(FOM001/MIP/PMS/SOP/001)

IN CONFIDENCE

MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD
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 SUSPECTED POOR-QUALITY MEDICAL PRODUCTS AND HEALTH TECHNOLOGIES

Product category (Tick appropriate box):

☐Medicinal product ☐Blood and blood products. ☐Other.....
☐Herbal product ☐Medical device/ Invitro Diagnostics
☐Vaccine ☐Cosmeceuticals

Name of Facility: County: Sub- County:
Facility Address. Facility Telephone:

PRODUCT IDENTITY

Bran Name				Generic Name			
Batch/Lot Number/ Unique identifiers (blood & blood products)		Date of Manufacture		Date of Expiry		Date of Receipt	
Name of Manufacturer		Address		Country of Origin			
Name of Distributor/ Supplier		Distributor/ Supplier's Address			Telephone		

PRODUCT FORMULATION
(Tick appropriate box)

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

COMPLAINT
(Tick appropriate box/boxes)

☐Color change ☐Moulding
☐Separating ☐Change of Oduor
☐Powdering / crumbling ☐Mislabeling
☐Caking ☐Incomplete pack
☐Therapeutic ineffectiveness
☐Other.....

FOR MEDICAL DEVICE AND INVITRO DIAGNOSTIC

☐Packaging	☐Mechanism	☐Data	☐Failure to Calibrate
☐Labelling	☐Electrical	☐Software	☐Results
☐Sampling	☐Data	☐Environmental	☐Readings

Describe complaint in detail.....
.....
Was the cold chain maintained for both transportation and storage?.....
.....(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	

Reporter Details

Name of Initial Reporter:	Cadre/Designation:	Mobile no: Email :
Name of Person Submitting to PPB if different from reporter:	Cadre/Designation:	Mobile no: Email :

FOR OFFICIAL (PPB) USE ONLY

Report No: ...../...../..... Date Received ...../...../.....

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 program staff is not 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 INCASE MORE SAMPLES ARE REQUIRED FOR ANALYSIS. IN SUCH SITUATIONS THISIS AN INDICATIVE GUIDE ON THE NUMBER OF SUSPECTED POOR QILAOTY SAMPLES TOBE SUBMITTED

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
	≥ 10mL	50 Bottles
Inhalers	All	10 Packs
Raw material	All	5g
Medical Devices /Invitro Diagnostics	ALL	As shall be advised

EXPLANATION FOR PRODUCT PROBLEMS FOR MEDICAL DEVICES AND DIAGNOSTICS	
• Packaging – damaged, defective, suspect tampered • Labelling– insufficient instructions for use, illegible • Sampling – device doesn't collect/transfer specimen • Liquid – leak, splash • Mechanical – misalignment, jam • Electrical - unable to charge, power loss or fluctuation • Data – capture, display, or storage affecting product functionality	• Software – network, program, algorithm, or security affecting product functionality • Environmental – noise, temperature, humidity/ moisture, fungal/bacterial growth, or dust affecting product functionality • Failure to calibrate • Results- Increased rate of invalid or unreturnable test results • Reading-Obviously incorrect, inadequate or imprecise result or readings, Unable to obtain reading