

# **TANZANIA FOOD AND DRUGS AUTHORITY**



## **PUBLIC NOTICE**

**To all Medical Devices Importers and Dealers**

### **CALL FOR SUBMISSION OF INFORMATION ON MEDICAL DEVICES FOR IMPORTATION INTO 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.

The Authority wishes to inform its esteemed stakeholders that registration of medical devices is envisaged to start from July 2009. The 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.

To facilitate registration process, TFDA has drafted application guidelines for registration of medical devices. The guidelines have been posted on TFDA website ([http://www.tfda.or.tz/medical\\_devices\\_middle.php](http://www.tfda.or.tz/medical_devices_middle.php)) for comments from all stakeholders. The guidelines will be discussed by in-country stakeholders at the meeting to be organized before the end of April 2009. When registration starts, a transition period will be given prior enforcement of the law in relation to unregistered devices.

**To facilitate importation of medical devices from now and during transition period, the Authority is calling for submission of information on all medical devices to be imported into the country. Apart from the above, such information will enable the Authority to know who is dealing with devices and will form a basis for regulatory control during transition period. Acceptance of such information should not be construed as an endorsement by TFDA in relation to safety and performance of the device.**

Information should be submitted in MS Excell format both in a CD-ROM and in hard copies. The form for submission of information can be downloaded from <http://www.tfda.or.tz/downloads>

This exercise is expected to last on 31st August 2009 upon which assessment of the need for further extension of time will be conducted.

All Importers of medical devices are required to seek adequate support from manufacturers of medical devices so that they can obtain the required information for submission. The importers are further kindly requested to observe the timeframe given in this notice.

Your cooperation in this matter will be highly appreciated.

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