Establishing The Electronic Adverse Reaction Reporting Tool: The Tanzanian Perspective

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About TMDA

• The TMDA is mandated to ensure quality, safety and effectiveness of medicines, medical devices and diagnostics.
The paper-based AR reporting system has been in practice in Tanzania since 1987.

The adverse drugs event reporting is a voluntary action.

It takes a lot of effort to complete the traditional long paper-based form.

This affects the quality and quantity of reports submitted.

TMDA in partnership with College of Informatics and Virtual Education (CIVE) of the University of Dodoma (UDOM) developed an Adverse Reactions Electronic Reporting System.
A decade of regulatory harmonization

Before the use of electronic systems, adverse reactions were reported using the paper-based form through the mailbox, fax, email, and telephones.

1. Mail:  
Tanzania Food and Drugs Authority (TFDA)  
P. O. Box 77130, Dar es Salaam

2. Fax: 22-2450793

3. Phone: 22-2450512 / 2450751

4. Email: Via info@tfda.go.tz
Electronic Reporting Tool

- The e-tool which was designed to facilitate reporting of ARs to TMDA was launched in October, 2016.
- A total of 621 reports were submitted into the ARR system between October 2016 – June 2019.
- The system provides accessible to internet.
Electronic Reporting Tool

- The Adverse Reactions Reporting Tools provides vast options in reporting (web-based, mobile App and USSD) under one data repository (TMDA) comparing with the old tool using paper-based.

- The ARRT has remarkably shortened time for data entry into the **Vigiflow** (WHO system for reporting adverse reaction) as it allows exporting of electronic file in excel format.
Adverse Reaction Reporting Tool

1: Web-Based Reporting Tool
Accessed through
https://www.tfda.go.tz or
https://imis.tfda.go.tz/arrt/maskani

2: Mobile App Reporting Tool

3: USSD Reporting Tool
Reporting Using Web-based System

- The web-based system is accessible through TFDA website www.tfda.go.tz under E-Services menu, or

- Direct through https://imis.tfda.go.tz/arrt/maskani
Reporting AR Using Web-based System

Example: Reporting Medicines Adverse Reaction

- Reporting Forms
  - Green Forms – Used by patients or consumers
  - Yellow Forms – Used by Health Care Providers
  - Blue Forms – Used for reporting product quality issues
1: Interface for reporting medicines reaction

2: Reporting Flow

- Enter Patient Details
- Enter Adverse Reaction Details
- Enter Magnitude of Reaction / Effects Resulted
- Enter Medicine details
- Enter Herbal medicines details used by patient
- Enter Picture of affected area
- Enter Reporter Details
- Send Report