



# **PHARMACY TOOLKIT**

**STANDARD OPERATING PROCEDURES**

**FOR**

**PRIMARY HEALTHCARE FACILITIES**



Province of the  
**EASTERN CAPE**  
HEALTH

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## Abbreviations

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Abbreviation	Explanation
EML	Essential Medicine List
EPI	Expanded programme for immunisation
FEFO	First Expiry, First Out
FIFO	First In, First Out
GPP	Good Pharmacy Practice
IPCO	Infection and Prevention Control Officer
PBPA	Post-basic Pharmacist's Assistant
PHC facilities	Primary Health Care Facilities
PTC	Pharmacy and Therapeutics Committee
RP	Responsible Pharmacist
RPF	Referral Prescription Form
SAMF	South African Medicines Formulary
SAPC	South African Pharmacy Council
SOP	Standard Operating Procedure
STG	Standard Treatment Guidelines

## Definitions of Terms

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<b>Medication</b>	A pharmaceutical drug (medicine or medication or medicinal product) is any chemical substance formulated or compounded as a single active ingredient or in combination of other pharmacologically active substances. It may be in a separate but packed in a single unit pack as combination product intended for internal, or external or for use in the medical diagnosis, cure, treatment, or prevention of disease
<b>Medical supplies</b>	Medical supplies include surgicals e.g. gloves, needles, syringes, catheters etc. They are included under the functional area of pharmacy for the sake of convenience, as the principles involved in the keeping and supply of medicines and medical supplies are similar. It does not place an obligation on the pharmacy in an establishment to control the medical supplies. In many establishments these items fall under supply chain management. In cases where these items are not stored in the pharmacy, they may be found in a storage area
<b>Dispensary</b>	A dispensary is a suitable room in a PHC facility where the services are provided by a post-basic pharmacist's assistant (PBPA) or Professional Nurse (PN)
<b>Medicine room</b>	A medicine room is a suitable room designated as a storage area for medicine in a PHC facility. Medication is sent to consulting rooms each day where it is dispensed by a licensed health care professionals
<b>Dispensing</b>	As defined in terms of the Pharmacy Act means "the interpretation and evaluation of a prescription, the selection, manipulation or compounding of the medicine, the labelling and supply of the medicine in an appropriate container according to the Medicines Act and the provision of information and instructions to ensure the safe and effective use of the medicine by the patient"

# Introduction

This Pharmacy Toolkit contains 19 Standard Operating Procedures (SOPs) applicable to pharmaceutical services. By implementing these SOPs, PHC facilities will be able to comply with 28 National Core Standard Measures, 19 Ideal Clinic dashboard references and Good Pharmacy Practice.

The table below provides an overview of the NCS measures and the SOPs contained in this Toolkit.

	Standard Operating Procedures (SOP)	Purpose of SOP	Reference documents		
			Good Pharmacy Practice	NCS Measures	Ideal Clinic
1	Professional standards for dispensaries, medicine rooms and/or consulting rooms	To define the requirements of facilities, equipment and literature at dispensaries, medicines rooms and/or consulting room(s) in PHC facilities and mobile clinics	<b>Chapter 1 – Professional standards for premises</b>	<b>3.1.3.1.1 CHECKLIST –</b> Medicine is stored correctly as per Good Pharmacy Practice <b>3.1.3.1.2 CHECKLIST –</b> Procedures relating to the management of medicine as required by Good Pharmacy Practice are followed in the pharmacy/medicine room <b>3.1.3.1.3 CHECKLIST –</b> Medicines in the wards or consultation rooms are appropriately stored and managed <b>3.1.3.4.2 CHECKLIST –</b> Medical supplies are stored correctly	<ul style="list-style-type: none"> <li>• Dispensary room temperature appropriately controlled</li> <li>• Use of EDL and STGs for prescriptions implemented</li> </ul>
2	Scope of practice of dispensing personnel	To define the roles and responsibilities associated with the different levels at which pharmaceutical services operate and clarify the responsibilities of all categories of staff involved in the provision of pharmaceutical services at a PHC level	<b>Chapter 3 – Professional standards for pharmacy human resource</b>	<b>3.1.3.1.2 CHECKLIST –</b> Procedures relating to the management of medicine as required by Good Pharmacy Practice are followed in the pharmacy/medicine room	<ul style="list-style-type: none"> <li>• All Nursing staff trained on dispensing and prescribing</li> <li>• Use of EDL and STGs for prescriptions implemented</li> </ul>
3	Pest control in the dispensary or medicine room	To provide guidance on keeping the dispensary or medicine room pest free at all times	<b>Chapter 1 – Professional standards for premises</b>	<b>7.4.1.3.1</b> Records show that Pest Control is done monthly in all areas	

4	Daily routine and working hours	To regulate and standardize the manner in which pharmaceutical services are rendered and to provide for key control	Chapter 1 – Professional standards for premises	3.1.2.5.1 Duty rosters indicate that at least one pharmacist or pharmacist’s assistant or professional nurse in the clinics is on duty and available to dispense medicine as required during opening hours	
				3.1.2.6.1 A standard operating procedure is available which indicates how healthcare professionals can access medicines when the pharmacy/medicine room is closed	
5	Stock take	To ensure the accuracy of stock records by comparing actual stock on hand with stock records	Chapter 2 – Professional standards for services	<p>3.1.3.2.3 There is evidence that a stock take was done in the last 12 months for medicines</p> <p><b>3.1.2.2.1 CHECKLIST -</b> Tracer medical supplies are available in the area where medical supplies are stored</p> <p><b>3.1.3.5.2 CHECKLIST –</b> Physical stock corresponds to stock on the inventory management system as per Checklist 31221</p> <p><b>3.1.3.5.3</b> There is evidence that a stock take for supplies was done in at least the last 12 months</p>	Inventory Management: monitoring of medicines availability implemented (to avoid stock outs and expiry / use of BIN Cards implemented)



6	Ordering stock	To regulate and standardize ordering procedures	<p><b>Chapter 2 – Professional standards for services</b></p>	<p><b>3.1.2.1.1 CHECKLIST</b> – Tracer medicines as per applicable Essential Drugs List or formulary are available in the pharmacy/ medicine room</p> <p><b>3.1.2.2.1 CHECKLIST –</b> Tracer medical supplies are available in the area where medical supplies are stored</p> <p><b>3.1.2.3.2</b> A document outlining the delivery schedule for medicine is available</p> <p><b>3.1.2.4.2</b> A document outlining the delivery schedule for medicine is available</p> <p><b>3.1.3.1.2 CHECKLIST –</b> Procedures relating to the management of medicine as required by Good Pharmacy Practice are followed in the pharmacy/medicine room</p> <p><b>3.1.3.2.1</b> The stock control system shows minimum and maximum or re-order levels for medicines</p> <p><b>3.1.3.2.2 CHECKLIST –</b> Physical stock corresponds to the stock reflected in the inventory management system (as per checklist 31211)</p> <p><b>3.1.3.4.1</b> There is a procedure relating to the management of medical supplies/devices</p>	<ul style="list-style-type: none"> <li>• Inventory Management: computerized system for inventory management in place</li> <li>• Inventory Management: monitoring of medicines availability implemented (to avoid stock outs and expiry / use of BIN Cards implemented)</li> <li>• Inventory Management: Stock files in place and medicines ordered according to stock files</li> <li>• Availability of SOPs for medical depots (medical supplies and dry dispensary)</li> <li>• ART drugs available on site</li> <li>• TB drugs available</li> <li>• Vaccines available</li> <li>• EPI and Vitamin A available</li> <li>• ANC drugs available on site</li> <li>• STI drugs available</li> <li>• Chronic drugs available on site</li> <li>• Contraceptives available on site</li> <li>• Mental health drugs available on site</li> <li>• Medical commodities (dressings) available on site</li> </ul>
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7	Receiving stock	To ensure that all pharmaceutical stock invoiced to the PHC facility by the depot or hospital is received in good condition; to verify that stock received corresponds with stock ordered; to ensure that undelivered stock appears on the overdue issue list or back order list	<b>Chapter 2 – Professional standards for services</b>	<b>3.1.3.1.2 CHECKLIST –</b> Procedures relating to the management of medicine as required by Good Pharmacy Practice are followed in the pharmacy/medicine room	<ul style="list-style-type: none"> <li>• Inventory Management: computerized system for inventory management in place</li> <li>• Inventory Management: monitoring of medicines availability implemented (to avoid stock outs and expiry / use of BIN Cards implemented)</li> <li>• Inventory Management: Stock files in place and medicines ordered according to stock files</li> </ul>
8	Handling excess stock	To ensure optimal stock utilization and to prevent and minimize the expiration of stock	<b>Chapter 2 – Professional standards for services</b>	<b>3.1.3.1.2 C HECKLIST –</b> Procedures relating to the management of medicine as required by Good Pharmacy Practice are followed in the pharmacy/medicine room	
9	Condemnation and disposal of obsolete stock	To ensure that expired, damaged or obsolete stock is not dispensed to the public; that obsolete stock is separated from usable stock and disposed of in the correct manner; that no disposal of stock will take place prior to the approval from the Head of Department and Treasury	<b>Chapter 2 – Professional standards for services</b>	<b>3.1.3.1.2 CHECKLIST –</b> Procedures relating to the management of medicine as required by Good Pharmacy Practice are followed in the pharmacy/medicine room	

10	Safe dispensing of medication	To dispense legal prescriptions according to Good Pharmacy Practice requirements	<p><b>Chapter 2 – Professional standards for services</b></p>	<p><b>1.5.1.3.1 CHECKLIST – 3</b> random selected scripts in pharmacy are correlated with medication dispensed to ensure that all medication was received as prescribed</p> <p><b>3.1.3.1.2 CHECKLIST –</b> Procedures relating to the management of medicine as required by Good Pharmacy Practice are followed in the pharmacy/medicine room</p> <p><b>3.1.4.2.1</b> A standard operating procedure is available which outlines the dispensing of medicines according to the Pharmacy Act of 1974 and the Medicines and Related Act 101 of 1974</p> <p><b>3.1.4.2.3 CHECKLIST</b> – Dispensing is done in accordance with applicable policies and legislation including labelling</p> <p><b>3.1.4.3.1 CHECKLIST – A</b> random selection of 3 patients receiving medicine indicate that they have a clear understanding of how and when to take their medication and any other relevant information – Generic outpatient checklist</p> <p><b>3.1.4.4.1 CHECKLIST –</b> A random selection of 3 prescriptions audited shows that prescribing is done to facilitate rational use of medicine and in accordance with prescribing guidelines and policies</p>	<ul style="list-style-type: none"> <li>• All Nursing staff trained on dispensing and prescribing</li> <li>• Use of Essential Medicines List and STGs for prescriptions implemented</li> </ul>
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11	Referral prescriptions	To establish, standardize and regulate the referral prescription system between PHC facilities and hospital pharmacies; to ensure that chronic medication not included in PHC EML are available at the PHC facility nearest to the patient's home	<b>Chapter 2 – Professional standards for services</b>		<ul style="list-style-type: none"> <li>• All Nursing staff trained on dispensing and prescribing</li> <li>• Use of Essential Medicines List and STGs for prescriptions implemented</li> </ul>
12	Procurement, control and issue of schedule 5 and 6 medication	To standardize and regulate the management of schedule 5 and 6 medication at PHC facilities	<b>Chapter 2 – Professional standards for services</b>	<p><b>3.1.3.3.1</b> A standard operating procedure is available which indicates how schedule 5 and 6 medicines are stored / controlled / distributed in accordance with the Medicines and Related Substances Act of 1965</p> <p><b>3.1.3.3.2</b> The entries in the schedule 5 and /or 6 register are complete and correct and include date / name of person who administered it and balance in stock</p>	
13	Reporting and handling adverse reactions	To ensure that a system is in place to document and report adverse drug reactions	<b>Chapter 4 – Professional standards for pharmacy management</b>	<b>3.1.5.1.1</b> There are standard operating procedures for the monitoring of adverse drug reactions	
14	Product recall	To ensure that medication is immediately returned following any warning or product recall	<b>Chapter 4 – Professional standards for pharmacy management</b>		
15	Effective stock rotation	To prevent wastage and ensure a continuous supply of medication at all times; to prevent medication from expiring in the dispensary or medicine room	<b>Chapter 2 – Professional standards for services</b>	<b>3.1.3.1.2 CHECKLIST –</b> Procedures relating to the management of medicine as required by Good Pharmacy Practice are followed in the pharmacy/medicine room	

16	Separation and handling of medication returned from patients	To handle medication returned by patients in a manner that will not compromise its quality, efficacy and safety	<b>Chapter 2</b> – Professional standards for services		
17	Security of equipment and medication	To ensure that equipment is safely stored; that medication is secure; that approved store-keeping procedures and adequate stock control systems are maintained	<b>Chapter 1</b> – Professional standards for premises	<b>3.1.2.6.3</b> There is a locked emergency cupboard for the supply of medicines <b>3.1.3.1.1 CHECKLIST</b> – Medicine is stored correctly as per Good Pharmacy Practice	Medicine store is kept locked at all times
18	Emergency trays	To ensure constant availability of emergency medication	<b>Chapter 2</b> – Professional standards for services	<b>2.4.3.3.5 CHECKLIST EXTREME</b> – Emergency trolleys are standardized/ appropriately stocked and regularly checked	
19	Cold chain management	To ensure that cold chain products reach the patient in a safe, effective and optimal condition for treatment or immunization	<b>Chapter 2</b> – Professional standards for services	<b>3.1.3.1.2 CHECKLIST</b> – Procedures relating to the management of medicine as required by Good Pharmacy Practice are followed in the pharmacy/medicine room	Temperature sensitive items stored in a refrigerator



# SOP 1

## Professional Standards for Dispensaries, Medicine Rooms, Consulting Rooms and Medical Supply Storage Areas

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### Purpose

To define the requirements of facilities, equipment and literature at dispensaries, medicines rooms and/or consulting room(s) and medical supply storage areas in PHC facilities and mobile clinics

### Procedure

In facilities where there is a designated dispensary, a suitable area for providing advice and a waiting area for the patients must be provided which complies with Good Pharmacy Practice (GPP) standards

#### 1. Storage areas in dispensaries, medicine rooms, consulting rooms and medical supply storage areas to comply with the following:

- The name of the PBPA on duty (where applicable) to be clearly displayed in or outside the dispensary
- Areas to be spacious enough to allow for orderly arrangement of stock and proper stock rotation
- Storage areas to have sufficient shelving to accommodate all stock
- Storage areas for medication and medical supplies to be self-contained and secure
- Door to dispensary/medicine room to have two locks or a security gate
- Dispensary/medicine room to be locked when not in use
- Walls, floors, windows, ceiling, woodwork and all other parts of the dispensary/medicine room and medical supply storage area to be kept clean and in proper order
- Windows to be painted or have curtains and be secured with burglar bars
- Sufficient artificial light to allow for adequate visibility
- Free of pest infestations
- Ensure that the dispensary/medicine room is kept clean and tidy at all times using a cleaning schedule which includes daily, weekly and monthly tasks (Annexure 1)
- Stock to be neatly stored on shelves
- Stock to be kept on pallets and not on the floor
- Schedule 5 and 6 medication to be stored in a separate double-locked cupboard
- Room temperature to be kept between 18°C and 25°C and to be recorded twice per day
- The air-conditioner is in good working order
- A hand wash basin with hot and cold water is available
- The refrigerator is to be defrosted and/or cleaned according to a cleaning schedule
- All equipment to be cleaned regularly
- Ensure that the “no smoking” sign is displayed in an area that is visible to patients and staff

#### 2. The dispensary, medicine room and/or consulting rooms to have the following equipment

- Tablet counting tray(s)
- Measuring cylinders (25ml and 100ml)
- A refrigerator equipped with a suitable thermometer and capable of storing medication at temperatures between 2 – 8°C
- Where applicable a freezer for the storage of ice packs must be available and it should preferably be able to operate on

## SOP 1

### Professional Standards for Dispensaries, Medicine Rooms, Consulting Rooms and Medical Supply Storage Areas

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- electricity and gas
- The refrigerator is to be fitted with a warning system to indicate when refrigeration has failed or the temperature is below 2°C or above 8°C
- A suitable range of dispensing containers for medication
- The use of child-resistant closures is encouraged
- Labels for dispensing of medication
- Suitable refuse receptacles for appropriate waste disposal
- Telephone or other means of communication
- Room thermometer
- Air conditioner which should maintain temperatures at between 18–25°C

#### 3. All tracer medication to be available (Annexure 2)

#### 4. All tracer medical supplies to be available (Annexure 3)

#### 5. The following reference material in the latest editions to be available:

- SAMF
- Daily drug use or other drug interactions reference source
- GPP manual
- The latest copies of the STG and EML



# SOP 2

## Scope of Practice of Dispensing Personnel

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### Purpose

To define the roles and responsibilities associated with the different levels at which pharmaceutical services operate and clarify the responsibilities of all categories of staff involved in the provision of pharmaceutical services at PHC level

### Responsibilities

#### 1. PHC Facility Pharmaceutical Service

##### 1.1 Responsibilities of the PN and/or the Auxiliary Workers where available

- Ordering, dispensing and control of schedule 1 - 6 medication, according to the instruction of a person authorized in terms of the Medicines Act, i.e. a medical doctor
- Receiving, checking and unpacking medication according to provincial policies and procedures
- Reading and preparing prescriptions
- Selecting, labelling and supplying medication in an appropriate container, whilst adhering to legal requirements schedule
- Providing instructions regarding the correct use of medication supplied to the patient
- Ensuring that the medication is correctly stored
- Monitoring the rational use of medication
- Adhering to all provincial pharmaceutical service policies, procedures and GPP
- Keeping records and statistics
- Maintain patient files for prescriptions dispensed
- Managing stock control using the manual stock cards and/or an electronic stock management system for medicine supply management
- Providing relevant statistics for required reporting as per the District Health System such as ARVs dispensed, number of prescriptions dispensed, etc.
- Reading and preparing prescriptions
- Selecting, labelling and supplying medication in an appropriate container, whilst adhering to legal requirements schedule
- Providing instructions regarding the correct use of medication supplied to the patient
- Ensuring that the medication is correctly stored
- Monitoring the rational use of medication
- Adhering to all provincial pharmaceutical service policies, procedures and GPP
- Keeping records and statistics
- Maintain patient files for prescriptions dispensed
- Managing stock control using the manual stock cards and/or an electronic stock management system for medicine supply management
- Providing relevant statistics for required reporting as per the District Health System such as ARVs dispensed, number of prescriptions dispensed, etc.



## SOP 3

### Pest Control in the Dispensary, Medicine Room and Medical Supply Storage Area

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#### Purpose

To provide guidance on keeping the medicine-; storage-; dispensing- ; and consultation room at the PHC Facility pest free at all times

#### Procedure

##### 1. Inspection

- The facility manager or delegated person to perform a thorough examination of the premises
- Identify habitation areas including environmental conditions of moisture, darkness and heat, which favour breeding, and habitation of pests
  - Food and water are probable cause for entry and evidence of pest infestation
- An inspection must at least be performed on a weekly basis and on investigation should it appear, there must be an action plan in place
  - Report to the Responsible person in Charge
- A Pest Control Contractor visit and procedure must be done Quarterly

##### 2. Identification

- Correctly and accurately identify pests to ensure successful control and elimination
- Different types of pests include:
  - Flying insects
  - Crawling insects
  - Rodents
  - Bats

##### 3. Reporting

- Report infestations to the PHC Manager or Sub District Manager (as appropriate)
- Follow up with the relevant person until fumigation is completed

##### 4. Recording

- Complete the pest control record (Annexure 4) on date of treatment applied
- Ensure that the service provider issues a Pest Control Certificate that is kept on file signed off by both the facility manager and Contractor on the date of the visit



## **SOP 4**

### **Daily Routine and Working Hours**

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#### **Purpose**

To ensure that there is access to medicine during the operating hours of the PHC

#### **Procedure**

- The PHC facility needs to be open on days and times stipulated by PHC norms and standards
- Dispensing staff needs to adhere to working hour policies that govern the PHC facility
- Duty rosters should indicate that at least 1 PN and/or Auxiliary Worker is available to consult patients during the operating hours of the PHC facility
- PHC facility needs to adhere to Batho Pele principles with regards to waiting times and right of information on the use of medication to patients
- The PHC facility's consulting rooms must be adequately stocked in order to minimize excessive entry to the medicine store
- A key control register (Annexure 5) needs to be completed to ensure that the keys to the PHC Facility is only accessible to the responsible person



# SOP 5

## Stock Take

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### Purpose

To ensure the accuracy of stock records (medication and medical supplies) by comparing actual stock on hand with stock records

### Procedure

#### Preparation for Stock Take

- a. Ensure that the floor plan is prepared for the stores indicating where the stock is located
- b. Ensure that the location of the stock items is specific on the stock sheet
- c. Ensure that all items to be counted have been captured on the stock sheets
- d. Ensure that stock sheets issued are pre numbered and with the correct number of pages indicated
- e. Prepare attendance register of the counting team
- f. Prepare stock sheet control register
- g. Ensure number of stock count staff is adequate in relation to the number of items to be counted
- h. Ensure that the stock is arranged in easily accessible and tidy manner
- i. Ensure that the start and end point of a particular stock sub category is clearly indicated
- j. Ensure that all bin cards have been removed from the shelves
- k. Ensure that all stickers used in the previous stock count have been removed
- l. Ensure that any obsolete/redundant/ damaged items are removed to be counted separately
- m. List and verify all cut off and numbers/dates e.g. last GRV, last delivery note, internal requisition, etc.
- n. You should control the time of arrival and departure of the counters/checkers

#### Supervision

- a. Supervise the count team before, during and after the stock count
- b. Ensure that count staff complies with the counting instructions
- c. Conduct random spot checks whilst the count is being conducted on areas already counted
- d. Ensure that there is no collision between the two teams
- e. Ensure that stickers issued are signed for and any remainders/extras returned at the end of the count
- f. Ensure that all stock items are suitably tagged
- g. Spot checks must be performed to check if the stock sheets are completed corrected

#### Counting

- a. Ensure that items are counted as they are placed on the shelves and not according to the listing on the stock sheet
- b. Ensure that stickers for the relevant count should be used and placed conspicuously in respect of the items counted
- c. Ensure that the second count should not be made for any items where the first count has not been undertaken
- d. Ensure that the 2 teams count independently
- e. In the event that the second counter/checker finds items that have not been counted by the first, he informs the supervisor

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- f. Through enquiry and observation, document possible obsolete, damaged slow-moving and excess stock items for later consideration

### **Stock Records**

- a. Ensure that all items received on the days of stock count are not included on the count; these are to be counted separately, to be used for reconciliation
- b. Ensure that any or all items belonging to third parties are not included in the stock count
- c. Ensure that no items are removed/ issued during the stock count except for emergency
- d. In case of emergency: ensure that proper controls are attended to

### **Counting stock being received**

- a. Stock received during counting must be checked and kept separately
- b. Stock must be counted and recorded separately on the stock sheet
- c. Stock received during the count period must be included in the final stock report
- d. Any stock received after the count period will be excluded from the final stock count report

### **Emergency issue of stock**

- a. Issuing of stock during counting must be recorded manually
- b. A separate sheet should be kept for all issues done during the count
- c. Ensure that stock issued is deducted from the stock on hand at the end of the count

### **Verification**

- a. Should the count for an item differ for the two teams, you should carry out a verification count to ascertain the correct quantity
- b. The alteration procedure must be followed

### **Valuation**

- a. Ensure that the correct price obtained from the last invoices is entered on the stock sheets at the end of the count
- b. This needs to be done by the relevant official dealing with stock

### **Submissions**

- a. Ensure that all electronic sheets for counts, variances and valuations are submitted to the relevant head of institution for approval and thereafter submitted to the District Manager and relevant personnel

### **General**



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- a. Stock-taking will be carried out quarterly on the 31st of March, 30th of June, 31st of September and 31st of December or at any other time deemed necessary
  - b. Print out a stock take list with updated prices for each pair of official counting
  - c. Pharmacist assistant(s), auxiliary workers and any other person appointed by the Sub-district manager /Middle manager will do physical stock count
  - d. The pharmacist in charge/Clinic Supervisor will supervise the count. The pharmacist/financial officer at PHC level will capture the counts on the computer and do the accounting of the stock take
  - e. Stock sheets issued will be pre numbered and with the correct number of pages indicated
  - f. The appointed persons will sign for receipt of all stock sheets issued to them
  - g. The appointed persons will be grouped in pairs. One person will count and the other will capture the quantities on paper
  - h. The appointed persons will write their names and sign at the bottom of the stock sheet issued to them
  - i. Stock sheet entries should be in INK
  - j. Any alterations on the stock sheet should be brought to the attention of the supervisor who should initial the alteration together with you
  - k. Entries for the second count (checkers) should be in the specific column indicated and not in the column for the first count
  - l. Upon completion of counting kindly ensure that stock sheet is handed to the supervisor immediately
  - m. At the end of each day, please hand in all stock sheets to the supervisor to be collected again the following day
  - n. You are not allowed to retain the stock sheet overnight
  - o. The first group will be accountable for the count 1 and the second group for the count 2
  - p. The pharmacist/Clinic Supervisor in charge will then capture and check variances and correct it. Variances and financial implications will then be calculated accordingly
  - q. Spreadsheets contain all quantities and the total stock value of the pharmacy
  - r. Pharmacist/Clinic Supervisor evaluates values and compares it with previous stock takes to make sure there is no overstocking etc.
  - s. All of the above will then be given to the middle manager/Sub-District Manager
  - t. Copies of all stock reports are to be filed for 5 years

A discrepancy report (Annexure 6) to be compiled and submitted to the facility manager

- u. Copies of all stock reports are to be filed for 5 years



# SOP 6

## Ordering of Stock

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### Purpose

To regulate and standardize ordering procedures to ensure compliance with depot procedures

### Procedure

- Ensure that a copy of the depot SOP is available which can be obtained from the depot
- Ensure that adequate amounts (based on minimum and maximum stock levels per clinic) of tracer medicines (Annexure 2) as per applicable Essential Drugs List or formulary as well as additional medication required as per NCS (Annexure 7) are always available in the dispensary/medicine room
- Ensure that adequate amounts (based on minimum and maximum stock levels per clinic) of tracer medical supplies (Annexure 3) as well as additional medical supplies required as per NCS (Annexure 8) are always available in the dispensary/medicine room
- Ensure that a system to monitor stock levels and availability of medication and medical supplies is in place
- All orders to reach the pharmaceutical depot at scheduled times to ensure optimum stock availability
- An order and delivery schedule provided by the depot for medication (Annexure 9) to be available and visible
- Maximum physical stock not to exceed two month's supply
- All stock cards to be balanced by the ordering official
- Stock quantity indicated on stock cards to correspond with the quantity of physical stock (stock available on the shelf)
- The most recent overdue issue report to be available when placing an order
- Quantities ordered to be based on:
  - Physical stock
  - Quantity on back order
  - Consumption rate
  - Buffer stock
  - Lead time
- PHC medicine order forms (Annexure 10) to be completed with quantities, signature of authorised official, facility name, demander code and order date
- Signed orders to be forwarded to the sub-district pharmacist or supporting hospital for review and approval or directly to the depot for processing
- Signed orders to be submitted either by fax, direct delivery or via the approved computer system available at hospitals. A proof of order receipt form to accompany the order when sent to the depot
- Staff in charge of medicine room must contact the depot to confirm receipt of order and the original order form to be returned to PHC once captured on the system at the hospital
- The proof of order receipt form to be signed, dated and returned to the PHC facility
- A copy of the order to be filed at the PHC facility for a period of 5 years
- For schedule 6 medication, the appropriate order book to be used to order from the designated hospital pharmacy



# SOP 7

## Receiving Stock

---

### Purpose

- To ensure that all pharmaceutical stock invoiced to the PHC facility by the depot or hospital is received in good condition
- To verify that stock received corresponds with stock ordered
- To ensure that undelivered stock appears on the overdue issue list or back order list

### Procedure

- PBPA or PN to be the only person in the receiving area of PHC facility when stock is delivered
- Before receiving stock the PBPA or PN is to ensure that the seal on the delivery vehicle is intact
- PBPA or PN to break the seal on the delivery vehicle and document the seal number on the form supplied by the driver
- PBPA or PN to ensure that the correct stock is being delivered
- Stock to be off-loaded in an undercover, secure, lockable area
- PBPA or PN to count the number of boxes received and reconcile it with the quantity indicated on the delivery note
- PBPA or PN to sign for the number of boxes (not contents) received in the delivery note
- Driver and PBPA or PN to reseal the delivery vehicle with a new seal and record the seal number on the appropriate form before the delivery vehicle departs
- Cold chain medication to be unpacked and placed in the refrigerator immediately
- Stock received before 14h00 to be unpacked, counted and reconciled with the invoice immediately
- Staff to ensure that new stock is packed onto the shelves no later than 13h00 the following day
- Stock received after 14h00 to be unpacked, counted and reconciled with the invoice no later than 10h00 the following day and stock to be packed on the shelves by 16h00 that same day
- The facility manager to forward a report on the late delivery to the depot manager
- After receiving stock from the depot, contents of boxes need to be unpacked and reconciled with the invoice according to:
  - Actual quantity received
  - Description of item
  - Batch number
  - Expiry date
  - Condition of stock
- Stock to be coded with a permanent marker to ensure that it is stored in the correct place according to FEFO and FIFO principles
- The invoice to be signed by the PBPA or PN and countersigned by the facility manager as confirmation of receipt of the correct items
- Discrepancies to be investigated immediately and the depot or hospital to be notified within 72 hours
- Stock received to be recorded on stock cards which are to be balanced
- A copy of the signed invoice to be sent to the depot or hospital with the next delivery
- Trip sheets and invoices to be filed for a period of 5 years
- Records older than 5 years to be archived (records never to be destroyed)



# SOP 8

## Handling Excess Stock

---

### Purpose

To ensure optimal stock utilization and to prevent and minimize the expiration of stock

### Procedure

Excess stock to be identified, documented and utilized by the PHC facility or hospital attached to the PHC facility and/or neighbouring PHC facilities before expiration. The average physical stock in PHC facilities not to exceed a 2 month supply

### Excess stock in the facility

- Identify and document excess stock by listing the following:
  - Facility name
  - Date
  - Generic name
  - Stock code
  - Strength
  - Pack size
  - Quantity
  - Expiry date
- Circulate the list to all PHC facilities and hospitals in the sub district
- An internal requisition memo to be completed in triplicate by the requesting facility (the 1st copy remains at the requesting facility, the 2nd copy to accompany the facility supervisor and the 3rd copy to be sent to the issuing facility)
- An internal requisition memo to be completed in duplicate by the requesting facility (the 1st copy remains at the requesting facility, and the 2nd copy to be sent to the issuing facility)
- Upon receipt of the request, stock issues are to be indicated on the stock card
- The requesting facility to communicate and arrange for collection of stock

### Excess or incorrect stock received from the depot or hospital

- To be returned to the depot or hospital, or the facility may choose to retain the stock
- An order to be submitted to the depot or hospital to retain the excess or incorrect stock
- The depot or hospital to issue an invoice for the stock supplied
- Separate stock that was supplied without any invoice from other stock until an invoice is received and recorded





## SOP 9

### Condemnation and Disposal of Obsolete Stock

---

#### Purpose

- To ensure that expired, damaged or obsolete stock is not dispensed to the public
- To ensure that obsolete stock is separated from usable stock and disposed of in the correct manner
- To ensure that no disposal of stock will take place prior to the approval from the Head of Medical Control Council (schedule 5 & 6) and schedule 0 – 4 with the approval of the Pharmacist.

#### Procedure

##### For medication

- Expired or damaged stock to be immediately removed from the consultation rooms
- Pharmaceutical condemnation and disposal forms (Annexure 11) to be fully completed in duplicate, by a PBPA or PN
- Expired stock to be packed in green plastic bags that are sealed and numbered
- Bins to be accompanied by the pharmaceutical condemnation and disposal forms
- Hospital/sub-district pharmacist to collect from facilities and arrange for disposal
- Expired stock to be stored in a separate secure area
- Stock to be collected by an appointed waste disposal company
- Waste disposal company to supply facility with a disposal certificate
- Keep the records for reporting and auditing purposes

##### For Schedule 5 and 6 medicines

- Follow the same procedure as above for obsolete stock. All schedule 5 and 6 pharmaceuticals must be recorded on a separate pharmaceutical condemnation and disposal form
- Destruction may only take place after written authorization from the Medicine Control Council (MCC) or police has been received
- Quantities of any medication destroyed to be entered into a register on the date of destruction
- Inscriptions in the register to be signed by a pharmacist and the facility manager of the PHC facility who is to witness the removal of stock for destruction
- The authorization letter and destruction certificate to be referenced or attached to schedule 5 or 6 register and retained for a period of 5 years



# SOP 10

## Safe Dispensing of Medication

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### Purpose

To dispense legal prescriptions according to Good Pharmacy Practice requirements

### Procedure

#### Interpretation and evaluation of the prescription

- A PN or medical doctor is responsible for prescribing medication to patients
- PBPA or PN is responsible for receiving the prescription and confirming the authenticity thereof
- Each prescription to be assessed to ensure the optimal use of medication
- Repeat prescriptions may be for a maximum of 6 months
- Repeat prescriptions may only be written by a doctor
- No private prescriptions can be dispensed

#### Preparation and labelling of the prescribed medicine

- Selecting or preparing medication
  - A pharmacist, PBPA or PN is responsible for the selection and preparation of prescribed medication
  - Patient-ready packs to be correctly selected \*pay attention to the name of medication and strength.
  - Medication containers to be clearly labelled with the correct directions along with any other information for the safe, proper and effective use
  - The prescriber who signs the prescription (in the patient file) is also responsible for recording the date of dispensing and write all credentials as needed according to GPP
  - After consultation with the prescriber, the PBPA may alter the prescription as directed. The PBPA is to sign and date any alterations on the prescription
  - If all medication was not available at the time of dispensing, the patient is to be issued with an outstanding prescribed medicine note. The note must contain the following information:
    - Patient name
    - File number
    - Name of medication
    - Dose and duration
  - A pharmacist, PBPA or PN is responsible for the labelling of prescribed medication
  - Labels of dispensed products to be clear and legible
  - The following information to be indicated on the label in accordance with Regulation 8(4) of the General Regulations published in terms of the Medicines Act:
    - Generic name
    - Quantity
    - Strength
    - Schedule

## SOP 10

### Safe Dispensing of Medication

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- Patient name and number
- Directions for use
- Any warnings/additional information
- Dispensing date
- Name and address of clinic
- Labels must be attached to the medication container in such a way that it does not cover the generic name, batch number or the expiry date of the medicine
- Handwritten labels, as is often the practice, should be legible
- Record keeping
  - All prescriptions that have been dispensed must be recorded, by the pharmacist, PBPA or PN, in a permanent record (manual or electronic), e.g. in the patient file (or Dispensing Program in hospitals) and should contain the following information
    - Name of the medicine
    - Date of dispensing
    - Dosage form and quantity of medicine
    - Name and address of patient
    - Name of person who issued the prescription
    - Reference number

#### Safe Dispensing for Children

- Educational Systems: there should be continuous training provided for healthcare professionals in order to ensure that they are familiar with different dosage forms and methods for children
- Manufacturing and Regulatory Systems: more research and data on use of medications in paediatrics, unique labelling of different strengths of the same drug, distinct packaging of each drug produced by a single company to avoid confusion of drugs that look or sound alike
- Pharmacists should conduct regular training at PHC in order to keep all staff updated on new medicines, and refresh dispensing practices

#### Provision of information and instructions to the patient

- Patients to be identified by the PBPA or PN when dispensing medication to ensure that the correct medication is given to the correct patient
- A PBPA or PN to provide information and instructions to the patient or caregiver
- A patient information leaflet (which accompanies the medicine packs from the vendor) containing the information as prescribed in the general regulations published in terms of the Medicines Act should be available at the point of dispensing
- Information should be correctly structured to meet the needs of individual patients, i.e. provide information on paracetamol syrup for a paediatric patient, and paracetamol tablets for an adult patient
- Appropriate dosage to be given per age group

## SOP 10

### Safe Dispensing of Medication

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- Patient to be informed about the usage of their medication in terms of their diagnosis
- Patients to be advised on potential drug interactions, e.g. warnings such as “to be taken with food”, “keep cool” and “finish the course” for antibiotics
- Patients to be appropriately advised on the correct times for taking medication according to their dosage requirements. Professionals are advised to consult their reference guides to ensure that the correct information is given
- Appropriate reference guides i.e. SAMF or the package insert should be referred to in order to provide the correct counselling to patients
- Patients to be advised of the risks inherent in:
  - Not taking medication as prescribed
  - Sharing medication
  - Storing medication incorrectly
- Patients to be advised on potential side effects and whether or not they are to continue the treatment if side effects are experienced. It is imperative to have this conversation with patients as many may discontinue their treatment due to unexplained side effects
- In the event of a stock-out of one particular dosage form, e.g. paracetamol tablets for adults, careful consideration and consultation should be given when dispensing an alternative. It is not advisable to simply dispense paracetamol syrup as it is intended for paediatric use. This may result in a stock-out of the syrup as well as providing the incorrect dosage to an adult. Consult the EML for an alternative and if in doubt, contact the local hospital pharmacist for advice or the PBPA based at the clinic
- Patients should be given the opportunity to ask questions about the medication dispensed



# SOP 11

## Referral Prescriptions

---

### Purpose

- To establish, standardize and regulate the referral prescription system between PHC facilities and hospital pharmacies
- To ensure that chronic medication not included in PHC EML are available at the PHC facility nearest to the patient's home

### Procedure

- PHC facilities are only allowed to stock medication on the PHC EML
- All chronic treatment not available at the PHC facility to be dispensed from the hospital pharmacy on an individual patient basis
- Patients may only receive a maximum of 28 days' supply at a time
- Repeat prescriptions may only be written by a doctor
- Repeat prescriptions are valid for a maximum of six months i.e. five repeats

### At clinic level – Referring institution

- If a patient requires chronic medication not available at the PHC facility, the medical officer to prescribe the medication in the patient file and complete a referral prescription form (RPF)

#### *Procedure for completing the RPF:*

- Patient details are to be recorded on the appropriate section. This section can be completed by a PN or medical officer. It is then removed and placed in the patient file at the referring institution
- A medical officer to complete the next appropriate section indicating the required medication and dosage
- If the RPF is not completed in full it may not be dispensed as it is an illegal prescription
- New acute and chronic prescriptions and repeat chronic referral prescriptions to be filed separately at the PHC facility
- The above files to be submitted to the relevant hospital pharmacy (referral institution)
- New acute and chronic prescriptions to be submitted within 24 hours
- Repeat chronic referral prescriptions to be submitted at least once a week
- When issuing referral medication at the PHC facility the PN to sign and indicate the patient collection date at the bottom of the appropriate section on the RPF

### At hospital pharmacy – Referral institution

- Pharmacist receives and records the referral prescriptions into a register reflecting the PHC facility names and date of receipt
- New acute and chronic prescriptions to be dispensed and returned within 24 hours of receipt
- If a patient is in dire need of medication the PN at the PHC facility to communicate verbally with the hospital pharmacist for permission to send the patient with the referral prescription to collect the required medication
- The referral prescription to be retained in the pharmacy until it can be returned to the relevant PHC facility

## SOP 11

### Referral Prescriptions

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- Repeat chronic referral prescriptions to be dispensed and returned to the applicable PHC facility within two weeks
- The cost of non-PHC EML items is carried by the referral institution
- The following information must be recorded on the RPF:
  - The quantity dispensed
  - Date dispensed
  - Signature of pharmacist or PBPA
- If the patient does not collect his/her medication at the PHC facility within one month, necessary steps are to be taken to trace the patient. If the patient is untraceable the medication must be returned to the hospital pharmacy



# SOP 12

## Procurement, Control and Issue of Schedule 5 and 6 Medication

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### Purpose

To standardize and regulate the management of schedule 5 and 6 medication at PHC facilities

### Procedure

#### 1. Ordering and receiving

##### 1.1 Schedule 5 medication

- Medication is ordered from the depot on the PHC Schedule 5 order form
- A PBPA or PN may place an order for, receive and control medication
- Any discrepancy in orders received to be reported within 48 hours
- Invoices to be recorded in the schedule 5 register (obtained on order from the depot or from the hospital pharmacy)
- Non-erasable pens to be used to make any entries in the register
- The correct register to be fully completed, immediately on receipt and issuing of medication
- Original copies of invoices should be signed and dated by a facility manager, PBPA or PN

##### 1.2 Schedule 6 medication

- Schedule 6 medication to be ordered by completing the appropriate form and submitting it to the relevant hospital
- Quantity of medication ordered to be written in words and numbers
- All schedule 6 orders to be authorized by a medical doctor
- A PBPA or PN may place an order, receive and control schedule 6 medication
- Any discrepancy in schedule 6 orders to be reported immediately
- Invoices to be recorded in the schedule 6 register (obtained on order from the depot or from the hospital pharmacy)
- Non-erasable pens to be used to make any entries in the register
- The correct register to be completed in full, immediately on receipt and issuing of medication
- Original copies of invoices should be signed and dated by a facility manager, PBPA or PN

#### 2. Storing and controlling

- Medication is locked in schedule 5 and 6 cupboards at all times
- A running balance is kept following all entries
- As with any medication kept in the clinic, the physical quantities should tally with the records in the register, but it is a legal requirement for Schedule 5 and 6 medication to be fully accounted for by the facility manager
- The register is to be balanced once a month and countersigned by the facility manager, thereby ensuring compliance with the Medicines and Related Substance Act 101 of 1965
- The PHC coordinator or the designated pharmacist (e.g. sub-district pharmacist) should balance the schedule 6 register on a quarterly basis
- Medication should be stored according to FEFO (first expired, first out) and FIFO (first in, first out) principles

## SOP 12

### Procurement, Control and Issue of Schedule 5 and 6 Medication

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- Orders, invoices and schedule 5 and 6 registers must be kept in the facility for 5 years
- The PBPA or PN is responsible for recording breakages or damages of schedule 5 and 6 medicines in a PHC facility

#### 3. Dispensing schedule 5 and 6 medicine to patients

- An authorized prescriber to prescribe the scheduled medication on the patients' prescription (in patient file)
- Prescriptions to be signed and the prescriber's qualifications clearly written
- PBPA or PN to record the dispensed medication in the schedule 5 and 6 register (Annexure 12) and sign the prescription
- Due to the prescriber level, schedule 6 medication will be pre-packed at the hospital. The designated person will dispense in the prescribed manner. However, this does not need to be recorded in the register

# SOP 13

## Reporting and Handling Adverse Drug Reactions

---

### Purpose

To ensure that a system is in place to document and report adverse drug reactions

### Procedure

- Determine the nature of the adverse drug reaction
- The prescriber or professional nurse to whom the reaction was reported to complete the Adverse Drug Reaction and Product Quality Problem Report Form (Annexure 13)
- The CDC and national adverse drug reaction forms to be completed for vaccine-related events
- If more than one adverse drug reaction is reported with a specific medicine, determine if more than one batch is involved
- All completed forms to be sent to the hospital PTC pharmacist
- District pharmacist or hospital pharmacy representative on the hospital PTC to fax or post the form to the provincial PTC
- The provincial PTC pharmacist to advise on the course of action to be taken
- PHC facility manager to follow up with the secretary of the hospital PTC if no reply is obtained



# SOP 14

## Product Recall

---

### Purpose

To ensure that medication is immediately returned following any warning or product recall

### Procedure

- Provincial depot to forward the recall document to the sub district pharmacist to inform and take appropriate action with the PHC facility
- Recalling of medicines from patients where possible
- PN or PBPA to verify if any of the recalled stock is available at the PHC facility. Make sure to include any sealed boxes and the bulk store-room's stock as well
- PN or PBPA to immediately remove all recalled stock from consulting rooms
- All recalled stock to be separated from normal stock in the PHC facility
- A credit request form to be completed for the recalled stock
- PN or PBPA to arrange for a pick-up note from the depot
- PN or PBPA to ensure that a credit note is received from the provincial depot once the stock has been uplifted
- Records to be appropriately filed by the PHC facility and reconciled at the end of the month
- PN or PBPA to ensure that replacement medication is available to provide continuous service delivery



# SOP 15

## Effective Stock Rotation

---

### Purpose

- To prevent wastage and ensure a continuous supply of medication at all times
- To prevent medication from expiring in the dispensary or medicine room

### Procedure

- Expiry dates of all medication to be checked when:
  - Receiving medication
  - Packing medication on shelves
  - Issuing medicine to consulting rooms
  - Dispensing medication to patients
- The expiration date of received stock to be within 3 months unless prior arrangements were made with the depot or hospital
- Stock items in PHC facilities to be rotated using the FEFO or FIFO method
  - FEFO method - Stock items with a shorter expiry date to be stored in front of those with a longer expiry date
  - FIFO method - Stock items that are newly received to be stored behind the stock items already on the shelves
- Expiration dates to be written in red ink
- This policy also applies to cold chain items
- The supporting hospital or sub district pharmacist to be notified if the facility has excess stock which can be redistributed to other facilities





## SOP 16

### Separation and Handling of Medicines Returned from Patients

---

#### Purpose

To handle medication returned by patients in a manner that will not compromise its quality, efficacy and safety.

It is the responsibility of all healthcare workers to advise patient of the correct procedure to be followed when medicines have to be returned.

**Scope:** This procedure covers all medicines returned which have either expired or the patient is not using anymore.

#### Procedure

- Medication returned by patients never to be re-used
- Place returned medication in a designated quarantine area (this can be the same area or pharmaceutical waste container used for expired medication). The medication to be stored in a sealed box and labelled as "returns from patient"
- Condemn the returned medication as per 'SOP 9 – Condemnation and disposal of obsolete stock' on a separate manifest than the expired medication



# SOP 17

## Security of Equipment and Medication

---

### Purpose

- To ensure that equipment is safely stored in all available storage areas; medicine room, bulk storage, consulting rooms, medicine trolleys, emergency trolleys and medicine cupboards
- That medication is secure
- That approved store-keeping procedures and adequate stock control systems are maintained

### Procedure

#### 1. Security of equipment and medicine

- All outside doors into the dispensary/medicine room to be locked and have a security gate (or to have 2 locks on the door if no security gate)
- All windows to have burglar bars
- All windows to be welded closed
- Medicine cupboards in consulting room(s) to be locked when not in use and when the PN leaves the room during office hours
- Electrical equipment to be safe and regularly maintained
- Proper provision to be made for adequate number of electrical sockets. Precautions to be taken to avoid trailing wires across floors, work surfaces or sinks

#### 2. Key control

- A key policy to control access to the dispensary/medicine room to be in place and signed by all relevant staff
- A register to be available to record handing over of keys (Annexure 5 )
- Ensure that all keys to the dispensary/medicine room be kept by the PBPA or PN at all times

#### 3. During working hours

- Access into the dispensary/medicine room to be strictly controlled and unauthorised personnel, e.g. general assistants, maintenance staff, supervisors, program managers should only be allowed access under supervision of authorised personnel
- Only the PBPA or PN to be allowed into the dispensary/medicine room unless otherwise authorized

#### 4. After working hours

- The facility manager to have a duplicate set of keys to the dispensary/medicine room for emergency situations



# SOP 18

## Emergency Trays

---

### Purpose

To ensure constant availability of emergency medication (Annexure 14) at all health facility levels

### Procedure

The PBPA or PN to supply all consulting rooms with an emergency tray and anaphylactic shock pack

#### 1. At the hospital (If and when emergency packs are prepared at hospital)

- A pharmacist or PBPA to pack medication for the emergency tray into a brazier bin/cardboard box and seal with clear plastic
- Schedule 5 medication in emergency trays to be recorded in the schedule 5 register
- An emergency tray control list to be included in the box
- Sealed emergency trays to be sent to all PHC facilities

#### Role of Sub-district pharmacist when there is no pharmacist at the hospital:

- To check the emergency tray, for completeness, expiry dates, to standardise, and ensure availability of medicines
- Approve the order for emergency medication and send so depot as a special order which is to be processed as soon as possible and delivered to the facility

#### 2. At PHC facilities

- All consulting rooms to have an emergency tray
- There should be a fully equipped emergency trolley kept at an easily accessible place in the PHC facility, but with only small trays with adrenalin and hydrocortisone injection (with the necessary syringes and needles) in each consulting room. When necessary the trolley could be called for while the first dose of adrenalin is administered. The trolley should be checked by a dedicated person as described in the SOP, but the tray is the responsibility of the professional nurse working in the particular consulting room.
- In case of a box being received with a broken seal, the box is to immediately be kept in a separate area and reported to the sub-district pharmacist if any or sub-district manager to be replaced.
- Schedule 5 medication in emergency trays to be recorded in the schedule 5 register
- All medication used during an emergency to be recorded on the Emergency Tray Return Form (Annexure 15), stating the clinic name, date, name and signature of the person who administered the medications as well as the type of medication used
- The form is to be returned to the hospital with the tray
- Trays to be checked for expired medicine by PN or PBPA on a monthly basis
- Consult the EDL and STG for correct emergency procedure in the case of Anaphylaxis
- Include the protocol which must be put on the wall near the emergency trolley

The protocol outlined below details the procedure which is to be followed in the event of a patient going into anaphylactic shock:

---

## Emergency Procedure in the Case of Anaphylaxis

### Step 1

Give adrenaline 1:1000

Age 0 – 3 years: 0.1ml subcutaneous at once

4 – 7 years: 0.2ml subcutaneous at once

8 – 14 years: 0.3ml subcutaneous at once

Requirements: insulin syringe and webcol

10 units = 0.1ml

20 units = 0.2ml

30 units = 0.3ml

### Step 2

Dilute remainder of the adrenaline with 10ml normal saline

Set up the drip set and run 0.9% normal saline fast

Administer small amounts of diluted adrenaline slowly IV

- i. Either directly into the vein OR
- ii. Through the side drip of the drip set OR
- iii. Through an endotracheal tube

Requirements: green needle, 10ml syringe, blue butterfly, paediatric drip set, micropore, webcol, 24g yellow Jelco needle.

### Step 3

Give hydrocortisone sodium succinate

Age less than 1 year: 100mg

1 – 3 years: 200mg

4 – 7 years: 300mg

8 – 9 years: 400mg

10 and above: 500mg

Administer slowly IV through the drip set

Requirements: 2ml syringes (3), yellow needles (3), webcol

# SOP 19

## Cold Chain Management

---

### Purpose

To ensure that cold chain products reach the patient in a safe, effective and optimal condition for treatment or immunization  
Scope: covers all refrigerators in the facility including consulting rooms if available

### Procedure

#### 1. General rules

- Storage temperature to be maintained between 2 and 8°C
- All refrigerators used to store medication to have thermometers and an alarm system
- Refrigerators should always be fully functional and in the event of a power failure, follow the procedure below
- Electrical refrigerators to be connected to a standby generator (or use a gas refrigerator if no generator is available)

#### 2. The refrigerator

- Vaccines and cold chain medication to be stored in a designated refrigerator according to FEFO principles
- Polio vaccines to be stored in the refrigerator in the shelf nearest to the freezer and must not be frozen
- Measles vaccines to be stored on the shelf nearest the freezer
- Other vaccines to be stored in the middle shelves with the diluents
- Bottles of salt water to be stored on the bottom shelf, in the vegetable drawer and on the fridge door to help stabilize the temperature
- Thermometers to be placed on a shelf in the centre of the refrigerator
- Vaccines are always to be stored with a thermometer
- No vaccines should be frozen
- The shake test should be done on suspected batches to determine whether the vaccine was frozen before or not as per GPP Manual and or Cold Chain Manual
- No medication to be stored in the door compartments of domestic refrigerators, the salad trays or evaporator plates
- No food to be stored in the refrigerator
- The refrigerator should always contain stored ice packs inside the freezer compartment

#### 3. Receiving of cold chain items

- Cooler boxes to be offloaded first and packed out immediately
- When cooler boxes are opened, there should be a freeze tag which should be checked on arrival in order to determine the condition of the cold chain: Freeze tag which is marked with an X means that the cold chain has been broken and if there is a check mark this means that it has been maintained.
- For polio vaccines, check the vaccine vial monitor (VVM) and a VVM chart is to be placed on the door of the refrigerator (Appendix 17)
- If the reflected temperature is not within the prescribed range or a colour change on the VVM is observed, contact the depot immediately and follow the instructions given. Record the name of the contact person

# SOP 19

## Cold Chain Management

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- Contents of the cooler box and stock is to be packed into the refrigerator immediately and then be reconciled with invoices

### 4. The cooler box

- Line the bottom and the sides of the cooler box with conditioned ice packs (i.e. ice packs that have been left outside the freezer for a few minutes until the surface of the ice packs are moist)
- Pack the polio and measles vaccines nearest to the ice packs
- Wrap all other vaccines and other cold chain medication in newspapers to avoid direct contact with ice packs and place them on top of the polio and measles vaccines
- Place dial thermometers or cold chain monitors on top between the medication
- Cover medication with another layer of newspapers
- Conditioned ice packs is to be placed on top of the newspapers
- Close the lid and make sure it seals properly and that there are no cracks in the cooler box
- During stock usage the cooler box temperature is to be monitored when opened to avoid being out of range according to the National Cold Chain act and Immunisation Manual
- Unused stock that was previously taken out in a cooler box to be used first

### 5. Daily tasks

- Thermometer to be checked and recorded daily at 08h00 and 16h00 for all designated refrigerators in the clinic
- A temperature chart (Annexure 16) is to be attached to the door of every refrigerator
- Records to be kept for 6 months
- Thermostat to be adjusted if necessary

### 6. Monthly tasks

- Defrost and clean the refrigerator as follows:
  - Pack stock in cooler box as described above before defrosting the refrigerator
  - Switch off power supply
  - Ensure that the cold chain is maintained while the refrigerator is being cleaned
  - Ensure that the inside of refrigerator is cleaned with the appropriate cleaning solution and wiped dry
  - Ensure that the door gasket is cleaned thoroughly along the bottom edge on upright units
  - Determine whether the freezing compartment needs defrosting (more than 10mm of ice in the evaporator) and defrost if necessary
  - Ensure that the condenser coil on the back of the refrigerator is cleaned and dust removed from the compressor
  - Ensure that the door seals tightly
  - Restart the refrigerator and allow the temperature to fall below 8oC before packing the stock back into the refrigerator
- Complete the Fridge Temperature Chart



# SOP 19

## Cold Chain Management

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### 7. Power/temperature failure

- Do not open the door until the power is restored or another suitable refrigerator is available
- Report the following to the facility manager
  - Reading on the thermometer when the power failure was noted
  - Estimated duration of power failure
  - Maximum temperature once power is reconnected
  - Reading on the polio VVM
  - Date of the incident
- If the facility has more than one refrigerator, provide information on all affected refrigerators
- Handle contents of refrigerator according to the indications in the National Cold Chain act and Immunisation Manual
- Record the cause of the failure
- If the power failure continues for longer than 36 hours, the OM should make the decision to have the goods transported to a neighbouring clinic or hospital; the goods must be packed in cooler boxes, the nearest facility contacted and the goods transported immediately for storage until the power returns
- The Domestic refrigerator and Minus 40 refrigerator is engineered to maintain temperatures for up to 48 hours following a power failure provided it is not opened repeatedly. It is advisable to remove the vaccines required daily and place these in cooler boxes for administration



## NCS Checklists linked to Standard Operating Procedure

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	<b>NCS Checklist Number</b>	<b>SOP</b>
1	Checklist 1.5.1.3.1	10
2	Checklist 2.4.3.3.5	18
3	Checklist 3.1.2.1.1 & 3.1.3.2.2	6
4	Checklist 3.1.2.2.1 & 3.1.3.5.2	2; 5; 6
5	Checklist 3.1.3.1.1	1; 17
6	Checklist 3.1.3.1.2	1; 2; 6; 7; 8; 9; 10; 15; 19
7	Checklist 3.1.3.1.3	1
8	Checklist 3.1.3.4.2	1
9	Checklist 3.1.4.2.3	10
10	Checklist 3.1.4.3.1	10
11	Checklist 3.1.4.4.1	10

## Checklist 1.5.1.3.1

### CHECKLIST DOMAIN 1 – PATIENT RIGHTS

#### 1.5 Reducing delays in care

Waiting times in busy areas are managed to improve patient satisfaction and care

Number of checklist	Criterion	Checklist reference	Measure	
1.5.1.3.1	Patients obtain their medicines from the pharmacy on the day of their scheduled visit.	Filing system organization	CHECKLIST – 3 random selected scripts in pharmacy are correlated with medication dispensed to ensure that all medication was received as prescribed	
Number of questions	Planned number of responses	Unit where assessed	Type of assessment	
3	3	C04 MC14 MC14A CX04	DR	
<p>Instructions: Randomly select 3 patient scripts in the pharmacy and ask whether the pharmacist can show what medication was dispensed against this script. If all the medication as prescribed was dispensed then mark “Yes”. If patient has not received all medication as prescribed mark as “no”.</p>				
No	Question / Aspect	Yes	No	Comment
1	Patient 1			
2	Patient 2			
3	Patient 3			
Actual Score (Sum of positive responses)				
Maximum possible score (Sum of all questions minus the not applicable responses)				

## Checklist 2.4.3.3.5

### CHECKLIST DOMAIN 2 – PATIENT SAFETY

#### 1.4 Clinical Risk

#### 1.5 Specific safety protocols are in place for high risk groups of patients

Number of checklist	Criterion	Checklist reference	Measure
2.4.3.3.4 2.4.3.3.5	The safety of patients who require resuscitation is assured	Emergency Trolleys	Emergency trolleys are standardised, appropriately stocked regularly and checked
	<b>Planned number of responses</b>	<b>Unit where assessed</b>	<b>Type of assessment</b>
26	26	P01C P02 P03C P04 P05 P06 P07_1C P07_2C P07_3C	
P10_1C PC01C PC01  P11 P01 P02 P03 P04_1 P05_1 P06 P07_1 P07_2 P08 P09 P10_1P11 P12 P13	OBS	Emergency Trolleys	Emergency trolleys are standardised, appropriately stocked regularly and checked

Instructions: Check the contents of the emergency trolley against the list below. Ask if the equipment is functional and mark Yes or No. Only for the highlighted equipment check if an operator's manual is available.

Only for the highlighted equipment check if the consumables used in the equipment's operations is available.

No	Question / Aspect	Functional	Not functional	Comments
	<b>Extreme Measures</b>			
1	AED machine/ECG monitor / defibrillator, pads, paddles and electrodes			
2	Laryngoscope with blades (Adult + Paeds)			
3	Tracheal tubes adult as appropriate			
4	Tracheal tubes Paediatric as appropriate			
5	Manual resuscitator device / ambubag (adult)			
6	Manual resuscitator device/ ambubag (paeds)			
7	Oxygen masks and/or nasal cannula (Adult + Paeds)			
8	Emergency medications according to local protocol is available and have not expired			
9	AED and emergency trolley are checked on a daily basis			
Actual Score (Sum of positive responses)				
Maximum possible score (Sum of all questions minus the not applicable responses)				

No	Question / Aspect	Functional	Not functional	Comments
	<b>Extreme Measures</b>			
1	Universal precautions equipment (gloves, eye protection, face-mask)			
2	Blood pressure cuffs			
3	Glucometer			
4	Thermometer			
5	Pulse oximeter			
6	Scissors			
7	Oropharyngeal airways/ Naso-pharyngeal airways			
8	Laryngeal mask airways			
9	Xylocaine spray			
10	KY jelly/Remicaine Gel			
11	ET tubes – plaster/tie to secure (Adult + Paeds)			
12	Magill forceps – pediatric and adult			
13	Nasogastric tubes (Adult + Paeds)			
14	Oxygen supply – Ready for Use (portable and fixed unit)			
15	Suction catheters (6F to 14F)			
17	Suction devices (portable or fixed power)			
Actual Score (Sum of positive responses)				
Maximum possible score (Sum of all questions minus the not applicable responses)				

## Checklist 3.1.2.1.1 and 3.1.3.2.2

### CHECKLIST DOMAIN 3 – PHARMACEUTICAL SERVICES

#### 3.1 Pharmaceutical services

The provision of medicines and medical supplies (including disposables) supports the delivery of care

Number of checklist	Criterion	Checklist reference	Measure
3.1.2.1.1 + 3.1.3.2.2	Medicines required for care of patients of the health establishment are in stock (in accordance with applicable Essential Drugs List or formulary)	EDL availability	Tracer medicines as per applicable (EDL) Essential Drugs List or formulary are available in the pharmacy/ medicine room
Number of questions	Planned number of responses	Unit where assessed	Type of assessment
Universal:27 Hospitals:16 ARV: 12	55	C04 CC04	OBS
<p><b>Instructions:</b> Check in the pharmacy/medicine room to see that each of the listed items are present or equivalently available and not expired.</p> <p>Universal list to be used at all institutions (hospitals, CHCs &amp; clinics). Hospital list only in hospital pharmacies. If the health establishment is an ART site, also assess those listed ART medicines.</p> <p>Ticking the column marked 'stock available if the item is in stock. Tick in the column marked 'No stock available' if there is no stock.</p> <p>Choose five random items and check if the physical stock corresponds with the balance on the stock control system. Tick in the column marked 'stock levels correspond' if the correct levels appear in both physical stock and on the stock control system. Tick in the column marked 'Stock levels DO NOT correspond' if there is no correlation between stock levels. Please insert a comment if you observe anything which is of concern.</p>			

No	Question / Aspect	Stock available	No stock available	Stock levels Correspond	Stock levels Do Not Correspond	Comment
	<b>Universal list (all facilities)</b>					
1	Adrenaline Injection 1mg/ml					
2	Amoxicillin Suspension 125mg/5ml					
3	Amoxicillin capsules 250mg or 500mg					
4	Cefixime capsules 400mg					
5	Ceftriaxone Injection					
6	Co-trimoxazole Suspension 50 or 100ml					
7	Co-trimoxazole tablets 480mg or 960mg					
8	Diazepam injection 10mg/2ml					
9	DTaP – IPV/Hib vaccine					
10	Hydrochlorothiazide tablets 12.5 or 25mg					
11	Ibuprofen tablets 200mg					
12	Insulin Soluble 100IU/ml					
13	Metformin tablets 500mg or 850mg					
14	Norethisterone or Medroxyprogesterone Injection					
15	Oral Rehydration Salt (ORS)					
16	Paracetamol 50ml or 100ml syrup 120mg/5ml					
17	Paracetamol tabs 500mg					
18	Salbutamol Inhaler					
19	Sodium Chloride 0.9% 1L					
20	Vitamin A					
21	Rif. 150/INH 75/PZA 400/EMB 275 mg					
22	Rifampicin 150mg/INH 75mg					
23	Ethambutol tablets 400mg					
24	Isoniazid tablets 100mg					
25	Streptomycin Inj 1g/3ml or 5g/15ml					
26	Rif. 60/INH 30/PZA 150 mg tablets					
27	Rifampicin 60/INH 30mg dispersible					
	Actual Score ( Sum of positive responses)					
	Maximum possible score ( Sum of all questions minus the not applicable responses)					



No	Question / Aspect	Stock available	No stock available	Stock levels Correspond	Stock levels Do Not Correspond	Comment
<b>Hospital list (hospital pharmacies only)</b>						
1	Amikacin injection					
2	Budesonide or Beclomethasone					
3	Carbamazepine tablets					
4	Enalapril or Perindopril tablets					
5	Furosemide injection					
6	Haloperidol injection					
7	Heparin injection					
8	Hydrocortisone injection					
9	Magnesium sulphate					
10	Modified Ringers Lactate or Ringers lactate					
11	Morphine injection					
12	Phenytoin Inj					
13	Prednisone					
14	Oxytocin					
15	Tetanus Toxoid					
16	Simvastin10mg					
Actual Score (Sum of positive responses)						
Maximum possible score (Sum of all questions minus the not applicable responses)						
<b>ART sites</b>						
1	Abacavir 20mg/ml solution					
2	Lamivudine 10mg/ml solution					
3	Lopinavir/Ritonavir 80/20mg/ml solution					
4	Nevirapine 10mg/ml solution					
5	Efavirenz 50mg capsules					
6	Efavirenz 600mg tablets					
7	Lamivudine 150mg tablets or 300mg capsules					
8	Lamivudine 150mg/Zidovudine 300mg tablets (PEP)					
9	Nevirapine 200mg tablets					
10	Stavudine 30mg capsules					
11	Tenofovir 300mg tablets					
12	Zidovudine 300mg tablets					
Actual Score (Sum of positive responses)						
Maximum possible score (Sum of all questions minus the not applicable responses)						

## Checklist 3.1.2.2.1 & 3.1.3.5.2

### CHECKLIST DOMAIN 3 – PHARMACEUTICAL SERVICES

#### 3.1 Pharmaceutical services

The provision of medicines and medical supplies (including disposables) supports the delivery of care

Number of checklist	Criterion	Checklist reference	Measure
3.1.2.2.1 3.1.3.5.2	Medical supplies required for care of patients of the health establishment are in stock  Medicines and medical supplies are managed in compliance with relevant legislation and principles of medicine supply management	Tracer medicine, EDL availability  Stock control	CHECKLIST - Tracer medical supplies are available at the time of the audit in the area where medical supplies are stored  There is an up-dated computerised or manual (stock cards) inventory management system for medicines in place  Physical stock corresponds to stock on the inventory management system
Number of questions	Planned number of responses	Unit where assessed	Type of assessment
24	24	C04 CC04	OBS
<p><b>Instructions:</b> Check in the pharmacy/surgical store/Dry Dispensary Store/Consumable Store (hospitals &amp; CHCs) or medicine/store room in PHC clinics to see that each of the listed items is present.</p> <p>Tick in the column marked 'stock available' if the item is in stock. Tick in the column marked 'No stock available' if there is no stock</p> <p>Choose five random items and check if the physical stock corresponds with the balance on the stock control system. Tick in the column marked 'stock levels correspond' if the correct levels appear in both physical stock and on the stock control system. Tick in the column marked 'Stock levels DO NOT correspond' if there is no correlation between stock levels.</p> <p>Please insert a comment if you observe anything which is of concern.</p>			

No	Question / Aspect	Stock available	No stock available	Stock levels Correspond	Stock levels Do Not Correspond	Comment
	<b>Universal list (all facilities)</b>					
1	Blood tubes					
2	Dressing pack					
3	Gloves (sterile) All Sizes					
4	Gloves (unsterile) All Sizes					
5	Hand soap					
6	Hand towels					
7	Hb slides					
8	Intravenous administration set					
9	Intravenous cannulae All Sizes					
10	Syringes All Sizes					
11	Masks N95 Particulate respirator					
12	Micropore All Sizes					
13	Nappies (Adult + Paeds)					
14	Needles All Sizes					
15	Oxygen masks					
16	Suction catheter					
17	Tegaderm					
18	Urinary catheters All Sizes					
19	Urine bags					
Actual Score ( Sum of positive responses)						
Maximum possible score ( Sum of all questions minus the not applicable responses)						

## Checklist 3.1.3.1.1

### CHECKLIST DOMAIN 3 – CLINICAL SUPPORT SERVICES

#### 3.1 Pharmaceutical services

The provision of medicines and medical supplies (including disposables) supports the delivery of care

Number of checklist	Criterion	Checklist reference	Measure
3.1.3.1.1	Medicines are stored and managed in compliance with the Pharmacy Act 53 of 1974, Medicines and Related Substances Act 101 of 1965 and relevant rules and regulations	Good Pharmacy Practice Medicine storage	Medicine is stored correctly as per Good Pharmacy Practice
Number of questions	Planned number of responses	Unit where assessed	Type of assessment
19	19	C04 CC04	OBS
<p><b>Instructions:</b> In the medicine storage area (pharmacy/pharmacy store in hospitals and some CHCs and medicine rooms in PHC clinics) observe whether there is compliance with each of the aspects listed below. Tick in the Yes column if they are compliant and in the No column if not compliant.</p>			

No	Question / Aspect	Yes	No	Comment
1	Medicines are stored in a secure pharmacy store (hospitals & CHCs) or medicine room (PHC clinics)			
2	The pharmacy, pharmacy store or medicine room is fitted with burglar bars			
3	There is sufficient space in the pharmacy, pharmacy store or medicine room for orderly arrangement of stock and proper stock rotation			
4	The pharmacy, pharmacy store or medicine room is kept locked.			
5	There are no cracks, holes or signs of water damage in the pharmacy, pharmacy store or medicine room (Yes if no cracks etc. and No if there is)			
6	The storage area is clean and tidy (shelves are dusted, floor is swept, and walls are clean)			
7	Medicines are stored neatly on shelves according to a classification system			
8	There are no medicines stored in direct contact with the floor (Yes if not stored on floor and No if stored on floor)			
9	There is no evidence of pests in the pharmacy, pharmacy store or medicine room (Yes if no evidence of pests and No if evidence)			
10	Control of access to pharmacy, pharmacy store or medicine room is of such a nature that only authorized persons have access to the medicine			
<b>Maintenance of the cold chain</b>				
11	Each refrigerator has a working dial/digital thermometer or alcohol/mercury thermometer (Not a minimum/maximum thermometer)			
12	The temperature in the refrigerator is between 2 and 8°C			
13	The temperature inside the refrigerator is measured twice a day and recorded on a chart			
14	No medicines or vaccines are stored in the refrigerator door (Yes if no storage in door and No if stored in door)			
15	No food is stored in the refrigerator (Yes if no food are stored and No if food are stored)			
16	The ice in the refrigerator is less than 10mm thick			
17	A backup system is available for storage of medicines when defrosting the refrigerator			
18	There a standby generator or other emergency power system for use in case of a power failure.			
19	A system is in place to ensure the cold chain is maintained from the time of dispensing to the time of receipt by the end-user (patient)			
Actual Score (Sum of positive responses)				
Maximum possible score (Sum of all questions minus the not applicable responses)				

## Checklist 3.1.3.1.2

### CHECKLIST DOMAIN 3 – CLINICAL SUPPORT SERVICES

#### 3.1 Pharmaceutical services

Medicines and medical supplies are managed in compliance with relevant legislation and principles of medicine supply management

Number of checklist	Criterion	Checklist reference	Measure	
3.1.3.1.2	Medicines are stored and managed in compliance with the Pharmacy Act 53 of 1974, Medicines and Related Substances Act 101 of 1965 and relevant rules and regulations	Good Pharmacy Practice Medicine supply management principles	Procedures relating to the management of medicine as required by Good Pharmacy Practice are followed in the pharmacy	
Number of questions	Planned number of responses	Unit where assessed	Type of assessment	
8	8	C04 CC04	OBS	
<p><b>Instructions:</b> : In the area used for medicine storage (pharmacy/pharmacy store in hospitals and some CHCs and medicine rooms in clinics) observe whether there is compliance with each of the aspects listed below. Tick in the Yes column if they are compliant and in the No column if not compliant.</p>				
No	Question / Aspect	Yes	No	Comment
1	Standard operating procedures are available for procurement of medicine, receiving of medicine, storage of medicine, issuing of medicine and cold chain management			
2	Documentation showing proof of ordering of stocks of medicine is available			
3	Documentation showing proof of receipt of stocks of medicine is available			
4	A system is in place to ensure packing and issuing of medicine according to FEFO and FIFO principles (as applicable)			
5	A system is in place to check expiry dates on medicine in the pharmacy and pharmacy store (hospitals and CHCs) or in the medicine room (PHC clinics)			
6	No expired medicines are observed in the pharmacy or pharmacy store or medicine room (Yes if no expired medicines are observed and No if observed)			
7	A system is in place to write off any expired medicine			
8	The member of staff responsible for the stocks of medicine in the health establishment is aware what the budget is for the current financial year			
Actual Score (Sum of positive responses)				
Maximum possible score (Sum of all questions minus the not applicable responses)				

## Checklist 3.1.3.1.3

### CHECKLIST DOMAIN 3 – CLINICAL SUPPORT SERVICES

#### 3.1 Pharmaceutical services

Medicines and medical supplies are managed in compliance with relevant legislation and principles of medicine supply management

Number of checklist	Criterion	Checklist reference	Measure
3.1.3.1.3	Medicines are stored and managed in compliance with the Pharmacy Act 53 of 1974, Medicines and Related Substances Act 101 of 1965 and relevant rules and regulations	Medicines storage Good Pharmacy Practice	CHECKLIST - Medicines in the wards or consultation rooms are appropriately stored and managed
Number of questions	Planned number of responses	Unit where assessed	Type of assessment
13	1	P07 P01C P03C CC04 P07_1 P07_2C P07_3C  P01 P07_2 C04	OBS

**Instructions:** Observe the listed aspects below in the cupboards or medicine trolleys where medicines are kept in the ward/consulting room. Tick in the Yes column if they are compliant and in the No column if not. Some degree of professional judgment is required to decide if there is compliance or not.

No	Question / Aspect	Yes	No	Comment
1	Medicines are stored in a secure cupboard or medicine trolley			
2	There is sufficient space in the cupboard or medicine trolley for orderly arrangement of medicines and proper stock rotation			
3	The cupboard or medicine trolley is kept locked			
4	The cupboard or medicine trolley is clean and tidy			
5	Medicines are stored neatly according to a classification system			
6	There are no medicines stored in direct contact with the floor			
7	There is no evidence of pests in the cupboard or medicine trolley			
8	Control of access to cupboard or medicine trolley is of such a nature that only authorized persons have access to the medicine			
9	Documentation showing proof of ordering of stocks of medicine is available			
10	Documentation showing proof of receipt of stocks of medicine is available			
11	A system is in place to ensure packing and issuing of medicine according to FEFO and FIFO principles (as applicable)			
12	A system is in place to check expiry dates of medicine			
13	No expired medicines are observed			
Actual Score (Sum of positive responses)				
Maximum possible score (Sum of all questions minus the not applicable responses)				

## Checklist 3.1.3.1.3

### CHECKLIST DOMAIN 3 – CLINICAL SUPPORT SERVICES

#### 3.1 Pharmaceutical services

Medicines and medical supplies are managed in compliance with relevant legislation and principles of medicine supply management

Number of checklist	Criterion	Checklist reference	Measure
3.1.3.4.2	Medical supplies are stored and managed in compliance with medicine supply management principles	Medicines storage Good Pharmacy Practice	Medical supplies are stored correctly
Number of questions	Planned number of responses	Unit where assessed	Type of assessment
9	9	C04 CC04	OBS

**Instructions:** In the medical supplies storage area observe whether there is compliance with each of the aspects listed below. Tick in the Yes column if they are compliant and in the No column if not.

No	Question / Aspect	Yes	No	Comment
1	Medical supplies are stored in a secure storage area			
2	There is sufficient space in the storage area for orderly arrangement of stock and proper stock rotation			
3	The storage area is kept locked			
4	There are no cracks, holes or signs of water damage in the storage area			
5	The storage area is clean and tidy (shelves are dusted, floor is swept, and walls are clean)			
6	Medical supplies are stored neatly on shelves according to a classification system			
7	There are no medical supplies stored in direct contact with the floor			
8	There is no evidence of pests in the storage area			
9	Control of access to the storage area of such a nature that only authorized persons have access to the medical supplies			
Actual Score (Sum of positive responses)				
Maximum possible score (Sum of all questions minus the not applicable responses)				



## Checklist 3.1.4.2.3

### CHECKLIST DOMAIN 3 – CLINICAL SUPPORT SERVICES

#### 3.1 Pharmaceutical services

The prescribing and dispensing of medicines comply with relevant regulations and protocols and promote the quality use of medicine

Number of checklist	Criterion	Checklist reference	Measure	
3.1.4.2.3	Practices for dispensing medicines comply with the Pharmacy Act 53 of 1974, Medicines and Related Substances Act 101 of 1965 and relevant regulations	Dispensing of medicines	Dispensing is done in accordance with applicable policies and legislation (including labelling)	
Number of questions	Planned number of responses	Unit where assessed	Type of assessment	
8	24	C04 CC04	OBS	
<p><b>Instructions:</b> Observe the pharmacist/ pharmacist's assistant or nurse dispensing medicine to 3 patients. Check each interaction meets the listed aspects. Mark Y for Yes if they are compliant and in the N for No if not compliant.</p>				
No	Question / Aspect	Yes	No	Comment
1	A pharmacist (hospitals and CHCs) or pharmacist's assistant or dispensing PHC nurse (PHC clinics) dispenses the medicine			
2	The pharmacist/ pharmacist's assistant/nurse checks the prescription for legality and appropriateness prior to dispensing			
3	Labels of dispensed medicines are clear and legible			
4	The label affixed to the medicine contains at least the following information – the name of the medicine, the name of the patient, directions for use of the medicine, name and address of the health establishment, date of dispensing, reference number			
5	The pharmacist/assistant/nurse identifies the patient when supplying medicine			
6	Patient is given instructions on the use of the medicine			
7	The patient is given the opportunity to ask questions about the medicine dispensed			
8	The following information is recorded in a permanent record (manual or electronic record) – name of the medicine, date of dispensing, dosage form and quantity of medicine, name and address of patient, name of person who issued the prescription and reference number (Tick Yes if all appears and No if any is not appearing)			
Actual Score (Sum of positive responses)				
Maximum possible score (Sum of all questions minus the not applicable responses)				

## Checklist 3.1.4.3.1

### CHECKLIST DOMAIN 3 – CLINICAL SUPPORT SERVICES

#### 3.1 Pharmaceutical services

The prescribing and dispensing of medicines comply with relevant regulations and protocols and promote the quality use of medicine

Number of checklist	Criterion	Checklist reference	Measure	
3.1.4.3.1	Patients are counselled appropriately to ensure adherence to therapy	Patient counselling	A random selection of 3 patients receiving medicine indicate that they have a clear understanding of how and when to take their medication, and any other relevant information (generic outpatient checklist)	
Number of questions	Planned number of responses	Unit where assessed	Type of assessment	
5	15	C04 P01 P02 CC04	PI	
<b>Instructions:</b> Interview 3 patients who have received medicines and ask them the questions below. Mark Y for Yes if they are compliant and in the N for No if not compliant.				
No	Question / Aspect	Yes	No	Comment
1	Did the pharmacist/pharmacist's assistant/nurse explain to you what each medicine is for?			
2	Did the pharmacist/pharmacist's assistant/nurse explain to you when to take your medicines?			
3	Did the pharmacist/pharmacist's assistant/nurse explain if you can take the medicine with or without food?			
4	Did the pharmacist/pharmacist's assistant/nurse explain to you what side effects you could expect from the medicines?			
5	Did the pharmacist/pharmacist's assistant/nurse give you the opportunity to ask any questions or discuss anything that worries you about your medicine?			
Actual Score (Sum of positive responses)				
Maximum possible score (Sum of all questions minus the not applicable responses)				

## Checklist 3.1.4.4.1

### CHECKLIST DOMAIN 3 – CLINICAL SUPPORT SERVICES

#### 3.1 Pharmaceutical services

The prescribing and dispensing of medicines comply with relevant regulations and protocols and promote the quality use of medicine

Number of checklist	Criterion	Checklist reference	Measure	
3.1.4.4.1	Prescribing is done in accordance with applicable guidelines and policies	Prescribing	A random selection of 3 prescriptions audited, shows that prescribing is done to facilitate rational use of medicine and in accordance with prescribing guidelines and policies	
Number of questions	Planned number of responses	Unit where assessed	Type of assessment	
10	30	C04 CC04	PRA	
<b>Instructions:</b> Ask to see 3 scripts and check for compliance against the aspects listed below. Mark Y for Yes if they are compliant and in the N for No if not compliant.				
No	Question / Aspect	Yes	No	Comment
1	The name of patient			
2	Age and sex of the patient			
3	Address of patient			
4	Date of prescription			
5	Name, qualification and practice number of prescriber			
6	Name of the medicine			
7	The total number of doses or duration of the medicine is clearly indicated			
8	The dosage form and dose of the medicine is clearly indicated			
9	The script is legible			
10	The script is signed by the doctor or prescribing nurse (must be handwritten)			
Actual Score (Sum of positive responses)				
Maximum possible score (Sum of all questions minus the not applicable responses)				



## References

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1. Good Pharmacy Practice in South Africa, 4th Edition
2. Pharmacy Act 153 of 1974 as amended
3. Medicines and Related Substances Act 101 of 1965 as amended
4. National Infection, Prevention and Control Policy
5. General Conditions of Service
6. Public Finance Management Act 1 of 1999
7. South African National Drug Policy
8. National Cold Chain & Immunisation Manual
9. PHC Supervision Manual
10. National Core Standards
11. Ideal clinic

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# Annexure 1 – Cleaning Checklist

Dispensary/Medicine Room Cleaning Checklist												
Facility Name	Month			Year			Signature (Supervisor)					
<b>Week 1</b>	<b>Frequency</b>						<b>Initial/Signature (Cleaner)</b>					
Check refrigerator thermometer and adjust thermostat if necessary	D	W	M	M	T	W	T	F	S	S	S	
	D	W	M	M	T	W	T	F	S	S	S	
Sweep and mop floors	D	W	M	M	T	W	T	F	S	S	S	
Dust and wipe air conditioner	D	W	M	M	T	W	T	F	S	S	S	
Clean walls	D	W	M	M	T	W	T	F	S	S	S	
Clean windows	D	W	M	M	T	W	T	F	S	S	S	
Polish floors (if applicable)	D	W	M	M	T	W	T	F	S	S	S	
Defrost refrigerators and clean with appropriate cleaning solution	D	W	M	M	T	W	T	F	S	S	S	
Clean condenser coil on refrigerator	D	W	M	M	T	W	T	F	S	S	S	
Clean curtains (if applicable)	D	W	M	M	T	W	T	F	S	S	S	

## Annexure 2 – Tracer Medication

PHC Weekly Tracer Drug Availability Monitoring Tool							
Facility							
Month							
			Weeks of the month out of stock				
No	Code No	Tracer Item	Week 1	Week 2	Week 3	Week 4	Week 5
<b>Ampoules</b>							
1	2982	Adrenaline inj					
2	0847	Hydrocortisone 100mg inj					
3	0885	Magnesium sulphate inj					
4	0880	Lignocaine 1%					
<b>Powders</b>							
5	0618	Oral Rehydration sol.					
<b>Inhalers</b>							
6	0756/0760/0686	Budesonide / Beclomethasone 50mcg/100mcg					
7	0737	Salbutamol inhaler					
<b>Liquids</b>							
8	0518	Co-Trimoxazole					
9	0563/4	Paracetamol					
10	2239	Chlorhexidine & Alcohol (Hibitane in Alcohol) 0.5/70%					
<b>Tablets</b>							
11	0119	Amlodipine 5mg					
12	0153/4	Carbamazepine tabs					
13	0193/3967/4046	Co-Trimoxazole					
14	0219/20/21/0368	Enalapril / Perindopril					
15	2153/4/2210	Ferrous sulph/fumarate					
16	2158/9 2930/2160	Glibenclamide /Gliclazide					
17	0253	Glyceryl Trinitrate					
18	2161/2	HCTZ 12,5mg/25mg					
19	2879/2927/2164/2165/ 3297	Ibuprofen					
20	3263/4316/2270/2205	Orphenadrine/Biperiden					
21	0319/2850/2167/8	Metformin					



## Annexure 2 – Tracer Medication

22	2230/2849/0311	Methyldopa 250mg					
23	2027/0358	Paracetamol 500mg					
24	2926	Prednisone 5mg 28					
25	0424	Simvastatin 10mg					
26	3303/6/9/8/4	Valproate Sodium CR 200, 300, 500mg					
27	3301/3740/1	Vitamin A					
<b>Antibiotics</b>							
28	0011/3874	Amoxicillin 125mg/5ml/250mg/5ml					
29	2188/9/3260	Amoxicillin 250mg/500mg caps					
30	4045	Cefixime 400mg 1's					
31	0029/31/32	Ceftriaxone 250mg/500mg/1g inj					
32	0053	Erythromycin susp 100ml					
33	2931/2194	Erythromycin 250mg 20/40					
34	0021	Benzathine Penicillin G inj 2.4Mu					
35	0074	Nystatin Oral Susp					
<b>Family Planning</b>							
36	0965/6	Medroxyprogesterone/Norethisterone					
<b>Vaccines</b>							
37	2983	BCG					
38	TBC	Hexaxim					
39	1053	Measles					
40	1062	Oral Polio					
41	4072	Pneumococcal					
42	4071	Rotavirus					
43	2072	Td					
44	2056	Rabies Vaccine					
45	2074	Tetanus toxoid					
<b>Fridge</b>							
46	0859/0863	Actrapid/Humulin R					
47	0857/2131	Actraphane/Humulin 30/70					
48	0911/0909	Oxytocin 5IU/10IU					
<b>Vacolitres</b>							
49	1266	Ringers Lactate 1L					
51	1332	Sodium chloride 0,9% 1L					
52	2041/1313/1323	Dextrose 5% 50ml, 200ml,1000ml					

## Annexure 2 – Tracer Medication

<b>Malaria</b>							
53	3976	Artemether20mg/Lumefantrine 120mg					
54	3154	Malaria test kit					
<b>Diagnostics</b>							
55	1067	Pregnancy test					
56	3705	Test strip Blood glucose					
<b>S5</b>							
57	0804	Diazepam 5mg/ml inj					
58	0243	Fluoxetine 20mg caps					
59	3861/3065/2197	Haloperidol tablets 1.5mg/5mg					
60	3861/3065/2198	Zuclopenthixol 50mg/ml					
<b>TB</b>							
61	2198	Ethambutol 400mg					
62	2199/4105	Isoniazid 100mg/300mg					
63	2200	Pyrazinamide 500mg					
64	4070/3799/ 3968/3801	Rif 150/Inh 75/Pza 400/ Etha 275					
65	3809	Rif 150/ Inh 75					
66	3750	Rif 300/ Inh 150					
67	4287/4288	Rif 60/Inh 60					

## Annexure 3 – Medical Supplies List

List of Medical Supplies	
	Universal list (all facilities)
1	Blood tubes
2	Dressing pack
3	Gloves (sterile) All Sizes
4	Gloves (unsterile) All Sizes
5	Hand soap
6	Hand towels
7	Hb slides
8	Intravenous administration set
9	Intravenous cannulae All Sizes
10	Syringes All Sizes
11	Masks N95 Particulate respirator
12	Micropore All Sizes
13	Nappies (Adult + Paeds)
14	Needles All Sizes
15	Oxygen masks
16	Suction catheter
17	Tegaderm
18	Urinary catheters All Sizes
19	Urine bags

**Annexure 4 – Pest Control Record**

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Pest Control Record						
Facility Name					Year	
Areas treated	Company Name	Name of agent	Signature of agent	Facility manager signature	Date	

# Annexure 5 – Key Control Register

Key Control Register					
Facility Name		Month		Year	
Key Taken Sign if you take the key			Key Returned Sign if you bring back the key		
Date	Printed Name	Signature	Date	Printed Name	Signature

# Annexure 6 – Discrepancy Report Form

Discrepancy Report Form											
Facility Name						Month	Year		Reason for Discrepancy	FM Signature	
	Date	Name	Stock on hand as per stock card	Rand Value	Physical Stock Count	Rand Value	Difference in Rands				
<b>TOTAL RAND VALUE</b>											

## Annexure 7 – Additional Medication as per NCS

List of Additional Medication	
1	Lignocaine 10% spray bottle 50ml
2	Chlorhexidine Gluconate 0.5% in Alcohol 70% (handrub)
3	Chlorhexidine Gluconate 0.5% in Alcohol 70% (skinrub)
4	Chlorhexidine Gluconate 0.05% in water 500ml
5	Chlorhexidine Gluconate 4% scrub 500ml
6	Gluteraldehyde 2% sol 1L
7	Mebendazole 100mg/5ml 30ml
8	Povidone Iodine 10mg/ml Solution 1L
9	Sodium Hypochlorite or Organic N-chloro sachets
10	Lignocaine HCL 2% gel 20g
11	Lubricating jelly, glycerine sachets
12	Mebendazole 500mg tab 1's
13	Haemacue Cuvettes
14	Test Strip Glucose machine
15	Test Strip Urine (Combur 9)
16	Test HIV screening (Abon)
17	Test HIV confirmation (First response)

## Annexure 8 – Additional Medical Supplies as per NCS

List of Additional Medical Supplies	
1	Apron disposable
2	Band Identification infants and mother (white)
3	Clamp Cord (maternity units)
4	Collar Cervical S/M/L
5	Mask surgical Queen Charlotte
6	Tape Autoclave 12mmx50m
7	Thermometers disposable (Nextemp)
8	Thermometers dial bi-metal fridge
9	Sterilisation bags sz 4 / 7 / 11
10	Tube Feeding 5F / 8F
11	Electrode ECG adult & Paed
12	Airways Pharyngeal (Guedels) 0/ 00/ 000 / 1 / 2 / 3 / 4 / 5
13	Cannula nasal Adult & Child & Infant
14	Humidifier
15	Nebuliser Adult & Paed
16	Resuscitator set 2.0 / 2.5 / 3mm
17	Resuscitator neonatal Single use
18	Tube Endotracheal Cuffed 6 / 6.5 / 7
19	Tube Endotracheal Non-Cuffed 2 /2.5 / 3.0 /3.5 / 4mm
20	Labels for dispensing tab / mix / INH / Vag / Ext



## Annexure 9 – Order and Delivery Schedule

	<b>Monday 21</b>	<b>Tuesday 22</b>	<b>Wednesday 23</b>	<b>Thursday 24</b>	<b>Friday 25</b>
<b>Week 1</b>	Kouga (11) NM (6)	Buffalo City – Peddie (12)	Amahlathi (13)	Maletswai (20)	Camdeboo (10)
<b>Week 2</b>	Ixuba Yethemba (16) NM (7)	Nkonkobe (14)	Makana (4)	Emalahleni (5)	Lukhanji (15)
<b>Week 3</b>	Kouga extra (11) NM (8)	Buffalo City – East London (1)	Buffalo City – Mdantsane (2)	Buffalo City – KWT (3)	Camdeboo (10)
<b>Week 4</b>	NM (9)	Elundini/Senqu (17)	Makana (4)	Emalahleni (5)	Lukhanji (15)

# Annexure 10 – Medication Order Form

Medication Order Form				
Facility Name		Month		Year
Name of medication	Quantity	Facility Manager		Date

## Annexure 11 – Pharmaceutical Condemnation and Disposal Form

Pharmaceutical Condemnation and Disposal Form										
Facility	Item code	Date			Form No.		Reason for condemnation			
		Generic Name	Dosage Form	Condition of Stock	Batch No.	Expiry date		Quantity	Price	

## Annexure 12 – Schedule 5 and 6 Register

Schedule 5 and 6 Drug Register											
Facility name	Drug name and dosage	Reference number	Supplied/dispensed by	Issued to	Authorised prescriber	Received	Dispensed	Balance			
Date	Pack size										

# Annexure 13 – Adverse Drug Reaction and Product Quality Problem Report

## ADVERSE DRUG REACTION AND PRODUCT QUALITY PROBLEM REPORT FORM

(Identities of reporter and patient will remain strictly confidential)

### NATIONAL ADVERSE DRUG EVENT MONITORING CENTRE



Medicines Control Council,  
The Registrar of Medicines,  
Department of Health

Tel: (021) 447-1618  
Fax: (021) 448-6181



In collaboration with the WHO International Drug Monitoring Programme

#### PATIENT INFORMATION

Name (or initials): ..... Age: ..... Weight (kg): .....  
Sex:  M  F DOB: ...../...../..... Height (cm): .....

#### ADVERSE REACTION/PRODUCT QUALITY PROBLEM

Adverse reaction<sup>1</sup>  and/or Product Quality problem<sup>2</sup>  Date of onset of reaction: ...../...../.....  
Time of onset of reaction: .....h.....min

Description of reaction or problem (Include relevant tests/lab data, including dates):

#### 1. MEDICINES/VACCINES/DEVICES (include all concomitant medicines)

Trade Name & Batch No. (Asterisk Suspected Product)	Daily Dosage	Route	Date Started	Date Stopped	Reasons for use

#### ADVERSE REACTION OUTCOME (Check all that apply)

Death       life-threatening      Event reappeared on rechallenge:  Y  N      Recovered:  Y  N

Disability       Hospitalisation       Y  N  Rechallenge not done      Sequelae:  Y  N  
 congenital anomaly       Other.....      Treatment (of reaction).....  
 required intervention to      Describe Sequelae: .....  
 prevent permanent      .....  
 impairment/damage      .....

COMMENTS: (e.g. relevant history, Allergies, Previous exposure, Baseline test results/lab data)

#### 2. PRODUCT QUALITY PROBLEM:

Trade Name	Batch No	Registration No	Dosage form & strength	Expiry Date	Size/Type of container

Product available for evaluation?  Y  N

#### REPORTING DOCTOR/PHARMACIST Etc.:

NAME: ..... QUALIFICATIONS: .....

ADDRESS: ..... Signature: ..... Date: .....

TEL: (.....).....

This report does not constitute an admission that medical personnel or the product caused or contributed to the event

## Annexure 14 – Emergency Tray

Facility Name	Year
Item	Quantity
Activated Charcoal	1 x 50g
Adrenaline 1mg/ml	2 x 1ml
Atropine 0,5mg/ml	3 x 1ml
Calcium gluconate 10%	1 vial
Dextrose 50%	1 x 20ml
Diazepam 10mg/2ml	2 x 2ml
Furosemide 20mg/2ml	2 x 2ml
Haloperidol 5mg/ml	1 vial
Hydrocortisone 100mg	1 vial
Isosorbide dinitrate sublingual 5mg	1 bot
Lignocaine 2%	2 vials
Magnesium sulphate 50%	2 vials
Promethazine 25mg/ml	2 x 1ml
Salbutamol inhalant fluid	1 x 20ml
Sodium Bicarbonate 8,5%	1 x 50ml
Sodium Chloride 0,9%	1 x 10ml
Sodium Chloride 0,9%	1 x 1000ml
Syringes	2 x 2ml; 2 x 10ml
Tongue Depressors	2
Water for injection	2 x 10ml
Administration Sets	1x 20 drops; 1x 60 drops
Airway	1 x 1000; 1 x 100; 1 x 10
Butterflies	1
Insulin Syringes	2 x 1ml
Jelco	1 x 23g
Needles	2 x Green 2 x Brown 2 x Pink
½ Strength Darrows	1 x 500ml
Webcol	2

# Annexure 15 – Emergency Tray Form





Emergency Tray Form													
Date Prepared	Item code	Generic name	Expiry data	Unit of issue	Prepared by	Quantity in box	Quantity used	Value of items					

# Annexure 16 – Room Temperature Chart

Month		Department																																						
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31								
°C	30																																							
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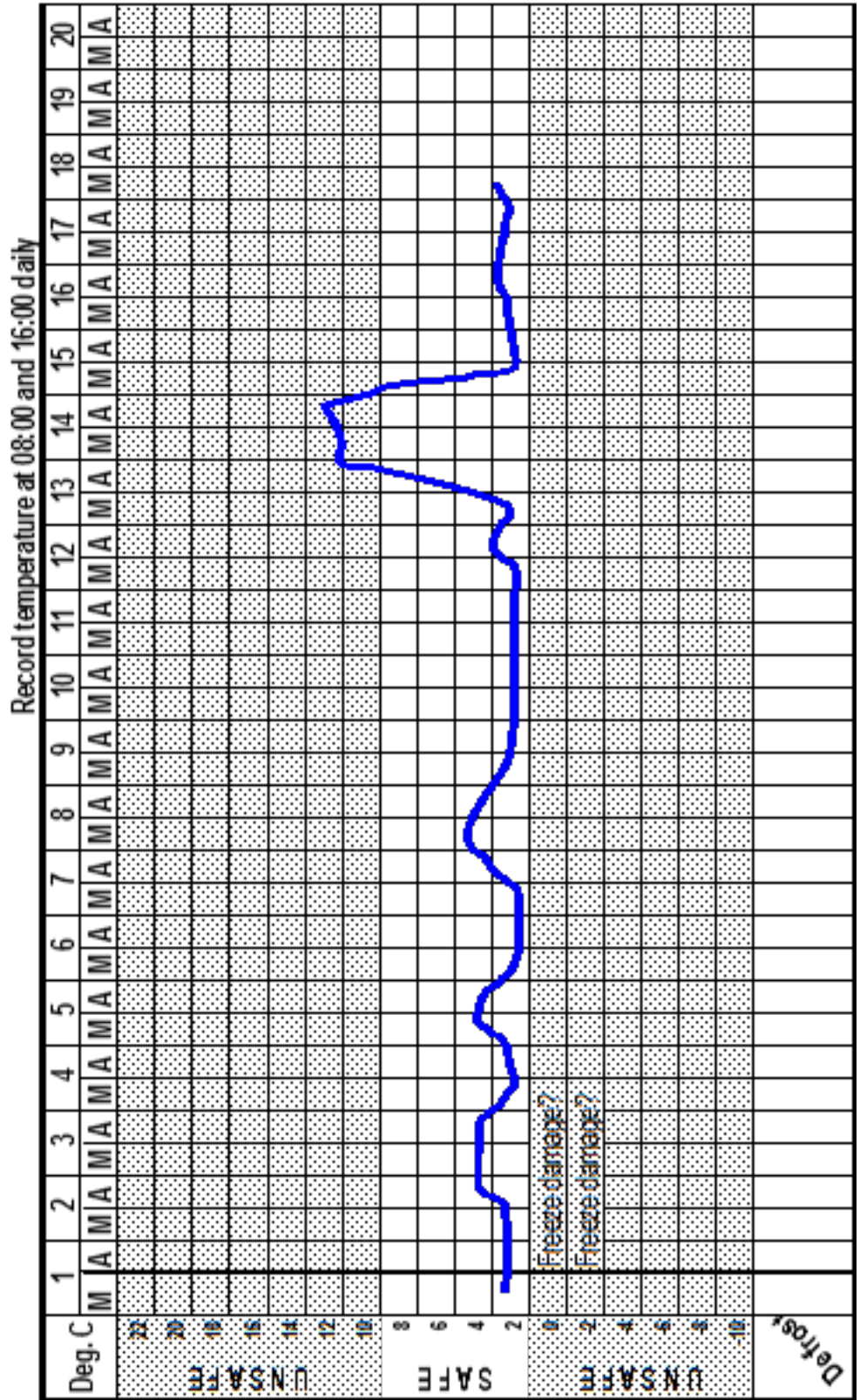


## Annexure 17 – VMM Table

Symbol	Explanation	Stage
	The inner square is lighter than the outer circle. If the expiry date has not passed, <b>USE</b> the vaccine	I
	As the time passes the inner square is still lighter than the outer circle. If the expiry date has not passed, <b>USE</b> the vaccine	II
	<b>Discard Point:</b> the colour of the inner square matches that of the outer circle <b>DO NOT USE</b> the vaccine	III
	Beyond the discard point: inner square is darker than the outer circle <b>DO NOT USE</b> the vaccine	IV

Source: WHO ([www.who.int](http://www.who.int))

# Annexure 18 – Fridge Temperature Chart



## Annexure 19 – Freezer Tags

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