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## TANZANIA FOOD AND DRUGS AUTHORITY



### PUBLIC NOTICE

#### REQUIREMENTS ON IMPORTATION OF SYRINGES INTO TANZANIA

##### 1. Introduction

In support of the Ministry of Health and Social Welfare policy on safe injections and healthcare waste management and in order to protect safety of patients and embrace new technology, TFDA issued a public notice in April 2010 for implementation of the decision of phasing out and limiting use of standard disposable syringes in favour of auto disable syringes (AD).

AD syringes are a type of re-use prevention syringes which disable automatically after use. Besides AD syringes, there are other re-use prevention types termed as types II which have to be disabled voluntarily after use.

For effective implementation of this decision, a guide to importers of medical devices regarding the importation of syringes into the country is hereby issued as follows.

##### 2. General requirements

All Applications for importation of syringes into the country shall be eligible for consideration and approval if the following general requirements are met:-

- 2.1 AD syringes are pre-qualified by World Health Organization and also registered by TFDA.
- 2.2 Application for importation permit shall consist either of AD syringe only or AD and standard disposable syringes and/or type II re-use prevention syringes in a ratio of 90%:10%. The 10% of standard disposable syringe and type II re-use prevention syringes is to cater for specific procedures like naso-gastric feeding; blood drawing and delicate aspirations. Application for importation permit consisting of standard disposable syringes and/or type II re-use prevention syringes of nominal capacity of 10ml and below will not be honoured.

- 2.3 Application for importation of standard disposable syringes and type II re-use prevention syringes of nominal capacity of more than 10ml will be honoured without any restriction till further notice.
- 2.4 All types of syringes sterilized by Ethylene Oxide (EO) gas must be packed either in blister pack or ribbon pouch. Syringes packed in polybags are completely not acceptable. It should be noted that polybags are considered not appropriate for (EO) sterilization and therefore sterility of syringes packed in polybags is not assured.
3. Specific requirements

The procedures for importation of syringes will remain the same as the general procedures for importation of medical devices to Tanzania. However, the following specific requirements in relation to syringes must be observed for better control of importation:-

- 3.1 Application for import permit for syringes must be lodged in separate proforma invoices.
- 3.2 The brand name and type of syringe in bracket should be indicated clearly in proforma invoice.
- 3.3 In the case where an application (proforma invoice) contain both autodisable and standard disposable syringes and/or type II re-use prevention syringes the quantities to be imported should be clearly indicated and must be in ratio of 90%:10%

Note

Registration of medical devices including syringes in Tanzania started in January, 2010 and the application guideline for registration of medical devices is available at TFDA headquarters through TFDA website: [www.tfda.or.tz](http://www.tfda.or.tz).

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