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## **TANZANIA FOOD AND DRUGS AUTHORITY**



# **GUIDELINES FOR APPLICATION FOR REGISTRATION OF TRADITIONAL MEDICINAL PRODUCTS**

**Revision No. 00**

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## **FOREWORD**

The Tanzania Food and Drugs Authority (TFDA) was established under the Tanzania Food, Drugs and Cosmetics Act 2003, Cap 219 with the mission of protecting and promoting public health by ensuring quality, safety and effectiveness of food, medicines, cosmetics and medical devices. One of the TFDA functions is to conduct pre-marketing evaluation of the regulated products to ensure that they meet standards of quality, safety and effectiveness before they are registered i.e. being officially allowed into the market.

In trying to streamline and effectively control traditional medicinal products these guidelines have been developed by TFDA to outline requirements for registration of traditional medicinal products in Tanzania.

In order to enable applicants to provide the required information to demonstrate that the products they intend to register comply with the acceptable standards of quality and safety, the Authority provides submission guidelines on the required minimum documentation in content and format.

All applicants are encouraged to familiarize with the guidelines and follow them strictly when preparing and submitting applications for registration of traditional medicinal products. Adherence to guidelines will ensure that all relevant information is provided in applications submitted for registration. This will facilitate efficient and effective evaluation as well as approval process.

In spite of the importance of adherence to the guidelines, the Authority does not intend to inhibit innovation, they only provide for minimum requirements thereby giving room for applicants to submit additional data. It is anticipated that the guidelines will be revised regularly in response to the experiences gathered from their utilization. We therefore welcome comments and views at any time for improvement and update of these guidelines.



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## GLOSSARY OF TERMS

The terms listed below are defined specifically for the purpose of these guidelines:

**‘Active ingredient’** means a natural substance(s) or extract intended to be used in the preparation of traditional medicinal product as a therapeutically active material.

**‘Dosage form’** means the form in which the traditional medicinal product is presented.

**‘Excipient’** means any component of a finished dosage form which has no therapeutic value.

**‘Good manufacturing practice (GMP)’** means that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization.

**‘Herbal medicine’** means a medicinal product that contains active ingredients one or more natural substances that are derived from plants to which may be added natural substances of animal or mineral origin.

**‘Modified traditional medicinal product’** means traditional medicinal products that have been processed, packaged and labelled by use of advanced technology into dosage form.

**‘Product Dossier’** means file(s) containing detailed technical information of a particular product.

**‘Product’** means traditional medicinal product.

**‘Raw traditional medicinal product’** means any product consisting of a substance or a mixture of substances produced by drying, extracting, crushing or comminuting, compressing natural substances of a plant, animal or mineral origin or any part of such substances.

**‘Shelf life’** means that length of time in which the traditional medicinal product are given before they are considered unsuitable for sale or consumption or it is amount of time that a properly packaged and stored product will last before undergoing chemical or physical changes, remaining within the specified uncertainty.

**‘Traditional health practitioner’** means a person registered under Section 17 or 18 of the “Traditional and Alternative Medicines Act, 2002” to practice traditional medicine in Tanzania.

**‘Traditional medicinal product’** means any product used in Tanzanian local systems of therapeutics, in which the product consist solely of one or more naturally occurring substances of a plant, animal or mineral origin.

## INTRODUCTION

During the last decade, the use of traditional medicinal products has expanded and gained popularity in the country. They have not only been used for primary health care in rural areas but have also been used in urban areas.

With the expansion in the use of these products in the country, quality and safety have become a challenge to both Tanzania Food and Drugs Authority and the public. These guidelines have been developed to provide requirements in support of quality and safety for those who wish to register traditional medicinal products.

Registration of traditional medicinal products is intended to protect the public against health hazards that may be associated with consumption of the products. In Tanzania there is notable increase of use and demand for traditional medicinal products whereby it is believed that around 60% of the population visit traditional health practitioners for their health needs (MoHSW Statistics). This population needs to be protected against the possible hazards that may be associated with consumption of traditional medicinal products. Risks of these products may arise from exogenous contaminants such as pesticides or from the chemical properties of constituents and/or ingredients used to formulate the products. They may also arise from quality defects which are likely to occur during preparation and deterioration or contamination during transport or storage as quality controls are not usually adequate or safety is not assured thus causing adverse effects which can range from mild to life threatening.

This document provides a set of guidelines to applicants on the requirements for application for registration of modified traditional medicinal products. It is expected that the guidelines will assist applicants to fulfil the legal requirements for registration of traditional medicinal products as provided under Section 22 of the Tanzania Food, Drugs and Cosmetics Act No.1 of 2003. This section prohibits manufacture for sale, sell, offer, supply or import of any product regulated under the Act including traditional medicinal product, unless the product is registered by TFDA.

It is being emphasized that, these guidelines address locally used products. It covers raw and modified traditional medicinal products. However, presently, there is no licensing requirement for local sale of raw traditional medicinal products that are not of modern finished dosage forms. The guidelines do not cover traditional medicinal products from outside Tanzania. Traditional medicinal products that are imported are registered as conventional medicines.

The guidelines have been divided into seven sections and five annexes.

Section one provides general requirements on how to file an application, payment of relevant fees and processing of applications. Section 2 provides regulatory classification of traditional medicinal products while section 3 gives requirements on registration of raw traditional medicinal products and section 4 prescribe specific requirements for registration of modified traditional products.

Section 5 provides labelling requirements for traditional medicinal products and section 6 covers requirements for promotional activities. Section 7 provides requirements on new/additional indications for registered products.



The application form for registration of modified traditional medicinal products is provided as *annex I* to the guidelines. Applicants will be required to fill in this application form and submit it to the Authority along with other documentation as provided in the guidelines.

Applicants are requested to carefully read these guidelines, prepare dossiers and submit them in hard-copy as well as in electronic forms on a CD-ROM. The guidelines prescribe minimum information required and as far as possible evaluation of dossiers submitted will be based on these guidelines. However, since science is ever changing and taking into account that it is not always possible to keep pace in amending the guidelines, TFDA will in the interest of patient safety and well being not accept outdated methods and techniques and will evaluate products based on the current state of scientific knowledge and standards.

Applicants are therefore encouraged to keep abreast with scientific developments and use current scientific information to develop and test their products.

These guidelines can be also obtained from TFDA website '[www.tfda.or.tz](http://www.tfda.or.tz)'.



## **1.0 GENERAL REQUIREMENTS**

Applications shall be done by submitting a dully filled in application form (*Annex I*) accompanied with information as prescribed in these guidelines. All documents shall be in Kiswahili or English languages.

### **1.1 Applicant**

Application for registration of traditional medicinal product can be made by owner of the product (an individual, body corporate, partnerships or registered business) responsible for the manufacturing or ordering the product for sell or distribution.

The applicant shall be responsible for the product, information supplied in support of his application for registration and alterations thereof. He/She should monitor the product on the market and inform the Authority immediately after the detection of any problem relating to a registered product such as, its safety or serious preparation defects which may endanger public health.

### **1.2 Applications**

#### **1.2.1 First time application**

A separate application is required for each product, i.e. products containing the same ingredients but made to a different specification (in terms of strength or content of active ingredients, dosage form, etc).

Applications shall be made by submitting a dully filled in application form which shall be accompanied with:-

- (i) CD containing a dully filled in application form in soft form in text or word format.
- (ii) A copy of certificate of incorporation for companies or registration of the other forms of ownership of the business in Tanzania (if applicable).
- (iii) Certificate of registration for traditional health practitioner issued by The Traditional and Alternative Health Practice Council of Tanzania.
- (iv) Five labelled samples of the smallest commercial pack (with enclosed patient information leaflet).
- (v) Non refundable application fee of 50,000/= per product.
- (iv) An appropriate and complete index/list of the various sections and documents of the submission.

#### **1.2.2 Application for alteration of a registered product**

Whenever an applicant wishes to make any alteration to a product he/she must apply to and obtain approval from the Authority in respect of a registered product before introducing it on the market. An application for alteration shall be accompanied with:

- (i) Detailed description of the alteration with supporting reasons.
- (ii) Samples of the altered product.
- (iii) Alteration fees of Tshs 30,000/= per alteration

### **1.2.3 Application for renewal of registration**

Applications for renewal of registration of traditional medicinal products shall be submitted at least 30 days before the expiry date of registration. Failure to submit the application before the deadline will mean that the holder of the registration certificate does not wish to renew registration of the product.

Renewal of registration shall be made by submitting a dully filled and signed in Application Form for Renewal of Registration of a registered modified traditional medicinal product. It shall be accompanied with:

- (i) Consolidated report of all changes if any (reported and unreported) which had been made with respect to the product during the validity of its registration
- (ii) Report on safety of the product such as adverse reactions observed during the lifetime of the product.
- (iii) Two commercial samples of each package size being applied for registration. The samples must be in the form and container in which it shall be marketed.
- (iv) Renewal application fees of Tshs 50,000/= per product.

### **1.2.4 Confidentiality**

All information pertaining to applications for registration of the product shall not be disclosed by TFDA to any other person without prior approval of the applicant.

## **1.3 Documentation**

### **1.3.1 Paper type and binding**

Data shall be presented on A4 and 80g/m<sup>2</sup> paper with readily readable letters of at least 12 font size. Every page shall be numbered sequentially. Extension sheets, tables, diagrams and other supporting documents shall as far as possible be of the same size, well-annotated, numbered and appropriately referenced or cross-referenced.

All sections of the dossier must be bound separately and arranged sequentially on a 1.00 mm or more diameter stainless spring and clamped with a stainless steel binder of not less than 1.0 mm thick in an A4 expandable spring file. The file shall be of cardboard or paper material of not less than 600gsm. Two or more sections separated by clearly marked dividers may be bound in a single file provided that the total number of pages does not exceed 500. The papers must unless otherwise justified be printed on both sides. Whenever two or more sections are bound in a single file, the binding shall be in such a manner as to allow sections to be detached for evaluation by different experts.

### **1.3.2 Official references**

When direct reference is made to specifications, quality control procedures, test methods, data etc. in official compendia, texts or standard publications, reprints or authenticated copies of relevant pages shall be enclosed. References to pharmacopoeias should specify the year of issue.

### **1.3.3 Expert reports**

Expert reports shall accompany documentation on safety of the ingredients and /or product if applicable. All copies should be authenticated by authorized signatories and stamped 'official applicant'.

## **1.4 Submission, payment of fees and processing of applications**

### **1.4.1 Submission of application**

All applications shall be addressed and submitted in person or by courier to: *The Director General, Tanzania Food and Drugs Authority, EPI-Mabibo External, P. O. Box 77150, Dar es Salaam, Tanzania.* When an application has been received, an acknowledgement will be issued together with a reference number for each product.

### **1.4.2 Payment of fees**

Fees shall be paid in favour of the Tanzania Food and Drugs Authority directly to the bank through account No. 6503900110 of the National Microfinance Bank. All bank charges shall be borne by the applicant, who shall also make sure he sends an advice note giving details of the payment in particular the name of the applicant, the product or products paid for and amount of fees paid.

For each registered product an annual retention fees shall be paid on or before the end of January of each calendar year for which the fees are due.

### **1.4.3 Processing of applications**

Processing of an application shall only be done on complete applications. The Authority will make its final decision based on the data submitted in the dossier. However, the Authority may during evaluation of the product request for clarification by issuing queries. Once a query has been raised, the processing shall be halted until after the query has been attended to. If they are more than one query, the responses must be submitted in one transaction. If not submitted within 90 days from the date of the query letter, it will be deemed that, the applicant has withdrawn the application and it will automatically expire.

The processing of an application takes about 180 days. Immediately after the processing is completed applicants will be informed accordingly.

The Authority as part of the evaluation of the product may conduct pre-registration Good Manufacturing Practice (GMP) inspection to verify compliance thereof.

## **1.5 Issuance of registration certificate**

When a product is found to have complied with all the prescribed registration requirements, the applicant will be informed to that effect. A certificate of registration together with such conditions as the Authority may determine shall be issued.

A duplicate of the certificate may be issued upon request and on payment of Tshs 20,000/=.

### **1.6 Validity of registration**

The registration of a product shall be valid for three years unless sooner suspended, cancelled or revoked by the Authority or terminated by the registration holder. The validity of registration shall be subject to payment of annual retention fees of Tshs 20,000/ per product immediately after a product is registered.

### **1.7 Termination of product registration**

The Authority may by giving reasons in writing refuse, suspend, cancel or revoke the registration of a product, or amend the conditions of its registration.

The registration holder may by giving a 60 days written notice and reasons to the Authority terminate the registration of a registered product.

### **1.8 Appeals and application for review**

- (i) Any person aggrieved by a decision of the Authority in relation to any application for registration of a traditional medicinal product may petition the Authority to review its decision. The petition shall be done in writing by giving reasons based on the information that was already in the hands of the Authority at the time the decision was made. New information will only be considered if submitted in a new application.
- (ii) The Authority may review its own decision, vary or reject.
- (iii) If a person is dissatisfied by the decision after review, may appeal to the Minister responsible for health whose decision shall be final.

## **2.0 CLASSIFICATION OF TRADITIONAL MEDICINAL PRODUCTS**

A large variety of different types of traditional medicinal products are available on the Tanzanian market, ranging from raw plant materials through modified and packaged products. It would be very difficult, if not impossible; to implement a mechanism for registration of all types of products without the use of an appropriate classification system.

In the context of these guidelines, the products have been grouped into two categories based on their mode of processing:

### **2.1 Raw traditional medicinal products**

Raw traditional medicinal product refers to raw herbs, minerals or animal parts with medicinal properties, which are used in traditional medicines. The products are in natural states, or have undergone simple processing, such as cutting, drying, communiting or crushing.

These products basically fall under two broad categories, mainly those sold in loose or bulk form, and those that are simple pre-packed for sale (stating information such as product name, brand name, ingredients, indications, dosages and/or instructions for use on the packaging materials).

## **2.2 Modified traditional medicinal products**

These are locally prepared products that have been modified by addition of excipients such as suspending agent, preservatives, anti-microbials, surfactants, emollients or other pharmaceutical aids.

The preparation methodologies of these medicines are more advanced and are in dosage forms i.e. tablets, capsules, syrups, ointments, creams, lotion, solutions etc.

## **3.0 REGISTRATION OF RAW TRADITIONAL MEDICINAL PRODUCTS**

Raw traditional medicinal products will not be eligible for registration by TFDA under this guideline but Traditional Health Practitioners (THPs) must ensure that:

- (i) The content of heavy metal in the product does not exceed the acceptance limit indicate in the bracket below:-
  - (a) Arsenic (5 ppm),
  - (b) Copper (150 ppm),
  - (c) Lead (20 ppm)
  - (d) Mercury (0.5ppm).

Any other heavy metal present in the product should be specified and the level should be justified.

- (ii) The herbs are collected from areas free from environmental contaminants such as industrial pollution, mining areas, pesticides etc.
- (iii) The labels and packaging materials of the products (if any) do not stipulate any of the 21 diseases/conditions which are non permissible indications for traditional medicines provided in *annex II*.
- (iv) They possess certificates of registration for Traditional Health Practitioners issued by the Traditional and Alternative Health Practice Council of Tanzania.
- (v) The sale of raw medicinal herbs shall be restricted to registered facilities of Traditional Health Practitioners only.

## **4.0 REGISTRATION OF MODIFIED TRADITIONAL MEDICINAL PRODUCTS**

### **4.1 Requirements for active ingredients**

Submission of information pertaining to active ingredients contained in modified traditional medicinal products should be as provided below:-

#### **4.1.1 Products containing new single ingredient**

The following documents should be provided:-

##### **a) Extract form**

- (i) Information on the taxonomy of the ingredient
- (ii) Techniques and methods in preparing/processing the extract and subsequently the product
- (iii) Information on the use and safety of the ingredient.

##### **b) Powder/Granules**

- (i) Information on the taxonomy of the ingredient
- (ii) Techniques and methods in preparing/processing the extract and subsequently the product
- (iii) Information on the use and safety of the ingredient.

#### **4.1.2 Products containing single or multiple ingredients (ingredients which are known to be used traditionally):**

- (i) The source of the product information e.g. WHO monograph on selected medicinal plants, Chinese Pharmacopoeia and Ayurvedic Pharmacopoeia.
- (ii) Proof or evidence of the use traditionally.

#### **4.1.3 Products containing multiple ingredients (ingredients which are not known to be used traditionally):**

- (i) Information on the use and safety of every new ingredient
- (ii) Concentration of each new ingredient should be shown.

### **4.2 Quality control tests and specifications**

All modified traditional medicines must be tested and should comply with the following specifications:-

#### **4.2.1 Limit test for heavy metals**

- (i) Lead: NMT 10.0 mg/kg or 10.0 mg/litre (10.0ppm)
- (ii) Arsenic: NMT 5.0 mg/kg or 5.0 mg/litre (5.0ppm)
- (iii) Mercury: NMT 0.5 mg/kg or 0.5 mg/litre (0.5ppm)
- (iv) Cadmium: NMT 0.3 mg/kg or 0.3 mg/litre (0.3ppm)



#### 4.2.2 Disintegration Test (for tablets, capsules and pills)

##### Disintegration time:

Uncoated tablets:	NMT 30 minutes
Film-coated tablets:	NMT 30 minutes
Sugar-coated tablets:	NMT 60 minutes
Enteric-coated Tablets:	Does not disintegrate for 120 minutes in acid solution but to disintegrate within 60 minutes in buffer solution
Capsules :	NMT 30 minutes
Pills :	NMT 120 minutes

#### 4.2.3. Test for Uniformity of Weight (tablets and capsules only)

Not more than 2 capsules / tablets exceed the limit by  $\pm 10\%$  from the average weight and no tablet / capsule exceed the limit by  $\pm 20\%$  from the average weight.

#### 4.2.4 Uniformity of volume for liquid/semi-solid preparations

Not more than  $\pm 2\%$  from the average volume

#### 4.2.5 Test for Microbial Contamination

Route of Administration	TAMC (CFU/g or CFU/ ml)	(CFU/g or CFU/ ml)	Test for Specified Microorganisms
Rectal Use	NMT $2 \times 10^3$	NMT $2 \times 10^2$	
Oromucosal Use Gingival Use Cutaneous Use Nasal Use Auricular Use	NMT $2 \times 10^2$	NMT $2 \times 10^1$	Absence of <i>Staphylococcus aureus</i> in 1g or 1ml Absence of <i>Pseudomonas aeruginosa</i> in 1g or 1ml
Vaginal Use	NMT $2 \times 10^2$	NMT $2 \times 10^1$	Absence of <i>Staphylococcus aureus</i> in 1g or 1ml Absence of <i>Pseudomonas aeruginosa</i> in 1g or 1ml Absence of <i>Candida albicans</i> in 1g or 1ml
Trans-dermal patches (limits for one patch including adhesive layer and backing)	NMT $2 \times 10^2$	NMT $2 \times 10^1$	Absence of <i>Staphylococcus aureus</i> in 1 patch Absence of <i>Pseudomonas aeruginosa</i> in 1 patch

Inhalation use (Special requirement apply to liquid preparations for nebulisation)	NMT 2x 10 <sup>2</sup>	NMT 2 x 10 <sup>1</sup>	Absence of <i>Staphylococcus aureus</i> in 1g or 1ml Absence of <i>Pseudomonas aeruginosa</i> in 1g or 1ml Absence of bile-tolerant gram negative bacteria in 1g or 1ml
Special Ph. Eur. provision for oral dosage forms containing raw materials of natural (animal, vegetal or mineral) origin for which antimicrobial pre-treatment is not feasible and for which the competent authority accepts TAMC of the raw material exceeding 10 <sup>3</sup> CFU per gram or millilitre	NMT 2x 10 <sup>4</sup>	NMT 2 x 10 <sup>2</sup>	NMT 2 x 10 <sup>2</sup> CFU of bile-tolerant gram- negative bacteria in 1g or 1ml Absence of <i>Salmonella</i> in 10g or 10ml Absence of <i>Escherichia coli</i> in 1g or 1ml Absence of <i>Staphylococcus aureus</i> in 1g or 1ml
Special Ph. Eur. provision for traditional medicinal products consisting solely of one or more herb (whole, reduced or powdered):  Products to which boiling water is added before use  Products to which boiling water is not added before use	NMT 2x 10 <sup>7</sup>  NMT 2x 10 <sup>5</sup>	NMT 2 x 10 <sup>5</sup>  NMT 2 x 10 <sup>4</sup>	NMT 2 x 10 <sup>2</sup> CFU of <i>Escherichia coli</i> in 1g or 1ml  NMT 2 x 10 <sup>3</sup> CFU of bile-tolerant gram-negative bacteria in 1g or 1ml Absence of <i>Escherichia coli</i> in 1g or 1ml Absence of <i>Salmonella</i> in 10g or 10ml

Two certificates of analysis of finished product from recently manufactured two batches should be presented.

**Key:** TAMC : Total Aerobic Microbial Count  
TYMC : Total Yeasts & Moulds Count  
NMT : Not more than  
CFU: Colony Forming Unit

## 5.0 LABELLING REQUIREMENTS FOR TRADITIONAL MEDICINAL PRODUCTS

### 5.1 Container label

Every immediate container of any product shall be affixed with a label bearing the following particulars pertaining to the contents of such container in clearly legible and indelible letters in Kiswahili or Kiswahili and English languages.

- (a) Proprietary/trade name
- (b) The dosage form of the product
- (c) Names and quantities of active ingredient(s) in the container expressed in the appropriate unit or volume of the pharmaceutical product.
- (d) Name and address of trade mark owner
- (e) In case of contract manufacturing, the name and address of manufacturer printed in the same letter size as those of the trade mark owner as follows:  
“*Manufactured for.....(name and address of registrant) by.....(name and address of manufacturer)*”.
- (f) Where applicable the instruction:
  - i. “Shake well before use”
  - ii. “For external use only”
- (g) The instruction “keep out of reach of children”
- (h) Where practicable, what is the medicine used for and how much and how often should it be taken.
- (i) The batch or lot number of the product
- (j) The manufacturing and expiry date of the product
- (k) The name and concentration (content) of preservatives, where present
- (l) Storage instructions and shelf life
- (m) A disclaimer stating that ‘*Efficacy*’ of this product has not been proved by TFDA”.
- (n) If symptoms persist, consult a doctor
- (o) After registration, the registration number should appear on the label

In case the product package bears both the immediate container label and outer container label the above requirements shall apply to the outer label as well.

### 5.2 Patient information leaflet

All patient information leaflets must be printed with the following words; ‘Read all information in this leaflet carefully before you start taking this traditional medicinal product and keep it as you may need to read it again. This traditional medicinal product has been prescribed for you; do not pass it on to others as it may harm them, even if their symptoms are the same as yours.’

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your traditional health practitioner, doctor or pharmacist.'

The leaflet must also contain the following information:-

- (a) Name of product
- (b) Description of product
- (c) Names and quantities of each ingredient present in the product.
- (d) What is this medicine used for? (see acceptable indications annex IV)
- (e) A disclaimer stating that the '*Efficacy of this medicine has not been proved by TFDA*'.
- (f) How much and how often should you use this medicine?
- (g) When should you not take this medicine?
- (h) Undesirable effects
- (i) What other medicine or food should be avoided whilst taking this medicine?
- (j) What should you do if you miss a dose?
- (k) How should you keep this medicine?
- (l) Signs & Symptoms of taking too much medicine.
- (m) What to do when you have taken more than the recommended dosage?
- (n) Care that should be taken when taking this medicine?
- (o) When should you consult your traditional health practitioner, doctor or pharmacist?
- (p) Name and address of trade mark owner
- (q) If symptoms persist, consult a doctor.

### 5.3 Special labeling requirements

For products containing Camphor, the following warning should be stated on the label: can cause convulsion, contraindicated in children below 2 years of age. Caution must be exercised when older children are treated. avoid direct application into nostrils

Precaution: 'It is dangerous to place any camphor – containing product into the nostril of children. A small amount applied this way may cause immediate collapse'

- Avoid contact with the eyes
- Do not apply to wounds or damaged skin

(i) For products containing Ginseng (including all *Panax* genus) state:

- Safe use of ginseng in pregnant women and children has not been established.
- Safety on long term use has not been established

(ii) For products containing Flower parts, state:

- This product may contains pollen which may cause severe allergic reactions, including fatal anaphylactic reactions in susceptible individuals.
- Asthma and allergy sufferers may be at greater risks.

- (iii) For product containing *Chelidonium Majus*, state :
- Warning: This Product may cause adverse reaction to the liver.
- (iv) For product containing Senna Leaf (*Cassia*) and Rhubarb/Radix et, Rhizoma Rhei, state:
- Do not use when abdominal pain, nausea or vomiting is present.
  - Frequent or prolonged used of this preparation may result independence towards the product and ‘imbalanced electrolytes’.
- (v) For product containing Alfalfa (*Medicago sativa*), state:
- Text Box: This product contains Alfalfa (*Medicago sativa*). Individuals with a predisposition to systemic lupus erythematosus should consult their physician before consuming this product.
- (vi) For product containing St. John’s Wort, state: The product may interact with other medicines. Please consult a doctor / pharmacist before using it.
- (vii) For product containing *Pelargonium sidoides*, state: In very rare cases, pelargonium sidoides may cause hypersensitivity reactions.
- (viii) For product containing Benzyl Alcohol/ Phenylmethanol (as preservative), state: As this preparation containing Benzyl Alcohol, its use should be avoided in children under 2 years of age. Not to be used in neonates.
- (ix) For product containing *Ginkgo biloba* / Ginkgo extract, state: ‘Please consult your physician/ pharmacist if you are on or intend to start using any other medicines and before you undergo any surgical/dental procedure’ as the use of Ginkgo may increase the tendency of bleeding,
- (x) For product containing royal jelly, state: - This product contains royal jelly and may cause severe allergic reactions including fatal anaphylactic reactions in susceptible individuals. Asthma and allergy sufferers may be at the greater risk.
- (xi) For product containing *Propolis* (topical preparation), state: Propolis may cause allergic skin reaction.
- (xii) For product containing ‘Anti-diarrhoea’, state: Contraindicated in children below 1 year old.
- (xiii) For product with indication ‘To regulate menstruation / to improve menstrual flow’, state: Contraindicated in pregnant women.
- (xiv) For product with indication ‘To reduce body weight’, state: Balanced diet and regular exercise are essential.

For further guidance see annex III, annex IV and annex V

## 6.0 PROMOTION

All traditional medicinal products should not be advertised with any direct or indirect reference to the list of 21 diseases and conditions which are non-permissible indications for traditional medicinal products as shown in *annex II*.

In addition, no advertisement will be allowed for serious medical diseases, disorders and conditions, including osteoporosis, insomnia, hepatitis, thyroid disorders, heart or cardiovascular diseases, genetic disorders, infectious diseases and sexually transmitted diseases.

A list of some of the general health claims is provided in Table I below to illustrate the kind of claims that may be used in the advertisement of modified/modified traditional products, based on traditional/ longstanding use, as documented in approved traditional medicine literature.

**Table I: Examples of General Health Claims**

Used as a liver tonic or to support liver function
For energy and general health maintenance
Helps to maintain healthy vision
Helps to support urinary tract function
Promotes joint mobility
Promotes healthy hair & skin
Promotes vitality/energy

All advertisements for modified/modified traditional medicinal products that contain medicinal claims or therapeutic claims will require approval from the Authority.

The promotion and advertisement activities to the public for raw traditional medicinal products are strictly prohibited.

## 7.0 NEW / ADDITIONAL INDICATION

New/additional indication is defined as an indication which is not previously approved for a registered product. This includes a new therapeutic indication or indication for new age group (example usage in children). New/additional indications can be requested through an application for a variation to the particulars of a registered product, provided these are low level claims and appropriate to the product.

**TANZANIA FOOD AND DRUGS AUTHORITY**



No.....

**APPLICATION FORM FOR REGISTRATION OF MODIFIED TRADITIONAL MEDICINAL PRODUCT**

**1.0 Product Particulars**

1.1 Trade Name:

\_\_\_\_\_

1.2 Dosage form:

\_\_\_\_\_

1.3 Physical description of the product:

\_\_\_\_\_

1.4 Product origin (e.g. Village, District, Region)

\_\_\_\_\_

1.5 Duration the product has been on the Tanzanian market:

\_\_\_\_\_

1.6 Names and quantities of ingredients per specified quantity of the product:  
Specify quantity of the product e.g. one tablet, 5 mls liquid etc

SN	Local Name(plant or other ingredient used)	Botanical name ( <i>Latin Binomial name</i> ),	Part of the plant/animal used	Quantity used per dosage unit	Function (active or excipient)

1.7 What is the medicine used for

\_\_\_\_\_

1.8 Dosage and method of administration:

\_\_\_\_\_

1.1.1 Packing and Pack size(s) State the size of the smallest commercial size and describe the packaging materials which come into contact with the product the liner and seal if any. State what materials they are made from:

\_\_\_\_\_

1.10 Recommended shelf-life and brief description of the method used for the determination of shelf life:

\_\_\_\_\_

1.11 Recommended storage conditions before and if applicable after reconstitution:

\_\_\_\_\_

\_\_\_\_\_

**2.0 Particulars of applicant**

2.1 Name: \_\_\_\_\_

2.2 Physical address (plot/block No./street/Village/district/region):

\_\_\_\_\_

Postal Address: \_\_\_\_\_

City /Town: \_\_\_\_\_

Phone: \_\_\_\_\_ Mobile.....Fax: \_\_\_\_\_

Email: \_\_\_\_\_

**3.0 Name of manufacturer if different from applicant**

3.1 Name: \_\_\_\_\_

3.2 Physical address (plot/block No./street/Village/district/region):

\_\_\_\_\_

Postal address: \_\_\_\_\_

City /Town: \_\_\_\_\_

**DECLARATION BY THE APPLICANT**

I ..... (full name) do hereby certify that all the information filled in this form and all the accompanying documents are true and correct to the best of my knowledge and confirm that the information referred to in this application is available for verification.

Signature \_\_\_\_\_

Date \_\_\_\_\_

Official Stamp/Seal \_\_\_\_\_



**ANNEX II****NON-PERMISSIBLE INDICATIONS**

1. Blindness
2. Leprosy
3. Cancer
4. Menstrual disorders
5. Cataract
6. Paralysis
7. Drug addiction
8. Tuberculosis
9. Deafness
10. Sexual dysfunctions
11. Diabetes
12. Infertility
13. Epilepsy or fits
14. Impotency
15. Hypertension
16. Frigidity
17. Insanity/mental illness
18. Conception and pregnancy
19. Kidney diseases
20. Malaria
21. HIV/AIDS

## **ANNEX III**

### **INDICATIONS ACCEPTABLE FOR TRADITIONAL MEDICINAL PRODUCTS**

#### **GENERAL HEALTH MAINTENANCE**

“Traditionally used....

1. for general health / for health
2. for general health maintenance / for general well being.
3. for health and strengthening the body
4. for relief of body heat
5. for general debility, weakness after illness or childbirth
6. for loss of appetite.
7. for difficulty in sleep
8. for relief of fatigue
9. as an aid to overcome fatigue during physical exertion
10. to expel wind and invigorate vital energy
11. to improve appetite
12. for relieving waist ache and body weakness
13. for relieving dizziness, sweating, and difficulty in sleep
14. for reducing body odour
15. for reducing toothache
16. to relieve tired eyes
17. for healthy eyes

#### **BLOOD & BODY FLUID**

“Traditionally used....

1. for improving blood circulation
2. to improve urination
3. for improving bowel movement
4. for relieving mild vomiting
5. for reducing minor swelling

#### **BONE, MUSCLE AND JOINT**

“Traditionally used....

1. for strengthening muscle and bone
2. for relieving muscular ache
3. for relieving waist ache and backache
4. for relief of joints and muscular pain
5. for relieving muscles sprain

#### **PAIN & FEVER**

“Traditionally used....

1. to relieve / alleviate pain
2. for relieving fever
3. for relieving headache
4. for relieving pain and itchiness related to piles
5. for symptomatic relief of body heat

## **COUGH & COLD**

“Traditionally used.....

1. for relief of fever, cough and cold
2. for relief of sore throat
3. for reducing phlegm and relief of cough, sore throat and body
4. for relief of throat irritations and cough
5. for relief of nasal congestion
6. for relief of sore throat and cough
7. for relief of mouth ulcers due to heat

## **DIGESTIVE SYSTEM**

“Traditionally used....

1. for relief of stomach ache, mild diarrhoea
2. for relief of flatulence, stomach ache, mild diarrhoea, and loss of appetite
3. for relief of mild diarrhoea, vomiting and improve appetite
4. for relief of mild constipation
5. to improve appetite and digestion
6. for relieving abdominal pain
7. for relief of stomach ache, constipation, mild vomiting and indigestion

## **WOMEN'S HEALTH**

“Traditionally used.....

1. to relieve menstrual pain, headache and to regulate menstruation
2. to reduce body weight
3. for relief of vaginal discharge
4. for general wellbeing and strengthen the body after childbirth
5. for women after childbirth to reduce body weight
6. for symptomatic relief of vaginal discharge and mild itch
7. to improve menstrual flow, for relief of menstrual pain, vaginal discharge and flatulence
8. for strengthening body muscle
9. to relieve symptoms of menopause

## **MEN'S HEALTH**

“Traditionally used....

1. for energy and men's health / for vitality

## **OTHERS**

“Traditionally used.....

1. for symptomatic relief of pain and itch associated with insect bites
2. for relief of minor burns
3. for relief minor cuts or relief of minor bruises
4. to help maintaining healthy skin, nail and hair
5. for reducing pimples and mild itch

**Annex IV****PROHIBITED VISUAL / GRAPHICS ON LABEL OF TRADITIONAL MEDICINAL PRODUCTS**

<b>No.</b>	<b>Issue</b>	<b>Example</b>	<b>Note</b>
1	Marketing strategy	<b>Example:</b> “Money back guarantee” “Buy 1 free 1” “Backed by Tsh. 5 million product Liability Insurance”	Such statements are Prohibited.
2	Usage guide which promotes use of other product(s)	<b>Example:</b> “After consumption of this product (Product A), for better results, it is Recommended to take Product B”	Prohibited on product label
3	Consumer testimonial		Prohibited on product label
4	Clinical trial results or any information on clinical trial done on product	Example :- “Clinically tested” “Randomized double blind placebo control clinical study”	Such statements are Prohibited.
5	Reference to Hadith/ Al-Quran/Bible/Religious books		Prohibited on product label
6	Opinion of prominent figure(s) on product or its active ingredient/ content	<b>Example:</b> Opinion of product/ formulation innovator	Prohibited on product label
7	Label design (graphic and color) similar to labels from another company		Prohibited on product label
8	Statement on herbal origin	<b>Example:</b> Source from the Mountains of Uluguru	Allowed if proven true
9	Introduction of founder/ manufacturer		Prohibited on product label
10	Name/ Statement / Logo/ registered trademark	<b>Example:</b> “Dr. ABC’s Formula” “Nothing like it”	Prohibited on product label

11	Logo with Certification	<b>Example:</b> ISO certification	Prohibited on product label
12	Graphics or picture of internal organs	<b>Example:</b> Kidney, Heart, Nerves.	Prohibited on product label
13	Photograph of celebrities	<b>Example:</b> Artiste, Sports person(s), Politician	Prohibited on product label
14	Sex symbol (male or female)	(♀ and / or ♂)	Prohibited on product label
15	Graphics which are incoherent with the indication	<b>Example:</b> - Noted indication is for constipation, but graphics on label shows a slim-looking lady which denotes indication for weight loss - Indication for urination but label graphics contains picture of a water hose.	Prohibited on product label
16	Other statements	<b>Example:</b> - This product is blended with premium quality - Certified chemical residue free	Prohibited on product label

**Note:**

- (a) This list is not meant to be exhaustive.
- (b) It may be reviewed as and when it is deemed necessary.
- (c) TFDA reserves the right to disallow any other words, phrases or graphics for product label which in its opinion is misleading, improper or not factual.

**Annex V****LIST OF NON PERMISSIBLE NAMES FOR TRADITIONAL PRODUCTS**

S/N	Issue	Example
1	Prohibited use of superlative – Names which indicates superiority in efficacy	Example: Power, Superior, Pure, Safe, Healthy, VIP, Good
2.	Prohibited use of names which may cause ambiguity/confusion	
3	Prohibited use of names which may be offensive or indecent	Example: SENXBIG=SEnXBIG(label) Sexy, Enjoy, Paradise, Heavenly, Blue boy, Casanova, Desire
4	Prohibited use of product names which has elements of ludicrous belief Statements referring to ancient believe/negative spirits/supernatural power	Example: Words such as miracle, magic, magical, miraculous, saintly, heavenly
5	Prohibited use of product names similar to the existing approved product names Product names similar to the spelling and pronunciation of words of the existing product names	Example: Tenormin vs Tenormine vs Tenormy
6	Prohibited use of product names which may cause ambiguity/confusion in the nature of product (drug/food/beverage) Product names similar to a food/beverage product	Example: Juice, Health drink, Beverage,
7	Prohibited use of product names which represents professional advice or opinion	Example: Dr Sunny, Dr Noortier Rooibose Tea, Professo
8	Prohibited use of product names which represent weight loss/slimming properties	Example: Slim, Trim, Trimnfit
9	Other prohibited product names	Example: IQ, Smart

**Note:**

- (a) This list is not meant to be exhaustive.
- (b) It may be reviewed as and when it is deemed necessary.
- (c) TFDA reserves the right to disallow any other words or phrases for product names which in its opinion is misleading, improper or not factual.

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