Guidelines for Procurement, Distribution and use of Antiretroviral Drugs in Ethiopia

Drug Administration and Control Authority (DACA) of Ethiopia

Addis Ababa
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Guidelines for Procurement, distribution and use of Anti-retroviral Drugs

1. Introduction

Ethiopia is among the least developed countries in the world in terms of economic development. The current population is about 67 million, with annual population growth rate of 2.6%.

Ethiopia is one among the countries with the highest HIV/AIDS prevalence in the world and is the third in number of population living with HIV/AIDS.

The data currently available indicate that HIV/AIDS epidemic has affected a large segment of the urban population and the number of people infected with HIV is increasing every year. It is estimated that the prevalence rate is 6.6%, and there are above 2.2 million people infected with HIV.

There are above 200,000 children infected with HIV. Mother to child transmission is by far the largest source of HIV infection in children under the age of 15.

Prevention programs will help contain future HIV infections, however, it must not be forgotten the need of HIV infected Ethiopians, who need support and care.

Providing care and support to infected and affected citizens have synergistic effect to the prevention and control of the spread of HIV/AIDS epidemic

The major components of care and support include:

- Psychosocial support
- Management of opportunistic infections
- Use of ARV drugs for:
    - Treating AIDS patients and
    - Prevention of transmission of the virus from mother to child

Hence the use of ARV drugs in the management of HIV/AIDS is one of the interventions for the management and prevention of HIV/AIDS

In recent years powerful anti-retroviral drugs have become available. These drugs do not cure from HIV/AIDS and their long term effectiveness is not yet known. They reduce viral load of plasma levels to undetectable levels and have a beneficial clinical effects. HIV related symptoms may disappear, the incidence of opportunistic infections is reduced and quality of life improves. Launching of the use of ARVs for treatment of AIDS patients, PMTCT and Post exposure prophylaxis requires continuous availability and proper use of these Drugs.

In general due to the need of huge, and sustainable resource/funds to ensure continuous availability of needed ARV drugs, the complexity of the regimens and need of careful monitoring, launching of the use of ARV Drugs for the treatment of PLWHA and PMTCT as well as PEP requires:

- Coordinated efforts of the government, and all stakeholders.

- Best use of the existing health infrastructures
- Best use of the available funds and opportunities through proper procurement, distribution and use of ARV drugs, which requires guideline on procurement, distribution and use of ARV drugs.

Objectives of the Guideline

1. To ensure optimal use of resources/opportunity to increase access to ARV drugs.
2. To ensure continuous availability of ARV Drugs of proven quality, efficacy and safety at an affordable price.
3. To ensure proper procurement, storage, inventory control, distribution, recording and reporting of ARV Drugs.
4. To ensure rational use of ARV Drugs through rational prescribing, dispensing and patient use monitoring.

2. Procurement of ARV Drugs

2.1 Ensuring Sustainable resource/funds

Launching of the use of ARV Drugs for treatment of PLWHA, and PMTCT as well as PEP requires ensuring sustainable financial resources/opportunities and expanding the programme on such basis, in order to ensure continuous availability and proper use of these Drugs as treatment with these drugs is life long and is expensive for a country like ours.

For a country like ours, with high HIV/AIDS prevalence such a huge finance resources needed to launch ART program could not be secured by government only and hence coordinate efforts are required.. Various mechanisms for making ARV drug available, affordable and favorable conditions for private investors, local and international organizations are created by the government.

2.2 Quality Assurance /marketing Authorization

No ARV Drugs shall be marketed/made available for use unless and otherwise:

a) The safety, efficacy and quality is approved Drug Administration and Control Authority (DACA) before it is imported (through purchase and donation) and made available by local manufacturers.

b) Any institution which is Authorized to import ARV Drugs including starting and packaging materials shall get pre-import approval from DACA by presenting purchase order, which should include the necessary detail about the finished drug product, starting and packaging materials using format intended for such purpose (Annex I).

2. No ARV Drugs shall be imported or locally manufactured if it is not in the list of Drugs for Ethiopia, unless and otherwise for research purpose authorized by DACA.

2.3 Selection and estimating ARV Drug requirement 2

2.3.1 Selection of ARV Drugs

1. Any import (Purchase and Donation) and Local manufacture of ARV Drugs shall be limited to those ARV drugs that appear in the list of Drugs for Ethiopia (LIDE) giving priority to those essential ARV drugs

2. The ARV Drugs , to be used for treating PLWHA as well as for PEP, shall be handled and used at least at zonal and equivalent private and NGO Hospital level, which should also be authorized. The hospitals should fulfill all the necessary requirements to diagnose and counsel HIV/AIDS, treat PLWHA and PEP with ARV Drugs. Which include:

   a) Functional Laboratory service for Diagnosis, and monitoring HIV/AIDS patients including hematological and biochemical tests to detect toxicity.

   b) Staffed with Physicians (GP, Pediatrician, Internist, Gynecologist), Laboratory technologists, pharmacists, Nurse and counselors, who are adequately trained in their respective fields on proper use of ARV Drugs, Laboratory Diagnoses and monitoring and counseling.

3. ARV drugs to be used for PMTCT shall be handled at hospital/ health center level and the health institutions should fulfill all necessary requirements needed for VCT and monitoring the use of the ARV Drugs, which include:

   a) Functioning laboratory service for diagnose and monitoring the use of ARV drugs.

   b) Staffed with Physicians/health Officers, Laboratory technologists/technician, pharmacy personnel, Nurse and counselors, who are trained in their respective fields on proper use of ARV Drugs, Laboratory Diagnoses and monitoring and counseling.

Therefore, ARV drugs should be selected:

1. On the basis of the purpose of use of the drugs, which may include:

   - Treating of people with HIV/AIDS
   - Prevention of transmission of HIV from mother to child and or
   - Post exposure prophylaxis of health workers.

2. On the basis of level of the health institution and List of Drugs for Ethiopia

3. As per the guidelines for use of ARV drugs in Ethiopia

2.3.2. Estimating ARV Drugs requirement

1. The annual requirement of ARV Drugs shall be determined at user hospital, and health center (for PMTCT), Regional and National level whenever applicable.

2. The annual requirement of ARV Drugs in the public sector shall be determined at user health institution level which should be compiled at regional and national level as the case may be.

3. The annual ARV drug requirement of DRUG Retail Out -let shall be determined at the retail out let

4. The Annual needs of ARV Drugs of each hospital or health centre, shall be determined on the basis of the

   a) Estimated total number of: AIDS patients who need ARV treatment and or, PMTCT

   b) The agreed upon guidelines for use of ARV drugs in Ethiopia.

   The total annual need shall be estimated on the number of estimated cases to be treated annually at each hospital and adding up the annual need of all hospitals and or Health centre , running ARV therapy and PMTCT .

5. **Buffer stock/safety stock** shall be kept to minimize shortage due to variables:

   a) Any new Hospital that will initiate ARV therapy shall keep three months buffer stock

   b) One year buffer stock shall be kept at National level.

6. **Allowance** (for service expansion and unavoidable wastage.)

   - Ten percent is added to the annual national estimated requirement to make allowance for service expansion and an unavoidable wastage.

2.4 Execution of Procurement/purchase/

A. Foreign purchase for Public sector.

Requisitioning

1. The Treatment centres /Hospital /Health Centres (for PMTCT only/ shall compile data and calculate their need (including buffer stock and allowance) and send their requisition to regional health Bureaus and the health Bureaus shall send the requisition of the hospital(s) to MOH.

2. RHB and /or MOH shall compile all requests and estimate annual needs including/ buffer stock and allowance also shall estimate the total value and make reconciliation whenever necessary.

3. RHB and/or MOH or other public sector institutions shall present the National requirements to secure fund before executing foreign purchase.

Execution of Purchase

1. MOH or other authorized Public Sector shall execute purchase of ARV drugs following appropriate method of procurement for Treatment center under it

2. Whenever the required ARV Drug is obtained only from a single supplier direct purchases should be exercised.

3. Procurement shall be done in bulk with individual items in the same box. Each box shall be numbered and contain packing list.

4. The marking on the carton (box) and labeling on the immediate container shall be in accordance with requirements to be specified in the tender document.

5. Only ARV Drugs, evaluated and approved by Drug Administration and Control Authority (DACA), shall be purchased.

6. MOH, DACA and HAPCO shall negotiate for Price reduction of ARV drugs with suppliers and their selling shall be controlled unlike the other drugs.

7. Any purchase order to import ARV Drugs shall be approved by DACA before it is sent to foreign supplier. The purchase order shall include detail information and accompanied with necessary documents as per Annex I.

8. All deliveries of ARV Drugs shall be by Airplane to Addis Ababa Air Port.

9. MOH or other Authorized Institution shall workout the procurement schedule and notify RHB the expected date of arrival and RHB shall further notify the hospital.

B. Foreign Purchase by NGO

When NGOs want to be involved in the provision of ARV drugs through health institutions under MOH, RHB, NGO or any Other Public Organization, there should exist a contractual agreement with MOH or RHB for a period of at least 3 years so as to make available ARV drugs for the treatment of PLWHA, PMTCT and or PEP in at least one treatment centre .

The process involves the following steps

Requisitioning

1. The Treatment centre /Hospital or health centre/ only for PMTCT / shall compile data and calculate their need (including buffer stock and allowance) and send their requisition to regional health Bureaux and the health Bureaux shall send the requisition of the hospital to MOH.

2. The NGO treatment center shall estimate its annual requirement (including buffer stock and allowance) send the requisition to the NGO after getting official approval by the respective RHB.

3. The NGO shall Compile the requisition of the hospitals and or Health centres if they are more than one.

4. MOH or RHB or Other Public Sector or NGOs (for their health institutions) shall compile all requests and estimated annual needs including /buffer stock and allowance/ and also shall estimate the total value and make adjustment whenever necessary.

5. MOH or RHB shall present the request to NGO and secure fund before executing procurement/purchase.

Execution of foreign Purchase

1. NGO shall execute purchase of ARV drugs following an appropriate method of procurement.

2. NGO shall workout the procurement schedule and notify RHB and the treatment center(s) the expected date of arrival.

C. Private Sector Import

1. Licensed pharmaceutical Importers are required to register ARV drugs within the LIDE as per the registration guideline before embarking on procurement.

2. Special consideration shall be given for the registration of ARV drugs to speed up the evaluation and registration process.

3. A particular ARV drug registered by a pharmaceutical importer shall be procured following the procurement procedure for other drugs but should ensure the continuity of supply of ARV drugs.

4. Documents and certificates required for any other drug during importation shall be binding to ARV drugs also.

5. Any purchase order to import ARV drug shall be approved by DACA before it is sent to the suppliers and the purchase order shall include detail information and accompanied with necessary documents as per Annex I.

6. MOH, DACA and HAPCO shall negotiate for Price reduction of ARV drugs with suppliers and their selling shall be controlled unlike the other drugs.

D. Donation of ARV Drugs

1. When NGOs want to be involved in the provision of ARV drugs through health institutions under MOH, RHB, NGO or any Other Public Organization, there should exist a contractual agreement with MOH or RHB for a period of at least 3 years so as to make available ARV drugs for the treatment of PLWHA, PMTCT and or PEP in at least one treatment centre .

2. If the source of ARV drugs of the NGO is donation in kind the requirement mentioned above are also applicable.

3. MOH or RHB or other Public sector and NGO shall execute purchase of ARV drugs following appropriate method of procurement.

Donation of ARV drugs in kind should follow the following steps.

1. Any donor shall sign contractual agreement with either MOH or RHB or any other Public sector and in the contractual agreement the duration of supply of such drugs shall be indicated, which should not be less than one year.

2. All ARV drugs donation should be based on the basis of officially written request of MOH or Regional Health Bureaus approved by MOH or any other public sector beneficiaries such as Ministry of Defence.

3 All donation ARV Drugs should appear on the list of drug for Ethiopia, as per the National Guidelines for Use of ARV drugs in Ethiopia and in accordance with the level of the recipient health institution.

4. All in kind donation of ARV drugs shall be obtained from reliable source and comply with the quality standard in both the donor and recipient country.

5. The Safety, Efficacy and Quality, of donated ARV drugs shall be assured by DACA before they are imported through pre-import/order approval.

6. Any requisition to import donation ARV Drugs shall be approved by DACA before it is sent to foreign supplier/ Donors.

7. The requisition for in kind donation of all ARV drugs shall contain a minimum information and accompanied with necessary documents as per Annex I:

8. The minimum quantity to be donated should not be at least less than the quantity needed to treat one person for one year as per the guidelines for use of Antiretroviral Drugs in Ethiopia.

E. Research Centers

1. Any Research on ARV drug in Ethiopia, requires authorization from DACA and the output of the research should be approved by DACA before it is disseminated and used.

2. Research centers who want to procure ARV drugs shall get permission from DACA, and also notify MOH and other relevant bodies ahead of the time.

3. When requesting for import of ARV drugs the following information should be indicated.

    a) Name and address of the procuring agent.
    b) Name and address of the facility or research centers .
    c) Name, strength and dosage form and quantity of ARV drugs to be procured.

4. Research center should get approval by submitting research proposal to DACA to conduct research.

5. Procurement is allowed only for those items within the LIDE unless and otherwise the research is to be done on new drug.

6. Research center shall notify, whether the supply of ARV drug is free of charge, at subsidized cost or sold at market price.

2.5 Port Clearance and Storage

1. All ARV drugs procured by the public sector, private, NGO, Research centre or donated shall be exempted from any type of Tax as per the policy governing the ARV drugs supply and use.

2. MOH or other public sector shall be responsible for port clearance of those ARV drugs, procured for Health institutions under MOH and RHB. And health institution under them respectively

3. Private importers, NGOs and Research institutions are responsible for port clearance of their respective ARV drugs.

4. To obtain port clearance permit from DACA all the required documents and original invoices and or packing list, Bill of loading/Airway Bill, Bath analysis certificate, certificate of origin and gift certificate for donated drug should be presented to DACA.

5. All necessary precautions and security measures should be taken by the respective institutions during port clearance and transportation to central warehouse.

6. Delivery to the port should be avoided during weekends in order to minimize loss and pilferage before clearance.

7. Any discrepancy between the invoices, packing list, and actual quantity at the port should be immediately reported to DACA.

8. Customs office at the port shall give special consideration during temporary storage at the port. It shall provide safe and protected store.

9. If private importers, NGOs and Research centers contract out the port clearance and transportation to central warehouse of the respective organization, they shall notify the name, address and other supportive information of the clearing agent.

2.6 Local Purchase

Only Hospitals , Health centres and Community pharmacies, who have special authorization from DACA, are allowed to locally purchase ARV drugs from authorized local importer and whole salers/ distributors following an appropriate method of procurement after getting authorization from DACA.

3. Distribution

3.1 Receipt and inspection

1. As soon as the ARV drugs arrive at MOH, RHB, other Public sectors, Private importers, NGO and User health institutions:

   a) They should be kept separately until physical inspection is undertaken.

   b) The type and quantity received shall be checked against the requisition, purchase order and invoice or packing list

   c) The quality, packaging, shelf life and labeling as well as the accompanying documents (as per Annex I) shall be checked in order to verify whether they meet the required standards as stated in the terms and conditions

2. Any discrepancy in type, quantity, quality, shelf life, labeling and packaging shall be reported using the format meant for this purpose (Annex III) to DACA with a copy to RHB as well as to the NGO, if it is supplied by NGO.

3.2 Storage of ARV Drugs

1. ARV drugs should be stored in accordance with storage condition mentioned on their label and for those drugs and diagnostics which require cold storage a cold chain storage facilities should be made available in the store and during transportation.

2. ARV drugs should be kept in a separate and secured lockable store or cabinet in a store and dispensary and the key should be kept in the hand of authorized pharmacist or other pharmacy personnel.

3.3 Distribution/delivery of ARV drugs

A. Public Sector

1. Distribution of ARV drugs shall be made only to those authorized hospitals and health centres for which the ARVs are procured.

2. Each hospital (treatment center) and or health centre shall prepare a requisition of ARV drugs using format (Annex II) and submit the original to MOH and a copy to the respective RHB or Other public sector.

3. MOH or RHB or other public sector shall issue the requested ARV drugs after reviewing the quantity whenever necessary, to the pharmacist /Druggist/ delegated by the respective hospital or RHB. Each hospital shall collect its share at the MOH warehouse.

4. MOH shall issue a copy of the issuing voucher (model 22) to the respective RHB for follow-up and information.

5. Distribution of ARV drugs to hospitals shall be made two to four times a year and the schedule of distribution shall be worked out by the Ministry and notified to the relevant hospitals before hand.

6. Maximum security and storage measure should be taken during transporting ARV drugs from central warehouse to the respective hospitals.

B. NGOs

1. Distribution of ARV drugs shall be made only to those authorized Hospital and or health centre for which the ARV Drugs are procured.

2. NGOs shall keep records of the name, status and address and signature of the receiving person.

3. NGO shall issue a copy of the issuing voucher and other relevant document to the respective RHB for follow-up and information.

4. Maximum security measures should be taken during storage and transporting ARV drugs from central warehouse to the respective hospitals.

C. Private Importers

1. Private importers and whole distributors shall distribute only to those Authorized Community pharmacies and hospitals and health centres based on their official written request, approved by DACA.

2. Private pharmaceutical importers shall keep all the necessary records and issue only using an official issuing voucher (invoice).

3. Private Pharmaceutical importers shall send ARV drug distribution report to DACA using format (Annex III) meant for this purpose.

3.4 Inventory Control

1. All ARV drugs :

   a) Shall be cleared from port shall be entered into a receiving voucher or model 19 (for public sector), shall be ssued/delivered using issuing voucher or model 22 (for public sector)

   b) Shall be issued/delivered using issuing voucher or model 22 (for Public sector)

2. Receipt and issue shall be recorded on a stock record card (Annex IV) to control the volume and movement of the stock at the time of procurement and distribution body (MOH, NGOs and Research center) and at user institution level.

3. MOH, RHB, other Public Sector, NGOs, Hospital, health center and retail pharmacy shall keep a stock record card (Annex IV) for each ARV drugs. Stock balance of each ARV drug shall be updated whenever ARV drugs are issued or received.

4. Consumption and stock balance shall be reported every quarter from distributors, the user treatment center and retail pharmacy to DACA, with a copy to the respective RHB using format intended for such purpose (Annex VII)

5. Pharmacies/Dispensaries (in treatment center) shall keep prescriptions presented to them after dispensing and adjust the stock accordingly.

6. Annual consumption shall be reported using format (Annex VII) meant for such purpose to DACA, RHB, NGO. etc.

4. USE

4.1 Prescribing

1. ARV drugs shall be prescribed:

   a) To PLWHA only by authorized physicians, who is adequately trained in proper use of ARV drugs for treating PLWHA and PEP and working in an authorized hospital as per the national guideline.

   b) For PMTCT only by authorized physicians or Health Officers, who adequately trained in proper use of ARV drugs PMTCT and working in authorized Hospital or health center as per the guideline. .

2. The hospital and health centre should also have adequately trained laboratory technologist and counselor as well as well organized laboratory facilities with a capacity to monitor use of ARV drugs.

3. The Prescriber shall prescribe ARV drugs as well as monitor their usage as per the National Guidelines for use of ARV drugs in Ethiopian.

4. The Prescriber shall select the appropriate ARV drugs from those available in LIDE on the basis of the patient characteristics, health conditions and other factors.

5. The Prescriber shall only prescribe ARV drug using a standard prescription paper (Annex VIII) following correct prescription writing .The prescriber shall write:

   c) Name, strength, dosage form, dose, number of doses per day, route of administration and duration of treatment.

   b) His/her full name, qualification, Reg. No., signature.

6. ARV drug prescription should be a code so that dispenser could easily identify the prescription without threatening the confidentiality of the case.

7. The prescriber shall closely monitor his/her patient and ARV drug use. ARV therapy is not a cure

4.2 Dispensing

1. ARV Drugs shall be dispensed by a pharmacist or other pharmacy personnel (only for PMTCT), who is adequately trained in management and use of ARV Drugs.

2. A pharmacist or other pharmacy personnel should only fill ARV Drug prescription paper after making sure that it is legible and written correctly by authorized physician or health officer (for PMTCT) from authorized Hospital and or Health Center.

3. ARV Drugs dose sufficient only for 24 hours shall be dispensed for an in-patient.

4. The maximum quantity of ARV Drugs dispensed to out-patient PLWHA shall not be more than quantity needed for one month.

5. List of authorized prescriber, with registration number, signature, working place and other detail information shall be submitted to dispensing pharmacies.

6. The Pharmacist or other pharmacy personnel should counsel the patient and during counseling s/he should inform the patient that:

    i. ARV therapy is not a cure
    ii. ARV drug should be taken for indefinite period.

    a) Adverse effects that may occur (potentially serious and self limiting ones)
    b) Drug interactions
    c) The need for compliance and the danger of discontinuation
    d) Factors that affect absorption
    e) Storage condition

7. The pharmacist or other pharmacy personnel shall write his/her Full name, Qualification, Reg. No. And signature on the filled prescription.

8. Dispensed ARV Drugs Prescription shall be registered in Patient Prescription Registration Book (Annex IX).

9. Filled prescription shall be kept for 5 years being filed by date, months and years

10. Dispenser shall compile Number of User patients and their age, Sex and ARV drugs dispensed and report such compiled information to DACA and RHB using a format meant for such purpose(Annex X).

11. Medication profile of each patient should be kept once put on ART. Because it helps to monitor treatment out comes and emergency of resistance.

4.3 Pre and Post ART initiation volunteer counseling

1. Prescribers, Dispensers and Counselors should be equipped to answer questions on different ART drug regimens, the requirements for clinical monitoring of ART, the expected results, the possibility of treatment failure, the criteria for changing or cessation of therapy.

2. The prescriber, pharmacist and other pharmacy personnel and counselor should be competent enough to give patient counseling service in their respective area.

    a) Date of the prescription
    b) Patient's full name, age, sex, Address, card. No.,
    c) Diagnosis (ICD Code No.)

5. Records and Reports

5.1 Records

1. Every importer/wholesaler shall keep records of:
    f) Imported ARV Drugs
    g) Distributed ARV Drugs

2. Every Health Institution shall keep records of:-
    a) ARV Drugs purchase or received by donation on model 19.
    b) Dispensed ARV Drugs to in-patent/out patient

3. Every Retail Pharmacy shall keep records of purchase ARV Drugs, and all invoices related to them in a chronological file for not less than five years.

5.2 Reports

1. Every importer shall send reports of imported and distributed to DACA at the end of every quarter and at the end of every year.

2. Every Health Institution shall send reports of purchased and dispensed ARV drugs at the end of every quarter and at the end of every year to the Regional Health Bureau.

3. Every Retail Pharmacy shall send reports of purchased and dispensed ARV drugs to Regional Health Bureau at the end of every quarter and at the end of every year.

4. Every Regional Health Bureau shall send reports of ARV Drugs purchased and consumed at the end of every quarter and at the end of the every year to the Drug Administration and Control Authority using format (Annex VII) meant for such purpose.

5. If any theft of ARV Drugs is undertaken in an Institution, it shall upon discovery notify the Regional Health Bureau or Local Regional Health Bureau representative or the Local Police force within the next working day.

6. Disposal

ARV Drugs no longer useful, due to expiry or damage, shall be disposed under the direct supervision of representative of DACA or Regional Health Bureau.

Annex – I

PURCHASE ORDER

To _____ No. _____
_____ Date _____

Dear Sirs,

Please kindly supply the following goods subject to the General terms and conditions of contract shown overleaf and mentioned below.

Item No.	Description (Name, Strength, Dosage form) of Drug	Unit	Quantity	Unit Price	Total Price

Shipping Instruction _____
Delivery _____
Method (items) of payment _____

Accompanying documents
- Packing list
- Chamberized invoice
- Airway bill
- Certificate of origin
- Batch analysis certificate
- Free sales certificate

TERMS AND CONDITIONS OF CONTRACT

1. Products should have minimum 80% of its shelf life on arrival at Addis Ababa/port of entry.

2. Language used for writing label, leaflet and other documents shall be in English.

3. All packing should be suitable for road, air and sea transport under tropical conditions.

4. The label of the immediate container should at least include:-
   - The name of the product, brand and Generic/INN
   - Pharmaceutical dosage form and route of administration
   - Qualitative and quantitative composition of active ingredient(s)
   - Quantity in container, Technical directions for use
   - Handling and storage requirements
   - Batch number, manufacturing and expiry dates
   - Name and address of the Manufacturer

5. Accompanying invoice should be as per the purchase order including Batch number, manufacturing and expiry date of each item.

6. Every product should be accompanied by a leaflet in its immediate container. A leaflet must bear adequate information for use and it should at least include:

   - The name of the product; brand and generic/INN
   - Description appearance, pharmaceutical dosage form and route of administration
   - Qualitative and quantitative composition of active ingredients
   - Clinical pharmacology, indication(s), warnings, precautions, contraindications, Adverse reactions/side effects
   - Dosage and administration (directions for use)
   - Over dosage, storage instruction, package quantity, Name and address of manufacturer.

Annex - II Drug and Medical Supplies Requisition form

Ref. No. _____
Date _____

Name and level of the requesting institution _____
Address: Region _____

Ser. No	Description (Name, Strength, Dosage form) of Drug	Unit	Quantity		Remark
			Requested	Issued	

Requested by
Name _____
Signature _____
Date _____

Approved by
Name _____
Signature _____
Date _____

Annex III - Discrepancy Reporting Form/Reporting form

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

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

Reported by _____ Reviewed by _____
Signature _____ Signature _____
Date _____ Date _____
Action taken and by whom _____
_____
Name _____ Sign. _____ Date _____

Anne x IV. Stock record card

Name of Health Institution _____ Maximum Stock Level _____
Name, strength and dosage for of item _____ Recorder Stock Level_____
_____ Minimum Stock Level _____
Unit of Issue _____ Location _____ Average monthly consumption _____

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

N.B. A stock record card should be updated and filled by other than a store keeper

Annex V – BIN CARD

Name of the health institution ________________________________
Name, strength and dosage form of drug ________________________
____
Unit of issue ____

Date	Document Number (receiving or issuing form no.)	Received from or Issued to	Quantity			Expiry Date	Remark
			Received	Issued	Balance		

N.B. Bin card shall be kept fixed on the shelf- on which the item is kept.

Annex VI- ARV Drugs 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		Ending stock	Unit price	Total price		Stock out period	Remark
				Received	Cosnrumed / issured			Issued/ consumed	Balance		

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

N.B: Budget year - Hamle 1st _____ Sene 30

Annex VII – ARV Annual Drug Consumption Reporting Form

Name of the Health Institution _____
Region _____ Zone _____ Woreda _____ Town _____
Reporting Period _____ to _____ 200____
Reporting consumption period Form _____ to _____

Ser. No.	Description	Unit	Quantity			Balance in stock at the end of the year	Total Quantity made available	Value in Birr		Remark
			In stock at the bef. Of the year	Received in the year	Consumed in the year			Consumed	Balance	

Reported by _____
Signature _____
Date _____

Approved by _____
Signature _____
Date _____

Annex VIII– Prescription Paper

No. .....

Name of the patient: _____ Age _____ Sex _____
Address: Region _____ Town _____ Woreda _____
Kebele _____ House No. _____ Card No. _____
In patient ☐ Out patient ☐ Section/ward _____
Diagnosis (ICD code No.) _____

Treatment given (Drug name, strength, dosage, dose and duration (or Code No.)	Price of each item (for Dispenser use only)
Rx	
	Total

Prescriber's spenser's
Full name _____ _____
Qualification _____ _____
Registration No. _____ _____
Signature _____ _____

* Sea over leaf

Annex IX – ARV Drug Out/In Patie nt Prescription Registration Book

Ser. No	Date	Patient's				Diagnosis	Treatment (name, strength, dosage for dose of drug)	Physicians			
		Name	Card No.	Age	Sex			Name	Qualification	Ref. No	Working Hospital

Remark: You can write the name, strength, dosage form and quantity of not dispensed drugs on the remark column.

N. B.

1. The prescription should bear the seal of the health institution.

2. Prescribes should:

    * Write the prescription correctly and legibly.
    * Treat prescription as personal property.
    * Be receptive to call from dispenser who is trying to verify prescription.
    * Use ICD number for the diseases that have impact on social stigma.
    * Refill as per the list of refilled drugs; if necessary.

3. Dispensers should:

    * Review prescription carefully and verify with prescribers if incorrectly prescribed.
    * Keep bland and filled prescription properly in pharmacy section.
    * Register and keep filled prescription for at least 2 years.
    * Not dispense copied prescription.
    * Dispense single prescription for one time only unless stated as "Refill".

Annex X - Medication Record (Medication Profile)

Patients full name ___________________________

Medication	# of Tablets or Capsules Per Dose	# of Doses Per Day	Times of Day	Special Instructions	Things to watch Out For

Annex IX – ARV Drug Out/In Patient Prescription Registration Book

Ser. No	Date	Patient's				Diagnosis	Treatment (name, strength, dosage for dose of drug)	Physicians			
		Name	Card No.	Age	Sex			Name	Qualification	Ref. No	Working Hospital

Remark: You can write the name, strength, dosage form and quantity of not dispensed drugs on the remark column.