8 መሠረታዊ የሆኑ፣ በፅንስ ስም የሚጠሩና ተመጣጣኝ ዋጋ ያላቸውን መድኃኒቶች ለሚያቀርቡ የግል አስመጭና አከፋፋዮች በመንግሥት በኩል አስፈላጊው ማትጊያ ይሰጣቸዋል።

2.9 የውጭ ግዥ የአገር ውስጥ ምርትን በማያዳክምበት ሁኔታ እንዲ ካሄድ ይደረጋል። ሆኖም የአገር ውስጥ አምራቾች ሞኖፖሊን እንዳይፈጥሩ አስፈላጊው ጥንቃቄ ይወሰዳል።

2.10 በዕርዳታም ሆነ ከጤና ፕሮግራሞች ጋር በተያያዘ ሁኔታ የሚመጡ መድኃኒቶች በአገሪቱ ፍላጎት ላይ የተመሠረቱና በአገሪቱ ያለውን የመድኃኒቶች ሕግ የተከተሉ እንዲሆኑ ይደረጋል።

3. ስለክምችት አያያዝና ማከፋፈል

3.1 ለመድኃኒት አያያዝ አመቺ የሆኑና ለየአካባቢው የአየር ጠባይ የሚስማሙ መጋዘኖች ስለሚቋቋሙበት ሁኔታ መለኪያዎች ይወጣሉ። መለኪያዎችን የሚያሟሉ መጋዘኖች በመግቢያ ኬላዎችና በማከፋፈያ አውታሮች መኖራቸው ይረጋገጣል።

3.2 መድኃኒቶችን ከወደብና ከማከፋፈያ አውታሮች ለማንሳት ቅድሚያ ይሰጣል። ወደ ተጠቃሚው በወቅቱ ለማድረስም የተጠናከር የማጓጓዣ አገልግሎት እንዲኖር ይደረጋል።

3.3 የመድኃኒት ብክነትና እጥረት እንዳይደርስ ለመከላከል፣ የመ ድኃኒት ፍላጎትን ለመተንበይ እንዲቻል በማንኛውም አውታር የተጠናከረ የመድኃኒት ክምችት ቁጥጥር፣ ክትትልና የመረጃ ልውውጥ ይካሄዳል።

3.4 የመድኃኒት ክፍፍሉ የሚከናወነው የጤና ድርጅቶችና የመድኃኒት ችርቻሮ ተቋሞች እንደየደረጃቸው እንዲያዙት በሚፈቀድላቸው የመድኃኒት መዘርዝሮች መሠረት ይሆናል።

3.5 በመንግሥት በኩል የሚደረገው ክፍፍል ሲከናወን ቅድሚያ

GENERAL POLICY

1. Determine the types of drugs to be used in the health services on the basis of the country's health problems and capability.
2. Provide essential drugs in line with the responsibilities of the government for public health care.
3. Facilitate the gradual integration of traditional drugs with modern medicine by giving due attention to traditional practices and identifying the beneficial and harmful aspects through investigation and research.
4. Offer incentives to public and private industries involved in the production of raw and packing materials directly related to the manufacture of drugs.
5. Give special incentives to manufacturers who manufacture essential drugs and market them in their generic names.
6. Create favourable conditions to encourage private investors to participate in the manufacture, import and distribution of drugs.
7. Establish an effective system of drug administration and control at all levels, especially by developing the capacity to ensure drug safety, efficacy and quality.
8. Make the necessary efforts to establish rational use of drugs among the health professionals and the public at large.

EFDA

In this policy, DRUG means any substance or mixture of substances or medical equipments or supplies, used for human and animal health care (i.e. diagnosis, treatment, mitigation or prevention of diseases or symptoms) including poisons, narcotics and psychotropic substances chemicals, blood and blood products, vaccines, sera, radio-active pharmaceuticals, pharmaceutical cosmetics and sanitary products.

OBJECTIVES OF THE POLICY

1. To meet the country's demand for essential drugs and to systematize its supply, distribution and use.
2. To create conducive situations to make the prices of drugs compatible with the people's purchasing power.
3. To ensure the safety, efficacy and quality of drugs.
4. To develop a domestic drug manufacturing capacity and gradual supply to the export market.
5. To expand the training of manpower, drugs research and development.
6. To devise ways and means for the utilization of traditional drugs in the regular health services after ensuring their safety and efficacy.

CCRDA

ፋርማሲዎች ይሰጣል።

4. የመድኃኒት አስተዳደርና ቁጥጥር

4.1 መድኃኒቶች ገበያ ላይ ከመዋላቸው በፊት ደህንነታቸው፣ ፈዋሽነታቸው፣ ጥራታቸውና ዋጋቸው እንዲሁም ሌሎች አስፈላጊ መረጃዎች በብሔራዊ የመድኃኒት አማካሪ ኮሚቴ እየተገመገሙ እንዲመዘገቡ ይደረጋል።

4.2 መድኃኒቶች አስፈላጊውን መለኪያ አሟልተው ከተመዘገቡ በኋላ ለመመዝገባቸው ማረጋገጫ የምሥክር ወረቀት ይሰጣል። በአገልግሎት ላይ የዋሉ መድኃኒቶችም በየወቅቱ እየተገመገሙ በድጋሚ እንዲመዘገቡ ይደረጋል።

4.3 የመድኃኒቶች የጥራት መመዘኛዎችና ደረጃዎች ይዘጋጃሉ። የጥራት ምርመራ የሚያካሂዱ የመንግሥት ላብራቶሪዎች በማዕከልና በክልል ደረጃ ይጠናከራሉ።

4.4 ከመድኃኒት ማምረቻ ድርጅቶች፣ ከመድኃኒት ማከፋፈያ ቦታዎችና ከመድኃኒት ችርቻሮ ድርጅቶች...ወዘተ ናሙና እየተወሰደ የጥራት ቁጥጥር ይደረጋል። ችግር የሚታይባቸውም መድኃኒቶች ከገበያ ይወገዳሉ።

4.5 የጤና ባለሙያዎችና ሕሙማን መድኃኒቶች ስለሚያሳዩት አዲስ ጎጂ ባህርያትና ጠቀሜታ መረጃ የሚያስተላልፉበት መንገድ ይቀየሳል። አስፈላጊዎቹ መረጃዎችም ከተጠናቀሩና ከተመረመሩ በኋላ ውጤቱ በአገርና በዓለም አቀፍ ደረጃ እንዲታወቅ ይደረጋል።

4.6 የፖሊሲ አስፈፃሚው አካል ጉብረተሰቡ መድኃኒቶችን በሕጋዊ ዋጋ ማግኘቱን ለማረጋገጥ የዋጋ ቁጥጥሩን ከሚመለከታቸው መሥሪያ ቤቶች ጋር በመተባበር ይሠራል።

4.7 ፖሊሲውን በተግባር ለመተርጎም የሚወጡትን ሕጎችና ደንቦች ለማስፈፀም የሚችሉ ብቃት ያላቸው ኢንስፔክተሮች ይመደባሉ።

4.8 በመድኃኒቶች ላይ ክሊኒካዊ ሙከራ ለማካሄድ የሚያስችሉ ሕጎችና ደንቦች ይወጣሉ።

4.9 የናርኮቲክና ሳይኮትሮፒክ መድኃኒቶች አቅርቦትን፣ አያያዝን፣ ሥርጭትን፣ አጠቃቀምንና አወጋገድን በሚመለከት ሕጎችና ደንቦች ወጥተው በሥራ ላይ ይውላሉ።

4.10 በናርኮቲክና በሳይኮትሮፒክ ዓለም አቀፋዊ ስምምነቶች መሠረት የቁጥጥሩን ተግባር በተቀናጀ መልክ ለማካሄድ የተለያዩ መሥሪያ ቤቶች በአባልነት የሚገኙበት ብሔራዊ ኮሚቴ ይቋቋማል።

4.11 የጨረር አፍላቂ መድኃኒቶች፣ የመርዞችና ኬሚካሎች ዝርዝር ይወጣሉ። ስለአያያዛቸው፣ ስለስርጭታቸው፣ ስለአጠቃቀ ማቸው፣ ስለአወጋገዳቸውና ስለጉዳት ካሣ መመሪያ ወጥቶ በሥራ ላይ ይውላል።

4.12 የመድኃኒት ባለሙያዎችን የመመዝገብ፣ የመሰየምና የሙያ ፈቃድ የመስጠቱ ተግባር በሚመለከተው አካል እንዲከናወን ይደረጋል።

4.13 ማንኛውም የመድኃኒት አምራች፣ አስመጭ፣ ጅምላ አከፋፋይና የችርቻሮ ድርጅት እንዲሁም መድኃኒትነክ ኮስሞቲክ ኢንዱስትሪና የመድኃኒት ጥራት መመርመሪያ ላብራቶሪ ሊቋቋም

The Transitional Government of Ethiopia:

1. Aware of the importance of health for public welfare and productivity and the role of drugs in health care;
2. Convinced of the need for a just and equitable distribution of pharmaceutical services to all citizens and aware of the fact that to implement this goals pharmaceutical services should ensure the participation of the community based on the principles of a free market economy and in a decentralized manner throughout the regions;
3. Cognizant of the country's large expenditure allocated to drugs from its limited resources;
4. Conscious of the need for a strong drugs administration and regulation to maintain public health and safety, in a situation where most of the drugs are imported with possibilities of both desirable and undesirable effects;
5. Aware of the impact of the lack of a drug policy on manufacturing, import, distribution utilization and also in the use of traditional drugs.

Hereby issues the following policy which safeguards the interest of the majority of the people based on the principle of self-reliance. The activities, structures, participation and control system involved in implementing the policy are also indicated.

CRDA

the procurement and distribution of imported drugs was haphazard and unjust that the majority of the rural community hardly had access to modern drugs. Furthermore, the failure to have a strong system of drugs administration and control has resulted in massive wastage during storage and distribution. Apart from the low administrative and technical capacities to ensure the safety, efficacy and quality of all drugs, the control on narcotics, psychotropic drugs and poisons was particularly weak.

Though it is incumbent that drug services should take into account the social conditions, psychological make up and financial capacity of the society, the indiscriminate practice that prevailed in drug prescription, dispensing, data collection, dissemination of information and promotion, gave way to the rampant existence of a situation in which patients prescribed and self administered drugs thereby jeopardizing their own safety.

Since medical equipments in health institutions are mostly old and obsolete problems of maintenance, handling and use exist aggravated by a low standard of technical, managerial and operational capacity.

Accordingly, the issuance of a drug policy, which is part and parcel of the health policy and in line with the transition period charter and the economic policy of Ethiopia, should be given high priority in order to direct the various features of the sector.

የሚችለው ከፖሊሲው አስፈፃሚው አካል ፈቃድ ሊያገኝ ... ይሆናል። ሥራውም የሚካሄደው የሙያ ፈቃድ በሚሰጠው የመድኃኒት ባለሙያ የቴክኒክ ኃላፊነት ብቻ ይሆናል።

5. የሰው ኃይል ሥልጠናና አጠቃቀም

5.1 በመድኃኒት ሙያ የሚሰጠው መደበኛ ሥልጠና ከሀገሪቱ የጤና ችግሮች ጋር የተገናዘበና በከፍተኛና በመለስተኛ ደረጃ ይሆናል። በመለስተኛ ደረጃ የሠለጠኑ ባለሙያዎች የከፍተኛ ደረጃ ሥልጠና የሚያገኙበት መንገድ ይቀየሳል።

5.2 የባዮሜዲካል ቴክኖሎጂ ትምህርትና ሥልጠና በሀገር ውስጥ የሚሰጥበት ሁኔታ ይመቻቻል።

5.3 ለመድኃኒት ባለሙያዎች ከመደበኛ ሥልጠና በተጨማሪ የተጠናከረ የተግባር ሥልጠናና ተከታታይ ትምህርት ይሰጣል።

5.4 የመድኃኒት ባለሙያዎች ተፈላጊውን ሥልጠና ካጠናቀቁ በኋላ ለጎበረተሰቡ በሙያቸው ከፍተኛ አገልግሎት ሊሰጡ በሚችሉበት መንገድ እንዲሰማሩ ሁኔታዎች ይመቻቻሉ።

5.5 አሠልጣኝና ተጠቃሚ ክፍሎች ሥልጠናውንና አጠቃቀሙን በተቀናጀ ሁኔታ እንዲያካሂዱ ይደረጋል።

5.6 ባለሙያዎችን ለሥራ የሚያተጋ እንደየሚሠሩበት የሥራ ባህሪይ ያተለያየ ማበረታቻ እንዲያገኙ ይደረጋል።

CCRDA

6. ስለመድኃኒት መረጃዎችና ማስተዋወቅ

6.1 ለባለሙያዎችና ለተጠቃሚው ኅብረተሰብ በሚተላለፉ የመ ድኃኒት መረጃዎች ይዘትና ስርጭት ላይ ክትትልና ቁጥጥር ይደረጋል።

6.2 መድኃኒቶችን በሚመለከት ልዩ ልዩ ወቅታዊና ትክክለኛ መረጃዎችንና የመረጃ ምንጭ ጽሑፎች እየተዘጋጁ ለባለሙያዎች ይሰራጫሉ።

6.3 መድኃኒቶችን የማስተዋወቅ ሥራ በመድኃኒት ሙያ በሠለጠኑና በተመዘገቡ ባለሙያዎች እንዲካሄድ ይደረጋል። በመገናኛ ብዙሃን የሚካሄደው የማስተዋወቅ ተግባርም ቁጥጥርና ክትትል ይደረግበታል።

6.4 ነፃ የመድኃኒት ናሙናዎች ለሽያጭ እንዳይውሉ ቁጥጥር እየተደረገባቸው ለሚመለከታቸው የጤና ባለሙያዎች ብቻ እንዲከፋፈሉ ይደረጋል።

7. ስለንግድ ወኪሎችና ሚኒስቴር ቢሮዎች

7.1 የሚኒስቴር መረጃዎችን ስርጭት ለማስፋፋት ይረዳ ዘንድ አምራች ፋብሪካዎች ሚኒስቴር ቢሮዎችን እንዲያቋቁሙ ይፈቀዳል። ሆኖም ተግባራቸው ተፈላጊውን ፈር እንዲይዝ ለማድረግ የማቋቋሚያና የመቆጣጠሪያ ደንብ ይዘጋጃል። ሥራውም ብቃት ባላቸው የዘርፉ ባለሙያዎች እንዲመራ ይደረጋል።

implementing them, the laws and regulations were not periodically revised or adjusted to the progress made within the sector and the relative modernization which was under way in the country.

Although "A Primary Health Care Strategy" was adopted by the Dergue regime as the country's health service guide, there was no drug related policy, law or regulation enacted except the points raised in the strategy and indicated in the Ten Year Perspective Plan drafted in 1985. If at all there was any activity in the Pharmaceutical sector during this era, it took the form of over emphasizing the role of the public at the expense of the private sector. Conversely, the major attention of the regime was directed to the pursuit of war which caused reduction in the availability of drugs, both in variety and quantity, which in conjunction with natural calamities aggravated the health problems.

The masses of the Ethiopian people still rely mainly on traditional drugs to prevent or cure diseases. Yet, there was little effort made to investigate their safety and efficacy so as to encourage wider application. Even the limited research capacity that existed did not focus on resolving concrete problems in the pharmaceutical sector, particularly on assessing the safety and efficacy of traditional drugs widely used by the community.

Regarding the supply of drugs, the endeavor towards strengthening local production capacity was minimal.

GRDA

NATIONAL DRUG POLICY
OF THE
TRANSITIONAL GOVERNMENT OF ETHIOPIA

Introduction

Based on economic development and the living standard of its people Ethiopia is considered to be one of the least developed countries. Although the fundamental cause for this is the backward socio-economic system which prevailed for centuries, recent man-made and natural calamities have played a significant role in aggravating the situation. Thus, the major problems which are apparent in the health and pharmaceutical sectors are reflections of the cumulative effects of these state of affairs.

The most prominent and general weaknesses in the sector are that the services do not match to the needs and capabilities of the broad masses and that the limited resources allocated to the sector were not used in an appropriate, efficient and effective manner.

During the Imperial rule, attempts were made to create a health care system that involved the participation of the private sector in the supply and services of drugs. To administer this system some isolated laws and regulations were issued. In addition to the problem encountered in

7.2 የመድኃኒት ፋብሪካዎችንና አቅራቢዎችን ወክሎ መሥራት ይፈቀዳል። ሥራውም የፖሊሲ አስፈፃሚው አካል ፈቃድ በሚሰጣቸው የዘርፉ ባለሙያዎች እንዲመራ ይደረጋል። የኮሚሽን ኤጀንሲም ሥራ በዚህ መሠረት ይፈፀማል።

8. <u>የመድኃኒት አጠቃቀም</u>

8.1 በሐኪም ትዕዛዝና ያለሐኪም ትዕዛዝ ሰበሽተኞች የሚታደሉ መድኃኒቶች ዝርዝር ይወጣል።

8.2 አንድ ወጥ የመድኃኒት ማዘዣ ቅጽ በአገር አቀፍ ደረጃ ተዘጋጅቶ ሥራ ላይ ይውላል። በአጠቃቀሙም ላይ ቁጥጥር ይካሄዳል።

8.3 የጤና ባለሙያዎች መድኃኒቶችን ለበሽተኞች በሚያዙበት ወቅት በፅንስ ስም ማዘዣ እንዲጽፉ አስፈላጊው ቅስቀሳና ትምህርት ይሰጣል።

8.4 የመድኃኒት እደላ (ዲስፔንሲንግ) ፈቃድ ባላቸው ባለሙያዎች ኃላፊነትና የቅርብ ክትትል እንዲመራ ይደረጋል። ባለሙያዎችና ድርጅቶች የመድኃኒት እደላ መመሪያን እንዲያከብሩ ክትትልና ቁጥጥር ይደረጋል።

8.5 ፋርማሲስቱ በንግድ ስም የታዘዘውን መድኃኒት በፅንስ ስም በሚጠራው ተክቶ ማደል ይችላል።

8.6 ኅብረተሰቡ ስለመድኃኒቶች አጠቃቀም ትክክለኛ ግንዛቤ እንዲያገኝ ትምህርት፣ ቅስቀሳ፣ ምክር...ወዘተ በተገኘው መንገድ ሁሉ ይሰጣል።

CCRDA

9. የህገረሰብ መድኃኒቶች

9.1 ዘርፉን በምርምርና ስርፀት ለማጠናከር ትኩረት ይሰጣል። በዘርፉ የሚደረገው ምርምር በቅድሚያ ኅብረተሰቡ በሰፊው ጥቅም ላይ ባዋላቸው የህገረሰብ መድኃኒቶች ላይ ይሆናል።

9.2 የኅብረተሰቡን ጤና ለመጠበቅ የሚያገለግሉና ደህንነታቸውና ፈዋሽነታቸው የታመነባቸው መድኃኒቶች ጥቅም ላይ የሚውሉበት ሁኔታ ይመቻቻል። የግል ተሳትፎም ይበረታታል።

10 ምርምርና ስርፀት

10.1 የመድኃኒት ሴክተርን ለማጎልበት የሚረዳ ተስማሚ ቴክኖሎጂና አውቀት ወደ ሀገር ውስጥ እንዲገባ ሁኔታዎች ይመቻቻሉ። ለሚያስገቡም በመንግሥት በኩል አስፈላጊው ማበረታቻና እገዛ ይደረጋል።

10.2 በመድኃኒት ሴክተሩ የምርምርና ስርፀት ተግባር የሚዳብርበት ሁኔታ ይመቻቻል። ክንውኑም በመድኃኒት ማምረቻ ፋብሪካዎች፣ በመድኃኒት ቅመማ ላብራቶሪዎች፣ በማሠልጠኛና በምርምር ተቋሞች...ወዘተ ይሆናል።

10.3 የመድኃኒት ምርምርና ስርፀትን ለማካሄድ የሚያስችል ራሱን የቻለ አንድ የምርምር ማዕከል እንዲቋቋም ይደረጋል።

10.4 የመድኃኒት አገልግሎቱን ግለትም የግዥ ሥልት፣ የክምችት

አያያዝ፣ ሥርጭት፣ አጠቃቀም...ወዘተ በብቃትና በጥራት በየደረጃው ለማጎልበት የሚረዱ የጥናትና ምርምር ሥራዎች እንዲካሄዱ ይደረጋል።

10.5 ምርምርና ሥርፀት የሙያ ሥነምግባር ጠብቆ እንዲካሄድ ይደረጋል።

10.6 ለመድኃኒት ተመራማሪዎች በምርምራቸው ውጤት ላይ የተመሠረተ ማበረታቻ የሚሰጥበትና የምርምር ውጤቶች ባለቤትነት (ፖተንት) የሚረጋገጥበት ዘዴ ይቀየሳል።

11. የመድኃኒት ዋጋ

ሕዝቡ ባለው አቅም መድኃኒት ለማግኘት እንዲችል ሁኔታዎችን ለማመቻቸት መንግሥት ጥረት ያደርጋል።

12. ብሔራዊ፣ አህጉራዊና ዓለም አቀፋዊ ግንኙነቶች

12.1 ፖሊሲው የሚያቅፋቸውን ዘርፎች ለማጠናከርና ለማስፋፋት የሚረዱ ብሔራዊ፣ አህጉራዊና ዓለም አቀፋዊ ግንኙነቶች ይፈጠራሉ።

12.2 ናርኮቲክና ሳይኮትሮፒክ፣ ጨረር አፍላቂ መድኃኒቶችንና መርዞችን በተመለከተ አገሪቱ የገባቻቸውንና የምትገባቸውን ዓለም አቀፋዊ ግዴታዎች ለመፈፀም ተገቢው ትኩረት ይሰጣል።

13. የፖሊሲው አፈፃፀም

ፖሊሲውን ተግባራዊ ለማድረግ ሕጎች፣ ደንቦችና መመሪያዎች ይወጣሉ።

CRDA

የናርኮቲክና ሳይኮትሮፒክ መድኃኒቶች ማዘዣ ወረቀቶች አገልግሎት ለመቆጣጠር የወጣ መመሪያ

GUIDELINE TO CONTROL NARCOTIC DRUGS & PSYCHOTROPIC SUBSTANCES PRESCRIPTION PAPERS

የጤና ጥበቃ ሚኒስቴር
MINISTRY OF HEALTH

አዲስ አበባ
ሰኔ 1988
Addis Ababa
June 1996

CCRDA

B.S.P.E.

such report shall contain the following information:

* Name and address of the institution,
* License number,
* Date of theft,
* Local Police Department notified,
* Type of theft and
* List of Narcotic Drugs or Psychotropic Substances missed.

27. Cessation of Business

A licensed institution which ceases to operate as a business and transfer such business activity to another person shall return the license and filled prescriptions to the Ministry of Health and the drugs to the supplier under the supervision of the Ministry of Health.

28. Penalty

Any person or institution who fails to comply with this Guideline shall be punishable by Law.

CCRDA

የናርኮቲክና ሳይኮትሮፒክ መድኃኒቶች ለመቆጣጠርና በአግባቡ ጥቅም ላይ ለማዋል የወጣ መመሪያ

ጤና ለሕዝብ የተደለደለ ሕይወትና ምርታማነት መሠረት መሆኑንና ናርኮቲክና ሳይኮትሮፒክ መድኃኒቶች በጤና አገልግሎት ውስጥ ያላቸውን ድርሻ በመገንዘብ፣

የናርኮቲክና ሳይኮትሮፒክ መድኃኒቶችን ሕገወጥ ምርት፣ ክፍፍልና አጠቃቀም መከላከል አስፈላጊ ሆኖ በመገኘቱ፣

የናርኮቲክና ሳይኮትሮፒክ መድኃኒቶች ምርት፣ ግስመጣት፣ መላክ፣ ክፍፍል፣ አስተዛዘዝ፣ ዕደላና አጠቃቀም ስርዓት ባለው መንገድ እንዲከናወን በማስፈለጉ፣

ለነዚህም አስተማማኝ የሆነ የናርኮቲክና ሳይኮትሮፒክ መድኃኒቶች ቁጥጥር ስርዓት መዘርጋት አስፈላጊ ሆኖ በመገኘቱ፣

በፋርማሲ ደንብ የሕግ ክፍል ማስታወቂያ ቁጥር 288/56 እና በአለም አቀፍ የናርኮቲክና ሳይኮትሮፒክ መድኃኒቶች ቁጥጥር ስምምነቶች መሠረት የሚከተለው መመሪያ ወጥቷል።

ክፍል አንድ
ጠቅላላ

1. አጭር ርዕስ፣

ይህ መመሪያ " የናርኮቲክና ሳይኮትሮፒክ መድኃኒቶችን ለመቆጣጠርና በአግባቡ ጥቅም ላይ ለማዋል የወጣ መመሪያ 02/88" ተብሎ ሊጠቀስ ይችላል።

2. ትርጓሜ፣

የቃል አገባብ ሌላ ትርጓሜ የሚያሰጠው ካልሆነ በስተቀር በዚህ መመሪያ ውስጥ፣

(1) "ናርኮቲክ" ማለት ኢትዬጵያ በተቀበለችው የተባበሩት መንግሥታት ድርጅት የናርኮቲክ መድኃኒቶች ቁጥጥር ስምምነት መሠረት አለም አቀፍ ቁጥጥር የሚደረግበትና የጤና ጥበቃ ሚኒስቴር ሀገራዊ ቁጥጥር እንዲደረግበት የሚወሰንበት ማንኛውም ነገር ነው።

(2) "ሳይኮትሮፒክ" ማለት ኢትዬጵያ በተቀበለችው የተባበሩት መንግሥታት ድርጅት የሣይኮትሮፒክ መድኃኒቶች ቁጥጥር ስምምነት መሠረት አለም አቀፍ ቁጥጥር የሚደረግበትና የጤና ጥበቃ ሚኒስቴር ሀገራዊ ቁጥጥር እንዲደረግበት የሚወሰንበት ማንኛውም ነገር ነው።

ክፍል ሁለት
ፈቃድና የፈቃድ አሰጣጥ ስርዓት

3. የፈቃድ አስፈላጊነት፣

(1) ማንኛውም ድርጅት ፈቃድ (ቅጽ NPS/21) ሳያገኝ ናርኮቲክ ሣይኮትሮፒክ መድኃኒቶችን ማምረት፣ ማስመጣት፣ መላክ፣ ማከፋፈል የኬሚካል ምርመራ ወይም ጥናታዊ ምርምር ማካሄድ አይችልም።

(2) ከላይ የተዘረዘሩትን ተግባራት ለማከናወን የሚፈልግ ማንኛውም ድርጅት የጤና ጥበቃ ሚኒስቴር በሚያወጣው ቅጽ መሠረት ማመልከቻውን አሚልቶ ማቅረብ አለበት።

(2). Drug Administration and Control Department of the Ministry of Health shall give destruction certificate, Form NPS/14, to institutions under the Ministry of Health for the disposal of Narcotic Drugs or Psychotropic Substances. Institutions under Regional Health Bureaus shall get the certificate from their respective Regional Health Bureaus or Zonal Health Departments. Copy of the certificate given by Regional Health Bureaus or Zonal Health Departments shall be sent to Drug Administration and Control Department of the Ministry of Health.

(3). Narcotic Drugs or Psychotropic Substances seized in illicit traffic, illicit manufacture (clandestine laboratory) and illicit market shall be disposed, in accordance with the International Treaty requirement, under the direct supervision of a committee whose members are from Ministry of Health, Ministry of Justice, Customs Authority and other relevant Ministries.

26. Theft of Narcotic Drugs or Psychotropic Substances

If any theft of Narcotic Drugs or Psychotropic Substances under taken in an institution, it shall upon discovery notify the Ministry of Health, local Ministry of Health representative or the local Police Force within the next working day on Form NPS/22.

FDRE

(2). Every Health Institution shall send reports of purchased and dispensed narcotic drugs and psychotropic substances at the end of every year on Forms NPS/15/A & NPS/15/B to Drug Administration and Control Department of the Ministry of Health.

PART SIX
MISCELLANEOUS

24. Storage

Narcotic drugs, psychotropic substances and invoices, registers, prescriptions and the like therefore shall be stored in a strong locked metal cupboard or in a special room the key to which shall at all times remain in the possession of the authorized professional.

25. Disposal

(1). Narcotic drugs and psychotropic substances no longer useful, due to expiry or damage, shall be destroyed under the direct supervision of the representative of the Ministry of Health.

4. የተለየ ፈቃድ ስለሚያዩ የሥራ መስኮች፣

(1) የሚከተሉትን ተግባራት ለማከናወን የተለየ ፈቃድ ያስፈልጋል።

(ሀ) ናርኮቲክ ወይም ሣይኮትሮፒክ መድኃኒቶችን ለማምረት፣

(ለ) ናርኮቲክ ወይም ሣይኮትሮፒክ መድኃኒቶችን ለማስመጣት ወይም ለመላክ፣

(ሐ) ናርኮቲክ ወይም ሣይኮትሮፒክ መድኃኒቶችን ለማከፋፈል፣

(መ) በናርኮቲክ ወይም ሣይኮትሮፒክ መድኃኒቶች የኬሚካል ምርመራ ለማድረግ፣

(ሠ) በናርኮቲክ ወይም ሣይኮትሮፒክ መድኃኒቶች ጥናታዊ ምርምር ለማድረግ፣

(2) የናርኮቲክ መድኃኒቶችን የማምረት፣ የማስመጣት፣ የመላክ፣ የማከፋፈል፣ የኬሚካል ምርመራ ወይም የጥናታዊ ምርምር ፈቃድ የሚሰጠው ለመንግሥታዊ ድርጅቶች ብቻ ይሆናል።

(3) የሣይኮትሮፒክ መድኃኒቶችን የማምረት፣ የማስመጣት፣ የመላክ፣ የማከፋፈል የኬሚካል ምርመራ ወይም የጥናታዊ ምርምር ፈቃድ የሚሰጠው ሕጋዊ ለሆኑ ድርጅቶች ብቻ ይሆናል።

CCRDA

5. ፈቃድ የማያስፈልገው ተግባር፣

ማንኛውም ሰው በህኪም ትዕዛዝ ለግሉ ሕክምና ናርኮቲክ ወይም ሣይኮትሮፒክ መድኃኒቶችን ይዞ ቢገኝና ብዛቱና መጠኑ ከታዘዘለት መጠን በልጦ እስካልተገኘ ድረስ በአንቀጽ 4 የተጠቀሰውን ፈቃድ አያስፈልገውም።

6. ፈቃድ የሚያስከለክሉ ተግባራት፣

በአንቀጽ 4 የተጠቀሰው ፈቃድ የማይሰጠው፣

(1) የፋርማሲ ደንብን በመተላለፍ የተከለከሉና የሚያስቀጡ ተግባራትን ላከናወነ፣

(2) ማንኛውም ንብረት ነክ በሆነ ወንጀል ወይም በቁማር፣ በሱሰኝነት፣ በሕገወጥ የናርኮቲክ ወይም ሣይኮትሮፒክ መድኃኒቶች አዘዋዋሪነት፣ ወይም እነዚህኑ ወንጀሎች ለመፈጸም ሙከራ ያደረገ ወይም ያጭበረበረ ወይም የተጭበረበሩ መረጃዎችን የተጠቀመ ወይም የሀሰት መታወቂያ ወይም ማስረጃ የተጠቀመ ወይም ለመጠቀም ያቀደ ሲሆን፣

(3) እምነት በማጉደል የሥነሥርዓት እርምጃ ተወስዶበት ከኃላፊነት ወይም ከሥራው የተወገደ፣

(4) ናርኮቲክ ወይም ሣይኮትሮፒክ መድኃኒቶችን ለመያዝ አመቺ የሆነ ክፍል፣ ቁሣቁስና ጥበቃ ከሌለ፣

(c). Dispensed narcotic drugs or psychotropic substances to in-patients, on forms NPS/08/A & NPS/08/B;

(d). Dispensed narcotic drugs or psychotropic substances to a patient on the grounds of a prescription, on forms NPS/09/A and NPS/09/B;

(3). Every Pharmacy/Drug Shop shall keep records of purchased narcotic drugs or psychotropic substances, and all invoices related to them in a chronological file for not less than five years.

23. Reports

(1). Every importer, exporter or manufacturer shall send reports of imported, exported, distributed or manufactured narcotic drugs or psychotropic substances to Drug Administration and Control Department of the Ministry of Health:

(a). at the end of every quarter on Forms NPS/01, NPS/01/A, NPS/02 & NPS/02/A;

(b). at the end of every year on Forms NPS/03 & NPS/04;

(b). at the end of every quarter on Form NPS/05.

FDRE

(2) አመልካቹ በግሥልክቻው ላይ የሚታዩ ግድፈቶችን ለማሻሻል እንዲችል ዕድል ከተሰጠው በዚህ አንቀጽ ንውስ አንቀጽ 1 የተጠቀሰው የጊዜ ገደብ ስህተቶችን እስኪታረሙ ወይም ግድፈቶችን እንዲሻሻሉ የተሰጠው ጊዜ እስኪያበቃ ድረስ የሚቆይ ይሆናል።

(3) በአንቀጽ 7 ሥር በተዘረዘረው ሁኔታዎች ላይ ለውጥ ሲደረግ ባለፈቃዱ ወዲያውኑ ለጤና ጥበቃ ሚኒስቴር ሪፖርት ማድረግ አለበት።

9. <u>ፈቃድ ስለማገድና መሰረዝ፣</u>

1) ፈቃዱ የሚሰረዘው፣

(ሀ) ለአንድ ዓመት ሥራ ላይ ካልዋለ ሲሆን የተሰጠው የጊዜ ገደብ ሊራዘም የሚችለው በቂ ምክንያት ከቀረበ ብቻ ነው።

(ለ) በአንቀጽ 6 በተጠቀሰው መሠረት ባለፈቃዱ ጥፋተኛ ሆኖ ከተገኘ፣

(2) ፈቃድ ሲታገድም ሆነ ሲሰረዝ ጉዳዩ የሚመለከታቸው መ/ቤቶች እንዲያውቁት ይደረጋል።

psychotropic substances shall not be dispensed after the lapsing of fifteen days as from the date on which it was issued.

(3). A pharmacist or druggist shall dispense narcotic drugs or psychotropic substances only on the prescription of a licensed medical practitioner to prescribe narcotic drugs or psychotropic substances in Ethiopia.

(4). No narcotic drug or psychotropic substance prescription paper shall:

* return to the bearer;
* not be used more than once.

PART FIVE
<u>RECORDS AND REPORTS</u>

21. <u>General</u>

(1). All narcotic drugs and psychotropic substances manufactured, imported, exported or distributed by an institution shall be registered on the day of the activity accomplished. All other information as may be required by Ministry of Health shall also be recorded in a separate book.

(2). The said register book shall be submitted to Ministries of Health and Justice on request.

GRDA

practitioner.

(3). A medical practitioner shall not prescribe narcotic drugs or psychotropic substances to any patient for purpose other than those for appropriate treatment.

20. **Dispensing of Narcotic Drugs or Psychotropic Substances**

(1). No narcotic drug or psychotropic substance prescription paper shall be met which does not fulfill the following requirements:

(a). It shall bear the name, age, sex, address, card no. of the patient.

(b). It shall bear name, strength, dosage form, quantity of the drug; date of prescribing and clear direction for use.

(c). It shall have been legibly written and signed by a medical practitioner whose name, license number and address shall also be legibly written on the prescription.

(d). It shall bear the official seal of the Health Institution from which it is prescribed.

10. **የተከለከለ**

(1) ማንኛውም ድርጅት ናርኮቲክ ወይም ሣይኮትሮፒክ መድኃኒቶችን ከሌሎች መድኃኒቶች ወይም ዕቃዎች ጋር አሽጉ ማስመጣት፣ መላክ ወይም ማጓጓዝ አይፈቀድለትም፣

(2) ማንኛውም ድርጅት ናርኮቲክ ወይም ሣይኮትሮፒክ መድኃኒቶችን ሲያስመጣ፣ ሲልክ ወይም ሲያጓጉዝ ለስርቆት አመቺ ያልሆነ አሽግ መጠቀም ይኖርበታል።

(3) ናርኮቲክ መድኃኒቶች በፖስታ ቤት ወይም በባሕር ማስመጣት ወይም መላክ አይቻልም፣

(4) የጉምሩክ ባለስልጣን የጤና ጥበቃ ሚኒስቴርን ፈቃድ ሳያገኝ ናርኮቲክ ወይም ሣይኮትሮፒክ መድኃኒቶችን ከመግቢያ ኬላው መልቀቅ አይችልም።

11. **የማስመጣት ወይም የመላክ ልዩ ፈቃድ አስፈላጊነት፣**

(1) ያለ ጤና ጥበቃ ሚኒስቴር ልዩ ፈቃድ ማንኛውንም ናርኮቲክ ወይም ሣይኮትሮፒክ መድኃኒቶች ማስመጣት ወይም መላክ አይቻልም፣

CCRDA

(2) ማንኛውም ናርኮቲክ ወይም ሳይኮትሮፒክ መድኃኒቶችን ለማስመጣት ወይም ለመላክ የተፈቀደለት ድርጅት ናርኮቲክ ወይም ሳይኮትሮፒክ መድኃኒት ሲያስመጣ ወይም ሲልክ ከጤና ጥበቃ ሚኒስቴር ልዩ የማስመጣት ፈቃድ ቅጽ NPS 11/A ልዩ የመላክ ፈቃድ ቅጽ NPS 11/B በቅድሚያ ማግኘት አለበት።

12. <u>የማስመጣት ወይም የመላክ ልዩ ፈቃድ ለማግኘት የሚቀርብ ማመልከቻ፣</u>

(1) የማስመጣት ወይም የመላክ ልዩ ፈቃድ ለማግኘት ጤና ጥበቃ ሚኒስቴር ባዘጋጀው የማመልከቻ ቅጽ NPS/10 ፣

- የ አመልካቹ ስምና አድራሻ፣
- የ ላኪው ወይም የሚላክለት ድርጅት ስምና አድራሻ፣
- የመድኃኒቱ ስም፣ ጥንካሬ፣ ዓይነትና ብዛት፣

ተሞልቶ መቅረብ አለበት። ቅጹን ከጤና ጥበቃ ሚኒስቴር መድኃኒት አስተዳደርና ቁጥጥር መምሪያ ማግኘት ይቻላል ።

(2) ጤና ጥበቃ ሚኒስቴር ማመልከቻውን ለመመለስ፣ የተጠየቀውን መጠን ለመቀነስ፣ ወይም የተጠቀሰውን ክብደት ለማሻሻል ወይም አስፈላጊ ያልሆኑ መድኃኒቶችን ከዝርዝሩ የማውጣት ሥልጣንና ኃላፊነት አለው።

(4). No medical personnel shall prescribe narcotic drugs and psychotropic substances for himself.

18. <u>Persons Entitled to Issue Prescriptions</u>

(1). A prescription for narcotic drug or psychotropic substance may be issued only by an individual practitioner who is authorized to prescribe narcotic drugs or psychotropic substances in which he is licensed to practice his profession.

(2). A prescription issued by an individual practitioner and communicated to a pharmacist or druggist by an employee or agent of the individual practitioner shall be acceptable.

19. <u>Manner of Issuance of Prescription</u>

(1). Any prescription for narcotic drugs or psychotropic substances shall:

(a). be dated as of, and signed on, the day when issued;

(b). bear the full name, age, sex, address and card number of the patient; and

(c). bear the name, address, and license number of the practitioner. A practitioner may sign a prescription in the same manner as he would sign a check or legal document.

CRDA

(3). Narcotic drugs or psychotropic substances arriving at customs port shall be delivered or exported only on submission of approval of clearance for their release issued by Ministry of Health. The Customs Service at the port of entry shall, on import or export, collect the certificate of clearance for release or export from the person effecting the transaction. Copies of the said certificate of clearance shall be kept by the Ministry of Health, Customs service at the port of entry and the institution effecting the transaction.

PART FOUR
PRESCRIPTION AND DISPENSING AGAINST PRESCRIPTION

17. Prohibition

(1). No medical personnel shall prescribe narcotic drug or psychotropic substance on other prescription paper except on the special prescription papers for narcotic drug or psychotropic substance.

(2). No Pharmacy or Drug Shop shall dispense narcotic drugs or psychotropic substances without Narcotic Drug or Psychotropic Substance special prescription papers.

(3). No person shall use narcotic drugs and psychotropic substances unless they are prescribed for him by a medical personnel who is licensed to prescribe.

CCRDA

(4). No medical personnel shall prescribe narcotic drugs

13. የማስመጣት ልዩ ፈቃድ ስለመጠየቅ፣

(1) የጤና ጥበቃ ሚኒስቴር ማንኛውም ናርኮቲክ ወይም ሣይኮትሮፒክ መድኃኒት ወደ አገር እንዲገባ የሚፈቅደው፣

(ሀ) መድኃኒቱ በብሔራዊ የመድኃኒት መዘርዝር ውስጥ የታቀፈ ከሆነ፣

(ለ) መድኃኒቱ በአገሪቱ ውስጥ ለጤና አገልግሎት ተግባር ወይም ለሣይንሣዊ ምርምር ተግባር ወይም ለሌላ ሕጋዊ ተግባር አስፈላጊ መሆኑ ሲረጋገጥ፣

(ሐ) የናርኮቲክና የሣይኮትሮፒክ መድኃኒቶች የአገር ውስጥ አቅርቦትና ለሣይንሣዊ ምርምር ተግባር የሚይበቃ ሆኖ ሲገኝ ይሆናል።

14. የማስመጣት ልዩ ፈቃድ ኮፒዎች ስርጭት፣

(1) የጤና ጥበቃ ሚኒስቴር የማስመጣት ልዩ ፈቃድ ዋናው ኮፒ (አንደኛው ኮፒ) ለአስመጪው ይሰጣል። አስመጪው ኮፒውን ለላኪው ድርጅት ይልካል። ላኪው ድርጅትም መድኃኒቶችን መላክ እንዲችል ልዩ ፈቃዱን ለሚመለከተው የመንግሥት ባለሥልጣን ያስረክባል።

(2) ሁለተኛው ኮፒ በጤና ጥበቃ ሚኒስቴር በኩል በላኪው አገር ለሚገኘው ተቆጣጣሪ ባለሥልጣን ይላካል።

(3) ሶስተኛው ኮፒ በጤና ጥበቃ ሚኒስቴር በኩል መድኃኒቱ በሚገባበት ኬላ ለሚገኝ የጉምሩክ ባለሥልጣን ተወካይ ይላካል። በዚህ ኮፒ ላይ የተጠቀሰው ከመድኃኒቱ ጋር ከመጣው መረጃ ጋር ተመሣሣይ ለመሆኑ ይነጻጸራል። በሁለቱ ኮፒዎች መካከል ልዩነት ከታየ የኬላው ጉምሩክ ባለሥልጣን ፈቃድ ሣይሰጥ ለመድኃኒት አስተዳደርና ቁጥጥር መምሪያ ሪፖርት በማቅረብ ስለታየው ልዩነት መረጃ ይጠይቃል፣ እውነታው ይመረመራል፣ መመሪያ እስከሚሰጥበት ድረስ እንዲገባ አይፈቀድም።

(4) አራተኛው ኮፒ በጤና ጥበቃ ሚኒስቴር ቀሪ ይሆናል።

15. <u>የማስመጣት ልዩ ፈቃድ ስረዛና የአገልግሎት ጊዜ ገደብ፣</u>

(1) ማንኛውም ድርጅት በየጊዜው የማስመጣት ልዩ ፈቃድ መጠየቅ ይኖርበታል። በአንድ ጊዜ የሚሰጠው የማስመጣት ልዩ ፈቃድም ከዘጠና /90/ ቀን በላይ አያገለግልም።

(2) የማስመጣት ፈቃዱ ከተሰጠ በኋላ የሚሰረዘው፣ ፈቃድ የተሰጠው አካል መድኃኒቱን በተሰጠው የጊዜ ገደብ ወደ አገር ያላስገባ መሆኑ ሲረጋገጥ ወይም ሲጠፋ ይሆናል። የተሰጠው ፈቃድ መጥፋቱን የሚያረጋግጥ ማስረጃ ከቀረበ የጠፋው ፈቃድ ተሰርዞ በምትኩ አዲስ ፈቃድ ይሰጣል።

15. <u>Cancellation of Special Import Permit & Expiration Date</u>

(1). Any licensed institution shall apply for a special import permit for each consignment. Such special permit shall be valid only for ninety (90) days.

(2). An import permit shall be canceled after being issued provided no shipment has been made or in the event that a permit is lost.

(3). Nothing in this part shall affect the right, hereby reserved by Ministry of Health, to cancel a permit at any time for proper cause.

16. <u>Import Declaration and Clearance from the Port of Entry</u>

(1). Narcotic drugs or psychotropic substances that are not confirmed by a drug control laboratory and duly registered in the record of Ministry of Health shall not be released from Customs port of entry.

(2). The customs service at the port of entry shall forward the special export permit to the Ministry of Health with a report on the reverse side of it, showing the name of the port of entry, date of entry and name and net quantity of each substance upon arrival of the substance at the port of entry.

FDA

(1). The original copy (copy 1) of the special permit shall be issued by the Ministry of Health to the importer. The importer shall transmit this copy to the foreign exporter. The foreign exporter shall submit the copy to the proper governmental authority in the exporting country, if required, as a prerequisite to the issuance of an export authorization.

(2). The duplicate copy (copy 2) shall be forwarded by Ministry of Health to the proper governmental authorities of the exporting country.

(3). The triplicate copy (copy 3) shall be forwarded by Ministry of Health to the Customs Authority at the port of entry. The Customs Service at the port of entry shall compare this copy with the original copy (copy 1) and the bill of lading upon arrival of the merchandise. If a discrepancy is noted between corresponding items upon different copies of a permit bearing the same serial number when compared by the Customs Service at the port of entry, it shall refuse to permit entry of the merchandise until the facts are communicated to Drug Administration and Control Department of Ministry of Health and further instructions are received.

(4). The quadruplet copy (copy 4) shall be retained by Ministry of Health.

GERDA

የመሰረዝ መብቱ የተጠበቀ ነው።

16. <u>ስለገቡ መድኃኒቶች ማሳወቅና ከኪላ እንዲወጡ መፍቀድ፣</u>

(1) በመድኃኒት ጥራት መቆጣጠሪያ ላቦራቶሪ ያልተረጋገጡ ወይም ዓይነታቸውና መጠናቸው በጤና ጥበቃ ሚኒስቴር ሪኮርድ ያልተያዙ ናርኮቲክ ወይም ሣይኮትሮፒክ መድኃኒቶች ከጉምሩክ መጋቢያ ኪላ እንዲለቀቁ አይፈቀድም።

(2) ፈቃድ ተሰጥቶት የመግቢያ ኪላ የደረሰ መድኃኒት በኪላው ያለው የጉምሩክ ባለሥልጣን መ/ቤት ከመድኃኒቱ ጋር ከደረሰው የመላኪያ ልዩ ፈቃድ በስተጀርባ ላይ መድኃኒቱ የገባበት ኪላ ስም፣ የገባበት ቀን፣ የመድኃኒቱ ስምና የተጣራ መጠን በመግለጽ ለጤና ጥበቃ ሚኒስቴር ሪፖርት ይልካል።

(3) በኪላ የሚገኘው የጉምሩክ ባለሥልጣን ተወካይ መድኃኒቶች ሲመጡም ሆነ ሲላኩ ጤና ጥበቃ ሚኒስቴር መድኃኒቱ እንዲለቀቅ የሰጠውን ፈቃድ ጉዳዩን ከሚያስፈጽመው ግለሰብ በመቀበል ትክክለኛነቱን ያረጋግጣል። ሪኮርድ ይይዛል፡ የዚሁ የመልቀቂያ ፈቃድ ኮፒዎች በጤና ጥበቃ ሚኒስቴር፣ በመግቢያ ኪላ የጉምሩክ ባለሥልጣን ጽ/ቤትና መድኃኒቱን በሚያስመጣው ወይም በሚልከው ድርጅት ይያዛል።

ክፍል አራት
ስለ ማዘዝና ስለማደል

17. የተከለከለ፣

(1) ማንኛውም ናርኮቲክ ወይም ሳይኮትሮፒክ መድኃኒት እንዲያዝ የተፈቀደበት የሕክምና ባለሙያ በናርኮቲክ ወይም ሳይኮትሮፒክ ልዩ ማዘዣ ወረቀት ካልሆነ በስተቀር በሌላ ማዘዝ አይችልም።

(2) ማንኛውም መድኃኒት ቤት ወይም መድኃኒት መደብር በናርኮቲክ ወይም ሳይኮትሮፒክ ልዩ ማዘዣ ወረቀት አማካኝነት ካልሆነ በስተቀር ናርኮቲክ ወይም ሳይኮትሮፒክ መድኃኒት ማደል አይችልም።

(3) ማንኛውም ሰው በዚህ መመሪያ መሠረት ናርኮቲክና ሳይኮትሮፒክ መድኃኒቶችን ለማዘዝ በተፈቀደለት የሕክምና ባለሙያ ሳይታዘዝለት መድኃኒቶችን መጠቀም አይፈቀድለትም፣

(4) አንድ የሕክምና ባለሙያ ናርኮቲክ ወይም ሳይኮትሮፒክ መድኃኒት ለራሱ ማዘዝ አይችልም።

Form NPS/10 shall be obtained from Drug Administration and Control Department of the Ministry of Health P.O.Box 1234 Addis Ababa.

(2). The Ministry of Health shall have the power to reject an application, reduce the quantity/weight requested, or exclude certain items from the list of requisition.

13. Issuance of Special Import Permit

(1). The Ministry of Health shall authorize importation of any Narcotic Drug or Psychotropic Substance if it finds that:

(a). the substance is included in the National List of Drugs.

(b). the substance is necessary to provide medical and scientific needs or other legitimate needs of the country.

(c). the domestic supply of any Narcotic Drug or Psychotropic Substance is inadequate for scientific studies.

FDRE FDA

drugs or psychotropic substances from the port of entry unless it is authorized by the Ministry of Health.

11. Requirement of Special Import or Export Permit

(1). No import or export of narcotic drugs or psychotropic substances shall be allowed, unless it is authorized by a special permit of the Ministry of Health.

(2). Institutions licensed to import or export narcotic drugs or psychotropic substances shall obtain Import Authorization Certificate (Form NPS/11/A) or Export Authorization Certificate (Form NPS/11/B) for each consignment to be imported or exported from Ministry of Health.

12. Application for Import or Export Permit

(1) An application for a permit to import or export narcotic drugs or psychotropic substances shall be made on form NPS/10. Each application shall show:

* the name and address of the applicant;
* the name and address of the importer or exporter;
* the name, dosage form, strength & quantity of the drug.

Form NPS/10 shall be obtained from Drug

18. አንዲያዝ የተፈቀደለት ባለሙያ፣

(1) ናርኮቲክ ወይም ሣይኮትሮፒክ መድኃኒት ማዘዝ የሚችለው በሙያው አንዲሠራ ሕጋዊ ፈቃድ ያገኘና ናርኮቲክና ሣይኮትሮፒክ መድኃኒቶችን እንዲያዝ የተፈቀደለት ሕክምና ባለሙያ ብቻ ይሆናል።

(2) ሕጋዊ ፈቃድ ባለው የሕክምና ባለሙያ የተፃፈ ማዘዣ ወረቀት በተወሳዩ ሲቀርብ መድኃኒት ቤቶችና መድኃኒት መደብሮች ሊቀበሉት ይገባል።

19. የማዘዣ ወረቀት አስተላለፍ ሥርዓት፣

(1) ማንኛውም የናርኮቲክ ወይም ሣይኮትሮፒክ ማዘዣ ወረቀት፣

(ሀ) ትእዛዙ የተፃፈበት ቀን፣

(ለ) የበሽተኛው ስም፣ ዕድሜ፣ ጸታ፣ አድራሻና የካርድ ቁጥር፣

(ሐ) ያዘዘው ባለሙያ ስም፣ አድራሻ፣ የፈቃድ ቁጥርና፣ ፊርማ መያዝ ይኖርበታል። ባለሙያው ማዘዣ ወረቀት ላይ የሚፈርመው ፊርማ በማንኛውም ሕጋዊ ዶኩሜንትና የባንክ ቼክ ላይ የሚኖረው ፊርማ ዓይነት መሆን አለበት፣

(2) ማዘዣ ወረቀቶች በብዕር ቀለም በእጅ የተጻፉና የተፈረሙ መሆን አለባቸው።

©CRDA

(3) አንድ የሕክምና ባለሙያ ናርኮቲክ ወይም ሣይኮትሮፒክ መድኃኒቶች ለበሽተኛው የሚያዘው ለሕክምና ተግባር ካልሆነ በስተቀር ለሌላ ጉዳይ መሆን የለበትም።

20. ናርኮቲክ ወይም ሣይኮትሮፒክ መድኃኒቶችን ስለማደል።

(1) ማንኛውም የናርኮቲክ ወይም ሣይኮትሮፒክ ማዘዣ ወረቀት ከዚህ በታች የተዘረዘሩትን ግዴታዎች ካላሟላ አገልግሎት ሊሰጥ አይችልም።

(ሀ) የበሽተኛው ስም፣ ዕድሜ፣ ጸታ፣ አድራሻና ካርድ ቁጥር በግልፅ የተፃፈበት፣

(ለ) የመድኃኒቱ ስም፣ ጥንካሬ፣ የዝግጅት ዓይነት፣ ብዛት፣ የታዘዘበት ቀንና የአወሳሰድ መመሪያ በግልፅ የተፃፈበትና

(ሐ) የሕክምና ባለሙያውን ስም፣ አድራሻና የፈቃድ ቁጥር በግልፅ የሠፈረበት፣

(መ) የታዘዘበት ጤና ድርጅት ማህተም ያለበት መሆን አለበት፣

(2) ማንኛውም ናርኮቲክ ወይም ሣይኮትሮፒክ መድኃኒትን የያዘ ማዘዣ ወረቀት ከታዘዘበት ቀን ጀምሮ ከአሥራ አምስት ቀን በኋላ አገልግሎት አይሰጥበትም።

9. Suspension and Revocation of a License

(1). The license shall be revoked:

(a). if it has not been made use of within one calendar year. The time limit can be extended if due interest is substantiated.

(b). if the licensee was found guilty of one of the offenses listed under of Article 6.

(2). The competent authorities shall be immediately informed about any withdrawal or revocation of the license.

PART THREE
IMPORT, EXPORT AND TRANSIT

10. Prohibition

(1). No institution shall import or export narcotic drugs or psychotropic substances packing them with other drugs or items.

(2). Any institution shall import or export narcotic drugs or psychotropic substances in tamper proof packs.

(3). Importing or exporting narcotic drugs through the post office or by sea shall be prohibited.

FDRE

(1). The application (Form NPS/20) for obtainment of a license under Article 4 shall be submitted in duplicate to the Ministry of Health and shall contain the following information:

(a). Name in full, profession, nationality of the applicant.

(b). Name of the institution and its address.

(c). The kind of trade in Narcotic Drugs and Psychotropic Substances to be thought.

(d). Name, type and strength of Narcotic Drugs or Psychotropic Substances to be employed.

8. **Decision Taking**

(1). Ministry of Health shall make its decisions upon granting the license within three months following application.

(2). If the applicant is given the opportunity to remedy any defects of application, the time limit fixed in this Article sub article 1 shall be suspended until the correction of the defects or until the expiry of the time limit fixed for the correction.

(3). The holder of the license shall immediately report to the Ministry of Health of any modification of the data specified in Article 7.

(3) ማንኛውም ፈቃድ ያገኘ ወይም ኃላፊነት ያለበት ወይም ሣይኮትሮፒክ መድኃኒቶች የሚያዘው ማዘዣ ወረቀቱ በኢትዮጵያ ውስጥ ናርኮቲክና ሣይኮትሮፒክ መድኃኒቶችን እንዲያዝ ፈቃድ በተሰጠው የሕክምና ባለሙያ የተፃፈ እንደሆነ ብቻ ነው።

(4) ማንኛውም የናርኮቲክ ወይም የሣይኮትሮፒክ ማዘዣ ወረቀት፣

- መድኃኒቱ ከታደለበት በኋላ ለአምፌዉ ተመልሶ አይሠጥም፣
- ከአንድ ጊዜ በላይ ጥቅም ላይ አይውልም፣

ክፍል አምስት
ሪኮርድና ሪፖርት

21. ጠቅላላ

(1) ናርኮቲክና ሣይኮትሮፒክ መድኃኒቶች ያመረተ፣ ያስመጣ፣ የላከ፣ ወይም ያከፋፈለ ድርጅት፣ ሥራው በተሰራበት ዕለት ሪኮርድ ይይዛል። በተጨማሪም ሚኒስቴሩ የሚፈልጋቸው ሌሎች መረጃዎች በተለየ መዝገብ ሪኮርድ ይይዛሉ።

(2) የሪኮርድ መዝገቡ የጤና ጥበቃ ሚኒስቴር ወይም የፍትሕ ሚኒስቴር በሚጠይቁበት ጊዜ ይሰጣል።

CCRDA

(3) ናርኮቲክና ሣይኮትሮፒክ መድኃኒቶችን ለማምረት፣ ለማስመጣት፣ ለመላክ ወይም ለማከፋፈል ፈቃድ የተሰጠው ድርጅት ስለመድኃኒቶቹ ዘገባ በጤና ጥበቃ ሚኒስቴር ለመድኃኒት አስተዳደርና ቁጥጥር መምሪያ ያቀርባል።

22. <u>ሪኮርድ ፣</u>

(1) ማንኛውም አስመጪ/ ጅምላ አከፋፋይ፣

(ሀ) ያስመጣቸውን ናርኮቲክ መድኃኒቶች በቅጽ NPS/01፣

(ለ) ያስመጣቸው ሣይኮትሮፒክ መድኃኒቶች በቅጽ NPS/02 ፣

(ሐ) ያከፋፈላቸው ናርኮቲክ መድኃኒቶች በቅጽ NPS/01/A

(መ) ያከፋፈላቸው ሣይኮትሮፒክ መድኃኒቶች በቅጽ NPS/02/A ፣

ሪኮርድ መያዝ አለበት።

(2) ማንኛውም ጤና ድርጅት፣

(ሀ) የገዛቸው ናርኮቲክ ወይም ሣይኮትሮፒክ መድኃኒቶች በሞዴል 19፣ በቅጾች NPS/06/A እና NPS/06/B፣

(2). Any one who has been convicted of any offence against property, gambling, drug abuse, drug trafficking, or enactment to commit any such offence, or forgery, the use of forged documents, assumption of false identity, or false testimony, or any one convicted of planning to commit any such offence.

(3). Any one who has previously been subjected to disciplinary dismissal from public office on grounds of detrimental to honor or trust.

(4). Where adequate rooms, facilities and securities for the participation in the trade in narcotic drugs or psychotropic substances fail to exist.

(5). Where there is no guarantee for the safety and control of the trade in or the manufacture of narcotic drugs or psychotropic substances.

(6). If the application conflicts with the implementation of the Pharmacy Regulation or International Conventions on narcotic drugs or psychotropic substances or with the decisions, orders or recommendations of intergovernmental Narcotic Drugs and Psychotropic Substances Control Bodies.

FDRDA

(e). Conducting research with Narcotic Drugs or Psychotropic Substances;

(2). A license to manufacture, import, export or distribute narcotic drugs or perform chemical analysis or research on same shall be issued only to governmental institutions.

(3). A license to manufacture, import, export or distribute psychotropic substances or perform chemical analysis or research on same shall be issued only to legalized institutions.

5. **Exception of Compulsory Licensing**

A license pursuant to Article 4 shall not be required for a person who, may posses narcotic drugs or psychotropic substances for his/her own private use and for strictly medical purposes, provided that the quantity of such substances does not exceed the quantity prescribed by a licensed physician.

6. **Prohibition from Licensing**

The license under Article 4 shall not be granted to:

(1). Any one who has been convicted of any of the offenses specified in the Pharmacy Regulation.

(ለ) ለመድኃኒት ማደያ ክፍል ያከፋፈላቸው ናርኮቲክ ወይም ሣይኮትሮፒክ መድኃኒቶች በሞዴል 22፣ በቅጾች NPS/07/A እና NPS/07/B፣

(ሐ) በማዘዣ ወረቀት መሠረት ለውስጥ ታካሚዎች ያደላቸዉ ናርኮቲክ ወይም ሣይኮትሮፒክ መድኃኒቶች በቅጾች NPS/08/A እና NPS/08/B ፣

(መ) በማዘዣ ወረቀት መሠረት ለተመላላሽ ታካሚዎች ያደላቸው ናርኮቲክ ወይም ሣይኮትሮፒክ መድኃኒቶች በቅጾች NPS/09/A እና NPS/09/B ሪኮርድ መያዝ አለበት።

(3) ማንኛውም መድኃኒት ቤት ወይም መድኃኒት መደብር ናርኮቲክ ወይም ሣይኮትሮፒክ መድኃኒቶችን የገዛበትን ኢንቮይሶች በፋይል እንደ ቅደም ተከተላቸው ከአምስት ዓመት ለማያንስ፣ ጊዜ ሪኮርድ መያዝ አለበት።

23. ሪፖርት

(1) ማንኛውም አስመጪ፣ ላኪ፣ ወይም አምራች ድርጅት ስለ አስመጣቸው፣ ያላካቸው፣ ያአከፋፈላቸው ወይም ያመረታቸውን ናርኮቲክ ወይም ሣይኮትሮፒክ መድኃኒቶች አስመልክቶ፣

(ሀ) በየሩብ ዓመቱ መጨረሻ በቅጾች NPS/01፣ NPS/01/A NPS/02 እና NPS/02/A፣

CCRDA

(ለ) በየዓመቱ መፈረሻ በቅጾች NPS/03 እና NPS/04፣

ለጤና ጥበቃ ሚ/ር መድኃኒት አስተዳደርና ቁጥጥር መምሪያ ሪፖርት መላክ አለበት፣

(2) ማንኛውም የጤና ድርጅት ስለ ገዛቸውና ስለአደላቸው ናርኮቲክ ወይም ሣይኮትሮፒክ መድኃኒቶች አስመልክቶ በየዓመቱ መፈረሻ በቅጾች NPS/15/A እና NPS/15/B በጤና ጥበቃ ሚኒስቴር ሥር ከሆነ ለጤና ጥበቃ ሚኒስቴር መድኃኒት አስተዳደርና ቁጥጥር መምሪያ፣ በክልል የሚገኝ ከሆነ ለክልል ጤና ቢሮ ሪፖርት መላክ አለበት።

ክፍል ስድስት
ልዩ ልዩ ድንጋጌዎች

24. ስለ አያያዝ፣

የናርኮቲክና ሣይኮትሮፒክ መድኃኒቶች፣ እንቮይሶች፣ የሪኮርድ ቅጾችና ደብተሮች፣ የማዘዣ ወረቀቶችና የመሳሰሉትን ቁልፍ ባለው የብረት ሳጥን ወይም በተለየ ክፍል ውስጥ መቀመጥና ቁልፉም በተፈቀደለት ባለሙያ እጅ መያዝ አለበት

25. ስለ አወጋገድ፣

(1) የአገልግሎት ጊዜያቸው በማብቃታቸው ወይም በመበላሸታቸው የተነሳ ጥቅም የማይሰጡ ናርኮቲክ ወይም ሣይኮትሮፒክ መድኃኒቶች የጤና ጥበቃ ሚኒስቴር ተወካይ በተገኙበት እንዲወገዱ ይደረጋል፣

PART TWO
LICENSE AND LICENSING PROCEDURE

3. **Requirements for Licensing**

(1). No institution shall manufacture, import, export, distribute narcotic drugs or psychotropic substances or perform chemical analysis or research on same unless it is licensed (Form NPS/21).

(2). Any institution which wishes to engage in the aforementioned activities shall apply on a form that may be prescribed by the Ministry of Health.

4. **A Separate license for Independent Activities**

(1). The following groups of activities are deemed to be independent of each other:

(a). Manufacturing Narcotic Drugs or Psychotropic Substances;

(b). Importing or Exporting Narcotic Drugs or Psychotropic Substances;

(c). Distributing Narcotic Drugs or Psychotropic Substances;

(d). Conducting chemical analysis with Narcotic Drugs or Psychotropic Substance;

CRDA

PART ONE
GENERAL

1. **Short Title**

This Guideline may be cited as "Guideline to Control Narcotic Drugs and Psychotropic Substances and to Regulate their Use and Trade therein 02/96".

2. **Definitions**

In this Guideline, unless the context provides otherwise;

(1). "Narcotic Drug" shall mean any drug subject to control according to Narcotic Drugs conventions of the United Nations ratified by Ethiopia. This shall also include a drug that is categorized as narcotic drug by the Ministry of Health.

(2). "Psychotropic Substance" shall mean any substance subject to control according to psychotropic substances convention of the United Nations ratified by Ethiopia. This shall also include a substance that is categorized as psychotropic substance by the Ministry of Health.

(2) የጤና ጥበቃ ሚኒስቴር መድኃኒት አስተዳደርና ቁጥጥር መምሪያ በጤና ጥበቃ ሚኒስቴር ስር የሚገኙ ጤና ተቋማት ለተወገዱት ናርኮቲክ ወይም ሣይኮትሮፒክ መድኃኒቶች ሰርቲፊኬት (ቅጽ NPS/14) ይሰጣል። በየክልሉ ለሚወገዱት ናርኮቲክ ወይም ሣይኮትሮፒክ መድኃኒቶች ሰርቲፊኬት የሚሰጠው በክልል ጤና ቢሮዎች ወይም የዞን ጤና መምሪያዎች ይሆናል። የክልል ጤና ቢሮዎች የሰጡት ሰርቲፊኬትና ከዞን ጤና መምሪያዎች የደረሱዋቸው ሪፖርቶች ቅጅ ለጤና ጥበቃ ሚኒስቴር መድኃኒት አስተዳደርና ቁጥጥር መምሪያ ይልካሉ።

(3) በሕገወጥ ዝውውር፣ ምርት ወይም ገበያ እንዳሉ የሚያዙትን ናርኮቲክ ወይም ሣይኮትሮፒክ መድኃኒቶች ዓለም አቀፍ ስምምነቶች በሚደነገጉት መሠረት ከጤና ጥበቃ ሚኒስቴር፣ ከፍትሕ ሚኒስቴር፣ ከጉምሩክ ባለሥልጣን የሌሎች አስፈላጊ መ/ቤቶች ተወካዮች የሚገኙበት ኮሚቴ ተቋቁሞ እንዲወገዱ ይደረጋል።

26. **ስለ ተሰረቁ**

ማንኛውም የናርኮቲክ ወይም ሣይኮትሮፒክ መድኃኒቶች ስርቆት መካሄዱ ሲታወቅ ቢዘገይ በሚቀጥለው የሥራ ቀን ለጤና ጥበቃ ሚኒስቴር፣ ለአካባቢው የጤና ጥበቃ ሚኒስቴር ተወካይ ወይም ለአካባቢው ፖሊስ ሁኔታው በቅጽ NPS/22 ሪፖርት መደረግ ይኖርበታል። ሪፖርት ቅጹ የሚከተሉት መረጃዎች ይይዛል፣

- የድርጅቱን ስምና አድራሻ፣

GORDA

- የፈቃዱን ቁጥር፣
- ስርቆቱ የተካሄደበት ቀን፣
- ሪፖርት የቀረበለት የአካባቢው ፖሊስ፣
- የስርቆቱን ዓይነት፣ እና
- የተሰረቁት ናርኮቲክ ወይም ሣይኮትሮፒክ መድኃኒቶች ዝርዝር፣

27. ሥራ ስለማቋረጥ፣

ፍቃድ የተሰጠው ድርጅት ሥራውን አቋርጦ ፍቃዱን ለሌላ ሰው የሚያስተላልፍ ከሆነ፣ ፈቃዱና አገልግሎት የተሰጠባቸው ማዘዣ ወረቀቶችን ለጤና ጥበቃ ሚኒስቴር ሲመልስ መድኃኒቶቹ በጤና ጥበቃ ሚኒስቴር ተቆጣጣሪነት ለገዘበት ድርጅት ይመልሳል።

28. ቅጣት፣

ይህንን መመሪያ ተላልፎ የሚገኝ ማንኛውም ግለሰብ ወይም ድርጅት በሕግ ይቀጣል።

GUIDELINE TO CONTROL NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES AND TO REGULATE THEIR USE AND TRADE THEREIN

WHEREAS, recognizing the significant role of health in proper life and productivity of the people, and so is realized that narcotic drugs and psychotropic substances share a vital role in the health service;

WHEREAS, it is found necessary to deter the illicit production, distribution and use of narcotic drugs and psychotropic substances;

WHEREAS, it is found necessary to maintain the proper production, import, export, distribution, prescribe, dispense and use of narcotic drugs and psychotropic substances;

WHEREAS, to achieve these ends it is essential to lay down a secured narcotic drugs and psychotropic substances control system;

NOW THEREFORE in accordance with the Pharmacy Regulation Legal Notice No. 288/64 and the International Narcotic Drugs and Psychotropic Substances Conventions, a Guideline is hereby issued as follows.

FDRE

የናርኮቲክና ሳይኮትሮፒክ መድኃኒቶች ማዘዣ ወረቀቶች አገልግሎት ለመቆጣጠር የወጣ መመሪያ

GUIDELINE TO CONTROL NARCOTIC DRUGS & PSYCHOTROPIC SUBSTANCES PRESCRIPTION PAPERS

የጤና ጥበቃ ሚኒስቴር

MINISTRY OF HEALTH

አዲስ አበባ

ሰኔ 1988

Addis Ababa

June 1996

B.S.P.E.

CRDA

የቃል አገባቡ ሌላ ትርጓሜ የሚያሰጠው ካልሆነ በስተቀር በዚህ መመሪያ ውስጥ፣

(1) "ናርኮቲክ" ማለት ኢትዬጵያ በተቀበለችው የተባበሩት መንግሥታት ድርጅት የናርኮቲክ መድኃኒቶች ቁጥጥር ስምምነት መሠረት አለም አቀፍ ቁጥጥር የሚደረግበትና የጤና ጥበቃ ሚኒስቴር ሀገራዊ ቁጥጥር እንዲደረግበት የሚወሰንበት ማንኛውም ነገር ነው።

(2) "ሳይኮትሮፒክ" ማለት ኢትዬጵያ በተቀበለችለው የተባበሩት መንግሥታት ድርጅት የሳይኮትሮፒክ መድኃኒቶች ቁጥጥር ስምምነት መሠረት አለም አቀፍ ቁጥጥር የሚደረግበትና የጤና ጥበቃ ሚኒስቴር ሀገራዊ ቁጥጥር እንዲደረግበት የሚወሰንበት ማንኛውም ነገር ነው።

(3) ማዘዣ ወረቀት" ማለት ፈቃድ ባለው የሕክምና ባለሙያ ተፈርሞ ለሕሙማን የሚሰጥ ማንኛውም የናርኮቲክ ወይም ሳይኮትሮፒክ መድኃኒት ማዘዣ ወረቀት ነው።

3. <u>አስፈፃሚ አካል፣</u>

ይህንን መመሪያ እንዲያስፈጽሙ፣ የመድኃኒት አስተዳደርና ቁጥጥር መምሪያ፣ የክልል ጤና ቢሮዎችና የዞን ጤና መምሪያዎች ሙሉ ኃላፊነትና ሥልጣን ተሰጥቶዋቸዋል።

which it was issued.

(g). the right drug is prescribed in the right prescription paper.

(2). Every drug retail outlet shall register the necessary information on Form NPS/19 and keeps the prescription papers in a locked cupboard for five years. The drug retail outlets shall send their reports up to December 31 and June 30, every year, to their respective Regional Health Bureaus. The Regional Health Bureau shall compile the reports of all drug retail outlet under it and shall send up to January 31 and July 31, every year, to Drug Administration and Control Department of the Ministry of Health.

(3). Every drug retail outlet shall inform the Drug Administration and control Department, the nearby health institution or Police Department about individuals or professionals who try to use the missing prescription papers from health institutions on the next working day.

(4). No drug retail outlet shall refill a prescription paper.

(5). Every drug retail outlet shall write the name of the dispenser, signature and the date of dispensing on each filled prescription paper after dispensing a drug to a patient.

CCRDA

10. Lost or Stolen Prescription Papers

Any drug retail outlet shall inform the Drug Administration and Control Department, the near by representative of the Ministry of Health or Police Department about the stolen or lost unused prescription papers on the next working day.

11. Disposal

Every drug retail outlet shall request the institution in charge of disposing expired or damaged drugs for the disposal of used prescription papers.

12. Penalty

Any person or institution who fails to comply with this Guideline shall be punishable by Law.

CCRDA

የናርኮቲክና ሣይኮትሮፒክ መድኃኒቶች ማዘዣ ወረቀቶች አገልግሎት ለመቆጣጠር የወጣ መመሪያ

በሁሉም ጤና ድርጅቶች የታተሙና አንድ ወጥ የሆኑ ማዘዣ ወረቀቶች አገልግሎት ላይ እንዲውሉ በማስፈለጉ፣

የናርኮቲክና ሣይኮትሮፒክ መድኃኒቶች ትክክለኛ ያልሆነ አስተዛዘዝ፣ እንዳለና አጠቃቀም ለመከላከል አስፈላጊ ሆኖ በመገኘቱ፣

የማዘዣ ወረቀቶቹ ሕትመት፣ ስርጭትና አያያዝ ስርዓት ባለው መንገድ እንዲከናወን በማስፈለጉ፣

ለነዚህም አስተማማኝ የሆነ የማዘዣ ወረቀቶች ቁጥጥር ስርዓት መዘርጋት አስፈላጊ ሆኖ በመገኘቱ፣

በፋርማሲ ደንብ የሕግ ክፍል ማስታወቂያ ቁጥር 288/56 እና በአለም አቀፍ የናርኮቲክና ሣይኮትሮፒክ መድኃኒቶች ቁጥጥር ስምምነቶት መሠረት የሚከተለው መመሪያ ወጥቷል።

1. አጭር ርዕስ

ይህ መመሪያ "የናርኮቲክና ሣይኮትሮፒክ መድኃኒቶች ማዘዣ ወረቀቶች አገልግሎት ለመቆጣጠር የወጣ መመሪያ ቁጥር 03/88" ተብሎ ሊጠቀስ ይችላል።

(ሀ) በጤና ጥበቃ ሚኒስቴር ሥር ያሉት ጤና ተቋማትና የግል ጤና ድርጅቶች ከመድኃኒት አስተዳደርና ቁጥጥር መምሪያ የድጋፍ ደብዳቤ ከቅፅ NPS/13/A ጋር በማያያዝ ሲጠየቅና፣

(ለ) በክልል ጤና ቢሮዎች ሥር የሚገኙ ጤና ተቋማት ከሆኑ ደግሞ ከክልሉ ጤና ቢሮ የድጋፍ ደብዳቤ ከቅጽ NPS/13/A ጋር በማያያዝ ሲጠየቅ ማዘዣ ወረቀቶቹ ይሸጣል።

(4) ማንኛውም የማከፋፈያ አውታር የማዘዣ ወረቀቶችና ማንኛውም ሪኮርድ የተያዘባቸውን ዶክሜንቶች ልክ እንደናርኮቲክና ሳይኮትሮፒክ መድኃኒቶች ቁልፍ ባለው ቁምሣጥን ወይም የተለየ ቁልፍ ባለው ክፍል መያዝ አለበት፡ ቁልፉም በድርጅቱ የቴክኒክ ኃላፊ እጅ መያዝ አለበት።

(5) የመንግሥት ማከፋፈያ አውታር ስላከፋፈሉዋቸው ማዘዣ ወረቀቶች፣ ብዛት ዓይነትና ሴሪ ቁጥር በየሩብ ዓመቱ በቅጽ NPS/05 ሞልቶ በጤና ጥበቃ ሚኒስቴር ለመድኃኒት አስተዳደርና ቁጥጥር መምሪያ ሪፖርት መላክ አለበት።

6. <u>የማዘዣ ወረቀቶቹ አገልግሎት በክልል ጤና ቢሮዎችና በዞን ጤና መምሪያዎች</u>

የክልል ጤና ቢሮ ወይም የዞን ጤና መምሪያ የፋርማሲና የባሕል መድኃኒት ቡድን፣

(5). **Records and Reports**

(a). Every pharmacy section of a health institution shall keep records of:

(1). prescription papers filled for out patients on Form NPS/09/A and Form NPS/09/A;

(2). prescription papers delivered to sections on Form NPS/24.

(b). Every Health Institution shall send reports of purchased, used and quantity in stock of prescription papers at the end of December 31, every year, on Forms NPS/18 either to Drug Administration and Control Department of the Ministry of Health or Regional Health Bureau.

(c). The report mentioned above in 5(b) shall be sent by health institutions to Regional Health Bureau. The Regional Health Bureau shall compile the reports of all health institutions under it and shall send up to January 31, every year, to Drug Administration and Control Department of the Ministry of Health.

(d). The health institutions under Ministry of Health shall send their report up to December 31, every year, directly to Drug Administration and Control Department of the Ministry of Health.

CCRDA

(e). Non governmental health institutions shall keep records in accordance to the conditions mentioned above in 5(a). The health institutions under Regional Health Bureau and in Addis city shall send their reports up to December 31, every year, to the Regional Health Bureau and Drug Administration and Control Department respectively.

Instructions to be Followed by Drug Retail Outlets

(1). Any drug retail outlet shall fill a prescription paper if:

(a). the information mentioned in Article 6 sub article 2(c) are fulfilled and the seal of a health institution is stamped.

(b). the prescription is not a copy or photo copy and un deleted.

(c). the internationally or nationally controlled narcotic drugs or psychotropic substances are not prescribed on the same prescription paper.

(d). not more than one type of narcotic drug or psychotropic substance is prescribed in one prescription paper.

(e). the serial number of the prescription paper is not deleted.

4. የማዘዣ ወረቀቶች ስለማሳተም፣

(1) ከመድኃኒት አስተዳደርና ቁጥጥር መምሪያ በስተቀር ማንኛውም ድርጅት ማዘዣ ወረቀቶችን ማሳተም አይችልም።

(2) የመድኃኒት አስተዳደርና ቁጥጥር መምሪያ ዓለም አቀፋዊ መስፈርትን የሚያሟሉና ለቁጥጥር አመቺ የሆኑ ማዘዣ ወረቀቶች በማዕከላዊነት ያሳትማል።

(3) የመድኃኒት አስተዳደርና ቁጥጥር መምሪያ አገልግሎቱ ቀጣይነት እንዲኖረው የመጠባበቂያ ክምችት በመያዝ በየጊዜው ያሳትማል።

(4) ማዘዣ ወረቀቶች በየጊዜው በሚታተሙበት ጊዜ የሴሪ ቁጥሮች ተከታታይነት ለመጠበቅ ቁጥሮች ከቆሙበት እንዲቀጥሉ ይደረጋል።

5. የማዘዣ ወረቀቶች አገልግሎት በመንግሥት ማከፋፈያ አውታሮች፣

(1) ማንኛውም የመንግሥት ማከፋፈያ አውታር ከመድኃኒት አስተዳደርና ቁጥጥር መምሪያ በሚሰጠው ኮታ መሠረት የማዘዣ ወረቀቶችን በበቂ መጠን ያከማቻል።

(2) ማከፋፈያ አውታሮች በሚከተሉት የመድኃኒት ክፍፍል ሥርዓት በመጠቀም ከመድኃኒት አስተዳደርና ቁጥጥር መምሪያ በሚወጣው የድልድል መመሪያ መሠረት ያከፋፍላሉ።

(3) ማንኛውም የማከፋፈያ አውታር የማዘዣ ወረቀቶችን እንዲገዛ የተፈቀደለት የጤና ተቋም በተደጋጋሚ ለመግዛት በሚጠይቅበት ጊዜ፣

FDRE

ማዘዣ ወረቀቶቹን አንዲይዝ የተፈቀደለት ተቋም የግዥ ጥያቄውን በቅጽ NPS/13/A ሞልቶ፣ በጤና ጥበቃ ሚኒስቴር ሥር የሚተዳደር ከሆነ ለመድኃኒት እስተዳደርና ቁጥጥር መምሪያ፣ በክልል ጤና ቢሮ ሥር የሚተዳደር ከሆነ ለክልል ጤና ቢሮ ማቅረብ አለበት።

(3) የመድኃኒት አስተዳደርና ቁጥጥር መምሪያ ወይም የክልል ጤና ቢሮዎችና በሚቀርብላቸዉ የመጠየቅያ ቅጽ መሠረት ጠያቂው ድርጅት ከሚሰጠው አገልግሎት ደረጃና ለመያዝ ከተፈቀደለት ናርኮቲክና ሣይኮትሮፒክ መድኃኒቶች ዓይነት ጋር በማገናዘብ የመግዣ ፈቃድ ለሚመለከተው የማከፋፈያ አውታር ይልካሉ።

(4) በማዕከል የሚገኙ መንግሥታዊ ያልሆኑ ድርጅቶች ወይም የግል ጤና ድርጅቶች በዚህ አንቀጽ ንዑስ አንቀጽ 2 በተጠቀሰው መሠረት የግዢ ጥያቄያቸውን ለመድኃኒት አስተዳደርና ቁጥጥር መምሪያ፣ በክልል የሚገኙ ደግሞ ለክልል ጤና ቢሮዎች ያቀርባሉ።

8. <u>የማዘዣ ወረቀቶች አገልግሎት በጤና ድርጅቶች</u>

(1) <u>የተከለከለ፣</u>

(ሀ) ማንኛውም ሀገራዊ ቁጥጥር የሚደረግበት ናርኮቲክ መድኃኒት ከናርኮቲክ ማዘዣ ወረቀት /ቅጽ /NPS/16/ ወጪ በሌላ ማዘዣ ወረቀት ማዘዝ የተከለከለ ነው።

card number, in patient room number and bed number shall be written clearly.

(2). The name, strength, dosage form quantity and direction for use of the drug prescribed shall be written clearly

(3). The name, date prescribed and signature of the prescriber shall be filled clearly.

(3). <u>Storage</u>

(a). Prescription papers purchased by a hospital, health centre or health station and used prescription papers shall be stored in a strong locked cupboard or in a special room the key to which shall at all times remain in the possession of the pharmacist or authorized professional.

(b). The pharmacy section shall keep receipt and issue models, record and report books in accordance to sub article 3(a).

(c). Every ward shall keep prescription papers and record books in accordance to sub article 3(a) the key to which shall at all times remain in the possession of the head nurse or authorized professional.

CCRDA

(a). Hospital, health centre or health station pharmacy section shall register receipt of prescription papers on model 19 and shall put the seal of the health institution or pharmacy section on each prescription paper.

(b). The pharmacy section shall issue and register on model 22 and Form NPS/24 for the requisition forwarded in model 20 by ward head nurses or authorized professional.

(c). Head nurses or authorized professionals shall distribute the prescription pads to prescribers, in their respective section, daily and shall collect them at the end of working hours.

(d). The pharmacy section shall receive used prescription papers and shall issue un used ones in return.

(e). One prescription pad from each type shall be issued at a time for every section.

(f). Non governmental health institutions shall follow their own system of distribution to perform the conditions mentioned under sub article 4(a) through 4(e).

ማዘዣ ወረቀቶችን ከመድኃኒት አስተዳደርና ቁጥጥር መምሪያ በሚሰጠው ኮታና መመሪያ መሠረት ያከፋፍላል::

(2) ማዘዣ ወረቀት ለመግዛት የተፈቀደለት ተቋም በተደጋጋሚ ለመግዛት ጥያቄ በሚያቀርብለት ወቅት የመግዣ ፈቃድ ቅፅ NPS/13/A ከአሳሪ ደብዳቤ ጋር ለሚመለከተው የመንግሥት ማከፋፈያ አውታር ይልካል::

(3) የማዘዣ ወረቀቶቹና ማንኛውም ሪኮርድ የተያዘባቸው ዶክመንቶች ልክ እንደ ናርኮቲክና ሣይኮትሮፒክ መድኃኒቶች ቁልፍ ባለው ቁምሣጥን ወይም የተለየ ቁልፍ ባለው ክፍል መያዝ አለበት:: ቁልፉም በመድኃኒት ማከማቻና ማከፋፈያ ኃላፊ እጅ መያዝ አለበት::

(4) የተረከበውን፣ ያከፋፈለውንና በክምችት ላይ ያሉትን ማዘዣ ወረቀቶች ብዛትና መለያ ቁጥራቸውን በመጥቀስ በዓመት አንድ ጊዜ እስከ ጥር 30 ባለው ጊዜ ሪፖርት በቅፅ NPS/18 በማጠናቀር ለመድኃኒት አስተዳደርና ቁጥጥር መምሪያ መላክ አለበት::

7. ስለማዘዣ ወረቀቶች ግዢ፣

(1) ማንኛውም የማዘዣ ወረቀት እንዲገዛ የተፈቀደለት ተቋም ናርኮቲክና ሣይኮትሮፒክ መድኃኒቶች ከሚገዛበት ከአንድ የተወሰነ የመንግሥት ማከፋፈያ ድርጅት ብቻ ካልሆነ በስተቀር ከተለያዩ ማከፋፈያ አውታሮች መግዛት አይችልም::

CRDA

(ሀ) ናርኮቲክ ወይም ሣይኮትሮፒክ መድኃኒቶች እንዲያዝ የተፈቀደለት ባለሙያ መድኃኒቱን ካዘዘ በኋላ ዋናውን ለታካሚው በመስጠት ኮፒውን ከጥራዙ ጋር በማስቀረት ሥራውን ሲጨርስ ጥራዙን ላስረከበው ባለሙያ ይመልሳል::

(ለ) ከላይ በንዑስ አንቀጽ 2 ፊደል ሀ የተጠቀሰው ባለሙያ በማዘዣ ወረቀቱ ላይ ሲፅፍ ቢሳሳት ወይም ሀሳቡ ቢቀየር የተበላሸውን ማዘዣ ወረቀት አንድ ጊዜ በማጠፍ ከጥራዙ ጋር ሳይገነጠል መተው አለበት::

(ሐ) ከላይ በንዑስ አንቀጽ 2 ፊደል ሀ የተጠቀሰው ባለሙያ በማዘዣ ወረቀቶች ላይ በሚፅፍበት ጊዜ ከዚህ በታች የተዘረዘሩትን ሁኔታዎች አሟልቶ መፃፍ ይኖርበታል::

(1) ስለሚታዘዝለት ታካሚ የተሟላ መረጃ ማለትም ሙሉ ስም፣ ጸታ፣ ዕድሜ፣ አድራሻ፣ የካርድ ቁጥር የተኛበት ክፍልና የአልጋ ቁጥር መፃፍ አለበት::

(2) የታዘዘው መድኃኒት ስም፣ ጥንካሬ፣ የዝግጅቱ ዓይነት፣ መጠንና አወሳሰድ በግልፅ እንደሚነበብ ሁኖ መፃፍ አለበት::

(3) ያዘዘው ባለሙያ ሙሉ ስም፣ የታዘዘበት ቀንና ፊርማ መሞላት አለበት:

(e). Hospital, health centre or health station institutions shall present their purchase request in accordance to this Article sub article 2 to Drug Administration and Control Department if they are under the Ministry of Health or to Regional Health Bureau if they are under the Regional Health Bureau.

8. Use of Prescription Papers in Health Institutions

(1). Prohibition

(a). No nationally controlled narcotic drug shall be prescribed on other prescription paper except on narcotic drug prescription paper (Form NPS/16).

(b). No nationally controlled psychotropic substance shall be prescribed on other prescription paper except on psychotropic substance prescription paper (Form NPS/17).

(c). Narcotic drug or psychotropic substance prescription papers shall not be used to prescribe drugs other than those mentioned in this Article sub article 1(a) and 1(b).

(d). Prescribing more than one type of drug in a single prescription paper shall be prohibited.

CCRDA

after the lapsing of fifteen days as from the date on which it was issued.

(f). No health institution shall dispose used prescription papers by its own.

(g). No professional licensed to prescribe narcotic drugs or psychotropic substances shall use the prescription papers other than the health institution he is working.

(2). Use

(a). The professional licensed to prescribe narcotic drugs or psychotropic substances shall give the original copy to the patient and keep the second copy within the pad and hand over to the person in charge at the end of the working hour.

(b). The professional mentioned in sub article 2(a) shall fold wrongly written prescription paper and leave it intact with the pad.

(c). The professional mentioned in sub article 2(a) shall write the under mentioned requirements at all times of prescribing.

ማዘዣ ወረቀት / ቅጽ NPS/17/ ወጪ በሌላ ማዘዣ ወረቀት ማዘዝ የተከለከለ ነው።

(ሐ) የናርኮቲክ ወይም ሳይኮትሮፒክ ማዘዣ ወረቀቶችን በመጠቀም በዚህ አንቀጽ ንዑስ አንቀጽ 1 ፊደል ሀ እና ለ ከተጠቀሱት መድኃኒቶች ውጭ ሌላ ዓይነት መድኃኒት ማዘዝ የተከለከለ ነው።

(መ) በአንድ ማዘዣ ወረቀት ከአንድ የመድኃኒት ዓይነት በላይ መታዘዝ የለበትም።

(ሠ) ማንኛውም የናርኮቲክ ወይም የሳይኮትሮፒክ ማዘዣ ወረቀት ከተጻፈበት ቀን ጀምሮ ከ15 ቀን በኋላ አያገለግልም።

(ረ) ማንኛውም ጤና ድርጅት አገልግሎት የተሰጠባቸው ማዘዣ ወረቀቶች ራሱ ማስወገድ የተከለከለ ነው።

(ሸ) ማንኛውም ናርኮቲክ ወይም ሳይኮትሮፒክ መድኃኒት እንዲያዝ የተፈቀደለት ባለሙያ ከማሰራበት ጤና ድርጅት ውጪ ማዘዣ ወረቀቶቹን እንዲጠቀም አይፈቀድም።

CCRDA

(5). Every Distribution Agency shall send reports about the type, quantity and serial number of distributed prescription papers at the end of every quarter on Form NPS/05 to Drug Administration and Control Department of the Ministry of Health.

6. <u>Use of Prescription Papers in Regional Health Bureaus and Zonal Health Departments</u>

The Pharmacy and Traditional Medicine Team of Regional Health Bureau or Zonal Health Department shall:

(1). distribute prescription papers to the health institutions under the Regional Health Bureau on the basis of the quota and directive given by the Drug Administration and Control Department.

(2). issue a supporting letter along with Form NPS/13/A to a health institution requesting purchase of prescription papers and shall send to the concerned Distribution Agency.

(3). store prescription papers and recording documents, the same way like narcotic drugs and psychotropic substances, in a strong locked cupboard or in a special room the key to which shall at all times remain in the possession of the head of store and distribution unit.

(ለ) ክፍሎች በኃላፊ ነርሶች ወይም ለነዚህ ክፍሎች በተመደቡ ባለሙያዎች በኩል ጥያቄዎቻቸውን በሞዴል 20 ሞልተው በሚያቀርቡበት ጊዜ ፋርማሲ ክፍሉ በሞዴል 22 ወጪ በማድረግ በቅጽ NPS/24 ይመዘግባቸዋል።

(ሐ) ኃላፊ ነርሶች ወይም ለነዚህ ክፍሎች የተመደቡ ባለሙያዎች በየክፍሎቻቸው ለሚገኙ ሐኪሞች በሥራ ሰዓት በየቀኑ ያድላሉ። የሥራ ሰዓት በሚያበቃበት ጊዜ ማዘዣ ወረቀቶችን ይሰበስባሉ።

(መ) የመድኃኒት አገልግሎት የተሰጠባቸው ማዘዣ ወረቀቶች ተመላሽ ሲደረጉለት በምትካቸው አዲስ ማዘዣ ወረቀቶች ይሰጣል።

(ሠ) ለአንድ ክፍል በአንድ ጊዜ ከየዓይነቱ አንድ ማዘዣ ወረቀት ይሰጣል።

(ረ) ከመንግሥት ውጭ የሆኑ ጤና ድርጅቶች የራሳቸውን የገቢና ወጪ ስርዓት በመከተል በንዑስ አንቀጽ 4 ከፊደል ሀ እስከ ሠ የተጠቀሱትን የስርጭት ሂደቶች ተግባራዊ ያደርጋሉ።

(5) <u>ሪኮርድ አያያዝና ሪፖርት አላላክ፣</u>

(ሀ) ማንኛውም የጤና ድርጅት ፋርማሲ ክፍል

(1) ለተመላላሽ በሽተኞች አገልግሎት የተሰጠባቸውን ማዘዣ ወረቀቶች በቅጾች NPS/09/A እና NPS/09/B መሠረት መረጃዎችን ይመዘግባል።

CRDA

(4). send reports of the quantity received, distributed, quantity in stock and serial number of prescription papers at the end of January, every year, on Form NPS/05 to Drug Administration and Control Department of the Ministry of Health.

7. Purchase of Prescription Papers

(1). No institution shall purchase prescription papers from different distribution agencies except from where it purchases narcotic drugs or psychotropic substances.

(2). Every institution known by the Ministry of Health and entitled to handle prescription papers shall fill its requisition in Form NPS/13/A and present to Drug Administration and Control Department if it is under the Ministry of Health or to Regional Health Bureau if it is under the Regional Health Bureau.

(3). The Drug Administration and Control Department or the Regional Health Bureaus shall issue purchase permit and send to a distributing agency on the basis of the standard of service rendered and the type of narcotic drugs or psychotropic substances handled by the requesting institution

(3) አያያዝ፣

(ሀ) ለሆስፒታል፣ ለጤና ጣቢያ ወይም ለክሊኒክ አገልግሎት እንዲውሉ የተገዙትንና አገልግሎት የሰጡትን ማዘዣ ወረቀቶች ቁልፍ ባለው ሣጥን ወይም የተለየ ክፍል ውስጥ በጥንቃቄ መቀመጥና ቁልፉም በኃላፊው ፋርማሲስት እጅ ወይም ለዚህ ቦታ የተመደበ ኃላፊ ባለሙያ እጅ መያዝ አለበት።

(ለ) ፋርማሲ ክፍሉ የገቢና ወጪ ሞዴሎችና ሌሎች የሪኮርድና የሪፖርት መዛግብት በንዑስ አንቀጽ ፌደል ሀ በተጠቀሰው መሠረት ይይዛል።

(ሐ) ለክፍሎች አገልግሎት እንዲውሉ ወጪ የተደረጉ ማዘዣ ወረቀቶችና የሪኮርድ መዛግብት በያንዳንዱ ክፍል በንዑስ አንቀጽ 3 ፊደል ሀ በተጠቀሰው መሠረት ይያዛሉ። ቁልፉም በኃላፊ ነርስ እጅ ወይም ለዚህ ቦታ የተመደበ ኃላፊ ባለሙያ እጅ መያዝ አለበት።

(4) ስርጭት፣

(ሀ) የሆስፒታል፣ የጤና ጣቢያ ወይም የክሊኒክ ፋርማሲ ክፍል የተረከባቸው ማዘዣ ወረቀቶች በሞዴል 19 ገቢ ካደረገ በኋላ የጤና ድርጅቱ ወይም የፋርማሲ ክፍሉ ማሕተም ያትምባቸዋል።

CCRDA

(ሠ) ከመንግሥት ውጭ የሆኑ ጤና ድርጅቶች በፊደል ሀ በተዘረዘረው ሁኔታ መሠረት ሪኮርድ የሚይዙ ሲሆን ሪፖርቶቻቸውንም በክልሎች የሚገኙ ከሆነ ለክልል ጤና ቢሮዎች አዲስ አበባ የሚገኙት ደግሞ ለመድኃኒት አስተዳደርና ቁጥጥር መምሪያ በየዓመቱ እስከ ታህሣሥ 30 ድረስ ይላኩ።

9. <u>የመድኃኒት ችርቻሮ ድርጅቶች ማድረግ ስለሚገባቸው</u>

(1) ማንኛውም የመድኃኒት ችርቻሮ ድርጅት በሚቀርብለት ማዘዣ ወረቀት አገልግሎት የሚሰጠው፣

(ሀ) በአንቀጽ 6 ንዑስ አንቀጽ 2 ፊደል ሐ የተጠቀሱትን መረጃዎች መሟላታቸውንና የጤና ድርጅቱ ማህተም መኖሩን፣

(ለ) ማዘዣ ወረቀቱ ኮፒ ወይም ፎቶ ኮፒ አለመሆንና ስርዝ ድልዝ የሌለበት መሆኑን፣

(ሐ) ዓለም አቀፍና ሀገራዊ ቁጥጥር የሚደረግባቸው ናርኮቲክ ወይም ሣይኮትሮፒክ መድኃኒቶች በአንድ ማዘዣ ወረቀት አለመታዘዙን፣

(መ) ከአንድ በላይ ናርኮቲክ ወይም ሣይኮትሮፒክ መድኃኒት በአንድ ማዘዣ ወረቀት አለመታዘዙን፣

(ሠ) የማዘዣ ወረቀቱ ሴሪ ቁጥር አለመጥፋቱን፣

(ረ) ማዘዣ ወረቀቱ ከተጻፈበት ጊዜ ጀምሮ 15 ቀናት አለማለፉን፣

The Drug Administration and Control Department, Regional Health Bureaus and Zonal Health Departments shall be delegated to execute the Provisions of this Guideline.

4. <u>Printing of the Prescription Papers</u>

(1). No institution shall print the prescription papers except the Drug Administration and Control Department.

(2). The Drug Administration and Control Department shall print prescription papers centrally which shall meet international standards and easy for control.

(3). The Drug Administration and Control Department shall keep safety stock and print new ones when ever necessary in order to ensure the continuity of the service.

(4). The serial number of the newly printed prescription papers shall be continued from where the last one has stopped.

CCRDA

5. **Use of Prescription Papers in Government Distribution Agencies**

(1). Every Government Distribution Agency shall maintain an optimum stock of the prescription papers based on the quota given by the Drug Administration and Control Department.

(2). The Distribution Agencies shall distribute prescription papers on the basis of their distribution system and on the directive given from the Drug Administration and Control Department.

(3). Every Distribution Agency shall sell prescription papers to health institutions when the health institutions:

(a). under the Ministry of Health or private shall present their requisitions filled in Form NPS/13/A with supporting letter from Drug Administration and Control Department.

(b). under the Regional Health Bureaus shall present their requisitions filled in Form NPS/13/A with supporting letter from Regional Health Bureau.

(4). Every Distribution Agency shall store prescription papers and recording documents, the same way like narcotic drugs and psychotropic substances, in a strong locked cupboard or in a special room the key to which shall at all times remain in the possession of the technical head of the Agency.

(2) ለክፍሎች የተሰጡ ማዘዣ ወረቀቶች በቅጽ NPS/24 መሠረት መረጃዎችን ይመዘግባል፡፡

(ለ) ማንኛውም ጤና ድርጅት ስለተገዙ፣ በጥቅም ላይ ስለዋሉና በክምችት ላይ ስላሉ ማዘዣ ወረቀቶች ከነ ሴሪ ቁጥራቸው በቅጽ NPS/18 በመመዝገብ ሪፖርት በየዓመቱ እስከ ታህሣሥ 30 ባለው ጊዜ ለጤና ጥበቃ ሚኒስቴር መድኃኒት አስተዳደርና ቁጥጥር መምሪያ ወይም ለክልል ጤና ቢሮ መላክ ይኖርበታል፡፡

(ሐ) ከላይ በፊደል ለ የተጠቀሰው ሪፖርት የሚቀርበው በክልል የሚገኙ ጤና ድርጅቶች ለክልል ጤና ቢሮ ይላክና የክልል ጤና ቢሮም የደረሱትን ሪፖርቶች በማጠናቀር በጤና ጥበቃ ሚኒስቴር ለመድኃኒት አስተዳደርና ቁጥጥር መምሪያ በየዓመቱ እስከ ጥር 30 ቀን ድረስ ባለ ጊዜ ሪፖርት ይልካል፣

(መ) በጤና ጥበቃ ሚኒስቴር ሥር የሚተዳደሩ ጤና ድርጅቶች በቀጥታ ወደ መድኃኒት አስተዳደርና ቁጥጥር መምሪያ በየዓመቱ እስከ ታህሣሥ 30 ቀን ባለ ጊዜ ሪፖርት ይልካሉ፡፡

CCRDA

ማንኛውም የጤና ተቋም ጥቅም ላይ ያልዋሉ ማዘዣ ወረቀቶች መሠረቃቸው ወይም መጥፋታቸው ሲደርስበት ቢዘገይ በሚቀጥለው የሥራ ቀን ለመድኃኒት አስተዳደርና ቁጥጥር መምሪያ፣ ለአካባቢው የጤና ጥበቃ ሚኒስቴር ተወካይ ወይም ለአካባቢው ፖሊስ ማሳወቅ አለበት።

11. <u>አወጋገድ፣</u>

ማንኛውም የችርቻሮ ድርጅት አገልግሎት የተሰጠባቸውን የማዘዣ ወረቀቶች ለማስወገድ በሚፈለግበት ጊዜ የመጠቀሚያ ጊዜያቸው ወይም የተበላሸ መድኃኒቶች እንዲያስወግድ ሥልጣን ያለው ክፍል እንዲያስወግድለት መጠየቅ አለበት።

12. <u>ቅጣት፣</u>

ይህንን መመሪያ ተላልፎ የሚገኝ ማንኛውም ግለሰብ ወይም ድርጅት በሕግ ይቀጣል።

<u>PSYCHOTROPIC SUBSTANCES PRESCRIPTION PAPERS</u>

WHEREAS, it is found necessary to have standard, printed and uniform prescription papers for all health institution;

WHEREAS, it is found necessary to prevent the irrational prescribing, dispensing and use of narcotic drugs and psychotropic substances;

WHEREAS, it is found necessary to maintain the proper printing, distribution and storage of prescription papers;

WHEREAS, to achieve these ends it is essential to lay down a secured prescription papers control system;

NOW THEREFORE in accordance with the Pharmacy Regulation Legal Notice No. 288/64 and the International Narcotic Drugs and Psychotropic Substances Conventions, a Guideline is hereby issued as follows.

CCRDA

this Guideline may be cited as "Guideline to Control Narcotic Drugs and Psychotropic Substances Prescription Papers 03/96".

2. Definitions

In this Guideline, unless the context provides otherwise;

(1). "Narcotic Drug" shall mean any drug subject to control according to Narcotic Drugs Conventions of the United Nations ratified by Ethiopia. This shall also include a drug that is categorized as narcotic drug by the Ministry of Health.

(2). "Psychotropic Substance" shall mean any substance subject to control according to psychotropic substances convention of the United Nations ratified by Ethiopia. This shall also include a substance that is categorized as psychotropic substance by the Ministry of Health.

(3). "Prescription Paper" shall mean an order for narcotic drugs or psychotropic substances written and signed by a duly licensed medical personnel to prescribe narcotic drugs or psychotropic substances.

ይሆናል።

(2) ማንኛውም የመድኃኒት ችርቻሮ ድርጅት መድኃኒቱን ካደለ በኋላ አስፈላጊውን መረጃ በቅፅ NPS/19 በመዝገብ በመያዝ ማዘዣ ወረቀቶችን ለአምስት ዓመት ቁልፍ ባለው ሣጥን መያዝ አለበት። የዚህ መዝገብ ቅጂ ለክልል ጤና ቢሮዎች በየዓመቱ እስከ ታህሣሥ እና ሰኔ 30 ላይ ሪፖርት ያቀርባል። የክልል ጤና ቢሮዎቹም በየዓመቱ እስከ ጥርና ሐምሌ 30 ድረስ ሪፖርቱን አጠናቅረው ለመድኃኒት ኢስተዳደርና ቁጥጥር መምሪያ ይልካሉ።

(3) ማንኛውም የችርቻሮ ድርጅት ከጤና ድርጅቶች በጠፋ ማዘዣ ወረቀት አላግባብ የሚጠቀሙ ሰዎች ወይም ባለሙያዎች በሚያጋጥሙበት ጊዜ ለመድኃኒት አስተዳደርና ቁጥጥር መምሪያ ወይም በአካባቢው ወደ አለው ጤና ተቋም ወይም ፖሊስ በአስቸኳይ በተገኘው ያመገናኛ አውታር ማስታወቅ አለበት።

(4) ማንኛውም የችርቻሮ ድርጅት በአንድ ማዘዣ ወረቀት ላአንድ ጊዜ በላይ መድኃኒት ማደል አይቻልም።

(5) ማንኛውም የጤና ተቋም መድኃኒቱን ለበሽተኛው ካደለ በኋላ ያደለው ባለሙያ ስም፣ ፊርማና ያደለበት ቀን የተሰጠበትን ቀን በማዘዣ ወረቀቱ ላይ መፃፍ አለበት።

CCRDA