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THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

GUIDELINES FOR LISTING OF TOBACCO PRODUCTS

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ABBREVIATIONS AND ACRONYMS

ISO	-	International Organization for Standardization
TBS	-	Tanzania Bureau of Standard
TMDA	-	Tanzania Medicines and Medical Devices Authority
TZS	-	Tanzanian Standards
WHO	-	World Health Organization
WHO FCTC	-	World Health Organization Framework Convention on Tobacco Control

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Dr. Yonah H. Mwalwisi
DIRECTOR OF HUMAN AND VETERINARY MEDICINES

GLOSSARY OF TERMS

For this guideline, the following words or phrases are defined as follows.

Act

Means the Tobacco Products (Regulation) Act, Cap 121.

Additive

Means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in it becoming a component or otherwise affecting the characteristic of any tobacco product (including any substances intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding).

Authority

Means the Tanzania Medicines and Medical Devices Authority, or its acronym “TMDA”.

Cigars

Means a tube of tobacco that is thicker than a cigarette, wrapped in tobacco leaf, lit, and smoked. Cigars include regular cigars, cigarillos, and little filtered cigars.

Chewing tobacco

Means a type of shredded or twisted smokeless tobacco that the user keeps in his or her mouth, between the cheek and gum’’.

Cigarette

Means any roll of tobacco wrapped in paper or any substance not containing tobacco and any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filler, or its packaging or labeling, is likely to be offered to or purchased by consumers.

Dissolvable tobacco

Means a tobacco that dissolve in your mouth and do not require spitting or discarding of the product. Dissolvable tobacco products are non-combustible tobacco products”.

Electronic cigarettes

Means a battery powered device that people use to heat liquid into a vapor that can be inhaled. They’re also called e-cigarettes, e-cigs, or vapes.

Tobacco product

Means tobacco leaves, extract of tobacco leaves cigarattes, cigars, cigarirus, handrolling tobacco and includes other smoking tobacco products such as, pipe tobacco, fine tobacco and any chewing tobacco which is manufactured whole or partly from tobacco or any substance used as a substitute of tobacco.

Harmful and potentially harmful constituents

Means any chemicals or chemical compounds in a tobacco product or in tobacco smoke that is, or potentially is, inhaled, ingested, or absorbed into the body, including as an aerosol (vapor) or any other emission; and causes or has the potential to cause direct or indirect harm to users or non-users of tobacco products.

Importer

Means person or institution authorized to import tobacco products for sale, offer for sale, distribute, supply, donate or use in Mainland Tanzania.

Manufacture

Means the processing, packing, labeling and distribution of tobacco products.

Manufacturer

Means any person or entity who manufactures or is associated with the manufacture of tobacco products, including the processing, packaging, labeling and distribution of tobacco products.

Listing of tobacco products

Means an official recognition by the Authority of a tobacco product to be marketed or distributed in Mainland Tanzania.

Passive smoke

Means both smoke from the burning end of a cigarette or other tobacco product and smoke exhaled by the smoker.

Pre-market review

Means an assessment of tobacco product applications to determine whether they meet scientific and evidentiary standards appropriate for the protection of public health and also forms the scientific foundation for listing.

Roll-your-own tobacco

Means any tobacco product which, because of its appearance, type, packaging, or labeling is suitable for use and likely to be offered to or purchased by consumers as tobacco for making cigarettes.

Smokeless tobacco

Means any tobacco products that are used by means other than smoking and including chewing, sniffing, placing the product between the teeth and gum and application to the skin; and these exclude nicotine replacement therapies such as Nicorette.

Smoke constituent

Means a chemical or chemical compound in mainstream or side stream tobacco smoke that either transfer from any component of the combustible tobacco product to the smoke that is formed by the combustion or heating of tobacco, additives, or other components of the tobacco product such as carbon monoxide.

Distributor

This means any person who furthers the distribution of a tobacco product, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption.

Hookah

Means a water pipe that are used to smoke specially made tobacco that comes in different flavors, such as apple, mint, cherry, chocolate, coconut, licorice, cappuccino, and watermelon. Also called water pipes.

Pipe tobacco

Means a tube with a small bowl at one end that is filled with tobacco, lit, and smoked.

Smoking tobacco

Means a tobacco product that are burned and smokes inhaled by users.

Sniffing tobacco

Means a finely grounded tobacco usually sold in round cans. Can be placed between the cheek and gum or may be sniffed.

FOREWORD

Tanzania recognizes that, the use of tobacco products is a major public health problem. Data published by the WHO in 2022 shows that tobacco products killed nearly 8 million people globally. It is estimated that tobacco use accounts for 15% of deaths from cardiovascular disease, 24% of those from cancer, and 45% of those from chronic respiratory diseases globally. Generally, tobacco products are reported to be the leading cause of 6 out of 8 leading diseases.

The WHO published the Framework Convention on Tobacco Control (WHO FCTC), which contains policy objectives and strategies for control of tobacco products and their disclosures. The FCTC provides guidance on tobacco product regulations to reduce their demand and contribute to wider tobacco control objectives.

Tanzania signed the WHO-FCTC on 29th July 2007 and is therefore obliged to implement the framework. In addition, Tanzania published regulations governing tobacco product use in 2003 and revised them in 2014 with the aim of reducing tobacco product consumption in the country and the subsequent health hazards.

A report released by WHO-FCTC and the Global Youth Tobacco Surveys (GYTS) of 2003 and 2008 conducted in three regions namely Arusha, Dar es Salaam and Kilimanjaro provided valuable data on youth exposure to second-hand tobacco use or passive smoking. The findings from the Arusha survey reported an increase in exposure to tobacco smoke amongst students outside their homes. Exposure was high in 2003 with nearly one in five students (18.1%) living in homes where others smoked in their presence and approximately one-quarter of the students (23.1%) were exposed to smoke in public places. By 2008, 15.7% of students were observed to live in homes where others smoked in their presence and one-third (34.7%) were exposed to smoke in public places.

Due to an increase in tobacco products consumption with a reciprocal increase in tobacco-related diseases and as an effort to protect and promote public health, the Minister responsible for health has designated TMDA as the regulator of tobacco products. This designation has been delineated in the Tobacco Products (Regulations) (Designation of Inspectors) Notice, GN 360, which was published on 30/4/2021. In tandem with this designation, the TMDA has assumed the roles of inspection, enforcement and regulation of tobacco products.

TMDA has developed these guidelines to guide manufacturers, importers, and/or distributors on listing of tobacco products.

In view of this, the stakeholders are required to abide with the requirements prescribed in this guideline during submission of information for listing of tobacco products.

Adam M. Fimbo
DIRECTOR GENERAL

1. INTRODUCTION

Tobacco product is one of the most challenging products to regulate due to their history of use, nature of the business and addiction they cause. Smoking tobacco products can cause long-term health problems like heart disease, cancer, and diabetes, among many others.

In recognizing the associated health risks of tobacco use and to separate tobacco farming and regulation of products, the Tobacco Products (Regulation) Act, Cap, 121 was enacted in 2003. The Act provided for regulation of the manufacture, distribution, sale, promotion, advertising and use of tobacco products. To further streamline and interpret the regulatory process, the Tobacco Products Regulations were developed in 2014.

Nevertheless, despite the existence of the Act and Regulations in force, the institutional framework to oversee the national control and coordination mechanism was not established. It is against this background, the Minister responsible for health has designated TMDA as the regulator of tobacco products.

TMDA has crafted these guidelines to prescribe the minimum requirements for listing of tobacco products. It is anticipated that manufacturer, importers and distributors will familiarize themselves with these guidelines and submit the required information for listing of the tobacco products.

2. LEGAL BASIS

TMDA was appointed by the Minister responsible for health as an inspector of the tobacco products. This designation has been delineated in the Tobacco Products (Regulations) (Designation of Inspectors) Notice, GN 360, which was published on 30/4/2021.

As an inspector TMDA is mandated to enforce the Tobacco Products (Regulation) Act, 2003 and the Tobacco Products Regulations, 2014.

3. SCOPE

The guideline is intended to provide guidance to tobacco products stakeholders with information on the requirements for the listing of tobacco products.

This guideline is applicable to tobacco product including tobacco leaves, extract of tobacco leaves cigarettes, cigars, cigarirus, handrolling tobacco and includes other smoking tobacco products such as, pipe tobacco, fine tobacco and any chewing tobacco which is manufactured whole or partly from tobacco or any substance used as a substitute of tobacco.

4. REQUIREMENT FOR LISTING OF TOBACCO PRODUCTS

4.1 General Requirements

4.1.1 Who can apply and how to apply for listing of tobacco product in Tanzania.

i. Every person who owns or operates any domestic business engaged in manufacturing or selling of regulated tobacco products may submit application for listing of tobacco products;

ii. Apply for listing of tobacco product to the Authority by submitting a duly filled in application form as provided in **Appendix I** of these guidelines. The submission shall be made electronically through TMDA online application system.

iii. Separate and complete application for listing shall be submitted for each product. Product with different sizes, flavours, colours, brand name, manufacturers shall constitute separate application.

iv. Every application shall be accompanied by appropriate fees as specified in the Fees and Charges Regulations in force at the time of application;

4.1.2 The authority shall list the tobacco product if it is satisfied that: -

i. The product meets the prescribed standards;
ii. The premises and manufacturing facility have been licensed to manufacture by the Authority; and
iii. It complies with any other requirements as may be prescribed by the Authority

4.1.3 The Authority may during assessment of application require the applicant to submit
Samples, additional documents and give clarification as the case may be.

4.1.4 The processing of an application shall be kept on hold until such samples, documents or clarification is provided.

4.1.5 If the applicant fails to respond to the issues in sub section 4.1.3 above within 30 days from the date of request the application shall be closed and the registration of the product may only be considered upon submission of a new application.

4.1.6 The Authority after being satisfied that the product complies with requirements prescribed in these guidelines will list the product, inform the applicant via online trader portal and issue the approval notice.

4.1.7 Where the Authority refuses to list the product; it shall notify the applicant in writing of such decision and the reason(s) thereof.

4.1.8 If the applicant is not satisfied with the decision of the Authority he may, within 60 days from the date of notification furnish the Director General with representations to review its decision. The Authority after considering the submitted representations may list the product or if not satisfied it will uphold its initial decision.

4.1.9 The listing of a product shall be valid for three (3) years unless suspended, cancelled or revoked by the Authority or withdrawn by the applicant.

4.1.10 If for any reason the applicant changes any matter related to a listed product including but not limited to change of composition, packaging, labelling or any other change, shall before marketing the changed product, notify and obtain approval of the Authority of the changes. The notice to the Authority shall be submitted in a filled application form provided as **Appendix II** citing the reason(s) for such change and appropriate fees as prescribed in fees and charges regulation in force at the time of application.

4.1.11 The Authority will evaluate the reasons provided in the notice referred to under sub-section 4.1.10 and if satisfied with such reasons it will approve the changes by issuing an approval notice. If not satisfied the Authority will not approve the changes and it will notify the applicant of the reasons thereof.

4.1.12 The applicant may at any time by giving notice in writing to the Authority withdraw the listed product.

4.1.13 Applications for re-listing of tobacco products shall be made at least 30 days before the expiry of the listed period and payment of application fees as specified in the Fees and Charges Regulations.

4.2 Specific Requirements

4.2.1 An application for listing of tobacco products shall be made through the TMDA online portal and shall be accompanied by the following: -

i. A cover letter;

ii. A duly filled-in application form as provided in **Appendix I** to these guidelines;

iii. Product composition, including additives as described in the following format;

S/N	Name of the Ingredients	Quantity per unit	Function (use)

iv. Product specifications and certificates of analysis;

v. Artwork of the product displaying labelling information;

4.2.2 Upon satisfaction that the provided information meets or does not meet the requirements of the regulations, guidelines, applicable standards, or any other standards appropriate for the protection of public health, the Authority shall list or reject the listing of the tobacco product.

4.3 Re-listing of the Tobacco Product

4.3.1 If the validity of the listing for the tobacco product expiry and applicant wish to continue with the selling and distribution of the products shall file an application for re-listing of the product through TMDA online portal. The following should be accompanied with the information prescribed in section 4.2.1.

4.3.2 Declaration of any changes in the composition of the product.

5. CHANGE HISTORY

Revision No:	Date	Author	Description of change	Section(s) Modified	Approvals
Nil	Nil	Nil	Nil	Nil	Nil

6. APPENDICES

Appendix I: Application Form for Listing of Tobacco Product

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1.0 ADMINISTRATIVE INFORMATION	
1.1	Type of the application (tick as appropriate) New Listing ☐ Re-listing (renewal) ☐
1.2	Type of the product (tick as appropriate) Domestic product ☐ Imported product ☐
1.3	Proprietary name of the product:
1.4	Name and address (physical and postal) of Applicant
Company Name: Address: Country: Telephone: E-mail:	
1.5	Role of applicant (tick as appropriate) Manufacturer ☐ Distributor ☐ Wholesale ☐ Importer ☐ For wholesaler, importer or distributor, specify: Name of the supplier of the product: Physical address of the supplier: Email address of the supplier:
1.6	Type of product (tick as appropriate): Cigarettes ☐ processed tobacco leaves ☐ Cigar ☐ hand rolling tobacco ☐ Other specify……

1.7	Method of use (tick as appropriate): smoking ☐ Chewing ☐ Other specify……
1.8	Packing/Pack size:
1.9	Visual description/appearance of the product:
1.10	Storage conditions:
1.11	Name(s) and physical address (es) of the manufacturer of the tobacco product:
Company Name: Address: Country: Telephone: E-mail:	
2.0 Declaration by an applicant	
I, the undersigned certify that all the information in this form and accompanying documentation is correct, complete and true to the best of my knowledge. It is hereby confirmed that fees will be paid/have been paid according to the TMDA fees andregulation Name: …… …….. Position in the company:…… Signature: …… Date:…….. Official stamp:…… * Note: If fees have been paid, attach proof of payment	

Appendix II: Application Form for Changes of Listed Tobacco Product

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1 Brand name:	
1.1 Type of Tobacco Product Cigarettes ☐ processed tobacco ☐ Cigar ☐ hand rolling tobacco ☐	
1.2 Method of Use Smoking ☐ Chewing ☐ Other Specify…….	
3 Type of change(s)	
3.1 Scope (*Please specify scope of the change(s) in a concise way*)	
3.2 Background for change & Justification for change(s) (*if applicable*) *Please give a brief background explanation for the proposed change(s) to your listing as well as a justification in case of consequential change(s)*	
3.3 Present	3.4 Proposed
Applicant should clearly show the differences between the proposed version and the current version.	
4 Applicant Name: Address: Country Phone: Email:	
5.0 Declaration by an applicant I, the undersigned certify that all the information in this form and accompanying documentation is correct, complete and true to the best of my knowledge. It is hereby confirmed that fees will be paid/have been paid according to the TMDA fees and regulation Name: …… Position in the company: …….. Signature: …… Date: …… Official stamp: ……	