

# TANZANIA FOOD AND DRUGS AUTHORITY



## PUBLIC NOTICE

### COHORT EVENT MONITORING (CEM) OF ARTEMETEHR + LUMEFANTRINE (ALu)

#### **Introduction**

Tanzania Food and Drugs Authority (TFDA) is a regulatory body under the Ministry of Health and Social Welfare which is responsible for protecting and promoting public health by ensuring quality and safety of food, drugs, cosmetics and medical devices.

One of the core functions of TFDA is to monitor drug events and the science and activities relating to the detection, assessment, understanding and prevention of drug events or any other drug related problem is known as pharmacovigilance. Pharmacovigilance aims at getting the best outcome of treatment with drugs. It identifies the risks and risk factors associated with drugs in the shortest possible time after marketing.

When communicated effectively, information on events gathered allows for evidence based prescribing with potential for preventing many adverse reactions and ultimately helps each patient to receive optimum therapy at a lower cost to the health system.

#### **What is Cohort Event Monitoring (CEM)?**

Cohort Event Monitoring (CEM) is a prospective, observational study of drug events that occur during the use of medicines in the early post-marketing phase. It ensures that patients are monitored from the time they begin treatment. It also involves patients in watching, feeling and monitoring their treatments.

#### **Objectives of CEM**

- Provide incidence rates for adverse drug events as a measure of risk

- Characterize known adverse reactions
- Detect signals of unrecognized reactions
- Detect interactions with other medicines, complementary and alternative medicines, foods and concomitant diseases
- Identify risk factors and thus provide evidence for effective risk management
- Assess safety in pregnancy and lactation
- Provide a measure of comparative risks between medicines
- Detect drug inefficacy, which might be due to: faulty administration, poor storage conditions, poor quality product, counterfeiting and drug interactions
- Provide cohorts for further study of safety issues if required in the future

### **Cohort Event Monitoring (CEM) of Artemether/Lumefantrine (ALu)**

TFDA is in the process of conducting CEM of an anti-malarial drug namely Artemether/Lumefantrine (ALu). CEM will involve documentation of safety of ALu which is used as a first line treatment of uncomplicated acute falciparum malaria in Tanzania mainland. ALu is known to be effective, but further assessment of its safety under large-scale operational needs to be fully assessed.

### **Cohort Size**

A total cohort of 10500 patients will be followed up for development of events after using ALu.

### **CEM Sites**

CEM will be implemented at the sites (hospitals, health centres and/or dispensaries) in Dar-es-Salaam, Kilimanjaro, Arusha and Mwanza. Depending on the experience and after assessment of progress of the programme other sites will be added.

### **Why reporting events due to ALu?**

It is important that all events due to ALu whether related or not are reported in order to:-

- Detect problems related to the use of ALu and communicate the findings in a timely manner
- Contribute to the assessment of benefit, harm, effectiveness and risk of ALu, leading to the prevention of harm and maximization of benefit

- Improve public health, patient care and safety in relation to the use of ALu
- Encourage the safe, rational and more effective (including cost-effective) use of ALu
- Promote understanding, education and clinical practice in pharmacovigilance and its effective communication to the public

### **What to report?**

Any untoward medical occurrence in a patient who has administered ALu and which does not necessarily have a causal relationship with ALu. It can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with ALu, whether or not related to the medicine.

The information should be communicated by filling in special Questionnaires prepared by TFDA. The following should be included in the report:-

- Patient details,
- Patient medical history of significance,
- Details of medicines
- Reaction details
- Reporter details
- Date of report

### **Who should report?**

- Medical/Clinical officers
- Pharmacists
- Pharmacovigilance focal persons
- Nurses
- Patients

### **How to report?**

- Patients should report events to medical/clinical officers, pharmacists and nurses to the hospitals, health centers and dispensaries where they were treated.
- Medical/clinical officers and nurses should observe and ask for events from patients and report them to pharmacists and pharmacovigilance focal persons by filling in questionnaires

- Pharmacists and pharmacovigilance focal persons should send questionnaires to TFDA zone offices, pharmacovigilance centers at referral hospitals and/or TFDA headquarters, where applicable

### **When to report?**

The questionnaires should be filled in soon after the event has occurred.

### **Where to report?**

Patients should report events to

- Medical/Clinical officers
- Pharmacists
- Nurses

Medical/clinical officers, pharmacists and nurses should send completed questionnaires to:

- TFDA headquarters
- TFDA zone offices
- Zone pharmacovigilance centres
- Pharmacovigilance focal persons

For more information please visit or contact us through the following addresses:

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