**COAST PROVINCIAL GENERAL HOSPITAL**
**ANTIRETROVIRAL THERAPY (ART) PROGRAMME**

# Standard Operating Procedures for Pharmaceutical Services

**March 1, 2005**

Prepared with assistance from


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## About RPM Plus

The Rational Pharmaceutical Management (RPM) Plus Program works in more than 20 developing and transitional countries to provide technical assistance to strengthen drug and health commodity management systems. The Program offers technical guidance and assists in strategy development and program implementation both in improving the availability of health commodities—pharmaceuticals, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, HIV/AIDS, infectious diseases, and family planning and in promoting the appropriate use of health commodities in the public and private sectors.

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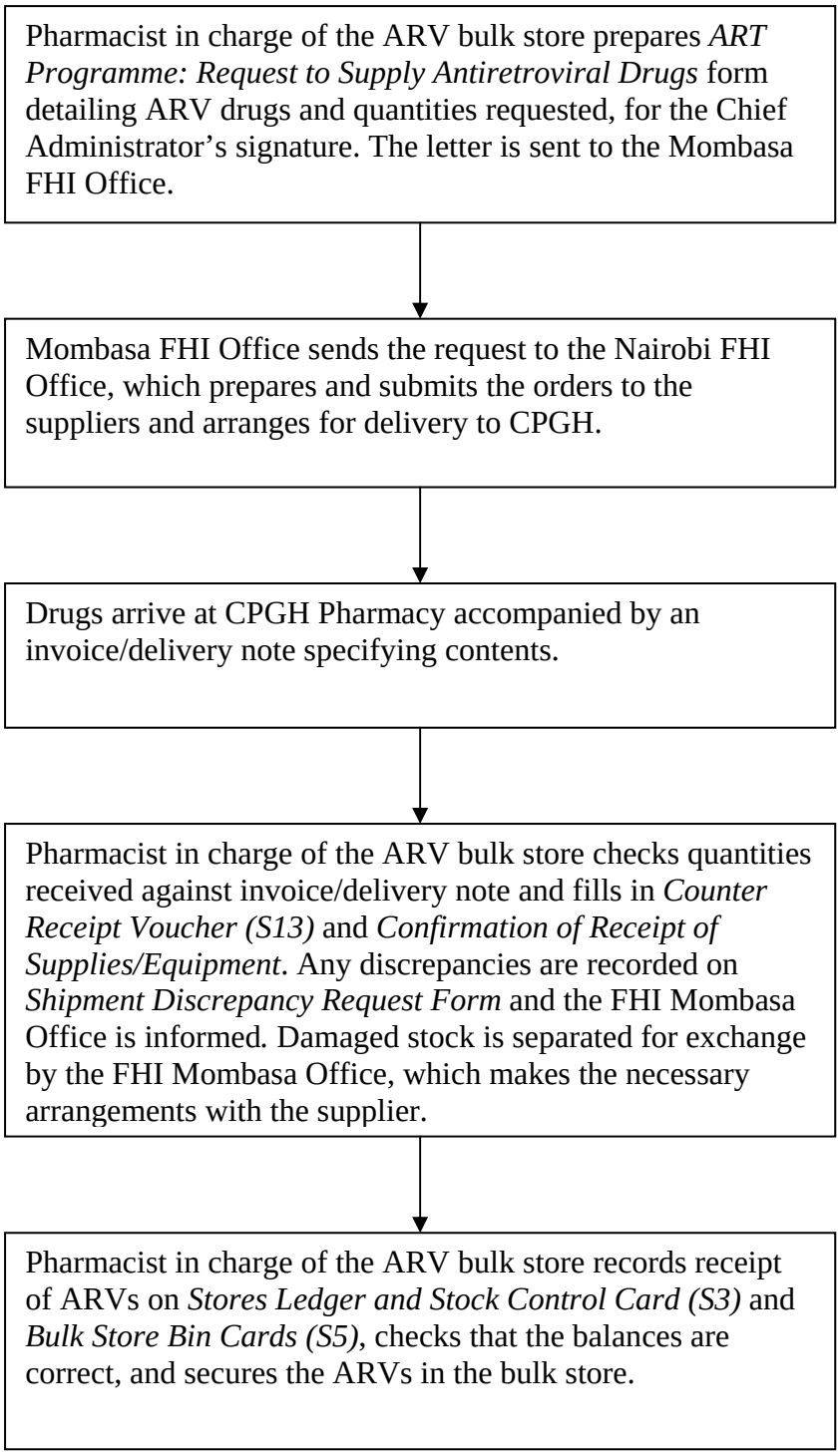
## ACRONYMS AND ABBREVIATIONS

| | |
|---|---|
| ADR | adverse drug reaction |
| ART | antiretroviral therapy |
| ARV | antiretroviral [drug] |
| AZT | zidovudine |
| B/F | brought forward |
| CBC | complete blood count |
| CCC | Comprehensive Care Clinic |
| C/F | carried forward |
| CM | cryptococcal meningitis |
| CNS | central nervous system |
| CPGH | Coast Provincial General Hospital |
| DAART | Directly Administered Antiretroviral Therapy |
| ddI | didanosine |
| d4T | stavudine |
| DUR | drug utilization review |
| EFV | efavirenz |
| E.O.Q. | Economic Order Quantity |
| FDC | fixed-dose combination |
| FEFO | first-expiry, first-out |
| FIFO | first-in, first-out |
| FHI | Family Health International |
| GOK | Government of Kenya |
| IMPACT | Implementing AIDS Prevention and Care [Project] [FHI] |
| IDV | indinavir |
| IP | inpatient |
| KEMSA | Kenya Medical Supplies Agency |
| kg | kilogram |
| Ksh. | Kenya shilling |
| LFT | liver function test |
| LPV/r | lopinavir/ritonavir |
| $m^2$ | square metre |
| mg | milligram |
| ml | millilitre |
| MOH | Ministry of Health |
| MSH | Management Sciences for Health |
| NFV | nelfinavir |
| NVP | nevirapine |
| OC | oesopageal candidiasis |
| OP | outpatient |

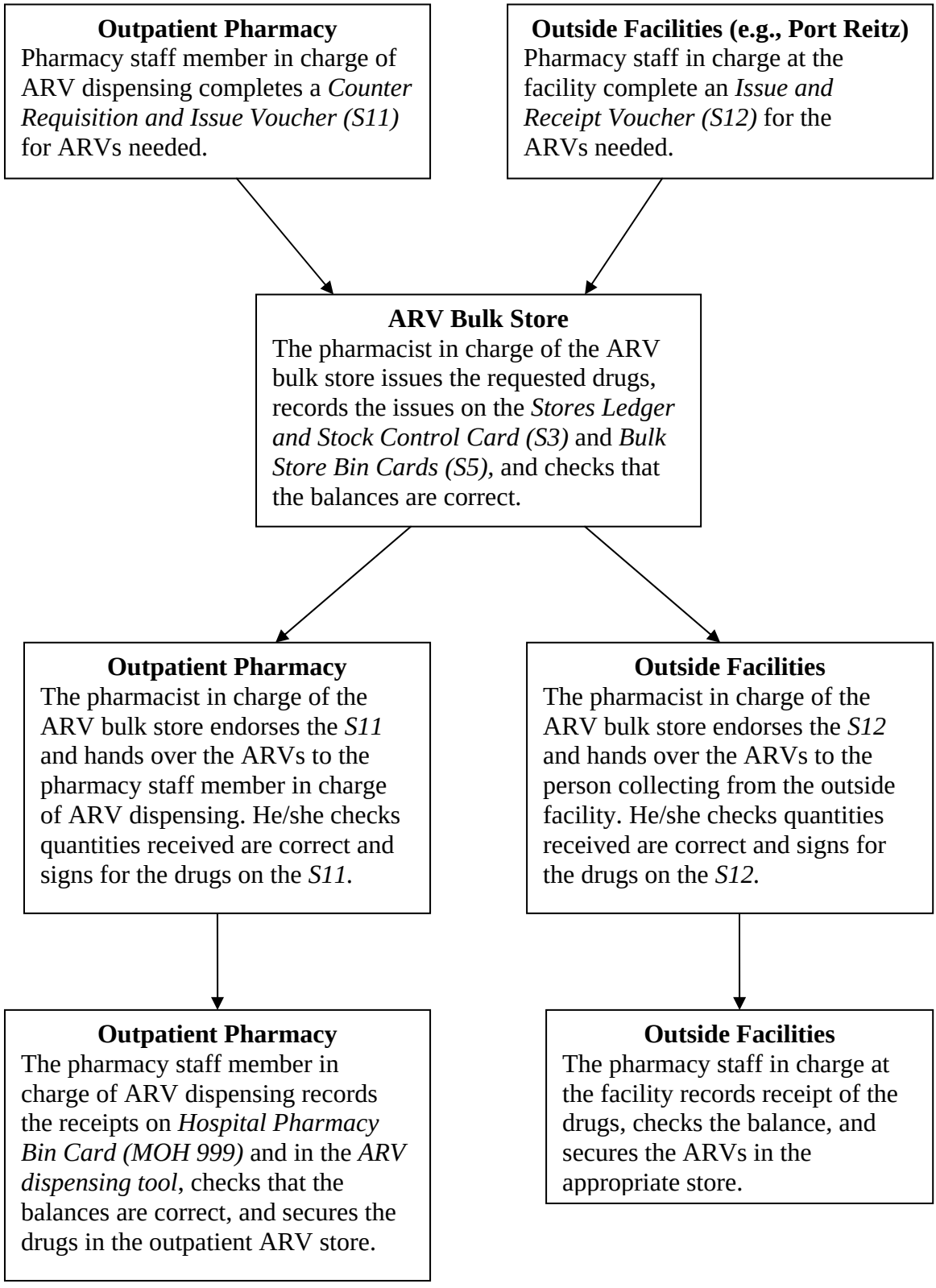
| | |
|---|---|
| PEP | post-exposure prophylaxis |
| PN | peripheral neuropathy |
| RPM Plus | Rational Pharmaceutical Management Plus [Program] |
| RTV | ritonavir |
| S.A. | surface area |
| SOP | standard operating procedure |
| SP | starter pack |
| STD | standard [regimen] |
| TAP | Technical Assistance Partners [FHI/IMPACT; MSH/RPM Plus; Population Council/Horizons] |
| 3TC | lamivudine |
| USAID | U.S. Agency for International Development |
| WHO | World Health Organisation |
| wt | weight |
| ZDV | zidovudine |

## CPGH ANTIRETROVIRAL (ARV) DRUG MANAGEMENT FLOW CHARTS

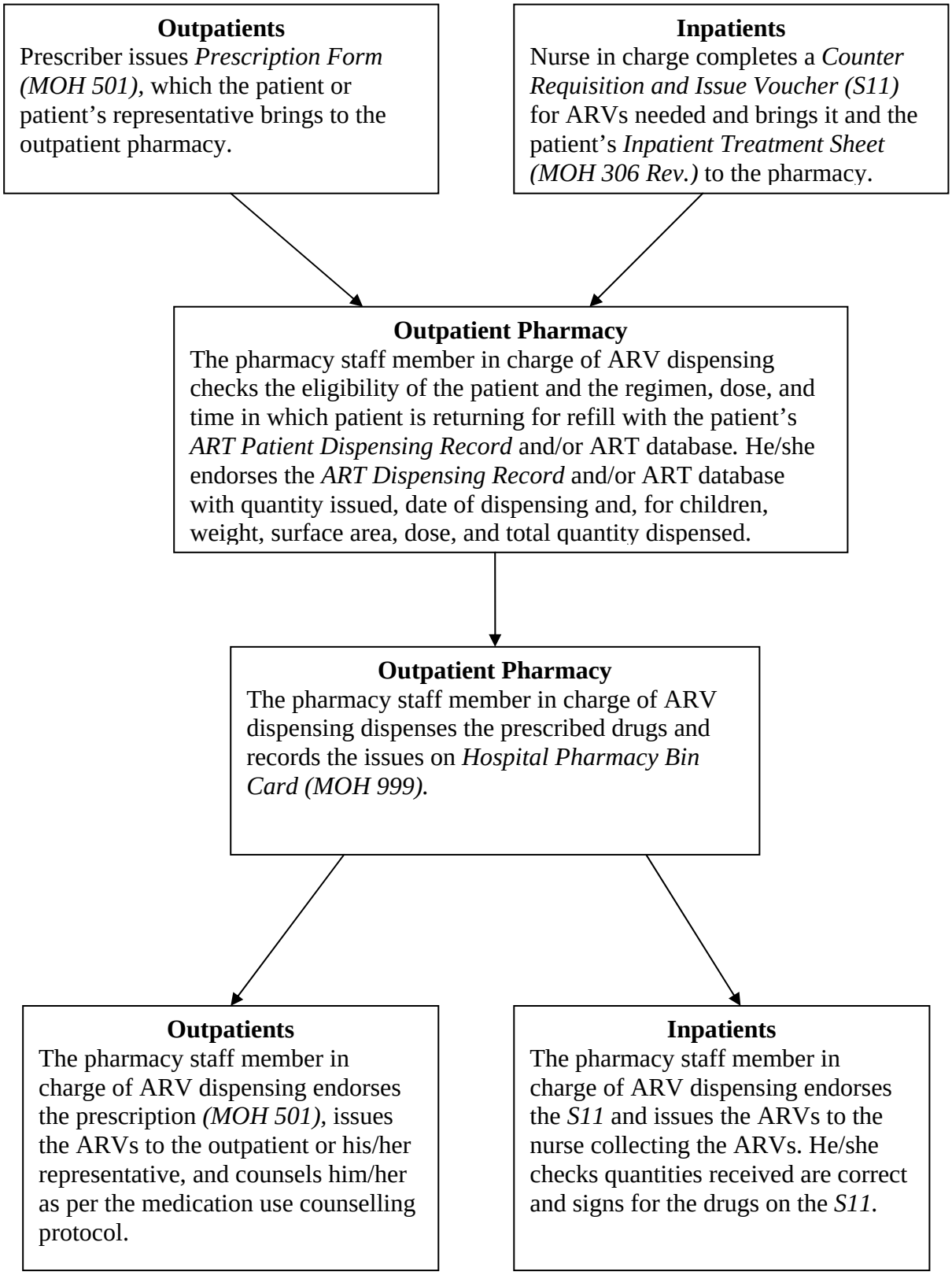
### Requesting and Receipt of USAID-Funded Antiretroviral Drugs



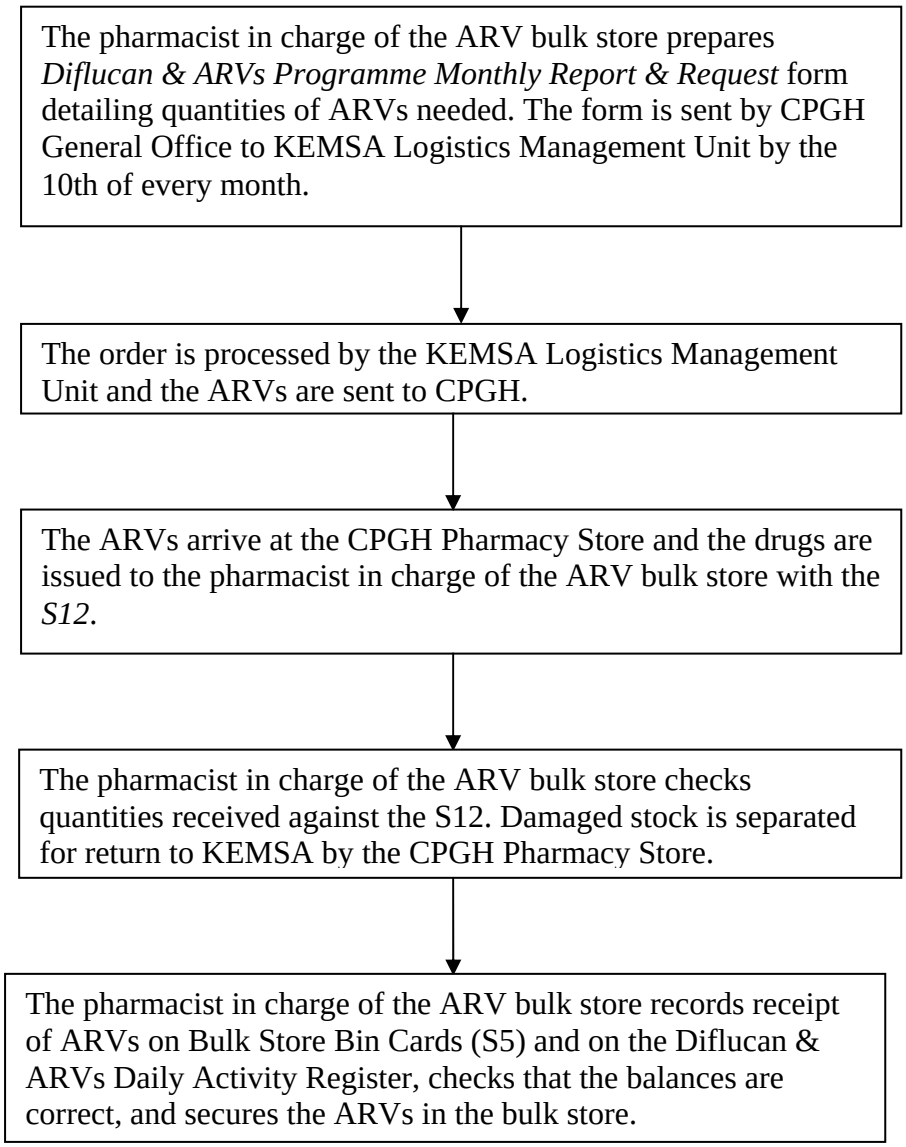
## Issuing USAID-Funded Antiretroviral Drugs from the ARV Bulk Store



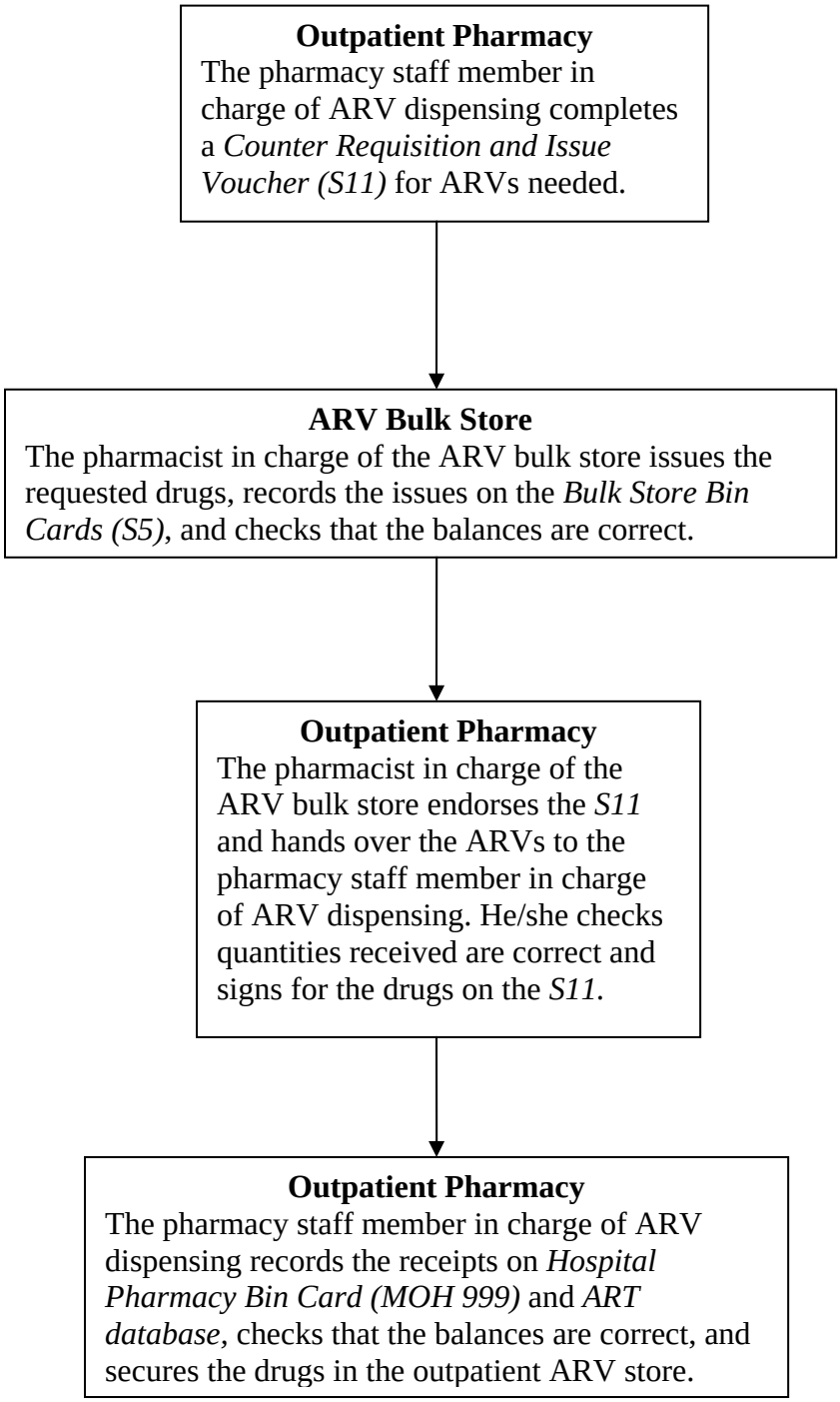
## Dispensing USAID-Funded Antiretroviral Drugs from the Outpatient Pharmacy



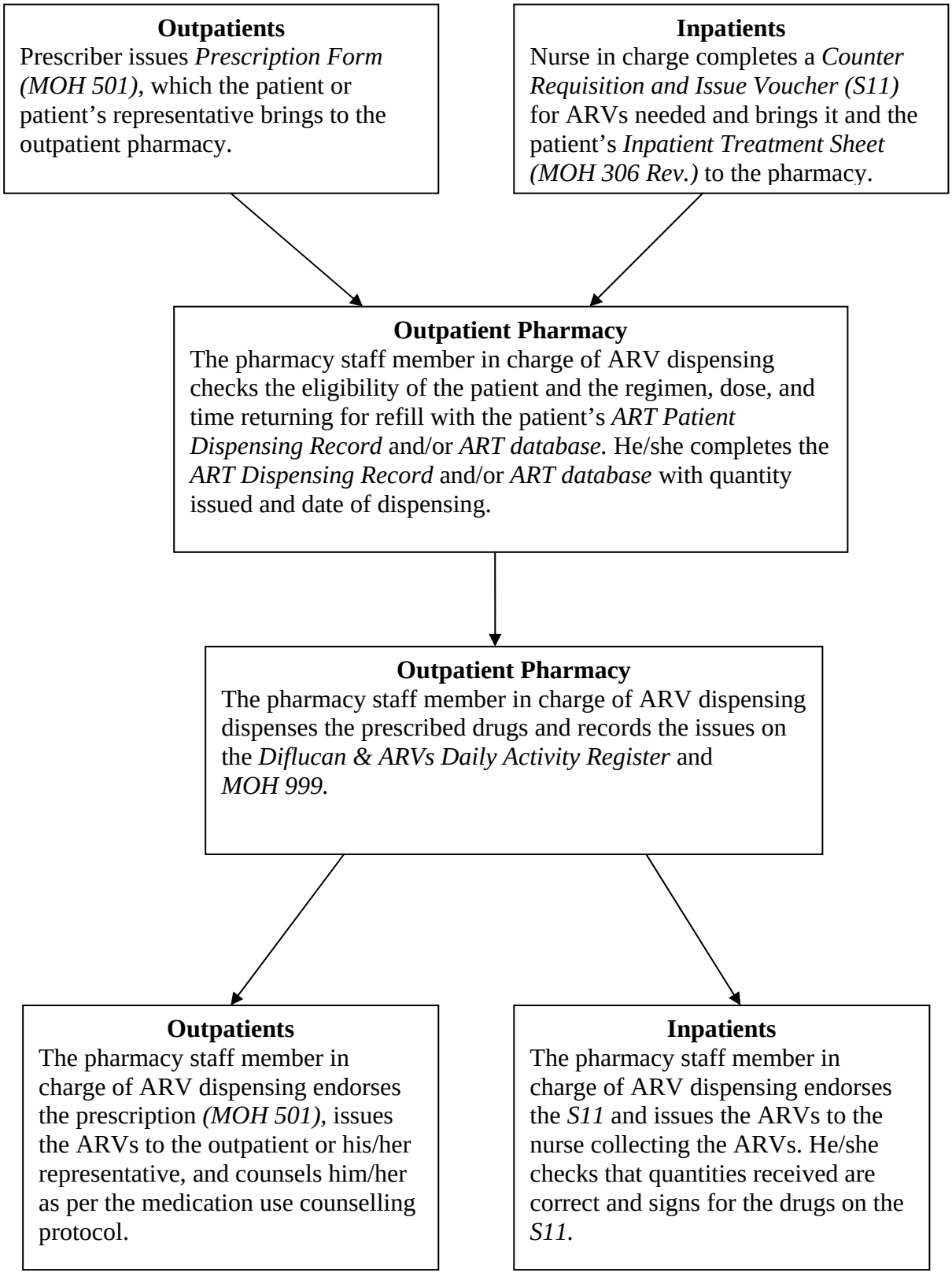
## Requesting and Receipt of GOK Antiretroviral Drugs



## Issuing GOK Antiretroviral Drugs from the ARV Bulk Store



## Dispensing GOK Antiretroviral Drugs from the Outpatient Pharmacy



## ROLES AND RESPONSIBILITIES OF THE CPGH PHARMACY DEPARTMENT IN SUPPORT OF THE ART PROGRAMME

**Pharmacist in charge of the ART programme:**

- Represents the pharmacy on the CPGH ART Eligibility Committee. As Secretary, takes the minutes of the meetings.
- Maintains a list of eligible patients.
- Maintains a signature file of doctors who are authorised to prescribe for ART patients.
- Works with the CPGH ART team and the CPGH training coordinator to organise continuing education on ART.
- Prepares and presents Adverse Drug Reaction (ADR) summary reports to the CPGH ART Eligibility Committee and makes recommendations on action to be taken.
- Assists in implementing prescribing and drug utilization reviews (DURs). Prepares ARV DURs for review by the CPGH ART Eligibility Committee.
- Carries out periodic spot checks of ARV storage and record keeping on wards at CPGH.
- Assists the pharmacist in charge of the ARV bulk store in preparing and submitting the *ART Programme – Pharmacy Activity Report.*
- Represents the pharmacy at other meetings relevant to the ART Programme as necessary.
- Maintains confidentiality and keeps patient information and records secure.

***USAID-Funded ARVs:***

- Liaises with the Directly Administered Antiretroviral Therapy (DAART) coordinator in support of the DAART study.
- Works with FHI/IMPACT to arrange exchange of ARV drugs near expiry with suppliers.

***GOK ARVs:***

- Works with KEMSA to arrange return of ARV drugs near expiry.

**Pharmacist in charge of the ARV bulk store:**

- Ensures that he/she or a designated proxy is available to receive or issue stock from the ARV bulk store when needed.
- Ensures that the ARV bulk store is kept locked at all times. Keeps the key to the ARV bulk store in his/her possession or hands it over to a designated proxy.

- Completes the temperature logs for the ARV bulk store twice daily and the ARV bulk store refrigerator once daily. Files temperature logs at the end of each month and opens up new logs for the coming month.

- Alerts the pharmacist in charge of the ART Programme, the Chief Pharmacist, and/or the Chief Administrator immediately if the temperature falls outside of acceptable limits.

- Prepares and submits the *ART Programme – Pharmacy Activity Report.*

- Maintains confidentiality and keeps patient information and records secure.

***USAID-funded drugs:***

- Quantifies needs and requisitions ARVs from FHI. Alerts the pharmacist in charge of the ART Programme if stock has less than 8 months' expiry, to arrange for an exchange.

- Receives ARVs into the ARV bulk store. Completes and files the *S13* copies. Ensures all receipts of ARV stocks are entered in the *S3* and *S5* records at time of receipt. Completes and files a *Shipment Discrepancy Report* if discrepancies arise. Endorses the original invoice/delivery note to FHI Mombasa Office with completed *Confirmation of Receipt of Supplies/Equipment* form together with the *CPGH/FHI ART Delivery Book* and arranges for collection by FHI. If there are any discrepancies, attaches a copy of the *Shipment Discrepancy Report* to the original invoice/delivery note.

- Issues ARVs from the bulk store. Issues ARVs on first-expiry, first-out (FEFO), otherwise first-in, first-out (FIFO) basis. Ensures all issues of ARV stocks are entered in the *S3* and *S5* records at time of issue.

- Ensures that the stock balances on the *S3* and *S5* correspond to the physical stock in the ARV bulk store when receiving or issuing ARVs and when handing over responsibility to another staff member. Completes and files a *Stock Count Discrepancy Report* if discrepancies arise.

***GOK drugs:***

- Quantifies needs and requisitions ARVs from KEMSA using the *Diflucan & ARVs Programme Monthly Report & Request.* Alerts the pharmacist in charge of the GOK ART Programme if stock has less than six months' expiry and, based on consumption, is unlikely to be used, to arrange for return or exchange.

- Receives ARVs into the ARV bulk store. Completes and files the *S12* copies. Ensures that all receipts of ARV stocks are entered in the *S5* and *Diflucan & ART Daily Activity Register* records at time of receipt. Completes and files a *Shipment Discrepancy Report* if discrepancies arise. If there are any discrepancies, attaches a copy of the *Shipment Discrepancy Report* to the original *S12*.

- Issues ARVs from the bulk store. Issues ARVs on FEFO, otherwise FIFO, basis. Ensures that all issues of ARV stocks are entered in the *S5* records at the time of issue.

- Ensures that the stock balances on the *S5* correspond to the physical stock in the ARV bulk store when receiving or issuing ARVs and when handing over responsibility to another staff member. Completes and files a *Stock Count Discrepancy Report* if discrepancies arise.

**Pharmacy staff member in charge of dispensing ARVs from the outpatient pharmacy:**

- Ensures that he/she or a designated proxy is available to issue stock to and counsel ART patients at all times during the rota period assigned.

- Ensures that the ARV cupboard is kept locked at all times. Keeps the key to the ARV cupboard in his/her possession or hands it over to a designated proxy.

- Once or twice weekly, checks the prescription records and the Eligibility List for new patients and requisitions sufficient ARVs for the next week from the ARV bulk store.

- Receives ARV stock into the outpatient pharmacy. Completes and files the *S11* copies. Ensures all receipts of ARV stocks are entered in the *MOH 999* and the *ARV dispensing tool* at time of receipt.

- Ensures that the stock balance on the *MOH 999* and the ART dispensing tool corresponds to the physical stock in the ARV cupboard when receiving stock. Completes and files a *Stock Count Discrepancy Report* if discrepancies arise.

- Issues ARVs on FEFO, otherwise FIFO, basis. Ensures all issues of ARV stocks are entered in the *MOH 999* and the *ARV dispensing tool* at time of issue. Endorses and files the *S11* for issues to inpatients.

- Checks the validity of prescriptions with Signature Records held on file and eligibility of patients with the Eligibility List.

- Uses the *ART Patient Dispensing Record* and/or the *ARV dispensing tool* to check:

    - For new prescriptions or changed regimens, and that the prescription is in accordance with ART Programme standard regimens

    - For discrepancies in repeat prescriptions, and that the dose prescribed is correct for the weight and surface area given for children and patients on stavudine (d4T) and didanosine (ddI)

    - That the collection time for a repeat prescription is appropriate

- Completes the *ART Patient Dispensing Record* and/or the *ARV dispensing tool* and endorses the prescription with quantities given. Files all ART prescriptions on a daily basis in a separate file.

- Counsels outpatients or their representatives, covering all key counselling points and using the *Antiretroviral Therapy—Patient Counselling Information* table.

- Completes the temperature logs for the ARV outpatient pharmacy twice daily. Files temperature logs at the end of each month and opens up new logs for the coming month.

- Alerts the pharmacist in charge of the ART Programme, the Chief Pharmacist and/or the Chief Administrator immediately if the temperature falls outside of acceptable limits.

- Maintains confidentiality and keeps patient information and records secure.

- Ensures all issues are entered in the *Diflucan and ART Daily Activity Register* at the time of issue.

**Pharmacy staff member in charge of preparing prepacks for the DAART study:**

- Before prepacking:
    - Ensures the workspace area is clear.
    - Checks that the stock bottle(s) contain(s) the correct drug, strength/concentration, and dosage form that is to be prepacked.
    - Checks that the expiry date is appropriate.
    - Inspects the medication from the stock bottle for broken or discoloured tablets or capsules. Inspects packaging containers to make sure they are clean and not damaged.
    - Collects the appropriate number of labels for the number of prepacks needed.
    - Fills in the appropriate information on the labels.
    - Fills out the *ARV Prepacking Record.*
- After obtaining the necessary checks from the pharmacist in charge of checking, prepares and labels the prepacks.
- After obtaining a final check from the pharmacist in charge of checking:
    - Clears the workspace area and puts away all drugs, labels, and packaging materials.
    - Ensures all issues of ARV stocks are entered in the *MOH 999* and the *ARV dispensing tool* at time of issue.
    - Files away the *ARV Prepacking Record.*

**Pharmacist in charge of checking prepacking for the DAART study:**

- Before prepacking begins checks that:
    - The stock bottle(s) to be used contain(s) the correct drug, strength/concentration, and dosage form and the expiry date is appropriate.

  - Entries made in the *ARV Prepacking Record* are correct.
  - The correct labels have been selected and the information has been filled in correctly.
  - The number of labels and containers are the same and corresponds to the number of prepacks to be prepacked.

- Once prepacking is complete:
  - Checks 10% of the packages to ensure that the prepacks contain the correct drug, strength, dosage form, and quantity and are labelled correctly.
  - Checks that no excess labels or empty containers are left.
  - Checks that the number of capsules/tablets left in the bulk container(s) reconciles with the number expected.

- Completes the *ARV Prepacking Record*:
  - Initials the final prepacking check.
  - Initials the reconciliation check of bottles, labels, and drugs.
  - Signs as the verifying pharmacist that correct prepacking procedures have been followed.

**Coast Provincial General Hospital**
**Antiretroviral Programme**

# Standard Operating Procedures

## For Pharmaceutical Services

| Coast Provincial General Hospital | |
|---|---|
| **Requesting USAID-Funded Antiretroviral Drugs** | |
| Number of pages: 3 | Procedure number: 101 |
| Prepared by: Name:<br>Title:<br>Date: | Reviewed by: Name:<br>Title:<br>Date: |

**Objective:**

To describe the procedure for requesting USAID-funded antiretroviral drugs from FHI/IMPACT for the ART Programme.

**Responsibility:**

- Pharmacist in charge of the ARV bulk store or his/her designated proxy
- Pharmacist in charge of the USAID-funded ART Programme

**Resources:**

Form used to request ARVs from FHI:

***ART Programme: Request to Supply Antiretroviral Drugs***

- Is a single-page letter.

**Procedure:**

- The pharmacist in charge of the ARV bulk store or his/her designated proxy completes the *ART Programme: Request to Supply Antiretroviral Drugs* form as described below.
- The pharmacist in charge of the USAID-funded ART Programme checks the request and forwards it through the Chief Pharmacist to the Chief Administrator for his/her signature.
- The Chief Administrator returns the signed letter to the pharmacist in charge of the USAID-funded ART Programme, who forwards it to the Mombasa ART Programme Technical Assistance Partners (TAP) Coordinator at the FHI Mombasa Office.

Steps for completing the *ART Programme: Request to Supply Antiretroviral Drugs* form:

1. For each ARV preparation enter:
    - The number of packs in stock in the ARV bulk store with expiry date (e.g.. *60 packs – 7/05; 140 packs 11/05)*
    - The number of packs requested

- Date the delivery is needed by

2. Sign, stamp, and record name and the date that the request was prepared.

3. Chief Administrator or designated proxy signs and records name and date.

**Distribution:**

- The original is forwarded to the Mombasa ART Programme TAP Coordinator at the FHI Mombasa Office.

- One copy of the completed and signed *ART Programme: Request to Supply Antiretroviral Drugs* is kept in the ARV bulk store.

- One copy of the completed and signed *ART Programme: Request to Supply Antiretroviral Drugs* is retained by the Chief Pharmacist.

- The *ART Programme: Request to Supply Antiretroviral Drugs* is used to check receipts of ARVs from FHI—to check for discrepancies between what was ordered and what is received and/or listed on the invoice.

# Coast Provincial General Hospital
# ART Programme: Request to Supply Antiretroviral Drugs

To: Technical Assistance Partners (TAP) Coordinator, Mombasa ART Programme, FHI/IMPACT

Coast Provincial General Hospital requests the following supplies for the USAID-funded ART Programme:

| Product | Form | Strength | Pack Size | No. Packs in Stock in ARV Bulk Store with Expiry Date | No. Packs Requested | Date Needed By |
|---|---|---|---|---|---|---|
| Zidovudine/lamivudine (Combivir) | Tablets | 300/150mg | 60 | | | |
| Didanosine (ddI) | Tablets | 25mg | 60 | | | |
| Didanosine (ddI) | Tablets | 200mg | 60 | | | |
| Didanosine (ddI) | Powder for solution | 883mg/5ml | 2g/4oz | | | |
| | | | 4g/8oz | | | |
| Efavirenz (EFV) | Capsules | 50mg | 30 | | | |
| Efavirenz (EFV) | Capsules | 200mg | 90 | | | |
| Efavirenz (EFV) | Tablets | 600mg | 30 | | | |
| Efavirenz (EFV) | Liquid | 30mg/ml | 180ml | | | |
| Indinavir (IDV) | Capsules | 400mg | 180 | | | |
| Lamivudine (3TC) | Tablets | 150mg | 60 | | | |
| Lamivudine (3TC) | Liquid | 10mg/ml | 240ml | | | |
| Lopinavir/ritonavir (LPV/r) (Kaletra) | Capsules | 133.33/ 33.33mg | 180 | | | |
| Lopinavir/ritonavir (LPV/r) (Kaletra) | Liquid | 80/20mg/ml | 160ml | | | |
| Nelfinavir (NFV) | Tablets | 250mg | 270 | | | |
| Nevirapine (NVP) | Tablets | 200mg | 60 | | | |
| Nevirapine (NVP) | Suspension | 10mg/ml | 240ml | | | |
| Stavudine (d4T) | Capsules | 15mg | 60 | | | |
| Stavudine (d4T) | Capsules | 20mg | 60 | | | |
| Stavudine (d4T) | Capsules | 30mg | 60 | | | |
| Stavudine (d4T) | Capsules | 40mg | 60 | | | |
| Stavudine (d4T) | Powder for solution | 1mg/ml | 200ml | | | |
| Zidovudine (AZT, ZDV) | Capsules | 100mg | 100 | | | |
| Zidovudine (AZT, ZDV) | Tablets | 300mg | 60 | | | |
| Zidovudine (AZT, ZDV) | Syrup | 50mg/5ml | 200ml | | | |
| | | | | | | |
| | | | | | | |

Request prepared by:
…… *(Name)* …….. *(Signature)* Date……/200….

Kindly confirm the receipt of this request and arrange for deliveries to be made to CPGH Pharmacy.
Yours sincerely,

…… *(Name)* …….. *(Signature)* Date……/200….
Chief Administrator

| Coast Provincial General Hospital | |
|---|---|
| **Receipt of USAID-Funded Antiretroviral Drugs at ARV Bulk Store** | |
| Number of pages: 6 | Procedure number: 102 |
| Prepared by: Name:<br>Title:<br>Date: | Reviewed by: Name:<br>Title:<br>Date: |

**Objective:**

To describe correct USAID-funded antiretroviral drug receiving procedure at the ARV bulk store.

**Responsibility:**

- Documentation and receipt of the ARVs will be performed by the receiving officer (the designated pharmacist in charge of the ARV bulk store or his/her designated proxy).

**Resources:**

Forms used for documenting receipt of USAID-funded ARVs:

***Counter Receipt Voucher (S13):***

- Is a serially numbered, single-copy form.
- Is used for payment for goods delivered.
- Is also used to check entries on the invoice from the supplier.
- Is an important document to be kept under lock and key at the ARV bulk store.

***ART Programme: Confirmation of Receipt of Supplies/Equipment***

- Is a single-page form.

***CPGH/FHI ART Delivery Book***

- Is a bound book.

Forms needed to check receipt of ARVs:

- *ART Programme: Request to Supply Antiretroviral Drugs*

**Procedure:**

The receiving officer will:

- Meet with the delivery personnel and sign for the delivery.

- Before signing, inspect and check the order against the invoice/delivery note and *ART Programme: Request to Supply Antiretroviral Drugs* and look for the following discrepancies:

    - Broken, cracked, or leaking bottles or bottles where seals are broken
    - Broken tablets
    - Drugs that arrive past their expiration date
    - Items that have no labels
    - Refrigerated items that arrive at room temperature or are warm
    - Inappropriate storage procedure during transportation of refrigerated items
    - Requirements from the tender that have not been met
    - Items listed on the invoice that are missing from the shipment
    - Items received that were not ordered or were not listed on the invoice

- Record all discrepancies on the *Shipment Discrepancy Report* as described in procedure 301: *Shipment Discrepancy Report*.

- Separate all damaged or expired medications and inform the FHI Mombasa Office, who will arrange for an exchange with the supplier.

- Send all refrigerated items directly to ARV bulk store refrigerator.

- Record all ARV items delivered (whether they were donated or purchased) on a *Counter Receipt Voucher (S13).* An *S13* and directions for completing it are shown below.

- Check off each item received and endorse the invoice/delivery note with the quantity received and any discrepancies. Sign, stamp, and date the invoice/delivery note.

- Complete *ART Programme: Confirmation of Receipt of Supplies/Equipment.* The pharmacist in charge of the ART Programme forwards it through the Chief Pharmacist to the Chief Administrator for his/her signature.

- The Chief Administrator returns the signed form to the pharmacist in charge of the ART Programme, who completes the *CPGH/FHI ART Delivery Book*. The Mombasa ART Programme Technical Assistance Partners (TAP) Coordinator at the FHI Mombasa Office arranges for the signed *ART Programme: Confirmation of Receipt of Supplies/Equipment* and the *CPGH/FHI ART Delivery Book* to be collected from CPGH.

Steps for completing the *Counter Receipt Voucher (S13):*

1. Enter Ministry (*of Health*) Dept./Branch (*Medical*) and Unit (*CPGH/ART*)

2. Record:

    - Source of items(s)

    - Code number (number listed in the Kenya Essential Drug List that is specific to each drug, strength/concentration, and dosage form)

- Description of item
  - Generic name
  - Strength/concentration
  - Dosage form
- Unit of issue (e.g., number of tablets per package)
- Quantity of units received
- Value
- Remarks (record *S3* number—specific to each drug, strength/concentration, and dosage form—and expiry date for each ARV preparation received)
- Order number
- Invoice number

3. The issuing officer (person delivering the items) and the receiving officer sign the *Counter Receipt Voucher (S13)* and records date and designation.

Steps for completing the *ART Programme: Confirmation of Receipt of Supplies/ Equipment:*

1. For each ARV preparation received enter:

   - The product name, form, strength, and pack size
   - The number of packs requested
   - The number of packs received
   - Batch number of stock received
   - Expiry date of stock received
   - Date the delivery is received

2. Sign, stamp, and record the date that the request was received.

3. Chief Administrator or designated deputy signs and records name and date.

Steps for completing the *CPGH/FHI ART Delivery Book:*

1. For each delivery note/invoice sent to FHI enter:

   - No: The next consecutive number
   - Date the document is sent to FHI
   - Delivered to: FHI
   - Content: Invoice or Delivery Note and the document number
   - Signature of the person receiving the document
   - Date and time the document is received

**Distribution:**

- The original invoice/delivery note is sent to FHI Mombasa Office with the *ART Programme: Confirmation of Receipt of Supplies/Equipment* together with the *CPGH/FHI ART Delivery Book.* If there are any discrepancies, a copy of the *Shipment Discrepancy Report* is also attached to the original invoice/delivery note.

- The *S13* forms are stored in the ARV bulk store under the custody of the designated pharmacist. They are kept with the booklet containing the *Stores Ledger and Stock Control Card (S3)* forms.

- The completed *S13* is used to complete the *Stores Ledger and Stock Control Cards* (*S3*) and *Bulk Store Bin Cards (S5)* as described in procedure 103: *Record Keeping for USAID-Funded Antiretroviral Drugs at ARV Bulk Store.*

**FORM: S13**

**Serial No:……..……**

**REPUBLIC OF KENYA**

# COUNTER RECEIPT VOUCHER

Ministry……Dept./Branch……..Unit:……..

Received the items listed below from (Source)……..……..

| Code No. | Item Description | Unit | Quantity | Value | Remarks |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| Order No. | | Invoice No. | | | OR |

Issuing Officer:……Signature……. Designation:……

Certified that the quantities received have been taken on-charge.

Receiving Officer:……Signature……..... Designation:……

Account No:…… Date: ……

GPK 090-1980bKS—5/2002

## ART Programme:
## Confirmation of Receipt of Supplies/Equipment

To: Technical Assistance Partners (TAP) Coordinator, Mombasa ART Programme
FHI/IMPACT
P.O. Box 16981
Mombasa
Tel: 041 314065/6, Fax: 041 228507

This is to confirm the receipt of the following supplies and/or equipment provided by the Programme to Coast Provincial General Hospital/Port Reitz District Hospital/Bomu Medical Centre/Magongo Health Centre:

| Product | Form | Strength | Pack/Item Size | Amount Requested | Amount Received | Batch Number of Stock Received | Expiry Date of Stock Received | Date Received |
|---|---|---|---|---|---|---|---|---|
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These items have been taken on-charge vide ref. nos:
…….

Received by:……. Date……/200…
*(Name/Designation/Signature)*

Yours sincerely,

……
Chief Administrator/District MOH/Municipal MOH/Director, Bomu Date……..……/200…

| Coast Provincial General Hospital | |
|---|---|
| **Record Keeping for USAID-Funded Antiretroviral Drugs at ARV Bulk Store** | |
| Number of pages: 9 | Procedure number: 103 |
| Prepared by: Name:<br>Title:<br>Date: | Reviewed by: Name:<br>Title:<br>Date: |

**Objective:**

To describe procedures for maintaining records for all activities that concern USAID-funded ARV stock in the ARV bulk store.

**Responsibility:**

- Documentation and recording of all ARV drug receipts and issues from the ARV bulk store is the responsibility of the pharmacist in charge of the ARV bulk store or his/her designated proxy.

**Resources:**

Forms used for record keeping of USAID-funded ARVs:

***Stores and Ledger Stock Control Card (S3):***

- Is a serially numbered, single-copy card bound in a booklet.
- Must exist for each ARV preparation.
- Is used for checking physical stock against records in the ARV bulk store.
- Every receipt and issue must be entered **at the time** that stock is received or removed, without exception.

***Bulk Store Bin Card (S5):***

- Is a serially numbered, single-copy card.
- Must exist for each ARV preparation.
- Is used for ARV inventory control.
- Every receipt and issue must be entered **at the time** that stock is received or removed, without exception.
- A supply of *S5* cards is to be kept as a stock item in the ARV bulk store in the custody of the pharmacist in charge of the ARV bulk store.

Forms needed to complete record keeping:

- *Counter Receipt Voucher (S13)*

**Procedures:**

- When ARV drugs arrive at the ARV bulk store, the receiving officer completes the *Counter Receipt Voucher (S13)* as described in procedure 102: *Receipt of USAID-Funded Antiretroviral Drugs at ARV Bulk Store*.

- The information from the *S13* is used to complete the *Stores Ledger and Stock Control Card (S3).* An *S3* and directions for completing the form are described below.

- The information from the *S3* is used to complete the *Bulk Store Bin Card (S5).* An *S5* and directions for completing the form are described below.

- Receipts are to be entered in red ink and issues in blue or black ink.

- Cards must be used until all entries are completed on both sides of the card. Balances from the completed card must be transferred to a new card.

- The designated pharmacy staff should check the physical count of each ARV preparation in stock any time there is a receipt or issue at the ARV bulk store to ensure that the physical stock balance corresponds with that shown on the *Bulk Store Bin Card (S5*). If a difference is found, a *Stock Count Discrepancy Report* is completed as described in procedure 302: *Stock Count Discrepancy Report*.

Steps for completing the *Stores Ledger and Stock Control Card (S3):*

1. Complete a separate *S3* for differing strengths/concentrations and units of issue (i.e., for each different pack size).

2. Record for a new card:

    - Item code number (number listed in the Kenya Essential Drug List that is specific to each drug, strength/concentration, and dosage form)

    - Description of item
        - Generic name
        - Strength/concentration
        - Dosage form

    - Unit of Issue: pack size (e.g., number of tablets per package)

    - Enter Ministry (*MOH*); Department (*Medical*); Location (*CPGH/ART*)

    - Card No.: for first card for a new item write *New*

3. Receipts: record when receiving stock

    - Date: of receipt
    - Voucher Number: the serial number from the corresponding *S11*
    - Supplier/Requisitioning Office: source of goods or supplier
    - Quantity: number of units received
    - Invoice Unit Price: the supplier's cost per unit in Kenya shillings (e.g., Ksh. 300 per 100ml bottle)
    - Value: total value in Kenya shillings
    - Balances
        - Quantity: new stock balance
        - Value: total value of stock in Kenya shillings

4. Issues: record when issuing stock

    - Date: of issue
    - Voucher Number: the serial number from the corresponding *S13*
    - Supplier/Requisitioning Office: department/unit requisitioning the drugs
    - Quantity: number of units ordered
    - Average Unit Price: average cost per unit in Kenya shillings (e.g., Ksh. 300 per 100ml bottle)
    - Value: total value in Kenya shillings
    - Balances
        - Quantity: quantity left in stock
        - Value: total value of stock remaining in Kenya shillings

5. Consumption Record: record

    - Monthly consumption: At the end of each month, calculate the monthly usage and record here. Do not count expired stock removed.
    - Annual Usage: At the end of each year, calculate the annual consumption and record here.

6. Forecast Requirements: record

    - Average Monthly Usage: Calculate from consumption records if usage is at steady state. If Programme is still scaling up, use current monthly usage.
    - Buffer Stock: safety stock to cater for any delays in the supply schedule

- Reorder Levels: the stock level at which an order is to be placed
- Reorder Quantity: stock to be ordered if usage is at steady state. If Programme is still scaling up, use current usage.
- E.O.Q. (Economic Order Quantity): minimum order quantity
- Size: dimensions of E.O.Q.
- Weight: of E.O.Q.
- Packaging: of E.O.Q.

7. Dues In: record details of outstanding orders placed by ARV bulk store

   - Date: of the order
   - Order: number
   - Quantity: ordered
   - Date received
   - Quantity received

8. Dues Out: record details of outstanding requisitions to be filled by ARV bulk store

   - Date: requisition was received
   - Order: number
   - Quantity: to be supplied
   - Date issued
   - Quantity issued

9. Lead time: Time between ordering and receiving drugs; this should be recalculated every three months for the ART Programme. Record:

   - Order: average time taken from when the pharmacist in charge of the ARV bulk store requests for an order to be made to when the supplier receives the order
   - Period: average time taken to receive this item in the ARV bulk store from when the supplier receives an order

10. Stock Checks: record

    - Date: of stock check
    - Surp: any surplus—stock in excess of stock balance
    - Def: any deficit—stock shortage compared to stock balance
    - Initials: of person performing the stock check

Steps for completing the *Bulk Store Bin Card* (*S5*):

1. Complete a separate bin card for differing strengths/concentrations and units of issue (i.e., for each different pack size)

2. Record for a new card:

- Item Code No. (number listed in the Kenya Essential Drug List that is specific to each drug, strength/concentration, and dosage form)

- Item Description:
  - Generic name
  - Strength/concentration
  - Dosage form

- Unit of issue: pack size (e.g., number of tablets per package)

- Storage requirements (e.g., refrigeration)

- Ledger Card Number (the serial number from the corresponding *S3* form)

- Stock location (if another location is also used, the two should be frequently reconciled)

- B/F from Card No.: for first card for a new item write *New*

- Balance B/F (Brought Forward) is entered as the first entry in a new card. For a new product write *New*. When a set of columns is completed on one side, the Balance C/F (Carried Forward) is recorded in the next set of columns at the Balance B/F.

3. Record when receiving stock:

   - Date: (stock received)

   - Issue/Receipt Voucher No.:

     - The reference number of the voucher for goods received from the supplier, local purchase, or exchange

     - Expiry date of product for each receipt

   - Receipt: quantity received

   - Balance: calculated by increasing the previous balance for goods received

   - Initials: of person receiving stock

4. Record when issuing stock:

   - Date: (stock issued)

   - Issue/receipt voucher no.: the reference number of the voucher for goods issued to the different user departments or units or other facility sites

   - Issue: quantity issued

   - Balance: calculated by decreasing the previous balance for goods issued

   - Initials: of person issuing stock

**Distribution:**

- The *S3* cards are kept in a serialized booklet and are stored in the ARV bulk store under the custody of the designated pharmacist. The *S3* cards are kept with the *Counter Receipt Voucher (S13)* forms.
- The *S5* cards are kept with the goods in the ARV bulk store. Each *S5* bin card is kept on top of the stock of the corresponding item.
- Old cards must be retained for 5 years from date of last entry.

**FORM: S3**

**GOVERNMENT OF KENYA**

**Serial No. ……..**

# STORES LEDGER AND STOCK CONTROL CARD

**ITEM CODE NO. ……**

**DESCRIPTION……...** **UNIT OF ISSUE……..**

**MINISTRY ……..** **DEPT./BRANCH……** **LOCATION……..**

| | | | RECEIPTS | | | ISSUES | | | BALANCES | | CONSUMPTION RECORD | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Date | Voucher Number | Supplier or Requisitioning Office | Quantity | Invoice Unit Price | Value | Quantity | Average Unit Price | Value | Quantity | Value | Month/Year | 20….. | 20….. | 20….. | 20….. |
| | B/F | Card No. | | | | | | | | | July | | | | |
| | | | | | | | | | | | August | | | | |
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| | | | | | | | | | | | June | | | | |
| | | | | | | | | | | | Annual Usage | | | | |
| | | | | | | | | | | | *FORECAST REQUIREMENTS* | | | | |
| | | | | | | | | | | | | 20….. | 20….. | 20….. | 20….. |
| | | | | | | | | | | | Average Monthly Usage | | | | |
| | | | | | | | | | | | Buffer Stock | | | | |
| | | | | | | | | | | | Reorder Levels | | | | |
| | | | | | | | | | | | Reorder Quantity | | | | |
| | | | | | | | | | | | E.O.Q. | | SIZE | | |
| | | | | | | | | | | | WEIGHT | | PACKAGING | | |
| | C/F | | | | | | | | | | | | | | |

| Date | Voucher Number | Supplier or Requisitioning Office | RECEIPTS | | | ISSUES | | | BALANCES | | DUES IN | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Quantity | Invoice Unit Price | Value | Quantity | Average Unit Price | Value | Quantity | Value | Date | Order | Qty | Date Received | Quantity Received |
| | B/F | Card No. | | | | | | | | | | | | | |
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| | | | | | | | | | | | Date | Voucher | Qty | Date Issued | Quantity Issued |
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| | | | | | | | | | | | STOCK CHECKS | | | | |
| | | | | | | | | | | | Date | | | | |
| | | | | | | | | | | | Surp. | | | | |
| | | | | | | | | | | | Def. | | | | |
| | C/F | Card No. | | | | | | | | | Initials | | | | |

FORM S5

**REPUBLIC OF KENYA**

## BIN CARD

ITEM CODE NO. ……... UNIT OF ISSUE ……... **SERIAL NUMBER:**

ITEM DESCRIPTION ……..… STORAGE REQUIREMENTS ……. LEDGER CARD NO. ……...

…….. LOCATION ……

| Date | Issue / Receipt Voucher No. | Receipt | Issue | Balance | Initials | Date | Issue / Receipt Voucher No. | Receipt | Issue | Balance | Initials |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | B/F From Card No. | B/F | | | | | | | | | |
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| Coast Provincial General Hospital | |
|---|---|
| **Internal USAID-Funded Antiretroviral Drug Distribution** | |
| Number of pages: 4 | Procedure number: 104 |
| Prepared by: Name:<br>Title:<br>Date: | Reviewed by: Name:<br>Title:<br>Date: |

**Objective:**

To describe the procedure for distributing USAID-funded antiretroviral drugs from the ARV bulk store to the outpatient pharmacy ARV stock or from the outpatient pharmacy ARV stock to the wards.

**Responsibility:**

Issuing:

- Pharmacist in charge of the ARV bulk store or his/her designated proxy; pharmacist or pharmaceutical technologist in charge of dispensing ARVs from the outpatient pharmacy

Receiving:

- Designated receiving officer: designated pharmacist or his/her designated proxy; the nursing officer in charge of the unit or his/her designated proxy

**Resources:**

Forms used to record ARV drug distribution:

***Counter Requisition and Issue Voucher (S11):***

- Is a serially numbered triplicate form.
- Is used for issue, delivery, and receipt of stock.
- Is used by the outpatient pharmacy to order from the ARV bulk store, and by wards and other departments to order from the outpatient pharmacy.
- Is kept in each department requiring its use. Additional supplies of the form can be requisitioned from the ARV bulk store.

Forms needed to complete internal drug distribution for issue of ARVs from the bulk store to the outpatient pharmacy:

- *Bulk Store Bin Cards (S5)*
- *Stores Ledger and Stock Control Card (S3)*
- *Hospital Pharmacy Bin Card (MOH 999)*

Forms needed to complete internal drug distribution for issue of ARVs from the outpatient pharmacy to the wards:

- *Stores Ledger and Stock Control Card (S3)*
- *Medication Treatment Sheet (MOH 306 Rev.)*
- *Hospital Pharmacy Bin Card (MOH 999)* and the *ARV dispensing tool*

**Procedure:**

1. Procedure for the outpatient pharmacy to order and receive ARVs from the ARV bulk store:

    - Complete *Counter Requisition and Issue Voucher (S11*) as described below.

    - Make appropriate entries on the *Bulk Store Bin Cards (S5)* and the *Stores Ledger and Stock Control Card (S3)* as described in procedure 103: *Record Keeping for USAID-Funded Antiretroviral Drugs at ARV Bulk Store* upon issue from the ARV bulk store.

    - Make appropriate entries on the *Hospital Pharmacy Bin Card (MOH 999)* and the *ARV dispensing tool* as described in procedure 106: *Record Keeping for USAID-Funded Antiretroviral Drugs at the Outpatient Pharmacy* upon receipt of ARVs at the outpatient pharmacy from the ARV bulk store.

2. Procedure for the outpatient pharmacy to issue ARVs to wards:

    - Complete *Counter Requisition and Issue Voucher (S11*) as described below.

    - Receive completed *Medication Treatment Sheet (MOH 306 Rev.)* as described in procedure 108: *Issuing USAID-Funded Antiretroviral Drugs to Inpatients*.

    - Ensure that the prescriber has signed the *Medication Treatment Sheet (MOH 306 Rev.).*

    - Check that the patient is on the ART Programme eligibility list.

    - Make appropriate entries on the *Hospital Pharmacy Bin Card (MOH 999)* and the *ARV dispensing tool* as described in procedure 106: *Record Keeping for USAID-Funded Antiretroviral Drugs at the Outpatient Pharmacy* upon issue to wards.

<u>Steps for completing the *Counter Requisition and Issue Voucher (S11*)</u>:

1. Designated person, authorised to requisition the stock, records:

    - Ministry (*of Health*) Depart./Branch (*Medical*) and Unit (e.g., CPGH/ART)

    - To (Issue point): e.g., ARV bulk store

    - Issue to (Point of use): receiving location (e.g., outpatient pharmacy)

    - Code No.: number listed in the Kenya Essential Drug List which is specific to each drug, strength/concentration, and dosage form

- Item Description:
  - Generic name
  - Strength/concentration
  - Dosage form

- Unit of Issue: the quantity in the container or pack size (e.g., 56 tablets per pack)

- Quantity Required: the number of units of issue required (e.g., 10 packets of 56 tablets each)

- Account No.: designated number if appropriate

- Date: of requisition

- Requisitioning Officer: name, designation, and signature

2. Designated person, authorised to issue the stock, records:

   - Quantity Issued: the number of units of issue which are actually issued

   - Value: of total amount of stock issued (calculated using average unit price)

   - Remarks/Purpose: expiry date of stock issued

   - Issued by: issuing officer's name and signature

   - Date: issued

3. Designated person authorised to receive the stock checks identity and quantity of ARV issued and records:

   - Received by: name, designation, and signature

**Distribution:**

The *Counter Requisition and Issue Voucher (S11*) is to be completed in triplicate:

- The original is kept by the ARV bulk store for stock issued to the outpatient pharmacy.

- For stock issued to inpatients, the original copy is retained by the outpatient pharmacy.

- Duplicate is retained by the initiating department.

- Triplicate remains in the *S11* book.

**FORM S11**

Serial No…….

**REPUBLIC OF KENYA**

# COUNTER REQUISITION AND ISSUE VOUCHER

Ministry …… Dept/Branch…… Unit……..

To (Issue point)……..
Please issue the stores listed below to (Point of use)……

| Code No. | Item Description | Unit of Issue | Quantity Required | Quantity Issued | Value | Remarks/Purpose |
|---|---|---|---|---|---|---|
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Account No: …… Date: ……

Requisitioning Officer: ……... Designation: …….. Sign: ……

Issued by: …… Signature: ……... Date: ……..

Received by: ……... Designation: …… Sign: ……

| Coast Provincial General Hospital | |
|---|---|
| **External USAID-Funded Antiretroviral Drug Distribution** | |
| Number of pages: 5 | Procedure number: 105 |
| Prepared by: Name:<br>Title:<br>Date: | Reviewed by: Name:<br>Title:<br>Date: |

**Objective:**

To describe the procedure for distributing USAID-funded antiretroviral drugs from the ARV bulk store to the pharmacy of a peripheral facility (e.g., Port Reitz District Hospital, Magongo Municipal Clinic, and Bomu [Mkomani] Medical Centre).

**Responsibility:**

- Issuing officer: The pharmacist in charge of the ARV bulk store is responsible for filling out the *Issue and Receipt Voucher (S12*) as described below.
- Receiving officer: Pharmacy staff or the nurse in charge of the pharmacy at the peripheral site or his/her designated proxy.
- Authorising officer: Designated person at the peripheral facility.

**Resources:**

Forms used to record external antiretroviral drug distribution:

***Issue and Receipt Voucher (S12):***

- Is serially numbered, bound in a book. Each voucher has six pages, one original and five copies.
- Is used to transfer USAID-funded ARV stocks from CPGH to other peripheral facilities.

Forms needed to complete external drug distribution:

- *Bulk Store Bin Cards (S5)*
- *Stores Ledger and Stock Control Card (S3)*

**Procedure:**

- The peripheral facility shall produce a signed letter *ART Programme: Request to CPGH to Supply Antiretroviral Drugs* with an accompanying *ARV Consumption Record* signed by designated authorising officer.

- When the letter of request and list is received, the pharmacist in charge of the ARV bulk store will complete the *Issue and Receipt Voucher (S12)* for the peripheral facility as described below.

- Make appropriate entries to the *Bulk Store Bin Cards (S5)* and the *Stores Ledger and Stock Control Card (S3*) as described in procedure 103: *Record Keeping for USAID-Funded Antiretroviral Drugs at ARV Bulk Store.*

Steps for completing the *Issue and Receipt Voucher (S12)*:

1. The pharmacist in charge of the ARV bulk store or designated proxy records:

   Under Supplier/Issuing Office:

   - Name of Facility: requesting drugs
   - Supplier/Issuing Office: *CPGH*
   - Min./Dept: *Health/Medical*
   - Address: of CPGH
   - Issuing officer: pharmacist's name
   - Designation and pharmacy stamp
   - Merchant name/Address: is left blank
   - Date: date stock issued
   - Issue approved by: name of designated authorising officer signing letter of request
   - Date: date of signed letter
   - Stores packed by: issuing pharmacist's name
   - Stores recorded by: issuing pharmacist's name
   - Mode of transportation: record how ARVs were sent, or if collected, by whom
   - Designation and pharmacy stamp
   - L.P.O. No.: is left blank
   - Delivery note: is left blank
   - Invoice: is left blank

   In grid:

   - Item code: number listed in the Kenya Essential Drug List which is specific to each drug, strength/concentration, and dosage form

   - Description: of item
     - Generic name
     - Strength/concentration
     - Dosage form

   - Unit: pack size of unit issued

   - Quantity Required/Ordered: number of packs ordered in letter of request

   - Quantity Issued/Received: number of packs actually issued

   - Quantity to follow: if applicable, number of packs to be issued at a later date

   - Rate: average cost per unit pack

- Total value: of stock supplied
- Stock Balance: CPGH stock balance
- Ledger Folio No.: *S3* number
- Certified that the above items/s has/have been Received/Issued and recorded on Ledger/Inventory: signed by issuing pharmacist
- Signature of Issuing Officer and Date

2. The requisitioning/receiving facility records upon receipt of ARVs:

   Under Requisitioning/Receiving Office:

   - Min./Dept.: e.g., Health /Port Reitz District Hospital
   - Indenting unit: *Pharmacy*
   - Address: of indenting unit
   - Receiving officer: name
   - Designation and stamp:
   - Reasons for demand: Write *A*
   - Indent approved by: the name of the designated authorising officer signing letter of request
   - Date: date of letter of request
   - Address for delivery: address of receiving facility
   - Receipt recorded by: name of person recording the receipt of ARVs
   - Chargeable to: is left blank
   - Vote/Head: is left blank
   - S/Head/Item No.: is left blank
   - Quantity Issued Received: number of packs received
   - Certified that the above items/s has/have been Received/Issued and recorded on Ledger/Inventory: signed by receiving pharmacist
   - Signature of Receiving Officer, stamp, and date

**Distribution:**

- The *S12* document has six pages.
  - The original is retained by CPGH ARV bulk store.
  - The receiving facility receives the second and third pages.
  - The fourth page is sent to the receiving facility's accounts department.
  - The fifth page is sent to the CPGH accounts department.
  - The sixth page remains in the book.

- The *S12* will be filed together with the letter of request and accompanying needs list from the peripheral facility in the CPGH ARV bulk store.

**FORM S12 (revised)** **REPUBLIC OF KENYA** **No……..**

# ISSUE AND RECEIPT VOUCHER

**Name of Facility: ……..**

| **Supplier/Issuing Office: ……** | | **Requisitioning/Receiving Office:……..** | |
|---|---|---|---|
| Min./Dept: ……..<br>Address: ……..<br>……..<br>Issuing officer: ……<br>Designation and stamp: ……..<br>Merchant: ……<br>Address: ……..<br>……..<br>Date: …… | Issue approved by: ……..<br>Date: ……..<br>Stores packed by: ……<br>Stores recorded by: ……..<br>Mode of transportation: ……..<br>Designation and stamp: ……..<br>L.P.O. No.: ……..<br>Delivery note: ……..<br>Invoice: …… | Min./Dept.: ……..<br>Indenting unit: ……<br>Address: ……..<br>……..<br>Receiving officer: ……<br>Designation and stamp: ……..<br>……..<br>Reasons for demand (see note 4): ……..<br>…….. | Indent approved by: ……<br>Date: ……<br>Address for delivery: ……..<br>……..<br>Receipt recorded by: ……<br>……..<br>Chargeable to: ……..<br>Vote/Head: ……..<br>S/Head/Item No.: ……..…… |

| Item | Item code | Description | Unit | Quantity Required/ Ordered | Quantity Issued/ Received | Quantity to follow | Rate | Total value | | Stock Balance | Ledger Folio. No. | Remarks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | Sh. | Cts. | | | |
| 1 | | | | | | | | | | | | |
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| 6 | | | | | | | | | | | | |
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| 8 | | | | | | | | | | | | |
| 9 | | | | | | | | | | | | |
| 10 | | | | | | | | | | | | |
| | | | | | | Total | | | | | | |

Certified that the above items/s has/have been Received/Issued and recorded on Ledger/Inventory

*Signature of Issuing Officer and Date*

*Signature of Receiving Officer and Date*

| Coast Provincial General Hospital | |
|---|---|
| **Record Keeping for USAID-Funded Antiretroviral Drugs at the Outpatient Pharmacy** | |
| Number of pages: 11 | Procedure number: 106 |
| Prepared by: Name:<br>Title:<br>Date: | Reviewed by: Name:<br>Title:<br>Date: |

**Objective:**

To describe the procedure for maintaining records of issues and receipts of USAID-funded ARV drugs at the outpatient pharmacy and of fees collected.

**Responsibility:**

Documentation and recording of all USAID-funded ARV receipts and issues from the ARV bulk store to the outpatient pharmacy is the responsibility of the designated pharmacist or pharmaceutical technologist in charge of dispensing ARVs or his/her designated proxy.

**Resources:**

Forms used for record keeping of ARVs in the outpatient pharmacy:

***Hospital Pharmacy Bin Card (MOH 999)*:**

- Must exist for each ARV preparation.
- Is a single-copy, loose-leaf form.
- Is used for ARV inventory control in the outpatient pharmacy.
- Entries must be made for every receipt and issue **at the time** that stock is received or removed, without exception.

***ART Patient Dispensing Record:***

- Is a single-copy, loose-leaf form.
- Has a summary reference page listing all patients and their ART regimens, with separate forms for adults and children.
- Is used to check for discrepancies in repeat ART prescriptions and to check whether patients are using more or less medicine than is expected.

***ARV Dispensing Tool:***

- Is an Access database.
- Is used to check for discrepancies in repeat ART prescriptions and to check whether patients are using more or less medicine than is expected.

**Procedure:**

- All receipts of stock from the ARV bulk store must be documented on *Hospital Pharmacy Bin Card (MOH 999)* and the *ARV dispensing tool* as described below.
- All issues of stock, both to outpatients and inpatients, must be documented on *Hospital Pharmacy Bin Card (MOH 999)* and the *ARV dispensing tool* as described below.
- All issues must be recorded on the *ART Patient Dispensing Record* as described below.
- All entries must be completed at time of receipt or issue.
- Receipts on *Hospital Pharmacy Bin Card (MOH 999)* are to be made in red ink and issues in blue or black ink.
- Each *Hospital Pharmacy Bin Card (MOH 999)* must be used until all entries are completed on both sides of the card. Balances from the completed card must be transferred to a new card.
- The designated pharmacy staff should check the physical count of each ARV preparation in stock any time there is a receipt or issue at the outpatient pharmacy to ensure that the physical stock balance corresponds with that shown on the *Hospital Pharmacy Bin Card (MOH 999)* under remarks and on the *ARV dispensing tool*. If a difference is found, a *Stock Count Discrepancy Report* is completed as described in procedure 302: *Stock Count Discrepancy Report*.

Steps for completing the *Hospital Pharmacy Bin Card (MOH 999):*

1. Complete a separate *MOH 999* for differing strengths/concentrations and units of issue (i.e., for each different pack size).
2. Record for a new card:
    - Hospital: *CPGH*
    - Description of item:
        - Generic drug name
        - Strength/concentration
        - Dosage form
        - Pack size
    - Unit of Issue: *1 tablet* or *1 capsule* or *1 ml.* If liquids are always issued in whole bottles, this can be the unit of issue (e.g., 240ml).
    - Code Number (number listed in the Kenya Essential Drug List which is specific to each drug, strength/concentration, and dosage form)
    - Remarks: record the balance brought forward or stock received for new product

3. Record when receiving stock:

    - Date: of receipt
    - Issue/Receipt Voucher Number: serial number from the *Counter Requisition and Issue Voucher (S11)*
    - From: *ARV bulk store*
    - Quantity: Record number of units (e.g., tablets; ml) received
    - Remarks: Record new stock balance (in units of issue)

4. Record when issuing stock:

    - Date: of issue
    - Issue/Receipt Voucher Number:
        - If issuing to wards, record inpatient number
        - If issuing to patient, record outpatient number
    - Issued:
        - To: record OP or IP/ward
        - Quantity issued
    - Issued by:
        - Name
        - Signature
    - Received by: For inpatients, signed by person receiving the drugs; for outpatients, name of prescribing doctor
        - Name
        - Signature
    - Remarks: Record new stock balance (in units of issue)

<u>Steps for completing the *ART Patient Dispensing Record*:</u>

1. For a new patient approved by the Eligibility Committee, record on the *ART Patient Dispensing Record* summary page for the relevant programme (e.g., USAID), either for adults or children and/or in the *ARV dispensing tool*:

    - ART Patient Record Number: fill in the next consecutive number
    - Patient's Name
    - OP/IP Number: patient's outpatient or inpatient number
    - Male (M) or Female (F)
    - Date Approved by Eligibility Committee

2. For a patient collecting his/her first prescription:

   - Check that the regimen follows the standard ART guidelines for the ART Programme. Alert the prescriber/Medical Officer in Charge of the ART Programme of any discrepancies before dispensing the prescription. Fill out a *Medication Error Report* as described in procedure 402: *Medication Error Reporting* for any errors discovered.

   - Record on the *ART Patient Dispensing Record* summary page:
     - Date Started on ART
     - Tick ARV drug preparations for current regimen in columns opposite Patient's Name

   - For **adults** start a new *ART Patient Dispensing Record - Adults* for each patient and record:
     - Programme: (e.g., USAID)
     - ART Patient Record No: from summary page
     - Patient's Name
     - IP/OP Number: patient's outpatient or inpatient number
     - Age
     - Sex
     - Allergies/ADR to ART
     - Date approved by the Eligibility Committee
     - Date started on ART
     - ART Regimen:
       - Date started on current regimen
       - Current regimen (drug name, form dose, frequency)
     - Dispensing Record:
       - Date: date first supply issued
       - No: days: number of days issued
     - DAART study: tick relevant column
       - Patient is on DAART study and received the supply in prepacks.
       - Patient is on DAART study and did not receive the supply in prepacks.
       - Patient is not on the DAART study.

   - For **children** start a new *ART Patient Dispensing Record - Children* for each patient and record:
     - Programme: (e.g., USAID)
     - ART Patient Record Number: from summary page
     - Patient's Name
     - IP/OP Number: patient's outpatient or inpatient number
     - Age
     - Sex
     - Allergies/ADR to ART
     - Date approved by the Eligibility Committee
     - Date started on ART
     - ART Regimen:
       - Date started on current regimen
       - Current regimen: drug name, form and strength/concentration, and frequency

- Dispensing Record:
  - Date: date first supply issued
  - Wt: current weight of patient in kg
  - S.A.: surface area in square metres
  - Abbreviation of each drug name (e.g., NVP) and current dose in ml for liquids, in mg for tablets
  - No: days: number of days issued
  - Qty disp.: total number of bottles or ml/units dispensed

3. For a repeat issue:

- Check the summary page and find the ART Patient Record Number and pull the *ART Patient Dispensing Record* for that patient or use the *ARV dispensing tool*.

- Use the *ART Patient Dispensing Record* or the *ARV dispensing tool* to countercheck the regimen and dose prescribed and that the patient is not collecting the prescription earlier or later than expected (by three or more days). Check current weight and/or surface area and that the dose is correct for current weight/surface area. Alert the prescriber/adherence nurse of any discrepancies before dispensing the prescription. Fill out a *Medication Error Report* as described in procedure 402: *Medication Error Reporting* for any errors discovered.

- Record for **adults:**
  - Date: date of issue
  - No: days: number of days issued
  - DAART study: tick relevant column
    - Patient is on DAART study and received the supply in prepacks.
    - Patient is on DAART study and did not receive the supply in prepacks.
    - Patient is not on the DAART study.

- Record for **children**:
  - Date: date of issue
  - Wt: current weight of patient in kg
  - S.A.: surface area in square metres
  - Abbreviation of each drug name (e.g., NVP) and current dose in ml for liquids, in mg for tablets
  - No: days: number of days issued
  - Qty disp.: total number of bottles or ml/units dispensed

- Record for both **adults** and **children:** if the regimen has been changed
  - Date discontinued: above the previous regimen
  - Date started on current regimen
  - Current regimen (drug name, form/dose, frequency)
  - Amend the Current ART Regimen on the summary page

- Record for both **adults** and **children:** if the regimen has been discontinued:
  - Date ART stopped
  - Date discontinued: above the previous regimen

**Distribution:**

- The *MOH 999* form is kept with the ARVs in the outpatient pharmacy in a secure locked cupboard.
- Old *MOH 999* forms must be retained for 5 years from date of last entry.
- *ART Patient Dispensing Records* are kept in the pharmacy with the *Prescription Forms (MOH 501)*.

**MOH 999**

**MINISTRY OF HEALTH**

# HOSPITAL PHARMACY BIN CARD

**Hospital:** ……..  **Unit of Issue:** …….

**Description of item:** ……  **Code Number:** ……...

| DATE | ISSUE/RECEIPT VOUCHER NUMBER | RECEIPT | | ISSUED | | ISSUED BY | | RECEIVED BY | | REMARKS |
|---|---|---|---|---|---|---|---|---|---|---|
| | | From | Quantity(Units) | To | Quantity(Units) | Name | Signature | Name | Signature | |
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# ART Patient Dispensing Record – ADULTS

**Summary Page**

**Programme: ……**

| ART Patient Record Number | Patient's Name | OP/IP Number | Male (M)/Female (F) | Date Approved by Eligibility Committee | Date Started on ART | Current ART Regimen (✓ as appropriate) | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | d4T Cap 30mg | d4T Cap 40mg | 3TC Tab 150mg | EFV Tab 600mg | NVP Tab 200mg | | Combivir Tab 300/150mg | IDV Cap 400mg | | ddI Tab 25mg | ddI Tab 200mg | AZT/ZDV Cap/Tab 100mg/300mg | Kaletra Cap 133/33mg | NFV Tab 250mg | | d4T Cap 15mg | d4T Cap 20mg | EFV Cap 200mg |
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# ART Patient Dispensing Record – CHILDREN

**Summary Page**

**Programme: ……**

| ART Patient Record Number | Patient's Name | OP/IP Number | Male (M)/Female (F) | Date Approved by Eligibility Committee | Date Started on ART | Current ART Regimen (✓ as appropriate) | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | AZT/ZDV Syr 50mg/5ml | AZT/ZDV Cap/Tab 100mg/300mg | 3TC Oral Soln 10mg/ml | 3TC Tab 150mg | NVP Oral Susp 10mg/ml | NVP Tab 200mg | EFV Cap 200mg | EFV Cap 50mg | EFV Liquid 30mg/ml | NFV Tab 250mg | IDV Cap 400mg | ddI Tab 25mg | ddI Tab 200mg | ddI Soln 88.3mg/5ml | d4T Oral Soln 1 mg/ml | d4T Cap 15 mg | d4T Cap 20 mg | d4T Cap 30 mg | Kaletra Cap 133/33 mg | Kaletra Oral Soln 80/20 mg/ml |
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# ART Patient Dispensing Record – ADULTS

**Programme:……..……..** **ART Patient Record No:……..**

| Patient's Name: | Age: | Sex: | Date approved by Eligibility Committee: |
|---|---|---|---|
| IP/OP Number: | Allergies/ADR to ART: | | Date started on ART: |
| | | | Date ART stopped: |

**ART Regimen** *(Record drug name, dose, and frequency)*

| Date started: | Date discontinued: | Date started: | Date discontinued: | Date started: | Date discontinued: |
|---|---|---|---|---|---|
| 1. | | 1. | | 1. | |
| 2 | | 2 | | 2 | |
| 3. | | 3. | | 3. | |

**Dispensing Record** *(Record date regimen dispensed; number of days dispensed; ✓relevant DAART Study column.)*

| Date | No. days | DAART study: Yes: Prepacks: Yes | Prepacks: No | No | Date | No. days | DAART study: Yes: Prepacks: Yes | Prepacks: No | No | Date | No. days | DAART study: Yes: Prepacks: Yes | Prepacks: No | No | Date | No. days | DAART study: Yes: Prepacks: Yes | Prepacks: No | No |
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**ART Patient Record No:……..**

# ART Patient Dispensing Record – CHILDREN

**Programme:……..……..** **ART Patient Record No:……..**

| Patient's Name: | Age: | Sex: | Date approved by Eligibility Committee: |
|---|---|---|---|
| IP/OP Number: | Allergies/ADR to ART: | | Date started on ART: |
| | | | Date ART stopped: |

**ART Regimen** *(Record drug name, form and strength/concentration, and frequency – RECORD DOSE below in dispensing record.)*

| Date started: | Date discontinued: | Date started: | Date discontinued: | Date started: | Date discontinued: |
|---|---|---|---|---|---|
| 1. | | 1. | | 1. | |
| 2 | | 2 | | 2 | |
| 3. | | 3. | | 3. | |

**Dispensing Record** *(Record date, current weight and surface area, drug name, dose dispensed, number of days and total quantity dispensed)*

| Date | Wt (kg) | SA | Drug | Dose (in ml) | No. days | Qty disp | Date | Wt (kg) | SA | Drug | Dose (in ml) | No. days | Qty disp | Date | Wt (kg) | SA | Drug | Dose (in ml) | No. days | Qty disp |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | 1. | | | | | | | 1. | | | | | | | 1. | | | |
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| Coast Provincial General Hospital | |
|---|---|
| **Issuing USAID-Funded Antiretroviral Drugs to Outpatients** | |
| Number of pages: 5 | Procedure number: 107 |
| Prepared by: Name:<br>Title:<br>Date: | Reviewed by: Name:<br>Title:<br>Date: |

**Objective:**

To describe correct procedures for issuing and dispensing USAID-funded antiretroviral drugs to outpatients. Good dispensing practices ensure that an effective form of the right drug is delivered to the right patient in the prescribed dosage and quantity, with clear instructions, and in a package that maintains the potency of the drug.

**Responsibility:**

- The authorised doctor/clinical officer is responsible for issuing the ART prescription *(MOH 501).*

- The designated pharmacist or pharmacy technologist is responsible for dispensing the ART prescription.

**Resources:**

Form used for issuing ARVs to outpatients:

***Prescription form (MOH 501)***

- Is a single-copy, loose-leaf form.

Forms used to record issues of ARVs to outpatients:

- *Hospital Pharmacy Bin Card (MOH 999)*
- *ART Patient Dispensing Records*
- *ARV dispensing tool*

**Procedure:**

1. Authorised physician completes *Prescription Form (MOH 501)* for each eligible patient. A properly completed *MOH 501* for the ART Programme must have the following information:

    - *CCC* written or stamped at the top of the prescription
    - Patient's full name
    - Department
    - Number: Patient outpatient (OP) number

- Weight in kg
- Surface area in square metres for children
- Date: date prescription was written
- Generic name of drug, e.g., lamivudine
- Strength/concentration
- Dosage form
- Quantity to be issued or duration (maximum one month)
- Frequency of drug administration (dosage)
- Prescriber's signature

2. Upon receiving *MOH 501* the designated pharmacist or pharmacy technologist must:

    - Check that the patient's name on the prescription is for the outpatient or patient's representative bringing the prescription.

    - Check that the patient is on the Eligibility List and the prescriber is authorised to prescribe ARVs.

    - Check that the regimen follows the standard ART guidelines for the ART Programme. Alert the prescriber/Medical Officer in Charge of the ART Programme of any discrepancies before dispensing the prescription.

    - Use the *ART Patient Dispensing Record* and/or the *ARV dispensing tool* to countercheck the regimen and dose prescribed and that the patient is not collecting the ARVs earlier or later than expected. Alert the prescriber/Medical Officer in Charge of the ART Programme of any discrepancies before dispensing the prescription.

    - For adults on d4T (stavudine) and ddI (didanosine), check that the dose is appropriate for the weight. Alert the doctor if the dose needs to be adjusted.

    - For children, check that the doses are correct for the weight and/or surface area. Alert the doctor if the dose needs to be adjusted.

    - If the dose has changed, ask the patient or patient's representative for previously issued bottles for relabelling.

    - Fill out a *Medication Error Report* as described in procedure 402: *Medication Error Reporting* for any errors discovered.

3. Fill the prescription using the ARVs in the outpatient pharmacy stock as described below, and endorse the prescription with the quantities issued for each drug.

4. Make entries in the *Hospital Pharmacy Bin Card (MOH 999)*, and the *ART Patient Dispensing Records*, and/or the *ARV dispensing tool* as described in procedure 106: *Record Keeping for USAID-Funded Antiretroviral Drugs at the Outpatient Pharmacy*.

5. Counsel the patient on the use of the medication as described in procedure 109: *Medication Use Counselling for Antiretroviral Therapy*.

Procedure for dispensing ARVs:

1. Work should begin in a clear workspace.

2. Pull the stock bottle from the ARV cupboard and match the following to the prescription:

    - Correct drug
    - Strength/concentration
    - Dosage form

3. Inspect the medication from the stock bottle. Look for the following:

    - Broken or discoloured tablets or capsules
    - Liquid medications that have changed colour or odour
    - Any cracks or chips in bottles

4. If any of the above are found, do not dispense medication to patient. Complete a *Stock Count Discrepancy Report* as described in procedure 302: *Stock Count Discrepancy Report* and discard the items according to procedure 502: *Disposal of USAID-Funded Antiretroviral Drugs*.

5. Inspect packaging container to make sure it is not damaged or soiled and that it is appropriate to drug product being packaged.

Procedure for dispensing ARV tablets or capsules:

1. Issue whole packs where possible.

2. If necessary, count out desired number of units using a spatula or knife on counting tray or clean sheet of paper. Avoid touching drug product with hands, as contamination may result.

3. Recount number of units before packing into the container.

4. Select the appropriate pre-printed label for the ARV preparation to be dispensed. Add the following information and label the package

    - Quantity
    - Batch No.
    - Expiry date
    - Times at which the drug is to be taken
    - Patient's name
    - Date

5. Follow standard pharmacy operating procedures to countercheck the product to make sure that package and labelling contain the correct drug, strength, quantity, dosage form, and directions for use.

Procedure for dispensing ARV liquids/powders:

1. Reconstitute powders as per manufacturer's instructions, if required.

2. **Issue whole packs unless an exception is absolutely necessary.** If you need to dispense a partial pack, make sure the bottle to contain the medicine is free of cracks or chips. If necessary, rinse bottles with clean water. Make sure that the label on the stock bottle is facing upward while pouring, to ensure that the label does not become soiled and unreadable.

3. Select the appropriate pre-printed label for the ARV preparation to be dispensed. Add the following information and label the bottle:

    - Quantity
    - Batch No.
    - Expiry date: Check the manufacturer's instructions for expiry dates of reconstituted medicines.
    - Dose
    - Frequency of administration
    - Times at which the drug is to be taken
    - Patient's name
    - Date

4. If the dose has changed since the last prescription, relabel previously issued bottles to reflect the new dose.

5. Follow standard pharmacy operating procedures to countercheck the product to make sure that package and labelling contain the correct drug, strength, quantity, dosage form, and directions for use.

**Distribution:**

- *Prescription Form (MOH 501)* is filed and kept for 5 years.

**REPUBLIC OF KENYA**

No. A. _____

# COAST PROVINCIAL GENERAL HOSPITAL

P.O. Box 90231, Mombasa

PRESCRIPTION FORM

**Name:** ……..…

**IP/OP. No:** …… **Date:**……..…...

**Ward……:** Clinic……

*Rx*

Doctor: …….

Sign:…….

| Coast Provincial General Hospital | |
|---|---|
| **Issuing USAID-Funded Antiretroviral Drugs to Inpatients** | |
| Number of pages: 7 | Procedure number: 108 |
| Prepared by: Name:<br>Title:<br>Date: | Reviewed by: Name:<br>Title:<br>Date: |

**Objective:**

To describe correct procedures for issuing and dispensing USAID-funded antiretroviral drugs to inpatients. Good dispensing practices ensure that an effective form of the right drug is delivered to the right patient in the prescribed dosage and quantity, with clear instructions, and in a package that maintains the potency of the drug.

**Responsibility:**

- The authorised prescriber is responsible for prescribing ARV medication orders on the *Medication Treatment Sheet (MOH 306 Rev.).*
- The nurse is responsible for recording administration of ARVs to inpatients on the *Medication Treatment Sheet (MOH 306 Rev.).*
- The designated pharmacist or pharmacy technologist in charge of dispensing ARVs is responsible for issuing the ARV drugs to the ward.

**Resources:**

***Medication Treatment Sheet (MOH 306 Rev.):***

- Is a record of all medication order(s) and medication administration, including routine, ARVs, DDA, PRN, and STAT orders.
- All drugs administered to the patient must be recorded.
- *MOH 306 Rev.* should never be used for requisitioning medications for patients who have been discharged

Forms used for issuing ARVs to inpatients:

- *Hospital Pharmacy Bin Card (MOH 999)*
- *ART Patient Dispensing Records*
- *ARV dispensing tool*

**Procedure:**

1. Authorised physician writes the ARV order on the *Medication Treatment Sheet (MOH 306 Rev.)* (see steps for completing *MOH 306 Rev.* below).

2. The nurse brings *MOH 306 Rev.* and a *Counter Requisition and Issue Voucher (S11)* completed as described in procedure 104: *Internal USAID-Funded Antiretroviral Drug Distribution* to the inpatient pharmacy.

3. Upon receiving *MOH 306 Rev.*:

    - Check that the patient is on Eligibility List and the prescriber is authorised to prescribe ARVs.

    - Check that the regimen follows the standard ART guidelines for the ART Programme. Alert the prescriber/Medical Officer in Charge of the ART Programme of any discrepancies before dispensing the prescription.

    - Use the *ART Patient Dispensing Record* and/or the *ARV dispensing tool* to countercheck the regimen and dose prescribed and that the nurse is not collecting the ARVs earlier or later than expected. Check the whole chart for drug interactions. Alert the prescriber of any discrepancies or problems before dispensing the ARVs.

    - For adults on d4T (stavudine) and ddI (didanosine), check that the dose is appropriate for the weight (ask the patient or their representative for latest weight if not on prescription). Alert the doctor if the dose needs to be adjusted.

    - For children, check that the doses are correct for the weight and/or surface area. Alert the doctor if the dose needs to be adjusted.

    - If the dose has changed, ask the nurse to return previously issued bottles for relabelling.

    - Fill out a *Medication Error Report* as described in procedure 402: *Medication Error Reporting* for any errors discovered.

4. Fill the prescription using the ARVs in the outpatient pharmacy stock as described below. Inpatients should be issued no more than a seven-day supply, although an exception can be made for ARV liquids when the smallest pack size can be issued.

5. Make entries in the *Hospital Pharmacy Bin Card (MOH 999)* and the *ART Patient Dispensing Records* and/or the *ARV dispensing tool* as described in procedure 106: *Record Keeping for USAID-Funded Antiretroviral Drugs at the Outpatient Pharmacy*. Endorse *MOH 306 Rev.* with the date and quantity given.

6. The designated pharmacy staff member completes the *Counter Requisition and Issue Voucher (S11)* and ensures the nurse receiving the drugs completes the *Counter Requisition and Issue Voucher (S11)* as described in procedure 104: *Internal USAID-Funded Antiretroviral Drug Distribution.* Retain the original copy.

7. The ARVs should be stored as per standard ward procedure for storing drugs in a secure, locked cabinet.

8. On discharge, the patient should be issued the drugs that have been held for them on the ward. The nurse should check that the supply issued is labelled with the correct dose. In addition, a *Prescription Form (MOH 501)* should be issued by the authorised prescriber as described in procedure 107: *Issuing USAID-Funded Antiretroviral Drugs to Outpatients.*

9. The pharmacist in charge of wards and the nurse in charge of the ward should regularly review the *Medication Treatment Sheet (306 Rev.)* to ensure that all required information is being correctly recorded.

10. For deceased patients, the ARVs should be returned to the pharmacy for either destruction or reuse if appropriate. If they are usable, the receipt of the ARVs should be entered into the *MOH 999.* If the drugs are not usable, they are removed for destruction as described in procedure 502: *Disposal of USAID-Funded Antiretroviral Drugs.*

Procedure for dispensing ARVs:

1. Work should begin in a clear workspace.

2. Pull the stock bottle from the ARV cupboard and match the following to the prescription:

    - Correct drug
    - Strength/concentration
    - Dosage form

3. Inspect the medication from the stock bottle. Look for the following:

    - Broken or discoloured tablets or capsules
    - Liquid medications that have changed colour or odour
    - Any cracks or chips in bottles

4. If any of the above are found, do not dispense the medication to patient. Complete a *Stock Count Discrepancy Report* as described in procedure 302: *Stock Count Discrepancy Report* and discard the items according to procedure 502: *Disposal of USAID-Funded Antiretroviral Drugs.*

5. Inspect packaging container to make sure it is not damaged or soiled and that it is appropriate to drug product being packaged.

Procedure for dispensing ARV tablets or capsules:

1. Issue whole packs where possible.

2. If necessary, count out desired number of units using a spatula or knife on counting tray or clean sheet of paper. Avoid touching drug product with hands, as contamination may result.

3. Recount number of units before packing into the container.

4. Select the appropriate pre-printed label for the ARV preparation to be dispensed. Add the following information and label the package:

    - Quantity
    - Batch No.
    - Expiry date
    - Times at which the drug is to be taken
    - Patient's name
    - Date

5. Follow standard pharmacy operating procedures to countercheck the product to make sure that package and labelling contain the correct drug, strength, quantity, dosage form, and directions for use.

Procedure for dispensing ARV liquids/powders:

1. Reconstitute powders as per manufacturer's instructions, if required.

2. **Issue whole packs unless an exception is absolutely necessary.** If you need to dispense a partial pack, make sure the bottle to contain the medicine is free of cracks or chips. If necessary, rinse bottles with clean water. Make sure that the label on the stock bottle is facing upward while pouring, to ensure that the label does not become soiled and unreadable.

3. Select the appropriate pre-printed label for the ARV preparation to be dispensed. Add the following information and label the bottle:

    - Quantity
    - Batch No.
    - Expiry date: Check the manufacturer's instructions for expiry dates of reconstituted medicines.
    - Dose
    - Frequency of administration
    - Times at which the drug is to be taken
    - Patient's name
    - Date

4. If the dose has changed since the last prescription, relabel previously issued bottles to reflect the new dose.

5. Follow standard pharmacy operating procedures to countercheck the product to make sure that package and label contain the correct drug, strength, quantity, dosage form, and directions for use.

Steps for completing *Medication Treatment Sheet (MOH 306 Rev.):*

1. At the time of patient's admission, the admitting doctor should record:

    - Patient's full name (all names must be included to ensure proper identification of the patient)
    - Inpatient No.
    - Ward and Bed No.
    - Allergies: to medications
    - Age
    - Sex
    - Name of Institution

2. All medication orders must be written on the *MOH 306 Rev.* by an authorised prescriber (doctor or clinical officer). The order should include:

    - Date and time the order was written
    - Drug name
    - Strength/concentration
    - Dose
    - Route of administration
    - Frequency of administration
    - Duration
    - Legible official name and signature and code of the prescriber

3. When a drug is administered to a patient, the nurse or doctor administering the drug will write:

    - Date and time of administration
    - Her/his signature

4. When for any reason an ordered drug cannot be administered, the nurse will write in the patient's nursing notes:

    - Name of the drug
    - Date and time the drug was to be administered
    - Reason why the drug could not be administered (e.g., patient not on ward; stock unavailable)
    - Fill out a *Medication Error Report* as described in procedure 402: *Medication Error Reporting*

**Distribution:**

- *Medication Treatment Sheet (MOH 306 Rev.)* is filed in the inpatient records.
- *Counter Requisition and Issue Voucher (S11)* is completed in triplicate:
    - The original copy is retained by the outpatient pharmacy.
    - Duplicate is retained by the initiating department.
    - Triplicate remains in the *S11* book.

**MOH 306 Rev.**

**MINISTRY OF HEALTH**

# MEDICATION TREATMENT SHEET

**Name:** ……  **Allergies:** ……

**Inpatient Number:** ……  **Age:** ……  **Sex:** ……

**Ward:** ……

**Bed No:** ……  **Name of Institution:** ……

| To be completed by clinician | | To be completed by Clinician or Nursing Staff | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| DATE | MEDICATIONS | TIME | DATE AND SIGNATURE | | | | | | | |
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NOTE: **USE RED PEN FOR DDA**

**ENTER YOUR SIGNATURE FOR EVERY DRUG GIVEN**

| Coast Provincial General Hospital | |
|---|---|
| **Medication Use Counselling for Antiretroviral Therapy** | |
| Number of pages: 38 | Procedure number: 109 |
| Prepared by: Name:<br>Title:<br>Date: | Reviewed by: Name:<br>Title:<br>Date: |

**Objective:**

Describe the process for counselling a patient on the use of antiretroviral therapy.

**Responsibility:**

Medication use counselling will be the responsibility of the pharmacy staff member dispensing ARVs to the patient or his/her representative. These staff members include the pharmacist and pharmacy technologist who have completed the ART training.

The *Antiretroviral Therapy – Patient Counselling Information* table, *Antiretroviral Therapy – Technical Side Effect Information* table, the *Antiretroviral Therapy – Technical Drug Interaction Information Presented by ARV Drug* table, and the *Antiretroviral Therapy – Technical Drug Interaction Information Presented by Interacting Drug* table should be updated annually under the supervision of the Chief Pharmacist at CPGH. The pharmacist should check the references noted in the tables and send any changes to the pharmacy contact at each ART site using this SOP.

**Resources:**

Forms used for counselling patient or his/her representative:

***Antiretroviral Therapy – Patient Counselling Information:***

- Is a table of ARV drug information used to counsel patient or his/her representative.

***Antiretroviral Therapy – Technical Side Effect Information:***

- Is a table of technical information on ARV drug side effects to inform pharmacists and prescribers.

***Antiretroviral Therapy – Technical Drug Interaction Information Presented by ARV Drug:***

- Is a table of technical information on ARV drug interactions, searchable by ARV drug, to inform pharmacists and prescribers.

***Antiretroviral Therapy – Technical Drug Interaction Information Presented by Interacting Drug:***

- Is a table of technical information on ARV drug interactions, searchable by drugs that can potentially interact with ARV drugs, to inform pharmacists and prescribers.

Resources used to prepare drug information tables:

***Overview of Antiretroviral Agents:***

- Available online through the U.S. Dept. of Health and Human Services at: http://www.aidsinfo.nih.gov/drugs/ (originally referenced 9/03)

***Scaling Up ART in Resource Limited Settings:***

- Available online through the World Health Organization at: http://www.who.int/docstore/hiv/scaling/guidelines.pdf) (originally referenced 9/03)

**Procedure:**

- Dispense the medications as described in procedure 107: *Issuing USAID-Funded Antiretroviral Drugs to Outpatients.*
- Counsel the patient or his/her representative using the guidance below and insert the information from the *Antiretroviral Therapy – Patient Counselling Information* table for each drug that the patient is taking.
- Counsel the patient or his/her representative at Window 4 of the pharmacy.

**Counselling Points for Patients on ART:**

1. **Introduce yourself:** Give your name and position (pharmacist or pharmaceutical technologist).
2. **Identify who is being counselled:** Is the person picking up the medicines the patient or caregiver or a representative?
3. **Check what the patient or his/her representative already knows about the medicines:** Ask the patient or his/her representative questions to see how much they already understand about the medications:

   *a. What did the doctor/nurse tell you the medication was for?*
   *b. How did the doctor/nurse tell you to take the medicines?*
   *c. What other information did the doctor/nurse tell you about taking this medication?*

4. **Make sure that the patient or his/her representative understands how these medications work:**

    a. *These medicines **(together)** are used to suppress the infection caused by the human immunodeficiency virus (HIV). HIV is the virus responsible for acquired immune deficiency syndrome (AIDS).*

    b. *The medicines you are receiving to treat your HIV infection will not cure or prevent HIV infection or AIDS; however, they will help keep HIV under control and they appear to slow down the destruction of the immune system, the body's defence against diseases. This may help delay the development of problems usually related to AIDS or HIV disease.*

    c. *These medicines will not keep you from spreading HIV to other people.*

    d. *People who receive these medicines may continue to have problems usually related to AIDS or HIV disease.*

5. **Check for questions and concerns:** *Do you have any questions or concerns, before I continue?* If you cannot address the patient's or his/her representative's questions or concerns, seek the advice of the doctor/nurse.

6. **Give medicine name and describe appearance:** Tell the patient or his/her representative the names of the medicines they are receiving. As you say the name (use the abbreviation) of the medicine, point to the name on the package label. Open the package and show the patient or his/her representative a tablet, or show the patient a picture of the tablet from a poster or other aid you keep in the pharmacy. Refer to *Antiretroviral Therapy – Patient Counselling Information* table.

7. **Give route of administration:** *For example, "You should take these medicines by mouth with a glass of water."*

8. **Give directions:** Explain to the patient or his/her representative the directions they should follow (number of pills or amount of fluid) and when to take the medication. Refer to *Antiretroviral Therapy – Patient Counselling Information* table. Explain that the medicines must be taken regularly, exactly as directed, and not to miss any doses:

    a. *These medications are meant only for you. Do not share these medications with others.*

    b. *These medications work best when there is a constant amount in the blood. To help keep the amount constant, do not miss any doses.*

    c. *Take the medicine exactly as the doctor/nurse told you. You should not take more of it or take it more often than the doctor/nurse has said.*

    d. *If you miss a dose, take it as soon as possible. However, if it is almost time for the next dose, skip the missed dose and go back to the regular dosing schedule. You should not take your missed dose and your next dose at the same time (or two doses at the same time).*

Give the patient a scenario and ask him what he would do. Make up an example that is based on the drugs the patient is receiving.

For example, the patient is supposed to take his/her medication at 8 in the morning and 8 at night. The patient remembers at 10 in the morning that he or she forgot the morning dose, what should the patient do? (Correct answer: patient should take the morning dose because it is not too close to evening dose.) What if the patient remembered that he or she forgot the morning dose at 6 in the evening, what should the patient do? (Correct answer: the patient should not take the forgotten dose but should take their evening dose as scheduled.)

*e. Keep taking the medication, even if you start to feel better. You will need to be on these or similar medications for the rest of your life.*

*f. If you don't take these medicines exactly as the doctor/nurse told you, they may not work. This is dangerous, because there are only a limited number of drugs that can be used to treat patients with HIV infections if these stop working.*

*g. Don't stop taking these medicines without checking with your doctor/nurse first.*

9. **Give information on the side effects of the medicines:** Refer to *Antiretroviral Therapy - Patient Counselling Information* table (the most common side effects are listed in **boldface** type).

   *a.* **Side effects to report at the next visit:** *These side effects usually do not need medical attention and go away during treatment as your body adjusts to the medicine. However, talk with your doctor if these side effects continue or are very bothersome.*

   *b.* **Side effects to report immediately:** *Check with your doctor **immediately** if you have the following side effects.*

10. **Taking other medicines/herbs/local medicine and drug interactions:** Ask the patient or his/her representative if the patient has any drug allergies. If the pharmacy keeps this information on file, double-check that the information is accurate. Ask the patient or his/her representative if the patient is taking any other medicines at the moment and check for interactions using the *Antiretroviral Therapy – Technical Drug Interaction Information Presented by Interacting Drug* table. Inform the prescriber of any interactions identified.

    Tell the patient:

    *a. Some medicines are not safe to take while you are taking ARV drugs.* Give the specific information listed in the "Drug Interactions" column of the *Antiretroviral Therapy – Patient Counselling Information* table.

    *b. You may or may not be able to tell if the other medicines are causing a problem.*

    *c. It is always best to check with your doctor before starting any new medicines (this includes herbals and vitamins).*

    *d. Avoid alcohol while taking ARV drugs.*

11. **Storage**:

    a. *Store the medication in a place where children cannot reach it.*

    b. *Store the medication in a cool and dry place. Do not store the medication in the bathroom, near the kitchen sink, or in other damp places. Heat or moisture may cause the medicine to not work as well.*

12. **Check the understanding of the patient or his/her representative**: by asking them to repeat back to you key information. Remind them of information they left out. You can say something like:

    a. *Can you repeat back to me the information I shared with you, so that I know if I missed telling you any important information.*

       Or

    b. *That was a lot of information. Just to make sure I covered all the information and you understood all of it, can you repeat back what we have covered?*

13. **Final check for questions and concerns:** *Do you have any questions or concerns?* If you cannot address the patient/caregiver's questions or concerns, seek the advice of the doctor/nurse.

# Antiretroviral Therapy – Patient Counselling Information

(Most common side effects are listed in **boldface** type.)

| Description | Directions | Side Effects | Drug Interactions |
|---|---|---|---|
| **Stavudine** (d4T), Zerit® | • This medication can be taken with or without food. | **Report immediately:**<br>• **Tingling, numbness, or pain in the hands/feet**<br>• Unusual tiredness, weakness, or muscle pain<br>• **Nausea, vomiting, or diarrhoea**<br>• Severe abdominal pain<br>• Fever, chills, or **rash**<br><br>**Report at next visit:**<br>• **Headache or difficulty sleeping** | * |
| 40mg capsule (dark orange) | Take 1 capsule twice a day. | | |
| 30mg capsule<br>(light orange and dark orange) | Take 1 capsule twice a day. | | |
| 1mg/ml oral solution | Children: (dose twice daily)<br><30kg 1mg/kg/dose<br>30–60kg 30mg/dose<br>Max. dose >60kg 40mg/dose | | |
| **Lamivudine** (3TC), Epivir® | • This medication can be taken with or without food. | **Report immediately:**<br>• Tingling, numbness, or pain in the hands/feet<br>• Unusual tiredness, weakness, or muscle pain<br>• **Nausea,** vomiting, or diarrhoea<br>• Severe abdominal pain<br>• Fever, chills, or **rash**<br><br>**Report at next visit:**<br>• **Dizziness, headache, or difficulty sleeping** | * |
| 150mg tablet<br>(white, diamond shaped) | Take 1 tablet twice a day. | | |
| 10mg/ml oral solution | Children: (dose twice daily)<br><30 days 2mg/kg/dose<br>>30 days or <60kg 4mg/kg/dose<br>Max. dose >60kg 150mg/dose | | |

| Description | Directions | Side Effects | Drug Interactions |
|---|---|---|---|
| **Efavirenz** (EFV), Stocrin® | • This medication should be taken preferably on an empty stomach. If it must be taken with food, avoid high-fat foods. | **Report immediately:**<br>• **Rash**<br>• **Nausea, vomiting, diarrhoea**<br>• Severe abdominal pain<br>• Severe depression or thinking you don't want to live anymore<br>**Report at next visit:**<br>(These side effects are rather common but tend to go away after about a month.)<br>• **Dizziness, headache, difficulty sleeping or concentrating**<br><br>**Inform patients that sometimes the drug causes abnormal or bad dreams, but that this should resolve within 2–4 weeks.** | * <br>There can be life-threatening problems if you take certain medicines with efavirenz.<br><br>The birth-control pill may not work effectively while taking efavirenz. Always use a barrier backup birth-control method (for example, a condom). This is very important because EFV can potentially cause problems with the development of a fetus. |
| 200mg capsule (gold) | Take 3 capsules at night. | | |
| 600mg capsule (yellow) | Take 1 capsule at night. | | |
| 30mg/ml syrup | Children**: (dose once daily)<br>10–15kg 270mg<br>15 to <20kg 300mg<br>20 to <25kg 360mg<br>25 to <33kg 450mg<br>33 to <40kg 510mg<br>Max dose >40kg 600mg<br><br>** These doses are for the syrup. Children who take the capsule will have a slightly lower total mg dose because of formulation issues. | | |
| **Nevirapine** (NVP), Viramune® | • This medication can be taken with or without food. | **Report immediately:**<br>• **Rash or fever**<br>• Muscle weakness or aches<br>• Yellow colour to skin or the whites of eyes<br>• Unusual tiredness or weakness<br>• Severe nausea, vomiting, or diarrhoea | * <br>The birth-control pill may not work effectively while taking nevirapine. Always use a barrier backup birth control method (for |
| 200mg tablet (white, oval) | Take 1 tablet once a day for the first 2 weeks of therapy, then take 1 tablet twice a day. | | |

| Description | Directions | Side Effects | Drug Interactions |
|---|---|---|---|
| 50mg/5ml oral suspension (white to off-white) | 4 mg/kg once a day for 2 weeks; thereafter, maintenance dose:<br>Children >2 months to <8 years:<br>7 mg/kg twice a day<br>Children >8 years: 4mg/kg twice daily<br>Maximum recommended dose: 400mg/day | **Report at next visit:**<br>• **Headache** | example, a condom). |
| **Zidovudine** (AZT, ZDV), Retrovir® | • Preferably should be taken at least 2 hours before or 2 hours after a meal.<br>• Suggest patients take with food (light, low-fat meal) if nausea and vomiting are a problem. | **Report immediately:**<br>• Fever or chills<br>• Sore throat<br>• Pale skin, **unusual tiredness or weakness**, shortness of breath, rapid heart beat<br><br>**Report at next visit:**<br>• **Nausea, headache, or difficulty sleeping** | * |
| 300mg tablet (white, round) | Take 1 tablet twice a day | | |
| 50mg/5ml syrup (colourless to pale yellow) | Children: (dose twice daily)<br><4 weeks 4mg/kg/dose<br>4 weeks–13 years 180mg/$m^2$/dose<br>>13 years 300mg/dose<br><br>Dose for prophylaxis (full-term newborn):<br>2 mg/kg orally every 6 hours starting within 12 hours of birth and continuing for 6 weeks | | |

| Description | Directions | Side Effects | Drug Interactions |
|---|---|---|---|
| **Didanosine** (ddI), Videx® | • Should be taken at least 2 hours before or 2 hours after a meal.<br>• Avoid drinking alcohol.<br>• Chew tablets and take with full glass of water. | **Report immediately:**<br>• Changes in vision<br>• Tingling, numbness, or pain in the hands/feet<br>• Unusual tiredness, weakness, or muscle pain<br>• **Nausea**, vomiting, or **diarrhoea**<br>• Severe abdominal pain<br>• Fever, chills, or rash<br><br>**Report at next visit:**<br>• **Anxiety, headache, or difficulty sleeping** | * There are many drugs that interact with didanosine; be especially careful to report any unusual symptom to your doctor when you start new drugs. |
| 200mg tablet (off-white to light orange/yellow, round) | For patients >60 kg:<br>Take the prescribed dose twice a day. | | |
| 50mg tablet (off-white to light orange/yellow, round) | For patients <60 kg:<br>Take the prescribed dose twice a day. | | |
| 10mg/1ml oral suspension | Children: (dose twice daily)<br><3 months: 50mg/$m^2$/dose<br>>3 months to <13 years: 90mg/$m^2$/dose<br>Max. dose >13 years or >60kg: 200mg/dose | | |
| **Lopinavir/Ritonavir** (LPV/r), Kaletra® | • Should be taken with food. | **Report immediately:**<br>• **Unusual tiredness, weakness,** or muscle pain<br>• **Nausea,** vomiting, or **diarrhoea**<br>• Severe abdominal pain<br>• Fever, chills, or **rash**<br>• Yellow colour to the skin or the whites of eyes<br><br>**Report at next visit:**<br>• **Headache or difficulty sleeping** | * There can be life-threatening problems if you take certain medicines with lopinavir/ritonavir. |
| 133.3mg/33.3mg capsule (orange) | Take 3 capsules twice a day. | | |
| 400mg/100mg/5ml oral solution | Children: (dose twice daily)<br>>6 months to 13 years: 225mg/$m^2$ LPV/ 57.5mg/$m^2$ ritonavir<br>Max. dose >40kg: 400mg LPV/100mg ritonavir | | |

*All patients should be counselled about drug interactions as follows for each ARV drug:

- *Some medicines are not safe to take while you are taking ARV drugs.* Give the specific information listed in the "Drug Interactions" column of this table
- *You may or may not be able to tell if the other medicines are causing a problem.*
- *It is always best to check with your doctor before starting any new medicines (this includes herbals and vitamins).*
- *Avoid alcohol while taking ARV drugs.*

**References:**

*Side Effects/Drug Interactions: Overview of Antiretroviral Agents.* Available online through the U.S. Dept. of Health and Human Services at: http://www.aidsinfo.nih.gov/drugs/

*Dosing/Drug Interactions: Scaling up ART in Resource Limited Settings.* Available online through the World Health Organization at: http://www.who.int/docstore/hiv/scaling/guidelines.pdf

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# Antiretroviral Therapy – Technical Side Effect Information

(Clinically severe side effects are listed in **boldface** type.)

| ART Drug | Side Effect | Considerations |
|---|---|---|
| **Stavudine** (d4T), Zerit® | Common:<br>• **Peripheral neuropathy (PN)**<br>• Headache<br>• Insomnia<br>• Rash<br>• Diarrhoea<br>• Nausea/vomiting<br>• Lipodystrophy<br><br>Rare:<br>• **Pancreatitis**<br>• **Lactic acidosis with hepatic steatosis**<br>• **Rapidly progressing ascending neuron weakness** | • Additional risk factors for pancreatitis include female gender, obesity, and prolonged nucleoside exposure. Suspend stavudine in patients with suspected lactic acidosis or pancreatitis. If pancreatitis remits, reinstitute stavudine with extreme caution only if necessary, but not in combination with other drugs known to cause pancreatitis (especially didanosine or hydroxyurea). Reinstitution of stavudine is not recommended after confirmed lactic acidosis.<br><br>• Additional risk factors for PN include advanced HIV disease, history of neuropathy, and concurrent neurotoxic drug therapy. Interrupting treatment with stavudine may cause PN to resolve. Some patients tolerate stavudine resumption at a decreased dose (approximately ½ original dose) after PN resolution. If PN returns again, permanent discontinuance of stavudine should be considered. |
| **Lamivudine** (3TC), Epivir® | Common:<br>• Dizziness<br>• Headache<br>• Insomnia<br>• Fatigue<br>• Nausea<br>• Rash<br><br>Rare:<br>• **Lactic acidosis with hepatic steatosis (less common than with stavudine)**<br>• **Peripheral neuropathy (less common than with stavudine)** | • Additional risk factors for pancreatitis include female gender, obesity, and prolonged nucleoside exposure. Suspend lamivudine in patients with suspected lactic acidosis or pancreatitis. If pancreatitis remits, reinstitute lamivudine with extreme caution only if necessary, but not in combination with didanosine. Reinstitution of stavudine is not recommended after confirmed lactic acidosis.<br><br>• Additional risk factors for PN include advanced HIV disease, history of neuropathy, and concurrent neurotoxic drug therapy. Interrupting treatment with lamivudine may cause PN to resolve. Some patients tolerate lamivudine resumption at a decreased dose after PN resolution. If PN returns again, permanent discontinuance of lamivudine should be considered. |

| ART Drug | Side Effect | Considerations |
|---|---|---|
| **Efavirenz** (EFV), Stocrin® | Common:<br>• Central nervous system (CNS) symptoms (esp. abnormal or bad dreams, dizziness, headache, somnolence, insomnia, confusion, difficulty concentrating)<br>• Mild rash<br>• Nausea/anorexia/vomiting<br>• Diarrhoea<br><br>Rare:<br>• **Severe rash**<br>• **Suicidal ideation**<br>• Visual disturbances<br>• Gynaecomastia<br>• Tinnitus<br>• Increased transaminase levels | • CNS symptoms are very common and have been reported to occur in at least 50% of patients. These symptoms were reported to be severe in 2% of patients, and 2% of patients discontinued therapy as a result. Symptoms usually began during the first or second day of therapy and resolve after the first 2–4 weeks of therapy. Dosing at bedtime is recommended to improve tolerability. This drug has been shown (in clinical use) to often cause abnormal or bad dreams. Typically the bad dreams resolve within 2–4 weeks. Warning patients ahead of time may encourage compliance.<br><br>• In most patients, mild rash resolves within 1 month with continuing efavirenz therapy. Efavirenz may be reinitiated in patients interrupting therapy because of mild rash. Severe rash (Stevens-Johnson syndrome) is rare, but if it occurs the efavirenz should be permanently discontinued.<br><br>• EFV has been proven teratogenic in monkeys. Do not use in pregnancy unless no other therapy is available and the potential benefits outweigh the potential risks to the fetus. |
| **Nevirapine** (NVP), Viramune® | Common:<br>• Headache<br><br>Rare:<br>• **Rash**<br>• **Hepatitis, including hepatic necrosis**<br>• Lipodystrophy | • Patients experiencing a mild rash during the 14-day lead-in period should not have their dose increased until the rash resolves. Patients experiencing a severe rash should have nevirapine discontinued immediately. Stevens-Johnson syndrome has been reported. Women have a higher risk of rash.<br><br>• Monitor patients intensively during the first 12–16 weeks of therapy to detect potentially life-threatening hepatotoxicity or skin reactions. Most cases occur within the first 4–6 weeks of therapy.<br><br>• If severe hepatic, skin, or hypersensitivity reactions occur, nevirapine should not be restarted. |

| ART Drug | Side Effect | Considerations |
|---|---|---|
| **Zidovudine** (AZT, ZDV) Retrovir® | Common:<br>• Nausea/anorexia<br>• Headache<br>• Insomnia<br>• Malaise<br>• Asthenia<br><br>Rare:<br>• **Bone marrow suppression**<br>• **Anaemia**<br>• **Neutropenia**<br>• **Lactic acidosis with hepatic steatosis**<br>• Myopathy | • Although many references recommend that zidovudine be taken on an empty stomach, nausea and vomiting may result, which may deter patients from taking the drug. Suggest patients take with food (light, low-fat meal) if nausea and vomiting are a problem.<br><br>• Myopathy has been associated with prolonged therapy.<br><br>• Reduction in haemoglobin may occur as early as 2–4 weeks after the start of therapy. Neutropenia usually occurs after 6–8 weeks. Significant anaemia and or neutropenia may require a dose interruption until evidence of marrow recovery has occurred. |
| **Didanosine** (ddI) or Videx® | Common:<br>• Anxiety<br>• Headache<br>• Insomnia<br>• Diarrhoea<br>• Nausea<br><br>Rare:<br>• **Pancreatitis**<br>• **Peripheral neuropathy**<br>• **Lactic acidosis with hepatic steatosis**<br>• **Retinal changes and optic neuritis** | • Additional risk factors for pancreatitis include female gender, obesity, and prolonged nucleoside exposure. Didanosine should be withheld if pancreatitis is suspected, and discontinued if pancreatitis is confirmed. The manufacturer suggests discontinuing didanosine in patients who require life-sustaining treatment with other drugs known to cause pancreatitis. Pancreatitis is dose related (increased dose, increased chance for pancreatitis). |

| ART Drug | Side Effect | Considerations |
|---|---|---|
| **Lopinavir/ Ritonavir** (LPV/r), Kaletra® | Common:<br>• Headache<br>• Insomnia<br>• Abnormal stools<br>• Diarrhoea<br>• Weakness/tiredness<br>• Nausea<br>• Rash<br><br>Rare:<br>• **Pancreatitis**<br>• **Increased bleeding in haemophiliac patients**<br>• **Elevated transaminase enzymes**<br>• Fat redistribution and lipid abnormalities<br>• Hyperglycaemia<br>• Asthenia | • Patients with hypertriglyceridemia or hypercholesterolemia should be evaluated for risk of cardiovascular events and pancreatitis. Interventions may include dietary modification, lipid-lowering agents, or discontinuation of lopinavir/ritonavir.<br><br>• Cases of worsening glycaemic control among patients with pre-existing diabetes and cases of new-onset diabetes, including diabetic ketoacidosis, have been reported.<br><br>• Monitor patients with pre-existing (or at risk for) transaminase elevations for further elevations. |

## References:

*Guidelines for the Use of Antiretroviral Agents.* Available online through the U.S. Dept. of Health and Human Services at: http://www.aidsinfo.nih.gov/guidelines/

*Scaling up ART in Resource Limited Settings.* Available online through the World Health Organization at: http://www.who.int/docstore/hiv/scaling/guidelines.pdf

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# Antiretroviral Therapy – Technical Drug Interaction Information Presented by ARV Drug

(Drugs with clinically severe interactions are listed in **boldface** type.)

(Interacting drugs under each ARV drug are listed in decreasing order of clinical significance.)

| ARV Drug | Severity and Interacting Drug(s) | Nature of Reaction | Considerations |
|---|---|---|---|
| **Stavudine** (d4T), Zerit® | **Didanosine with or without hydroxyurea**<br><br>**Alcohol, asparaginase, azathioprine, estrogens, frusemide, lamivudine, methyldopa, nitrofurantoin, pentamidine, ribavirin, sulphonamides, sulindac, tetracyclines, thiazide diuretics, valproic acid, zalcitabine** | Lactic acidosis, pancreatitis (potentially fatal) | • Use with caution and only if potential benefit outweighs potential risk. Suspend stavudine in patients with suspected lactic acidosis or pancreatitis. If pancreatitis remits, reinstitute stavudine with extreme caution only if necessary, but not in combination with didanosine or hydroxyurea.<br><br>• Reinstitution of stavudine is not recommended after confirmed lactic acidosis. |
| | **Chloramphenicol, cisplatin, dapsone, didanosine, ethambutol, ethionamide, hydralazine, isoniazid, lithium, metronidazole, nitrofurantoin, phenytoin, ribavirin, vincristine, zalcitabine** | May cause or exacerbate peripheral neuropathy (PN). | • Avoid unnecessary use of interacting drugs. Interrupting treatment with stavudine may cause PN to resolve. Some patients tolerate stavudine resumption at a decreased dose after PN resolution. If PN returns again, permanent discontinuance of stavudine should be considered. |
| | **Zidovudine** | Metabolism of stavudine reduced. | • Concomitant use is not recommended. |

| ARV Drug | Severity and Interacting Drug(s) | Nature of Reaction | Considerations |
|---|---|---|---|
| **Lamivudine** (3TC), Epivir® | **Alcohol, asparaginase, azathioprine, estrogens, frusemide, hydroxyurea, methyldopa, nitrofurantoin, pentamidine, ribavirin, stavudine, sulphonamides, sulindac, tetracyclines, thiazide diuretics, valproic acid, zalcitabine** | Lactic acidosis, pancreatitis (potentially fatal) | • Use with caution and only if potential benefit outweighs potential risks. Suspend lamivudine in patients with suspected lactic acidosis or pancreatitis. If pancreatitis remits, reinstitute lamivudine with extreme caution only if necessary, but not in combination with didanosine.<br>• Reinstitution of stavudine is not recommended after confirmed lactic acidosis. |
| | **Chloramphenicol, cisplatin, dapsone, didanosine, ethambutol, ethionamide, hydralazine, isoniazid, lithium, metronidazole, nitrofurantoin, phenytoin, ribavirin, stavudine, vincristine, zalcitabine** | May cause or exacerbate PN. | • Avoid unnecessary use of interacting drugs. Interrupting treatment with lamivudine may cause PN to resolve. Some patients tolerate lamivudine resumption at a decreased dose after PN resolution. If PN returns again, permanent discontinuance of lamivudine should be considered. |
| | Sulphamethoxazole/trimethoprim | May decrease clearance of lamivudine by 30%. | • Monitor patient for toxicity associated with lamivudine. |

| ARV Drug | Severity and Interacting Drug(s) | Nature of Reaction | Considerations |
|---|---|---|---|
| **Efavirenz** (EFV), Stocrin® | **Astemizole, cisapride, ergot derivatives, midazolam, terfenadine, triazolam (potentially any drug metabolized by CYP3A4)** | May cause life-threatening adverse events such as cardiac arrhythmias, prolonged sedation, or respiratory depression. | • Concomitant use is not recommended. |
| | **Warfarin** | Clinical effects of warfarin increased or decreased. | • Monitor warfarin level closely. |
| | **Alcohol, psychoactive drugs, especially midazolam and triazolam** | Prolonged sedation. | • Avoid concomitant therapy or monitor patient very closely. |
| | **Ethinyl estradiol (hormonal contraceptives)** | Increased ethinyl estradiol level (clinical effect unknown). | • Addition of a reliable barrier contraception method recommended. |
| | Lopinavir/ritonavir | Plasma concentrations of lopinavir/ritonavir are decreased. | • Avoid unnecessary use or monitor efficacy of protease inhibitor and consider dose adjustment if indicated. |
| | Rifabutin or rifampicin or rifapentine | Rifabutin concentration may be decreased.<br>Rifampicin may decrease efavirenz concentration. | • Monitor patient for rifabutin efficacy. May consider increasing rifabutin dose to 400–650mg once daily or 600mg 3 times a week. Rifapentine is not recommended. |
| | **Phenobarbital or St. John's Wort *(Hypericum perforatum))*** | Decreased efavirenz concentration. | • Administer with caution. Monitor patient for loss of virologic response and resistance (due to decreased efavirenz). |
| | Clarithromycin (possibly erythromycin) | Plasma concentration of clarithromycin may be decreased (erythromycin has not been studied). | • Monitor patient for clarithromycin (erythromycin) efficacy or use alternative agent. Concomitant use is not recommended. |
| | Nevirapine | Studies have not been performed. | • Concomitant use is not recommended. |

| ARV Drug | Severity and Interacting Drug(s) | Nature of Reaction | Considerations |
|---|---|---|---|
| **Nevirapine** (NVP), Viramune® | **Rifampicin** or rifabutin or rifapentine | Increased levels of rifampicin and rifabutin, and/or decreased levels of nevirapine. | • Dosage adjustments or therapeutic substitutions may be necessary. Effect is more pronounced with rifampicin, and thus co-administration of rifampicin and nevirapine is not recommended. Rifapentine is not recommended. |
| | **Ethinyl estradiol (hormonal contraceptives)** | Decreased contraceptive concentration. | • Hormonal contraceptives should not be used as the primary means of contraception. |
| | Lopinavir/ritonavir | Decreased levels of lopinavir/ritonavir. | • Administer with caution. Monitor patient for loss of virologic response and resistance (due to decreased lopinavir/ritonavir). |
| | Ketoconazole | Reduced ketoconazole concentration, increased nevirapine concentration. | • Monitor patient for ketoconazole efficacy; co-administration is not recommended. |
| | Cimetidine, macrolide antibiotics (clarithromycin, erythromycin), any drug metabolized by CYP3A4 | Nevirapine may lower other drug concentration, or nevirapine concentration may be increased. | • Dosage adjustments may be necessary. |
| | Prednisone or prednisolone | Increased incidence and severity of rash. | • Monitor patient. |
| | Methadone | Decreased methadone concentration. | • May need to retitrate methadone dose to effect. |
| | **St. John's Wort *(Hypericum perforatum)*** | Decreased nevirapine concentration. | • Monitor patient for loss of virologic response and resistance (due to decreased nevirapine). |

| ARV Drug | Severity and Interacting Drug(s) | Nature of Reaction | Considerations |
|---|---|---|---|
| **Zidovudine** (AZT, ZDV), Retrovir® | **Cytotoxic agents, radiation, bone marrow depressants such as ganciclovir or interferon-alpha** | Increased histologic toxicity of zidovudine. | • Monitor patient carefully. |
| | **Cidofovir + probenecid (probenecid is causative drug)** | Increased zidovudine concentrations, patients may develop myalgia, fever, and rash. | • On days that cidofovir, probenecid, and zidovudine are co-administered, zidovudine should be temporarily discontinued or zidovudine dose should be reduced by 50%. |
| | Doxorubicin, ribavirin, stavudine | Drugs may antagonize one another. | • Concomitant use is not recommended. |
| | Acetaminophen, aspirin, atovaquone, benzodiazepines, cimetidine, indomethacin, morphine, sulphonamides, valproic acid | May increase zidovudine concentration or other drug concentration. | • Monitor patient for drug toxicity. |
| | Rifampicin | Decreased zidovudine level. | • Monitor patient for loss of virologic response and resistance (due to decreased zidovudine). |
| | Acyclovir, clarithromycin, fluconazole, methadone, nelfinavir, phenytoin, ritonavir | Theoretically may interfere with zidovudine level, but there are no specific data to support this effect. | • Monitor patients carefully. |

| ARV Drug | Severity and Interacting Drug(s) | Nature of Reaction | Considerations |
|---|---|---|---|
| **Didanosine** (ddI) or Videx® | **Alcohol, asparaginase, azathioprine, estrogens, frusemide, hydroxyurea, lamivudine, methyldopa, nitrofurantoin, pentamidine, ribavirin, stavudine, sulphonamides, sulindac, tetracyclines, thiazide diuretics, valproic acid** | Increased risk of pancreatitis. | • Avoid concomitant use or use with extreme caution. Manufacturer suggests discontinuing didanosine in patients who require life-sustaining treatment with other drugs known to cause pancreatitis. Didanosine should be suspended if pancreatitis is suspected and discontinued if pancreatitis is confirmed. |
| | **Chloramphenicol, cisplatin, dapsone, ethambutol, ethionamide, hydralazine, isoniazid, lithium, metronidazole, nitrofurantoin, phenytoin, ribavirin, stavudine, vincristine, zalcitabine** | Increased risk of peripheral neuropathy. | • Avoid concomitant use or use with extreme caution. |
| | **Tenofovir disoproxil fumarate** | Increased absorption of didanosine. | • Co-administration should be undertaken only with extreme caution, and patients monitored closely for didanosine-related toxicities. Consider decreasing didanosine dose. |
| | **Allopurinol** | Increased toxicity of didanosine. | • Concomitant use is not recommended. |
| | Ganciclovir | Increased toxicity of didanosine. | • Monitor patient for increased toxicity of didanosine. |
| | Itraconazole, ketoconazole | Decreased concentration of itraconazole or ketoconazole. | • Avoid concomitant use if possible; therapy failure with itraconazole or ketoconazole is possible. Manufacturer recommends itraconazole or ketoconazole be administered at least 2 hours prior to didanosine. |
| | Protease inhibitors | Potential decreased effect of protease inhibitors if taken at the same time. | • Separate dosing of protease inhibitors and didanosine. |
| | Dapsone | Treatment failures with dapsone (for *Pneumocystis carinii* pneumonia prevention) have occurred. | • Avoid concomitant use. Manufacturer suggests separating doses by 2 hours. |
| | Fluoroquinolones, tetracyclines | Decreased effect of fluoroquinolones or tetracyclines. | • Separate dosages of drugs by at least 2 hours. |
| | Methadone | Decreased didanosine concentration. | • Monitor patient for loss of virologic response and resistance (due to decreased didanosine). |

| ARV Drug | Severity and Interacting Drug(s) | Nature of Reaction | Considerations |
|---|---|---|---|
| **Lopinavir/ Ritonavir** (LPV/r), Kaletra® | **Astemizole, cisapride, ergot derivatives, flecainide, midazolam, pimozide, propafenone, rifampicin, terfenadine, triazolam, quinidine (any drug metabolized by CYP3A4 or CYP2D6)** | May cause life-threatening adverse events such as cardiac arrhythmias, prolonged sedation, or respiratory depression. | • Concomitant use is not recommended. |
| | **Atorvastatin, cerivastatin, lovastatin, simvastatin** | Increased risk of myopathy or rhabdomyolysis. | • Concomitant use is not recommended. Pravastatin and fluvastatin have the least potential for interaction. Atorvastatin may be used with caution. |
| | **Ethinyl estradiol (hormonal contraceptives)** | Decreased contraceptive concentration. | • Hormonal contraceptives should not be used as the primary means of contraception. |
| | Amiodarone, amprenavir, atovaquone, bepridil, carbamazepine, clarithromycin, cyclosporine, delavirdine, desipramine, dexamethasone, didanosine, efavirenz, felodipine, indinavir, itraconazole, ketoconazole, lignocaine, methadone, metronidazole, nevirapine, nicardipine, nifedipine, oral contraceptives, phenobarbitone, phenytoin, quinacrine, rifabutin, rifapentine, saquinavir, sirolimus, tacrolimus, theophylline, voriconazole, warfarin | Increased or decreased other drug concentration. | • Monitor patient for signs of toxicity or efficacy of other drug.<br>• Do not exceed 200mg ketoconazole daily.<br>• Consider decreasing rifabutin to 150mg once every other day.<br>• Monitor anticonvulsant levels.<br>• Methadone dose may need to be increased.<br>• Bepridil is not recommended. |
| | **St. John's Wort *(Hypericum perforatum)*** | Decreased lopinavir/ritonavir concentration | • Monitor patient for loss of virologic response and resistance (due to decreased lopinavir/ritonavir). Concomitant use is not recommended. |
| | Sildenafil | Increased sildenafil concentration | • Co-administration is not recommended. Expect increased risk of hypotension, syncope, and visual changes. |

**References:**

*Guidelines for the Use of Antiretroviral Agents.* Available online through the U.S. Dept. of Health and Human Services at: http://www.aidsinfo.nih.gov/guidelines

*Scaling up ART in Resource Limited Settings.* Available online through the World Health Organization at: http://www.who.int/docstore/hiv/scaling/guidelines.pdf)

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# Antiretroviral Therapy – Technical Drug Interaction Information Presented by Interacting Drug

(Clinically severe interactions are listed in **boldface** type.)

**Key: *Concomitant use is not recommended** **M: Monitor patient carefully** **R: Recommendation or suggested action**

| **ARV Agent → Interacting Drug ↓** | **Didanosine (ddI) or Videx®** | **Efavirenz (EFV), Stocrin®** | **Lamivudine (3TC), Epivir®** | **Lopinavir/ Ritonavir (LPV/r), Kaletra®** | **Nevirapine (NVP), Viramune®** | **Stavudine (d4T), Zerit®** | **Zidovudine (AZT, ZDV), Retrovir®** |
|---|---|---|---|---|---|---|---|
| **Acetaminophen (see Paracetamol)** | | | | | | | ↑ Zidovudine M |
| **Acyclovir** | | | | | | | M |
| **Alcohol** | ***Pancreatitis (potentially fatal)** | ***Prolonged sedation** | ***Lactic acidosis, pancreatitis (potentially fatal)** | | | ***Lactic acidosis, pancreatitis (potentially fatal)** | |
| **Allopurinol** | ***Didanosine toxicity** | | | | | | |
| **Amiodarone** | | | | M | | | |
| **Amprenavir** | | | | M | | | |
| **Asparaginase** | **Pancreatitis (potentially fatal) M** | | **Lactic acidosis, pancreatitis (potentially fatal) M** | | | **Lactic acidosis, pancreatitis (potentially fatal) M** | |
| **Aspirin** | | | | | | | ↑ Zidovudine M |
| **Astemizole** | | ***Life-threatening adverse events: cardiac arrhythmias** | | ***Life-threatening adverse events: cardiac arrhythmias** | | | |
| **Atorvastatin** | | | | ***Increased risk of myopathy** | | | |

| **Key: *Concomitant use is not recommended** | | | **M: Monitor patient carefully** | | | **R: Recommendation or suggested action** | |
|---|---|---|---|---|---|---|---|
| **ARV Agent → Interacting Drug ↓** | **Didanosine (ddI) or Videx®** | **Efavirenz (EFV), Stocrin®** | **Lamivudine (3TC), Epivir®** | **Lopinavir/ Ritonavir (LPV/r), Kaletra®** | **Nevirapine (NVP), Viramune®** | **Stavudine (d4T), Zerit®** | **Zidovudine (AZT, ZDV), Retrovir®** |
| **Atovaquone** | | | | | | | ↑ Zidovudine M |
| **Azathioprine** | **Pancreatitis (potentially fatal) M** | | **Lactic acidosis, pancreatitis (potentially fatal) M** | | | **Lactic acidosis, pancreatitis (potentially fatal) M** | |
| **Benzodiazepines** | | | | | | | ↑ Zidovudine M |
| **Bepridil** | | | | * | | | |
| **Carbamazepine** | | | | M anticonvulsant levels | | | |
| **Cerivastatin** | | | | ***Increased risk of myopathy** | | | |
| **Chloramphenicol** | **Peripheral neuropathy M** | | **Peripheral neuropathy M** | | | **Peripheral neuropathy M** | |
| **Cimetidine** | | | | | R: Dose adjustments may be necessary | | ↑ Zidovudine M |
| **Cisapride** | | ***Life-threatening adverse events: cardiac arrhythmias** | | ***Life-threatening adverse events: cardiac arrhythmias** | | | |
| **Cisplatin** | **Peripheral neuropathy M** | | **Peripheral neuropathy M** | | | **Peripheral neuropathy M** | |

| **Key: *Concomitant use is not recommended** | | | **M: Monitor patient carefully** | | | **R: Recommendation or suggested action** | |
|---|---|---|---|---|---|---|---|
| **ARV Agent →**<br>**Interacting Drug**<br>**↓** | **Didanosine (ddI) or Videx®** | **Efavirenz (EFV), Stocrin®** | **Lamivudine (3TC), Epivir®** | **Lopinavir/ Ritonavir (LPV/r), Kaletra®** | **Nevirapine (NVP), Viramune®** | **Stavudine (d4T), Zerit®** | **Zidovudine (AZT, ZDV), Retrovir®** |
| **Clarithromycin** | | *↓<br>Clarithromycin concentration<br>M | | M | R: Dose adjustments may be necessary | | M |
| **Cyclosporine** | | | | M | | | |
| **Dapsone** | ***Peripheral neuropathy**<br>**Dapsone treatment failure reported** | | **Peripheral neuropathy**<br>**M** | | | **Peripheral neuropathy**<br>**M** | |
| **Delavirdine** | | | | M | | | |
| **Desipramine** | | | | M | | | |
| **Dexamethasone** | | | | M | | | |
| **Didanosine** | | | **Lactic acidosis, pancreatitis (potentially fatal)**<br>**Peripheral neuropathy**<br>**M** | M | | **Lactic acidosis, pancreatitis (potentially fatal)**<br>**Peripheral neuropathy**<br>**M** | |
| **Doxorubicin** | | | | | | | * |
| **Efavirenz** | | | | M | | | |

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|---|---|---|---|---|---|---|---|
| **ARV Agent →**<br>**Interacting Drug ↓** | **Didanosine (ddI) or Videx®** | **Efavirenz (EFV), Stocrin®** | **Lamivudine (3TC), Epivir®** | **Lopinavir/ Ritonavir (LPV/r), Kaletra®** | **Nevirapine (NVP), Viramune®** | **Stavudine (d4T), Zerit®** | **Zidovudine (AZT, ZDV), Retrovir®** |
| **Ergot derivatives** | | ***Life-threatening adverse events: cardiac arrhythmias/ prolonged sedation/ respiratory depression** | | ***Life-threatening adverse events: cardiac arrhythmias/ prolonged sedation/ respiratory depression** | | | |
| **Erythromycin** | | ↓ (Potentially) erythromycin concentration<br>M | | | R: Dose adjustments may be necessary | | |
| **Estrogens** | **Pancreatitis (potentially fatal)**<br>**M** | | **Lactic acidosis, pancreatitis (potentially fatal)**<br>**M** | | | **Lactic acidosis, pancreatitis (potentially fatal)**<br>**M** | |
| **Ethambutol** | **Peripheral neuropathy**<br>**M** | | **Peripheral neuropathy**<br>**M** | | | **Peripheral neuropathy**<br>**M** | |
| **Ethinyl estradiol (hormonal contraceptives)** | | ***Use alternative birth control** | | ***Use alternative birth control** | ***Use alternative birth control** | | |
| **Ethionamide** | **Peripheral neuropathy**<br>**M** | | **Peripheral neuropathy**<br>**M** | | | **Peripheral neuropathy**<br>**M** | |
| **Felodipine** | | | | M | | | |

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|---|---|---|---|---|---|---|---|
| **ARV Agent →**<br>**Interacting Drug ↓** | **Didanosine (ddI) or Videx®** | **Efavirenz (EFV), Stocrin®** | **Lamivudine (3TC), Epivir®** | **Lopinavir/ Ritonavir (LPV/r), Kaletra®** | **Nevirapine (NVP), Viramune®** | **Stavudine (d4T), Zerit®** | **Zidovudine (AZT, ZDV), Retrovir®** |
| **Flecainide** | | | | ***Life-threatening adverse events: cardiac arrhythmias** | | | |
| **Fluconazole** | | | | | | | M |
| **Fluoroquinolones** | ↓ Effect of fluoroquinolones<br>R: separate doses by at least 2 hours | | | | | | |
| **Frusemide** | **Pancreatitis (potentially fatal)**<br>**M** | | **Lactic acidosis, pancreatitis (potentially fatal)**<br>**M** | | | **Lactic acidosis, pancreatitis (potentially fatal)**<br>**M** | |
| **Ganciclovir** | M<br>R: didanosine toxicity possible | | | | | | **↑ Histologic toxicity**<br>**M** |
| **Hydralazine** | **Peripheral neuropathy**<br>**M** | | **Peripheral neuropathy**<br>**M** | | | **Peripheral neuropathy**<br>**M** | |
| **Hydroxyurea** | ***Pancreatitis (potentially fatal)**<br>**Peripheral neuropathy** | | **Lactic acidosis, pancreatitis (potentially fatal)**<br>**Peripheral neuropathy**<br>**M** | | | **Lactic acidosis, pancreatitis (potentially fatal)**<br>**Peripheral neuropathy**<br>**M** | |
| **Indinavir** | | | | M | | | |
| **Indomethacin** | | | | | | | ↑ Zidovudine<br>M |

| **Key: *Concomitant use is not recommended** | | | **M: Monitor patient carefully** | | | **R: Recommendation or suggested action** | |
|---|---|---|---|---|---|---|---|
| **ARV Agent →**<br>**Interacting Drug ↓** | **Didanosine (ddI) or Videx®** | **Efavirenz (EFV), Stocrin®** | **Lamivudine (3TC), Epivir®** | **Lopinavir/ Ritonavir (LPV/r), Kaletra®** | **Nevirapine (NVP), Viramune®** | **Stavudine (d4T), Zerit®** | **Zidovudine (AZT, ZDV), Retrovir®** |
| **Interferon-alpha** | | | | | | | **↑ Histologic toxicity**<br>**M** |
| **Isoniazid** | **Peripheral neuropathy**<br>**M** | | **Peripheral neuropathy**<br>**M** | | | **Peripheral neuropathy**<br>**M** | |
| **Itraconazole** | *Itraconazole failure reported | | | M | | | |
| **Ketoconazole** | *Ketoconazole failure reported | | | R: Do not exceed 200mg ketoconazole daily | *↓ Ketoconazole,<br>↑ Nevirapine | | |
| **Lamivudine** | **Pancreatitis (potentially fatal)**<br>**Peripheral neuropathy**<br>**M** | | | | | **Lactic acidosis, pancreatitis (potentially fatal)**<br>**Peripheral neuropathy**<br>**M** | |
| **Lignocaine** | | | | M | | | |
| **Lithium** | **Peripheral neuropathy**<br>**M** | | **Peripheral neuropathy**<br>**M** | | | **Peripheral neuropathy**<br>**M** | |
| **Lopinavir/ritonavir** | | ↓ Lopinavir/ ritonavir concentration<br>M | | | ↓ Lopinavir/ ritonavir concentration<br>M | | |
| **Lovastatin** | | | | ***Increased risk of myopathy** | | | |

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|---|---|---|---|---|---|---|---|
| **ARV Agent → Interacting Drug ↓** | **Didanosine (ddI) or Videx®** | **Efavirenz (EFV), Stocrin®** | **Lamivudine (3TC), Epivir®** | **Lopinavir/ Ritonavir (LPV/r), Kaletra®** | **Nevirapine (NVP), Viramune®** | **Stavudine (d4T), Zerit®** | **Zidovudine (AZT, ZDV), Retrovir®** |
| **Methadone** | ↓ Didanosine concentration M | | | R: Methadone dose may need to be ↑ | R: Methadone dose may need to be ↑ | | M |
| **Methyldopa** | **Pancreatitis (potentially fatal) M** | | **Lactic acidosis, pancreatitis (potentially fatal) M** | | | **Lactic acidosis, pancreatitis (potentially fatal) M** | |
| **Metronidazole** | **Peripheral neuropathy M** | | **Peripheral neuropathy M** | M | | **Peripheral neuropathy M** | |
| **Midazolam** | | ***Life-threatening adverse events: prolonged sedation** | | ***Life-threatening adverse events: prolonged sedation** | | | |
| **Morphine** | | | | | | | ↑ Zidovudine M |
| **Nelfinavir** | | | | | | | M |
| **Nevirapine** | | * | | ↓ Lopinavir/ ritonavir concentration M | | | |
| **Nicardipine** | | | | M | | | |
| **Nifedipine** | | | | M | | | |

| **Key: *Concomitant use is not recommended** | | | **M: Monitor patient carefully** | | | **R: Recommendation or suggested action** | |
|---|---|---|---|---|---|---|---|
| **ARV Agent →**<br>**Interacting Drug ↓** | **Didanosine (ddI) or Videx®** | **Efavirenz (EFV), Stocrin®** | **Lamivudine (3TC), Epivir®** | **Lopinavir/ Ritonavir (LPV/r), Kaletra®** | **Nevirapine (NVP), Viramune®** | **Stavudine (d4T), Zerit®** | **Zidovudine (AZT, ZDV), Retrovir®** |
| **Nitrofurantoin** | **Pancreatitis (potentially fatal)**<br>**Peripheral neuropathy**<br>**M** | | **Lactic acidosis, pancreatitis (potentially fatal)**<br>**Peripheral neuropathy**<br>**M** | | | **Lactic acidosis, pancreatitis (potentially fatal)**<br>**Peripheral neuropathy**<br>**M** | |
| **Paracetamol** | | | | | | | ↑ Zidovudine<br>M |
| **Pentamidine** | **Pancreatitis (potentially fatal)**<br>**M** | | **Lactic acidosis, pancreatitis (potentially fatal)**<br>**M** | | | **Lactic acidosis, pancreatitis (potentially fatal)**<br>**M** | |
| **Phenobarbitone** | | ↓ Efavirenz concentration<br>M | | M anticonvulsant levels | | | |
| **Phenytoin** | **Peripheral neuropathy**<br>**M** | | **Peripheral neuropathy**<br>**M** | M anticonvulsant levels | | **Peripheral neuropathy**<br>**M** | M |
| **Pimozide** | | | | ***Life-threatening adverse events: cardiac arrhythmias/ prolonged sedation/ respiratory depression** | | | |
| **Prednisone/ Prednisolone** | | | | | ↑ Incidence/ severity of rash | | |

| **Key: *Concomitant use is not recommended** | | **M: Monitor patient carefully** | | **R: Recommendation or suggested action** | | | |
|---|---|---|---|---|---|---|---|
| **ARV Agent →**<br>**Interacting Drug ↓** | **Didanosine (ddI) or Videx®** | **Efavirenz (EFV), Stocrin®** | **Lamivudine (3TC), Epivir®** | **Lopinavir/ Ritonavir (LPV/r), Kaletra®** | **Nevirapine (NVP), Viramune®** | **Stavudine (d4T), Zerit®** | **Zidovudine (AZT, ZDV), Retrovir®** |
| **Probenecid** | | | | | | | **↑ Zidovudine**<br>**R: discontinue or reduce zidovudine dose temporarily**<br>**M** |
| **Propafenone** | | | | ***Life-threatening adverse events: cardiac arrhythmias/ prolonged sedation/ respiratory depression** | | | |
| **Quinacrine** | | | | M | | | |
| **Ribavirin** | **Pancreatitis (potentially fatal)**<br>**Peripheral neuropathy**<br>**M** | | **Lactic acidosis, pancreatitis (potentially fatal)**<br>**Peripheral neuropathy**<br>**M** | | | **Lactic acidosis, pancreatitis (potentially fatal)**<br>**Peripheral neuropathy**<br>**M** | * |
| **Rifabutin** | | ↓ Rifabutin concentration<br>M<br>R: consider increasing dose to rifabutin 400–650mg daily | | R: consider ↓ rifabutin to 150mg every other day | ↓ Nevirapine concentration<br>OR<br>↑↑ rifabutin concentration<br>M | | |

| **Key: *Concomitant use is not recommended** | | | **M: Monitor patient carefully** | | | **R: Recommendation or suggested action** | |
|---|---|---|---|---|---|---|---|
| **ARV Agent →**<br>**Interacting Drug**<br>**↓** | **Didanosine (ddI) or Videx®** | **Efavirenz (EFV), Stocrin®** | **Lamivudine (3TC), Epivir®** | **Lopinavir/ Ritonavir (LPV/r), Kaletra®** | **Nevirapine (NVP), Viramune®** | **Stavudine (d4T), Zerit®** | **Zidovudine (AZT, ZDV), Retrovir®** |
| **Rifampicin** | | ↓ Efavirenz concentration | | ***Life-threatening adverse events: cardiac arrhythmias/ prolonged sedation/ respiratory depression** | ***↓ Nevirapine concentration OR ↑ rifampicin concentration** | | ↓ Zidovudine<br>M |
| **Rifapentine** | | * | | * | * | | |
| **Ritonavir** | | | | | | | M |
| **Saquinavir** | | | | M | | | |
| **Sildenafil** | | | | *↑ Hypotension/ syncope | | | |
| **Simvastatin** | | | | ***Increased risk of myopathy** | | | |
| **Sirolimus** | | | | M | | | |
| **St. John's Wort** | | *↓ Efavirenz concentration | | *↓ Lopinavir/ ritonavir concentration | *↓ Nevirapine concentration | | |
| **Stavudine** | **Pancreatitis (potentially fatal)**<br>**Peripheral neuropathy**<br>**M** | | **Lactic acidosis, pancreatitis (potentially fatal)**<br>**Peripheral neuropathy**<br>**M** | | | | *↓ Stavudine metabolism |

| **Key: *Concomitant use is not recommended** | | | **M: Monitor patient carefully** | | | **R: Recommendation or suggested action** | |
|---|---|---|---|---|---|---|---|
| **ARV Agent →**<br>**Interacting Drug**<br>**↓** | **Didanosine (ddI) or Videx®** | **Efavirenz (EFV), Stocrin®** | **Lamivudine (3TC), Epivir®** | **Lopinavir/ Ritonavir (LPV/r), Kaletra®** | **Nevirapine (NVP), Viramune®** | **Stavudine (d4T), Zerit®** | **Zidovudine (AZT, ZDV), Retrovir®** |
| **Sulphamethoxazole/ trimethoprim** | | | ↓ Lamivudine clearance<br>M | | | | |
| **Sulphonamides** | **Pancreatitis (potentially fatal)**<br>**M** | | **Lactic acidosis, pancreatitis (potentially fatal)**<br>**M** | | | **Lactic acidosis, pancreatitis (potentially fatal)**<br>**M** | ↑ Zidovudine<br>M |
| **Sulindac** | **Pancreatitis (potentially fatal)**<br>**M** | | **Lactic acidosis, pancreatitis (potentially fatal)**<br>**M** | | | **Lactic acidosis, pancreatitis (potentially fatal)**<br>**M** | |
| **Tacrolimus** | | | | M | | | |
| **Tenofovir disoproxil fumarate** | ***Monitor patients for didanosine toxicity** | | | | | | |
| **Terfenadine** | | ***Life-threatening adverse events: cardiac arrhythmias** | | ***Life-threatening adverse events: cardiac arrhythmias** | | | |

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|---|---|---|---|---|---|---|---|
| **ARV Agent →**<br>**Interacting Drug ↓** | **Didanosine (ddI) or Videx®** | **Efavirenz (EFV), Stocrin®** | **Lamivudine (3TC), Epivir®** | **Lopinavir/ Ritonavir (LPV/r), Kaletra®** | **Nevirapine (NVP), Viramune®** | **Stavudine (d4T), Zerit®** | **Zidovudine (AZT, ZDV), Retrovir®** |
| **Tetracyclines** | **Pancreatitis (potentially fatal)**<br>↓ Effect of tetracyclines<br>R: separate doses by at least 2 hours | | **Lactic acidosis, pancreatitis (potentially fatal)**<br>**M** | | | **Lactic acidosis, pancreatitis (potentially fatal)**<br>**M** | |
| **Theophylline** | | | | M theophylline levels | | | |
| **Thiazide diuretics** | **Pancreatitis (potentially fatal)**<br>**M** | | **Lactic acidosis, pancreatitis (potentially fatal)**<br>**M** | | | **Lactic acidosis, pancreatitis (potentially fatal)**<br>**M** | |
| **Triazolam** | | ***Life-threatening adverse events: prolonged sedation** | | ***Life-threatening adverse events: prolonged sedation** | | | |
| **Valproic acid** | **Pancreatitis (potentially fatal)**<br>**M** | | **Lactic acidosis, pancreatitis (potentially fatal)**<br>**M** | | | **Lactic acidosis, pancreatitis (potentially fatal)**<br>**M** | ↑ Zidovudine<br>M |
| **Vincristine** | **Peripheral neuropathy**<br>**M** | | **Peripheral neuropathy**<br>**M** | | | **Peripheral neuropathy**<br>**M** | |
| **Voriconazole** | | | | M | | | |
| **Warfarin** | | **M warfarin level** | | | | | |

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|---|---|---|---|---|---|---|---|
| **ARV Agent →**<br>**Interacting Drug ↓** | **Didanosine (ddI) or Videx®** | **Efavirenz (EFV), Stocrin®** | **Lamivudine (3TC), Epivir®** | **Lopinavir/ Ritonavir (LPV/r), Kaletra®** | **Nevirapine (NVP), Viramune®** | **Stavudine (d4T), Zerit®** | **Zidovudine (AZT, ZDV), Retrovir®** |
| **Zalcitabine** | **Pancreatitis (potentially fatal)**<br>**Peripheral neuropathy**<br>**M** | | **Lactic acidosis, pancreatitis (potentially fatal)**<br>**Peripheral neuropathy**<br>**M** | | | **Lactic acidosis, pancreatitis (potentially fatal)**<br>Peripheral neuropathy<br>**M** | |
| **Zidovudine** | | | | | | *↓ Stavudine metabolism | |

**References:**

*Guidelines for the Use of Antiretroviral Agents.* Available online through the U.S. Dept. of Health and Human Services at: http://www.aidsinfo.nih.gov/guidelines/

*Scaling up ART in Resource Limited Settings.* Available online through the World Health Organization at: http://www.who.int/docstore/hiv/scaling/guidelines.pdf

**This information sheet is current as of September 29, 2004. It should be revised annually under the supervision of the Chief Pharmacist at CPGH. The pharmacist should check the references above and send any changes to the pharmacy contact at each ART site using this SOP.**

| Coast Provincial General Hospital | |
|---|---|
| **Prepacking Antiretroviral Drugs for the DAART Study** | |
| Number of pages: 4 | Procedure number: 110 |
| Prepared by: Name:<br>Title:<br>Date: | Reviewed by: Name:<br>Title:<br>Date: |

**Objective:**

To describe correct and safe prepacking procedures for antiretroviral drugs.

**Responsibility:**

- Designated pharmacist in charge of checking prepacking for the ART Programme or his/her proxy (pharmacist) will be responsible for verifying that correct prepacking procedures are followed.

- Designated pharmacy staff (pharmacist or pharmacy technologist) for prepacking will be responsible for prepacking of ARVs.

- The same person will not be responsible for both activities.

**Resources:**

Forms used for prepacking ARVs:

***ARV Prepacking Record:***

- Is a single loose-leaf form.

**Procedure:**

1. Only one drug product should be prepacked at any one time in a work area. Work should begin in a clear workspace.

2. When removing the stock bottle(s) from storage, double check that the stock bottle(s) contain(s) the correct drug, strength/concentration, and dosage form that is to be prepacked. Check that the expiry date is appropriate.

3. Inspect the medication from the stock bottle. Look for broken or discoloured tablets or capsules. If any of the above are found, do not dispense them to patient. Complete a *Stock Count Discrepancy Report* as described in procedure 302: *Stock Count Discrepancy Report*. Discard the items according to procedure 502: *Disposal of USAID-Funded Antiretroviral Drugs.*

4. Inspect packaging containers that will be given to the patients to make sure they are clean, not damaged, and appropriate for the drug product being packaged.

5. Collect the appropriate number of labels for the number of prepacks needed.

6. Fill in the labels as appropriate with:

    - Quantity
    - CPGH Prepacking Batch No.
    - Expiry date: 6 months from the date of prepacking for loose capsules or tablets, or the expiry date, whichever is less. For blister-packed ARVs use the manufacturer's expiry date.
    - Times of day that the medicine should be taken (may be left blank if prepacks are being prepared in advance)
    - Patient name (may be left blank if prepacks are being prepared in advance)
    - Date of dispensing (may be left blank if prepacks are being prepared in advance)

7. Fill out the *ARV Prepacking Record* as described below.

8. Before the prepacking begins, the pharmacist in charge of prepacking will check that:

    - The stock bottle(s) contain(s) the correct drug, strength/concentration, and dosage form.
    - The expiry date is appropriate.
    - The entry in the *ARV Prepacking Record* is correct.
    - The correct labels have been selected and that the information filled in correctly.
    - The number of labels and containers are the same and corresponds to the number of prepacks to be prepacked.

9. Count out correct number of units (tablets or capsules) using a spatula or knife on counting tray or clean sheet of paper. Avoid touching drug product with hands, as contamination may result.

10. Recount number of units before packaging to reduce error risk.

11. Once prepacking is complete, the pharmacist in charge of prepacking will check 10% of the packages to make sure that:

    - The prepacks contain the correct drug, strength, dosage form, and quantity.
    - The prepacks are labelled correctly.
    - No excess labels or empty containers are left.
    - The number of capsules/tablets left in the bulk container(s) reconciles with the number expected.

12. Clean the area and put away all drugs, labels, and packaging materials.

13. Prepacks should be stored under cool, dry conditions in a locked cabinet until the medicines are dispensed.

Steps for completing the *ARV Prepacking Record*:

1. Before beginning prepacking, the staff member prepacking records:

    - CPGH batch no.
    - Date of prepacking
    - Drug name
    - Drug strength and form
    - Number of tablets/capsules per prepack
    - Number of prepacks to be prepared
    - Manufacturer name
    - Manufacturer batch no.
    - Manufacturer expiry date
    - Prepack expiry date
    - Number of units (tablets/capsules) removed for prepacking

2. Before the prepacking begins, the pharmacist in charge of prepacking checks the products, labels, containers, and initials:

    - Label check
    - Product check

3. When prepacking is complete, the staff member prepacking records:

    - Number of units (tablets/capsules) used for prepacking
    - Number of units (tablets/capsules) remaining
    - Signs and writes name as the prepacker

4. After the reconciliation check of bottles, labels, and drugs, and the final check of 10% of the prepacks, the pharmacist-in-charge of prepacking:

    - Initials the reconciliation check of bottles, labels, and drugs.

    - Signs and records name for the final prepacking check.

    - Signs and records name as the verifying pharmacist that correct prepacking procedures have been followed.

**Distribution:**

- Form should be filed in the pharmacy and kept for 2 years.

# Coast Provincial General Hospital
# ARV Prepacking Record

| | | | |
|---|---|---|---|
| CPGH batch no: | | Date of prepacking: | |
| | | | |
| Drug name: | | Drug strength and form: | |
| Number of units (tablets/capsules) per prepack: | | Number of prepacks to prepare: | |
| | | | |
| Manufacturer name: | | Manufacturer batch no: | |
| Manufacturer expiry date: | | Prepack expiry date: | |
| | | | |
| Label check by: *(Initials)* | | Product check by: *(Initials)* | |
| | | | |
| Number of tablets/capsules removed for prepacking: | | Reconciliation check of bottles, labels and drugs by: *(Initials)* | |
| Number of tablets/capsules used for prepacking: | | | |
| Number of tablets/capsules remaining after prepacking is complete: | | | |

| | | |
|---|---|---|
| Prepacker: | *Name:* | *Signature:* |
| Final prepacking check by: | *Name:* | *Signature:* |
| Verifying pharmacist: | *Name:* | *Signature:* |

| Coast Provincial General Hospital | |
|---|---|
| **Requesting GOK Antiretroviral Drugs** | |
| Number of pages: 5 | Procedure number: 201 |
| Prepared by: Name:<br>Title:<br>Date: | Reviewed by: Name:<br>Title:<br>Date: |

**Objective:**

To describe the procedure for requesting GOK antiretroviral drugs from KEMSA for the ART Programme.

**Responsibility:**

- Pharmacist in charge of the ARV bulk store or his/her designated proxy
- Pharmacist in charge of the GOK ART Programme

**Resources:**

Form used to request ARVs from KEMSA:

***Diflucan & ARVs Programme Monthly Report & Request:***

- Is a two-page form with a duplicate copy.

**Procedure:**

1. The pharmacist in charge of the ARV bulk store or his/her designated proxy completes the *Diflucan & ARVs Programme Monthly Report & Request* as described below.

2. The pharmacist in charge of the GOK ART Programme checks the request and forwards it through the Chief Pharmacist to the General Office.

3. The General Office forwards the original *Diflucan & ARVs Programme Monthly Report & Request*, completed as described in procedure 202: *Receipt of GOK Antiretroviral Drugs at the ARV Bulk Store*, together with the original copies of the *Diflucan & ART Daily Activity Register* to the KEMSA Logistics Management Unit. The reports may be faxed or e-mailed to KEMSA *in addition to* sending the hard copies.

4. The *Diflucan & ARVs Programme Monthly Report & Request* must reach KEMSA by the 10th of each month.

Steps for completing the *Diflucan & ARVs Programme Monthly Report & Request:*

1. Facility Name: Enter *CPGH*.

2. Province: Enter *Coast.*

3. District: Enter *Mombasa*.

4. Facility Code:

5. Period of Reporting: Enter the beginning date and ending date for the time period that the report covers.

6. Date of Visit (where applicable): Only used during a supervisory visit. Record the date the report is completed.

7. For each ARV preparation, for the period covered by the report, enter:

    - Beginning Balance: Record the total quantity of usable drug in the ARV bulk store and in the outpatient pharmacy store for each regimen. Do not break down the components of patient packs.

    - Received this Period: For each drug product, record the total quantity received by the facility.

    - Total Quantity dispensed: Record the total amount issued to patients by the facility.

    - Adjustments: Enter the quantity of any loss as a negative figure and any positive adjustment as a positive figure. Record the reason for the loss or adjustment in the Comments section.

    - Withdrawal: Indicate the total quantity of any drug returned to KEMSA. Record the reason for the return, e.g., short expiry, in the Comments section.

    - Physical Count: Enter the total sum of physical counts of usable drug at both the ARV bulk store and the outpatient pharmacy store.

    - Earliest Expiry: Date and Amount: Enter the shortest expiry date of stock held for that product and the total quantity in stock with that expiry.

    - Quantity Needed: Enter the amount of each drug product needed.

8. ARVs: For each regimen, total the number of patients 25–60kg and above 60kg receiving each type of ARV and PEP regimen.

9. Comments: Record explanations and details on adjustments and withdrawals made.

10. Submitted by: Record name, designation, contact information, and date, and sign the form.

**Distribution:**

- The original *Diflucan & ARVs Programme Monthly Report & Request* together with the original completed copies of the *Diflucan & ART Daily Activity Register* is forwarded to the KEMSA Logistics Management Unit.

- One copy each of the completed and signed *Diflucan & ARVs Programme Monthly Report & Request* and *Diflucan & ART Daily Activity Register* is kept in the ARV bulk store.

- The *Diflucan & ARVs Programme Monthly Report & Request* is used to check receipts of ARVs from KEMSA—to check for discrepancies between what was ordered and what is received and/or listed on the *S12*.

# MINISTRY OF HEALTH
# DIFLUCAN & ARVs PROGRAMME
## MONTHLY REPORT & REQUEST

**Facility Name: _____ Province: _____ District: _____**

**Facility Code: _____ Period of Reporting: Beginning: _____ Ending: _____**

**Date of the visit (where applicable): _____**

| Commodity | Beginning Balance | Received this Period | Total Quantity dispensed | Adjustments | Withdrawal | Physical Count | Earliest Expiry | | Quantity Needed |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Date | Quantity | |
| Diflucan Tablets 200mg | | | | | | | | | |
| Diflucan Suspension Bottles | | | | | | | | | |
| Diflucan Infusion Bottles | | | | | | | | | |
| | | | | | | | | | |
| 1st Line STD Regimen (<60kg) a. NVP 200mg Tabs (SP) | | | | | | | | | |
| b. d4T 30mg Caps/Tabs | | | | | | | | | |
| c. 3TC 150mg Tabs | | | | | | | | | |
| d. d4T 30mg/3TC FDC | | | | | | | | | |
| e. NVP 200mg Tabs (CP) | | | | | | | | | |
| f. d4T 30/3TC/NVP FDC | | | | | | | | | |
| 1st Line STD Regimen (>60kg) a. NVP 200mg Tabs (SP) | | | | | | | | | |
| b. d4T 40mg Caps | | | | | | | | | |
| c. 3TC 150mg Tabs | | | | | | | | | |
| d. d4T 40mg/3TC FDC | | | | | | | | | |
| e. NVP 200mg Tabs (CP) | | | | | | | | | |
| f. d4T 40/3TC/NVP FDC | | | | | | | | | |
| 1st Line Non-STD Regimen: Option A : < 60kg a. EFV 600mg Tabs | | | | | | | | | |
| b. d4T 30mg Caps/Tabs | | | | | | | | | |
| c. 3TC 150mg Tabs | | | | | | | | | |
| d. d4T 30mg/3TC FDC | | | | | | | | | |
| Option A: > 60kg a. EFV 600mg Tabs | | | | | | | | | |
| b. d4T 40mg Caps/Tabs | | | | | | | | | |
| c. 3TC 150mg Tabs | | | | | | | | | |
| d. d4T 40mg/3TC FDC | | | | | | | | | |

| Commodity | Beginning Balance | Received this Period | Total Quantity dispensed | Adjustments | Withdrawal | Physical Count | Earliest Expiry | | Quantity Needed |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Date | Quantity | |
| **Post Exposure Prophylaxis:** | | | | | | | | | |
| **Option 1** | | | | | | | | | |
| **a. ZDV 300mg Caps/Tabs** | | | | | | | | | |
| **b. 3TC 150mg Tabs** | | | | | | | | | |
| **c. ZDV/3TC 300/150 FDC** | | | | | | | | | |
| **Option 2 (<60 Kg)** | | | | | | | | | |
| **d. 3TC 150mg Tabs** | | | | | | | | | |
| **e. d4T 30mg Caps/Tabs** | | | | | | | | | |
| **f. d4T30mg/3TC FDC** | | | | | | | | | |
| **Option 2 (>60 Kg)** | | | | | | | | | |
| **g. 3TC 150mg Tabs** | | | | | | | | | |
| **h. d4T 40mg Caps/Tabs** | | | | | | | | | |
| **i. d4T40mg/3TC FDC** | | | | | | | | | |

| Diflucan | | CM | | | OC | | |
|---|---|---|---|---|---|---|---|
| | **Age** | **Below 13 Years** | **Above 13 Years** | Total | **Below 13 Years** | **Above 13 Years** | Total |
| **Tablets** | **1st Visit** | | | | | | |
| " | **Revisit** | | | | | | |
| Total | | | | | | | |
| | | | | | | | |
| **Suspension** | **1st Visit** | | | | | | |
| " | **Revisit** | | | | | | |
| Total | | | | | Total | | |

| ARVs | 25 - 60 Kg | Above 60 Kg |
|---|---|---|
| **1st Line STD Regimen** | | |
| **1st Line Non-STD Regimen** | | |
| **PEP Option 1** | | |
| **PEP Option 2** | | |

**Comments:**

_____

_____

_____

**Submitted By:** _____ _____ _____

**Name** **Signature** **Designation**

**Contact:** _____ **Date:** _____

**KEY:** **CM** – Cryptococcal Meningitis, **OC** – Oesophageal Candidiasis**, PEP** – Post Exposure Prophylaxis, **d4T –** Stavudine, **3TC** – Lamivudine, **NVP** – Nevirapine, **ZDV** – Zidovudine,
**EFV** – Efavirenz

Send an original copy to **THE LOGISTICS MANAGEMENT UNIT, P.O. BOX 46566, 00100 GPO, NAIROBI** by the 10th of every month.

| Coast Provincial General Hospital | |
|---|---|
| **Receipt of GOK Antiretroviral Drugs at ARV Bulk Store** | |
| Number of pages: 4 | Procedure number: 202 |
| Prepared by: Name:<br>Title:<br>Date: | Reviewed by: Name:<br>Title:<br>Date: |

**Objective:**

To describe the correct GOK antiretroviral drug receiving procedure at the ARV bulk store.

**Responsibility:**

- Documentation and receipt of the ARVs will be performed by the receiving officer (the designated pharmacist in charge of the ARV bulk store or his/her designated proxy).

**Resources:**

Form used for documenting receipt of GOK ARVs:

***Diflucan & ART Daily Activity Register:***

- Is a one-page form completed in duplicate.
- Every receipt must be entered **at the time** that stock is received, without exception.

Forms needed to check receipt of ARVs:

- *Issue and Receipt Voucher (S12)*
- *Diflucan & ARVs Programme Monthly Report & Request*

**Procedure:**

The receiving officer will:

1. Meet with the delivery personnel and sign for the delivery.

2. Before signing, inspect and check the order against the *S12* copy and *Diflucan & ARVs Programme Monthly Report & Request* and look for the following discrepancies:

   - Broken, cracked, or leaking bottles or bottles where seals are broken
   - Broken tablets
   - Drugs that arrive past their expiration date
   - Items that have no labels
   - Refrigerated items that arrive at room temperature or are warm
   - Inappropriate storage procedure during transportation of refrigerated items

- Items listed on the invoice that are missing from the shipment
- Items received that were not ordered or were not listed on the *S12*

3. Record all discrepancies on the *Shipment Discrepancy Report* as described in procedure 301: *Shipment Discrepancy Report*.

4. Separate all damaged or expired medications and inform the CPGH pharmacy store, which will arrange for return to KEMSA.

5. Send all refrigerated items directly to ARV bulk store refrigerator.

6. Record all ARV items delivered on the *Diflucan & ART Daily Activity Register*. The *Diflucan & ART Daily Activity Register* and directions for completing it are shown in procedure 205: *Record Keeping for GOK Antiretroviral Drugs at the Outpatient Pharmacy*.

7. Check off each item received and endorse the *S12* with the quantity received and any discrepancies. Sign, stamp, and date the *S12*. An *S12* and directions for completing it are shown in procedure 105: *External USAID-Funded Antiretroviral Drug Distribution*.

**Distribution:**

- The *Diflucan & ART Daily Activity Register* is kept with the GOK ARVs in the outpatient pharmacy in a secure, locked cupboard.

- The copy of the *S12* is filed in the ARV bulk store.

| Coast Provincial General Hospital | |
|---|---|
| **Record Keeping for GOK Antiretroviral Drugs at ARV Bulk Store** | |
| Number of pages: 2 | Procedure number: 203 |
| Prepared by: Name:<br>Title:<br>Date: | Reviewed by: Name:<br>Title:<br>Date: |

**Objective:**

To describe the correct procedure for maintaining records for all activities that concern GOK ARV stock in the ARV bulk store.

**Responsibility:**

- Documentation and recording of all ARV drug receipts and issues from the ARV bulk store is the responsibility of the pharmacist in charge of the ARV bulk store or his/her designated proxy.

**Resources:**

Form used for record keeping of GOK ARVs at the ARV bulk store:

***Bulk Store Bin Card (S5):***

- Is a serially numbered, single-copy card.
- Must exist for each ARV preparation.
- Is used for ARV inventory control.
- Every receipt and issue must be entered **at the time** that stock is received or removed, without exception.
- A supply of *S5* cards is to be kept as a stock item in the ARV bulk store in the custody of the pharmacist in charge of the ARV bulk store.

Forms needed to complete record keeping:

- *Issue and Receipt Voucher (S12)*

**Procedure:**

1. When ARV drugs arrive at the ARV bulk store, the receiving officer checks and completes an *Issue and Receipt Voucher (S12)* and uses the information from the *S12* to complete the *Bulk Store Bin Card (S5).* An *S5* and directions for completing the form are

described in procedure 103: *Record Keeping for USAID-Funded Antiretroviral Drugs at ARV Bulk Store*.

2. Receipts are to be entered in red ink and issues in blue or black ink.

3. Cards must be used until all entries are completed on both sides of the card. Balances from the completed card must be transferred to a new card.

4. The designated pharmacy staff should check the physical count of each ARV preparation in stock any time there is a receipt or issue at the ARV bulk store to ensure that the physical stock balance corresponds with that shown on the *Bulk Store Bin Card (S5*). If a difference is found, a *Stock Count Discrepancy Report* is completed as described in procedure 302: *Stock Count Discrepancy Report*.

**Distribution:**

- The *S5* cards are kept with the goods in the ARV bulk store. Each *S5* bin card is kept on top on the stock of the corresponding item.

- Old cards must be retained for 5 years from date of last entry.

| Coast Provincial General Hospital | |
|---|---|
| **Internal GOK Antiretroviral Drug Distribution** | |
| Number of pages: 3 | Procedure number: 204 |
| Prepared by: Name:<br>Title:<br>Date: | Reviewed by: Name:<br>Title:<br>Date: |

**Objective:**

To describe the procedure for distributing GOK antiretroviral drugs from the ARV bulk store to the outpatient pharmacy ARV stock or from the outpatient pharmacy ARV stock to the wards.

**Responsibility:**

Issuing:

- Pharmacist in charge of the ARV bulk store or his/her designated proxy; pharmacist or pharmaceutical technologist in charge of dispensing ARVs from the outpatient pharmacy

Receiving:

- Designated receiving officer: designated pharmacist or his/her designated proxy; the nursing officer in charge of the unit or his/her designated proxy

**Resources:**

Forms used to record ARV drug distribution:

***Counter Requisition and Issue Voucher (S11):***

- Is a serially numbered, triplicate form.
- Is used for issue, delivery, and receipt of stock.
- Is used by the outpatient pharmacy to order from the ARV bulk store, and by wards and other departments to order from the outpatient pharmacy.
- Is kept in each department requiring its use. Additional supplies of the form can be requisitioned from the ARV bulk store.

Forms needed to complete internal drug distribution for issue of ARVs from the bulk store to the outpatient pharmacy:

- *Bulk Store Bin Cards (S5)*
- *Hospital Pharmacy Bin Card (MOH 999)*
- *ARV dispensing tool*

Forms needed to complete internal drug distribution for issue of ARVs from the outpatient pharmacy to the wards:

- *Medication Treatment Sheet (MOH 306 Rev.)*
- *Hospital Pharmacy Bin Card (MOH 999)*
- *Diflucan & ART Daily Activity Register*
- *ART Patient Dispensing Record*
- *ARV dispensing tool*

**Procedures:**

1. Procedure for the outpatient pharmacy to order and receive GOK ARVs from the ARV bulk store:

    - Complete *Counter Requisition and Issue Voucher (S11*) as described in procedure 104: *Internal USAID-Funded Antiretroviral Drug Distribution*.

    - Make appropriate entries on the *Bulk Store Bin Cards (S5)* as described in procedure 203: *Record Keeping for GOK Antiretroviral Drugs at ARV Bulk Store* upon issue from the ARV bulk store.

    - Make appropriate entries on the *Hospital Pharmacy Bin Card (MOH 999)* and the *ARV dispensing tool* as described in procedure 205: *Record Keeping for GOK Antiretroviral Drugs at the Outpatient Pharmacy* upon receipt of ARVs at the outpatient pharmacy from the ARV bulk store.

2. Procedure for the outpatient pharmacy to issue ARVs to the wards:

    - Complete *Counter Requisition and Issue Voucher (S11*) as described in procedure 104: *Internal USAID-Funded Antiretroviral Drug Distribution*.

    - Receive completed *Medication Treatment Sheet (MOH 306 Rev.)* as described in procedure 207: *Issuing GOK Antiretroviral Drugs to Inpatients*.

    - Ensure that the prescriber has signed the *Medication Treatment Sheet (MOH 306 Rev.).*

    - Check that the patient is on the ART Programme eligibility list.

    - Make appropriate entries on the *Hospital Pharmacy Bin Card (MOH 999),* the *ART Patient Dispensing Record,* and/or the *ARV dispensing tool*, and the *Diflucan & ART*

*Daily Activity Register* as described in procedure 205: *Record Keeping for GOK Antiretroviral Drugs at the Outpatient Pharmacy* upon issue to wards.

**Distribution:**

The *Counter Requisition and Issue Voucher (S11*) is to be completed in triplicate:

- The original is kept by the ARV bulk store for stock issued to the outpatient pharmacy.
- For stock issued to inpatients, the original copy is retained by the outpatient pharmacy.
- Duplicate is retained by the initiating department.
- Triplicate remains in the *S11* book.

| Coast Provincial General Hospital | |
|---|---|
| **Record Keeping for GOK Antiretroviral Drugs at the Outpatient Pharmacy** | |
| Number of pages: 6 | Procedure number: 205 |
| Prepared by: Name:<br>Title:<br>Date: | Reviewed by: Name:<br>Title:<br>Date: |

**Objective:**

To describe the procedure for maintaining records of issues and receipts of GOK ARV drugs at the outpatient pharmacy and of fees collected.

**Responsibility:**

Documentation and recording of all GOK ARV receipts from the ARV bulk store to the outpatient pharmacy and issues from the outpatient pharmacy is the responsibility of the designated pharmacist or pharmaceutical technologist in charge of dispensing ARVs or his/her designated proxy.

**Resources:**

Forms used for record keeping of ARVs in the outpatient pharmacy:

***Hospital Pharmacy Bin Card (MOH 999):***

- Must exist for each ARV preparation.
- Is a single-copy, loose-leaf form.
- Is used for ARV inventory control in the outpatient pharmacy.
- Entries must be made for every receipt and issue at the time that stock is received or removed, without exception.

***Diflucan & ART Daily Activity Register:***

- Is a single-page form completed in duplicate.
- Every receipt and issue must be entered **at the time** that stock is received or removed, without exception

***ART Patient Dispensing Record:***

- Is a single loose-leaf form.
- Has a summary reference page listing all patients and their ART regimens.
- Is used to check for discrepancies in repeat ART prescriptions and to check whether patients are using more or less medicine than is expected.

***ARV Dispensing Tool:***

- Is an Access database.
- Is used to check for discrepancies in repeat ART prescriptions and to check whether patients are using more or less medicine than is expected.

**Procedure:**

1. All receipts of stock from the ARV bulk store must be documented on *Hospital Pharmacy Bin Card (MOH 999)*, and/or the *ARV dispensing tool* as described in procedure 106: *Record Keeping for USAID-Funded Antiretroviral Drugs at the Outpatient Pharmacy* and *Diflucan & ART Daily Activity Register* as described below.

2. All issues of stock, both to outpatients and inpatients, must be documented on *MOH 999* and/or in the *ARV dispensing tool* and *Diflucan & ART Daily Activity Register* as described below.

3. All issues must be recorded on the *Government of Kenya Ministry of Health Drugs: ART Patient Dispensing Record – Summary Page* as described below and on the *ART Patient Dispensing Record* as described in procedure 106: *Record Keeping for USAID-Funded Antiretroviral Drugs at the Outpatient Pharmacy*.

4. All entries must be completed at time of receipt or issue.

5. Receipts on *MOH 999* are to be made in red ink and issues in blue or black ink.

6. Each *MOH 999* must be used until all entries are completed. Balances from the completed card must be transferred to a new card.

7. The designated pharmacy staff should check the physical count of each ARV preparation in stock any time there is a receipt at the outpatient pharmacy to ensure that the physical stock balance corresponds with that shown on the *MOH 999* and/or in the *ARV dispensing tool*. If a difference is found, a *Stock Count Discrepancy Report* is completed as described in procedure 302: *Stock Count Discrepancy Report*.

Steps for completing the *Diflucan & ART Daily Activity Register:*

1. Complete a new form each month. Record for a new register:

   - ART Facility Code:
   - Facility Name: Enter *CPGH*
   - District: Enter *Mombasa*
   - Province: Enter *Coast*

2. Balance B/F:

   - Date: that the balance is brought forward
   - Balance brought forward from previous form or quantity received for a new register *under the relevant column for each ARV preparation*

3. Record when receiving stock:

    - Date: of receipt
    - Quantity: Record number of units (e.g., tablets; ml) received *under the relevant column for each ARV preparation*
    - On Hand: Record new stock balance (in units of issue) under the relevant column for each ARV preparation

4. Record when issuing stock:

    - Date: of issue
    - Client's No.: Record the OP or IP number
    - Name (Optional): of client
    - Age: (C) for a child (less than 13 years) or (A) for adult
    - Diagnosis: for diflucan only
    - (N) for new client or (R) for a revisit
    - Doctor Prescribing (Name): record doctor's name
    - For inpatients record:
        - Receiving (nurse): receiving nurse's name
        - Ward
    - Signature of dispensing pharmacist:
    - Quantity issued: *record under the relevant column for each ARV preparation*

5. When the form is full or at the end of the month, *record under the relevant column for each ARV preparation*:

    - Total Quantity Dispensed: for each ARV preparation
    - Balance C/F: Balance carried forward to new form
    - Total Number of Patients per ART Regimen

Steps for completing the *Government of Kenya Ministry of Health Drugs: ART Patient Dispensing Record – Summary Page:*

1. For a new patient approved by the Eligibility Committee, record on the *Government of Kenya Ministry of Health Drugs: ART Patient Dispensing Record – Summary Page*:

    - ART Patient Record Number: Fill in the next consecutive number
    - Patient's Name
    - OP/IP Number: Patient's outpatient or inpatient number
    - Male (M) or Female (F)
    - Date Approved by Eligibility Committee

2. For a patient collecting his/her first prescription:

    - Check that the regimen follows the standard ART guidelines for the ART Programme. Alert the prescriber/Medical Officer in Charge of the ART Programme of any discrepancies before dispensing the prescription. Fill out a *Medication Error Report* as described in procedure 402: *Medication Error Reporting* for any errors discovered.

- Record on the *Government of Kenya Ministry of Health Drugs: ART Patient Dispensing Record – Summary Page*:

    - Date Started on ART
    - Tick ARV drug preparations for current regimen in columns opposite Patient's Name

**Distribution:**

- The *Diflucan & ART Daily Activity Register* and the *MOH 999* forms are kept with the ARVs in the outpatient pharmacy in a secure, locked cupboard.

- The original completed *Diflucan & ART Daily Activity Register* together with the original copies of the *Diflucan & ARVs Programme Monthly Report & Request* are forwarded to the KEMSA Logistics Management Unit.

- One copy each of the completed *Diflucan & ART Daily Activity Register* and the *Diflucan & ARVs Programme Monthly Report & Request* is kept in the ARV bulk store.

- Old *MOH 999* forms must be retained for 5 years from date of last entry.

- *ART Patient Dispensing Records* are kept in the pharmacy with the *Prescription Forms (MOH 501)*.

**MINISTRY OF HEALTH**

**DIFLUCAN & ART DAILY ACTIVITY REGISTER**

**ART Facility Code:** _____

**Facility Name:** _____

**District:** _____

**Province:** _____

| | | |

# Government of Kenya Ministry of Health ARV Drugs

## ART Patient Dispensing Record – Summary Page

| ART Patient Record Number | Patient's Name | IP/OP Number | Male (M)/Female (F) | Date Approved by Eligibility Committee | Date Started on ART | Current ART Regimen (✓ as appropriate) | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | **1st Line Standard Regimen Below 60kg** (d4T 30mg// 3TC 150mg/ NVP 200mg) | **1st Line Standard Regimen Above 60kg** (d4T 40mg// 3TC 150mg/ NVP 200mg) | **1st Line Non-Standard Regimen Below 60kg** (d4T 30mg// 3TC 150mg/ EFV 600mg) | **1st Line Non-Standard Regimen Above 60kg** (d4T 40mg// 3TC 150mg/ EFV 600mg) | **2nd Line Non-Standard Regimen** (ZDV 300mg// 3TC 150mg/ EFV 600mg) | **3rd Line Non-Standard Regimen** (ZDV 300mg// 3TC 150mg/ NVP 200mg) | | |
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| Coast Provincial General Hospital | |
|---|---|
| **Issuing GOK Antiretroviral Drugs to Outpatients** | |
| Number of pages: 3 | Procedure number: 206 |
| Prepared by: Name:<br>Title:<br>Date: | Reviewed by: Name:<br>Title:<br>Date: |

**Objective:**

To describe correct procedures for issuing and dispensing GOK antiretroviral drugs to outpatients. Good dispensing practices ensure that an effective form of the right drug is delivered to the right patient in the prescribed dosage and quantity, with clear instructions, and in a package that maintains the potency of the drug.

**Responsibility:**

- The authorised doctor/clinical officer is responsible for issuing the ART prescription *(MOH 501).*

- The designated pharmacist or pharmacy technologist is responsible for dispensing the ART prescription.

**Resources:**

Forms used for issuing ARVs to outpatients:

***Prescription form (MOH 501)***

- Is a single-copy, loose-leaf form.

Forms used to record issues of ARVs to outpatients:

- *Hospital Pharmacy Bin Card (MOH 999)*
- *Diflucan & ART Daily Activity Register*
- *ART Patient Dispensing Records*
- *ARV dispensing tool*

**Procedure:**

1. Authorised physician completes *Prescription Form (MOH 501)* for each eligible patient. A properly completed MOH 501 is described and an MOH 501 shown in procedure 107: *Issuing USAID-funded Antiretroviral Drugs to Outpatients.*

2. Upon receiving the *MOH 501* the designated pharmacist or pharmacy technologist must:

    - Check that the patient's name on the prescription is for the outpatient or patient's representative bringing the prescription.

    - Check that the patient is on the eligibility list and the prescriber is authorised to prescribe ARVs.

    - Check that the regimen follows the standard ART guidelines for the ART Programme. Alert the prescriber/Medical Officer in Charge of the ART Programme of any discrepancies before dispensing the prescription.

    - Use the *ART Patient Dispensing Record* and/or the *ARV dispensing tool* to countercheck the regimen and dose prescribed and that the patient is not collecting the ARVs earlier or later than expected. Alert the prescriber/Medical Officer in Charge of the ART Programme of any discrepancies before dispensing the prescription.

    - For adults on d4T (stavudine), check that the dose is appropriate for the weight. Alert the doctor if the dose needs to be adjusted.

    - Fill out a *Medication Error Report* as described in procedure 402: *Medication Error Reporting* for any errors discovered.

3. Fill the prescription using the ARVs in the outpatient pharmacy stock as described below, and endorse the prescription with the quantities issued for each drug.

4. Make entries in the *MOH 999*, the *Diflucan & ART Daily Activity Register* and the *ART Patient Dispensing Record*, and/or the *ARV dispensing tool* as described in procedure 205: *Record Keeping for GOK Antiretroviral Drugs at the Outpatient Pharmacy*.

5. Counsel the patient on the use of the medication as described in procedure 109: *Medication Use Counselling for Antiretroviral Therapy*.

Procedure for dispensing ARVs:

1. Work should begin in a clear workspace.

2. Pull the stock bottle from the ARV cupboard and match the following to the prescription:

    - Correct drug
    - Strength/concentration
    - Dosage form

3. Inspect the medication from the stock bottle. Look for the following:

    - Broken or discoloured tablets or capsules
    - Bottles with any cracks or chips

4. If any of the above are found, do not dispense the medication to the patient. Complete a *Stock Count Discrepancy Report* as described in procedure 302: *Stock Count Discrepancy*

*Report* and discard the items according to procedure 503: *Disposal of GOK Antiretroviral Drugs*.

5. Inspect packaging container to make sure it is not damaged or soiled and that it is appropriate to drug product being packaged.

Procedure for dispensing ARV tablets or capsules:

1. Issue whole packs where possible.

2. If necessary, count out desired number of units using a spatula or knife on a counting tray or a clean sheet of paper. Avoid touching the drug product with hands, as contamination may result.

3. Recount the number of units before packing into the container.

4. Select the appropriate pre-printed label for the ARV preparation to be dispensed. Add the following information and label the package:

   - Quantity
   - Batch No.
   - Expiry date
   - Times at which the drug is to be taken
   - Patient's name
   - Date

5. Follow standard pharmacy operating procedures to countercheck the product to make sure that the package and label contain the correct drug, strength, quantity, dosage form, and directions for use.

**Distribution:**

- *Prescription Form (MOH 501)* is filed and kept for 5 years.

| Coast Provincial General Hospital | |
|---|---|
| **Issuing GOK Antiretroviral Drugs to Inpatients** | |
| Number of pages: 4 | Procedure number: 207 |
| Prepared by: Name:<br>Title:<br>Date: | Reviewed by: Name:<br>Title:<br>Date: |

**Objective:**

To describe correct procedures for issuing and dispensing GOK antiretroviral drugs to inpatients. Good dispensing practices ensure that an effective form of the right drug is delivered to the right patient in the prescribed dosage and quantity, with clear instructions, and in a package that maintains the potency of the drug.

**Responsibility:**

- The authorised prescriber is responsible for prescribing ARV medication orders on the *Medication Treatment Sheet (MOH 306 Rev.).*
- The nurse is responsible for recording administration of ARVs to inpatients on the *Medication Treatment Sheet (MOH 306 Rev.).*
- The designated pharmacist or pharmacy technologist in charge of dispensing ARVs is responsible for issuing the ARV drugs to the ward.

**Resources:**

Forms used for issuing ARVs to inpatients:

***Medication Treatment Sheet (MOH 306 Rev.):***

- Is a record of all medication order(s) and medication administration including routine, ARVs, DDA, PRN, and STAT orders.
- All drugs administered to the patient must be recorded.
- *MOH 306 Rev.* should never be used for requisitioning medications for patients who have been discharged.

Forms used to record issues of ARVs to inpatients:

- *Hospital Pharmacy Bin Card (MOH 999)*
- *Diflucan & ART Daily Activity Register*
- *ART Patient Dispensing Records*
- *ARV dispensing tool*

**Procedure:**

1. Authorised physician writes the ARV order on the *Medication Treatment Sheet (MOH 306 Rev.).* Steps for completing the *MOH 306 Rev*. and an *MOH 306 Rev*. are shown in procedure 108: *Issuing USAID-Funded Antiretroviral Drugs to Inpatients*.

2. The nurse brings *MOH 306 Rev.* and a *Counter Requisition and Issue Voucher (S11)* completed as described in procedure 204: *Internal GOK Antiretroviral Drug Distribution* to the inpatient pharmacy.

3. Upon receiving *MOH 306 Rev.*:

    - Check that the patient is on the eligibility list and the prescriber is authorised to prescribe ARVs.

    - Check that the regimen follows the standard ART guidelines for the ART Programme. Alert the prescriber/Medical Officer in Charge of the ART Programme of any discrepancies before dispensing the prescription.

    - Use the *ART Patient Dispensing Record* and/or the *ARV dispensing tool* to countercheck the regimen and dose prescribed and that the nurse is not collecting the ARVs earlier or later than expected. Check the whole chart for drug interactions. Alert the prescriber of any discrepancies or problems before dispensing the ARVs.

    - For adults on d4T (stavudine), check that the dose is appropriate for the weight (ask the patient or their representative for latest weight if not on prescription). Alert the doctor if the dose needs to be adjusted.

    - If the dose has changed, ask the nurse to return previously issued bottles for relabelling.

    - Fill out a *Medication Error Report* as described in procedure 402: *Medication Error Reporting* for any errors discovered.

4. Fill the prescription using the ARVs in the outpatient pharmacy stock as described below. Inpatients should be issued with no more than a 7-day supply.

5. Make entries in the *MOH 999, Diflucan & ART Daily Activity Register,* and the *ART Patient Dispensing Records* and/or the *ARV dispensing tool* as described in procedure 205: *Record Keeping for GOK Antiretroviral Drugs at the Outpatient Pharmacy*. Endorse the *MOH 306 Rev.* with the date and quantity given.

6. The designated pharmacy staff member completes the *Counter Requisition and Issue Voucher (S11)* and ensures that the nurse receiving the drugs completes the *Counter Requisition and Issue Voucher (S11)* as described in procedure 104: *Internal USAID-Funded Antiretroviral Drug Distribution.* Retain the original copy.

7. The ARVs should be stored as per standard ward procedure for storing drugs in a secure, locked cabinet.

8. On discharge, the patient should be issued with the drugs held on the ward. The nurse should check that the supply issued is labelled with the correct dose. In addition, a *Prescription Form (MOH 501)* should be issued by the authorised prescriber as described in procedure 206: *Issuing GOK Antiretroviral Drugs to Outpatients.*

9. The pharmacist in charge of wards and the nurse in charge of the ward should regularly review the *Medication Treatment Sheet (306 Rev.)* to ensure that all required information is being correctly recorded.

10. For deceased patients, the ARVs should be returned to the pharmacy for either destruction or reuse if appropriate. If the drugs are usable, the receipt of the ARVs should be entered into the *MOH 999* and/or the *ARV dispensing tool* and the *Diflucan & ART Daily Activity Register* as described in procedure 205: *Record Keeping for GOK Antiretroviral Drugs at the Outpatient Pharmacy*. If the drugs are not usable, they are removed for destruction as described in procedure 503: *Disposal of GOK Antiretroviral Drugs.*

Procedure for dispensing ARVs:

1. Work should begin in a clear workspace.

2. Pull the stock bottle from the ARV cupboard and match the following to the prescription:

    - Correct drug
    - Strength/concentration
    - Dosage form

3. Inspect the medication from the stock bottle. Look for the following:

    - Broken or discoloured tablets or capsules
    - Bottles with any cracks or chips

4. If any of the above are found, do not dispense the medication to the patient. Complete a *Stock Count Discrepancy Report* as described in procedure 302: *Stock Count Discrepancy Report* and discard the items according to procedure 503: *Disposal of GOK Antiretroviral Drugs*.

5. Inspect the packaging container to make sure it is not damaged or soiled and that it is appropriate to the drug product being packaged.

Procedure for dispensing ARV tablets or capsules:

1. Issue whole packs where possible.

2. If necessary, count out the desired number of units using a spatula or knife on a counting tray or a clean sheet of paper. Avoid touching the drug product with hands, as contamination may result.

3. Recount the number of units before packing into the container.

4. Select the appropriate pre-printed label for the ARV preparation to be dispensed. Add the following information and label the package:

    - Quantity
    - Batch No.
    - Expiry date
    - Times at which the drug is to be taken
    - Patient's name
    - Date

5. Follow standard pharmacy operating procedures to countercheck the product to make sure that the package and label contain the correct drug, strength, quantity, dosage form, and directions for use.

**Distribution:**

- *Medication Treatment Sheet (MOH 306 Rev.)* is filed in the inpatient records.

- *Counter Requisition and Issue Voucher (S11)* is completed in triplicate:

    - The original copy is retained by the outpatient pharmacy.
    - Duplicate is retained by the initiating department.
    - Triplicate remains in the *S11* book.

| Coast Provincial General Hospital | |
|---|---|
| **Shipment Discrepancy Report** | |
| Number of pages: 4 | Procedure number: 301 |
| Prepared by: Name:<br>Title:<br>Date: | Reviewed by: Name:<br>Title:<br>Date: |

**Objective:**

To describe the procedure for documenting any discrepancies between the shipping invoice and the shipment received.

**Responsibility:**

- Receiving officer (the designated pharmacist in charge of the ARV bulk store or his/her designated proxy) and a witnessing pharmacy staff member.

**Resources:**

Forms used for recording shipping discrepancies

***Shipment Discrepancy Report***

- Is a duplicate form.

Forms needed to complete *Shipment Discrepancy Report*:

- *Counter Receipt Voucher (S13)*
- Shipment invoice
- *Issue and Receipt Voucher (S12)*

**Procedure:**

1. Errors in shipment must be recorded on the *Shipment Discrepancy Report*. Errors in shipping may include the following:
   - Damaged products, including:
     - Broken, cracked, or leaking bottles or bottles where seals are broken
     - Broken tablets
     - Drugs that arrive past their expiration date
     - Items that have no labels
     - Refrigerated items that arrive at room temperature or are warm
     - Inappropriate storage procedure during transportation of refrigerated items
   - Requirements from the tender that have not been met
   - Items listed on the invoice/delivery note/*S12* that are missing from the shipment
   - Items received that were not ordered or were not listed on the invoice/delivery note/*S12*

2. The form should be completed by the receiving officer and should be witnessed by another pharmacy staff member.

Steps for filling out the *Shipment Discrepancy Report:*

1. Record:
    - Date: date of shipment
    - Received by: name of receiving officer
    - Witnessed by: name of witnessing pharmacy staff member
    - Invoice Number
    - Transport Company: name of transport company
    - Vehicle Reg. No.: delivery vehicle registration number
    - Driver Name
    - Number of boxes received
    - No. of Other Containers Received: describe the type received, e.g., *drum*
    - For each item that is damaged, missing, or incorrect, fill out:
        - Serial No.: found on the *S13* where the product is recorded (if you are reporting items missing from the shipment, this will be left blank)
        - Item Description
            - Generic drug name
            - Strength/concentration
            - Dosage form
        - Code No.: number listed in the Kenya Essential Drug List which is specific to each drug, strength/concentration, and dosage form
        - Unit: unit of issue (i.e., number of tablets per package)
        - Quantity Broken, Quantity Missing, Quantity in Error: items broken/missing/issued in error
        - Comments: describing nature of error (i.e., broken bottles, expiration date for drugs delivered expired, missing drugs, or drugs received that were not ordered or not listed on invoice, etc.)

2. Signatures and names of receiving officer and witnessing pharmacy staff member

**Distribution:**

- For USAID-funded drugs, give the original copy of the *Shipment Discrepancy Report* to the Chief Administrator to forward to FHI for action and keep one copy on file with the *Counter Receipt Voucher (S13*) for this shipment in the ARV bulk store.

- For GOK drugs, give the original copy of the *Shipment Discrepancy Report* to the Chief Administrator and keep one copy on file with the *Issue and Receipt Voucher (S12)* for this shipment in the ARV bulk store.

## Coast Provincial General Hospital
## SHIPMENT DISCREPANCY REPORT

Date: ….....

Received by: ……

Witnessed by: …….

**Details of Shipment**

Invoice Number: …….

Transport Company: ……... Vehicle Reg. No.: ……

Driver Name: ……...

No. of Boxes Received: ……... No. of Other Containers Received: …….

**Details of Discrepancies**

**Breakages**:

| Serial No. | Item Description | Code No. | Unit | Quantity Broken | Comments |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |
| | | | | | |

**Items Missing:**

| Item Description | Code No. | Unit | Quantity Missing | Comments |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |

**Items Issued in Error:**

| Serial No. | Item Description | Code No. | Unit | Quantity in Error | Comments |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |
| | | | | | |

**Any other discrepancies or comments:**

Signature and name of receiving officer: …… Signature and name of witness: …….

| Coast Provincial General Hospital | |
|---|---|
| **Stock Count Discrepancy Report** | |
| Number of pages: 4 | Procedure number: 302 |
| Prepared by: Name:<br>Title:<br>Date: | Reviewed by: Name:<br>Title:<br>Date: |

**Objectives:**

- To describe the procedure for documenting any discrepancies between physical counts of the ARVs held at the ARV bulk store and the quantity recorded on the *Bulk Store Bin Card (S5).*

- To describe the procedure for documenting any discrepancies between physical count of the ARVs held at the outpatient pharmacy and the quantity recorded on the *Hospital Pharmacy Bin Cards (MOH 999)* and/or in the *ARV dispensing tool*.

- To describe the procedure for documenting any discrepancies between the records of ARV stock issued and stock received during transfer of stock from the ARV bulk store and the outpatient pharmacy.

**Responsibility**:

- The designated pharmacist in charge of the ARV bulk store or his/her designated proxy and a witnessing pharmacist.

- The designated pharmacy staff member in charge of the outpatient pharmacy or his/her designated proxy and a witnessing pharmacist.

- The designated pharmacist in charge of the ARV bulk store or his/her designated proxy and the designated pharmacy staff member in charge of the outpatient pharmacy or a witnessing pharmacist.

**Resources:**

Form used to record stock count discrepancy:

***Stock Count Discrepancy Report***

- Is a duplicate form.

Forms needed to fill complete *Stock Count Discrepancy Report*:

- *Bulk Store Bin Card (S5)*
- *Stores Ledger and Stock Control Card (S3)*
- *Hospital Pharmacy Bin Cards (MOH 999)*
- *ARV dispensing tool*

**Procedure:**

- A *Stock Count Discrepancy Report* is completed when a physical count in the ARV bulk store is different from the count recorded on the *Bulk Store Bin Card (S5)* or when the physical count of ARVs kept in the outpatient pharmacy is different from the count recorded on the *Hospital Pharmacy Bin Cards (MOH 999)* and/or in the *ARV dispensing tool.*

- It can also be used to record broken or damaged tablets/bottles that cannot be dispensed to patients.

- Countercheck any discrepancy in the ARV store on the *Bulk Store Bin Card (S5)* with the corresponding *Stores Ledger and Stock Control Card (S3).*

- Countercheck any discrepancy in the outpatient pharmacy on the *Hospital Pharmacy Bin Cards (MOH 999)*and/or the *ARV dispensing tool* with the *Prescription forms (MOH 501).*

- Give a full explanation for any discrepancy reported (e.g., circumstances where a drug preparation was lost, discovery of drugs or drug packaging that are damaged or expired and must be destroyed, or the accidental loss of drug via spillage, etc.).

Steps for completing the *Stock Count Discrepancy Report*:

1. Record:

    - Date

    - Serial No.: from *S5* or *MOH 999*

    - Item Code No.: from *S5* or *MOH 999*

    - Bin Card No.: from *S5* or *MOH 999*

    - Unit of Issue

    - Item Description:
        - Generic name
        - Strength/concentration
        - Dosage form

    - Location: *ARV bulk store* or *outpatient pharmacy*

    - Recorded Count: the count recorded on *S5* or *MOH 999* or in the *ARV dispensing tool*

    - Physical Count

    - Difference: between the recorded count and the physical count

    - For the ARV bulk store record:
        - Count recorded on corresponding *Stores Ledger and Stock Control Card (S3)*

- A complete explanation of the discrepancy, including reason for discrepancy (expiration of product, damaged product, spillage, etc.)

2. The form should be signed and dated by both the person performing the physical count and a witness:

   - The designated pharmacist in charge of the ARV bulk store or his/her designated proxy and a witnessing pharmacist.

   - The designated pharmacy staff member in charge of the outpatient pharmacy or his/her designated proxy and a witnessing pharmacist.

   - The designated pharmacist in charge of the ARV bulk store or his/her designated proxy and the designated pharmacy staff member in charge of the outpatient pharmacy or a witnessing pharmacist.

**Distribution:**

- Give the original copy of the *Stock Discrepancy Report* to the Chief Administrator and keep one copy on file with the *Bulk Store Bin Cards (S5)* in the ARV bulk store or the *Hospital Pharmacy Bin Cards (MOH 999)* in the outpatient pharmacy.

## Coast Provincial General Hospital
## Stock Count Discrepancy Report

Date: …… Serial No: …….

Item Code No: ……. Bin Card No: ……....

Unit of Issue: ……... Item Description: …….

Location: ……. ……...

| **Discrepancy Description** | |
|---|---|
| Recorded Count: …… Physical Count: …….. Difference: ……. | |
| For discrepancies in the ARV bulk store count recorded on corresponding *Stores Ledger and Stock Control Card (S3)*:<br>…….... | |
| **Details and Explanation of Discrepancy** | |
| ☐ Damaged | Details of damage/breakage and cause: |
| ☐ Expired<br><br>Date of shipment: ……<br>Date of expiry: …… | Details of expired stock and quantity removed: |
| ☐ Accidental loss | Details and explanation: |
| ☐ Unknown | Details and explanation: |

…… ……
Pharmacy staff member in charge: name and signature Date

…… ……
Witnessing pharmacist: name and signature Date

| Coast Provincial General Hospital | |
|---|---|
| **Exchanging Short-Dated USAID-Funded Antiretroviral Drugs** | |
| Number of pages: 3 | Procedure number: 303 |
| Prepared by: Name:<br>Title:<br>Date: | Reviewed by: Name:<br>Title:<br>Date: |

**Objectives:**

- To describe the procedure for exchanging short-dated stocks of USAID-funded ARVs.

**Responsibility**:

- Pharmacist in charge of the ARV bulk store or his/her designated proxy
- Pharmacist in charge of the USAID-funded ART Programme

**Resources:**

Form used to exchange short-dated stock:

***ART Programme: Request to Exchange Short-Dated Antiretroviral Drugs***

- Is a single-page letter.
- Is used to exchange short-dated USAID-funded ARV stocks.

Forms needed to complete exchange of short-dated stock:

- *Stores and Ledger Stock Control Card (S3)*
- *Bulk Store Bin Card (S5)*

**Procedure:**

1. The pharmacist in charge of the ARV store or his/her designated proxy completes the *ART Programme: Request to Exchange Short-Dated Antiretroviral Drugs* as described below and makes the appropriate adjustments in *Stores and Ledger Stock Control Card (S3)* and the *Bulk Store Bin Card (S5)*.

2. The pharmacist in charge of the USAID-funded ART Programme checks the request and forwards it through the Chief Pharmacist to the Chief Administrator for his/her signature.

3. The Chief Administrator returns the signed letter to the pharmacist in charge of the ART Programme, who makes a copy and forwards it to the Mombasa ART Programme Technical Assistance Partners (TAP) Coordinator at the FHI Mombasa Office.

4. The TAP Coordinator or his/her designated deputy checks the identity, quantity, and expiry date of the drugs to be returned, signs the copy, informs the supplier, and arranges for the drugs to be collected from CPGH.

Steps for completing the *ART Programme: Request to Exchange Short-Dated Antiretroviral Drugs*:

1. For each ARV preparation being returned for exchange, enter:

    - The number of packs being returned for exchange
    - The expiry date of the ARV product returned
    - The number of packs requested in exchange

2. Sign, stamp, and record the date that the request was prepared.

3. The request is signed and dated by the Chief Administrator at CPGH.

**Distribution:**

- *ART Programme: Request to Exchange Short-Dated Antiretroviral Drugs*
    - The completed and signed original is forwarded to the TAP Coordinator.
    - One copy is kept in the CPGH ARV bulk store.

# Coast General Provincial Hospital
# ART Programme: Request to Exchange Short-Dated Antiretroviral Drugs

To: Technical Assistance Partners (TAP) Coordinator, Mombasa ART Programme, FHI/IMPACT

Coast Provincial General Hospital requests that the following USAID-funded antiretroviral drugs for the ART Programme be exchanged for longer-dated stock:

| Product | Form | Strength | Pack Size | # Packs Returned for Exchange | Expiry Date of Stock Returned | # Packs Requested in Exchange |
|---|---|---|---|---|---|---|
| Zidovudine/lamivudine (Combivir) | Tablets | 300/150mg | 60 | | | |
| Didanosine (ddI) | Tablets | 25mg | 60 | | | |
| Didanosine (ddI) | Tablets | 200mg | 60 | | | |
| Didanosine (ddI) | Powder for solution | 883mg/5ml | 2g/4oz | | | |
| | | | 4g/8oz | | | |
| Efavirenz (EFV) | Capsules | 50mg | 30 | | | |
| Efavirenz (EFV) | Capsules | 200mg | 90 | | | |
| Efavirenz (EFV) | Tablets | 600mg | 30 | | | |
| Efavirenz (EFV) | Liquid | 30mg/ml | 180ml | | | |
| Indinavir (IDV) | Capsules | 400mg | 180 | | | |
| Lamivudine (3TC) | Tablets | 150mg | 60 | | | |
| Lamivudine (3TC) | Oral soln | 10mg/ml | 240ml | | | |
| Lopinavir/ritonavir (LPV/r) (Kaletra) | Capsules | 133.33/ 33.33mg | 180 | | | |
| Lopinavir/ritonavir (LPV/r) (Kaletra) | Solution | 80/20mg/ml | 160ml | | | |
| Nelfinavir (NFV) | Tablets | 250mg | 270 | | | |
| Nevirapine (NVP) | Tablets | 200mg | 60 | | | |
| Nevirapine (NVP) | Oral suspn | 10mg/ml | 240ml | | | |
| Stavudine (d4T) | Capsules | 15mg | 60 | | | |
| Stavudine (d4T) | Capsules | 20mg | 60 | | | |
| Stavudine (d4T) | Capsules | 30mg | 60 | | | |
| Stavudine (d4T) | Capsules | 40mg | 60 | | | |
| Stavudine (d4T) | Powder for solution | 1mg/ml | 200ml | | | |
| Zidovudine (AZT, ZDV) | Capsules | 100mg | 100 | | | |
| Zidovudine (AZT, ZDV) | Tablets | 300mg | 60 | | | |
| Zidovudine (AZT, ZDV) | Syrup | 50mg/5ml | 200ml | | | |

Request prepared by:

…… *(Name )* ……..*(Signature)* Date……/200….

Kindly confirm the receipt of this request and arrange for collection of short-dated stock and for deliveries of replacement stock to be made to CPGH Pharmacy.

Yours sincerely,

**……..** Date……/200….

Chief Administrator

| Coast Provincial General Hospital | |
|---|---|
| **Expiry Date Monitoring of Antiretroviral Drugs** | |
| Number of pages: 3 | Procedure number: 304 |
| Prepared by: Name:<br>Title:<br>Date: | Reviewed by: Name:<br>Title:<br>Date: |

**Objective:**

To describe the procedure for tracking the expiry dates of antiretroviral drugs (ARVs) to alert supply/stock managers when ARVs should be removed from stock for exchange or destruction. Many drug suppliers will take back short-dated stock for exchange, but only if it is received with a certain minimum expiry—usually six months. Some programs may have arrangements to move short-dated stock to other sites where consumption is higher. When drugs cannot be returned for exchange, the chart alerts staff to remove expired stock so that it does not get issued in error.

**Responsibility:**

- Pharmacist in charge of the ARV bulk store

**Resources:**

***Chart to Track the Expiry Dates of Drugs***

- Is a laminated chart designed to hang on the wall.

**Procedure:**

1. The chart is designed to be reusable. Use the DRY pen provided. If you use a permanent marker, you will need to use spirit or other ink remover to make changes.

2. The chart has three columns for three years. The first column should be used for the current year.

3. At the beginning of each year, shift the years on the column headings to delete the old year and add the next new year. The original second year now becomes the first year. Shift the stickers for the drugs that remain on the chart at the beginning of the new year to the new columns.

4. Each product has space to list three different batches/lots of drugs. If you have more than three batches/lots, record the three that expire first.

5. (yellow) marks the expiry warning date; (red) marks the month when the drug expires.

6. Contact the product supplier to find out the minimum expiry date that they will accept for exchange, or check with the program manager as to when he/she wants to be alerted about short-dated stock. Consider adding one month to this minimum date to allow for transport back to the supplier. Place the yellow warning dots on the month in which action must be taken.

7. For the three months before the yellow warning dot, enter the current stock level of that batch/lot in the relevant grid. The stock levels also show the rate of use and determine how much, if any, stock to return.

8. Remove the red dot only after the expired stock has been destroyed or removed from stock.

9. When a batch/lot expires or is used up, erase the entry and replace it with the next batch to expire. When drugs/supplies are received, enter the new batch/lot number and expiry date on the chart.

10. If a drug expires after the three years covered in the chart, record the drug in the chart, but do not include the stickers. When updating the chart at the beginning of the new year, if the drug is still in stock and expires within the three years, add the stickers accordingly.

11. To reduce the number of entries and help with chart maintenance, make two separate charts for syrups and tablets/capsules.

**Display of Chart:**

- Hang the *Chart to Track the Expiry Dates of Drugs* on a wall for easy reference.
- You may need to use more than one chart, depending on the number of drugs

# Chart to Track the Expiry Dates of Drugs

| Drug Name | Batch No/ Date of Mgf. | Year:…… | | | | | | | | | | | | Year:…… | | | | | | | | | | | | Year:…….. | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | J | F | M | A | M | J | J | A | S | O | N | D | J | F | M | A | M | J | J | A | S | O | N | D | J | F | M | A | M | J | J | A | S | O | N | D |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

| Coast Provincial General Hospital | |
|---|---|
| **Antiretroviral Therapy Adverse Drug Reaction Monitoring and Reporting** | |
| Number of pages: 24 | Procedure number: 401 |
| Prepared by: Name:<br>Title:<br>Date: | Reviewed by: Name:<br>Title:<br>Date: |

**Objectives:**

The purpose of the ART Adverse Drug Reaction (ADR) Monitoring and Reporting procedure at CPGH is twofold:

- To minimise adverse outcomes by early detection of ADRs in individual ART patients
- To continuously improve treatment approaches, policies, procedures, and training by analysis of aggregate ADR data from ART patients

**Policy:**

ADR identification, reporting, and review are essential components of ART Programme patient care at CPGH and contribute to optimal outcomes and patient safety. All ART patients' ADRs will be reported on an ADR form. The forms will be reviewed, compiled, and examined for trends. The information will be entered into the ART report, and appropriate actions will be taken in response to the report. Note: During the first three months of ART ADR monitoring and reporting, all ADRs, regardless of severity or causality, will be recorded on ADR forms to instill a *notification culture* within the programme.[1] The ADR form will be used to report on ADRs to ART and other drugs used in the programme.

**Definitions:**[2]

***Adverse drug reaction*:** a response to a medicine that is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or the modification of physiological function

***Serious adverse drug reaction:*** any reaction that is fatal, life-threatening, permanently/significantly disabling, requires or prolongs hospitalization, causes a congenital anomaly, or requires intervention to prevent permanent impairment or damage

***Grading of severity of ADRs***[3]

- Grade 1: Mild
  Transient or mild discomfort, no limitation in activity; no medical intervention/ therapy required

- Grade 2: Moderate
  Mild-to-moderate limitation in activity; some assistance may be needed; no or minimal medical intervention/therapy required

- Grade 3: Severe
  Marked limitation in activity, some assistance usually required; medical/intervention/ therapy required, hospitalisation possible

- Grade 4: Life-threatening
  Extreme limitation in activity, significant assistance required; significant medical intervention/therapy required, hospitalisation or hospice care probable

**Responsibility:**

The roles of core team members are listed in Table 1.

**Table 1: Role of Core Team Members**

| Core Team Member | Role in ADR Monitoring, Reporting, and Review |
|---|---|
| Triage nurse<br>ART nurse<br>Nutritionist<br>Pharmacist<br>Pharmaceutical technologist<br>Laboratory technologist | • Understand the definition of an ADR.<br>• Understand what signs or comments from patients might indicate ADRs.<br>• Refer all patients with suspected ADRs to the Medical Officer (MO)/ Registered Clinical Officer (RCO).<br>• Laboratory technologist will consider ADR referral for patients with unscheduled labs or abnormal lab values for blood sugar, CBC, LFTs, bicarbonate, chloride, lipid levels, and will refer patients with suspected ADRs to the pathologist, who will refer to the MO/RCO. The laboratory technologist/pathologist will refer to the ADR document *Estimating Severity Grading* for guidance in determining suspect lab values for a possible ADR referral.<br>• If the laboratory technologist suspects an ADR, he/she will store the original sample and will immediately request that a fresh blood specimen be collected as soon as possible. |
| Registered Clinical Officer and Medical Officer | • Understand the definition of an ADR.<br>• Assess patients for ADRs on all routine visits using:<br>o Objective evidence (labs, vital signs, and physical exam)<br>o Subjective evidence (patient counselling)<br>• Evaluate and treat patients when appropriate.<br>• For an initial period the RCO will refer all patients with suspected ADRs to the MO. At a period to be determined by the ART Eligibility Committee, the RCO will only refer to the MO patients with suspected serious ADRs, ADRs that require treatment, or complicated, unclear, or unusual cases. |

| Core Team Member | Role in ADR Monitoring, Reporting, and Review |
|---|---|
| | • Counsel the patient regarding when to return to the clinic for an extra visit to assess the ADR, changing drug therapy, etc.<br>• Counsel the patient regarding the signs that the reaction has abated or accelerated and what to do in each case.<br>• Document suspected ADR in a progress note in medical record.<br>• Write the name of the drug suspected of causing the ADR that falls into the probability categories *definite* or *probable* in red pen/red sticker on the cover of the medical record.<br>• Complete one ADR form for each ADR and place the original form in the record.<br>• Ensure that a duplicate copy of the ADR form is received by the pharmacist in charge of the ART Programme.<br>• Refer to the document *Estimating Severity Grading* for guidance in determining severity. |
| ART nurse | • Understand the definition of an ADR.<br>• Initially counsel all patients regarding the possibility of ADRs. Inform patients of signs and symptoms that may indicate an ADR.<br>• Instruct patients that in the event of an ADR, they should return to the clinic immediately if the reaction is life-threatening or contact the MO/RCO as soon as possible in all other instances.<br>• Continually screen patients for ADRs according to Standard Operating Procedures.<br>• For an initial period, only the MO will complete the ADR form. Refer all patients with suspected ADRs to the MO/RCO.<br>• After a period to be determined by the ART Eligibility Committee, complete first section of one ADR form for each ADR reported. Refer patients with suspected ADR to the MO/RCO with the ADR form.<br>• Work with the pharmacist in charge of the ART Programme and the Records Officer to ensure the original ADR form is placed in the patient's record. |
| Pharmacist<br>Pharmaceutical technologist | • Understand the definition of an ADR.<br>• Counsel all patients regarding the possibility of ADRs. Inform patients of signs and symptoms that may indicate an ADR.<br>• Instruct patients that in the event of an ADR, they should return to the clinic immediately if the reaction is life-threatening or contact the MO/RCO as soon as possible in all other instances.<br>• For an initial period, only the MO will complete the ADR form. Refer all patients with suspected ADRs to the MO/RCO.<br>• After a period to be determined by the ART Eligibility Committee, complete one ADR form for each ADR reported. Refer patients with suspected serious ADRs or patients requiring treatment to the MO/RCO. |

| Core Team Member | Role in ADR Monitoring, Reporting, and Review |
|---|---|
| Pharmacist in charge of the ART Programme or designated deputy | • Work with the Records Officer and the nursing staff to make sure that the original ADR form is placed in the patient record and the duplicate is received by the pharmacist.<br>• Work with the MO/RCO to calculate the probability that an ADR was caused by a specific drug using the (modified) Naranjo Method[4] and complete the *ART ADR Report*. Refer ADR reports to the ART Eligibility Committee for review.<br>• Maintain a file of all completed ADR forms and related reports.<br>• Review ADR forms on an ongoing basis and alert the ART Eligibility Committee of unusual trends or findings.<br>• Provide verbal feedback at ART Eligibility Committee meetings, or written feedback to staff regarding outcomes of referred ADRs (to encourage continued reporting).<br>• Prepare *ADR Summary Report*.<br>• Present the *ADR Summary Report* and findings to the ART Eligibility Committee. |

## Procedure:

- **STAFF ADR EDUCATION**

1. Orientation for all core team members includes a session describing the importance, definition, flow of reporting, and recognition of ADRs.

2. In addition, specific instruction regarding completion of the *ART ADR Form* will be provided for the RCO/MO.

3. Education regarding report generation, report assessment, and Uppsala Monitoring Centre/manufacturer reporting will be provided for the pharmacist in charge of the ART Programme.

4. The ART Eligibility Committee will be responsible for ensuring the staff receives ongoing education, as appropriate, based on pertinent information gleaned in the ADR reports.

- **ADR FORM COMPLETION AND ACTIONS ON AN INDIVIDUAL LEVEL**

1. For an initial period, to be determined by the ART Eligibility Committee, all suspected ADRs will be referred to the MO and only the MO will complete the ADR form.

2. The ART Eligibility Committee will determine when selected ADRs will not need to be referred to the MO and can be dealt with by the RCO.

3. Similarly, the ART Eligibility Committee will determine when staff other than the MO and RCO can complete the ADR form and which ADRs they should refer to the MO or RCO.

## I. ADR Reporting Flow (for the initial period)

1. Patient presents with clinical symptoms or signs, or staff member (triage nurse, ART nurse, nutritionist, pharmaceutical technologist, or laboratory technologist) suspects an ADR. (If patient initially presents to MO with ADR complaint, MO will proceed with step 3 below.)

2. Patient is referred to the MO.

3. The MO:

   - Counsels patient.
   - Records suspected ADR both in a progress note and in red pen/red sticker on the front of the record, when warranted.
   - Treats patient.
   - Records suspected ADR on *ART ADR Form* and documents actions taken (Part A)
   - Places the original form in the record.
   - Gives a carbon copy of the *ART ADR Form* to the pharmacist in charge of the ART Programme or to the ART nurse to give to the pharmacist.

4. The pharmacist in charge of the ART Programme:

   - Works with the Records Officer to ensure that one copy of the *ART ADR Form* is placed in patient's record.
   - Reviews the *ART ADR Form*
   - Works with the MO to complete the form and to assign a probability category as outlined in Section II below.
   - Generates an *ART ADR Report*, which is attached to the *ART ADR Form*.
   - Refers the report to the next ART Eligibility Committee meeting.

5. The ART Eligibility Committee:

   - Reviews the *ART ADR Report* and the ADR probability estimation.
   - Decides to take appropriate actions in response to ADRs and/or *ART ADR Reports* as outlined in Section III, Table 2.

## II. Steps for Completing the *Antiretroviral Therapy Adverse Drug Reaction (ADR) Form*

Record

1. Information on the patient:
   - Patient Name
   - I.D. No.
   - Age
   - Gender
   - Pregnancy status
   - Weight
   - Height

2. Information on the person reporting the ADR:
   - Name
   - Title
   - Signature
   - Clinician's name (if not the reporter)

3. Information on drugs taken – record drug suspected of causing the ADR first and then other drugs taken:
   - Name
   - Batch number
   - Expiry date
   - Daily dose prescribed
   - Route
   - Start date
   - Stop date
   - Indication
   - Were the drugs taken at the intended dosage: Yes or No
   - Were drugs stored in the appropriate conditions: Yes or No

4. Information on the reaction:
   - Tick all boxes that describe the ADR
   - Date the ADR started
   - Date the ADR stopped
   - Additional information (e.g., nature, localisation, results of tests, etc.)

5. Grade the severity of the ADR

6. Information on outcome: tick all relevant boxes and describe further details as appropriate:
   - Action taken
   - Patient outcomes from ADR
   - Interventions required

## III. Steps for Completing the *Antiretroviral Therapy Adverse Drug Reaction (ADR) Report*

1. Prepare a report for each ADR form submitted. Record

    - Patient Name
    - Patient I.D. No.: CCC number
    - Date ADR reported
    - ADR form No: serial number from *Antiretroviral Therapy Adverse Drug Reaction (ADR) Form*
    - Symptoms that describe the ADR
    - Drug Name
    - Dose and Frequency
    - Drugs Given at Correct Dose: Yes or No
    - Start Date
    - Stop Date
    - ADR Listed in Labelling: Yes or No; check if the ADR is listed in the most recent product information for the drug
    - Drug is less than 5 years old: Yes or No
    - Batch number
    - Probability Score and Probability Category: calculated by the (modified) Naranjo Method
    - Comments

2. Record the date the ADR report is presented to the ART Committee and the Action Taken

## IV. ADR Probability Estimation

The probability that an ADR was caused by a specific drug will be determined using the (modified) Naranjo Method.[4]

| | ADR Probability Score | | |
|---|---|---|---|
| Answer the questions, circle the pertinent score, sum all responses to give a total score, and choose the corresponding probability category. | **Yes** | **No** | **Do Not Know** |
| 1. Are there previous conclusive reports on this reaction? | +1 | 0 | 0 |
| 2. Did the adverse reaction appear after the suspected drug was administered? | +2 | -1 | 0 |
| 3. Did the adverse reaction improve when the drug was discontinued? | +1 | 0 | 0 |
| 4. Did the adverse reaction reappear when the drug was readministered? | +2 | -1 | 0 |
| 5. Are there alternative causes (other than the drug) that could on their own have caused the reaction? | -1 | +2 | 0 |
| 6. Was the reaction more severe when the dose was increased, or less severe when the dose was decreased? | +1 | 0 | 0 |
| 7. Did the patient have a similar reaction to the same or similar drugs in any previous exposure? | +1 | 0 | 0 |
| 8. Was the adverse reaction confirmed by any objective evidence? | +1 | 0 | 0 |
| **Total** | | | |

**Probability Category: Definite ≥9, Probable 5–8, Possible 1–4, Doubtful ≤0**

## V. ADR Actions on an Individual Level

Possible actions that could be taken by ART Eligibility Committee to an *ART ADR Report* on an individual level are outlined in Table 2.

**Table 2: ADR Actions on an Individual Level**

| ADR Form Field Response | Possible Actions |
|---|---|
| **Serious** ADRs associated with ADR Probability Category **Definite** or **Probable**<br>• **Not** listed in the product labelling<br>or<br>• Occurring in drugs less than 5 years old since first approved by the Pharmacy and Poisons Board | • Refer the patient to the ART Programme Eligibility Committee for further assessment<br>• Notify the Scientific Committee. The Scientific Committee could decide to inform the Steering Committee, who may:<br>o Notify the Pharmacy and Poisons Board, who may<br>o Notify the manufacturer |
| **Serious** ADRs associated with ADR Probability Category **Definite** or **Probable** listed in the product labelling | • Refer the patient to the ART Programme Eligibility Committee for further assessment<br>• Notify the Scientific Committee |
| Grade 1 and 2 ADRs associated with ADR Probability Category **Definite** or **Probable not** listed in the product labelling | • Refer the patient to the ART Programme Eligibility Committee for further assessment<br>• Notify the Scientific Committee |
| ADRs occurring when the intended medications were not taken at the intended dosages | • The MO/RCO/RNO/pharmacist will contact the ART nurse and take appropriate action (ensure patient receives additional counselling, etc.) |

- **ADR SUMMARY REPORT AND ACTIONS ON AN AGGREGATE LEVEL**

## I. ADR Reporting Flow

1. Pharmacist in charge of the ART Programme:

    - Reviews the *ART ADR Forms* and *ART ADR Reports* and prepares the *ADR Summary Report* at the end of each month.

    - Looks for unusual trends.

    - Reviews the *Actions Taken* section of the reports submitted to ensure that appropriate actions have been taken as decided by the ART Eligibility Committee based on the outline in Table 2.

    - Presents the *ADR Summary Report* to the ART Eligibility Committee at the first meeting of each month.

    - Reports on unusual trends.

    - Reports on inappropriate actions taken.

2. The ART Eligibility Committee:

    - Reviews the *ADR Summary Report* and if necessary, the raw data.

    - Decides to take appropriate actions in response to *ADR Summary Reports* and/or on unusual trends and/or inappropriate actions taken (possible actions are outlined in Section III Table 3).

    - Forwards the *ADR Summary Reports* and presents the findings to the Scientific Committee.

3. The Scientific Committee reviews the *ADR Summary Reports* and decides on appropriate action to be taken (possible actions are outlined in Section III, Table 3).

## II. Steps for Completing the *ADR Summary Report*

The *ADR Summary Report* is a compilation of the data elements on the *ART ADR Form and ART ADR Report*.

The *ADR Summary Report—Part I* reports for all ARV drugs used in the ARV Programme.

Record

1. Year

2. ADR rate per total ART patients:
    - Calculated by dividing the total number of ADRs for the month by the total number of patients receiving ART

3. Total number of ADRs, reported by:
   - Age group
   - ADR probability category
   - Actions taken
   - Patient outcomes from ADR
   - Interventions required from ADR

4. Suspected drugs: names of the specific drugs

The *ADR Summary Report—Part II* reports by each ARV drug used in the ART Programme.

Record

1. Drug Name

2. Year

3. ADR rate per total ART patients taking the drug:
   - Calculated by dividing the total number of ADRs for an individual drug for the month by the total number of patients receiving the ARV drug

4. Total number of ADRs, reported by suspected drug by:
   - Age group
   - ADR probability category
   - Actions taken
   - Patient outcomes from ADR
   - Interventions required from ADR
   - ADRs reported

The *ADR Summary Report—Part III* reports for a specific side effect for an ARV drug used in the ART Programme if deemed necessary to determine trends

Record

1. Drug Name

2. ADR

3. Year

4. ADR rate per total ART patients taking the drug
   - Calculated by dividing the total number of a specific ADR for the month by the total number of patients receiving the ARV drug

5. Total number of ADRs, reported by suspected drug by:
   - Age group
   - ADR probability category
   - Actions taken
   - Patient outcomes from ADR
   - Interventions required from ADR

## III. ADR Actions on an Aggregate Level

Once ADR data has been collected for 6 months, it may be useful for the ART Eligibility Committee and/or the Scientific Committee to set numerical thresholds for specific data elements as triggers for action.

Suggested trends and actions for the data fields appearing on the *ADR Summary Report* and the *ART ADR Form* appear in Table 3 below. This table is not all-inclusive; it merely provides a starting point for the ART Eligibility Committee and/or the Scientific Committee and/or Steering Committee to use when evaluating the *ART ADR Reports*.

**Table 3: ADR Actions on an Aggregate Level**

| Trends | Possible Actions |
|---|---|
| An increase in suspected/probable ADRs associated with a specific age group, gender, pregnancy status, drug class, or particular drug | • Notify the Scientific Committee.<br>• Drug may be used cautiously in particular groups with extra patient monitoring (lab or clinic visits) required.<br>• Drug may not be given to particular groups.<br>• Drug may be removed from treatment plan.<br>• ADR may be reported to the Pharmacy and Poisons Board by the Steering Committee on the recommendation of the Scientific Committee. Pharmacy and Poisons Board may inform the manufacturer.<br>• ART Eligibility Committee and/or Scientific Committee will investigate possible causes of this increase and take appropriate corrective or preventative actions. |
| **Serious** ADRs associated with ADR Probability Category **Definite** or **Probable**<br>• **Not** listed in the product labelling<br>or<br>• Occurring in drugs less than 5 years old since first approved by the Pharmacy and Poisons Board | • Notify the Scientific Committee<br>• Drug may be used cautiously with extra patient monitoring (lab or clinic visits) required<br>• Drug may be removed from treatment plan<br>• ADR may be reported to the manufacturer and/or the Pharmacy and Poisons Board by the Steering Committee on the recommendation of the Scientific Committee |
| Appropriate actions are not being taken in response to suspected ADRs as decided by the ART Eligibility Committee and/or based on the outline in Table 2. | • A training session could be organised.<br>• Discuss with individual prescribers. |

**Distribution:**

- A copy of the *ART ADR Form* is kept in the patient record, and a duplicate copy is kept on file in the Pharmacy with a copy of the *ART ADR Report*.
- The *ADR Summary Reports* are held on file in the Pharmacy.
- All reports are kept in a confidential file.

**References:**

1. Uppsala Monitoring Centre/WHO. 2000. *Safety Monitoring of Medicinal Products: Guidelines for Setting up and Running a Pharmacovigilance Centre.* P. 8. <http//www.who-umc.org/pdfs/guidelines/pdf> (accessed Oct. 14, 2004).

2. Uppsala Monitoring Centre/WHO. 2000. *Safety Monitoring of Medicinal Products: Guidelines for Setting up and Running a Pharmacovigilance Centre.* P. 20. <http//www.who-umc.org/pdfs/guidelines/pdf> (accessed Oct. 14, 2004).

3. International Centers for Tropical Disease Research Network/National Institute of Allergy and Infectious Diseases/National Institutes of Health. 2003. *ICTDR Investigator Manual: Monitoring and Reporting Adverse Events.* P. 17. <http://www.icssc.org/Documents/ICTDR_AE_Manual_February_6_2003_final.pdf> (accessed Oct. 14, 2004).

4. Naranjo, C. A., U. Busto, E. M. Sellers, P. Sandor, I. Ruiz, E. A. Roberts, E. Janecek, C. Domecq, and D. J. Rosenblatt. 1981. A Method for Estimating the Probability of Adverse Drug Reactions. *Clinical Pharmacology and Therapeutics* 30:239–245.

Form No. _____

# Antiretroviral Therapy Adverse Drug Reaction (ADR) Form

Please place original form in the patient's record and return duplicate to ART pharmacist.

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Patient** | Patient Name | | | | | **Reporter** | Reporter's Name, Title, Signature |
| | Patient ID No. | | | | | | |
| | Age | Gender M / F | Pregnant YES/NO | Weight | Height | | Clinician's Name (if not the reporter) |

| **Suspected Drug** | Suspected Drug Name, Batch No./Expiry | Daily Dose | Route | Start Date | Stop Date | Indication |
|---|---|---|---|---|---|---|
| | 1._____ | _____ | _____ | _____ | _____ | _____ |
| | Other drug(s) taken in the last 3 months. (Continue on back if needed.) | | | | | |
| | 2._____ | _____ | _____ | _____ | _____ | _____ |
| | 3._____ | _____ | _____ | _____ | _____ | _____ |
| | 4._____ | _____ | _____ | _____ | _____ | _____ |
| | 5._____ | _____ | _____ | _____ | _____ | _____ |
| | 6._____ | _____ | _____ | _____ | _____ | _____ |
| | 7._____ | _____ | _____ | _____ | _____ | _____ |
| | 8._____ | _____ | _____ | _____ | _____ | _____ |
| | 9._____ | _____ | _____ | _____ | _____ | _____ |
| | Were the intended medications taken at intended dosage? Yes No (circle one) | | | | | |
| | Were the drugs stored in appropriate conditions? Yes No (circle one) | | | | | |

| | **Tick all boxes that describe the ADR.** | | |
|---|---|---|---|
| **Reaction** | □ Pain/tingling/numbness in extremities | □ Chills/fever | □ Unusual fatigue |
| | □ Abdominal or back pain | □ Insomnia | □ Unusual bruising/bleeding |
| | □ Nausea/vomiting/diarrhoea | □ Rash | □ Other_____ |
| | □ Anxiety, depression | □ Headache | _____ |
| | □ Persistent muscle pain/weakness | □ Dizziness | |
| | Date ADR Started: ____/____/_____ Date ADR Stopped: ____/____/_____ | | |
| | Describe additional details (nature, localisation, results of tests, course, risk factors): | | |

| **Severity** | **Tick the grade of severity of the ADR.** |
|---|---|
| | □ Grade 1: Mild — Transient or mild discomfort, no limitation in activity; no medical intervention/ therapy required |
| | □ Grade 2: Moderate — Mild to moderate limitation in activity, some assistance may be needed; no or minimal medical intervention/therapy required |
| | □ Grade 3: Severe — Marked limitation in activity, some assistance usually required; medical/intervention/ therapy required, hospitalisation possible |
| | □ Grade 4: Life-threatening — Extreme limitation in activity, significant assistance required; significant medical intervention/therapy required, hospitalisation or hospice care probable |

| **Outcome** | **Tick all applicable boxes for sections A, B, and C.** | | |
|---|---|---|---|
| | **A-Action Taken** | **B-Patient Outcomes from ADR** | **C-Interventions Required** |
| | □ Discontinued suspected drug | □ Symptoms resolved/improved | □ Patient counselled |
| | □ Decreased dose | □ Permanent/significant disability | □ Drug required to treat ADR |
| | □ Other_____ | □ Congenital abnormality | □ Additional clinic visit |
| | _____ | □ Life-threatening | □ Additional labs |
| | _____ | □ Patient death | □ Hospitalisation |
| | | □ Other_____ | □ Other_____ |

# Antiretroviral Therapy Adverse Drug Reaction (ADR) Report

**Complete one report per ADR form submitted and attach to duplicate copy of *Antiretroviral Therapy ADR Form.***

| **Patient Name:** | **Patient ID No.:** | **Symptoms that describe the ADR:** |
|---|---|---|
| **Date ADR Reported:** | **ADR form No.:** | |

| **Drug Name** | **Dose & Frequency** | **Drug Given at Correct Dose Yes/No** | **Start Date** | **Stop Date** | **ADR Listed in Labelling Yes/No** | **Drug Is <5 Years Old** | **Batch No.** | **Expiry Date** | **Probability Score** | **Probability Category** | **Comments** |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | |
| | | | | | | | | | | | |
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| ***Date presented to the Eligibility Committee*** | ***Action Taken*** |
|---|---|
| | |

# *Adverse Drug Reaction Summary Report – Part I*

| ***Year : 200___*** | ***Jan*** | ***Feb*** | ***March*** | ***April*** | ***May*** | ***June*** | ***July*** | ***Total*** |
|---|---|---|---|---|---|---|---|---|
| **ADR Rate per Total ART Patients** | | | | | | | | |
| | | | | | | | | |
| **Total ADRs** | | | | | | | | |
| Age <1 | | | | | | | | |
| Age 1–12 | | | | | | | | |
| Age >12 | | | | | | | | |
| No. pregnant patients | | | | | | | | |
| Males | | | | | | | | |
| Females | | | | | | | | |
| | | | | | | | | |
| **ADR Probability Category** | | | | | | | | |
| Definite | | | | | | | | |
| Probable | | | | | | | | |
| Possible | | | | | | | | |
| Doubtful | | | | | | | | |
| | | | | | | | | |
| **Actions Taken** | | | | | | | | |
| Discontinued suspected drug | | | | | | | | |
| Decreased dose of suspected drug | | | | | | | | |
| Other | | | | | | | | |
| | | | | | | | | |
| **Patient Outcomes from ADR** | | | | | | | | |
| Symptoms resolved/improved | | | | | | | | |
| Permanent/significant disability* | | | | | | | | |
| Congenital abnormality* | | | | | | | | |
| Life-threatening* | | | | | | | | |
| Patient death* | | | | | | | | |
| Other | | | | | | | | |
| | | | | | | | | |
| **Interventions Required from ADR** | | | | | | | | |
| Patient counselled | | | | | | | | |
| Drug required to treat reaction | | | | | | | | |
| Additional clinic visit | | | | | | | | |
| Additional labs | | | | | | | | |
| Hospitalisation* | | | | | | | | |
| Other | | | | | | | | |
| | | | | | | | | |
| **Suspected Drugs** | | | | | | | | |
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# *Adverse Drug Reaction Summary Report – Part II*

| ***Drug Name:*** | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| ***Year : 200___*** | ***Jan*** | ***Feb*** | ***March*** | ***April*** | ***May*** | ***June*** | ***July*** | ***Total*** |
| **ADR Rate per Total ART Patients Taking the Drug** | | | | | | | | |
| | | | | | | | | |
| **Total ADRs** | | | | | | | | |
| Age <1 | | | | | | | | |
| Age 1–12 | | | | | | | | |
| Age >12 | | | | | | | | |
| No. pregnant patients | | | | | | | | |
| Males | | | | | | | | |
| Females | | | | | | | | |
| | | | | | | | | |
| **ADR Probability Category** | | | | | | | | |
| Definite | | | | | | | | |
| Probable | | | | | | | | |
| Possible | | | | | | | | |
| Doubtful | | | | | | | | |
| | | | | | | | | |
| **Actions Taken** | | | | | | | | |
| Discontinued suspected drug | | | | | | | | |
| Decreased dose of suspected drug | | | | | | | | |
| Other | | | | | | | | |
| | | | | | | | | |
| **Patient Outcomes from ADR** | | | | | | | | |
| Symptoms resolved/improved | | | | | | | | |
| Permanent/significant disability* | | | | | | | | |
| Congenital abnormality* | | | | | | | | |
| Life-threatening* | | | | | | | | |
| Patient death* | | | | | | | | |
| Other | | | | | | | | |
| | | | | | | | | |
| **Interventions Required from ADR** | | | | | | | | |
| Patient counselled | | | | | | | | |
| Drug required to treat reaction | | | | | | | | |
| Additional clinic visit | | | | | | | | |
| Additional labs | | | | | | | | |
| Hospitalisation* | | | | | | | | |
| Other | | | | | | | | |
| | | | | | | | | |
| **ADRs Reported** | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
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| | | | | | | | | |
| | | | | | | | | |

# *Adverse Drug Reaction Summary Report – Part III*

| ***Drug Name:*** | | | | ***ADR:*** | | | | |
|---|---|---|---|---|---|---|---|---|
| ***Year : 200___*** | ***Jan*** | ***Feb*** | ***March*** | ***April*** | ***May*** | ***June*** | ***July*** | ***Total*** |
| **ADR Rate per Total ART Patients Taking the Drug** | | | | | | | | |
| | | | | | | | | |
| **Total ADRs** | | | | | | | | |
| Age <1 | | | | | | | | |
| Age 1–12 | | | | | | | | |
| Age >12 | | | | | | | | |
| No. pregnant patients | | | | | | | | |
| Males | | | | | | | | |
| Females | | | | | | | | |
| | | | | | | | | |
| **ADR Probability Category** | | | | | | | | |
| Definite | | | | | | | | |
| Probable | | | | | | | | |
| Possible | | | | | | | | |
| Doubtful | | | | | | | | |
| | | | | | | | | |
| **Actions Taken** | | | | | | | | |
| Discontinued suspected drug | | | | | | | | |
| Decreased dose of suspected drug | | | | | | | | |
| Other | | | | | | | | |
| | | | | | | | | |
| **Patient Outcomes from ADR** | | | | | | | | |
| Symptoms resolved/improved | | | | | | | | |
| Permanent/significant disability* | | | | | | | | |
| Congenital abnormality* | | | | | | | | |
| Life-threatening* | | | | | | | | |
| Patient death* | | | | | | | | |
| Other | | | | | | | | |
| | | | | | | | | |
| **Interventions Required from ADR** | | | | | | | | |
| Patient counselled | | | | | | | | |
| Drug required to treat reaction | | | | | | | | |
| Additional clinic visit | | | | | | | | |
| Additional labs | | | | | | | | |
| Hospitalisation* | | | | | | | | |
| Other | | | | | | | | |
| | | | | | | | | |

# Antiretroviral Therapy (ART) Adverse Drug Reaction (ADR) Monitoring and Reporting Flow Chart

### Preparation of ADR Form and Actions to be taken on an INDIVIDUAL Level

**Patient** presents with clinical signs or symptoms, or **staff member** suspects an ADR. Referral is made to the Medical Officer.

↓

**Medical Officer**
- Counsels patient referred by staff members, or newly presenting
- Records suspected ADR in both a progress note and in red pen/red sticker on the front of the record if warranted
- Treats patient according to the procedures set out in the ART Programme clinical standard operating procedures

↓

**Medical Officer**
- Records suspected ADR on ADR form and documents actions taken
- Places the original form in record
- Gives a carbon copy of the ADR form to the pharmacist in charge of the ART Programme or to the ART nurse to deliver to the pharmacist

↓

**Pharmacist in charge of the ART Programme**
- Works with the Records Officer to ensure one copy of the ADR form is placed in the patient's record
- Reviews ADR form
- Works with the MO to complete the form and assign an ADR probability category

↓

**Pharmacist in charge of the ART Programme**
- Generates an ADR report which is subsequently attached to the ADR form
- Refers the report to the ART Eligibility Committee

↓

**ART Eligibility Committee**
Reviews the ADR report and the ADR probability estimation

↓

**ART Eligibility Committee**
Decides to take appropriate actions in response to ADRs and/or ADR reports

↓

**Serious** ADRs associated with ADR Probability Category **Definite** or **Probable**

- **Not** listed in the product labelling

Or

- Occurring in drugs < 5 years old since first approved by the Pharmacy and Poisons Board

↓

- Refer patient to the ART Programme Eligibility Committee for further assessment
- Notify the Scientific Committee
- Steering Committee to notify the Pharmacy and Poisons Board on the recommendation of the Scientific Committee. The MOH to notify the manufacturer, if appropriate.

**Serious** ADRs associated with ADR Probability Category **Definite** or **Probable** listed in the product labelling

Grade I and II ADRs associated with ADR Probability Category **Definite** or **Probable not** listed in the product labelling

↓

- Refer patient to the ART Programme Eligibility Committee for further assessment
- Notify the Scientific Committee

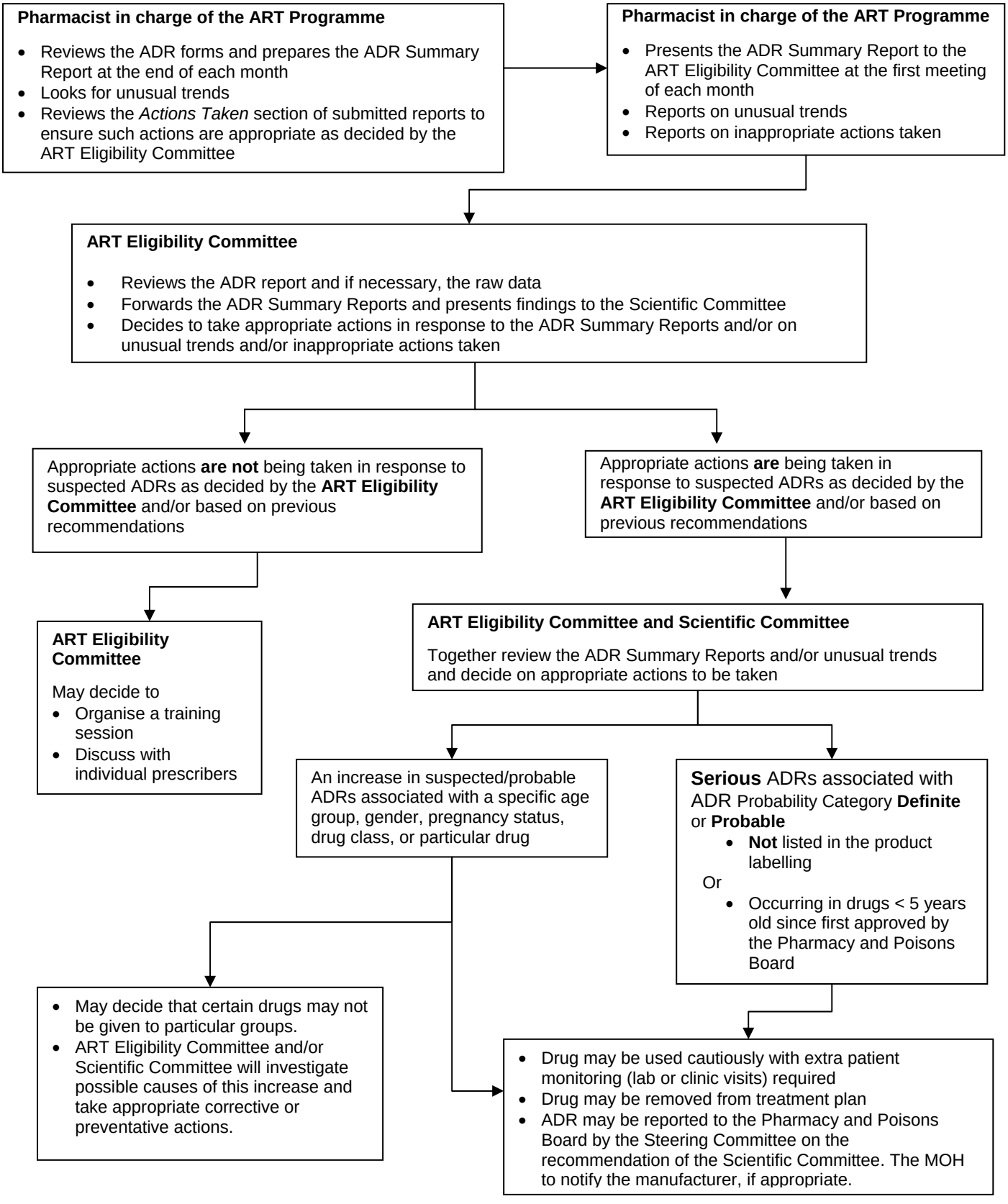
ADRs occurring when the intended medications were not taken at the intended dosages

↓

The MO/RCO/RNO/ pharmacist will contact the ART nurse and take appropriate action.

# Antiretroviral Therapy (ART) Adverse Drug Reaction (ADR) Monitoring and Reporting Flow Chart

## Preparation of ADR Summary Report and Actions to be taken on an AGGREGATE Level



| Coast Provincial General Hospital | |
|---|---|
| **Medication Error Reporting** | |
| Number of pages: 4 | Procedure number: 402 |
| Prepared by: Name:<br>Title:<br>Date: | Reviewed by: Name:<br>Title:<br>Date: |

**Objectives:**

To describe the procedure for reporting medication errors. *Medication Error Reports* are used to make improvements in the medication systems (i.e., design, method of administering medication, training, supervision and monitoring).

**Responsibility:**

- Any hospital health care worker that recognises a medication error.

**Resources:**

Form used to record a medication error:

***Medication Error Report:***

- Is a single loose-leaf form.
- Should be used at all locations where patients receive medications (e.g., outpatient department, wards, operating theatres, radiology department).
- Each ward and department should obtain forms from the ARV bulk store.
- Will be used to make improvements in the medication systems (i.e., design, method of administering medication, training, supervision and monitoring).
- There will not be any legal consequences to recording an error.
- Is not part of the patient's medical record.

**Procedure:**

1. Use the *Medication Error Report* to report:

    - Incorrect drug administered to patient
    - Omitting an ordered dose
    - Incorrect time of administration
    - Incorrect dose
    - Incorrect dosage form
    - Unauthorised prescriber
    - Administration of expired drug
    - Administration of medication to the wrong patient
    - For the ART Programme, to keep a record of prescribing errors

2. Serious medication errors should be investigated by the appropriate person in charge of the concerned department and by the Chief Administrator. This could include the nurse in charge of the unit, the Head of Clinical Services, and/or the Chief Pharmacist.

Steps for completing the *Medication Error Report*:

1. Record:

    - Date and time of error: fill in date and time at which error was made, if known
    - Location of error: state the location(s) at which the incident occurred (e.g., ward name)
    - Patient's name, IP/OP number, and diagnosis
    - Responsible doctor informed at (time/date):
    - By: name and position of person who informed the doctor
    - Staff involved:
        - Positions of staff who were, in any way, involved in the medication error.
        - Names of persons to whom error was immediately reported.
    - Full description: provide a full description of error, including the name of the drug(s) concerned, dosage, route of administration, how the error occurred, and immediate consequences.
    - Patient's status: indicate what the status of the patient was following the medication error
    - Counter measures taken: describe any measures that were taken to counter the effect of the medication error (e.g., gastric lavage).
    - Comments/review by responsible doctor
    - Comments by other responsible person in charge
    - Signature and position of staff completing report
    - Date of report: date report prepared

**Distribution:**

- Original report is forwarded to the responsible person in charge, who discusses it with the doctor/nurse in charge and makes relevant comments indicating an opinion on why the error occurred. Comments from other hospital staff are included as appropriate.
- The completed report is forwarded to the Chief Administrator, who decides on appropriate action to be taken to prevent a repetition of the error, if any.
- A duplicate copy is given to the Chief Pharmacist.
- All reports are kept in a confidential file.

## Coast Provincial General Hospital
## Medication Error Report (Confidential)

1. Date and time of error: _____

2. Location of error: _____

3. Patient's name, IP/OP number and diagnosis: _____

4. Responsible doctor informed at (time/date): _____

By: _____

5. Staff involved: _____

_____

6. Full description (e.g., drug, dosage, route, consequences): _____

_____

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7. Patient's status: _____

_____

8. Counter measures taken: _____

_____

9. Comments/review by responsible doctor: _____

_____

10. Comments by responsible person in charge: _____

_____

Signature: _____ Date of report: ____/____/_____

Position: _____

| Coast Provincial General Hospital | |
|---|---|
| **Temperature Control** | |
| Number of pages: 5 | Procedure number: 501 |
| Prepared by: Name:<br>Title:<br>Date: | Reviewed by: Name:<br>Title:<br>Date: |

**Objective:**

To describe procedures to ensure that antiretroviral drugs are stored at appropriate temperatures to maintain the quality of the products.

**Responsibility:**

- Designated pharmacist in charge of the ARV bulk store or his/her designated proxy
- Designated pharmacy staff member in charge of dispensing for the outpatient pharmacy or his/her designated proxy

**Resources**:

Forms used for temperature control:

- ***Temperature Control Log: ARV Bulk Store***
- ***Temperature Control Log: ARV Bulk Store Refrigerator***
- ***Temperature Control Log: Outpatient Pharmacy ARV Store***

**Procedure:**

1. Monitor the temperature of the ARV bulk store and the outpatient pharmacy TWICE daily. Monitor the temperature of the ARV bulk store refrigerator ONCE daily.

2. Complete the *Temperature Control Log: ARV Bulk Store, Temperature Control Log: ARV Bulk Store Refrigerator,* and the *Temperature Control Log: Outpatient Pharmacy ARV Store* as described below.

3. Acceptable limits for the ARV storage areas are:

   - ARV bulk store and outpatient pharmacy temperature 18–25°C
   - ARV bulk store refrigerator temperature 2–8°C

4. Report temperatures not within acceptable range to the ART Pharmacist or his/her proxy IMMEDIATELY.

5. Check to ensure that the ARV bulk store air-conditioning system is working effectively on a regular basis.

6. Report any problems with the air-conditioning system to the ART Pharmacist or his/her proxy IMMEDIATELY.

7. The ART pharmacist or his/her proxy should inform the Chief Pharmacist and alert the Deputy Administrator and/or Chief Administrator of the need to take immediate action to repair the air-conditioning and/or cool the storage area.

8. The ART pharmacist or his/her proxy should immediately take action as per the pharmacy contingency plan. Alternative measures may include using a fan to cool the ARV bulk store or moving the ARVs to a secure, temperature-controlled storage area.

9. The ART pharmacist is responsible for following up on repairs/action to be taken on a daily basis.

Steps for completing *Temperature Control Log: ARV Bulk Store*

- A.M./P.M. Time: Enter the time the temperature is checked.
- Recorded temp (°C): write down the temperature.
- Acceptable Yes(✓)/No:
  - ✓ if the temperature is within the acceptable range.
  - Write NO if the temperature is outside of the acceptable range.
- Initials

Steps for completing *Temperature Control Log: ARV Bulk Store Refrigerator*

- Time: enter the time the temperature is checked on that day.
- Recorded temp (°C): write down the temperature .
- Within acceptable range:
  - ✓ if the temperature is within the acceptable range.
  - Write NO if the temperature is outside of the acceptable range.
- Initials

Steps for completing *Temperature Control Log: Outpatient Pharmacy ARV Store*

- A.M./P.M. Time: enter the time the temperature is checked .
- Recorded temp (°C): write down the temperature.
- Acceptable Yes(✓)/No:
  - ✓ if the temperature is within the acceptable range.
  - Write NO if the temperature is outside of the acceptable range.
- Initials

**Distribution:**

- The logs in use are pinned up in the relevant area.
- Completed logs are kept on file in the ARV bulk store.

## Coast Provincial General Hospital
## Temperature Control Log: ARV Bulk Store

**Month/Year: ……...../200__**

**Acceptable Range: +18–25°C**

| Date | A.M. Time | Recorded Temp (°C) | Acceptable Yes(✓)/No | Initials | P.M. Time | Recorded Temp (°C) | Acceptable Yes(✓)/No | Initials |
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## Coast Provincial General Hospital
## Temperature Control Log: ARV Bulk Store Refrigerator

**Month/Year: ……..200__**

**Acceptable Range: 2–8°C**

| Date | Time | Recorded Temp (°C) | Within Acceptable Range Yes(✓)/No | Initials |
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## Coast Provincial General Hospital
## Temperature Control Log: Outpatient Pharmacy ARV Store

**Month/Year: ……...../200__**

**Acceptable Range: +18-25°C**

| Date | A.M. Time | Recorded Temp (°C) | Acceptable Yes(✓)/No | Initials | P.M. Time | Recorded Temp (°C) | Acceptable Yes(✓)/No | Initials |
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| Coast Provincial General Hospital | |
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| **Disposal of USAID-Funded Antiretroviral Drugs** | |
| Number of pages: 5 | Procedure number: 502 |
| Prepared by: Name:<br>Title:<br>Date: | Reviewed by: Name:<br>Title:<br>Date: |

**Objectives:**

To describe the procedure for accounting for damaged or expired USAID-funded drugs, or patient returns of USAID-funded antiretroviral drugs that are set aside for disposal.

**Responsibility:**

- The designated pharmacist in charge of the ARV bulk store or his/her designated proxy and a witnessing pharmacy staff member.
- The designated pharmacist in charge of dispensing ARVs from the outpatient pharmacy or his/her designated proxy and a witnessing pharmacy staff member.

**Resources:**

Forms used for recording the removal of ARVs for disposal

***ART Programme: Notification of ARVs Set Aside for Disposal***

- Is a single-page form.

***Report of the Board of Survey on Stores (Unserviceable and Surplus to Requirements) (F.O. 58)***

- Is a single-page form.

Other forms used in recording the removal of ARVs for disposal

- *Stock Count Discrepancy Report*

**Procedure:**

1. The pharmacist in charge of the ARV bulk store:
    - Separates damaged or expired ARVs and makes the necessary adjustments to the *Stores Ledger and Stock Control Card (S3)* and *Bulk Store Bin Cards (S5)* as described for issuing stock in procedure 103: *Record Keeping for USAID-Funded Antiretroviral Drugs at ARV Bulk Store.*

- Completes a *Stock Count Discrepancy Report* as described in procedure 302: *Stock Count Discrepancy Report.*

2. The pharmacist in charge of dispensing ARVs from the outpatient pharmacy:

   - Removes damaged or expired ARVs for storage in the ARV bulk store.

   - Makes the necessary adjustments to the *Hospital Pharmacy Bin Card (MOH 999)* and the *ARV dispensing tool* as described for issuing stock in procedure 106: *Record Keeping for USAID-Funded Antiretroviral Drugs at the Outpatient Pharmacy.*

   - Completes a *Stock Count Discrepancy Report* as described in procedure 302: *Stock Count Discrepancy Report.*

3. Keep all stock set aside for destruction, including patient returns, separate from other stock in the ARV bulk.

4. Complete the *ART Programme: Notification of ARVs Set Aside for Disposal* as described below.

5. The pharmacist in charge of the ART Programme checks the notification and forwards it through the Chief Pharmacist to the Chief Administrator for his/her signature.

6. The Chief Administrator returns the notification to the pharmacist in charge of the ART Programme, who forwards it to the Mombasa ART Programme Technical Assistance Partners (TAP) Coordinator at the FHI Mombasa Office.

7. The FHI TAP coordinator inspects the drugs set aside for destruction and signs and dates the verification.

8. Complete the *Report of the Board of Survey on Stores (Unserviceable and Surplus to Requirements) (F.O. 58)* as described below and submit the *F.O. 58* to Board of Survey.

9. The Board of Survey is convened and boards the drugs. A list of drugs and their value is sent to the Permanent Secretary for Health, who authorises the destruction of the ARVs.

Steps for completing *ART Programme: Notification of ARVs set aside for disposal*

1. Record:

   - Date set aside

   - Location: *ARV bulk store* or *outpatient pharmacy*

   - Bin card number: from *S5* or *MOH 999*

   - Item description:
     - Generic name
     - Strength/concentration
     - Dosage form

   - Unit of issue

- Quantity set aside for disposal

- A complete explanation of the reason why the drugs were set aside for disposal (damaged product, expiration of product, unusable patient returns, etc.)

2. The form is signed and dated by both the person setting aside the stock for disposal and a witnessing pharmacist.

Steps for completing *Report of the Board of Survey on Stores (Unserviceable and Surplus to Requirements) (F.O.58)*

1. Record:

   - Ministry of: *Health;* Department: *Medical;* Station: *Coast Provincial General Hospital*

   - Complete the table:
     - Column 1: Item No.
     - Column 2: Article: generic name; strength/concentration; dosage form
     - Column 3: Quantity: write in quantity to be destroyed
     - Column 4: Date of Purchase: write date the product was delivered to CPGH
     - Column 5: Original value: insert value if known
     - Column 6: State whether Unserviceable or Surplus: *Unserviceable*

2. Signature and Official Designation of Officer-in-Charge of Stores: Sign; state position, and date the form.

**Distribution:**

*ART Programme: Notification of ARVs Set Aside for Disposal*

- The original is forwarded to the Mombasa ART Programme TAP Coordinator at the FHI Mombasa Office.

- One copy of the completed and signed *ART Programme: Notification of ARVs Set Aside for Disposal* is kept in the ARV bulk store.

- One copy of the completed and signed *ART Programme: Notification of ARVs Set Aside for Disposal* is retained by the Chief Pharmacist.

# Coast Provincial General Hospital
# ART Programme: Notification of ARVs Set Aside for Disposal

To Technical Assistance Partners (TAP) Coordinator, Mombasa ART Programme, FHI/IMPACT

Coast Provincial General Hospital wishes to notify you that the following antiretroviral drug purchased by FHI for the Mombasa ART Programme has been set aside for disposal.

| | | |
|---|---|---|
| Date set aside: ……. | Location: …… | Bin card number: …… |
| Item description: ……. | Unit of issue: ……... | Quantity set aside: …… |
| **Details and Explanation** | | |
| ☐ Damaged | Details of damage/breakage and cause | |
| ☐ Expired<br><br>Date of shipment: ……<br>Date of expiry: …… | Details of expired stock and explanation: | |
| ☐ Patient returns<br><br>Patient's name: ……<br>Date dispensed: …….. | Details and explanation: | |
| ☐ Other | Details and explanation: | |
| …… Pharmacy staff member in charge of ARV bulk store: name and signature | | ……... Date |
| …… Witnessing Pharmacist: name and signature: | | ……... Date |

Please arrange to authenticate the ARV drugs set aside for disposal.

Yours sincerely,

**…….** Date……/200….
Chief Administrator

Verified by:
**…….** Date……/200…
FHI TAP Coordinator

**REPUBLIC OF KENYA** F.O. 58

# REPORT OF THE BOARD OF SURVEY ON STORES (UNSERVICEABLE AND SURPLUS TO REQUIREMENTS)

Ministry of …… ……Department Station…….

N.B.-Column Nos. 1–6 to be completed by the Department prior to the assembly of the Board.

| 1<br>ITEM No. | 2<br>ARTICLE | 3<br>QUANTITY | 4<br>DATE OF PURCHASE | 5<br>ORIGINAL VALUE | 6<br>State whether Unserviceable or Surplus | 7<br>BOARD'S REPORT ON CONDITION | 8<br>RECOMMENDATION OF BOARD FOR DISPOSAL | 9<br>ESTIMATED LOCAL SALEABLE VALUE IF SALE IS RECOMMENDED | 10<br>REMARKS |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | |

| | | DECISION OF: - | |
|---|---|---|---|
| .....*Signature and Official Designation of Officer-* ……*in-Charge of Stores*<br><br>*Date*……..*Station* | ……..Chairman<br>……..……..Member<br>……..……..……Member<br><br>*Date*……..*Station* | **ACCOUNTING OFFICER**<br>……<br>*Accounting Officer*<br><br>*Date*…… | **TREASURY**<br>……<br>*For Minister for Finance*<br><br>*Date*…… |

| Coast Provincial General Hospital | |
|---|---|
| **Disposal of GOK Antiretroviral Drugs** | |
| Number of pages: 2 | Procedure number: 503 |
| Prepared by: Name:<br>Title:<br>Date: | Reviewed by: Name:<br>Title:<br>Date: |

**Objectives:**

To describe the procedure for accounting for damaged or expired GOK drugs, or patient returns of GOK antiretroviral drugs that are set aside for disposal.

**Responsibility:**

- The designated pharmacist in charge of the ARV bulk store or his/her designated proxy and a witnessing pharmacy staff member.

- The designated pharmacist in charge of dispensing ARVs from the outpatient pharmacy or his/her designated proxy and a witnessing pharmacy staff member.

**Resources:**

Forms used for recording the removal of ARVs for disposal:

***Report of the Board of Survey on Stores (Unserviceable and Surplus to Requirements) (F.O. 58)***

- Is a single-page form.

Other forms used in recording the removal of ARVs for disposal:

- *Stock Count Discrepancy Report*

**Procedure:**

1. The pharmacist in charge of the ARV bulk store:

    - Separates damaged or expired ARVs and makes the necessary adjustments to the *Bulk Store Bin Cards (S5)* and *Diflucan & ART Daily Activity Register* as described for issuing stock in procedure 203: *Record Keeping for GOK Antiretroviral Drugs at ARV Bulk Store.*

    - Completes a *Stock Count Discrepancy Report* as described in procedure 302: *Stock Count Discrepancy Report.*

2. The pharmacist in charge of dispensing ARVs from the outpatient pharmacy:

    - Removes damaged or expired ARVs for storage in the ARV bulk store.

    - Makes the necessary adjustments to the *Hospital Pharmacy Bin Card (MOH 999)* and/or the *ARV dispensing tool* and *Diflucan & ART Daily Activity Register* as described for issuing stock in procedure 205: *Record Keeping for GOK Antiretroviral Drugs at the Outpatient Pharmacy.*

    - Completes a *Stock Count Discrepancy Report* as described in procedure 302: *Stock Count Discrepancy Report.*

3. Keep all stock set aside for destruction, including patient returns, separate from other stock in the ARV bulk store.

4. Complete the *Report of the Board of Survey on Stores (Unserviceable and Surplus to Requirements) (F.O. 58)* as described in procedure 502: *Disposal of GOK Antiretroviral Drugs* and submit the *F.O. 58* to the Board of Survey.

5. The Board of Survey is convened and boards the drugs. A list of drugs and their value is sent to the Permanent Secretary for Health, who authorises the destruction of the ARVs.

| Coast Provincial General Hospital | |
|---|---|
| **Security of Antiretroviral Drugs** | |
| Number of pages: 2 | Procedure number: 504 |
| Prepared by: Name:<br>Title:<br>Date: | Reviewed by: Name:<br>Title:<br>Date: |

**Objective:**

To describe correct security measures and responsibilities to decrease the risk of diversion of antiretroviral drugs.

**Responsibility:**

- Designated pharmacist in charge of the ARV bulk store or his/her designated proxy
- Designated pharmacy staff member in charge of dispensing ARVs in the outpatient pharmacy or his/her designated proxy

**Procedure:**

Storage of ARVs in the ARV bulk store:

1. All ARVs will be stored separately from other stock in a *locked* cupboard in the ARV bulk store.
2. Keep the door to the ARV bulk store and the cupboard(s) locked at all times.
3. Only the designated pharmacist in charge should have access to the ARV bulk store.
4. The designated pharmacist in charge of the ARV bulk store will:
    - Keep the key to the ARV bulk store and cupboard in his/her possession at all times whilst in the pharmacy.
    - Never leave the key outside of his/her direct control (e.g., the key should never be hung on the wall).

Storage of ARVs in the outpatient pharmacy:

1. All ARVs will be stored separately from other stock in a *locked* cupboard in the outpatient pharmacy.
2. The cupboard(s) should be locked at all times.
3. Only the designated pharmacist or pharmaceutical technologist should have access to the ARV cupboard(s) in the outpatient pharmacy.

4. The designated pharmacist in charge of dispensing ARVs in the outpatient pharmacy will:

    - Keep the key to the ARV cupboard in the outpatient pharmacy in his/her possession at all times.

    - Never leave the key outside of his/her direct control (e.g., the key should never be left on the dispensing counter).

Storage of ARVs on the wards:

1. All ARVs will be stored in a *locked* drug cupboard as per normal nursing procedures.

2. The cupboard(s) should be locked at all times.

3. Only the designated authorised nursing staff should have access to the cupboard where the ARVs are stored.

4. The designated nurse in charge of the ward will:

    - Keep the key to the drug cupboard in his/her possession at all times.

    - Never leave the key outside of his/her direct control (e.g., the key should never be hung on the wall).

| Coast Provincial General Hospital | |
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| **Internal Audit of Antiretroviral Drugs** | |
| Number of pages: 7 | Procedure number: 601 |
| Prepared by: Name:<br>Title:<br>Date: | Reviewed by: Name:<br>Title:<br>Date: |

**Objective:**

To describe the procedure for performing a bimonthly (every other month) audit on storage, prescribing, and dispensing of antiretroviral drugs (ARVs). The results of the internal audit will monitor the integrity of the ART Programme in regard to the correct management of the ARVs. Results of the internal audit may be used in external audits as a reference.

**Responsibility:**

Internal audit of ARVs will be performed by the CPGH Audit Committee every two months. The members of the CPGH Audit Committee will be appointed by the Chief Administrator.

**Resources:**

Forms needed:

***ART Programme: Pharmacy Internal Audit***

- Is a four-page report.

***ART Programme: Pharmacy Audit Feedback Report to Chief Administrator***

- Is a one-page report.

Forms used to calculate internal audit data:

- *Prescription Forms (MOH 501)*
- Patient eligibility list
- Authorised prescribers' signature record
- *ART Patient Dispensing Records*
- *Bulk Store Bin Cards (S5)*
- *Shipment Discrepancy Report*
- *Hospital Pharmacy Bin Cards (MOH 999)*
- *Stock Count Discrepancy Report*
- Temperature logs in ARV bulk store, ARV bulk store refrigerator, and outpatient pharmacy

**Procedure:**

1. The Audit Committee uses the *ART Programme: Pharmacy Internal Audit* form to perform the internal audit on the first day of every other month.

2. The Audit Committee performs the audit at a scheduled time and date.

3. The Audit Committee shares the results of the audit with the Chief Pharmacist and the pharmacist in charge of the ART Programme. The pharmacy department is given 15 days to rectify problems, if any.

4. After 15 days the Audit Committee completes the *ART Programme: Pharmacy Audit Feedback Report to Chief Administrator*.

5. The report is presented by the Audit Committee in a meeting with the Chief Administrator, Chief Pharmacist, and pharmacist in charge of the ART Programme, who will decide on the action(s) to be taken to correct any areas of concern.

**Distribution of Reports:**

- *ART Programme: Pharmacy Internal Audit* is retained by the Audit Committee.

- *ART Programme: Pharmacy Audit Feedback Report to Chief Administrator* is retained by the Audit Committee with a copy provided to the Chief Administrator and Chief Pharmacist.

**Form No: FMAF**

# COAST PROVINCIAL GENERAL HOSPITAL
# ART PROGRAMME: PHARMACY INTERNAL AUDIT

*(The audit will be carried out by the Audit Committee on the first day of every other month The result of the audit will then be shared with the Chief Pharmacist and pharmacist in charge of the ART Programme. The pharmacy department will be given 15 days to rectify the problems, if any. An audit report will then be prepared.)*

| Sr | Procedure | Month……. | Month…….. | Month…….. |
|---|---|---|---|---|
| **Adherence to Prescribing and Dispensing Guidelines** | | | | |
| 1. | a. Pick *x*[1] prescriptions at random issued in the month and write as Total Prescriptions.<br>b. Examine all the above prescriptions and count those which are issued to eligible clients and write as Total Eligible.<br>c. a and b should match. If they do not, write the reasons in remarks section and your instructions under advice. | Total Prescrip:<br>Total Eligible:<br><br>Remarks:<br><br>Advice: | Total Prescrip:<br>Total Eligible:<br><br>Remarks:<br><br>Advice: | Total Prescrip:<br>Total Eligible:<br><br>Remarks:<br><br>Advice: |
| 2. | a. Pick *x* prescriptions at random dispensed in the month and write as Total Dispensed.<br>b. Examine all the above prescriptions and count those which are dispensed to eligible clients and write as Total Eligible.<br>c. a and b should match. If they do not, write the reasons in remarks section and your instructions under advice. | Total Dispen:<br>Total Eligible:<br><br>Remarks:<br><br>Advice: | Total Dispen:<br>Total Eligible:<br><br>Remarks:<br><br>Advice: | Total Dispen:<br>Total Eligible:<br><br>Remarks:<br><br>Advice: |
| 3. | a. Pick *x* prescriptions at random dispensed in the month and write as Total Dispensed.<br>b. Examine all the above prescriptions and count those which bear authorised signatures and write as Total Authorised.<br>c. a and b should match. If they do not, write the reasons in remarks section and your instructions under advice. | Total Dispen:<br>Total Autho:<br><br>Remarks:<br><br>Advice: | Total Dispen:<br>Total Autho:<br><br>Remarks:<br><br>Advice: | Total Dispen:<br>Total Autho:<br><br>Remarks:<br><br>Advice: |

[1] The value of *x* depends on the number of prescriptions issued during the month. If the number is less than 5, take all; if the number is 5 or more, pick at least 5.

| Sr | Procedure | Month……. | Month…….. | Month…….. |
|---|---|---|---|---|
| 4. | a. Pick *x* prescriptions at random dispensed in the month and write as Total Dispensed.<br>b. Examine the ART Patient Dispensing Records for all the above prescriptions and count those which were dispensed either late or early by at least 3 days and write as Total Early/Late.<br>c. b should be as low as possible (ideally 0). If it is not a low number, write the reasons in remarks section and your instructions under advice. | Total Dispen:<br>Total Early/Late:<br><br>Remarks:<br><br>Advice: | Total Dispen:<br>Total Early/Late:<br><br>Remarks:<br><br>Advice: | Total Dispen:<br>Total Early/Late:<br><br>Remarks:<br><br>Advice: |
| **Stock in ARV Bulk and Outpatient Pharmacy Stores** | | | | |
| 5. | a. Pick 3 bin cards from the ARV bulk store at random and write the current stock.<br>b. Count the quantity of corresponding drugs and write the count stock.<br>c. a and b should match. If they do not, find out if the discrepancies are accounted for, state the reasons in remarks section, and write your instructions under advice, if any.<br>d. If the current stock of a drug is 0, take this as an out-of-stock situation, find out why this happened, and note in remarks section. | Bin Stock:<br>Count Stock:<br><br>Bin Stock:<br>Count Stock:<br><br>Bin Stock:<br>Count Stock:<br><br>Remarks:<br><br>Advice: | Bin Stock:<br>Count Stock:<br><br>Bin Stock:<br>Count Stock:<br><br>Bin Stock:<br>Count Stock:<br><br>Remarks:<br><br>Advice: | Bin Stock:<br>Count Stock:<br><br>Bin Stock:<br>Count Stock:<br><br>Bin Stock:<br>Count Stock:<br><br>Remarks:<br><br>Advice: |
| 6. | a. Pick 3 bin cards from the outpatient pharmacy store at random and write the current stock.<br>b. Count the quantity of corresponding drugs and write the count stock.<br>c. a and b should match. If they do not, find out if the discrepancies are accounted for, state the reasons in remarks section, and write your instructions under advice, if any.<br>d. If the current stock of a drug is 0, take this as an out-of-stock situation, find out why this happened, and note in remarks section. | Bin Stock:<br>Count Stock:<br><br>Bin Stock:<br>Count Stock:<br><br>Bin Stock:<br>Count Stock:<br><br>Remarks:<br><br>Advice: | Bin Stock:<br>Count Stock:<br><br>Bin Stock:<br>Count Stock:<br><br>Bin Stock:<br>Count Stock:<br><br>Remarks:<br><br>Advice: | Bin Stock:<br>Count Stock:<br><br>Bin Stock:<br>Count Stock:<br><br>Bin Stock:<br>Count Stock:<br><br>Remarks:<br><br>Advice: |

| Sr | Procedure | Month……. | Month…….. | Month…….. |
|---|---|---|---|---|
| 7. | a. Pick 3 bin cards from the ARV bulk store at random and note the date, name of the drug, and quantity issued to the outpatient pharmacy store.<br>b. Select the bin cards from the outpatient pharmacy store for the drugs listed in (a) and verify if the entries match with the quantities listed in (a).<br>c. a and b should match. If they do not, find out if the discrepancies are accounted for, state the reasons in remarks section, and write your instructions under advice, if any. | Bulk Bin Stock:<br>Phar Bin Stock:<br><br>Bulk Bin Stock:<br>Phar Bin Stock:<br><br>Bulk Bin Stock:<br>Phar Bin Stock:<br><br>Remarks:<br><br>Advice: | Bulk Bin Stock:<br>Phar Bin Stock:<br><br>Bulk Bin Stock:<br>Phar Bin Stock:<br><br>Bulk Bin Stock:<br>Phar Bin Stock:<br><br>Remarks:<br><br>Advice: | Bulk Bin Stock:<br>Phar Bin Stock:<br><br>Bulk Bin Stock:<br>Phar Bin Stock:<br><br>Bulk Bin Stock:<br>Phar Bin Stock:<br><br>Remarks:<br><br>Advice: |
| **Temperature Control** | | | | |
| 8. | a. Select 3 days at random from the month. Check the temperature log of the ARV bulk store and find out if the log was completed twice for each of the days selected. If yes, put √ against each day.<br>b. Next, if a day is checked, find out if the temperature was within the acceptable limits. If yes, put another √.<br>c. All days should have √√. If they do not, discuss and find out the reasons and list reasons in remarks section and your instructions under advice, if any. | Day x:<br>Day y:<br>Day z:<br><br>Remarks:<br><br>Advice: | Day x:<br>Day y:<br>Day z:<br><br>Remarks:<br><br>Advice: | Day x:<br>Day y:<br>Day z:<br><br>Remarks:<br><br>Advice: |
| 9. | a. Select 3 days at random from the month. Check the temperature log of the outpatient pharmacy and find out if the log was completed twice for each of the days selected. If yes, put √ against each day.<br>b. Next, if a day is checked, find out if the temperature was within the acceptable limits. If yes, put another √.<br>c. All days should have √√. If they do not, discuss and find out the reasons and list reasons in remarks section and your instructions under advice, if any. | Day p:<br>Day q:<br>Day r:<br><br>Remarks:<br><br>Advice: | Day p:<br>Day q:<br>Day r:<br><br>Remarks:<br><br>Advice: | Day p:<br>Day q:<br>Day r:<br><br>Remarks:<br><br>Advice: |

| Sr | Procedure | Month……. | Month…….. | Month…….. |
|---|---|---|---|---|
| 10. | a. Select 3 days at random from the month. Check the temperature log of the ARV bulk store refrigerator and find out if the log was completed once for each of the days selected. If yes, put √ against each day.<br>b. Next, if a day is checked, find out if the temperature was within the acceptable limits. If yes, put another √.<br>c. <u>All days should have √√.</u> If they do not, discuss and find out the reasons and list reasons in remarks section and your instructions under advice, if any. | Day p:<br>Day q:<br>Day r:<br><br>Remarks:<br><br><br>Advice: | Day p:<br>Day q:<br>Day r:<br><br>Remarks:<br><br><br>Advice: | Day p:<br>Day q:<br>Day r:<br><br>Remarks:<br><br><br>Advice: |

## COAST PROVINCIAL GENERAL HOSPITAL
## ART PROGRAMME: PHARMACY AUDIT FEEDBACK REPORT TO CHIEF ADMINISTRATOR

*(The report will be presented by the Audit Committee in a meeting with the Chief Administrator, Chief Pharmacist, and pharmacist in charge of the ART Programme. This document will be retained by the Audit Committee with a copy provided to the Chief Administrator and Chief Pharmacist.)*

| Sr | Procedure | **Month……..**<br>Signature of Chief Administrator:<br>Chief Pharmacist:<br>Audit Committee Chair: | **Month…….**<br>Signature of Chief Administrator:<br>Chief Pharmacist:<br>Audit Committee Chair: |
|---|---|---|---|
| **Adherence to Prescribing and Dispensing Guidelines** | | | |
| | 1. List of improvements from last audit<br>2. What was done to improve?<br>3. New issues this month<br>4. Issues still pending, with reasons | | |
| **Stock in ARV Bulk and Outpatient Pharmacy Stores** | | | |
| | 1. List of improvements from last audit<br>2. What was done to improve?<br>3. New issues this month<br>4. Issues still pending, with reasons | | |
| **Temperature Control** | | | |
| | 1. List of improvements from last audit<br>2. What was done to improve?<br>3. New issues this month<br>4. Issues still pending, with reasons | | |

| Coast Provincial General Hospital | |
|---|---|
| **Pharmacy Activity Report for the ART Programme** | |
| Number of pages: 6 | Procedure number: 602 |
| Prepared by: Name:<br>Title:<br>Date: | Reviewed by: Name:<br>Title:<br>Date: |

**Objective:**

To describe the procedure to prepare the two-weekly (every other week) *ART Programme: Pharmacy Activity Report*. The objectives of the report are:

- To monitor the integrity of the ART Programme in regard to the correct management of the ARVs—inventory management, breakages and losses, and record-keeping procedures.

- To serve as a management reporting tool on ART Programme activity, status of ARVs in stock and on order, and administrative and maintenance problems that are affecting the ART Programme.

**Responsibility:**

- The pharmacist in charge of the ART Programme prepares the *ART Programme—Pharmacy Activity Report*.

- The Chief Pharmacist and the Chief Administrator jointly review and comment on the report and take action as appropriate

**Resources:**

Forms needed:

***ART Programme—Pharmacy Activity Report***

- Is a four-page report.

Forms used to prepare the activity report:

- *Prescription Forms (MOH 501)*
- *Hospital Pharmacy Bin Cards (MOH 999)*
- *ARV Prepacking Record*
- *Bulk Store Bin Cards (S5)*
- *ART Programme: Request to Supply Antiretroviral Drugs*
- *Shipment Discrepancy Report*
- *Stock Count Discrepancy Report*
- *Chart to Track the Expiry Dates of ARVs*
- Temperature logs in ARV bulk store, ARV bulk store refrigerator, and outpatient pharmacy

**Procedure:**

- The pharmacist in charge of the ART Programme works with the pharmacist in charge of the ARV bulk store every two weeks to prepare the *ART Programme—Pharmacy Activity Report*.

- The pharmacist in charge of the ART Programme discusses the report in a meeting with the Chief Pharmacist and the Hospital Administrator. The Chief Pharmacist records any comments and signs the report.

**Distribution:**

- The completed report is kept by pharmacist in charge of the ART Programme.

**Form No: FWAR**

# COAST PROVINCIAL GENERAL HOSPITAL
# ART PROGRAMME: PHARMACY ACTIVITY REPORT

*(Prepared by the pharmacist in charge of ART Programme on a bimonthly basis. The report is to be reviewed in person with the Chief Pharmacist and the Chief Administrator. The Chief Pharmacist records comment and signs. The report is retained by the pharmacist in charge of the ART Programme.)*

<table>
<tr><td colspan="2">Facility Name:<br>Year:</td><td colspan="5">Month:……..</td></tr>
<tr><td>Sr</td><td>Activity</td><td colspan="3">Week 2 (From…..  To ……)<br>(Comment and signature of the Chief Pharmacist)</td><td colspan="3">Week 4 (From…..  To ……)<br>(Comment and signature of the Chief Pharmacist)</td></tr>
<tr><td rowspan="2">1.</td><td rowspan="2">Dispensing of ARV drugs</td><td>#New clients:</td><td>USAID</td><td>GOK<br>Pay / NPay</td><td></td><td>#New clients:</td><td>USAID</td><td>GOK<br>Pay / NPay</td></tr>
<tr><td>#Repeat clients:</td><td></td><td></td><td></td><td>#Repeat clients:</td><td></td><td></td></tr>
<tr><td>2.</td><td>DAART study</td><td>#Pre-packs prepared:</td><td colspan="3"></td><td>#Pre-packs prepared:</td><td colspan="2"></td></tr>
<tr><td></td><td></td><td>#Clients counselled:</td><td colspan="3"></td><td>#Clients counselled:</td><td colspan="2"></td></tr>
<tr><td>3.</td><td>Stock count<br>Do the bin cards and physical count of all the ARV drugs exactly match?<br>Put √ if yes. If no, give reasons.</td><td colspan="3">GOK<br>Bulk store:<br>Pharmacy:<br><br>Reasons:</td><td colspan="3">USAID<br>Bulk store:<br>Pharmacy:<br><br>Reasons:</td></tr>
</table>

| Sr | Activity | Week 2 | Week 4 |
|---|---|---|---|
| **4.** | **Stock on order**<br>*(List the ARV preparations on order.)* | GOK<br>ARV Qty<br>1…… ……..<br>2…….. …… ……..<br>3…… ……..<br>4…….. …… ……..<br>5…….. …… ……..<br>6…… . ……..<br>7…… ……..<br>8…….. …… …….. | USAID<br>ARV Qty<br>1…….. …… ……..<br>2…….. …… ……..<br>3…… ……..<br>4…….. …… ……..<br>5…….. …… ……..<br>6…….. …… ……..<br>7…… ……..<br>8…….. …… …….. |
| **5.** | **Stock received**<br>*(List the ARV preparations which were received during the last two weeks..)* | GOK<br>ARV Qty<br>1…… ……<br>2…… ……<br>3…… ……<br>4…… ……<br>5…… ……<br>6…… ……<br>7…… ……<br>8…… ……<br>USAID<br>ARV Qty<br>1…… ……<br>2…… ……<br>3…… ……<br>4…… ……<br>5…… ……<br>6…… ……<br>7…… ……<br>8…… …… | GOK<br>ARV Qty<br>1…….. ……<br>2…….. ……<br>3…….. ……<br>4…….. ……<br>5…….. ……<br>6…….. ……<br>7…….. ……<br>8…….. ……<br>USAID<br>ARV Qty<br>1…… ……<br>2……. ……<br>3……. ……<br>4……. ……<br>5……. ……<br>6…… ……<br>7…… ……<br>8…….. . …… |
| **6.** | **Stock losses**<br>*(List the ARV preparations which were damaged, expired, unaccounted for, etc., in the last month.)* | GOK<br>ARV Qty Reason:<br>1…… ……<br>2…….. ……<br>3…… ……<br>4…… …… | USAID<br>ARV Qty Reason:<br>1…….. ……<br>2…….. ……<br>3…… ……<br>4…….. … . …… |
| **7.** | **Short-dated stock**<br>*(List of ARV preparations with less than 8 months' expiry)*<br>Note: *Action* refers to activities such as alerting FHI or KEMSA for exchange, etc. | GOK<br>ARV Qty Action:<br>1…….. ……<br>2…….. ……<br>3…….. ……<br>4…….. …… | USAID<br>ARV Qty Action:<br>1…….. ……<br>2…….. … ……<br>3…… ……<br>4…….. … …… |

| Sr | Activity | Week 2 | Week 4 |
|---|---|---|---|
| **8.** | **Out of stock**<br>*(List of ARV preparations where the count of stock at the bulk store is at 0 level.)* | GOK<br>ARV — No. of days<br>1…….. …… — ……<br>2…….. …… — ……<br>3…… — ……<br>4…….. …… — …… | USAID<br>ARV — No. of days<br>1…….. …… — ……<br>2…….. …… — ……<br>3…… — ……<br>4…….. …… — …… |
| **9.** | **Bulk store and outpatient pharmacy stock correspond.**[1]<br>Put √ if yes. If the tally is not perfect, state the reasons. | GOK<br>Perfectly tally:<br>Only few tally:<br>Do not tally at all:<br><br>Reasons/actions: | USAID<br>Perfectly tally:<br>Only few tally:<br>Do not tally at all:<br><br>Reasons/actions: |
| **10.** | **Temperature control of ARV refrigerators Is satisfactory.**[2]<br>Put √ if yes. If it is not satisfactory, state the reasons. | ARV refrigerators:<br><br>Reasons/actions: | ARV refrigerators:<br><br>Reasons/actions: |
| **11.** | **Temperature control of ARV bulk store and outpatient pharmacy Is satisfactory**.[3]<br>Put √ if yes. If it is not satisfactory, state the reasons. | Bulk store:<br>Outpatient pharmacy:<br><br>Reasons/actions: | Bulk store:<br>Outpatient pharmacy:<br><br>Reasons/actions: |
| **12.** | **Are there any problems with equipment/storage cupboards or storage conditions that are affecting the ART Programme?** | Problems:<br><br><br>Request for help: | |

[1] Make a list of the drug and quantity that were issued from bulk store to outpatient pharmacy during the week and tally the list with the entries in the outpatient pharmacy bin cards.
[2] Check if the temperature was checked once a day and that the temperature was within the acceptable range.
[3] Check if the temperature was checked twice a day and that the temperature was within the acceptable range.

| Sr | Activity | Week 2 | Week 4 |
|---|---|---|---|
| **13.** | **Are there any other issues that are affecting the ART Programme (e.g., staffing, prescription forgeries, prescriptions for ineligible patients, etc.)?** | Issues:<br>1……..<br>2…….<br>3……..<br>(Describe if required.) | |
| **14.** | **ART Programme Pharmacy Staff Rota is prepared for the following two weeks.** | Yes/no | Yes/no |