TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

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FREQUENTLY ASKED QUESTIONS

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1 What is TMDA?

Tanzania Medicines and Medical Devices Authority (TMDA) is a semi-autonomous regulatory body under the Ministry of Health, Community Development, Gender, Elderly and Children (MoHCDGEC); which is responsible for protecting and promoting public health by ensuring safety, quality and effectiveness of medicines, medical devices and diagnostics. It was established under the Tanzania Medicines and Medical Devices Act, Cap 219.

2 What's the difference between TMDA and TFDA?

TMDA, formerly known as TFDA became operational on 1st July, 2003. However, the name TFDA was statutorily changed into TMDA on 1st July, 2019 after the amendment of the *Tanzania Food, Drugs and Cosmetics Act, Cap 219* by the Finance Act No. 8 of 2019. This resulted into parting in the regulation of medicinal products from that of food products. In view of this, TMDA is currently mandated to regulate three (3) types of products namely: medicines, medical devices and diagnostics whereas TFDA by then, was mandated to regulate five (5) types of products namely: food, medicines, cosmetics, medical devices and diagnostics**.**

3 When was TMDA established?

TMDA became operational with effect from 1st July, 2019 following the amendment of the *Tanzania Food, Drugs and Cosmetics Act, Cap 219*; whereby the regulation of two (2) types of products i.e. food and cosmetics were shifted from the then Tanzania Food and Drugs Authority (TFDA) to Tanzania Bureau of Standards (TBS).

4 What's the difference between TMDA and TBS?

TMDA is a regulatory body under the Ministry of Health, Community Development, Gender, Elderly and Children (MoHCDGEC) responsible for protecting and promoting public health by ensuring quality, safety and effectiveness of medicines, medical devices and diagnostics. It was established under the *Tanzania Medicines and Medical Devices Act, Cap 219.*

On the other hand, TBS is a parastatal organization under the Ministry of Industry and Trade and its broad mandate is to promote standardization and quality assurance in industry and commerce sectors.

5 Which types of products are TMDA regulating?

TMDA regulates human and veterinary medicines (which include herbal and biocidal products), medical devices and diagnostics.

6 Are traditional medicines regulated by TMDA?

No, TMDA does not regulate traditional medicines. Such medicines are regulated by Traditional and Alternative Heath Practice Council.

7 Are hand sanitizers regulated by TMDA?

Yes, hand sanitizers are considered as antiseptics which are categorized as medicinal products and therefore regulated by TMDA.

8 Are masks and other PPEs regulated by TMDA?

Yes, masks and other PPEs are classified as medical device products, thus their regulation is under TMDA.

9 What is the procedure of registering masks, PPEs and hand sanitizers?

To register masks, PPEs and hand sanitizers, you are required to fill an application form and submit the documents to TMDA along with the product samples.

10 Are there any side effects of using masks for a long time?

Masks are considered to be low risk products and hence categorized as *Class A* medical devices; there are no known side effects ever been reported and/or associated with the use of masks that could be injurious to health. Furthermore, manufacturers of masks provide instructions which specify the conditions and duration for the use of masks. If used appropriately and in line with manufacturer's instructions, masks have a great role in prevention of airborne diseases.

11 What are the risks of using PPEs to healthcare providers?

There are no risks to healthcare professionals when using appropriate PPEs and adhering to manufacturer's instructions. However, if the PPEs are not used correctly, they may not be able protect the healthcare workers.

12 How many pharmaceutical industries have been approved by TMDA?

As of April, 2020 a total of thirteen (13) domestic pharmaceutical industries that manufactures different dosage formulations have been approved by TMDA. Moreover, there are numerous foreign manufacturers which have been approved to supply pharmaceutical products in Tanzania.

13 How many industries for medical device and diagnostic industries have been approved by TMDA?

As of April, 2020 a total of eighty one (81) manufacturers have been approved by TMDA out of which, six (6) are domestic and seventy five (75) of them are foreign.

14 Are requirements for harmonization of medicines registration approved in EAC?

Yes, there are several guidelines which are approved under the EAC – MRH programme and have been adapted by individual NMRAs including Tanzania.

15 What are the benefits of harmonizing requirements in EAC and SADC regions?

Some of the benefits of the harmonization initiatives include the following:

- Efficient use of resources including experts in assessment of quality, safety and efficacy of medicines
- Provides a single point of submission of applications for product registration
- A single communication on the outcome of assessment is sent to the applicant, which could be deficiencies or approval

- Reducing burden of manufacturers to host inspectors from several countries at different times
- Cost reduction
- Improve availability of quality, safety and efficacious medicines among the public in the member states
- Beneficial to medicines manufacturers to access a larger market for their products

15 If an import permit has been issued, how long would it be valid?

The importation permits once issued are valid for a period of six (6) months and they can be used to clear imported products up to three (3) partial shipments.

16 What's the validity period for registration of medicines, medical devices and diagnostics?

All registered products have a validity of five (5) years from the registration issue date except for Antiseptics and Disinfectants which have a validity of three (3) years. The renewal applications of the products should be launched prior to their expiry.

17 Does TMDA register medical device accessories and spare parts?

Accessories and/or spare parts, supplied for the replacement of existing components of a registered medical device, are not considered to be medical devices unless they are likely to significantly change the characteristics or performance of the device. In the later case, the accessories and/or spare parts may be considered as medical devices in their own existence and therefore could require registration.

18 Does TMDA register rapid diagnostic tests (RDTs) for Corona virus detection?

TMDA welcomes the application for registration of RDTs for Corona virus, provided that they are intended for research and not for public use.

19 Which types of test kits does TMDA accept for Corona virus detection?

The devices for detection of Corona virus are polymerase chain reaction (PCR) machines that have been recommended by Ministry of Health, Community Development, Gender, Elderly and Children (MoHCDGEC).

20 How many ports of entry have been authorized to allow entry of products into the country?

There are 16 official ports of entry as per the existing regulations.

21 What's the percentage of substandard and falsified medicines in Tanzania?

Various studies have been conducted from time to time in line with other TMDA systematic enforcement measures including Post Marketing Surveillance (PMS) activities, whereby the market is considered to be generally safe.

For example, Mziray et al., (2017: 6:1) *Pharmaceutical Regulatory Affairs Journal,* a study conducted by TFDA (now TMDA) with the aim of monitoring the quality of registered anti-malarial medicines circulating on the market in Tanzania Mainland.

The results showed that a total of 1,444 samples of oral solid formulations from different types of anti-malarials

were sampled. Out of these, 132 (9.1%) failed labelling requirements of product information. A high percentage of samples passed the identification test by TLC (97.9%) and the disintegration test (99.8%). A small failure rate of 4.8% (7/145) was observed in confirmatory testing, from which only one of the samples (i.e. quinine sulphate 300 mg tablets) was confirmed to be falsified.

22 Does TMDA take part in promotion of pharmaceutical industry in Tanzania?

Yes, TMDA takes several measures in promoting the pharmaceutical industries as follows:

- Establishment of a special desk which can provide assistance to investors,
- Provision of technical support whenever required,
- Reduction in time for registration of medicines and premises,
- Conducting stakeholders meeting and distribution of information, education and communication (IEC) materials; participating in different exhibition and events to sensitize companies to invest in Tanzania,
- Provision of statistics and advice related to pharmaceutical products to investors, and
- Frequent training of technical staff from the manufacturing industries.

23 If a medicinal product is registered in Kenya or Uganda would it be accepted in Tanzania?

Only medicines that are recommended for registration directly by TMDA or under EAC harmonization initiatives are registered in Tanzania. However, medicinal products which are registered by other EAC NMRAs (including Kenya and Uganda) outside the EAC harmonization programs should be applied for registration in Tanzania.

24 Does TMDA charge any importation fees on donations?

Yes, a Free on Board (FOB) fee of 0.25% is charged on the value of consignment.

25 Which types of donations are accepted by TMDA?

Donation of products that meet standards of quality, safety and efficacy; and the requirements stipulated in the *Guidelines for Medicines and Medical Supplies Donations for Tanzania Mainland* issued by the Ministry of Health Community Development, Gender, Elderly and Children, are accepted by TMDA.

26 What are the procedures for recall of products set by TMDA?

Recall may be initiated by TMDA, manufacturer, registrant (or marketing authorization holder) after receiving complaints from customers or identification of products which are potentially life threatening through post marketing surveillance activities. Based on the relative health risk of defective products, the recall process is categorized in three classes. For example, *Class 1* recall is for products with highest risk and the recall should be completed within a period of 14 days.

27 Which methods of disposal are accepted by TMDA?

TMDA accepts disposal methods as proposed by the Authority and the National Environment Management Council.

28 Which types of inspection are conducted by TMDA?

There are various types of inspections which are done by TMDA, as follows:

- Routine inspection;
- Concise inspection;
- Follow-up inspection;
- Special inspection; and
- Any other types as the Authority may designate

29 Does TMDA have a Whistle blowing Policy?

Yes, TMDA do have a Whistleblowing Policy which facilitates the process of informing TMDA about any suspected serious misconduct or any breach or suspected breach of TMDA Act or Regulations that may adversely impact TMDA or be a threat to public interest or national security.