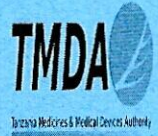




THE UNITED REPUBLIC OF TANZANIA



MINISTRY OF HEALTH, COMMUNITY DEVELOPMENT,  
GENDER, ELDERLY AND CHILDREN

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

FORM FOR REPORTING POOR QUALITY PRODUCTS

Note: Identities of reporter(s) will remain confidential

PRODUCT IDENTITY	
Brand Name: .....	Name and Address of Distributor/supplier ..... .....
Generic Name: .....	
Batch/Lot Number: .....	
Date of Manufacture: .....	
Expiry date: .....	
Country of Origin: .....	

PRODUCT INFORMATION (Tick appropriate box)	COMPLAINT (Tick appropriate box(es))
<input type="checkbox"/> Tablets / Capsules	<input type="checkbox"/> Colour change
<input type="checkbox"/> Oral suspension/ Syrups	<input type="checkbox"/> Turbid solution
<input type="checkbox"/> Injection	<input type="checkbox"/> Change of odour
<input type="checkbox"/> Cream/ Ointment /liniment / Paste	<input type="checkbox"/> Caking
<input type="checkbox"/> Powder for reconstitution of suspension	<input type="checkbox"/> Moulding
<input type="checkbox"/> Powder for reconstitution of injection	<input type="checkbox"/> Separating
<input type="checkbox"/> Eye drops	<input type="checkbox"/> Powdering / Crumbling
<input type="checkbox"/> Ear drops	<input type="checkbox"/> Incomplete Pack
<input type="checkbox"/> Nebulizer solution	<input type="checkbox"/> Mislabeling
<input type="checkbox"/> Diluent	<input type="checkbox"/> Other, please specify
<input type="checkbox"/> Other, please specify:	
Describe the complaint in detail:	

STORAGE CONDITIONS			
Does the product require refrigeration?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Other details (if necessary)
Was the product available at the facility?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Was the product dispensed and returned the client?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Was the product stored according to manufacture's recommendations?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Comments (if any)			

REPORTER NAME AND CONTACT ADDRESS	
Name of Reporter:	Contact Address:
Contact Phone No: .....	
E-mail: (if available) .....	
Date of this report: .....	
<i>Thank you for your cooperation</i>	<i>Ref No. (for official use)</i>



←---→ **First Fold** ←---→  
**Guide to filling the form**

**How to report?**

- Dully fill in the form as required
- Use a separate form for each patient
- Report direct to AUTHORITY through the following addresses:-



Mail :  
Tanzania Medicines and Medical Devices Authority,  
P. O. Box 77150, Dar es Salaam  
Fax: 22- 2450793  
Phone: 22-2450512 / 2450751/ 0658 445222



Internet; <http://www.tmda.go.tz>  
E-mail: [adr@tmda.go.tz](mailto:adr@tmda.go.tz)



The ADR reporting form and the guidelines are also available for downloading at <http://www.tmda.go.tz>

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

**What to report?**

Please report all undesirable patient effect suspected to be associated with drugs.

**Report even if:**

- You're not sure that the product caused the event
- You don't have all the details

**When to report?** As soon as possible

**Submission of follow-up reports:**

Any follow-up information for an ADR that has already been reported can be sent on another ADR form or it can be communicated directly to AUTHORITY by telephone, fax or e-mail. Please indicate that it is a follow-up report. It is very important that follow-up reports are identified and linked to the original report.

If posted in Tanzania

POSTAGE WILL BE PAID BY LICENCEE

**BUSINESS REPLY SERVICE**  
LICENCE No. BRS 01

**TO: THE DIRECTOR GENERAL**  
**TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY**  
**P. O. BOX 77150**  
**DAR ES SALAAM**

