Doc. No.: TMDA/DMC/MRE/G/012
Revision No. 01

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

GUIDELINES FOR SUBMISSION OF DOCUMENTATION FOR MARKETING AUTHORIZATION OF BIOCIDAL (ANTISEPTICS AND DISINFECTANTS) PRODUCTS

August, 2020

P. O. Box 77150, Mabibo External, Off Mandela Road, Dar es Salaam,
Tel: +255-22-2450512/2450751/ 2452108, Fax: +255-22-2450793, Website: www.tmda.go.tz,
Email: info@tmda.go.tz, Toll Free 0800110084

Table of Contents

Acknowledgements

This is the first revision of the Guidelines for Submission of Documentation for Marketing Authorization of Biocidal (Antiseptics and Disinfectants) Products. The revision has been done in order to address the challenges with regards to the registration requirements for biocidal products.

I would like to acknowledge the support from the management of TMDA for making the process of revising these guidelines successful.

My appreciation are also extended to all TMDA staff who were involved in the revision process of these guidelines and take a forefront to enhance the completion of the document, in particular; Mr. Felchism Apolnary, Ms. Engerasia Mtui, Mr. Alex Juma, Mr. Denis Mwangomo, Dr. Elirehema Mfinanga and Mr. Habibu Saburi for their active participation, compilation and editing of this revised guidelines.

Special thanks are also extended to TMDA esteemed stakeholders; the dealers in antiseptics and disinfectants, whose commendable and constructive inputs have been helpful in the improvement of the revised document.

Hamisallah

Akida M. Khea
Acting Director, Medical Products Control

Foreword

The Tanzania Medicines and Medical Devices Authority (TMDA) was established under the Tanzania Medicines and Medical Devices Act (TMMDA) Cap 219 with the mission of protecting and promoting public health by ensuring quality, safety and effectiveness of medicines including biocidal products, medical devices and diagnostics. One of the core functions of the Authority is to conduct pre-marketing assessment of the regulated products to ensure that they meet quality, safety and efficacy standards before they are registered and allowed to circulate into the market.

In trying to streamline and effectively control biocidal products, TMDA developed the first guidelines in 2015. This first edition has therefore been reviewed to reflect the current situation with regard to the requirements for registration of biocidal products.

According to these guidelines, all biocidal products including antiseptics and disinfectants must obtain a written authorization from TMDA prior to marketing of the products in Tanzania. It is therefore anticipated that all those who will be intending to market antiseptics and disinfectants in Tanzania will have to read these guidelines in order to understand the requirements stipulated hereunder.

The revised guidelines, have adopted a risk based approach and waived some of the requirements for marketing authorization of disinfectants and antiseptics in order to ease the process. Also, there are flexibilities with regards to submission of data for suitability of container closure system; stability; efficacy and safety requirements as compared to the previous edition.

The guidelines will provide understanding to applicants towards meeting the marketing authorization requirements, identifying relevant information required for marketing authorization and therefore facilitate the approval process and consequently avoid unnecessary delays in obtaining approval for these products.

The guidelines will be revised regularly to respond to any new requirements addressing the challenges for marketing authorization process as may arise from time to time in line with the legal framework for marketing authorization of biocidal products in Tanzania.

It is paramount to note that, stakeholders will continue to be given preference to recommend for any change at any time during the execution of these guidelines for improvement and updating of the document.

Adam M. Fimbo
Acting Director General

Introduction

The mandatory requirements for marketing authorization of any products regulated under the Tanzania Medicines and Medical Devices Act, Cap 219, particularly medicines, is provided under section 22 and 51 of the Act. In addition, section 122 (1)(dd) empowers the Minister for the time being responsible for health to make regulations for among other things, marketing authorization of biocidal products. Following these enabling sections, the Authority prepared the guidelines for registration of biocidal products in order to define the scope, the institutional and the objective of the framework for control of safety, quality and effectiveness of biocidal products.

The Authority has revised the First Edition of the guidelines for marketing authorization of biocidal products of February, 2015 and come up with this second edition of 2020. The objective of these revised guidelines is to facilitate the implementation of the regulations aforementioned.

Furthermore, the revised guidelines are devoted to address the new challenges with regards to the registration requirements for biocidal products. Some of these new requirements that have been introduced include simplification of marketing authorization of biocidal products to shorten time taken to obtain approval, to reduce conditions for marketing authorization and to encourage voluntary compliance from applicants.

The revised guidelines are divided into four parts as follows:-

Section 1: General requirements
Section 2: Antiseptic products
Section 3: Disinfectant products
Section 4: Annexes

However, the above relevant section shall be read together with, but not limited to glossary of terms which form part of these relevant and revised guidelines.

Glossary of Terms

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

"Act" means the Tanzania Medicines and Medical Devices Act, Cap 219.

"Active substance" means a biologically or chemically active substance or compound that is intended to be used in the manufacture of a product as an active compound (ingredient).

"Antiseptic" means a product that inactivates, reduces, prevents or arrests growth of microorganisms with the inherent intent to mitigate or prevent disease on the skin or mucous membrane (mouth washes only).

"Applicant" means a person who owns a formula or trademark of a product, who may be a manufacturer or a person to whose order and specifications the product is manufactured, and who shall be the marketing authorization holder and have the primary responsibility of the product on the Tanzanian market.

"Authority" means the Tanzania Medicines and Medical Devices Authority, or the acronym 'TMDA' established by Section 4 of the Act.

"Bactericide" means an antimicrobial agent capable of destroying bacteria, but not necessarily bacterial spores or mycobacteria.

"Biocidal product" means an active substance and preparation containing one or more active substances, put up in the form in which they are supplied to the user, intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means.

"Disinfectant" means an antimicrobial agent capable of destroying pathogenic and potentially pathogenic microorganisms on environmental surfaces and inanimate objects.

"Fungicide" means an antimicrobial agent capable of destroying fungi, including their spores.

"Manufacturer" means a person or firm that is engaged in the manufacture of antiseptic or disinfectant product(s).

"Mycobactericide" means an antimicrobial agent capable of destroying mycobacteria.

"Persistence' means a claim that the product will deliver a longer action than only the immediate reduction of microorganisms.

"Pharmacopoeia" means current edition of United States Pharmacopoeia (USP), British Pharmacopoeia (B.P.), European Pharmacopoeia (Ph. Eur), The International Pharmacopoeia (Int. Ph) and Japanese Pharmacopoeia.

"Product variants" means a range of products produced by the same manufacturer in the same site, similar in composition and intended for the same use but available in different colours, fragrances and flavours.

"Product" means antiseptic or disinfectant.

"**Marketing authorization holder**" means the holder of the marketing authorization for the biocidal products.

"**Registrant (Market Authorization Holder)**" means any person who may either be the trademark owner or person authorized by him, who has rights to sale the product and is responsible for placing the product on the Tanzanian market.

"Rubs" means antiseptic products to be used without water.

"Specifications" means the combination of physical, chemical, biological and microbiological test requirements that determine whether antiseptic or disinfectant product is suitable for the intended use.

"Sporicide" means an antimicrobial agent capable of destroying bacterial spores.

"Sterilant" means a chemical agent which is used to sterilize medical devices.

"Virucide" means an antimicrobial agent capable of destroying viruses.

"Washes" means antiseptic products to be used with water.

SECTION 1: GENERAL REQUIREMENTS

1.1 Who can apply and how to apply for marketing authorization of a disinfectant or antiseptic product in Tanzania

(a) An application for marketing authorization of a disinfectant or antiseptic shall be made by an applicant who intends to sell any disinfectant or antiseptic in Tanzania. An applicant can be any person who is a resident of Tanzania or a company incorporated in Tanzania and owns a formula or trademark of a product, who may be a manufacturer or a person to whose order and specifications the product is manufactured, and who shall be the marketing authorization holder and have the primary responsibility of the product on the Tanzanian market.

(b) Apply for marketing authorization of the product to the Authority by submitting a duly filled in application form as provided in **Annex I** of these guidelines accompanied with two (2) samples of smallest commercial packs of the product. The submission shall be made electronically through TMDA online application system.

(c) Submit separate application for each product or product variant.

(d) Every application shall be accompanied by appropriate fees as specified in the Fees and Charges Regulations in force at the time of application. Any application that will not be accompanied by appropriate fees will not be accepted.

1.2 The authority shall grant marketing authorization of a disinfectant or antiseptic if it is satisfied that:-

(a) The availability of that antiseptic/disinfectant is in the public interest;
(b) The disinfectant or antiseptic intended to be registered is of acceptable quality, safety and efficacy;
(c) the premises and manufacturing facility have been licensed to manufacture by the Authority;
(d) It complies with any other requirements as may be prescribed by the Authority

1.3 The Authority may during assessment of application require the applicant to submit additional samples, documents, and information and give clarification as the case may be. The processing of an application shall be kept on hold until such samples, documents, information or clarification is provided.

1.4 If the applicant fails to respond to the issues in sub section 1.3 above within 60 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. The

Authority after being satisfied that the product complies with requirements prescribed in these guidelines will register the product, inform the applicant via email that the product has been granted market authorization and issue the registration certificate.

1.5 Where the Authority refuses to approve the marketing authorization of a product; it shall notify the applicant in writing of such decision and the reason(s) thereof.

1.6 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 grant market authorization to the product or if not satisfied it will uphold its initial decision.

1.7 The market authorization of a product shall be valid for five (5) years unless suspended, cancelled or revoked by the Authority or withdrawn by a registrant.

1.8 For each registered product an annual retention fees as prescribed in the Fees and Charges Regulations shall be paid on or before the end of January of each year for which the fees are due.

1.9 If for any reason the registrant changes any matter related to a registered 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 change. The notice to the Authority shall be submitted in a filled application form provided as **Annex 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.

1.10 The Authority will evaluate reasons provided in the notice referred to under sub section 1.9 and if satisfied with such reasons it will approve the changes by issuing approval notice. If not satisfied the Authority will not approve the changes and it will notify the registrant the reasons thereof.

1.11 The registrant may at any time by giving notice in writing to the Authority withdraw the market authorization of the registered product.

1.12 Applications for renewal of market authorization shall be made at least 30 days before the expiry of existing market authorization by submitting the following through TMDA online application system:-

(a) Dully filled in application form for renewal of market authorization as outlined in **Annex III** of these guidelines.

(b) Two (2) samples of the smallest commercial packs from the same batch along with batch certificates of analysis.

(c) Non refundable application fees as specified in the Fees and Charges Regulations.

1.13 Every registrant shall be responsible for:-

(a) All information supplied in support of the application for market authorization and variation thereof.

(b) Ensuring safety, quality and efficacy of the registered product and that the product at all times complies with all requirements as provided in these guidelines.

(c) Effect voluntary and compulsory product recall whenever necessary.

(d) Observation of sanitation and hygiene in manufacturing premises and equipment.

1.14 Local technical Representative

Shall be responsible for facilitating communication with the Applicant and when the product is registered shall assume all legal responsibilities.

SECTION 2: ANTISEPTIC PRODUCTS

These guidelines do not apply to human-use topical products with medicinal claim.

2.1 Documentation requirements for marketing authorization

Documents to be included under this section should include information to demonstrate quality, efficacy and safety of the biocidal product.

2.1.1 Manufacturing and marketing authorization

Submit a valid Manufacturing license of manufacturing site of the product. Submit a Marketing Authorization to demonstrate that the product is registered or licensed in the country of origin.

2.1.2 Chemistry, Manufacturing and Controls

2.1.2.1 Chemistry

(a) Active substance should be identified by its non-proprietary name, chemical name and CAS number (if available).

(b) The formulation of a commercial pack and production scale batch should be provided in tabular form as indicated in the application form. This information should be in the form of a quantitative listing of all ingredients used in its manufacture and in the final product formulation, taking into account that the percentage of the chemical formulation components should add up to 100%.

2.1.2.2 Manufacturing process

(a) Describe all stages involved in the manufacture of the finished product. This shall be in the form of a detailed narrative and a simplified flow diagram accompanied by a list of equipment used at each stage. Basic principles involved should be clearly set out from dispensing to packaging. All stages should be illustrated i.e. filling, weight checking, labelling, packing in hardboard and sealing. All steps involved and their operations should be carefully described including the conditions subjected to each operation i.e. temperature, pH adjustments, processing time etc.

(b) Provide the manufacturing and packaging records.

2.1.2.3 Quality control

2.1.2.3.1 Specifications and analytical methods

Summarized specifications of the final product should be provided, i.e. the acceptable limits of the entire physical, chemical, biological and (where applicable) microbiological parameters.

Specification should include but not limited to:-

(a) Description
(b) Identity - test method should be specific for active substance(s)
(c) Assay - test method should be specific and stability indicating for active substance(s)

A full description of analytical and other control procedures carried out to ascertain the final product specifications stated above should be given.

Provide a copy of certificate of analysis of at least one batch of finished product.

2.1.2.3.2 Stability studies

The proposed shelf life should be justified by submission of stability data.

2.1.3 Efficacy and Safety

Submission of efficacy and safety data may be exempted from application of market authorization provided the product uses the known active ingredient at the concentration which has been established for the purpose of disinfection.

2.1.4 Data to support specific claims

2.1.4.1 Specific indications

If not specifically stated an antiseptic product will be considered to be antibacterial. If specifically indicated that the product is fungicides, virucides, sporocides or mycobacterides, evidence to support such a claim should be submitted.

2.1.4.2 Persistence claims

Persistence is defined as a claim that the product will deliver a longer action than only the immediate reduction of microorganisms on hands. Persistence claims for personal use products can only be made relative to bacteria. Should an applicant wish to make persistence claims against other organisms, a supporting scientific rationale outlining an appropriate test method should be provided (e.g. technology used or special formulation).

Professional-use surgical scrubs and preoperative patient skin preparations must demonstrate a minimum persistence of at least six (6) hours.

2.1.4.3 Time kill claims

Antiseptic products are expected to have a minimum time-to-effect of 30 seconds (for waterless hand rubs) to 1 minute (for washes or scrubs using water) upon completion of application according to the proposed directions for use. A claim that a product is fast-acting would have to be demonstrated by submission of relevant clinical studies.

2.1.4.4 Sterility

Any product claimed to have a sterilizing effect must be demonstrated with supporting data for such claim.

2.1.5 Container/closure system(s) and other packaging

The suitability of the container closure system(s) used for the storage, transportation (shipping) and use of the final product should be discussed.

2.1.6 Labelling

All antiseptic products intended to be sold in Tanzania must be labelled in English and/or Kiswahili. The applicant should provide art-work of the proposed label of the antiseptic product.

A label should contain a minimum of the following information:-

(a) Name of the product
(b) Active substance: the identity and concentration of each active substances
(c) Declaration of the net content
(d) Declaration of the batch number
(e) Name and address of the manufacturer
(f) Inclusion of appropriate symbols and cautionary statements
(g) Manufacturing date
(h) Expiry date
(i) Storage conditions
(j) Precautions and warnings
    i. For external use only. Do not ingest.
    ii. Avoid contact with the eyes.
    iii. Discontinue use and consult a health care practitioner if irritation and redness develops.
    iv. Keep out of reach of children.
    v. Flammable: Keep away from flame and heat (*if applicable*)

SECTION 3: DISINFECTANTS

3.1 Classification of Disinfectants

For the purpose of these guidelines disinfectants are classified based on the risk level of the device on which the product is intended to be used on as shown in the table below:

Table No. 3: Classifications of disinfectants

Disinfectant class	**Risk level of device**	**Device definition**	**Definition of disinfectant class**
Gaseous sterilant and critical device sporicide, also referred to as critical sporicide	Critical	Present a high risk of infection if they are not sterile, i.e. contaminated with any organism, including spores. Routinely penetrate the skin or mucus membranes into normally sterile areas of the body (e.g., implants, scalpels, needles, surgical instruments, laparoscopes), or come into direct contact with recalculating body fluids, (e.g., kidney dialysis tubing and dialyzers, or blood oxygenators).	A disinfectant which helps achieves sterilization.
High-level Disinfectant.	Semi critical	Contact with mucous membranes during use but do not usually penetrate normally sterile areas of the body, e.g. endoscopes, anesthesia breathing circuits, respiratory therapy equipment, dental mirrors, etc…	A disinfectant that kills all microbial pathogens, except Large numbers of bacterial endospores according to labeling.
Intermediate level.	Non critical	Contact only intact skin during routine Use, e.g. stethoscopes, bedpans, etc...	A disinfectant that kills all microbial pathogens, except bacterial endospores, when used according to labelling.
Low-level Disinfectant.			A disinfectant that kills pathogenic and potentially pathogenic microorganisms on hard

Disinfectant class	Risk level of device	Device definition	Definition of disinfectant class
			non-porous inanimate surfaces or inanimate objects, when used according to labelling. Veterinary hygiene biocide products are used for veterinary hygiene purposes including products used in areas in which animals are housed, kept or transported.

3.2 Documentation requirements for market authorization

Documents to be included under this section should include information to demonstrate quality, efficacy and safety of the product.

3.2.1 Manufacturing and marketing authorization

Submit a valid Manufacturing license of manufacturing site of the product. Submit a Marketing Authorization to demonstrate that the product is registered or licensed in the country of origin.

3.2.2 Chemistry, Manufacturing and Controls

3.2.2.1 Chemistry

(a) Active substance should be identified by its non-proprietary name, chemical name and CAS number (if available).

(b) The formulation of a commercial pack and production scale batch should be provided in tabular form. This information should be in the form of a qualitative and quantitative listing of all ingredients used in its manufacture and in the final product formulation, taking into account that the percentage of the chemical formulation components should add up to 100%.

3.2.2.2 Manufacturing process

(a) Describe all stages involved in the manufacture of the finished product. This shall be in the form of a detailed narrative and a simplified flow diagram accompanied by a list of equipment used at each stage. Basic principles involved should be clearly set out from dispensing to packaging. All stages should be illustrated i.e. filling, weight checking, labelling, packing in hardboard and sealing. All steps involved and their operations should be carefully described including the conditions subjected to each operation i.e. temperature, PH adjustments, processing time etc.

(b) Provide the manufacturing and packaging records.

3.2.2.3 Quality control

3.2.2.3.1 Specifications and analytical methods

Summarized specifications of the final product shall be provided, i.e. the acceptable limits of the entire physical, chemical, biological and (where applicable) microbiological parameters.

Specification should include but not limited to:-

(a) Description
(b) Identity - test method should be specific for active substance(s)
(c) Assay - test method should be specific and stability indicating for active substance(s)

A full description of analytical and other control procedures carried out to ascertain the final product specifications stated above should be given.

Provide a copy of certificate of analysis of at least one batch of finished product.

3.2.2.3.2 Stability studies

The proposed shelf life should be justified by submission of stability data.

3.2.3 Efficacy and Safety

Submission of efficacy and safety data may be exempted from application of registration provided the product uses the known active ingredient at the concentration which has been established for the purpose of disinfection.

3.2.4 Container/closure system(s) and other packaging

The suitability of the container closure system(s) used for the storage, transportation (shipping) and use of the final product should be discussed.

3.2.5 Labelling

All disinfectant product intended to be sold in Tanzania must be labelled in English and/or Kiswahili. The applicant should provide art-work of the proposed label of the disinfectant product.

A label should contain a minimum of the following information:-

(a) Name of the product
(b) Active substances: the identity and concentration of each active substance
(c) Net contents.
(d) Batch number
(e) Name and address of the manufacturer
(f) Inclusion of appropriate symbols and cautionary statements such as for pressurized metal cans
(g) Expiry date
(h) Storage conditions
(i) Intended use
(j) Directions for use
(k) Precautions and warnings
    i. For external use only. Do not ingest.
    ii. Avoid contact with the eyes.
    iii. Discontinue use and consult a health care practitioner if irritation and redness develops.
    iv. Keep out of reach of children.
    v. Flammable: Keep away from flame and heat (*if applicable*)

SECTION 4: ANNEXES

Annex I

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

APPLICATION FORM FOR MARKETING AUTHORIZATION OF BIOCIDAL (ANTISEPTIC/ DISINFECTANT) PRODUCT

General Instructions:

Please read all the instructions carefully prior to completing this Application form.

Provide as much detailed, accurate and final information as possible. Note that all areas are to be filled out by the applicant EXCEPT where indicated by grey areas which are for TMDA Official Use Only!

Please state the exact location (Annex number) of any appended documents in the relevant sections of the form.

A properly filled out and signed original copy of the application form with all its annexes must be submitted together with the product dossier. The entire dossier should be submitted electronically through TMDA online application system.

(This document should be submitted in word format)

Application Number	
Date of submission of the dossier	
Number of files	
Name of First Assessor	
Name of Second Assessor	
Date of first Assessment	
Date of second Assessment	
Outcome of the assessment	

1.0 ADMINISTRATIVE INFORMATION	
1.1	Type of the product application (tick as appropriate) Antiseptic ☐ Disinfectant ☐
1.2	Proprietary Name of the product
1.3	Generic name of the product
1.4	Name and strength of active substance(s)
1.5	Name and address (physical and postal) of Applicant and Local Technical Representative
1.5.1	Name and address (physical and postal) of Applicant
	(Company) Name: Address: Country: Telephone: Telefax: E-Mail:
1.5.2	Name and address (physical and postal) of Local Technical Representative
	(Company) Name: Address: Country: Telephone: Telefax: E-Mail:
1.6.	Form of the product: ☐Solution ☐Suspension ☐Gel ☐Aerosol ☐Emulsion ☐Gaseous ☐Powder ☐Bar ☐Tablet ☐ Cream ☐Others – specify....
1.6.1	Intended use:
1.7	Packing/pack size:
1.8	Visual description
1.9	Proposed shelf life (in months):
1.9.1	Proposed shelf life (after reconstitution or dilution):
1.9.2	Proposed shelf life (after first opening container):
1.9.3	Proposed storage conditions:
1.9.4	Proposed storage conditions after first opening:
1.10	Other sister products registered or applied for marketing authorization
1.10.1	Do you hold Marketing Authorization (s) of other product (s) containing the same active substance (s) in the TMDA? Yes/No If yes state; Product name (s), strength (s),

	pharmaceutical form (s): Indication(s):
1.10.2	Have you applied for Marketing Authorization medicinal product (s) containing the same active substance (s) in the TMDA? Yes/No If yes state; Product name (s), strength (s), pharmaceutical form (s): Indication(s):
1.11	Distribution category: Pharmacy Only ☐ General sale ☐ Others☐
1.12	Country of manufacture:
1.13	Product Marketing Authorisation in the country of manufacture. If not registered/licensed state reasons

☐Authorised Country: Date of authorisation (dd-mm-yyyy): Proprietary name: Authorisation number: ☐ Refused Country: Date of refusal (dd-mm-yyyy): Reason for Refusal:	☐ Withdrawn (by applicant after authorisation) Country: Date of withdrawal (dd-mm-yyyy): Proprietary name: Reason for withdrawal: ☐ Suspended/revoked (by competent authority) Country: date of suspension/revocation (dd-mm-yyyy): Reason for suspension/revocation: Proprietary name:

1.14	Name(s) and complete physical address(es) of the manufacturer(s)
1.14.1	Name(s) and physical address (es) of the manufacturing site of the finished product.

Company name:
Physical address:
Postal address:
Country:
Telephone:
Telefax:
E-Mail:

1.14.2	Name(s) and physical address(es) of the manufacturer(s) of the active substance(s)

Company name:
Physical address:
Postal address:
Country:
Telephone:
Telefax:
E-Mail:

1.15	Qualitative and Quantitative composition (active substance (s) and excipient(s) A note should be given as to which quantity the composition refers (e.g. ml or g).

Name of active substance(s)*	Reference/monograph standard	Quantity /unit (ml, g)	Quantity per batch	Reasons of inclusion
1.				
2.				
3.				
e.t.c				
Name Excipient(s)				
1.				
2.				
3				
e.t.c				

2.0 LABELLING

3.0 SUMMARIES

Provide condensed summaries of the key quality, efficacy and safety information from the product dossier. The summaries should include sufficient information from each section of the product dossier to provide an overview of the information submitted in the product dossier. The summaries should also emphasize critical key parameters of the product and provide discussion of key issues that integrates information from sections in the product dossier.

Chemistry, Manufacturing and Controls

	Chemistry
	Manufacturing process
	Quality control
	Specifications and analytical methods
	Stability studies

Efficacy and Safety

	Efficacy
	Safety

Data to support specific claims (for antiseptics)

	Products used in professional food premises
	Log reduction claims
	Persistence claims
	Time kill claims
	Sterility

4.0 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.
I also agree that I shall carry out vigilance to monitor the safety of the product in the market and provide safety update reports to TMDA.
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:……..

* Note: If fees have been paid, attach proof of payment

Issues to be communicated to the applicant

Annex II

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

APPLICATION FORM FOR VARIATION OF A REGISTERED BIOCIDAL (ANTISEPTIC/DISINFECTANT) PRODUCT

General Instructions:

Please read all the instructions carefully prior to completing this Application form.

Provide as much detailed and accurate information as possible. Note that all areas are to be filled out by the applicant EXCEPT where indicated by grey colour which are for TMDA Official Use Only!

All parts of the dossier that are affected by a variation shall be resubmitted according to the structure of the Guidelines on Application for Marketing authorization of Biocidal (Antiseptics and Disinfectants) products. Moreover, any further documentation required along with the change should be appended.

Summary(ies) of the intended change(s) should be presented in tabulated format in which the current state/situation and the situation after the intended change are compared in order to outline the scope of the change in a transparent manner. A justification should always follow why the change needs to be introduced.

A properly filled out and signed original copy of the variation application form with all its annexes must be submitted together with the product dossier. The entire dossier should be submitted electronically through TMDA online application system.

(This document should be submitted in word format)

Marketing authorization Number	
Date of submission of the dossier	
Number of files	
Name of Assessor	
Date of Assessment	
Outcome of the assessment	
1.0 ADMINISTRATIVE INFORMATION	
1.1	Type of the product application (tick as appropriate) Antiseptic ☐ Disinfectant ☐
1.2	Proprietary Name of the product
1.3	Generic name of the product
1.4	Name and strength of active substance(s)
1.5	Name and address (physical and postal) of Applicant
(Company) Name: Address: Country: Telephone: Telefax: E-Mail:	
1.5.1	Form of the product: ☐Solution ☐Suspension ☐Gel ☐Aerosol ☐Emulsion ☐Gaseous ☐Powder ☐Bar ☐Tablet ☐ Cream ☐Others – specify....
1.5.2	Intended use:
1.6	Packing/pack size:
1.7	Visual description
1.8	Proposed shelf life (in months):
1.8.1	Proposed shelf life (after reconstitution or dilution):
1.8.2	Proposed shelf life (after first opening container):
1.8.3	Proposed storage conditions:
1.8.4	Proposed storage conditions after first opening:
1. 9	Country of manufacture:
1.10	Name(s) and physical address (es) of the manufacturing site of the finished product.
Company name: Physical address: Postal address: Country: Telephone: Telefax: E-Mail:	
2.0 VARIATIONS	
2.1	Changes made to the product
2.2	Description of the changes
2.3	Justification for changes
3.0 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:…….. * Note: If fees have been paid, attach proof of payment

Annex III

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

APPLICATION FORM FOR RENEWAL OF MARKETING AUTHORIZATION OF BIOCIDAL (ANTISEPTIC/ DISINFECTANT) PRODUCT

General Instructions:

Please read all the instructions carefully prior to completing this Application form.

Provide as much detailed, accurate and final information as possible. Note that all areas are to be filled out by the applicant EXCEPT where indicated by grey areas which are for TMDA Official Use Only!

This application form should be accompanied by a Batch Manufacturing Record (BMR) & Batch Packaging Record of one recently manufactured production scale batch.
Please attach as an annex for any other document if applicable.

A properly filled out and signed original copy of the renewal application form with all its annexes must be submitted together with the product dossier. The entire dossier should be submitted electronically through TMDA online application system.

(This document should be submitted in word format)

Marketing authorization Number	
Date of submission of the dossier	
Number of files	
Name of Assessor	
Date of Assessment	
Outcome of the assessment	

1.0 ADMINISTRATIVE INFORMATION	
1.1	Type of the product application (tick as appropriate) Antiseptic ☐ Disinfectant ☐ Medicated Soap ☐
1.2	Proprietary Name of the product
1.3	Generic name of the product
1.4	Name and strength of active substance(s)
1.5	Name and address (physical and postal) of Applicant
(Company) Name: Address: Country: Telephone: Telefax: E-Mail:	
1.5.1	Form of the product: ☐Solution ☐Suspension ☐Gel ☐Aerosol ☐Emulsion ☐Gaseous ☐Powder ☐Bar ☐Tablet ☐ Cream ☐Others – specify....
1.5.2	Intended use:
1.6	Packing/pack size:
1.7	Visual description
1.9	Proposed shelf life (in months):
1.9.1	Proposed shelf life (after reconstitution or dilution):
1.9.2	Proposed shelf life (after first opening container):
1.9.3	Proposed storage conditions:
1.9.4	Proposed storage conditions after first opening:
1.10	Distribution category: Pharmacy Only ☐ General sale ☐ Others☐
1.11	Country of manufacture:
1.12	Product Marketing Authorisation in the country of manufacture. If not registered/licensed state reasons

☐Authorised Country: Date of authorisation (dd-mm-yyyy): Proprietary name: Authorisation number: ☐ Refused Country: Date of refusal (dd-mm-yyyy): Reason for Refusal:	☐ Withdrawn (by applicant after authorisation) Country: Date of withdrawal (dd-mm-yyyy): Proprietary name: Reason for withdrawal: ☐ Suspended/revoked (by competent authority) Country: date of suspension/revocation (dd-mm-yyyy): Reason for suspension/revocation: Proprietary name:

1.13	Name(s) and complete physical address(es) of the manufacturer(s)

1.13.1	Name(s) and physical address (es) of the manufacturing site of the finished product.

Company name:
Physical address:
Postal address:
Country:
Telephone:
Telefax:
E-Mail:

1.13.2	**Name(s) and physical address(es) of the manufacturer(s) of the active substance(s)**

Company name:
Physical address:
Postal address:
Country:
Telephone:
Telefax:
E-Mail:

1.14	Qualitative and Quantitative composition (active substance (s) and excipient(s) A note should be given as to which quantity the composition refers (e.g. ml or g).

Name of active substance(s)*	Reference/mono graph standard	Quantity /unit (ml, g)	Quantity per batch	Reasons of inclusion
1.				
2.				
3.				
e.t.c				
Name Excipient(s)				
1.				
2.				
3				
e.t.c				
2.0 LABELLING				

3.0 VARIATION

Submit summaries of all variations made to the product from last date of marketing authorization.

4.0 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. I also agree that I shall carry out vigilance to monitor the safety of the product in the market and provide safety update reports to TMDA. 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:…….. * Note: If fees have been paid, attach proof of payment
Issues to be communicated to the applicant	