THE UNITED REPUBLIC OF TANZANIA

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

TMDA
Tanzania Medicines & Medical Devices Authority

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

FORM FOR REPORTING POOR QUALITY PRODUCTS

Note: Identities of reporter(s) will remain confidential

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

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

STORAGE CONDITIONS			
Does the product require refrigeration?	❑ Yes	❑ No	Other details (if necessary)
Was the product available at the facility?	❑ Yes	❑ No	
Was the product dispensed and returned the client?	❑ Yes	❑ No	
Was the product stored according to manufacture's recommendations?	❑ Yes	❑ No	
Comments (if any)			

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

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

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