**THE UNITED REPUBLIC OF TANZANIA**



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

**PRESS RELEASE**

**STATEMENT MADE BY HON. UMMY A. MWALIMU (MP.) MINISTER FOR HEALTH, COMMUNITY DEVELOPMENT, GENDER, ELDERLY AND CHILDREN WHEN ANNOUNCING TFDA AS MATURITY LEVEL 3 INSTITUTION AS CATEGORIZED BY THE WORLD HEALTH ORGANIZATION (WHO)**

**TFDA OFFICES - DAR ES SALAAM**

**18 December 2018**

* **WHO Representative in Tanzania;**
* **Permanent Secretary - Ministry of Health, Community Development, Gender, Elderly and Children;**
* **Ambassador, Dr. Ben Moses, MAB Chairman;**
* **Acting DG - TFDA;**
* **TFDA Management;**
* **TFDA staff present here;**
* **Media Representatives;**
* **Distinguished Guests;**
* **Ladies and Gentlemen.**

Let me begin by welcoming you to TFDA and thnak you for attending this press conference. Let me also thank the Ministerial Advisory Board (MAB) through the Chairman and the entire Management team of TFDA fro inviting me at this press conference which aims at informing the public on the landmark achievement of TFDA to attain Maturity Level 3 status as classified by WHO.

**Ladies and Gentlemen**

Any government strives to ensure that its citizens remain healthy to increase productivity, sustainable human development and economic growth. Medicines plays a critical role in the healthcare system to ensure that those who are ill get cured and continue to be part of the community towards economic development.

Availability of medicines in the supply chain has been one of the pivotal agenda item with the current regime and my Ministry has been on the frontline to ensure that medicines are available at all times in our health facilities. This to a greater extent has been fulfilled unequivocally.

Nonetheless, despite the ostensible truth that medicines needs to be available, the matter of availability of good quality, safe and efficacious medicines in our market has equally been another critical policy under my Ministry.

**Ladies and Gentlemen**

Taking the quality, safety and efficacy perspectives into the cycle, the government, enacted the *Tanzania Food, Drugs and Cosmetics Act, Cap 219* back in 2003 that also established the Tanzania Food and Drugs Authority to oversee medicines regulation in this country. Since then the TFDA has been working tirelessly to set-up systems for effective regulation of medicines and henceforth protect public health. Such systems embrace the following:

* Medicines Evaluation and Registration System;
* Good Manufacturing Practices - GMP inspection;
* Import and Export Control System;
* Post - Marketing Surveillance System;
* Clinical Trials Control System;
* Pharmacovigilance System;
* Premises Registration and Licensing System;
* Medicines Inspection and Enforcement System;
* Recall and Disposal System;
* Medicines Advertisements Control System;
* Laboratory Access; and
* Quality Management System - QMS.

**Ladies and Gentlemen**

These systems are the ones which have been assessed by the World Health Organization (WHO) using its global benchmarking tool for assessment of regulatory authorities. The benchmarking exercise was done at different times over the course of many years back and after each round, the TFDA was advised on how to improve the systems.

After a series of consultations, and following the assessment which was done in November 2018, the TFDA has now been concluded to be operating at Maturity Level 3 category as per the WHO benchmarking ranking.

**Ladies and Gentlemen**

By attaining this status quo, the TFDA now becomes the first medicines regulatory authority in Africa to be ranked at this advanced level. This is a great achievement to TFDA, my Ministry and our country in general and I truly congratulate TFDA for reaching this level. You have made us proud and we are grateful for putting a landmark of our country in the international arena.

I have also been informed that, you are now amongst the 30% of the institutions which are Maturity Level 3 worldwide. This indeed deserves to be recognized and promulgated globally.

**Ladies and Gentlemen**

Despite this notable milestone, we need now to begin working towards Maturity Level 4 category to match authorities in the developed world such as the US - FDA, EU - EMA, Australian - TGA and the Canadian - Health Canada. I believe you can do this considering the experience that you have gained out of the Maturity Level 3 assessment.

**Ladies and Gentlemen**

Attaining this level needs now to be reflected into the real life situation to ensure that medicines that circulate in our market are of good quality, safe and efficacious. Still we need to support the TFDA in its efforts of regulating medical products in this country. Unscrupulous dealers needs to be identified and reported timely for swift regulatory actions to be taken against them.

My plea to the public is that please report all those who smuggle in substandard or falsified medical products through our borders so that we can take action to protect ourselves. You can report to any nearby TFDA offices, health facilities or police stations. We at the Ministry will go ahead supporting TFDA including issuing policy directives on matters related to medical products.

**Ladies and Gentlemen**

On the flip side, and in order to bring positive impact to the public after registering this milestone and responding to what President John Pombe Magufuli overly emphasized at the meeting which was held at Julius Nyerere International Convention Centre (JNICC) on 10th December, 2018, I'm directing TFDA to consider and work on the following matters which were also discussed and agreed during that meeting:

* TFDA should issue permits on a timely manner to ensure that businessmen conduct their businesses without any unnecessary delays which might also stagnate economic development.
* TFDA should establish a regular dialogue with TBS, TIC and GCLA and agree on matters that will bring industrial revolution and creating a conducive business environment for those who intend to invest on medicines, food, cosmetics, medical devices and diagnostics industry.
* TFDA should review its fees and charges regulations in order to reduce costs and bring competitive advantage to the business community;

**Ladies and Gentlemen**

Despite these directives, let me conclude by once again congratulating TFDA for the notable achievement and urge them not to be complacent and start working towards attaining Maturity Level 4 as alluded to previously. Since you are also ISO certified to 9001 standard and your laboratory is ISO/IEC 17025 accredited, I utterly believe that reaching Maturity Level 4 will be possible.

Conversely, as Tanzania is part of the East African Community (EAC) and the Southern Africa Development Community (SADC), I direct you to share your experience with our counterparts so that they can match your status quo in order to pull resources and have concerted efforts that will halt medicines which are of poor quality, substandard and falsified to cross our borders.

**Ladies and Gentlemen**

With these few remarks, I'm now ready to receive the Maturity Level 3 Certificate from WHO and handle it over to TFDA.

**Thank you for your attention**

**END**