

REPUBLIC OF KENYA



MINISTRY OF HEALTH

DEPARTMENT OF PHARMACY

HEALTH FACILITY LEVEL PHARMACEUTICAL SERVICES
STANDARD OPERATING PROCEDURES

July 2015

ACRONYMS AND ABBREVIATIONS

ADR	Adverse Drug Reaction
AMC	Average Monthly Consumption
AWL	Avoidable Waste and Losses
B/F	Brought Forward
BNF	British National Formulation
C/F	Carried Forward
CS	Closing Stock
CS	Current Stock
SCPF	Sub-County Pharmaceutical Facilitator
Disp	Dispensary
DMOH	District Medical Officer of Health
DOB	Date of Birth
DRAB	Drawing Rights Available Balance
FEFO	First-in-First-Out
HC	Health Center
IP	In Patient
KEMSA	Kenya Medical Supplies Agency
KSh	Kenya Shillings
M&E	Monitoring and Evaluation
Max MOS	Maximum Months
MCH	Maternal Child Health
MOH	Ministry of Health
MOS	Months of Stock
MSL	Maximum Stock Level
MTC	Medicines and Therapeutics Committee
NEMA	National Environmental Management Agency
OC	Order Costs
°C	Degrees Centigrade
OP	Out Patient
OPD	Out Patient Department
OQ	Order Quantity
OTC	Over the Counter
PPB	Pharmacy and Poisons Board
Rev	Revision
RHF	Rural Health Facility
SAE	Serious Adverse Effects
SOF	Standard Order Form
SOPs	Standard Operating Procedures
TOV	Total Order Value
VEN	Vital-Essential-Necessary

Pharmaceutical services

Standard operating procedures

SOP TITLE: ORDERING MEDICINES FROM KEMSA**Procedure Number: 1****Date Approved: July 2015****Valid up to: June 2016****Approved by**

Name:

Signature:

Date:

1) Objective

To describe the procedure for ordering medicines from KEMSA

2) Responsible Persons

The Pharmacist/ staff member in charge of managing medicines at the facility or his/her designated representative.

3) Tools Needed

- 3.1 *Standard Order Form (SOF)*
- 3.2 *Medicine Dispensing registers*
- 3.3 *Bin cards (S5)/ Stock Control Cards*
- 3.4 *Quantification Worksheet*

4) Definitions:

- 4.1 **SOF:** It is a triplicate form that serves two purposes – ordering of essential medicines from KEMSA and reporting medicine consumption related data. There are two kinds of SOFs: those designed for use at the health centres and dispensaries and those designed for use at the hospital level.
- 4.2 **Medicine Dispensing Registers:** Refers to facility approved registers for recording details of the patient and medicines dispensed to him/her.
- 4.3 **Bin (S5)/Stock control cards:** A tool used to record every movement of an item into or out of a store e.g. quantities received, issued, damaged, lost or expired. It is also used for verification of stock levels.
- 4.4 **Reporting period:** The set interval between two reports. This period also represents the order cycle i.e. after every 2 months for hospitals and after every 3 months for health centres and dispensaries.

5) Procedure

The Pharmacist/staff member in charge of managing medicines shall determine the order quantity by following steps 5.1 - 5.4 below, before completing the Standard Order Form:

- 5.1 Conduct a physical stock count at the bulk store and pharmacy store (where applicable) at the end of each reporting period, to obtain current stock.
- 5.2 Calculate the number of days out of stock from the bin/ stock control cards (preferably from the pharmacy store where applicable).
- 5.3 Sum up the total quantity of each medicine dispensed in complete units as captured in the medicine dispensing registers and bin cards at the pharmacy store for the reporting period, to obtain the total consumption.
- 5.4 Use the above information i.e. current stock, number of days out of stock and total quantity dispensed, to determine quantities to order as per **Procedure No. 2 - Quantification of Medicines**.
- 5.5 Complete the Standard Order Form (SOF) as described in the appendix.
- 5.6 Submit the SOF as follows:**
 - 5.6.1 SOF (RHF): Send the original and duplicate copies to the Sub-County Pharmaceutical Facilitator (SCPF), where applicable for approval. The SCPF will send the approved original copy to County Pharmacist
 - 5.6.2 SOF (Hospital): Send the original to KEMSA through the KEMSA LMIS website ie. lmis.kemsa.co.ke

6) Distribution and Storage of Tools

SOF (RHF and Hospitals)

- Printed copies should be kept within the facilities
- SCPF/SCMOH should print and file all the orders from the facilities
- A copy from each facility should be sent to the County Pharmacist

Note: copies of the completed SOF should be filed systematically (by date) for 6 years in a file that is specifically for that purpose, so that they may be retrieved easily.

Bin Cards (S5)/ Stock Control Cards

Bin cards should be kept next to the items in the store. Filled up bin cards should be filed separately and archived according to the prevailing laws or regulations.

Medicine Dispensing Registers

Medicine Dispensing Registers should be kept at the dispensing area. Filled registers should be archived according to the prevailing laws or regulations.

Pharmaceutical Services Standard Operating Procedures

SOP TITLE: QUANTIFICATION OF MEDICINES

Procedure Number: 2

Date Approved: July 2015

Approved by

Name:

Signature

Date:

Valid up to: June 2016

1) Objective

To describe the procedure for determining quantities of medicines to order

2) Responsible Persons

- 2.1. The staff in charge of the bulk store or his/her designated representative
- 2.2. The staff in charge of pharmaceutical services or his/her designated representative

3) Tools Needed

- 3.1 *Bin card (S5) /Stock control cards*
- 3.2 *Medicines dispensing register*
- 3.3 *Quantification worksheet*
- 3.4 *Standard Order Form (SOF)*

4) Definitions

- 4.1 **Consumption period** refers duration over which the total number of units used will be determined. The ideal consumption period is 365 days to ensure that variations in use due to change in weather or disease patterns are factored in.
- 4.2 **Maximum Months of Stock (Max MOS)** refers to the level above which the stock should not rise under normal conditions. The maximum level is usually set as a number of months of stock, and not as quantities. Quantities can vary depending on the consumption but the Months of stock (MOS), is a fixed number. For essential medicines, Maximum Months of Stock (Max MOS) at Hospital levels is 4 months and at health centre and dispensary levels is 6 months.
- 4.3 **Avoidable wastage and losses** refers to losses in medicine stock due to damage, deterioration, obsolescence, theft and expiry.

- 4.4 **Reporting period:** The set interval between two reports. This period also represents the order /distribution cycle. i.e. after every 2 months for hospitals and after every 3 months for health centres and dispensaries.

5) Procedure:

At the end of each reporting period, the staff in charge of the bulk store or pharmaceutical services shall carry out the quantification process and complete the quantification worksheet as follows:

- 5.1 Conduct a physical stock take of each of the medicines i.e. counts the number of complete units in stock to determine the closing stock (CS).
- 5.2 Calculate the consumption for the consumption period by adding all the quantities dispensed in the medicines dispensing register or all quantities issued in the bin card/ stock control card.
- 5.3 Alternatively, consumption can be calculated using the following formula:
Consumption = Opening Stock + Receipts – Closing Stock
- 5.4. Adjust consumption if needed for Avoidable Waste & Losses (AWL)
Consumption Adjusted for AWL= (C1) = Consumption – AWL (units)
- 5.5 Adjust for Stock-Outs if necessary to obtain consumption adjusted for Stock-Outs (C2)
C2 (units) = C1 (units) x CP (days) / Period in Stock (days)
- 5.6 Calculate Average Monthly Consumption (AMC)
AMC (units/month) = C2 / CP (Months)
- 5.7 Calculate Maximum Stock Level (MSL)
MSL (units) = AMC x Max MOS
- 5.8 Calculate the actual quantity to order (OQ)
OQ (units) = MSL – CS
- 5.9 Transfer the quantities to order to the updated KEMSA Standard Order Form issued by the sub-county pharmacist.

6) Distribution and Storage of Tools

- 6.1. Place bin cards next to the corresponding products at all times. Filled up bin cards shall be filed chronologically by medicine name in the bulk store.
- 6.2. Medicine Dispensing Register shall be stored in a locked cabinet for confidentiality and kept in the facility according to the prevailing laws or regulations on document archiving.
- 6.3 The quantification worksheet shall be filed in the medicine store for easy retrieval. A copy of the quantification worksheet should be sent with the Standard Order Form (SOF).

Pharmaceutical Services Standard Operating Procedures

SOP TITLE: STORAGE OF MEDICINES

Procedure Number: 3

Date Approved: July 2015

Valid up to: June 2015

Approved by

Name:

Signature

Date:

1) Objective

To describe the procedures and good practices for storage of medicines

2) Responsible Persons

- 2.1 Staff in charge of the bulk store/ pharmacy store or his/her designated representative
- 2.2. Pharmacy-in-charge or his/her designated representative designated representative

3) Tools Needed

- 3.1 *Bin cards (S5)/Stock control Card*
- 3.2 *Temperature logs/charts*
- 3.3 *Minimum and Maximum Thermometer*

4) Procedure

- 4.1 Record the details and quantities of each medicine received in its own bin/ stock control card upon receipt. Each commodity strength and formulation should have its own stock control/bin card.
- 4.2 Ensure that heat sensitive items are stored in a refrigerator or cold room as soon as possible upon receipt. Where applicable, the cold chain must be maintained throughout for the products that require it.
- 4.3 Routinely monitor the expiry dates using an appropriate tool e.g. Medicine Expiry Monitoring Chart

4.4 Storage Areas

- 4.4.1 Store medicines in a clean, well ventilated room that is free from pests.
- 4.4.2 Protect medicines from direct exposure to sunlight by using shades/curtains/white paint on windows or by keeping cupboards shut.

- 4.4.3 Protect medicines from moisture by ensuring that there is adequate drainage and that there are no leaking roofs or ceilings
- 4.4.4 Limit access to storage areas to authorized persons and keep storage areas locked when not in use. Designated authorized staff shall keep keys to storage areas in their possession at all times.
- 4.4.5 Loose items should be stored on shelves
- 4.4.6 Place bulky products on pallets. NO PRODUCTS SHOULD HAVE DIRECT CONTACT WITH THE FLOOR OR WALLS.
- 4.4.7 Ensure easy access to functional fire equipment and train staff on how to use them.

4.5. Stock Arrangement

- 4.5.1 Arrange medicines in a way that they are easy to find e.g. alphabetically, by dosage form or therapeutic class
- 4.5.2 Arrange medicines on shelves using the First-Expiry-First-Out (FEFO) principle
- 4.5.3 Place stock control/bin cards next to the corresponding products
- 4.5.4 Arrange bulky cartons on pallets with arrows pointing up and with labels, dates and manufacturers names clearly visible. If it is not possible, write the product name and expiry date clearly on the visible side.
- 4.5.5 Stack bulky cartons on pallets at least 10 cm off the floor, 30 cm away from walls and other stacks and no more than 2.5 m high to avoid crushing.
- 4.5.6 Store medicines away from flammable products or poisons.

4.6 Monitoring Temperature

- 4.6.1 Maintain a functional min-max thermometer in the bulk store, dispensing area, cold rooms/refrigerator
- 4.6.2 Assign one staff member on a permanent or rotational basis to monitor and record temperature of medicines storage areas.
- 4.6.3 Check the temperature in the bulk store, dispensing area, cold rooms/refrigerator TWICE DAILY in the morning and the evening when highest temperatures are observed and record in the corresponding temperature control log/chart.

Note:

Acceptable temperature range for the storage areas are:

- Bulk store and dispensing area: 18–25°C.
- Refrigerator or coldroom: 2–8°C.

Consider the individual medicines storage temperature requirement

- 4.6.4 Report temperatures not within acceptable range to the Pharmacist-in-charge or his/her representative IMMEDIATELY to take necessary action.
- 4.6.5 Where applicable check to ensure that the bulk store air-conditioning system or fan is working effectively on a daily basis.
- 4.6.8 Report any problems with air conditioning or fans to the Pharmacist In- charge or his/her representative IMMEDIATELY.

5) Distribution and Storage of Tools

- 5.1. Place bin cards next to the corresponding products.
- 5.2. Filled up bin cards shall be filed chronologically by medicine name in the bulk store.
- 5.3. Hang a temperature log for the cold room or refrigerator at the appropriate door in clear view at all times.
- 5.4. Hang a temperature log for the dispensing area and bulk store on the wall next to the minimum maximum thermometer and maintain a clear view at all times
- 5.5. Filled-up temperature logs shall be filed chronologically by date and kept in the dispensing area or bulk store as is applicable.

Pharmaceutical Services Standard Operating Procedures

SOP TITLE: ISSUING MEDICINES WITHIN THE FACILITY

Procedure Number: 4

Date Approved: July 2015

Valid up to: June 2016

Approved by

Name:

Signature

Date:

1) Objective

To describe the procedure for issuing medicines from the bulk store to the pharmacy store **and** from the pharmacy store to the dispensing area in the pharmacy and other dispensing points within the same facility

2) Responsible Persons

- 2.1 Staff in charge of the bulk store or his/her designated representative
- 2.2 Staff in charge of requesting medicines for dispensing area or his/her designated representative
- 2.3 Staff in charge of requesting medicines for other departments or his/her designated representative

3) Tool Needed

- 3.1 *Counter Requisition and Issue Voucher (S11)*
- 3.2 *Bin Cards (S5) / Stock control cards*
- 3.3 *Medicines dispensing register*

4) Procedure

- 4.1 Designated staff authorized to request the medicines completes a counter requisition and issue voucher (S11)
- 4.2 The designated staff authorized to issue the stock in the bulk store verifies the contents of the S11 or an equivalent document and retrieves the requested medicines.
- 4.3 The designated staff authorized to issue stocks in the bulk store/pharmacy store immediately up-dates bin cards as required.

- 4.4 Designated staff authorized to issue stocks in the bulk store completes the S11 or equivalent document and endorses it with date, name, designation and signature and issues the requested medicines to the relevant department.
- 4.5 Designated staff authorized to receive the stock in the dispensing area or other department checks the identity and quantities of medicine stock issued against the quantities indicated in the S11 or an equivalent document and endorse the S11 with their name, designation, and signature.
- 4.6 Designated staff authorized to receive stocks in the dispensing area makes appropriate entries in the medicines dispensing register for dispensing medicines or stock (bin) cards in facilities that have a dispensing store.
- 4.7 Designated staff authorized to receive stocks in other departments make appropriate entries in the corresponding registers or stock (bin) cards in the department.

Note: The procedure for issuing medicines from dispensing areas to other departments is similar to procedure 4.1-4.7 above

5) Distribution and Storage of Tools

- 5.1. The S11 is to be completed in triplicate
 - The original is kept in the bulk store for stock issued to the dispensing area and other departments.
 - Duplicate is retained and filed chronologically by date in the dispensing area or other requesting department
 - Triplicate remains in the S11 book.
- 5.2 Place bin cards next to the corresponding products at all times. Filled up bin cards shall be filed chronologically by medicine name in the bulk store.
- 5.3 File Medicines dispensing Register chronologically by date in the dispensing area.

Pharmaceutical Services Standard Operating Procedures

SOP TITLE: DISPENSING MEDICINES TO OUTPATIENTS

Procedure Number: 5

Date Approved: July 2015

Valid up to: June 2017

Approved by

Name:

Signature

Date:

1) Objective

To describe the procedure for dispensing medicines to out-patients

2) Responsible Persons

2.1 Authorized prescriber: The designated staff authorized to issue medicine prescriptions

2.2 Dispenser: The authorized staff responsible for dispensing medicines

3) Tools Needed

3.1 *Prescription form*

3.2 *Medicines dispensing register*

3.3 *Reference books e.g. British National Formulary, Martindale*

3.4 *Dispensing Aids*

3.5 *List of authorized Prescribers*

4) Definitions

4.1 **Authorized dispenser** refers to any health professional trained, registered and approved by the facility to dispense medicines

4.2 **Authorized prescriber** refers to any health professional trained, registered and approved by the facility to prescribe medicines. The name, signature and designation of all authorized prescribers should be captured in the „List of Authorized Prescribers.“

5) Procedure

5.1 An authorized prescriber issues a drug prescription for each eligible patient. A properly completed prescription must have the following information:

- Facility name
- Serial number
- Patient's full name
- Sex
- Age
- Patient reference number (Out-patient/In-patient number)
- Weight in kilograms (kg)
- Height in centimeters (cm) (for children where possible)
- Date prescription was written
- Generic name of medicines
- Strength/concentration of medicines
- Dosage form for medicines
- Quantity to be issued or number of days supply
- Route and frequency of medicine administration
- Prescriber's name
- Prescriber's signature

5.2 Upon receiving the prescription the designated dispenser shall:

- 5.2.1 Verify that the correct patient's name is on the prescription.
- 5.2.2 Verify that the prescriber is authorized to prescribe the drugs.
- 5.2.3 Check that the choice of medicine conforms to the specific National guidelines where applicable.
- 5.2.4 Check the prescription for correct dose, frequency, route of administration and duration. For children check that the dosages are correct for the weight and/or surface area
- 5.2.5 Check for any drug-drug; drug-disease; and drug-food interactions
- 5.2.6 Alert the prescriber and resolve any discrepancies or issues noted before filling the prescription.

5.3 Fill the prescription in the dispensing areas as described below:

- 5.3.1. Begin work in a clear and clean workspace.
- 5.3.2. Retrieve the stock from the bulk cupboard and match the following to the prescription:
 - Correct name of medicine
 - Strength/concentration
 - Dosage form
 - Quantity of tablets or syrup bottles required
- 5.3.3 Inspect the medication from the stock cabinet. Look for the following:
 - Broken or discoloured tablets or capsules
 - Liquid medications that have changed colour or odour
 - Any cracks or chips in bottles
 - Expiry date
- 5.3.3 If any of the above are found, do not dispense medication to patient. Separate the items from stock and prepare for disposal according to Procedure 10: Accounting for Medicines for Disposal. Where applicable, complete the Form for

Reporting Poor Quality of Medicines and send to the appropriate authorities (see Procedure No.9)

- 5.3.4 Inspect packaging container to make sure it is not damaged or soiled and that it is appropriate for medicine product being packaged.
- 5.3.5 Count the required number of tablets/capsules using a spatula on counting tray or clean sheet of paper or a digital counter. Avoid touching medicine product with hands, as contamination may result.
- 5.3.6 For powders, reconstitute as per manufacturer's instructions, if required.
- 5.3.7 Prepare an appropriate label for the medication to be dispensed. Include the following information on the label:
 - Generic name, strength, dosage form of medicine
 - Quantity
 - Dose and frequency of administration
 - Route of administration
 - Auxiliary instructions e.g. take with or without food
 - Patient's name
 - Dispensing Date
 - Name of facility dispensing medicines
- 5.3.8 Affix the label directly on the primary package (**do not affix labels to the outer packaging**)
- 5.4 Endorse the prescription with the quantities issued for each medicine and the dispenser's initials
- 5.5 Follow good pharmacy dispensing practices to countercheck the product to make sure that package contains the correct medicine, strength, quantity, dosage form; and that the label contains all the relevant information.
- 5.6 Make entries in the medicines dispensing register
- 5.7 Counsel the patient on the use of the medication as described in **Procedure 7 - Medication use counseling**.

6) Distribution and Storage of Tools

- 6.1 The dispensed Medicine Prescription shall be filed chronologically by date and stored in the facility according to the prevailing laws or regulations.
- 6.2. The medicine dispensing register shall be filed chronologically for easy retrieval and stored securely in the facility according to the prevailing laws or regulations.

SOP TITLE: MEDICATION USE COUNSELLING

Procedure Number: 6

Date Approved: July 2015

Valid up to: June 2017

Approved by

Name:

Signature

Date:

1) Objective

To describe the procedure for counseling a patient on the appropriate use of medicines

2) Responsible persons

Staff member responsible for dispensing medicine to the client/patient or care giver

3) Tools Needed

3.1 *Medication use counseling checklist.*

3.2 *National and/or facility formulary*

3.3 *Current Kenya National Standard Clinical Guidelines.*

3.4 *Other reference materials e.g. British National Formulary (BNF), Martindale etc.*

4) Definitions

4.1 *Private designated area* refers to a dispensing area that ensures patient confidentiality e.g. dispensing booth, separate dispensing/counseling room

5) Procedure:

The italicized texts in this procedure are suggestions of how you can communicate the key messages to the patient/ client/ caregiver

5.1 Dispense the medications as described in procedure 6: Dispensing *Medicines to Outpatients*.

5.2 In a private/designated area, follow these guidelines to assist in counseling the patient or his/her representative.

5.2.1 **Introduce yourself:** Give your name and position (e.g. pharmacist or pharmaceutical technologist). Explain to the patient how you will be involved in their treatment and what you can do for them. E.g. will be responsible for making sure they have adequate supply of medicines, dispensing and follow-up.

- 5.2.2 **Identify who is being counseled:** Is the person picking up the medicines the patient or caregiver or a representative?
- 5.2.3 **Check what the client, patient or his/her representative already knows about the medicines:** Ask the patient or his/her representative questions to see how much they already understand about the medications:
- *What did the clinician/nurse tell you the medication was for?*
 - *How did the clinician/nurse tell you to take the medicines?*
 - *What other information did the clinician/nurse tell you about taking this medication?*
- 5.2.4 **Make sure that the client, patient or his/her representative understands how these medications work.** *e.g. These medicines when used together control your blood sugar levels*
- 5.2.5 **Check for questions and concerns:** *Do you have any questions or concerns, before I continue?* If you cannot address the patient's or his/her representative's questions or concerns, seek the advice of the relevant health care provider.
- 5.2.6 **Give the generic name and describe appearance:** Tell the patient or his/her representative the names of the medicines they are receiving. As you say the name of the medicine, point to the name on the package label. Open the package and show the patient or his/her representative a tablet, or show the patient a picture of the tablet from a poster or other aid you keep in the pharmacy. If there has been a change in the colour or shape of the product due to change in manufacturer take extra time to explain to the patient why the product looks different.
- 5.2.7 **Explain the route of administration:** *For example, "Take these medicines by mouth with a glass of water."*
- 5.2.8 **Give directions:** Explain to the patient or his/her representative the number of pills they should take at a time, whether to take with meals or an empty stomach, what foods to avoid. Agree on what times are most convenient for the patient to take the medicines. Explain that the medicines must be taken regularly, exactly as agreed, and not to miss any doses:
- a) *These medications are meant only for you. Do not share these medications with others.*
 - b) *These medications work best when there is a constant amount in the blood. To help keep the amount constant, do not miss any doses.*
 - c) *Take the medicine exactly as agreed with the health care provider. You should not take more of it or take it more often than the health care provider has said.*
 - d) *If you miss a dose, take it as soon as possible. However, if it is almost time for the next dose, skip the missed dose and go back to the regular dosing schedule. You should not take your missed dose and your next dose at the same time (or two doses at the same time).*

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

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

- e) *Keep taking the medication, even if you start to feel better. Advise the patient to continue taking the medicines for the prescribed duration.*
- f) *If you don't take these medicines exactly as the health care provider told you, they may not work. This is dangerous, because some diseases might become resistant and condition becomes difficult to manage or leads to poor response to treatment and may lead to hospitalization and sometimes death.*
- g) *Don't stop taking these medicines without checking with your health care provider first.*

5.2.9 Give information on the side effects of the medicines: Refer to National treatment guidelines where applicable or other references and job aids you have at the facility. *Explain;-*

- a) **Common side effects.** *These side effects usually do not need medical attention and go away during treatment as your body adjusts to the medicine. e.g. drowsiness, cough, nausea etc .. However, talk with your clinician if these side effects continue or are very bothersome. Encourage client to read patient information leaflet.*
- b) **Severe side effects** should be **reported immediately**. *Advise the patient to report severe or unusual side effects to the prescriber and/or nearest health facility carrying along all the medicines they are taking.*
- c) *Actions to take if symptoms persist- Advise to return or contact the nearest health facility*

5.2.10 Taking other medicines e.g. OTCs, contraceptives, complementary & alternative medicines, food supplements, herbal and indigenous medicines: Ask the patient or his/her representative if they are taking any of the above. Check for possible interactions. Inform the clinician and/or resolve any identified interactions. Encourage the patient to avoid taking medicines whose effect is not known (e.g. herbal & complimentary Medicines). Also ask for any medicine allergies. If the pharmacy keeps this information on file, double-check that the information is accurate.

Tell the patient:

- a) *Some medicines are not safe to take while you are taking these medicines. Give the specific information.*
- b) *You may or may not be able to tell if the other medicines are causing a problem.*
- c) *It is always best to check with your doctor before starting any new medicines (this includes herbals and vitamins).*
- d) *Avoid alcohol while taking medicines (check for interaction).*

5.2.11 **Storage:** Advise the patient to store the medicines appropriately

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

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

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

OR

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

5.2.13 **Final check for questions and concerns:** *Do you have any questions or concerns?* If you cannot address the patient/caregiver's questions or concerns, consult medicine information resources or other members of the healthcare team

6) Distribution and Storage of Tools

- 6.1. Medication Use counseling checklist shall be displayed in dispensing area and shall remain visible to the dispenser at all times.
- 6.2. Drug Formulary list used in Kenya shall be displayed in dispensing area and shall remain visible to the dispenser at all times.
- 6.3. Other references should be kept in the dispensing area with easy access to the dispenser.

SOP TITLE: REPORTING ADVERSE DRUG REACTIONS

Procedure Number: 7

Date Approved: July 2015

Approved by

Name:

Signature

Date:

Valid up to: June 2017

1) Objective

To describe the procedure for reporting of Adverse Drug Reactions (ADRs) to medicines

2) Responsible persons

- 2.1 All healthcare providers (Clinicians, Nurses, Pharmacists, Dentists, Physiotherapists, Community Health workers, Nutritionist etc.)
- 2.2 Medicine and Therapeutics Committees (MTC)
- 2.3 Facility Pharmacist/Staff member in charge or MTC secretary or Clinical Pharmacist where available (To collect and forward ADR reports to national pharmacovigilance centre)

3) Tools Needed

- 3.1 *National Pharmacovigilance Guidelines*
- 3.2 *Suspected Adverse Drug Reaction (ADR) Reporting Form.*
- 3.3 *Adverse Drug Reaction (ADR) Alert Card*
- 3.4 *Patient's clinic record*
- 3.5 *Pharmacovigilance job aids*
- 3.6 *Current Kenya national treatment guidelines e.g. Standard Clinical Guidelines 2010*
- 3.7 *Other reference materials e.g. British National Formulary (BNF), Martindale: The Complete Drug Reference, www.medicinescomplete.com etc.*
- 3.8 *Medication use counseling checklist*

4) Definitions:

- 4.1 **Adverse Drug Reaction (ADR):** A response to a medicine that is noxious and unintended, and occurs at doses normally used in man for the prophylaxis, diagnosis, therapy of disease, or modification of physiological function

- 4.2 **Serious Adverse Effect (SAE):** any reaction that is fatal, life-threatening, permanently/significantly disabling, requires or prolongs hospitalization, causes a congenital anomaly, or requires intervention to prevent permanent impairment or damage
- 4.3 **Grading of severity of ADRs (Ref: Guidelines for the National Pharmacovigilance System in Kenya)**
- Grade 1: **Mild**
Transient or mild discomfort, no limitation in activity, no medical intervention/therapy required
 - Grade 2: **Moderate**
Mild to moderate limitation in activity; some assistance may be needed; no or minimal medical intervention/therapy required
 - Grade 3: **Severe**
Marked limitation in activity, some assistance usually required, medical/intervention/therapy required, hospitalization possible
 - Grade 4: **Life-Threatening**
Extreme limitation in activity, significant assistance required, significant medical intervention/therapy required, hospitalization or hospice care probable

5) Procedure:

- 5.1 On presentation of suspected ADR, the health personnel shall interview the patient and/or review the patient's clinic record.
- 5.2 Where applicable, the health personnel shall counsel the patient on use of medication (using the Medication Use Counseling Checklist and appropriate reference materials) and consult with clinician on management and issuance of ADR alert card.
- 5.3 The health personnel shall complete the suspected ADR reporting form as described below: **She/he shall:**
- 5.3.1 Tick to indicate whether it is an initial or follow-up report - **Fill in the:**
 - 5.3.2 Institution name/code number if applicable
 - 5.3.3 Patient's Name
 - 5.3.4 Patient's gender– indicate whether male or female
 - 5.3.5 Patient's IP/OP Number
 - 5.3.6 Patient's Date of Birth (DOB)
 - 5.3.7 Patient's address
 - 5.3.8 Patient's Source (Ward/Clinic)
 - 5.3.9 Patient's Weight (Kg)
 - 5.3.10 Patient's known allergies
 - 5.3.11 Patient's Pregnancy Status (Indicate trimester)
 - 5.3.12 Diagnosis of what patient was being treated for

- 5.3.13 Summary of the suspected ADR according to details given by patient or healthcare
- 5.4 **Document** all relevant medications the patient was taking up to three months prior to the onset date of the suspected ADR
- List all drugs, total daily dose, the start and stop dates and indication.
 - Tick the relevant box for any drug suspected to have caused the ADR (use appropriate reference materials to obtain required information)
- 5.5 **Select the severity** of the reaction from the following list and tick the appropriate box
- Mild
 - Moderate
 - Severe
 - Fatal
 - Unknown
- 5.6 **Select and document** action taken from the following (tick the appropriate box)
- Drug withdrawal
 - Dose increased
 - Dose reduced
 - Dose not changed
 - Unknown
- 5.7 **Select the outcome** from the following list and tick the appropriate box
- Recovering/resolving
 - Recovered/resolved
 - Requires or prolongs hospitalization
 - Causes a congenital anomaly
 - Requires interventions to prevent permanent damage
 - Unknown
- 5.8 **Select the causality of ADR** from the following list and tick the appropriate box
- Certain
 - Probable/Likely
 - Possible
 - Unlikely
 - Conditional/unclassified
 - Unassessable /unclassifiable
- 5.9 **Document any other comments:** Include any relevant laboratory and diagnostics reports. Add additional pages if needed. (A typed summary is acceptable and should be signed, dated and submitted with the Suspected ADR forms)
- 5.10 Fill your details i.e. Name, Date, E-mail, Telephone number, Designation and Signature as the person reporting the ADR or completing the Suspected ADR forms

- 5.11 The completed Suspected ADR reporting form shall be forwarded to the Facility Pharmacist for submission to PPB and Hospital Medicine and Therapeutic Committee for assessment of trends

6) Distribution and Storage of Tools

- 6.1 The completed Suspected ADR reporting form shall be submitted to the Facility Pharmacist (or the SCPF for the Health Centers and Dispensaries) who will distribute the copies as follows:
 - 6.1.1 The original is forwarded to the MTC's secretary or pharmacy in-charge or responsible clinical pharmacist for submission to PPB
 - 6.1.2 The 2nd copy is retained in the facility in the patient's file.
 - 6.1.3 The 3rd copy is maintained by the MTC's secretary or pharmacy in-charge or responsible clinical pharmacist (SCPF for Health Centers and Dispensaries)
- 6.2 All Suspected ADR reports shall be kept in a confidential file.
- 6.3 PPB to acknowledge receipt and provide feedback to the facility (MTC, facility-in-charge, pharmacy-in-charge, SCPF and County Pharmacist)

Pharmaceutical Services Standard Operating Procedures

SOP TITLE: REPORTING POOR QUALITY MEDICINAL PRODUCTS

Procedure Number: 8

Date Approved: July 2015

Valid up to: June 2016

Approved by

Name:

Signature

Date:

1) Objective

To describe the procedure for reporting poor quality medicinal products

2) Responsible persons

2.1 Qualified health personnel

2.2 Overall facility Pharmacist/Staff member in charge of Pharmacy

3) Tools Needed

3.1 *National Pharmacovigilance Guidelines*

3.2 *Poor Quality Medicinal Product form*

3.3 *Pharmacovigilance job aids*

3.4 *Bin cards*

3.5 *Temperature logs*

3.5 *Other reference materials e.g. British National Formulary (BNF), Martindale: The Complete Drug Reference, British Pharmacopoeia, Micromedex, www.medicinescomplete.com etc.*

4) Definitions

4.1 *Qualified health personnel* - Pharmacist or other health personnel trained on identifying and reporting product quality problems

5) Procedure:

5.1 The suspected poor quality product shall be quarantined or put aside and the qualified health personnel notified immediately.

The Pharmacist/Designee shall:

- 5.2 Assess the product quality and withdraw all unused quantities of the suspected poor quality product from the dispensing points at the facility and quarantine them in a designated area until a written order from the Chief Pharmacist is received authorizing use or disposal.
- 5.3 Fill in the following details in the Poor Quality Medicinal Product Form;**
- 5.3.1 Institution details (Name, Location, Facility address and contact information).
- 5.3.2 Product identification information (Brand name, Generic name, Batch number, Manufacturer details, Date of manufacture, Expiry date, Country of origin, Local distributor/supplier and date received in the facility.)
- 5.3.3 The product formulation and check/tick the relevant box under the product formulation. If „other“, the pharmacist/designee shall specify the details.
- 5.4 Document the product complaint by checking the appropriate space/box provided. If „other“, the pharmacist/designee shall specify the details.
- 5.5 Provide a detailed summary of the problem stating the extent and health implications, where necessary state steps taken within the facility. Add a separate typed and signed report with the form.
- 5.6 Fill in the storage conditions of the product as stated by the product monograph. Check the boxes as appropriate.
- 5.7 Attach copies of temperature logs indicating the facility storage conditions under which the product had been stored.
- 5.8 Add any additional comments to the section on any other comments; if none, the pharmacist/designee shall write „Not Applicable“.(A typed report shall be acceptable and should be signed, dated and submitted with the Poor Medicinal Quality Form.
- 5.9 Fill your details i.e. Name, Date, E-mail, Telephone number, Designation and Signature as the person reporting the poor quality medicinal product

6) Distribution and Storage of Tools:

- 6.1** The qualified health personnel shall submit the completed Poor Medicinal Quality form to the pharmacy in-charge or designee who shall distribute the copies as follows:
- 6.1.1 The original copy shall be forwarded to the SCPF who will report to the Pharmacy and Poisons Board (PPB) website for pharmacovigilance
- 6.1.2 The 2nd copy shall be forwarded to the KEMSA Regional Liaison Officer
- 6.1.3 The 3rd copy shall be maintained by the pharmacy in-charge or the MTC secretary
- 6.1.4 A 4th copy shall be sent to the County Pharmacist through the SCPF
- 6.2 All Poor Medicinal Products Quality reports shall be kept in a confidential file
- 6.3 PPB & KEMSA to acknowledge receipt and provide feedback to the facility (pharmacy-in-charge or MTC secretary) on action taken

SOP TITLE: ACCOUNTING FOR MEDICINES FOR DISPOSAL

Procedure Number: 9

Date Approved: July 2015

Approved by

Name:

Signature

Date:

Valid up to: June 2017

1) Objective

To describe the procedure for accounting for damaged expired or other unusable medicines (e.g. patients' medicine returns).

2) Responsible Persons

- 2.1 The staff in charge of the bulk store or his/her designated representative and a witnessing staff member.
- 2.2 The staff in charge of pharmaceutical services or his/her designated representative and a witnessing staff member.
- 2.3 The procurement officer or staff member in-charge of the hospital supplies department
- 2.4 The facility/ district disposal committee

3) Tools Needed

- 3.1 *Report of the Board of Survey on Stores (Unserviceable and Surplus to Requirements) (F.O. 58)*
- 3.2 *Bin (S5) /Stock control Cards*
- 3.3 *Medicines dispensing register*
- 3.4 *Counter Receipt and Issue Voucher (S11)*
- 3.5 *National procurement and disposal regulations*
- 3.6 *National pharmaceutical waste disposal guidelines; NEMA guidelines*

4) Procedure:

At the end of every quarter:

4.1 The staff member in charge of the bulk store shall:

- 4.1.1 Separate damaged, expired or unusable medicines from the usable stock and place them in a labeled quarantine area

- 4.1.2 Make the necessary adjustments to the corresponding bin cards/ stock control cards as described in the procedure for issuing stock. Indicate whether the items are expired, damaged or unusable.

4.2 The staff member in charge of pharmacy/ dispensing area shall:

- 4.2.1 Separate damaged expired or unusable medicines from usable stock at the dispensing area.
- 4.2.2 Make the necessary adjustments to the medicines dispensing register indicating whether the items are expired, damaged or unusable.

4.3 The staff member in charge of the bulk store shall:

- 4.3.1 Raise an S11 for receipt of the expired, damaged or unusable medicines from the dispensing area to the quarantine area.
- 4.3.2 Arrange the quarantined medicines systematically and maintain an inventory record which details the name of the medicine, batch number, quantity, expiry date, reason for quarantine (damaged/poor quality/ patient returns) and manufacturer.

At the end of each financial year (30th June):

- 4.4 The staff member in charge of the bulk store completes sections 1-6 of the Report of the Board of Survey on Stores (Unserviceable and Surplus to Requirements) (F.O. 58) and forwards a copy to the hospital or district procurement officer.
- 4.5 The Hospital or Sub-County Health Administrative Officer endorses the F.O. 58 with their signature, official designation and date and forwards to the Facility in charge.
- 4.6 The Sub-County Commodity TWG SCHAO and the SCPHO convenes a disposal committee according to the national public procurement and disposal regulations
- 4.7 The disposal committee shall review the completed F.O 58, examine the medicines, propose disposal method and complete sections 7-10 of the report.
- 4.8 The disposal committee members endorse the report and send a copy to the Department of Pharmacy Headquarters for approval from the accounting officer (Permanent Secretary, Ministry of Health) and the Treasury.
- 4.9 On receipt of the approved F.O. 58 form, the disposal committee shall undertake the disposal of the medicines according to the national pharmaceutical waste disposal guidelines, NEMA guidelines.

5) Distribution and Storage of Tools

- 5.1 A copy of the completed F.O. 58 shall be retained and filed at the facility bulk store for easy retrieval.

TOOLS

The tools listed in the above priority Pharmaceutical SOPs compilation may be divided into the three categories listed below and are to be obtained from different sources e.g.:

- At different departments of the health facility
- KEMSA Regional liaison officer
- Ministry headquarters
- Ministry websites
- Provincial Pharmacist
- Provincial Health offices
- District Health Offices
- World wide web (internet)

FORMS AND CHARTS

- 1) Adverse Drug Reaction (ADR) Alert Card
- 2) Bin card (S5)
- 3) Stock control cards
- 4) Counter Requisition and Issue Voucher (S11)
- 5) List of authorized Prescribers
- 6) Medication use counseling checklist.
- 7) Medicines dispensing register
- 8) Poor Quality Medicinal Product form
- 9) Prescription form
- 10) Quantification Worksheet
- 11) Report of the Board of Survey on Stores (Unserviceable and Surplus to Requirements) (F.O. 58)
- 12) Standard Order Form (SOF)
- 13) Suspected Adverse Drug Reaction (ADR) Reporting Form.
- 14) Patient's clinic record
- 15) Pharmacovigilance job aids
- 16) Temperature logs/charts
- 17) Medicine Expiry Monitoring Chart

REFERENCE DOCUMENTS

- 18) National Standard Clinical Guidelines
- 19) Public Health Programs' Guidelines
- 20) National and/or Facility Formulary
- 21) National Pharmaceutical Waste Disposal Guidelines
- 22) NEMA guidelines
- 23) National Pharmacovigilance Guidelines
- 24) Public Procurement and Disposal Act 2005 and Regulations 2006

- 25) Other Medicines-related Reference materials e.g. British National Formulary (BNF), Martindale: The Complete Drug Reference, British Pharmacopoeia, Micromedex, www.medicinescomplete.com etc.

EQUIPMENTS

- 26) Dispensing Aids
27) Minimum and Maximum Thermometer

For those requiring instructions to complete, copies are attached below.

KEMSA STANDARD ORDER FORM FOR HOSPITALS

Essential Medicines Standard Order Form (Hospitals), 5th Version												
Hospital name:		Facility Number				Total Outpatient workload			Reporting Period Beginning Date: End Date:			
KEMSA code no	Item description Name / form / strength	Order Unit Size	Standard Cost (Kshs)	Beginning/Openin g Balance	Total Receipts	Total Issues from Dispensing areas	Adjustments	Losses	Ending /Closing Balance	No. of days out of stock in the reporting period	Quantity To Order	Order Cost
a) Essential Medicines: Tablets and Capsules												
PHA0539	Acyclovir Tablets 400mg	100	326									
PHA0003	Albendazole Tablets 400mg	1,000	1,425									
PHA0005	Amitriptylline Tablets 25mg	1,000	228									
PHA0286	Amoxicillin /Clavulanic Acid 500mg/	10s	1,313									
PHA0009	Amoxicillin Capsules 250mg	1,000	1,665									
PHA0385	Artemether/lumefantrine Tablets 100	6	0.01									
PHA0386	Artemether/lumefantrine Tablets 100	12	0.01									
PHA0387	Artemether/lumefantrine Tablets 100	18	0.01	1086.8								
PHA0388	Artemether/lumefantrine Tablets 100	24	0.01									
PHA0001	Aspirin Tablets 300mg	1,000	352									
PHA0415	Atenolol Tablets 50mg	1,000	785									
PHA0021	Benzhexol Tablets 5mg	1,000	219									
PHA0026	Carbamazepine Tablets 200mg	1,000	902									
PHA0036	Chlorphenamine Tablets 4mg	1,000	121									
PHA0432	Ciprofloxacin Tablets 250mg	1,000	1,166									
PHA0436	Codeine Phosphate Tablets 30 mg	100	476									
PHA0048	Cotrimoxazole Tablets 480mg	1,000	820									
PHA0055	Diazepam Tablets 5mg	1,000	94									
PHA0440	Diclofenac Sodium Tablets 50 mg	1,000	248									
PHA0239	Digoxin Tablets 250mcg	500	235									
PHA0070	Doxycycline Capsules 100mg	1,000	726									
PHA0444	Enalapril Tablets 5mg	100	6,820									
PHA0073	Erythromycin Tablets 250mg	1,000	2,227									
PHA0078	Ferrous sulphate/Folic acid 200mg/4	1,000	66									
PHA0079	Flucloxacillin Capsules 250mg	1,000	2,904									
PHA0554	Fluconazole Capsules 50mg	100	190									
PHA0086	Furosemide Tablets 40mg	1,000	209									
PHA0414	Hydrochlorothiazide Tablets 50mg	1,000	211									
	Glibenclamide Tablets 5mg	1,000	160									
PHA0130	Ibuprofen Tablets f/c 200mg	1,000	297									
PHA0331	Ketoconazole Tablets 200mg	30	63									
PHA0146	Loperamide Capsules 2mg	100	506									
PHA0148	Magnesium Trisilicate Tablets	1,000	122									
PHA0378	Metformin Tablets 500mg	1,000	497									
PHA0155	Methyldopa Tablets f/c 250mg	1,000	26									
PHA0549	Metoclopramide Tablets 10mg	100	43									
PHA0160	Multivitamin Tablets	1,000	237									
PHA0166	Nifedipine Tablets s/r 20mg	1,000	219									
PHA0493	Omeprazole Capsules 20mg	1,000	814									
PHA0178	Paracetamol Tablets 100mg	1,000	219									
PHA0178	Paracetamol Tablets 500mg	1,000	293									
PHA0182	Phenobarbitone Tablets 30mg	100	127									
PHA0183	Phenytoin Tablets 50mg	1,000	282									
PHA0333	Praziquantel Tablets 600mg	100	798									
PHA0187	Prednisolone Tablets 5mg	1,000	327									
PHA0291	Quinine Sulphate Tablets 300mg	1,000	3,872									
PHA0201	Salbutamol Tablets 4mg, Scored	1,000	93									
PHA0214	Sulfadoxine/Pyrimethamine Tablets	1,000	2,364									
PHA0225	Tinidazole Tablets 500mg	1,000	957									
PHA0470	Zinc Sulphate Tablets 20mg	100	275									

KEMSA code no	Item description Name / form / strength	Order Unit Size	Standard Cost (Kshs)	Beginning / Opening Balance	Total Receipts	Total Issues from Dispensing areas	Adjustments	Losses	Ending / Closing Balance	No. of days out of stock in the reporting period	Quantity To Order	Order Cost
PHA0050	Darrow's ½ strength IV infusion 500	24	871									
PHA0051	Dextran 70/glucose 6%/5% infusion	24	11,286									
PHA0054	Diazepam inj 5mg/mL, 2mL amp	50	437									
PHA0348	Diclofenac inj 25mg/mL, 3mL amp	10	42									
PHA0487	Digoxin Inj 50mcg/ml, 2ml amp.	10	2,233									
PHA0080	Flucloxacillin inj 250mg	10	146									
PHA0085	Furosemide inj 10mg/mL, 2mL amp	10	9									
PHA0087	Gentamicin inj 10mg/mL, 2mL amp	100	275									
PHA0088	Gentamicin inj 40mg/mL, 2mL amp	100	275									
PHA0421	Glucose infusion 10%, 500mL(Dextr	24	898									
	Glucose infusion 5%, 250mL(Dextro	20	-									
PHA0052	Glucose infusion 5%, 500mL(Detros	24	713									
PHA0053	Glucose injection 50%, 100mL(Dext	50	1,898									
PHA0120	Heparin inj 5,000 IU/mL, 5mL vial	25	1,925									
PHA0123	Hydralazine inj 20mg amp pfr	10	1,098									
PHA0124	Hydrocortisone inj 100mg vial	10	220									
PHA0412	Insulin biphasic 30/70 100 IU/mL. 1	10	3,520									
PHA0139	Insulin soluble, human 100 IU/mL, 1	10	3,476									
PHA0145	Lidocaine inj 2% 30mL amp	10	330									
DEN0020	Lignocaine 2% / Adrenaline 1:80,000 Den	100	1,868									
DEN0028	Dental Needles Long	100	0.01									
DEN0029	Dental Needles Short	100	0.01									
PHA0287	Magnesium sulphate inj 50%, 10mL	10	2,165									
PHA0357	Metoclopramide inj. 5mg/ml, 2ml am	10	48									
PHA0156	Metronidazole inj 5mg/mL, 100mL v	96	688									
PHA0455	Morphine inj. 10mg/ml, 1ml amp.	10	437									
PHA0174	Oxytocin inj 10 IU/mL, 1mL amp	10	370									
PHA0290	Phytomenad.inj (Vit K) 10mg/mL, 1	5	413									
PHA0289	Phytomenad.inj (Vit K ₁) 2mg/mL, 0.	5	83									
PHA0192	Quinine Inj. 600mg/2ml	100	1,522									
PHA0351	Sod.stibogluconate inj 100mg/mL, 1	1	9,602									
PHA0204	Sodium bicarbonate inj 8.4%, 10mL	10	68									
PHA0169	Sodium chloride IV infusion 0.9%, 2	20	547									
PHA0170	Sodium chloride IV infusion 0.9%, 5	24	656									
PHA0094	Sodium lactate co IV infusion, 250m	20	811									
PHA0094	Sodium lactate co IV infusion, 500m	24	710									
PHA0229	Water for injection 10mL amp	100	276									

KEMSA code no	Item description Name / form / strength	Order Unit Size	Standard Cost (Kshs)	Beginning / Opening Balance	Total Receipts	Total Issues from Dispensing areas	Adjustments	Losses	Ending / Closing Balance	No. of days out of stock in the reporting period	Quantity To Order	Order Cost
d) Psychotropics												
PHA0038	Chlorpromazine inj 25mg/mL, 2mL a	10	60									
PHA0039	Chlorpromazine Tablets 100mg	1,000	516									
PHA0547	Flupenthixol decanoate inj 20mg/ml	10	94									
PHA0082	Fluphenazine decanoate inj 25mg/1	10	254									
PHA0447	Haloperidol Decan. Inj. 50mg/ml, 1	10	1,760									
PHA0091	Haloperidol Tablets 5mg	1,000	1,089									
e) Theatre Medicines												
	Atracurium besylate 10mg/ml	10	1,505									
PHA0429	Bupivacaine heavy spinal inj 5mg/m	10	715									
PHA0093	Halothane inhalation, 250ml	10	28,600									
PHA0142	Ketamine injection 50mg/mL, 10mL	10	4,158									
PHA0163	Neostigmine methylsulph. 2.5mg/mL	10	194									
PHA0175	Pancuronium bromide inj 2mg/mL, 2	10	273									
PHA0217	Suxamethonium chloride inj 50mg/m	10	330									
PHA0224	Thiopentone inj 500mg vial pfr	50	4,290									
f) Specialized Medicines												
	Azathioprine 50mg Tablets	100's	-									
	Ciclosporin A 50mg Capsules	30's	-									
PHA0461	Pralidoxine Mesylate inj. (PAM) 200m	5	62									
d) Essential Medicines: External Medicines/Other Items												
PHA0445	Absolute Ethanol(Methylated spirit)	4x5L	1,690									
PHA0411	Bedomethasone inhal.100mcg/dose	10	4,400									
PHA0235	Benzyl Benzoate Application 25%	5x100m	648									
PHA0280	Calamine Lotions 15 %	5x100m	550									
PHA0034	Chlorhexidine gluconate 5% soln (fo	4x5L	2,020									
PHA0044	Clotrimazole cream 1%,20g	25 tube	228									
PHA0045	Clotrimazole pessaries 200mg (+ ap	20	268									
NPH0270	Dispensing bottle, plastic 60mL	600	3,102									
PHA0069	Dispensing envelope plastic resealab	10x100	5,813									
NPH0271	Dispensing label, self-adhesive x 20	roll	100									
PHA0446	Ethanol denatured 70%	4x5L	1,492									
PHA0248	Hydrocortisone ointment 1%,15g	25 tube	550									
EQP0067	Measuring spoons, double sided 5/2	100	1,870									
PHA0186	Povidone iodine solution 10%	12x1L	2,112									
PHA0465	Silver Sulphadiazine cream 1%	250g	143									
PHA0205	Sodium hypochlorite solution 4-6%	4x5L	704									
PHA0223	Tetracycline eye ointment 1% 3.5g	50	825									
NPH0575	Triangular tablet counters	Piece	330									
f) Reproductive Health Supplies (currently supplied at no cost under pull system)												
NPH0021	Condom, female	1,000	0.01									
NPH0022	Condom, male	4,800	0.01									
KIT0007	Depot Medroxyprogesterone acetate 150mg inj	Kit (1x10 Ovals)	0.01									
PHA0255	Levonorgestrel implant 75mg	10 Pairs	0.01									
PHA0250	IUD Copper T	25's	0.01									
PHA0241	Levonorgestrel/ethinylestradiol tab 0.15mg/0.03mg (COC)	3x21	0.01									
	Levonorgestrel tab 30mcg (POP)	3x35	0.01									
PHA0263	Levonorgestrel tab 750mcg (EC), Pai	10	0.01									
Total Order Value												
Drawing Rights Available Balance												
Hospital Telephone Number				Hospital Email Address:								
Prepared by (name/Pharmacist i/c)		Mob. T el No.		Email address					Signature			
Authorised by (name/MedSup)		Mob. T el No.		Email address					Signature			

KEMSA STANDARD ORDER FORM FOR HEALTH CENTRES & DISPENSARIES

MoH Essential Medicines & Medical Supplies: Standard Order Form								
Health Facility (name/code no):					Level:	Disp	HC	
District:			Date:		Order no.			
	Item description Name / form / strength	Order Unit Size	Unit Cost (Kshs)	Current Stock (units)	AMC (units)	Order Qty (units)	Order cost (Kshs)	
1a) Essential Medicines (EM) for Dispensary Level								
PHA0002	Adrenaline (epinephrine) inj 1mg/1mL amp	1*	3.30					
PHA0385	AL tabs 20/120 mg	6	0.01					
PHA0386	AL tabs 20/120 mg	12	0.01					
PHA0387	AL tabs 20/120 mg	18	0.01					
PHA0388	AL tabs 20/120 mg	24	0.01					
PHA0003	Albendazole tab 400mg	1,000	915.85					
PHA0004	Aminophylline inj 25mg/mL, 10mL amp	1*	7.50					
PHA0011	Amoxicillin oral susp 125mg/5mL	100mL	22.00					
PHA0009	Amoxicillin cap 250mg	1,000	763.20					
PHA0001	Aspirin tab 300mg	1,000	114.50					
PHA0019	Benzathine penicillin inj 2.4 MU vial pfr	1	18.35					
PHA0235	Benzyl benzoate application 25%	100mL	23.65					
PHA0025	Benzylpenicillin inj 1MU vial pfr	1	4.60					
PHA0280	Calamine lotion 15%	100mL	38.20					
PHA0028	Ceftriaxone inj 250mg vial pfr	1	18.50					
PHA0032	Chloramphenicol inj 1g vial pfr	1	17.55					
PHA0034	Chlorhexidine gluconate soln 5%	5L	500.00					
PHA0035	Chlorpheniramine inj 10mg/1mL amp	1*	4.00					
PHA0431	Chlorpheniramine syrup 2mg/5mL	5L	167.90					
PHA0036	Chlorpheniramine tab 4mg	1,000	91.60					
PHA0485	Ciprofloxacin tab 250mg	100	95.40					
PHA0044	Clotrimazole cream 1%	20g	8.24					
PHA0435	Clotrimazole pessary 200mg	3	9.92					
PHA0046	Cotrimoxazole susp 240mg/5mL	50mL	13.00					
PHA0048	Cotrimoxazole tab 480mg	1,000	534.25					
PHA0054	Diazepam inj 5mg/mL, 2mL amp	1*	7.70					
PHA0070	Doxycycline cap 100mg	1,000	801.35					
PHA0073	Erythromycin tab 250mg	1,000	1,908.00					
PHA0083	Folic acid tab 5mg	1,000	74.00					
PHA0087	Gentamicin inj 10mg/mL, 2mL amp	1*	2.85					
PHA0088	Gentamicin inj 40mg/mL, 2mL amp	1*	2.35					
PHA0052	Glucose (dextrose) IV infusion 5%, 500mL	1*	27.00					
PHA0124	Hydrocortisone inj 100mg vial	1*	14.15					
PHA0284	Hydrocortisone ointment 1%	15g	19.10					
PHA0130	Ibuprofen tab f/c 200mg (scored)	1,000	270.20					
PHA0331	Ketoconazole tab 200mg	30	48.80					
PHA0145	Lidocaine (lignocaine) inj 2%, 30mL vial	1	22.00					
PHA0287	Magnesium sulphate inj 50%, 10mL amp	1*	160.00					
PHA0148	Magnesium trisilicate co tab	1,000	130.00					

MoH Essential Medicines & Medical Supplies: Standard Order Form

	Item description Name / form / strength	Order Unit Size	Unit Cost (Kshs)	Current Stock (units)	AMC (units)	Order Qty (units)	Order cost (Kshs)
PHA0357	Metoclopramide inj 5mg/mL, 2mL amp	1*	4.05				
PHA0373	Metoclopramide tabs 10mg	100	38.15				
PHA0158	Metronidazole susp 200mg/5mL	100mL	23.70				
PHA0159	Metronidazole tab 200mg	1,000	242.70				
PHA0284	Multivitamin syrup	5L	390.00				
PHA0160	Multivitamin tab	1,000	190.80				
PHA0170	Nystatin oral susp 100,000 IU/mL	30mL	25.20				
PHA0173	ORS sachet (for 500mL) new formula	1	2.60				
PHA0174	Oxytocin injection 10 IU/1mL ampoule	1*	13.50				
PHA0177	Paracetamol syrup 120mg/5mL	5L	285.00				
PHA0178	Paracetamol tab 500mg	1,000	267.05				
PHA0182	Phenobarbitone tab 30mg	100	28.00				
PHA0289	Phytomenadione (Vit K) inj 2mg/0.2mL amp	1*	62.00				
PHA0186	Povidone iodine solution 10%	1L	172.00				
PHA0187	Praziquantel tabs 600mg	100s	725.00				
PHA0192	Quinine dihydr. inj 300mg/mL, 2mL amp	1*	12.75				
PHA0291	Quinine sulphate tab 300mg f/c scored	1,000	3,534.40				
PHA0200	Salbutamol syrup 2mg/5mL	100mL	11.50				
PHA0202	Salbutamol tab 4mg (scored)	1,000	84.50				
PHA0169	Sodium chloride IV infusion 0.9%, 500mL (Normal saline)	1*	26.70				
PHA0094	Sodium lactate co IV infusion, 500mL (Hartmann's/Ringer-Lactate)	1*	27.20				
PHA0095	Silver nitrate gel 0.2%, 100gm	1*	477.00				
PHA0214	Sulfadoxine/pyrimethamine tab 500/25mg	1,000	1,760.55				
PHA0223	Tetracycline eye ointment 1%	5g	9.20				
PHA0229	Water for injection 10mL vial	1*	2.50				
PHA0470	Zinc sulphate tab 20mg	100	111.45				
1b) Additional Essential Medicines for HC Level							
PHA0005	Amitriptyline tab 25mg	1,000	221.35				
PHA0038	Chlorpromazine inj 25mg/mL, 2mL amp	1*	5.30				
PHA0458	Phenobarbitone inj 200mg/mL	1*	20.00				
2) Reproductive Health Supplies (for all levels)							
NPH0022	Condom, male	1	0.01				
KIT0007	Depot Medroxyprogesterone acetate 150mg inj	Kit (1x100vials)	0.01				
PHA0241	Levonorgestrel/ethinylestradiol tab 0.15mg/0.03mg (COC)	3x21	0.01				
PHA0346	Levonorgestrel tab 0.03mg (POP)	3x35	0.01				
PHA0263	Levonorgestrel tab 750mcg (EC)	2	0.01				
1b) Additional RH Supplies for HC Level							
PHA0408	Etonogestrel Implant 68mg	1	0.01				

*Order Qty for these items should be in **fixed multiples of Order Unit Size** (to be advised by KEMSA)

MoH Essential Medicines & Medical Supplies: Standard Order Form

Item description Name / form / strength	Order Unit Size	Unit Cost (Kshs)	Current Stock (units)	AMC (units)	Order Qty (units)	Order cost (Kshs)
3a) Essential Medical Supplies (EMS) for Dispensary Level						
NPH0139	Autoclave tape 19mm x 50m	roll	181.90			
NPH0031	Cotton crepe bandage 7.5cm x 5m	roll	12.00			
NPH0064	Cotton gauze bandage 5cm x 5m	Dozen	49.25			
NPH0154	Cotton gauze plain 36" x 100yds, 1,500g	roll	682.00			
NPH0152	Cotton wool, absorbent, 400g	roll	92.00			
NPH0270	Dispensing bottle, plastic 60mL	1	4.65			
PHA0069	Dispensing envelope plastic resealable	10x1000	2,964.90			
NPH0271	Dispensing label, self-adhesive x 200	roll	99.43			
NPH0057	IV cannula 18G	1	9.35			
NPH0058	IV cannula 20G	1	9.35			
NPH0060	IV cannula 22G	1	9.55			
NPH0061	IV cannula 24G	1	16.00			
PHA0137	IV infusion giving set with air inlet	1	8.64			
NPH0050	Gloves, latex examination, medium	50 prs	212.20			
NPH0052	Gloves, surgical 7.5 (sterile)	pair	26.00			
NPH0140	Maternity towels	pack	50.80			
PHA0069	Measuring spoons, 5ml	Piece	1.70			
NPH0072	Paraffin gauze dressing 10x10cm	10	150.00			
NPH0101	Scalpel blade #23 with handle	10	80.00			
NPH0010	Suture, polyglycolic acid 2/0 90cm on ½ circle 36mm taper cut needle	Dozen	826.00			
NPH0068	Suture, nylon 2/0 75cm on ½ circle 40mm reverse cutting needle	Dozen	85.40			
NPH0109	Syringe 2mL + needle 23G x 1"	100	330.00			
NPH0111	Syringe 5mL + needle 21G x 1.5"	100	388.40			
NPH0110	Syringe 10mL + needle 21G x 1.5"	100	580.00			
NPH0082	Sharps safe disposal box	1	140.00			
PHA0205	Sodium hypochlorite solution 4-6%	5L*	147.95			
NPH0180	Tongue depressor wooden	100	68.20			
NPH0186	Umbilical cord clamp	20s	55.00			
NPH0188	Zinc oxide strapping 7.5cm x 5m	roll	43.75			
3b) Additional EMS for HC Level						
NPH0146	Foley's catheter 16FG 30mL 2-way	1	20.30			
NPH0147	Foley's catheter 18FG 30mL 2-way	1	20.30			
PHA0154	Methylated spirit 95%	5L	375.00			
NPH0182	NG tube/feeding tube, size 6 (for pre-term)	1	5.35			
NPH0048	Nasogastric/feeding tube, size 8 (for term)	1	5.35			
NPH0184	Nasogastric/feeding tube, size 12	1	7.60			
NPH0046	Nasogastric/feeding tube, size 16	1	7.60			
NPH0045	Nasogastric/feeding tube, size 18	1	8.05			
NPH0212	Urine bag 200mL graduated with inlet/outlet	1	14.00			
Total Order Value:				Kshs		
Drawing Rights Available Balance:				Kshs		
Prepared by (name/designation)	Tel		Date		Signature	
Checked by (name/DPF)	Tel		Date		Signature	
Authorised by (name/DMoH)	Tel		Date		Signature	

NOTES ON TERMS USED ON THE SOFs

- 1) **Reporting Period** – This refers to the set interval between two reports. This period also represents the order cycle/ the last distribution cycle. i.e. after every two months for hospitals and after every 3 months for health centers and dispensaries.

***Example:** For a hospital submitting an SOF in July, the reporting period is May to June and begins on 1st of May and ends on 30th June. For a health centre submitting an SOF on 1st of July the reporting period is 1st April to 30th June.*

- 2) **Total Outpatient workload** – This is the Total Number of Outpatients seen in the reporting period as Captured on Form MoH 711
- 3) **Beginning/Opening Balance** – This is the total number of intact order sizes including items in the dispensing area at the Start of the reporting period. It is also equivalent to the Ending/ closing balance for the previous reporting period
- 4) **Total Receipts** – These are the total number of items including donations, receipts from KEMSA and Local procurement during the reporting period.
- 5) **Total Issues from Dispensing areas** – These are intact order sizes issues from the dispensing area
- 6) **Adjustments** – These are commodities either issued to or received from other facilities with the same source of supplies being KEMSA. These can either be a positive adjustment for Items received from other facilities or negative adjustment from items issued out to other facilities.
- 7) **Losses** – These are items that have left the supply chain in the reporting period other than client consumption. These include breakages, damaged commodities or pilferage commodities.
- 8) **Ending/Closing Balance** – These are intact quantities on the End date of the reporting period including intact commodities in the dispensing area. They are also equivalent to the Beginning / Opening balance for the next reporting period.
- 9) **Number of days out of stock in the reporting period** – These are the number of days in the reporting period that the item was not available at the dispensing area
- 10) **Quantity To Order** – This are the quantities required by the reporting entity for the next distribution cycle.
- 11) **Order Cost** – This is the cost of the commodities ordered which is obtained by multiplying the Standard cost (KSh) with the Quantities Ordered

STEPS FOR COMPLETING THE STANDARD ORDER FORM (SOF)

- 1) Fill in the information at the top of the first page.
 - a) Enter the name of your Health Facility in capital letters

- b) For Rural Health Facility (RHF) SOF, indicate the Level of your institution by marking (X) in the box marked Disp (Dispensary) or HC (Health Centre)
- c) Write the name of your District in the box provided
- d) Enter the Date on which the SOF is being completed

Note: The Order Number which is pre-printed at the top of the form (in red ink) is the order reference number for all queries or follow-up related to the order.

For each item on the SOF, complete steps 2-5 below:

- 2) Enter the **Current Stock (CS)** of the item i.e. the total number of complete, unopened order units in the bulk store and anywhere else in the service delivery points within the health facility, e.g. pharmacy
- 3) Enter the **Average Monthly Consumption (AMC)** as the average number of units consumed per month
- 4) Enter the calculated **Order Quantity (OQ)** in whole numbers
- 5) Enter the **Order Costs (OC)** in KSh

Order Cost = Unit Cost for the item X Order Quantity required

Note: where the calculated OQ is negative, enter N/A (i.e. not applicable) in the OC box instead of a value

Complete the information at the bottom of the last page of the SOF as follows:

- 6) Calculate the **Total Order Value (TOV)** by adding up the order costs for all the ordered items and enter the value obtained in the space provided on the form.
- 7) Where applicable, enter the **Drawing Rights Available Balance (DRAB)** in the space provided. This figure is provided by KEMSA and represents the current amount available to the health facility for use in ordering EMMS items on the SOF.
- 8) Compare the **Total Order Value** amount with the **Drawing Rights Available Balance** amount.
 - a) Where the total order value is less than the drawing rights (TOV < DRAB): continue with Step 9
 - b) Where the total order value is more than the drawing rights (TOV > DRAB): re-examine your order to find which Order Quantities can be reduced to bring the TOV to be equal to or less than DRAB

In order to do this systematically and rationally, it will be necessary to carry out an ABC and VEN analysis of the items ordered on the SOF.

- 9) Under the section of **Prepared By :**
- a) Enter your **name** in capital letters
 - b) Enter your **designation**
 - c) Enter your **telephone contact number** - This should be your mobile number and/or the telephone number of the health facility
 - d) Enter the date: This should be the date on which the order is **submitted**

MEDICINE DISPENSING REGISTER

Facility Name _____ Health Facility Code _____					Adrenaline 1mg/ml Injection																				
					Albendazole 400mg																				
					Amoxicillin 250mg																				
					Amoxicillin 125mg/5ml Syrup (100mls)																				
					Amoxicillin clavulanic acid 228.5mg Syrup (70mls)																				
					Benzyl Penicillin 600mg (IMU) Injection																				
					Ceftriaxone 1g Injection																				
					Chlorpheniramine 4mg																				
					Clotrimazole 1% cream																				
					Ciprofloxacin 250mg																				
					Cotrimoxazole 480mg																				
					Gentamycin 20mg/2ml Injection																				
					Hydrocortisone 1mg/ml Injection																				
					Insulin 70/30 10ml																				
					Insulin Soluble Human 10ml																				
					Methyldopa 250mg																				
					Metronidazole 200mg																				
					ORS 500ml sachet																				
					Tetracycline 1% eye ointment																				
Unit of Issue					Amp	Tabs	Caps	Bottle	Bottle	Vial	Vial	Tabs	Tube	Tabs	Tabs	Amp	Vial	Vial	Vial	Tabs	Tabs	S acket	Tube		
Stock Balance Brought Forward (A)																									
New stock received (B)																									
Total Stock on Hand (C) obtained by adding (A+B)																									
	Date of Issue	Name of Patients /Ward/Clinic	Patient OPD/IP Number	Prescription. No./Reference Number	Dispensers Name																				
1																									
2																									
3																									
4																									
5																									
6																									
7																									
8																									
9																									
10																									
11																									
12																									
13																									
14																									
15																									
16																									
17																									
18																									
19																									
20																									
Total quantity Issued (D) obtained by sum of rows 1-20																									
Losses and Expiry (E)																									
Stock Balance (G) obtained by (C-D-E)																									

STEPS FOR COMPLETING THE MEDICINE DISPENSING REGISTER

- 1) Enter the facility name and facility code.
- 2) **Date of Issue:** Enter the date during which the particular item is being issued.
- 3) **Patient Name/Ward/Clinic:** Enter the patient name/ward/clinic to which the tracer essential medicine is being dispensed.
- 4) **Patient OPD/IP number:** Enter the respective patient OPD/IP number.
- 5) **Prescription No/ Reference Number:** Enter the prescription number from the official prescription form or specific reference number.
- 6) **Dispensers Name:** Enter the name of the dispenser.
- 7) **Drug Product/Basic Unit:** The drug/product item name is pre-printed on the register. Enter the quantity (in basic units) of the particular tracer essential medicine dispensed to the patient or dispensing point e.g. Ward, MCH etc.
- 8) **Stock Balance Brought Forward (A):** This is the stock balance (G) of the medicines brought forward from the previous page. It should be entered in the respective column for each medicine.
- 9) Enter the **total Quantity in units** (e.g. tablets, capsules, and for liquids, enter in bottles etc) of each usable tracer essential medicine on hand in the facility.
- 10) **New Stock Received this period (B):** Enter the quantity of the medicines (in units e.g. tablets, bottles etc.) received from the facility bulk store/ storage area.
- 11) **Total Stock on Hand (C) :** For each medicine, add their respective values for Stock Balance Brought Forward (A) and New Stock Received (B). i.e. $C = A + B$
- 12) **Total Quantity Issued this period (D):** Once the page is full add up the totals for each medicine dispensed at the bottom of the page for the rows marked "Total quantity issued (D)", and enter the respective values.
 - If a product was not dispensed, enter "0" in the *Total Quantity issued* column for that product.
- 13) **Losses and Expiry (E):** Enter the quantity of any loss in the stock of the medicines during the dispensing process. The reason for the loss should be written in the "Remarks" column of the Monthly Summary Report for Consumption of Tracer Essential Medicines. This column is usually completed during stock-taking, but should also be completed whenever a loss occurs.
 - Losses include missing, defective, damaged or expired product and should be removed from inventory.
 - *Any missing, lost or unaccounted for stocks should be documented and suspected theft investigated according to the Government's policy.*
- 14) **Stock balance (G):** Enter the total sum of usable tracer essential medicine obtained by using the following formula:

Stock balance (G) = Total Stock on hand(C) - Total Quantity issued (D) - Losses and expiries.

- However, if there are any discrepancies, these should be indicated in the „*Remarks*’ column of the Monthly Summary Report for Consumption of Tracer Essential Medicines.
- 15) At the beginning of every month, start recording on a new page.

BIN CARD (S5)

FORM S5

REPUBLIC OF KENYA

BIN CARD

ITEM CODE No.	UNIT OF ISSUE	SERIAL NUMBER:
ITEM DESCRIPTION	STORAGE REQUIREMENTS	LEDGER CARD No.
.....		LOCATION

Date	Issue / Receipt Voucher No.	Receipt	Issue	Balance	Initials	Date	Issue / Receipt Voucher No.	Receipt	Issue	Balance	Initials
	B/F From Card No.	B/F									
	C/F										

STEPS FOR COMPLETING THE BIN CARD (S5)

- 1) Complete a separate bin card for differing strengths/concentrations and units of issue (i.e. for each different pack size)
- 2) Record for a new card:
 - Item Code No. (number listed in the KEMSA Medicines Catalogue that is specific to each drug, strength/concentration, and dosage form)
 - Item Description:
 - Generic name
 - Strength/concentration
 - Dosage form
 - Unit of issue: pack size (e.g., number of tablets per package)
 - Storage requirements (e.g., refrigeration)
 - Ledger Card Number (the serial number from the corresponding S3 form)
 - Stock location (if another location is also used, the two should be frequently reconciled)
 - B/F from Card No.: for first card for a new item write *New*
 - Balance B/F (Brought Forward) is entered as the first entry in a new card. For a new product write *New*. When a set of columns is completed on one side, the Balance C/F (Carried Forward) is recorded in the next set of columns at the Balance B/F.
- 3) Record when receiving stock:
 - Date: (stock received)
 - Issue/Receipt Voucher No.:
 - The reference number of the delivery document (S12/packing list/...) voucher for goods received from KEMSA
 - Expiry date of product for each receipt
 - Receipt: quantity received
 - Balance: calculated by adding up the previous balance and the total quantity of goods received
 - Initials: of person receiving stock
- 4) Record when issuing stock:
 - Date: (stock issued)
 - Issue/receipt voucher no.: the reference number of the issue voucher (S11/...) for goods issued to the different user departments or units or other facility sites
 - Issue: quantity issued
 - Balance: calculated by decreasing the previous balance for goods issued
 - Initials: of person issuing stock

STOCK CONTROL CARD

[illegible]

Date	Reference/Notes	Received	Issued	Balance
	Balance brought forward			
	Balance to carry forward			

STEPS FOR COMPLETING THE STOCK CONTROL CARD

- 1) **Item:** Write the description of the medicine item in the form: generic name, dose-form or presentation, size or strength e.g. Paracetamol tablets 500mg
- 2) **Order unit:** Enter the size of the unit in which the item is ordered e.g. 1,000 tabs
- 3) **Code number:** Enter the KEMSA medicine catalogue item number e.g. PHA 002
- 4) **Expiry dates:** Write the dates of expiry of the different batches of the medicine supplied. These dates shall be crossed out once each particular batch is used up e.g. 6/2010, 12/2009
- 5) **Max level:** This refers to the maximum months of stock or the maximum recommended stock level of the item e.g. 50,000. This figure is used during quantification and shall be calculated for each item and reviewed/revise annually
- 6) **Stock unit:** Enter the unit in which the item is stocked, received and issued e.g. tablet. This is always expressed in terms of *single units* of the item. Thus 2 tins of 1,000 paracetamol tabs = 2,000 stock units
- 7) **Date:** Enter the date on which a particular stock movement or action took place
- 8) **Reference/Notes:** Write the information regarding the stock movement or action:
 - for receipts include the source of the medicines and the invoice number
 - for issues indicate the place to which stock was issued
 - for stock management actions/ losses give information on the outcome of the action or nature of the loss e.g. physical inventory, damage
- 9) **Received:** Write the quantity of stock received/gained
- 10) **Issued:** Write the quantity of stock issued/removed/lost from usable stock
- 11) **Balance:** Write the balance left after each receipt or issue. To get the new balance add stock received/gained to the last balance or subtract stock issued/removed/lost from the last balance
- 12) **Balance brought forward:** Record the amount of the balance of stock carried forward from the previous stock card or starting amount (if new item/card)
- 13) **Balance to carry forward:** Record the amount of the balance of stock to be carried forward to the next page of the stock card

QUANTIFICATION WORKSHEET

Quantification Worksheet

[illegible]

STEPS FOR COMPLETING THE QUANTIFICATION WORKSHEET

- 1) **Column 1:** Write the name of the medicine, it's strength and dosage form
- 2) **Column 2:** Write the total consumption
- 3) **Column 3:** Enter the adjusted consumption for wastage and losses (AWL)
- 4) **Column 4:** Write the adjusted consumption for stock outs
- 5) **Column 5:** Write the average monthly consumption
- 6) **Column 6:** Enter the Maximum Months of Stock
- 7) **Column 7:** Enter the closing stock
- 8) **Column 8:** Write the calculated quantity to order

TEMPERATURE CONTROL LOG: BULK STORE/ OUTPATIENT PHARMACY STORE

Month/Year:/201__

(Acceptable Range: +18–25°C)

Date	A.M. Time	Recorded Temp (°C)	Acceptable Yes(✓)/No	Initials	P.M. Time	Recorded Temp (°C)	Acceptable Yes(✓)/No	Initials
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								

TEMPERATURE CONTROL LOG: BULK STORE /PHARMACY REFRIGERATOR

Month/Year:201__

(Acceptable Range: 2–8°C)

Date	Time	Recorded Temp (°C)	Within Acceptable Range Yes(✓)/No	Initials
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				

STEPS FOR COMPLETING TEMPERATURE CONTROL LOG: BULK STORE/ OUTPATIENT PHARMACY STORE

- 1) A.M./P.M. Time: Enter the time the temperature is checked.
- 2) Recorded temp ($^{\circ}\text{C}$): write down the observed temperature.
- 3) Acceptable Yes(☒) / No:
 - ☒ if the temperature is within the acceptable range.
 - Write NO if the temperature is outside of the acceptable range.
- 4) Initials: Write your Initials

STEPS FOR COMPLETING TEMPERATURE CONTROL LOG: BULK STORE REFRIGERATOR/ OUTPATIENT PHARMACY REFRIGERATOR

- 1) Time: enter the time the temperature is checked on that day.
- 2) Recorded temp ($^{\circ}\text{C}$): write down the temperature.
- 3) Within acceptable range:
 - ☒ if the temperature is within the acceptable range.
 - Write NO if the temperature is outside of the acceptable range.
- 4) Initials: Write your Initials

MEDICINE EXPIRY MONITORING CHARTMEDICINE EXPIRY MONITORING CHART

YEAR: 2011											
JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEPT	OCT	NOV	DEC
Paracetamol 500mg Tablets	Ceftriaxone 250 mg Vial	Ferrous Sulphate 50 mg	Folic Acid Tablets 5mg	AL 20/120 mg Tablets							
Tinidazole 500mg Tablets		Paracetamol 500 mg	Cotrimoxazole Suspension	Tinidazole 500mg Tablets							
				Amoxicillin 250mg Caps							
				Diazepam 5mg/ml Inj							

STEPS FOR FILLING THE MEDICINE EXPIRY MONITORING CHART

- 1) Enter the current year on the top row of the chart. E.g. 2010
- 2) During receipt of medicines, sort out the medicines according to the medicine name, formulation, strength and expiry date.
- 3) Enter the names of the medicines in the columns that correspond to their expiry dates.

Example: *Paracetamol 500mg Tablets with an expiry date of January 2011 will be listed under the first column of the 2011 Medicine Expiry Monitoring Chart*

COUNTER REQUISITION FORM

FORM S11

Serial
No.....

REPUBLIC OF KENYA

COUNTER REQUISITION AND ISSUE VOUCHER

Ministry

Dept/Branch.....

Unit.....

To (Issue point).....

Please issue the stores listed below to (Point of use).....

[illegible]

Account No:

Designation:

Date:

Requisitioning Officer:
.....

Signature:

Sign: _____

STEPS FOR COMPLETING THE S11:

- 1) Designated person, **authorised to requisition** the stock, records:
 - Ministry (*of Health*) Depart./Branch (*Medical*) and Unit (e.g., *facility name*)
 - To (Issue point): e.g., *Pharmacy store*
 - Issue to (Point of use): receiving location (e.g. *outpatient pharmacy*)
 - Code No.: number listed in the KEMSA Medicines Catalogue which is specific to each drug, strength/concentration, and dosage form
 - Item Description:
 - Generic name
 - Strength/concentration
 - Dosage form
 - Unit of Issue: the quantity in the container or pack size (e.g., 60 tablets per pack)
 - Quantity Required: the number of units of issue required (e.g., 10 packets of 60 tablets each)
 - Account No.: designated number if appropriate
 - Date: of requisition
 - Requisitioning Officer: name, designation, and signature
 - 2) Designated person, **authorised to issue** the stock, records:
 - Quantity Issued: the number of units of issue which are actually issued
 - Value: of total amount of stock issued (calculated using average unit price)
 - Remarks/Purpose: expiry date of stock issued
 - Issued by: issuing officer"s name and signature
 - Date: issued
 - 3) Designated person **authorized to receive** the stock checks identity and quantity of medicine issued and records:
 - Received by: name, designation, and signature
-

PRESCRIPTION FORM

Republic of Kenya, Ministry of Health (Form 501 rev)			
Facility:		Rx no.	
		District:	
Patient's Name:			Weight (kg)
Address:			
Age:	Sex:	OP/IP No.	
Diagnosis:			
Treatment		Quantity	
		Rx	Disp
Prescriber:			
Signature:		Date:	
Dispenser:			
Signature:		Date:	

First copy (for dispensing records)

SAMPLE LIST OF AUTHORIZED PRESCRIBERS

No.	Name of prescriber	Designation	Signature
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			
11.			
12.			
13.			
14.			
15.			


MEDICATION USE COUNSELING CHECKLIST

1. Introduce yourself ☐
2. Identify who is being counseled ☐
3. Check what the patient or his/her representative already knows about the medicines: ☐
 - a) What did the doctor/nurse tell you the medication was for?
 - b) How did the doctor/nurse tell you to take the medicines?
 - c) What other information did the doctor/nurse tell you about taking this medication?
4. Make sure the patient or his/her representative understands how these medications work e.g. whether they cure, suppress symptoms etc.) ☐
5. Ask for patient's questions and concerns ☐
6. Give the name of medicine and describe appearance ☐

Show the patient the identifier code on solid dosage forms and show the label, if possible open package and show the tablets. (Refer to patient counseling SOP information)
7. Name the route of administration ☐
8. Give directions/instructions ☐

Explain to the patient or his/her representative the directions they should follow (number of pills, amount of fluid, when to take, not to share/miss dose, not take more or less, missed doses to be taken soonest or skip and go to regular dosing schedule, no double dosing. Continues taking even when feeling better, otherwise medicines may not work and are limited. Do not stop taking drugs without doctor's knowledge).
9. Give information on the possible drug interactions (herbs, other medicines) ☐
10. Give information on the side effects of the medicines ☐
11. Give instructions on how the medication should be stored ☐
12. Check the understanding of the patient or his/her representative by asking them to repeat back to you key information. Remind them of information they left out ☐
13. Final check for questions and concerns ☐


ADVERSE DRUG REACTION ALERT CARD (Front)

	MINISTRY OF HEALTH PHARMACY AND POISONS BOARD LENANA ROAD, NAIROBI P.O. BOX 27663 - 00506 TEL: (020) 2716905/6 Ext 114 Fax: (020)-2713431 / 2713409	PV 4
	<u>ADVERSE DRUG REACTION ALERT CARD</u>	
PATIENT NAME:		
AGE: GENDER:		
DATE ISSUED: ADDRESS:		
SUSPECTED DRUG(S):		
DESCRIPTION OF REACTION:		
Other comments (if any):		
.....		
<i>Tafadhali hakikisha umebeba kadi hii kila wakati. Kumbuka kumwonyesha m hudumu wa afya kadi hii unapo pata matibabu</i>		<i>Please carry this card with you at all times and remember to produce it to your health care professional at each time of consultation.</i>

ADVERSE DRUG REACTION ALERT CARD (Back)

<u>CRITERIA FOR ISSUE OF A PATIENT ALERT CARD</u>
<p>The criteria for issue of the Patient Alert Card is as follows:</p> <p><i>The alert card is given to:</i></p> <ul style="list-style-type: none">◆ Patients who are hypersensitive / allergic / intolerant to a particular drug◆ Patients who develop a 'near-fatal' reaction to any particular drug◆ Patients who had a drug- induced morbidity to any drug◆ Patients who had hospital admission due to an ADR to any drug◆ Patients who developed an ADR which caused increase in the health care expenditure

FORM FOR REPORTING SUSPECTED ADVERSE DRUG REACTION (Yellow Form)



MINISTRY OF HEALTH
THE PHARMACY AND POISONS BOARD
 P. O. Box 27663-00506 NAIROBI
 Tel: (020)-2736905 / 4 Ext 154 Fax: (020) 2713431/2713409
 Email: pv@pharmacyboardkenya.org

IN CONFIDENCE

☐ Initial Report
☐ Follow-up Report

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

NAME OF INSTITUTION: _____ INSTITUTION CODE: _____

ADDRESS: _____ CONTACT: _____

PATIENT'S NAME/INITIALS: _____ ID/OP. NO.: _____ D.O.B: _____

PATIENT'S ADDRESS: _____ WARD/CLINIC: _____ GENDER: ☐ Male ☐ Female

ANY KNOWN ALLERGY: ☐ No ☐ Yes (specify) _____ PREGNANCY STATUS: ☐ Not Pregnant ☐ 1st Trimester ☐ 2nd Trimester ☐ 3rd Trimester

WEIGHT (kg): _____ HEIGHT (cm): _____

DIAGNOSIS: (What was the patient treated for): _____

BRIEF DESCRIPTION OF REACTION: _____

LAST OF ALL DRUGS USED IN THE LAST 3 MONTHS PRIOR TO REACTION <small>(include OTC and herbal) (see rear side of this form for additional drugs)</small>	DOSE	ROUTE AND FREQUENCY	DATE STARTED	DATE STOPPED	INDICATION	TICK (X) SUSPECTED DRUG(S)
1						
2						
3						
4						
5						

SEVERITY OF THE REACTION:
(Rate to scale provided)

☐ Mild
☐ Moderate
☐ Severe
☐ Fatal
☐ Unknown

ACTION TAKEN:

☐ Drug withdrawn
☐ Dose increased
☐ Dose reduced
☐ Dose not changed
☐ Unknown

OUTCOME:

☐ Recovering / resolving
☐ Recovered / resolved
☐ Requires or prolongs hospitalization
☐ Causes a congenital anomaly
☐ Requires intervention to prevent permanent damage
☐ Unknown

CAUSALITY OF REACTION:
(Rate to scale provided)


☐ Certain
☐ Probable / Likely
☐ Possible / Unlikely
☐ Conditional / Unclassified
☐ Unassessable / Unclassifiable

ANY OTHER COMMENT: _____

NAME OF PERSON REPORTING: _____ DATE: _____

E-MAIL ADDRESS: _____ PHONE NO. _____

DESIGNATION: _____ SIGNATURE: _____



You need not be certain ... just be suspicious !

Your support in this Pharmacovigilance program is appreciated.

Submission of a complaint does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the event. Patient's identity is held in strict confidence and programme staff is not expected to and will not disclose reporter's identity in response to any public request. Information supplied by you will contribute to the improvement of drug safety and therapy in Kenya. Once completed please send to: The Pharmacy and Poisons Board on the above address.

EXPLANATORY NOTES

CONFIDENTIALITY

All information collected in this form, identifies the reporter and patient, will remain confidential.

WHAT TO REPORT

An Adverse Drug Reaction (ADR) is defined as a reaction that is noxious and unintended, and occurs at doses normally used in man for prophylaxis, diagnosis or treatment of a disease, or for modification of physiological function.

Report all suspected adverse experiences with medications, especially those where the patient outcome is:

- Death
- Life-threatening (real risk of dying)
- Hospitalization (initial or prolonged)
- Disability (significant, persistent or permanent)
- Congenital anomaly
- Required intervention to prevent permanent impairment or damage

Report even if:

- You are not certain if the drug caused the reaction
- You do not have all the details

WHO CAN REPORT

All healthcare professionals (clinicians, dentists, nurses, pharmacists, physiotherapists, community health workers etc) are encouraged to report. Patients (or their next of kin) may also report.

Please use the space provided below for any further information. You may attach more pages to this form if required.

LIST OF ALL DRUGS USED IN THE LAST 3 MONTHS PRIOR TO REACTION (include OTC and herbal)	DOSE	ROUTE AND FREQUENCY	DATE STARTED	DATE STOPPED	INDICATION	YOUR CLINICAL SUSPECTED CAUSALITY
1						
2						
3						
4						
5						

Criteria for Assessment of Severity of an ADR

MM	<ul style="list-style-type: none"> The ADR requires no change in treatment with the suspected drug The ADR requires that the suspected drug be withheld, discontinued or otherwise changed. No antidote or other treatment is required No increase in length of stay
Moderate	<ul style="list-style-type: none"> The ADR requires that the suspected drug be withheld, discontinued or otherwise changed, and/or an antidote or other treatment is required Increase length of stay by at least one day The ADR is the reason for admission
Severe	<ul style="list-style-type: none"> The ADR requires intensive medical care The ADR causes permanent harm to the patient
Fatal	<ul style="list-style-type: none"> The ADR either directly or indirectly leads to the death of the patient

WHO-UMC Causality Assessment Scale

Causality Term	Assessment
Certain	<ul style="list-style-type: none"> Event or laboratory test abnormality, with plausible time relationship to drug intake Cannot be explained by disease or other drugs Response to withdrawal plausible (pharmacologically, pathologically) Event definitive pharmacologically or pathologically (i.e. as objective and specific medical disorder or a recognized pharmacological phenomenon) Rechallenge satisfactory, if necessary
Probable / Likely	<ul style="list-style-type: none"> Event or laboratory test abnormality, with reasonable time relationship to drug intake Could also be explained by disease or other drugs Response to withdrawal clinically reasonable Rechallenge not required
Possible	<ul style="list-style-type: none"> Event or laboratory test abnormality, with reasonable time relationship to drug intake Could also be explained by disease or other drugs Information on drugs withdrawal lacking or unclear
Unlikely	<ul style="list-style-type: none"> Event or laboratory test abnormality, with a time to drug intake that makes a relationship improbable (but not impossible) Disease or other drugs provide plausible explanation
Conditional / Unclassified	<ul style="list-style-type: none"> Event or laboratory test abnormality More data for proper assessment needed or Additional data under examination
Unassessable / unclassifiable	<ul style="list-style-type: none"> Report suggesting an adverse reaction Cannot be judged because of (insufficient) or contradictory information Data cannot be supplemented or verified

Your support to this Pharmacovigilance programme is appreciated.

Submission of a report does not constitute an admission that medical professional or manufacturer is the product caused or contributed to the event. Patient's identity is held in strict confidence and programme staff is not expected to and will not discuss reporter's identity in response to any public request. Information supplied by you will contribute to the improvement of drug safety and therapy in Kenya. Once completed, please send to: The Pharmacy and Poisons Board on the above address

WHAT HAPPENS TO THE SUBMITTED INFORMATION

All information submitted is handled in strict confidence. The Pharmacy and Poisons Board will assess causality and statistical analysis on each form. Data will periodically be used for review and suggest any interventions that may be required to the Ministry of Health. Data will also be submitted periodically to the Uganda Monitoring Centre - the WHO Collaborating Center for International Drug Monitoring in Sweden.

SUBMISSION OF INITIAL OR FOLLOW-UP REPORTS

It is important to tick the appropriate box on the top-right corner of the front page to indicate whether the report is an initial (original) report or is a follow-up (subsequent) report.

It is very important that follow-up reports are identified and linked to the original report.

WHERE TO REPORT

After completing this form, please forward the same to your Pharmacy Department for onward submission, or mail directly, to:

THE PHARMACY AND POISONS BOARD


Lenana Road,

P. O. Box 27663-00906 NAIROBI

Tel: (020)-2714908 / 4 Ext 114 Fax: (020)-2713431/2713409

E-mail: pv@pharmacyboardkenya.org

FORM FOR REPORTING POOR QUALITY MEDICINAL PRODUCTS (Pink Form)

 <div style="text-align: right;">PV 4</div>					
MINISTRY OF HEALTH PHARMACY AND POISONS BOARD DEPARTMENT OF PHARMACOVIGILANCE					
FORM FOR REPORTING POOR QUALITY MEDICINAL PRODUCTS					
Name of Facility		District Name		Province Name	
Facility Address		Facility Telephone			
PRODUCT IDENTITY					
Brand Name		Generic Name			
Batch/Lot Number	Date of Manufacture	Date of Expiry	Date of Receipt		
Name of Manufacturer		Country of Origin			
Name of Distributor/Supplier		Distributor/Supplier's Address			
PRODUCT FORMULATION (Tick appropriate box)			COMPLAINT (Tick appropriate box/boxes)		
<input type="checkbox"/> Oral tablets / capsules <input type="checkbox"/> Oral suspension / syrup <input type="checkbox"/> Injection <input type="checkbox"/> Diluent <input type="checkbox"/> Powder for reconstitution of suspension <input type="checkbox"/> Powder for reconstitution of injection <input type="checkbox"/> Eye drops <input type="checkbox"/> Ear drops <input type="checkbox"/> Nebuliser solution <input type="checkbox"/> Cream / Ointment / Liniment / Paste <input type="checkbox"/> Other			<input type="checkbox"/> Colour change <input type="checkbox"/> Separating <input type="checkbox"/> Powdering / crumbling <input type="checkbox"/> Caking <input type="checkbox"/> Moulding <input type="checkbox"/> Change of odour <input type="checkbox"/> Mislabeling <input type="checkbox"/> Incomplete pack <input type="checkbox"/> Other		
Describe complaint in detail:					
.....					
.....					
Storage Conditions					
Does the product require refrigeration?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Other details (if necessary):		
Was product available at facility?	<input type="checkbox"/> Yes	<input type="checkbox"/> No			
Was product dispensed and returned by client?	<input type="checkbox"/> Yes	<input type="checkbox"/> No			
Was product stored according to manufacturer/ MoH recommendations?	<input type="checkbox"/> Yes	<input type="checkbox"/> No			
Comments (if any)					
.....					
.....					
Name of Reporter			Contact number		
Cadre / Job Title			Signature		
Once completed one copy of this form should be e-mailed or posted to:					
Pharmacy and Poisons Board	Department of Pharmacovigilance	P. O. Box 27663-00506 NRB	Fax: 2713431	E-mail: pr@pharmacyboardkenya.org	
<small> Your support in this Pharmacovigilance program is appreciated. Submission of a complaint does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to an event. All information is held in strict confidence and progression staff is not expected to and will not disclose reporter's identity in response to any public request. Information supplied by you will contribute to the improvement of drug safety and therapy in Kenya. Once completed please send to: The Pharmacy and Poisons Board on the above address </small>					

REPORT OF THE BOARD OF SURVEY ON STORES (UNSERVICEABLE AND SURPLUS TO REQUIREMENTS)

Ministry of

.....Department

Station.....

N.B.-Column Nos. 1-6 to be completed by the Department prior to the assembly of the Board.

1 Item No.	2 Article	3 Quantity	4 Date of Purchase	5 Original Value	6 State whether Unserviceable or Surplus	7 Board's Report on Condition	8 Recommendation of Board for Disposal	9 Estimated Local Saleable Value if Sale Is Recommended	10 Remarks
.....Signature and Official Designation of Officer-in-Charge of Stores Date.....Station		ChairmanMemberMember Date.....Station			DECISION OF: -			
						ACCOUNTING OFFICER Accounting Officer Date.....		TREASURY For Minister for Finance Date.....	

STEPS FOR COMPLETING REPORT OF THE BOARD OF SURVEY ON STORES (UNSERVICEABLE AND SURPLUS TO REQUIREMENTS) (F.O.58)

- 1) Record:
 - Ministry of: Health; Department: Medical; Station: Facility name
 - Complete the table:
 - Column 1: Item No.
 - Column 2: Article- generic name; strength/concentration; dosage form
 - Column 3: Quantity- write in quantity (bottles, tablets, caps, mls etc) to be destroyed
 - Column 4: Date of Purchase-write date the product was received at the facility
 - Column 5: Original value: insert value if known
 - Column 6: State whether Unserviceable or Surplus- Indicate Unserviceable and the reason for disposal e.g. damaged, expired, unusable etc
- 2) Signature and Official Designation of Officer-in-Charge of Stores: Sign; state position, station and date the form.
- 3) Disposal Committee completes columns 7-10
 - Column 7: Condition – Indicate damaged, expired or unusable
 - Column 8: Recommendation of Board for Disposal : Describe methods for disposal e.g. incineration, burying etc
 - Column 9: Estimated Local Saleable Value if Sale is Recommended- Not applicable for medicines
 - Column 10: Remarks: Indicate any other useful information e.g. source of medicines, expiry date, batch number etc
- 4) Disposal Committee Chairman and Members: write their names, signatures, date and station.
- 5) Accounting Officer and Treasury officer write their names and signatures to reflect approval for disposal.

