PV 6
(rev.2.0)

IN CONFIDENCE

MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD
DEPARTMENT OF PHARMACOVIGILANCE
P.O. Box 27663-00506 NAIROBI
Tel: (020)-3562107 Ext 114, 0720 608811, 0733 884411 Fax: (020) 2713431/2713409
Email: pv@pharmacyboardkenya.org

FORM FOR REPORTING POOR QUALITY MEDICINAL PRODUCTS

Name of Facility	District Name:	County:
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)

- ☐ Oral tablets / capsules
- ☐ Oral suspension / syrup
- ☐ Injection
- ☐ Diluent
- ☐ Powder for reconstitution of suspension
- ☐ Powder for reconstitution of injection
- ☐ Eye drops
- ☐ Ear drops
- ☐ Nebuliser solution
- ☐ Cream / Ointment / Liniment / Paste
- ☐ Other ……

COMPLAINT
(Tick appropriate box/boxes)

- ☐ Colour change
- ☐ Separating
- ☐ Powdering / crumbling
- ☐ Caking
- ☐ Moulding
- ☐ Change of odour
- ☐ Mislabeling
- ☐ Incomplete pack
- ☐ Other .....

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Describe complaint in detail: ……

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(Attach sample for physical evaluation)

Storage Conditions

Does the product require refrigeration?	☐ Yes	☐ No	*Other details (if necessary):*
Was product available at facility?	☐ Yes	☐ No	
Was product dispensed and returned by client?	☐ Yes	☐ No	
Was product stored according to manufacturer / MoH recommendations?	☐ Yes	☐ No	

Comments (if any)

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Name of Reporter	Contact number	E-mail:
Cadre / Job Title	Signature	Date:

Once completed one copy of this form should be emailed or posted to:

Division of Medicine Information and Pharmacovigilance	P.O. Box 27663-00506 Nairobi	Fax: 2713431	E-mail: *pv@pharmacyboardkenya.org*

Your support towards the National Pharmacovigilance system is appreciated

Submission of a report 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

NB: THE BOARD WILL CONTACT YOU IN CASE MORE SAMPLES FOR ANALYSIS ARE REQUIRED. IN SUCH A SITUATION THIS IS AN INDICATIVE GUIDE ON NUMBER OF SUSPECTED POOR QUALITY SAMPLES TO BE SUBMITTED FOR ANALYSIS.

FORMULATION	PACK SIZE	MINIMUM NO. OF SAMPLES REQUIRED
Tablets/ capsules	All	100 Tablets/Capsules
Suspension/Syrups	≤ 50mL	20 Bottles
	10 □100mL	
	> 10mL	
	≥100mL	
Injectables	≤10mL	100 Vials/Ampoules
	10 □100mL	50Vials/Ampoules/Bottles
	≥100mL	10 Bottles
Creams/Ointments	≤ 5g	50 Tubes
	5 □50g	20Tubes/Jar
	≥ 50g	5Tubes/Jars
Eye/Ear Drops	< 10mL	100 Bottles
	≥	50 Bottles
Inhalers	All	10 Packs
Raw material	All	5g

Republic of Kenya

Ministry Of Medical Services and Ministry Of Public Health and Sanitation

Pharmacy and Poisons Board

SOP TITLE: REPORTING POOR QUALITY MEDICINAL PRODUCTS	
Date Approved: October 2011 **Valid up to:** September 2013	**Approved by** Name: Signature Date:

1. Objective

To describe the procedure for reporting poor quality medicinal products

2. Responsible persons

- Qualified health personnel
- Overall facility, pharmacist or staff member in charge

3. Tools Needed

3.1 Guidelines for National Pharmacovigilance System in Kenya February 2009
3.2 Form for Reporting Poor Quality Medicinal Product
3.3 Pharmacovigilance job aids
3.4 Bin cards
3.5 Temperature logs
3.6 Other reference materials e.g. British National Formulary (BNF), Martindale: The Complete Drug Reference, British Pharmacopoeia, Micromedex, www.medicinescomplete.com etc.
3.7 S11 Counter Issue and Receipt Voucher or any other appropriate ordering/issuing records

4. Definitions

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

5. Procedure:

The health personnel shall:

5.1 Quarantine the suspected poor quality medicinal product and notify the qualified health personnel immediately.

The Pharmacist/Designee shall:

5.2 Assess the product quality and withdraw all unused quantities of the suspected poor quality medicinal product from the dispensing points at the facility. Appropriate records e.g. S11 should be completed when withdrawing unused quantities.

5.3 Quarantine the withdrawn quantities in a designated area until a written order from the Chief Pharmacist is received authorizing use or disposal.

5.4 Assess whether the quality problem could be as a result of poor storage practices at the facility.

5.5 Fill in the following details in the Poor Quality Medicinal Product Form;

5.4.1 Institution details (Name, Location, County, Facility address and contact information).

5.4.2 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.)

5.4. 3 The product formulation and check/tick the relevant box under the product formulation. If 'other', the pharmacist/designee shall specify the details.

5.6 Document the product complaint by checking the appropriate space/box provided. If 'other', the pharmacist/designee shall specify the details.

5.7 Provide a detailed summary of the complaint stating the extent and health implications, where necessary state steps taken within the facility. Add a separate typed and signed report with the form.

5.8 Fill in the storage conditions of the product as stated by the product monograph. Check the boxes as appropriate.

5.9 Attach copies of temperature logs indicating the facility storage conditions under which the product had been stored.

5.10 Add any additional comments to the section on any other comments; if none, the pharmacist/designee shall write 'NONE'. (A typed report shall be acceptable and should be signed, dated and submitted with the Poor Quality Medicinal Product Report

5.11 Fill his/her details i.e. Name, E-mail, Telephone number, Designation, Signature as the person reporting the poor quality medicinal product and Date of reporting

5.12 Write any other useful additional information at the back of the form or on a separate sheet of paper that should be attached to the form.

Note: Where possible, samples of the poor quality medicinal products should be submitted with the report. Please refer to the rear side of the pink form or the table below for details on the required quantities of samples.

FORMULATION	PACK SIZE	MINIMUM NO. OF SAMPLES REQUIRED
Tablets/ capsules	All	100 Tablets/Capsules
Suspension/Syrups	≤ 50mL	20 Bottles
	10 – 100mL	
	> 10mL	
	≥100mL	
Injectables	≤10mL	100 Vials/Ampoules
	10 – 100mL	50Vials/Ampoules/Bottles
	≥100mL	10 Bottles
Creams/Ointments	≤ 5g	50 Tubes
	5 – 50g	20Tubes/Jar
	≥ 50g	5Tubes/Jars
Eye/Ear Drops	< 10mL	100 Bottles
	≥	50 Bottles
Inhalers	All	10 Packs
Raw material	All	5g

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 Pharmacy and Poisons Board (PPB)

6.1.2 The 2nd copy shall be maintained by the pharmacy in-charge or the MTC secretary

6.1.3 A 3rd copy shall be sent to the provincial pharmacist through the DMOH

6.1.4 Where medicines were supplied by KEMSA, a 4th copy shall be forwarded to the Regional Liaison Officer

6.2 All Poor Quality Medicinal Products reports shall be kept in a confidential file

6.3 PPB & KEMSA shall acknowledge receipt, provide and adequately document feedback to the facility/ pharmacy-in-charge or MTC secretary on action taken

7. Ordering for Reporting Tools

When stock of reporting tools are low, inform PPB in writing immediately for purposes of re-stocking.