APPLICATION FORM FOR RENEWAL OF REGISTRATION OF ANTISEPTICS/ DISINFECTANTS

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Proprietary name: Authorisation number: ☐ Refused Country: Date of refusal (dd-mm-yyyy): Reason for Refusal:	☐ Withdrawn (by applicant after authorisation) Country: Date of withdrawal (dd-mm-yyyy): Proprietary name: Reason for withdrawal: ☐ Suspended/revoked (by competent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

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

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