LIMPOPO PROVINCE PRIMARY HEALTH CARE (PHC) STANDARD OPERATING PROCEDURES

Revision 1 (February 2014)
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FOREWORD

Limpopo Pharmaceutical Services is proud to present the 2013 edition of *Standard Operating Procedures (SOPs) for Primary Health Care*. The previous edition was published on November 28, 1997, and the updating of these SOPs was long overdue. Revisions started in February 2013, following the National Core Standard assessments performed at clinics in 2012. In all clinics, one of the major shortcomings was the unavailability of updated SOPs, hence this initiative of compiling a new set of SOPs. Extensive work has been put into the compilation, and several people and organizations were consulted to realize this dream.

The SOPs in this booklet are twenty five in total, and they will be reviewed every two years. The importance of having SOPs in a working environment cannot be emphasized more, as they are living documents that detail written instructions on how to perform specific functions or activities. On a daily basis, primary health care personnel will be able to perform their duties in a standardized manner. It is the responsibility of every health care provider to ensure that the SOPs are implemented at operational level to ensure standardization of practices and procedures.

I am grateful to the pharmacists and other professionals who worked tirelessly, despite their demanding schedules. The number of comments and guidance received from individuals during this journey is appreciated.

It is our wish that all health care professionals at the facility level will make use of this document.

Head of Department (Dr. S. Kabane)
ACKNOWLEDGMENT

Pharmaceutical Services wishes to thank all the people and organizations that participated in the compilation of these SOPs. To try and mention all of them will risk leaving out some of the contributors.

It is important to mention that the SOPs were developed following the recommendation of Pharmaceutical Services management. The Regulatory Affairs and Quality Assurance division facilitated the process; our partners at the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program took part in the review, development, finalization, and printing; the Foundation for Professional Development sponsored the meetings; and ANOVA Health Institute printed the Mopani PHC copies.

The contributions of everyone involved are acknowledged with special thanks to the following:

Limpopo Department of Health
Pharmaceutical Services Provincial Office
Pharmaceutical Depot
Limpopo Hospital Pharmacy Managers
District Pharmaceutical Managers
Systems for Improved Access to Pharmaceuticals and Services (implemented by Management Sciences for Health)
Foundation for Professional Development
ANOVA Health Institute
SOP 01 – SOP FOR THE PREPARATION/REVISION OF AN SOP

Department of Health

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Objective

To lay down a procedure for the preparation, approval, authorization, control, and revision of SOPs

Standards

Measure of activity to be performed

Responsible staff

Personnel responsible for ensuring SOP implementation

Policies, references, and source materials

Laws, policies, acts, and regulations

Definition of terms and concepts

SOP: standard operating procedure

Tools, materials, and equipment

Tools or materials needed for the activity to be performed

Safety precautions

Any safety and/or security measures that must be

Monitoring and evaluation

Measure against the standard

Record keeping

Record of amendment of the SOP

Procedure
Write the SOP with the following headings:

SOP number

Sequence of the SOP
- SOP title – name of the SOP
- Institution – health facility
- Issue date – date the SOP was first issued
- Effective date - date of implementation
- Review date – date the SOP is to be reviewed (two years after issue date)

Number of pages including cover

Original author of the SOP
- Directorate developing the SOP

Issued by
- Directorate/section that developed the SOP

Record of amendment
- Date and record of changes made to a specific area in an SOP

Objectives
- Reason(s) for preparing the SOP in one or two sentences starting with “To”

Standards
- Expected level of effort to be attained

Responsible staff
- List the designation of the person/persons who are directly responsible for the operations mentioned in the SOP’s purpose

Policies, references, and source materials
- Provide a list of references or any other guiding documents that are the basis for the SOP; if there is no reference, fill in “NA” for not applicable
Definitions and concepts

- Include statements that explain the meaning of a term
- Include all abbreviations and their definitions; if there are no abbreviations fill in “NA” for not applicable

Tools, materials, and equipment

- List the tools, materials, and equipment needed to carry out the specific SOP

Safety precautions

- List the necessary precautions to take and consider when carrying out the SOP

Monitoring and evaluation

- List the standard intervals at which the effectiveness of the SOP will be reviewed

Record keeping

- Provide a list of documents needed to carry out the SOP

Procedure

- Write the procedure/method in short sentences, not in long paragraphs
- Mention all the checks to be carried out, records to be maintained, frequency of various operations, checks, etc.

Compiled by

- Name of the pharmacist(s) and pharmaceutical directorate

Checked by

- Name of the person with subject matter knowledge and the name of their department

Approved by

- Responsible pharmacist or designee

Authorized by

- Regulatory Affairs and Quality Assurance
SOP 02 – STOCK TAKE AT PRIMARY HEALTH CARE AND COMMUNITY HEALTH CENTRES

Department of Health

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Objective

To ensure compliance with Public Finance Management Act on stock taking

Standards

Stock on shelf should balance stock on the card/ stock control system

Responsible staff

- Assistant manager PHC
- Clinic (operational) manager
- Community service pharmacist
- District pharmacy managers
- Hospital pharmacists

Policies, references, and source materials

- Good Pharmacy Practice
- Managing Access to Medicines and Health Technologies
- Medicines and Related Substances Act (Act 101 of 1965) as amended
- Pharmacy Act (Act 53 of 1974) as amended
- Public Finance Management Act (Act 1 of 1999)

Definition of terms and concepts

- CHC: community health center
- PHC: primary health care
- RAQA: Regulatory Affairs and Quality Assurance
- SOP: standard operating procedure

Tools, materials, equipment, and other resources

- Stock take list/form
- Stock card
- Pens
<table>
<thead>
<tr>
<th>Safety precautions</th>
<th>Calculators</th>
<th>Computer and printer (for capturing)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Do not count unusable stock (expired, damaged, soiled, etc.)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Do not count stock already issued to consulting rooms</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Stock take is performed in September and March every year</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Stock take lists are to be completed in duplicate</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Counting team must initial each page on the stock take list/form</td>
<td></td>
</tr>
<tr>
<td>Monitoring and evaluation</td>
<td>Stock take records (Annex 1. Example of Limpopo Clinic Stock Take Sheet)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Value of stock counted (pre- and post-stock take values)</td>
<td></td>
</tr>
<tr>
<td>Record keeping</td>
<td>Completed stock take records and updated stock cards/stock control system</td>
<td></td>
</tr>
</tbody>
</table>

**Procedure**

<table>
<thead>
<tr>
<th></th>
<th>The operational manager at the clinic receives a notification from the Office of the Senior Manager, Pharmaceutical Services, informing all facilities about the dates of the stock take.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The operational manager informs all clinic personnel about the impending stock take.</td>
</tr>
<tr>
<td>2</td>
<td>Responsible nursing personnel order enough stock for the cubicles to avoid interruptions during stock take.</td>
</tr>
<tr>
<td>3</td>
<td>The responsible person (operational manager or his/her delegate) ensures that medicine store room is organized (pre-stock take arrangements) as follows:</td>
</tr>
<tr>
<td></td>
<td>• Stock is arranged according to expiry date and batch numbers</td>
</tr>
<tr>
<td></td>
<td>• Take note of stock stored in other locations</td>
</tr>
<tr>
<td></td>
<td>• Remove and record expired stock appropriately</td>
</tr>
<tr>
<td>4</td>
<td>A team of two or more people must work together in the stock take process (i.e., one to count and the other to enter quantities); enter physical quantity of stock counted and stock quantity as reflected on the card.</td>
</tr>
<tr>
<td>5</td>
<td>Enter date of stock take and physical stock count with a red pen on stock card and stock take list.</td>
</tr>
<tr>
<td>6</td>
<td>Check pack size on the stock take list/form before recording the quantity counted to ensure conformity.</td>
</tr>
<tr>
<td>7</td>
<td>Count physical stock on shelf and enter quantity and expiry date on list.</td>
</tr>
<tr>
<td>8</td>
<td>Additional items not listed on the stock take list/form or different pack sizes (e.g., paracetamol 500 mg tablets, pack of 20) should be recorded at the bottom of the stock take list.</td>
</tr>
<tr>
<td>9</td>
<td>If an item is out of stock in the store room, enter zero in the space provided on stock take list/form.</td>
</tr>
<tr>
<td>10</td>
<td>Verify completed stock take list/form pages before handing them to the operational manager.</td>
</tr>
<tr>
<td>11</td>
<td>The stock take list/form should indicate the name of the facility; operational manager and the stock take date.</td>
</tr>
<tr>
<td>12</td>
<td>The completed forms to be submitted to the hospital pharmacy for capturing.</td>
</tr>
<tr>
<td>13</td>
<td>The hospital pharmacy manager submits completed reports to the district pharmacy manager for consolidation and filing (for a minimum of 3 years).</td>
</tr>
<tr>
<td>14</td>
<td>The district pharmacy manager will submit the consolidated reports to the RAQA office at provincial Pharmaceutical Services.</td>
</tr>
<tr>
<td>15</td>
<td>RAQA will analyze the report and forward to the senior manager for recording on disclosure note.</td>
</tr>
<tr>
<td>16</td>
<td>The report of stock take analysis will be communicated to all relevant stake holders by RAQA.</td>
</tr>
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</table>
Annex 1. Example of Limpopo Clinic Stock Take Sheet

<table>
<thead>
<tr>
<th>Item Description</th>
<th>Pack Size</th>
<th>Physical stock</th>
<th>Expiry Date</th>
<th>Stock on Card</th>
<th>Price per pack</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amoxycillin 250mg cap</td>
<td>15</td>
<td>Capsule</td>
<td></td>
<td></td>
<td>R 2.20</td>
</tr>
<tr>
<td>Amoxycillin 125mg/5mlsusp</td>
<td>1</td>
<td>Bottle</td>
<td></td>
<td></td>
<td>R 3.84</td>
</tr>
<tr>
<td>Amoxycillin 125mg/5mlsusp</td>
<td>1</td>
<td>Bottle</td>
<td></td>
<td></td>
<td>R 3.16</td>
</tr>
<tr>
<td>Amoxycillin 250mg/5mlsusp</td>
<td>1</td>
<td>Bottle</td>
<td></td>
<td></td>
<td>R 4.73</td>
</tr>
<tr>
<td>Benzathine Pen. 1.2mu</td>
<td>1</td>
<td>Vial</td>
<td></td>
<td></td>
<td>R 4.83</td>
</tr>
<tr>
<td>Benzathine Pen. 2.4mu</td>
<td>1</td>
<td>Vial</td>
<td></td>
<td></td>
<td>R 6.67</td>
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<tr>
<td>Benzylpenicillin 1mu</td>
<td>1</td>
<td>Vial</td>
<td></td>
<td></td>
<td>R 4.42</td>
</tr>
<tr>
<td>Benzylpenicillin 5mu</td>
<td>1</td>
<td>Vial</td>
<td></td>
<td></td>
<td>R 6.80</td>
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<tr>
<td>Cefixime 400mg tablet</td>
<td>1</td>
<td>Tablet</td>
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<td>R 17.07</td>
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<tr>
<td>Ceftriaxone 250mg</td>
<td>1</td>
<td>Vial</td>
<td></td>
<td></td>
<td>R 2.00</td>
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<tr>
<td>Chloramphenicol eye oint</td>
<td>1</td>
<td>Tube</td>
<td></td>
<td></td>
<td>R 5.51</td>
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<tr>
<td>Doxycycline 100mg</td>
<td>1</td>
<td>Capsule</td>
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<td></td>
<td>R 2.34</td>
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<tr>
<td>Erythromycin susp</td>
<td>1</td>
<td>Bottle</td>
<td></td>
<td></td>
<td>R 8.81</td>
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<td>Erythromycin tabs</td>
<td>20</td>
<td>Tablet</td>
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<td>R 9.60</td>
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<td>Flucloxacillin susp</td>
<td>1</td>
<td>Bottle</td>
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<td>R 9.97</td>
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SOP 03 – STORAGE OF MEDICINES AND SURGICAL SUNDRIES

Department of Health

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<td>Storage of Medicines and Surgical Sundries</td>
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Objective

To ensure that all medicines and surgical sundries are securely and correctly stored in accordance with Good Pharmacy Practice

Standards

Stock must be stored in line with storage conditions as stated on the package insert

Responsible staff

- Facility operational manager
- Authorized nursing personnel
- Community service pharmacists
- Post-basic pharmacist assistant

Policies, references, and source materials

- Good Pharmacy Practice
- Managing Access to Medicines and Health Technologies
- Medicines and Related Substances Control Act (Act 101 of 1965) as Amended
- Occupational Health and Safety Act
- Pharmacy Act (Act 53 of 1974) as amended
- Public Finance Management Act (Act 1 of 1999)
- SA National Drug Policy, 1996

Definition of terms and concepts

- CHC: community health center
- FEFO: first expiry, first out
- FIFO: first in, first out
- PHC: primary health care
- SOP: standard operating procedure
Tools, materials, equipment, and other resources

- Refrigerators
- Emergency generator
- Stock cards
- Thermometers
- Air conditioners
- Temperature charts

Safety precautions

- Schedule 5 medicines must be stored in a lockable cupboard
- Thermo-labile medicines must be stored at 2 °C–8 °C
- Windows and doors must have burglar bars
- Stock must not be placed directly on the floor
- The temperature in the store room must be kept below 25 °C
- Shelves must be dusted weekly
- Flammable and hazardous substances must be stored separate from the rest of the stock

Monitoring and evaluation

- Stock losses due to incorrect storage conditions are unacceptable
- Expired stock should be removed from shelves
- All supplies are stored on shelves or in boxes on pallets, not on the floor
- Stock should be stored according to a classification system
- Stock should be protected from dust, sunlight, moisture, and pests (as per pest control policy)

Record keeping

Completed stock cards/stock control system reports

Procedure

1. Apply FIFO/FEFO principles in packing stock on shelves.

2. Pack stock according to a suitable classification system (therapeutic, tender group, etc.) in alpha-generic order.

3. Place the updated stock cards inside the brazier bin, except for thermo-labile products.

4. Control the temperature in the store through air conditioning.

5. Monitor the temperature in the store and record the temperature twice daily (morning and afternoon) in Annex 2 Daily Temperature Record Chart.

6. Maintain and monitor storage conditions for thermo-labile medicines in accordance with cold chain maintenance SOP 12

7. Use Annex 3 when defrosting the fridges.
Annex 2. Daily Temperature Record Chart

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<th>Month/year: ___________</th>
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<td>30</td>
<td></td>
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<td>31</td>
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</table>
Annex 3. Refrigerator Cleaning and Defrosting Record

<table>
<thead>
<tr>
<th>Date</th>
<th>Defrosted and cleaned by:</th>
<th>Checked by:</th>
</tr>
</thead>
<tbody>
<tr>
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</table>
# SOP 04 – HANDLING OF RETURNED MEDICINES AND SURGICAL SUNDRIES FROM PATIENTS

## Department of Health

<table>
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<th>SOP number</th>
<th>SOP-04</th>
<th>Revision no.:</th>
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<tr>
<td>SOP title</td>
<td>Handling of Returned Medicines and Surgical Sundries from Patients</td>
<td></td>
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<tr>
<td>Institution</td>
<td>Pharmaceutical Services</td>
<td></td>
</tr>
<tr>
<td>Issue date</td>
<td>September 2014</td>
<td></td>
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<td>Effective date</td>
<td>October 2014</td>
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<td>Issued by</td>
<td>Limpopo Dept. of Health: Directorate-Pharmaceutical Services</td>
<td></td>
</tr>
</tbody>
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## Objective
To ensure that medicines and surgical sundries from patients are recorded for disposal

## Standards
Proof that medicines and surgical sundries returned from patients are recorded and stored separately, marked “UNUSABLE STOCK”

## Responsible staff
- Community service pharmacist
- Facility operational manager
- Nursing personnel
- Pharmacists
- Post-basic pharmacist assistants

## Policies, references, and source materials
- Consumer Protection Act (Act 68 of 2008)
- Good Pharmacy Practice
- Managing Access to Medicines and Health Technologies
- Medicine and Related Substances Act (Act no 101 of 1965) Amended
- Pharmacy Act No. 53 of 1974
- Public Finance Management Act (Act 1 of 1999)
Definition of terms and concepts

- Quarantine: to separate and restrict the movement of items
- SOP: standard operating procedure

| Tools, materials, equipment, and other resources | Returned stock form |
| Safety precautions | All stock returned from patients to be separated from usable stock |
| Monitoring and evaluation | Records of returned stock from patients |
| Record keeping | Record of returned stock |

Procedure

1. Any medicine or surgical sundry returned by the patient should be recorded on Annex 4 (Returned Stock Form)
2. Place and store returned stock in the location marked “UNUSABLE STOCK”
3. For further steps, follow SOP 11 (Prevention and Management of Expired and Obsolete Stock)
## Annex 4. Returned Stock Form

<table>
<thead>
<tr>
<th>EXPIRED, DAMAGED AND UNUSABLE STOCK RETURN FORM (FACILITIES)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FROM (OUTLET)</strong></td>
</tr>
<tr>
<td><strong>TO (PHARMACY)</strong></td>
</tr>
</tbody>
</table>

### EXPIRED STOCK

<table>
<thead>
<tr>
<th>STOCK CODE</th>
<th>ITEM DESCRIPTION (GENERIC NAME)</th>
<th>STRENGTH</th>
<th>PACK SIZE</th>
<th>EXPIRY DATE</th>
<th>QUANTITY</th>
<th>UNIT PRICE</th>
<th>VALUE</th>
<th>REASON FOR EXPIRY</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>

### DAMAGED AND UNUSABLE STOCK

<table>
<thead>
<tr>
<th>STOCK CODE</th>
<th>ITEM DESCRIPTION (GENERIC NAME)</th>
<th>STRENGTH</th>
<th>PACK SIZE</th>
<th>EXPIRY DATE</th>
<th>QUANTITY</th>
<th>UNIT PRICE (if applicable)</th>
<th>VALUE (if applicable)</th>
<th>REASON FOR DAMAGED/UNUSABLE</th>
</tr>
</thead>
<tbody>
<tr>
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</tbody>
</table>

**RETURNED BY:**

- **NAME**
- **DESIGNATION**
- **SIGNATURE**
- **DATE**

**AUTHORIZED BY:**

- **NAME**
- **DESIGNATION**
- **SIGNATURE**
- **DATE**

**RECEIVED BY:**

- **NAME**
- **DESIGNATION**
- **SIGNATURE**
- **DATE**
## SOP 05 – ORDERING OF MEDICINES AND SURGICAL SUNDRIES

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<td>Institution</td>
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<td>Ordering of Medicines and Surgical Sundries</td>
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<td></td>
<td>September 2014</td>
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<td>Issued by</td>
<td>Limpopo Dept. of Health: Directorate-Pharmaceutical Services</td>
<td></td>
</tr>
</tbody>
</table>

### Objective
To ensure availability of medicines and surgical sundries at all times

### Standards
Availability of at least 92% of medicines and surgical sundries at the clinic

### Responsible staff
- Clinic operational manager
- Community service pharmacists
- District pharmacy manager
- Post-basic pharmacist assistants
- Responsible pharmacist

### Policies, references, and source materials
- Consumer Protection Act (Act 68 of 2008)
- Good Pharmacy Practice
- Managing Access to Medicines and Health Technologies
- Medicine and Related Substances Act (Act no 101 of 1965) amended
- Pharmacy Act No. 53 of 1974
- Public Finance Management Act (Act 1 of 1999)

### Definition of terms and concepts
- Authorized personnel: person authorized to place orders
- Emergency order: orders placed outside the normal ordering schedule
- Order form: approved Limpopo clinic order form
- SOP: standard operating procedure
| Tools, materials, equipment, and other resources | • Approved clinic order form  
• Stock cards  
• Schedule 5 medicine order book (TPH36) |
| Safety precautions | Guard against over/under-stocking |
| Monitoring and evaluation | Records of orders made to provincial pharmaceutical depot |
| Record keeping | Copy of orders |

**Procedure**

**A. General Unscheduled, Schedule 1-4 Items, and Medical Supplies**

1. Check physical stock on hand and on stock card (Annex 5. Example of Limpopo Province Stock Card)
2. Calculate quantities to be ordered using information from the stock card (minimum/maximum stock levels, average monthly consumption)
3. Fill in the order form in accordance with stock levels (Annex 6. Example of Limpopo Province Clinic order form).
4. Clinic and pharmacy personnel jointly place an order
5. Place an order by writing the appropriate quantities on the order form
6. Ensure that order is signed, authorized, and approved
7. Copy of the completed order form to be retained and filed at the clinic for a minimum of 3 years
8. Keep record of depot reference number (issued by the depot on receipt of facility order)

**B. Antiretrovirals, Home-Based Care, Emergency Orders, Emergency Trolley Items, and Mobile Clinics**

1. Follow procedures 1–7 above
2. Pharmacy personnel to capture and issue the order

**C. Schedule 5 Medicines**

1. Follow procedures 1 and 2 of section B above
Annex 5. Example of Limpopo Province Stock Card

Product Generic Name: ................................................................. Card No. ...........
Strength: ......... Dosage Form: ....................... Pack size/ Unit of Issue: .......... Stock Code: .................

Ave:........ Max stock .......... RECORD OF ORDERS, RECEIPTS & ISSUES Reorder factor: .......

<table>
<thead>
<tr>
<th>Date</th>
<th>Order No</th>
<th>Quantity Ordered</th>
<th>Invoice No</th>
<th>To / From</th>
<th>Quantity Received</th>
<th>Quantity Issued</th>
<th>Stock Balance</th>
<th>Unit Price</th>
<th>Remarks and Initials</th>
</tr>
</thead>
<tbody>
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</table>

TOTAL MONTHLY ISSUES

<table>
<thead>
<tr>
<th>Financial Year</th>
<th>APR</th>
<th>MAY</th>
<th>JUN</th>
<th>JUL</th>
<th>AUG</th>
<th>SEP</th>
<th>OCT</th>
<th>NOV</th>
<th>DEC</th>
<th>JAN</th>
<th>FEB</th>
<th>MAR</th>
<th>Usage</th>
<th>Expired</th>
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</thead>
<tbody>
<tr>
<td>FY:</td>
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</tbody>
</table>
Annex 6. Example of Limpopo Province Clinic Order Form

<table>
<thead>
<tr>
<th>Stock Cod</th>
<th>Generic Name</th>
<th>Pack Size</th>
<th>Alternative</th>
<th>Max Stock</th>
<th>Stock Ord</th>
</tr>
</thead>
<tbody>
<tr>
<td>3320</td>
<td>Amoxycillin Caps 250mg (15'S)</td>
<td>15</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3196</td>
<td>Amoxycillin Caps 500mg (15'S)</td>
<td>15</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3431</td>
<td>Amoxycillin/ Clavulanic Acid tabs 250/125</td>
<td>15</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2867</td>
<td>Amoxycillin 125mg/5ml Susp 100ml</td>
<td>100ml</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2827</td>
<td>Amoxycillin 250mg/5ml Susp 100ml</td>
<td>100ml</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0515</td>
<td>Amoxycillin/ Clavulanic Acid susp 250/62.5</td>
<td>100ml</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>3431</td>
<td>Amoxycillin/ Clavulanic Acid susp 125/31.25</td>
<td>100ml</td>
<td></td>
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</tr>
<tr>
<td>3174</td>
<td>Benzathine Penicillin G Inj 1.2Mu</td>
<td>vial</td>
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<td></td>
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<tr>
<td>0013</td>
<td>Benzathine Penicillin G Inj 2.4Mu</td>
<td>vial</td>
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<tr>
<td>0015</td>
<td>Benzylpenicillin Inj 1Mu</td>
<td>vial</td>
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<td>2999</td>
<td>Cefixime 400mg Tabs (1'S)</td>
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</tbody>
</table>
**Objective**

To ensure that receipt of medicines and surgical sundries is in accordance with Good Pharmacy Practice.

**Standards**

Information on products received corresponds with information on the received invoice.

**Responsible staff**

- Clinic operational manager
- Registered professional nurses

**Policies, references, and source materials**

- Good Pharmacy Practice
- Managing Access to Medicines and Health Technologies
- Medicine and Related Substances Act (Act no 101 of 1965) amended
- Pharmacy Act (Act No. 53 of 1974)
- Primary Health Care Supervision Manual
- Public Finance Management Act (Act 1 of 1999)

**Definition of terms and concepts**

- POD: proof of delivery
- Short-dated stock: stock to expire within six months
- SOP: standard operating procedure
- VVM: vaccine vial monitor
- CCM: cold chain monitor
Tools, materials, equipment, and other resources

- Stock cards
- Trolleys
- Scheduled 5 substances register

Safety precautions

- Guard against broken seals
- Poor quality
- Expired stock
- Leakages and damages
- Temperature of the cooler should be 2–8 °C

Monitoring and evaluation

Ticked, signed, and filed invoices

Record keeping

- Copy of signed invoices
- Summary of invoice/returns value report

Procedure

A. Receiving Clinic Stock

1. Check the integrity of the seal on the delivery vehicle

2. Look for signs of tampering; record and report the discrepancy to the dispatch manager at the depot within one working day

3. Record the seal number (with notes on tampering) on the proof of delivery (POD)

4. The driver breaks the seal in the presence of nursing personnel or any other authorized, delegated staff

5. Check the number of boxes/parcels delivered against the number of boxes on the delivery note

6. After the driver has left, identify the correct invoice and group the boxes/parcels accordingly

7. Unpack the stock received and compare the physical stock against the invoice by checking the following:
   - Correct product name
   - Correct product strength
   - Correct pack size, batch number, and expiry date
   - Correct quantity

8. Mark the item on the invoice and the delivery note with ticks if everything is correct

9. Take note of all discrepancies (tampering, batch number, expiry date, quantity, damaged stock, and short-dated stock) on the invoice

10. Sign the invoice after all checks are done

11. Record any discrepancies on the Annex 7 (Credit Request Form) and complete Annex 8 (Credit Register)

12. Send the credit request form to the hospital pharmacy to lodge the query at the depot and arrange for upliftment note (if applicable)

13. Update the credit request register when the credit is fulfilled

14. Transfer the stock information (date, order number, invoice number, quantity received, stock balance, unit price, and remarks) from the invoice to the stock card

15. Reconcile the invoices with the invoice value returns report

16. File invoices with the invoice value report in a systematic, organized manner

B. Cold Chain Items
<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Follow procedures 1 – 9 of section A above</td>
</tr>
<tr>
<td>2</td>
<td>Check all vaccine vial monitors (VVMs) and/or cold chain monitor cards (CCMs), and only accept if the VVMs are still within range and the CCMs do not indicate excess heating</td>
</tr>
<tr>
<td>3</td>
<td>For pharmaceutical products without indicators, accept delivery if ice packs are still partially frozen, or at least refrigerator cold</td>
</tr>
<tr>
<td>4</td>
<td>Record the temperature on the proof of delivery (POD) note</td>
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</tbody>
</table>

**C. For Schedule 5 Items**

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<tr>
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<tbody>
<tr>
<td>1</td>
<td>Follow procedures 1 – 9 of section A above</td>
</tr>
<tr>
<td>2</td>
<td>On receipt, the professional nurse (or other authorized person) shall record receipt in the S5 register</td>
</tr>
<tr>
<td>3</td>
<td>Keep all S5 medicines in a locked steel cupboard</td>
</tr>
</tbody>
</table>
Annex 7. Credit Request Form

**CREDIT REQUEST**

Return to: _____________________________________  Date: _________________

**HOSPITAL INFORMATION:**

Name: _____________________

Contact person: _____________________

Account: _____________________

**Tel:** _____________________

Fax: _____________________

**Ref:** _____________________

**TRANSACTION INFORMATION:**

Generic name: _____________________

Pack size: _____________________

Invoice No: _____________________

**Reason for Credit Request without Goods Returned (e.g., price, quantity, query, etc.)**

_________________________________________________

**GOODS RETURNED (Wrong or damaged item received, short dated stock, etc)**

<table>
<thead>
<tr>
<th>EXPIRY DATE</th>
<th>BATCH NO</th>
<th>QUANTITY</th>
<th>For office use only verified yes/no</th>
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</tbody>
</table>

**TOTAL**

Reason for return: _____________________

Date returned: _____________________  Truck number: _____________________

Driver: _____________________  Number of cartons: _____________________

Name of receiving clerk: _____________________

**Signature:** _____________________  **Date:** _____________________

For Depot Use

<table>
<thead>
<tr>
<th>Approved</th>
<th>Not Approved</th>
<th>Reasons:</th>
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<tbody>
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</table>

Credit Note Number

**NB:** Credit request and credit note should be attached together and sent to hospital.
Annex 8. Credit Request Register

<table>
<thead>
<tr>
<th>FACILITY NAME</th>
<th>CREDIT REQUEST NUMBER</th>
<th>STOCK NUMBER</th>
<th>ITEM DESCRIPTION</th>
<th>INVOICE NUMBER</th>
<th>DATE SENT (Hospital/Depot)</th>
<th>DATE OF CREDIT NOTE</th>
<th>CREDIT NOTE NUMBER</th>
<th>SIGNATURE</th>
<th>REMARKS</th>
</tr>
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# SOP 07 – Issuing of Stock to Consulting Rooms

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<td>Pharmaceutical Services</td>
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<td>Pharmaceutical Services</td>
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<td><strong>Issued by</strong></td>
<td>Limpopo Dept. of Health: Directorate-Pharmaceutical Services</td>
<td></td>
</tr>
</tbody>
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## Objective
To ensure availability of medicines and surgical sundries in consulting rooms

## Standards
- Updated stock cards
- Records of orders placed

## Responsible staff
- Clinic operational manager
- Professional nurse

## Policies, references, and source materials
- Good Pharmacy Practice
- Managing Access to Medicines and Health Technologies
- Medicine and Related Substances Act (Act no 101 of 1965) as amended
- Pharmacy Act (Act No. 53 of 1974) as amended
- Primary Health Care Supervision Manual
- Public Finance Management Act (Act 1 of 1999)

## Definition of terms and concepts
SOP: standard operating procedure

## Tools, materials, equipment, and other resources
- Stock cards
- Order forms
- Medicine trolleys
- Cooler boxes and ice packs
| Safety precautions | • Overstocking in the consulting rooms  
• Issuing of expired stock |
<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td>Monitoring and evaluation</td>
<td>Updated stock cards</td>
</tr>
</tbody>
</table>
| Record keeping | • Updated stock cards  
• Order forms |

**Procedure**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td>1</td>
<td>Responsible personnel receive the order</td>
</tr>
<tr>
<td>2</td>
<td>Responsible person evaluates the order (for stock on hand and order quantities)</td>
</tr>
<tr>
<td>3</td>
<td>Stock is issued to the consulting rooms and stock cards are updated</td>
</tr>
<tr>
<td>4</td>
<td>Stock is delivered to consulting rooms together with the order form (Annex 9. Consulting Room Order Form)</td>
</tr>
</tbody>
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Annex 9. Consulting Room Order Form

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Pack Size</th>
<th>Max Stock</th>
<th>Stock Ord</th>
<th>Stock Iss</th>
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<tr>
<td></td>
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# SOP 08 – MANAGING STOCK IN THE EMERGENCY TROLLEY

## Department of Health

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## Objective

To ensure that emergency medicines and surgical sundries are available and monitored at all times

## Standards

Updated emergency medicines and surgical sundries checklist

## Responsible staff

- Professional nurse
- Pharmacist
- Post-basic pharmacist assistants

## Policies, references, and source materials

- Good Pharmacy Practice
- Health Profession Act, Act 56 of 1974 as amended
- Managing Access to Medicines and Health Technologies
- Medicine and Related Substances Act (Act no 101 of 1965) as amended
- National Drug Policy 1996
- Nursing Act, Act 50 of 1978 as amended
- Pharmacy Act (Act No. 53 of 1974) as amended
- Primary Health Care Supervision Manual
- Public Finance Management Act (Act 1 of 1999)

## Definition of terms and concepts

SOP: standard operating procedure
| Tools, materials, equipment, and other resources | • Checklist for emergency trolley  
• Emergency medicine trolley |
| Safety precautions | • Short-dated stock to be monitored and managed  
• Guard against expired stock |
| Monitoring and evaluation | Compare updated checklist with record of stock in medicine trolleys |
| Record keeping | • Emergency trolley checklist (Annex 10. Example of Primary Health Care Emergency Tray Checklist)  
• Emergency trolley order form (Annex 11. Example of Primary Health Care Emergency Tray Order Form)  
• Order records |

**Procedure**

1. Keep approved emergency medicines as per attached checklist (Annex 10)
2. Authorized personnel should check the emergency trolley checklist daily
3. The date of the first item to expire should be used as the expiry date for the trolley, and it must be written in bold on the outside of the trolley
4. The authorized personnel must use the emergency tray order form (Annex 11) and replace all items used or expired in the emergency trolley
Annex 10. Example of Primary Health Care Emergency Tray Checklist

<table>
<thead>
<tr>
<th>ST. CODE</th>
<th>ITEM DISCRITION</th>
<th>PACK SIZE</th>
<th>LEVEL</th>
<th>QTY</th>
<th>EXP DATE 1</th>
<th>EXP DATE 2 (lf applicable)</th>
<th>MONTH/YEAR</th>
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<tr>
<td></td>
<td><strong>MEDICATION</strong></td>
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<td></td>
<td></td>
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<tr>
<td>0148</td>
<td>Adrenaline Inj 0.1Mg/ml 1:1000 1Ml</td>
<td>1</td>
<td>PHC</td>
<td>4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0156</td>
<td>Atropine Inj 0.5Mg/ml 1Ml</td>
<td>1</td>
<td>PHC</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0176</td>
<td>Dexamethasone Inj 4Mg/ml 1Ml</td>
<td>1</td>
<td>DIS</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0177</td>
<td>Dextrose In Water Inj 50% 50Ml</td>
<td>1</td>
<td>PHC</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0193</td>
<td>Furosemide Inj 10Mg/ml 2Ml</td>
<td>1</td>
<td>DIS</td>
<td>4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0200</td>
<td>Hydrocortisone Inj 100Mg/2ml</td>
<td>1</td>
<td>PHC</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0429</td>
<td>Labetalol Hcl 5Mg/ml Injection.</td>
<td>1</td>
<td>DIS</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0221</td>
<td>Lignocaine Inj 2% 5Ml I.V.</td>
<td>1</td>
<td>DIS</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0225</td>
<td>Magnesium Sulphate Inj 50% 2Ml</td>
<td>1</td>
<td>PHC</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>0236</td>
<td>Naloxone Inj 0.4Mg/ml 1Ml</td>
<td>1</td>
<td>DIS</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0266</td>
<td>Sodium Bicarb Inj 8.5% 50Ml</td>
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<td>PHC</td>
<td>1</td>
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<td></td>
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<tr>
<td>0268</td>
<td>Water For Inj 10Ml (Plastic)</td>
<td>1</td>
<td>PHC</td>
<td>2</td>
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Annex 11. Example of Primary Health Care Emergency Tray Order Form

<table>
<thead>
<tr>
<th>ST. CODE</th>
<th>ITEM DESCRIPTION</th>
<th>PACK SIZE</th>
<th>LEVEL</th>
<th>MAX</th>
<th>ON HAND</th>
<th>ORDER</th>
<th>ISSUE</th>
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<tr>
<td>0148</td>
<td>Adrenaline Inj 0.1Mg/ml 1:1000 1Ml</td>
<td>1 PHC</td>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0156</td>
<td>Atropine Inj 0.5Mg/ml 1Ml</td>
<td>1 PHC</td>
<td>2</td>
<td></td>
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<tr>
<td>0176</td>
<td>Dexamethasone Inj 4Mg/ml 1Ml</td>
<td>1 DIS</td>
<td>2</td>
<td></td>
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<td>0177</td>
<td>Dextrose In Water Inj 50% 50Ml</td>
<td>1 PHC</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
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</tr>
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<td>Furosemide Inj 10Mg/ml 2Ml</td>
<td>1 DIS</td>
<td>4</td>
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<tr>
<td>0200</td>
<td>Hydrocortisone Inj 100Mg/2ml</td>
<td>1 PHC</td>
<td>2</td>
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<td>Labetalol Hcl 5Mg/ml Injection</td>
<td>1 DIS</td>
<td>1</td>
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<tr>
<td>0221</td>
<td>Lignocaine Inj 2% 5Ml I.V.</td>
<td>1 DIS</td>
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<tr>
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<td>Magnesium Sulphate Inj 50% 2Ml</td>
<td>1 PHC</td>
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<tr>
<td>0236</td>
<td>Naloxone Inj 0.4Mg/ml 1Ml</td>
<td>1 DIS</td>
<td>2</td>
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### SOP 09 – COMMUNICATION CHANNELS ACROSS ALL HEALTH CARE LEVELS

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<td>Communication Channels across All Health Care Levels</td>
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#### Objective

To ensure effective communication across all health care levels

#### Standards

Feedback on correspondence

#### Responsible staff

- Clinic operational manager
- Manager pharmaceutical services (district)
- Responsible pharmacist

#### Policies, references, and source materials

- Good Pharmacy Practice
- Medicine and Related Substances Act (Act No. 101 of 1965) as amended
- Pharmacy Act (Act No. 53 of 1974) as amended
- Promotion of Access to Information Act (Act no.2 of 2000)
- Protection of Information Bill
- Public Finance Management Act (Act 1 of 1999)

#### Definition of terms and concepts

SOP: standard operating procedures

#### Tools, materials, equipment, and other resources

- Computers
- Fax
- Telephone
- Internet
<table>
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<tr>
<th>Safety precautions</th>
<th>Do not divulge information to unauthorized personnel</th>
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<td></td>
<td>• Communication channels observed</td>
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<td>Record keeping</td>
<td>Records of correspondence</td>
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**Procedure**

1. For all pharmacy-related issues, the lines of communication are as follows:
   - The operational Manager should communicate all pharmacy-related issues to the hospital Pharmacy Manager
   - For all administrative issues, follow the relevant communication lines with the sub-district office

2. Document all communication in an appropriate register book
# SOP 10 – SAFE PRESCRIBING AND DISPENSING OF MEDICINES

## Department of Health

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## Objective

To ensure that prescribing and dispensing are done in accordance with legislation

## Standards

Compliance with prescribing and dispensing practices in accordance with legislation

## Responsible staff

- Clinic operational manager
- Clinical nurse practitioner
- Community service pharmacist
- Medical practitioner
- Pharmacist
- Post-basic pharmacist assistants
- Responsible pharmacist

## Policies, references, and source materials

- Good Pharmacy Practice
- Health Professions Act (Act 56 of 1974) as amended
- Medicine and Related Substances Act (Act No. 101 of 1965) as amended
- National Drug Policy
- Nursing Act (Act 50 of 1978)
- Pharmacy Act (Act No. 53 of 1974) as amended
- Public Finance Management Act (Act 1 of 1999)
Definition of terms and concepts

- EML: essential medicines list
- SOP: standard operating procedure
- STG: standard treatment guidelines

Tools, materials, equipment, and other resources

- Tick register
- Prescription form
- EML and STG

Safety precautions

- Do not dispense expired medicines

Monitoring and evaluation

- Prescriptions and dispensing procedures complying with legislation

Record keeping

- Prescriptions records

Procedure

A. Prescribing

1. Assess the patient

2. Counsel patients on their conditions and prescribe treatment in accordance with STGs

3. The prescription should be written in the clinic register using indelible ink

   The following should appear legibly on the prescription:

   - Name of patient
   - Address of the patient
   - Date of prescription
   - Name, qualification, and practice number of prescriber
   - Name of medicine
   - Age and sex of the patient
   - Total number of doses or duration of medicine clearly indicated
   - Dosage form and dose of the medicine clearly indicated
   - Signature of the doctor or prescribing nurse

B. Dispensing

1. Interpret and evaluate patient prescription

2. Prepare and label the prescribed medicines

3. Provide information and instructions to the patient to ensure safe and effective use of medicine

   The dispensed medicines should have the following on the label:

   - Name and strength of the medicine
   - Batch number and expiry date
   - Quantity
   - Directions for use of the medicine
   - Name and address of the health establishment
   - Date of dispensing
   - Reference number

4. Patient should be given instructions on the correct use of dispensed medicines

5. The patient is given opportunity to ask questions
# SOP 11 – PREVENTION AND MANAGEMENT OF EXPIRED AND OBSOLETE STOCK

**Department of Health**

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<td>Prevention and Management of Expired and Obsolete Stock</td>
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## Objectives

- To prevent stock from expiring
- To ensure effective management and safe disposal of unusable stock

## Standards

- No expired/obsolete stock on the shelves
- Stock levels aligned to usage patterns

## Responsible staff

- Clinic operational manager
- Community service pharmacists
- Pharmacists
- Post-basic pharmacists assistants
- Professional nurse
- Responsible pharmacists

## Policies, references, and source materials

- Good Pharmacy Practice
- Managing Access to Medicines and Health Technologies
- Medicines and Related Substances Act (Act 101 of 1965) as amended
- Pharmacy Act (Act 53 of 1974) as amended
- Public Finance Management Act (Act 1 of 1999)
- Treasury Regulations, Chapter N
Definition of terms and concepts

- SOP: standard operating procedure
- PHC: primary health care
- FIFO: first in, first out
- FEFO: first expiry, first out

Tools, materials, equipment, and other resources

Expired-stock reporting form (Annex 4. Returned Stock Form)

Safety precautions

Unusable stock must be separated from usable stock

Monitoring and evaluation

Number of items expired

Record keeping

- Expired and obsolete stock register
- Stock cards

Procedure

1. Ensure that all stock on shelves are packed and issued according to FIFO/FEFO

2. All health care staff should collect expired/unusable stock on a monthly basis by monitoring the following:
   - Expiry dates
   - Damaged stock
   - Poor quality

3. Remove identified stock from shelves, record adjustments to stock records (cards); schedule 5 products must be recorded separately

4. Store unusable stock in a separate, secured area, clearly marked “damaged or expired goods, do not use”
# SOP 12 – MAINTENANCE OF COLD CHAIN AND CONTINGENCY PLANS

## Objective
To maintain and monitor optimum temperatures for all thermo-labile (heat sensitive) products throughout the entire management of pharmaceutical stock (receipt, storage, distribution, and administration).

## Standards
- No frozen vaccines
- Refrigerator defrosted monthly
- Temperature chart completed in the morning and afternoon

## Responsible staff
- Assistant manager PHC
- Clinic operational manager
- Community service pharmacists
- Pharmacists
- Post-basic pharmacists assistants

## Policies, references, and source materials
- Cold Chain and Immunization Operations Manual (latest edition)
- EML for Primary Health Care (latest edition)
- Good Pharmacy Practice
- Latest EPI guidelines
- National cold chain and immunization operations manual (latest edition)
- National Drug Policy
- Nursing Act (Act 50 of 1978)
- Public Finance Management Act (Act 1 of 1999)
**Definition of terms and concepts**

- EPI: expanded program on immunization
- SOP: standard operating procedure
- VVM: vaccine vial monitor

**Tools, materials, equipment, and other resources**

- Fridge
- Cooler box
- Ice packs
- Thermometer (dial thermometer)
- Temperature chart form (Annex 2. Daily Temperature Record Chart)
- Defrosting schedule
- Power failure form (Annex 11. Power Failure Form)
- Back-up system

**Safety precautions**

- Temperature should stay between 2°C and 8°C
- Do not use the vaccine if the VVM square is as dark as the circle or darker than the circle

**Monitoring and evaluation**

- Updated temperature charts
- Updated defrosting records

**Record keeping**

- Completed temperature charts
- Completed defrosting records

**Procedure**

Cold chain must be monitored and maintained at all stages of stock handling, i.e., receipt of products, storage, distribution, and administration.

**A. Receipt of Stock**

1. Accept if the stock if the VVMs are still within the safety range
2. Accept if the temperature of the cooler is between 2°C and 8°C

**B. Storage of Vaccines and Heat-Sensitive Pharmaceuticals in Refrigerators**

1. Store vaccines on the inside of the refrigerator, not in the door.
2. Store polio, measles, and BCG vaccines on the coldest shelves nearest the freezing compartment.
3. Store all other vaccines and diluents on the middle shelves.
4. Heat-sensitive pharmaceuticals that need to be stored in the fridges must be separated completely from the vaccines and can be stored on the lower shelves.
5. Store ice packs in the freezing compartment of the fridge if no freezer is available.

**C. Running and Monitoring Refrigerators and Cold Room**

1. Check the back-up generators or gas cylinders regularly (if available)
2. Have the cooler box and frozen ice packs ready at all times in case of power failure.
3. Equip each refrigerator with a working dial thermometer.
4. Read the temperature in the morning and afternoon and record it on the official temperature charts.
If the temperature is not 2–8 °C, please report to the clinic operational manager.

If there is a power failure, try not to open the fridge until power is restored.

**D. Defrosting and Cleaning the Refrigerator/Cold Room**

1. Defrost and clean the refrigerator monthly (Annex 3) or when there is visible ice build-up.

2. Place all vaccines and ice packs in cooler boxes before turning off the refrigerator.

3. When the ice has melted, clean the refrigerator and wipe it dry.

4. Record the date and sign the defrosting schedule form.

5. Turn the refrigerator back on.

6. Replace vaccines when the temperature is 2–8 °C.

**E. Contingency Plan (In the Event of a Power Failure)**

1. Keep the refrigerator door closed and switch to an emergency power supply until the power is restored.

2. When power is restored, check the temperature of the fridge and the VVM on vaccines as a proxy for other items; if in doubt, contact the hospital pharmacist or the EPI manager.

3. If an alternative refrigerator is available and the power failure persists for more than 24 hours, transfer the vaccines to the alternative refrigerator, following the SOP for the transport of vaccines (refer to Limpopo Depot SOP on Cold Chain Management, sub-section dispatch and delivery).


**F. Wastage**

1. Do not use vaccines beyond the VVM discard point or expiry date, whichever comes first.

2. Report expired or damaged stock as avoidable wastage.

3. Do not discard vaccines suspected of being stored outside the required temperatures without verifying.
### Annex 12. Power Failure Form

**FACILITY NAME:**

The following must be documented and reported immediately to the responsible pharmacist:

1. Date of power failure
2. Time of reporting
3. Temperature (at the time of reporting)
4. Actions taken

5. Period of power failure
   - From: __________
   - To: __________

6. Temperature (when power is restored)

6. Stock affected

<table>
<thead>
<tr>
<th>Item description</th>
<th>Batch no.:</th>
<th>Exp. date</th>
<th>Qty. (units)</th>
<th>Condition of stock (visual)</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.1</td>
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<td>7.5</td>
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<td>7.9</td>
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<tr>
<td>7.10</td>
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**REPORTED BY:**

<table>
<thead>
<tr>
<th>NAME</th>
<th>DESIGNATION</th>
<th>SIGNATURE</th>
<th>DATE</th>
</tr>
</thead>
</table>
**Objective**

To control handling of schedule 5 medicines to ensure compliance with legislation

**Standards**

- Up to date registers
- Physical stock on hand matches stock recorded on the register

**Responsible staff**

- Clinic operational manager
- Clinical manager
- Pharmacists
- Post-basic pharmacist assistant

**Policies, references, and source materials**

- Essential Medicines List
- Good Pharmacy Practice
- Medicine and Related Substances Act (Act no. 101 of 1965) as amended
- National Drug Policy
- Nursing Act (Act no. 33 of 2005) as Amended
- Pharmacy Act (Act no. 53 of 1974) as Amended

**Definition of terms and concepts**

- SOP: standard operating procedure
- S5 medicines: a category of medicines that have a small potential for abuse or addiction
### Tools, materials, equipment, and other resources
- Lockable steel cupboard
- S5 registers (TPH36)
- Clinic order form

### Safety precautions
- Keep S5 medicines and registers under lock and key
- Dispose according to the Limpopo Depot SOP 12 (Disposal/Destruction of Unusable Goods)
- Only authorized prescribers should prescribe S5 items

### Monitoring and evaluation
- S5 items cupboard is kept locked when not in use
- Updated S5 register

### Record keeping
- S5 substances register

### Procedure

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Follow the SOP for ordering</td>
</tr>
<tr>
<td>2</td>
<td>On receipt, the professional nurse will record in the S5 register.</td>
</tr>
<tr>
<td>3</td>
<td>Keep all S5 medicines in the locked steel cupboard.</td>
</tr>
<tr>
<td>4</td>
<td>Issue and record S5 medicines in the register.</td>
</tr>
<tr>
<td>5</td>
<td>Balance the register daily</td>
</tr>
</tbody>
</table>
**SOP 14 – HANDLING PRODUCT COMPLAINTS**

**Objective**
To ensure that a standardized handling and reporting procedure is used for complaints regarding the quality of medicines and surgical sundries

**Standards**
Records of complaints on product quality

**Responsible staff**
- Pharmacists
- Post-basic pharmacist’s assistants
- Clinic operational manager
- Professional nurse

**Policies, references, and source materials**
- Essential Medicines List
- Good Pharmacy Practice
- Medicine and Related Substance Control Act (Act 101 of 1965) Amended
- National Drug Policy
- Public Finance Management Act (Act 1 of 1999)

**Definition of terms and concepts**
- PTC: Pharmacy and Therapeutics Committee
- SOP: standard operating procedure

**Tools, materials, equipment, and other resources**
Product complaint form (Annex 13)
Safety precautions | Quarantine the products  
---|---  
Monitoring and evaluation  
Records of product complaints  
Record keeping  
Records of product complaints

**Procedure**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Any product complaints from clients or patient and health professionals, either written or verbal, shall be recorded on the complaint form in triplicate.</td>
</tr>
<tr>
<td>2</td>
<td>Keep the sample of the affected product.</td>
</tr>
<tr>
<td>3</td>
<td>Forward the completed form to the hospital pharmacist.</td>
</tr>
<tr>
<td>4</td>
<td>The pharmacist should verify the batch number, expiry date, and quantity of the product.</td>
</tr>
<tr>
<td>5</td>
<td>The pharmacist will forward the form to the Office of Regulatory affairs and Quality Assurance.</td>
</tr>
<tr>
<td>6</td>
<td>Follow up the complaint until finalised.</td>
</tr>
<tr>
<td>7</td>
<td>Provide feedback to the complainant and staff.</td>
</tr>
</tbody>
</table>
Annex 13. Product Complaint Form

PRODUCT COMPLAINT FORM

Note: This form does NOT replace the official "Report on Suspected Adverse Drug Event"

Hospital / Clinic Date:

1. Name of person lodging complaint: ...............................................................................................................................................................

1.1 Qualifications: ................................................................................ Designation: ...............................................................................................

1.2 Tel & fax number: .......................................................................................................................................................................................

1.3 Signature: ...............................................................................................................................................................................................

1.4 Department/section: .......................................................................................................................................................................................

2. NATURE OF COMPLAINT: Mark applicable problem(s)
   o Poor quality of preparation
   o Poor quality of packaging
   o Ineffective medicine - expected / claimed effect not attained
   o Unstable medicine
   o Other (please specify)

Please report fully. If possible, a sample of the product or empty container should be submitted with this complaint form.
...........................................................................................................................................................................................................

3. PRODUCT INFORMATION

3.1 Stock number: .......................................................................................................................................................................................

3.2 Trade name of the product: ...............................................................................................................................................................................

3.3 Name of manufacturer: ..............................................................................................................................................................................

3.4 Generic name: ...............................................................................................................................................................................................

3.5 Strength: .................................................................................................................................................................................................

3.6 Dosage form: (tablet, injection, etc.): ..................................................................................................................................................

3.7 Batch number ..........................................................................................................................................................................................

3.8 Expiry date..............................................................................................................................................................................................

3.9 Stock on hand of affected batch .........................................................................................................................................................

Please return the completed form to the responsible pharmacist in the institution/district, for forwarding to the quality assurance manager pharmaceutical services at the Pharmaceutical Depot.

Response/action: ..............................................................................................................................................................................................
...........................................................................................................................................................................................................

Depot representative: ___________________________ Date: ___________________________
## SOP 15 – SAFETY AND SECURITY OF MEDICINES AND SURGICAL SUNDRIES AT THE CLINIC

### Department of Health

<table>
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<th>SOP-15</th>
<th>Revision no.:</th>
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<td><strong>SOP title</strong></td>
<td>Safety and Security of Medicines and Surgical Sundries at the Clinic</td>
<td></td>
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<tr>
<td><strong>Institution</strong></td>
<td>Pharmaceutical Services</td>
<td></td>
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</table>

### Objective

To ensure safe keeping of medicines and surgical sundries at the clinic

### Standards

- Windows fitted with burglar bars
- Lockable burglar doors

### Responsible staff

- Clinic operational manager
- Pharmacists
- Post-basic pharmacist assistant
- Risk and security personnel

### Policies, references, and source materials

- Good Pharmacy Practice
- Medicine and Related Substances Act (Act no 101 of 1965) as amended
- Nursing Act (Act no 33 of 2005) as Amended
- Pharmacy Act (Act no 53 of 1974) as amended
- Public Finance Management Act (Act 1 of 1999)
- Risk and Security Management Policy

### Definition of terms and concepts

- SOP: standard operating procedure
- Cyclic stock take: counting items at random
| Tools, materials, equipment, and other resources | • Fire extinguisher  
• Burglar bars on windows and doors  
• Back-up generator  
• Security guards |
|----------------|--------------------------------------------------|
| Safety precautions | • Keep store room locked at all times when not in use  
• Tinted windows/curtains  
• Fire extinguisher serviced |
| Monitoring and evaluation | Store room kept locked when not in use |
| Record keeping | Fire extinguisher service records |

**Procedure**

<table>
<thead>
<tr>
<th></th>
<th>Medicine stores and medicine trolleys shall be locked when not in use.</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Keys should be kept safe at all times.</td>
</tr>
<tr>
<td>3</td>
<td>Access to medicines and surgical stores should be restricted at all times.</td>
</tr>
<tr>
<td>4</td>
<td>Protect all medicines and surgical sundries from environmental hazards, e.g. fire, moisture, sunlight, pests, and dust.</td>
</tr>
<tr>
<td>5</td>
<td>Conduct cyclic stock take regularly.</td>
</tr>
</tbody>
</table>
# SOP 16 – RECALL OF MEDICINES AND SURGICAL SUNDRIES

**Department of Health**

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<td>Recall of Medicines and Surgical Sundries</td>
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### Objective

To ensure that recall of medicines and surgical sundries is managed properly

### Standards

- No recalled stock in use
- Completed credit request forms

### Responsible staff

- Pharmacists
- Post-basic pharmacist assistants
- Clinic operational manager
- Nursing personnel

### Policies, references, and source materials

- Medicine and Related Substances Act (Act no. 101 of 1965) as amended
- Good Pharmacy Practice
- MCC Guidelines for Medicine Recall

### Definition of terms and concepts

Quarantine: keeping separate from the rest of the stock

### Tools, materials, equipment, and other resources

- Recall letter
- Invoices for credit
- Stock card
- Credit request form

### Safety precautions

Recalled stock should not be in use

### Monitoring and evaluation

All recalled stock returned
Record keeping

- Letters of recall
- Completed credit request form

Procedure

<table>
<thead>
<tr>
<th></th>
<th>Upon receipt of a batch recall notification, the following steps must be taken:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>- Verify that the product with the specific batch number under recall is present at the clinic.</td>
</tr>
<tr>
<td></td>
<td>- Remove the recalled batch from the storeroom and the consulting rooms.</td>
</tr>
<tr>
<td></td>
<td>- Quarantine the recalled stock.</td>
</tr>
<tr>
<td>2</td>
<td>Complete the credit request form in triplicate and report to the pharmacist.</td>
</tr>
<tr>
<td>3</td>
<td>Keep a record of letters of recall.</td>
</tr>
<tr>
<td>4</td>
<td>Return the recalled stock according to the specifications in the product recall notification and by following the credit request procedure as per the SOP on receiving.</td>
</tr>
<tr>
<td>5</td>
<td>If the stock has already been used up, report it to the pharmacist.</td>
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</table>
# SOP 17 – PRODUCTS REQUIRING SPECIAL STORAGE OR HANDLING INSTRUCTIONS

**Department of Health**

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<th>SOP-17</th>
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<td>SOP title</td>
<td>Products Requiring Special Storage and Handling Instructions</td>
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<tr>
<td>Date</td>
<td>Area amended</td>
</tr>
</tbody>
</table>

## Objective

To ensure that products that require special storage are handled properly

## Standards

- Secured storage area

## Responsible staff

- Pharmacists
- Post-basic pharmacist assistants
- Clinic operational manager
- Nursing personnel

## Policies, references, and source materials

- Pharmacy Act no. 53 of 1974 as amended
- Medicine and Related Substances Act (Act no. 101 of 1965)
- National Drug Policy
- Public Finance Management Act (Act 1 of 1999)
- Good Pharmacy Practice
- EPI and Cold Chain Manual

## Definition of terms and concepts

SOP: standard operating procedure
Tools, materials, equipment, and other resources
- S5 substances register
- Refrigerator
- Cooler boxes

Safety precautions
- Substances should be stored separately.
- S5 cupboard should always be locked when not in use.

Monitoring and evaluation
- Locked schedule S5 cupboard
- Up-to-date S5 register
- Up-to-date temperature charts
- Separate storage area for hazardous substances

Record keeping
- S5 substances register
- Temperature charts

Procedure

1. The products requiring special storage instructions include:
   - Thermo-labile medicines
   - S5 substances
   - Flammable substances
   - Hazardous substances

2. For ordering, receiving, storage, and issuing of those products, refer to the relevant SOPs.
Department of Health

<table>
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<tr>
<th>SOP number</th>
<th>SOP-18</th>
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<tr>
<td>SOP title</td>
<td>Good Housekeeping and Pest Control</td>
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</table>

Objective
To ensure that all areas where medicines and surgical sundries are stored are tidy, clean, and pest free

Standards
Clean and pest-free medicines and surgical sundries stores and consulting rooms

Responsible staff
- Clinic operational manager
- Nursing personnel
- Cleaning personnel

Policies, references, and source materials
- Medicines and Related Substances Act (Act no. 101 of 1965) as amended
- Occupational Health & Safety Act (Act no. 85 1993)
- National Environmental Management Act (Act 107 of 1998)
- Good Pharmacy Practice
- Agricultural Pest Act (Act no. 36 of 1983) as amended
- National Health Act (Act no. 61 of 2003)

Definition of terms and concepts
SOP: standard operating procedure
| Tools, materials, equipment, and other resources | • Cleaning equipment and material  
• Personal protective equipment  
• Cleaning schedule  
• Pest-control schedule |
| Safety precautions | • Personal protective equipment must be worn at all times when cleaning  
• Set out warning signs when cleaning |
| Monitoring and evaluation | A clean and pest-free environment |
| Record keeping | Cleaning and pest-control registers |

**Procedure**

| **A. General Cleaning** |
|---|---|
| **1** | The cleaners shall wipe walls, dust shelves, and mop floors according to schedule. |
| **2** | The cleaners shall sign and date the register in each area, once the cleaning is completed. |
| **3** | Clean vacuum cleaner, empty vacuum cleaner bag regularly, and maintain polishing equipment (if relevant). |
| **4** | The following must be adhered for a clean and hygienic environment: |
| | • Foodstuffs must not be left exposed and food crumbs must be removed. |
| | • Waste must be placed in proper containers with tight fitting lids. |
| | • Refuse bags must be tied tightly to prevent insects from entering. |
| | • Work orders must be submitted for the repair of holes in ceilings, vinyl coming loose from walls, loose or cracked tiles, etc., as these are ideal breeding places for cockroaches. |
| | • Tables must be kept clean and spills wiped up. |
| | • Notice boards must be securely taped to walls to prevent insects from breeding behind them. |
| | • The medicine store must be free from pests. |
| | • Clean spills and remove broken containers immediately. |
| | • Store supplies on shelves. |
| | • Place boxes on pallets. |
| | • Boxes must not be placed directly on the floor as moisture might rot the cardboard. |
| | • Establish a schedule depending on the traffic and best time of day for cleaning the floors. Keep floors clean and litter free at all times. |
| | • Use the relevant bin according to infection control waste classification. Use the relevant refuse bags to line the bins. Empty bins 1 or 2 times daily, depending on the rate of fill. |
| | • Flatten and remove empty boxes and containers as soon as possible after unpacking the goods to keep the floor area clear at all times. |
| | • Disinfect mops after use in organic chlorine disinfectant, e.g., Biocide D – 6 g sachet in 9 L of cold water for a 30-minute soaking. |
| | • Clean work surfaces twice daily, on opening and at the close of the day. If capacity doesn’t allow for twice daily, then clean on opening. |
• No boxes may be removed without flattening. Recycle paper and cardboard when possible.
• Windows, vents, and doors of offices not in use must be kept closed, and they must be kept clean.

### B. Pest-Control Measures

#### 1. Prevention
- Keep the garbage bins closed at all times.
- Empty garbage bins as frequently as possible.
- Wash, rinse, and sanitize garbage bins regularly.
- Keep all exterior openings tightly closed.
- Check doors for proper fit as part of the regular cleaning schedule.
- Check shipments for signs of pest infestations.
- Report any signs of infestation.

#### 2. Storage of pesticides
- Keep pesticides in their original containers.
- Store pesticides in a separate and locked cabinet.
- Store aerosol cans in a cool place.
- Dispose empty containers according to the manufacturers’ directions and local regulations.
- Keep a copy of the corresponding material safety data sheets on the premises.

#### 3. Control measures
- Use pesticides according to the manufacturers’ instructions.
- Initiate a request for fumigation, according to local arrangement and processes.
- Sign the pest-control register.
# SOP 19 – HANDLING CAMPAIGN STOCK

**Department of Health**

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<th>SOP-19</th>
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<td>Handling Campaign Stock</td>
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<tr>
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<td>Pharmaceutical Services</td>
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</table>

**Objective**

To ensure that campaign stock is managed effectively

**Standards**

- Separate campaign stock from the rest of the stock
- Stock to be updated on stock cards

**Responsible staff**

- Pharmacists
- Clinic operational manager
- Post-basic pharmacists’ assistants
- Nursing personnel

**Policies, references, and source materials**

- Pharmacy Act no. 53 of 1974 as amended
- Medicine and Related Substances Act (Act no. 101 of 1965)
- National Drug Policy
- Public Finance Management Act (Act 1 of 1999)
- Good Pharmacy Practice
- EPI manual
- Cold Chain Management Manual

**Definition of terms and concepts**

VVM: vaccine vial monitor
| Tools, materials, equipment, and other resources | Stock cards  
Cooler boxes  
Fridges  
Ice packs  
Thermometers |
<table>
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<tbody>
<tr>
<td>Safety precautions</td>
</tr>
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</table>
| Monitoring and evaluation | Updated stock cards  
Updated temperature charts |
| Record keeping | Stock cards  
Temperature charts |

**Procedure**

1. Campaign stock must be kept separate from the other stock.
2. Campaign stock must have separate stock cards.
## SOP 20 – MANAGEMENT OF CHRONIC REFERRAL SYSTEM

**Objective**
To standardize and regulate the chronic referral system at clinics to ensure that chronic medications are available to patients at the nearest clinic.

**Standards**
All chronic patients receive their treatment on time.

**Responsible staff**
- Medical officers
- Pharmacists
- Post-basic pharmacists' assistant
- Clinic operational manager
- Clinic nurses

**Policies, references, and source materials**
- Public Finance Management Act (Act 1 of 1999)
- Medicines and Related Substances Act (Act 101 of 1965) as Amended
- Nursing Act (Act 30 of 2005)
- National Drug Policy
- Good Pharmacy Practice
- Essential Medicines List

**Definition of terms and concepts**
SOP: standard operating procedure
| **Tools, materials, equipment, and other resources** | • Chronic referral forms  
• Computer and printer  
• Stationery  
• Packaging material  
• Transport  
• Telephone lines |
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<tbody>
<tr>
<td><strong>Safety precautions</strong></td>
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<tr>
<td><strong>Monitoring and evaluation</strong></td>
</tr>
<tr>
<td><strong>Record keeping</strong></td>
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**Procedure**

<table>
<thead>
<tr>
<th>1</th>
<th>The chronic referral form should be used only for chronic treatment, not acute treatment.</th>
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</thead>
<tbody>
<tr>
<td>2</td>
<td>The medical officer completes the chronic referral form.</td>
</tr>
</tbody>
</table>
| 3 | The patient will receive the first treatment at the Hospital Pharmacy.  
• The top part of the referral form is for the patient.  
• The second copy remains in the patient’s file.  
• The last copy remains in the pharmacy for refills. |
| 4 | Patients’ forms are to be reviewed every six months. |
| 6 | All chronic treatment will be dispensed at the clinic by the post-basic pharmacist assistant, community service pharmacist, and professional nurse. |

Dispensing should be done according to the following procedure:

- Interpret and evaluate the prescription
- Prepare and label the prescribed medicines
- Provide information and instructions to the patient to ensure the safe and effective use of medicine
- The dispensed medicines should have the following on the label:
  - The Generic name of the medicine
  - Direction for use of the medicine
  - Name & Address of the health establishment
  - Date of dispensing
  - Patient Reference number
# SOP 21 – CONTROL OF VISITS BY PHARMACEUTICAL REPRESENTATIVES

## Objective
To ensure that visits by pharmaceutical representatives are regulated at the clinic.

## Standards
- Records of approval from responsible pharmacist
- Records of visits

## Responsible staff
- Clinic operational manager
- Professional nurse
- Assistant manager PHC (local area)
- Responsible pharmacist

## Policies, references, and source materials
- Pharmacy Act (Act no. 53 of 1974) as Amended
- Medicine and Related Substances Act (Act no. 101 of 1965)
- Good Pharmacy Practice
- Essential Medicines List
- National Drug Policy

## Definition of terms and concepts
- EML: Essential Medicines List; list of medicines that satisfy the priority health care needs of the population

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**Department of Health**

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<td>Control of Visits by Pharmaceutical Representatives</td>
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<td>Pharmaceutical Services</td>
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**Department of Health**

**LIMPOPO PROVINCIAL GOVERNMENT**

**REPUBLIC OF SOUTH AFRICA**

**DOCUMENT CONTROL:**
- Copy Number: …………………………
- Issued to: …………………………
- Received by: …………………………
- Period Effective:
  - ……………………………………………………
- Adapted & copy to Pharmacy Services:………………………
- Date:……………………………………
| Tools, materials, equipment, and other resources | Visitors’ book |
| Safety precautions | No unauthorized visit by pharmaceutical representatives |
| Monitoring and evaluation | Check approval of visits against visitors’ book |
| Record keeping | Visit register |

**Procedure**

1. Pharmaceutical representatives must consult with the assistant manager (or any other delegated person) on their visit to the clinic.
2. The clinic must only allow pharmaceutical representatives that have an appointment and permission from the assistant manager.
3. Pharmaceutical representatives must inform the assistant manager of any activity or information regarding items on tender before giving information to clinic personnel.
4. Pharmaceutical representatives must not be permitted access to medicine rooms, medicine cupboards, medicine records, etc., for any reason.
5. Pharmaceutical representatives must not disrupt service delivery at the clinic.
6. Pharmaceutical representatives must sign the clinic visitors’ book upon entering the clinic.
# SOP 22 – MANAGEMENT OF ADVERSE DRUG REACTIONS

**Department of Health**

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<td>SOP title</td>
<td>Management of Adverse Drug Reactions</td>
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**Objectives**

- To ensure that adverse drug reactions are reported
- To ensure patient safety

**Standards**

Record of ADR reported

**Responsible staff**

- Clinic operational manager
- Professional nurse
- Pharmacists
- Post-basic pharmacist assistants
- Medical officers
- DTC members

**Policies, references, and source materials**

- Medicine and Related Substance Control Act (Act 101 of 1965) Amended
- National Drug Policy
- Good Pharmacy Practice
- Essential Medicines List

**Definition of terms and concepts**

- ADR: adverse drug reaction
- DTC: Drugs and Therapeutics Committee
- EML: Essential Medicine List
- Pharmacovigilance: prevention, detection, assessment, and reporting of ADRs
• RAQA: Regulatory Affairs and Quality Assurance
• STG: Standard Treatment Guidelines

<table>
<thead>
<tr>
<th>Tools, materials, equipment, and other resources</th>
<th>Adverse drug reaction reporting form (Annex 14)</th>
</tr>
</thead>
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<tr>
<td>Safety precautions</td>
<td>Withdraw the medicine from the patient</td>
</tr>
<tr>
<td>Monitoring and evaluation</td>
<td>ADR reports</td>
</tr>
<tr>
<td>Record keeping</td>
<td>ADR reports</td>
</tr>
</tbody>
</table>

### Procedure

1. Once a health care provider suspects an ADR, the provider must complete an ADR form (available in every STG and EML book) for each ADR.

2. Keep a chronological record of all ADRs. In each case, record investigations, results, and any other actions taken relating to the ADR.

3. The health care provider must send the ADR form to the responsible pharmacist.

4. The responsible pharmacist must submit the ADR form to the ADR/DTC in the hospital and also to the RAQA for reporting/surveillance purposes.

5. RAQA must send the form to the national ADR Event Monitoring Centre, c/o the Registrar of Medicines, Department of Health, Private Bag X828, Pretoria 0001.

6. Feedback must be given to the clinic/health care provider by the responsible pharmacist.
Annex 14. Adverse Drug Reaction Reporting Form

**PATIENT INFORMATION**

Name (or initials): ........................................... Age: ............. Weight (kg): ............

<table>
<thead>
<tr>
<th>Sex:</th>
<th>M</th>
<th>F</th>
</tr>
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<tbody>
<tr>
<td>DOB:</td>
<td>/</td>
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</table>

**ADVERSE REACTION / PRODUCT QUALITY PROBLEM**

- Adverse event(1) □ and/or product quality problem(2) □
- Date of onset of reaction: ....../....../......
- Time of onset of reaction: ......h ......min

Description of event or problem (include relevant tests/lab data, including dates):

<p>| 1. MEDICINES/VACCINES/DEVICES (asterisk suspected product – include all concomitant medicines) |
|-----------------------------------|------------|--------|-------------|-------------|-----------------------------|</p>
<table>
<thead>
<tr>
<th>Trade name &amp; batch no.</th>
<th>Daily dosage</th>
<th>Route</th>
<th>Date started</th>
<th>Date stopped</th>
<th>Reasons for use</th>
</tr>
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**ADVERSE EVENT OUTCOME (tick all that apply)**

- Death
- Disability
- Congenital anomaly
- Life-threatening
- Hospitalisation
- Other ............
- Event reappeared on rechallenge Y N
- Treatment (of reaction): .................
- Required intervention to prevent permanent impairment/damage

- Recovered: Y N
- Sequelae: Y N
- Describe sequelae:

**COMMENTS:** (e.g., relevant history, allergies, previous exposure, baseline test results/lab data)

**2. PRODUCT QUALITY PROBLEM:**

<table>
<thead>
<tr>
<th>Trade name</th>
<th>Batch no.</th>
<th>Registration no.</th>
<th>Dosage form &amp; strength</th>
<th>Expiry date</th>
<th>Size/type of container</th>
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Product available for evaluation? Y N

**REPORTING DOCTOR/PHARMACIST, ETC:**

- NAME: ...........................................
- QUALIFICATIONS: .........................................
- ADDRESS: ...........................................

- ........................................... ........................................... ....../....../......
- TEL: (......) ...........................................
- Signature Date
**SOP 23 – MANAGING MEDICATION ERRORS**

### Department of Health

<table>
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<th>Revision no.:</th>
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<td>Managing Medication Errors</td>
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### Objectives

- To encourage reporting medication errors to minimize risks to patients and ensure the safety and well-being of the patient concerned
- To ensure that there is a uniform procedure available for reporting medication errors

### Standards

- Records of medication errors

### Responsible staff

- Clinic operational manager
- Nursing personnel
- Pharmacists
- Post-basic pharmacist assistants
- Medical officer
- Quality assurance representative
- Occupational health and safety officer

### Policies, references, and source materials

- Pharmacy Act (Act no. 53 of 1974) as amended
- Medicine and Related Substances Act (Act no. 101 of 1965)
- National Drug Policy
- Nursing Act
- Health Professions Act
- Patients’ Rights Charter
**Definition of terms and concepts**

Medication error: any incorrect or wrongful administration of a medication, such as a mistake in dosage or route of administration, failure to prescribe or administer the correct drug or formulation for a particular disease or condition, use of outdated drugs, failure to observe the correct time for administration of the drug, or lack of awareness of adverse effects of certain drug combinations.

**Tools, materials, equipment, and other resources**

Medication error reporting form (Annex 15)

**Safety precautions**

Ensure that all medicines are checked by more than one person before dispensing to patients.

**Monitoring and evaluation**

Medication error reports

**Record keeping**

Medication error reports

### Procedure

<p>| | |</p>
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>1</td>
<td>All medication errors must be recorded in the medication error reporting form (Annex 15. Medication Error Reporting Form).</td>
</tr>
</tbody>
</table>
| 2 | The following, among other medication errors, must be reported:  
  - Incorrect dosage dispensed  
  - Medication not dispensed  
  - Incorrect medication administered  
  - Incorrect medicine dispensed  
  - Incorrect quantity dispensed  
  - Incorrect dose administered  
  - Incorrect route of administration  
  - Expired medicines or medicines that have been stored incorrectly dispensed/administered |
| 3 | The report on medication errors must be discussed with relevant health care professionals at the clinic. |
| 4 | Quality improvement plans must be developed and implemented. |
| 5 | Quality improvement strategies must be monitored and evaluated. |
### Annex 15. Medication Error Reporting Form

<table>
<thead>
<tr>
<th>MEDICATION ERROR</th>
<th>CODE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Misdiagnosis of the patient</td>
<td>MD</td>
</tr>
<tr>
<td>Medication issued to wrong patient</td>
<td>WP</td>
</tr>
<tr>
<td>Wrong medication issued to patient</td>
<td>WM</td>
</tr>
<tr>
<td>Wrong dose given to patient</td>
<td>WD</td>
</tr>
<tr>
<td>Contraindicated Medication</td>
<td>CM</td>
</tr>
<tr>
<td>Drug-Drug interaction</td>
<td>DD</td>
</tr>
<tr>
<td>No label on the medication</td>
<td>NL</td>
</tr>
<tr>
<td>Surgery on an incorrect site</td>
<td>SIS</td>
</tr>
<tr>
<td>Failure to remove all medical instruments</td>
<td>MI</td>
</tr>
<tr>
<td>Incorrect record keeping</td>
<td>RK</td>
</tr>
<tr>
<td>Incorrect storage of medicine</td>
<td>IS</td>
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</tbody>
</table>

Medication errors include the following:
# SOP 24 – SAFE ADMINISTRATION OF MEDICINES

**Department of Health**

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<th>SOP-24</th>
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<td>Safe Administration of Medicines</td>
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### Objective

To ensure that medicines are administered safely to patients at all times

### Standards

- No patient complaints

### Responsible staff

- Clinic operational manager
- Nursing personnel
- Pharmacists
- Post-basic pharmacist assistants
- Medical officer

### Policies, references, and source materials

- Pharmacy Act (Act no. 53 of 1974)
- Medicine and Related Substances Act (Act no. 101 of 1965)
- National Drug Policy
- Nursing Act
- Health Professions Act
- Good Pharmacy Practice
- Essential Medicines List
**Definition of terms and concepts**

SOP: standard operating procedure

**Tools, materials, equipment, and other resources**

- Appropriate surgical sundries
- Personal protective equipment

**Safety precautions**

- Put on appropriate personal protective equipment
- Administer per patient prescription

**Monitoring and evaluation**

- Up to date patient records

**Record keeping**

Tick registers

**Procedure**

1. Medicine must be administered by a professional nurse.
2. Administration of medicines should be done in accordance with WHO guidelines (Annex 16).
3. Ensure that any special cautions or precautions related to the administration of certain medicines are adhered prior to or after administration of the medicine (Annex 16).
4. Maintain an accurate record of all medicines administered to each patient including dates, times, and doses on the patient’s prescription record.
5. Sign the patient’s administration record each time a dose is given.
6. Report immediately any adverse reactions or any other unexpected events related to the administration of a medicine.
7. If for any reason a scheduled dose of a medicine is not given, a reason for the non-administration must be written in the patient’s prescription record.
8. All administration of medicines in the clinic must be done by the authorized health care practitioner.
Annex 16. WHO Guide on Good Prescribing (Illustrated)

Safe Administration of Medicines

Eye Drops

1. Wash your hands.
2. Do not touch the dropper opening.
3. Look upward.
4. Pull the patient’s lower eyelid down to make a ‘gutter’.
5. Bring the dropper as close to the gutter as possible without touching it or the eye.
6. Apply the prescribed amount of drops in the gutter.
7. Have the patient close the eye for about two minutes. Tell them not to shut the eye too tight.
8. Excess fluid can be removed with a tissue.
9. If more than one kind of eye drop is used, wait at least five minutes before applying the next drops.
10. Eye drops may cause a burning feeling, but this should not last for more than a few minutes. If it does last longer, consult a doctor or pharmacist.

When Giving Eye Drops to Children

1. Let the child lie back with head straight.
2. The child’s eyes should be closed.
3. Drip the amount of drops prescribed into the corner of the eye.
4. Keep the head straight.
5. Remove excess fluid.
Eye Ointment

1. Wash your hands.
2. Do not touch anything with the tip of the tube.
3. Tilt the patient’s head backwards a little.
4. Take the tube in one hand and pull down the lower eyelid with the other hand to make a ‘gutter’.
5. Bring the tip of the tube as close to the gutter as possible.
6. Apply the amount of ointment prescribed.
7. Have the patient close the eye for two minutes.
8. Remove excess ointment with a tissue.
9. Clean the tip of the tube with another tissue.

Steps 4 and 5
Ear Drops

1. Warm the ear drops by keeping the bottle in the hand for several minutes. Do not use hot water tap, no temperature control!
2. Tilt the patient’s head sideways or have the patient lie on one side with the ear upward.
3. Gently pull the lobe to expose the ear canal.
4. Apply the amount of drops prescribed.
5. Wait five minutes before turning to the other ear.
6. Use cotton wool to close the ear canal after applying the drops only if the manufacturer explicitly recommends this.
7. Ear drops should not burn or sting longer than a few minutes.
Nasal Drops

1. Have the patient blow their nose.
2. Have the patient sit down and tilt their head backward strongly or lie down with a pillow under the shoulders; keep the head straight.
3. Insert the dropper one centimeter into the nostril.
4. Apply the amount of drops prescribed.
5. Immediately afterward tilt head forward strongly (head between knees).
6. Have the patient sit up after a few seconds; the drops will then drip into the pharynx.
7. Repeat the procedure for the other nostril, if necessary.
8. Rinse the dropper with boiled water.

Steps 2 and 3

Step 5
Nasal Spray

1. Have the patient blow their nose.
2. Have the patient sit with their head slightly tilted forward.
3. Shake the spray.
4. Insert the tip in one nostril.
5. Close the other nostril and mouth.
6. Spray by squeezing the vial (flask, container) and have the patient sniff slowly.
7. Remove the tip from the nose and bend the head forward strongly (head between the knees).
8. Have the patient sit up after a few seconds; the spray will drip down the pharynx.
9. Tell the patient to breathe through the mouth.
10. Rinse the tip with boiled water.

Steps 4 and 5

Step 7
Transdermal Patch

1. For patch site, see instructions included with the drug or check with your pharmacist.
2. Do not apply over bruised or damaged skin, skin folds, or under tight clothing.
3. Change spots regularly.
4. Apply with clean, dry hands.
5. Clean and dry the area of application completely.
6. Remove patch from package, but do not touch the ‘drug’ side.
7. Place on skin and press firmly. Rub the edges to seal.
8. Remove and replace according to instructions.
Aerosol

1. Have the patient cough up as much sputum as possible.
2. Shake the aerosol before use.
3. Hold the aerosol as indicated in the manufacturer’s instructions (this is usually upside down).
4. Have the patient place their lips tightly around the mouthpiece.
5. Tilt the head backward slightly.
6. Tell the patient to breathe out slowly, emptying the lungs of as much air as possible.
7. Tell the patient to breathe in deeply and activate the aerosol, keeping the tongue down.
8. Have the patient hold their breath for ten to fifteen seconds.
9. Tell the patient to breathe out through the nose.
10. Have the patient rinse the mouth with warm water.
Inhaler with Capsules

1. Have the patient cough up as much sputum as possible.
2. Place the capsule(s) in the inhaler according to manufacturer’s instructions.
3. Have the patient breathe out slowly and empty lungs of as much air as possible.
4. Have the patient place their lips tightly around the mouthpiece.
5. Tilt head backward slightly.
6. Tell the patient to take a deep breath through the inhaler.
7. Have the patient hold their breath for ten to fifteen seconds.
8. Have the patient breathe out through the nose.
9. Tell the patient to rinse the mouth with warm water.
Suppository

1. Wash your hands.
2. Remove the covering (unless too soft).
3. If the suppository is too soft, let it harden first by cooling it (fridge or hold under cold running water, still packed!), then remove covering.
4. Remove possible sharp rims by warming in the hand.
5. Moisten the suppository with cold water.
6. Have the patient lie on his/her side and pull up their knees.
7. Gently insert the suppository, rounded end first, into the back passage.
8. Tell the patient to remain lying down for several minutes.
9. Wash your hands.
10. Tell the patient to try to not have a bowel movement during the first hour.
Vaginal Tablet with Applicator

1. Wash your hands.
2. Remove the wrapper from the tablet.
3. Place the tablet into the open end of the applicator.
4. Have the patient lie on their back, draw up their knees a little, and spread them apart.
5. Gently insert the applicator with the tablet in front into the vagina as far as possible; DO NOT use force!
6. Depress the plunger so that the tablet is released.
7. Withdraw the applicator.
8. Discard the applicator (if disposable).
9. Clean both parts of the applicator thoroughly with soap and boiled, lukewarm water (if not disposable).
10. Wash your hands.
Vaginal Tablet without Applicator

1. Wash your hands.
2. Remove the wrapper from the tablet.
3. Dip the tablet in lukewarm water just to moisten it.
4. Have the patient lie on their back, draw up their knees, and spread them apart.
5. Gently insert the tablet into the vagina as high as possible; DO NOT use force!
6. Wash your hands.
Applying Vaginal Creams, Gels, and Ointments

(Most of these drugs come with an applicator)

1. Wash your hands.
2. Remove the cap from the tube containing the drug.
3. Screw the applicator to the tube.
4. Squeeze the tube until the required amount is in the applicator.
5. Remove the applicator from the tube (hold the cylinder).
6. Apply a small amount of cream to the outside of the applicator.
7. Have the patient lie on their back, draw up their knees, and spread them apart.
8. Gently insert the applicator into the vagina as far as possible, DO NOT use force.
9. Hold the cylinder, and with the other hand, push the plunger down, thus inserting the drug into the vagina.
10. Withdraw the applicator from the vagina.
11. Discard the applicator if disposable or clean thoroughly (boiled water) if not.
12. Wash your hands.
General Practical Aspects of Injecting

Apart from the specific technique of injecting, there are a few general rules that you should keep in mind.

1. Expiry dates
   - Check the expiry dates of each item, including the drug.
   - If you make house calls, check the drugs in your medical bag regularly to make sure that they have not passed the expiry date.

2. Drug
   - Make sure that the vial or ampoule contains the right drug in the right strength.

3. Sterility
   - During the whole preparation procedure, material should be kept sterile.
   - Wash your hands before starting to prepare the injection.
   - Disinfect the skin over the injection site.

4. No bubbles
   - Make sure that there are no air bubbles in the syringe.
   - This is more important in intravenous injections.

5. Prudence
   - Once the protective cover of the needle is removed, extra care is needed.
   - Do not touch anything with the unprotected needle.
   - Once the injection has been given, take care not to prick yourself or somebody else.

6. Waste
   - Make sure that contaminated waste is disposed safely.
Aspirating from Ampoules (Glass, Plastic)

Materials Needed

Syringe of appropriate size, needle of required size, ampoule with required drug or solution, and gauze.

Technique

1. Wash your hands.
2. Put the needle on the syringe.
3. Remove the liquid from the neck of the ampoule by flicking it or swinging it fast in a downward spiralling movement.
4. File around the neck of the ampoule.
5. Protect your fingers with gauze if ampoule is made of glass.
6. Carefully break off the top of the ampoule (for a plastic ampoule, twist the top).
7. Aspirate the fluid from the ampoule.
8. Remove any air from the syringe.
9. Clean up; dispose of working needle safely; wash your hands.
Aspirating from a Vial

Materials Needed

Vial with required drug or solution, syringe of the appropriate size, needle of right size (im, sc, or iv) on syringe, disinfectant, and gauze.

Technique

1. Wash your hands.
2. Disinfect the top of the vial.
3. Use a syringe with a volume of twice the required amount of drug or solution and add the needle.
4. Suck up as much air as the amount of solution needed to aspirate.
5. Insert needle into (the top of) the vial and turn upside down.
6. Pump air into vial (creating pressure).
7. Aspirate the required amount of solution and 0.1 mL extra. Make sure the tip of the needle is below the fluid surface.
8. Pull the needle out of the vial.
9. Remove possible air from the syringe.
10. Clean up; dispose of waste safely; wash your hands.

![Step 4](image1.png)
![Step 5](image2.png)
![Step 8](image3.png)
Dissolving Dry Medicine

Materials Needed

Vial with dry medicine to be dissolved, syringe with the right amount of solvent, needle of the right size (im, sc, or iv) on the syringe, disinfectant, injection needle, and gauze.

Technique

1. Wash your hands.
2. Disinfect the rubber cap (top) of the vial containing the dry medicine.
3. Insert the needle into the vial, hold the whole upright.
4. Suck up as much air as the amount of solvent already in the syringe.
5. Inject only the fluid into the vial, not the air!
7. Turn the vial upside down.
8. Inject the air into the vial (creating pressure).
9. Aspirate the total amount of solution (no air).
10. Remove any air from the syringe.
11. Clean up; dispose of waste safely; wash hands.
Subcutaneous Injection

Materials Needed

Syringe with the drug to be administered (without air), needle (Gauss 25, short and thin; on syringe), liquid disinfectant, cotton wool, and adhesive tape.

Technique

1. Wash your hands.
2. Reassure the patient and explain the procedure.
3. Uncover the area to be injected (upper arm, upper leg, abdomen).
4. Disinfect skin.
5. ‘Pinch’ a fold of the skin.
6. Insert needle in the base of the skin-fold at an angle of 20 to 30 degrees.
7. Release skin.
8. Aspirate briefly; if blood appears; withdraw needle, replace it with a new one, if possible, and start again from step 4.
9. Inject slowly (0.5-2 minutes!).
10. Withdraw needle quickly.
12. Check the patient's reaction and give additional reassurance, if necessary.
13. Clean up; dispose of waste safely; wash hands.
Intramuscular Injection

Materials Needed

Syringe with the drug to be administered (without air), needle (Gauss 22, long and medium thickness; on syringe), liquid disinfectant, cotton wool, and adhesive tape.

Technique

1. Wash your hands.
2. Reassure the patient and explain the procedure.
3. Uncover the area to be injected (lateral upper quadrant major gluteal muscle, lateral side of upper leg, deltoid muscle).
4. Disinfect the skin.
5. Tell the patient to relax the muscle.
6. Insert the needle swiftly at an angle of 90 degrees (watch depth!).
7. Aspirate briefly; if blood appears, withdraw needle. Replace it with a new one, if possible, and start again from step 4.
8. Inject slowly (less painful).
11. Check the patient's reaction and give additional reassurance, if necessary.
12. Clean up; dispose of waste safely; wash your hands.
Intravenous Injection

Materials Needed

Syringe with the drug to be administered (without air), needle (Gauss 20, long and medium thickness; on syringe), liquid disinfectant, cotton wool, adhesive tape, and tourniquet.

Technique

1. Wash your hands.
2. Reassure the patient and explain the procedure.
3. Uncover arm completely.
4. Have the patient relax and support his arm below the vein to be used.
5. Apply tourniquet and look for a suitable vein.
6. Wait for the vein to swell.
7. Disinfect skin.
8. Stabilize the vein by pulling the skin taut in the longitudinal direction of the vein. Do this with the hand you are not going to use for inserting the needle.
9. Insert the needle at an angle of about 35 degrees.
10. Puncture the skin and move the needle slightly into the vein (3-5 mm).
11. Hold the syringe and needle steady.
12. Aspirate. If blood appears hold the syringe steady, you are in the vein. If it does not come, try again.
13. Loosen tourniquet.
14. Inject (very) slowly. Check for pain, swelling, hematoma; if in doubt whether you are still in the vein aspirate again!
16. Check the patient's reactions and give additional reassurance, if necessary.
17. Clean up; dispose of waste safely; wash your hands.

Step 8
Step 9
Steps 11 to 14
**SOP 25 – CLINIC SUPPORT VISIT BY PHARMACY PERSONNEL**

**Objective**
To ensure that clinics are supported by pharmacy personnel

**Standards**
- Records of visits
- Ordering schedule adhered to
- Monthly and quarterly reports

**Responsible staff**
- Clinic operational manager nursing personnel
- Pharmacists
- Post-basic pharmacist assistants
- District pharmacist
- Sub-district PHC managers

**Policies, references, and source materials**
- Pharmacy Act (Act no. 53 of 1974) as amended
- Medicines and Related Substances Act (Act no. 101 of 1965) as amended
- National Drug Policy
- Nursing Act (Act no. 33 of 2005) as amended
- Good Pharmacy Practice

**Definition of terms and concepts**
RAQA: Regulatory Affairs And Quality Assurance
SOP: standard operating procedure
| Tools, materials, equipment, and other resources | • Stock cards  
• Stock availability tool  
• National core standards tool  
• Transport |
| Safety precautions | Verify identity of the visitor |
| Monitoring and evaluation | • Well-managed medicine stores  
• Well-managed records |
| Record keeping | • Records of orders and receipts  
• Visitors register  
• Stock availability reports |

**Procedure**

1. During the support visit, one of the following can be carried out:
   - Check and report stock availability using the attached tool (Annex 17. Example of Limpopo Province Clinics Stock Availability Checklist).
   - Check and report stock accuracy (at least 50 items to be checked using the stock availability tool).
   - Check if stock is entered on the stock cards and is updated.
   - Check cold chain maintenance, e.g., temperature charts are up to date.
   - Check if expired stock is managed as per expired stock SOP (SOP 11).
   - Manage over/under-stocking and short-dated stock per Stock Management SOP (SOP 18)
   - Compile depot orders with the clinic nurse.

2. Perform and report on stock take with the assistance of nursing personnel at the clinic twice a year (end of March and end of the September).

3. Assess the clinic using the national core standard tool twice a year (end of May and end of October).

4. All reports should be forwarded to the responsible pharmacist who will in turn forward them to the district pharmacist. The district pharmacist will consolidate and forward to the RAQA office in the province.
## Annex 17. Limpopo Province Clinics Stock Availability Checklist

<table>
<thead>
<tr>
<th>Stock No</th>
<th>Stock Code</th>
<th>Generic Name</th>
<th>ST_DSPUM</th>
<th>Available</th>
<th>Alternative</th>
</tr>
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<tbody>
<tr>
<td>0136</td>
<td>PHC</td>
<td>Medroxyprogesterone Inj 150Mg/ml 1Ml</td>
<td></td>
<td>1</td>
<td></td>
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<tr>
<td>0137</td>
<td>PHC</td>
<td>Norethisterone Inj 200Mg/ml Long-Acting</td>
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<td>1</td>
<td></td>
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<tr>
<td>0135</td>
<td>PHC</td>
<td>Oral Contraceptive Progestogen</td>
<td></td>
<td>28</td>
<td></td>
</tr>
<tr>
<td>0139</td>
<td>PHC</td>
<td>Oral Contraceptive Triphasic Low</td>
<td></td>
<td>28</td>
<td></td>
</tr>
<tr>
<td>0148</td>
<td>PHC</td>
<td>Adrenaline Inj 0.1Mg/ml 1:1000 1Ml</td>
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<td></td>
</tr>
<tr>
<td>0152</td>
<td>PHC</td>
<td>Aminophyllin Inj For I.V. Use 25Mg/ml 10Ml</td>
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<td></td>
</tr>
<tr>
<td>0177</td>
<td>PHC</td>
<td>Dextrose In Water Inj 50% 50Ml</td>
<td></td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>0200</td>
<td>PHC</td>
<td>Hydrocortisone Inj 100Mg/2ml</td>
<td></td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>0218</td>
<td>PHC</td>
<td>Lignocaine Inj 1% 20Ml</td>
<td></td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>0225</td>
<td>PHC</td>
<td>Magnesium Sulphate Inj 50% 2Ml</td>
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<td>1</td>
<td></td>
</tr>
<tr>
<td>0253</td>
<td>PHC</td>
<td>Phytomenadione Inj 2Mg/0.2Ml</td>
<td></td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>0266</td>
<td>PHC</td>
<td>Sodium Bicarb Inj 8.5% 50Ml</td>
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<td>1</td>
<td></td>
</tr>
<tr>
<td>0268</td>
<td>PHC</td>
<td>Water For Inj 10Ml (Plastic)</td>
<td></td>
<td>1</td>
<td></td>
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</tbody>
</table>