

TANZANIA FOOD AND DRUGS AUTHORITY



PUBLIC NOTICE

1ST PHASE OF REGISTRATION OF MEDICAL DEVICES IN TANZANIA

Tanzania Food and Drugs Authority (TFDA) is a regulatory body responsible for control of safety and performance of medical devices among other products regulated by the Authority.

The term medical device is defined in the Tanzania Food, Drugs and Cosmetics Act of 2003 as instrument, apparatus, implement, medical equipment, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part or accessory, which is ;

- (a) recognized in the Official National Formulary, or Pharmacopoeia or any supplement to them;
- (b) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, in man or other animals or;
- (c) intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its principal intended purposes through chemical action within the body of man or other animals and which is not dependent upon being metabolised for the achievement of any of its principle intended purposes;

TFDA is empowered by law to register medical devices after ascertaining their safety and performance as provided under Section 51 of the Tanzania Food, Drugs and Cosmetics Act of 2003.

Registration of medical devices will be carried out in phases starting with few categories and slowly expanding the scope so as to ensure smooth transition.

The Authority wishes to inform its esteemed stakeholders that 1st phase of registration of medical devices will commence on 1st January, 2010.

In the first phase, TFDA will undertake and focus on registration of the following devices:-

1. Syringes particularly autodisable
2. Surgical sutures
3. Examination and surgical gloves

4. Scalp vein set
5. Intravenous cannulae
6. Catheters and tubes
7. Contraceptives including condoms
8. Needles
9. Administration Sets (Blood giving and taking sets, blood lancets and I.V giving sets)
10. Blood collection bags
11. Surgical dressing
12. Internal prosthetics replacements
13. Orthopaedic implants
14. Bone cements
15. Drug eluting stents
16. Intraocular lenses

Phase one will be undertaken for a period of 24 months up to 31st December, 2011 after which any unregistered product including the ones in a list of notified products will not be allowed to circulate in the market. Applicants and importers of medical devices are requested to observe this transition period given prior to enforcement of the law in relation to unregistered devices.

Applicants are encouraged to familiarize with the guidelines on submission of documentation for registration of medical devices and follow them when preparing and submitting applications for registration of medical devices. Adherence to these guidelines will ensure that all relevant information is provided in the dossiers submitted for registration. This will facilitate efficient and effective evaluation as well as approval process. It will also help to avoid queries which results in unnecessary delays in giving approvals.

The guidelines on submission of documentation for registration of medical devices can be down loaded freely at TFDA website www.tfda.or.tz or a hardcopy can be purchased at TFDA Offices at nominal price of Tsh. 20,000.00

Your cooperation in this matter will be highly appreciated.

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