Application form

The Medicines and Allied Substances Act, 2013 (Act No.3 of 2013)

APPLICATION FOR GRANT OF MARKETING AUTHORISATION OF COSMETICS FOR USE IN ZAMBIA

For Official Use
Application number

PART I: PARTICULARS OF THE APPLICANT

Applicant	Name: Physical and Postal Address: Phone: Fax: Email:
Contact Person[1]	Name: Designation: Phone: Fax: Email:
Local Responsible Person[2]	Name: Designation: Phone: Fax: Email:

1 *Contact person will be responsible for communicating with the Authority and a letter of Authorisation to communicate on behalf of the applicant should be submitted.*

2 *Should be a person, resident in Zambia, appointed by a foreign-based applicant to be responsible for all matters in respect of products granted marketing authorisation with Power of Attorney..*

PART II: PARTICULARS OF THE COSMETICS

Manufacturers	Name: Physical and Postal Address: Phone: Fax: Email:
Name and address of manufacturing Site	Name: Physical and Postal Address: Phone: Fax: Email:
Number of samples of the products submitted	
Generic name of the product *(Where applicable)*	
Brand name of the product	
Product composition per total quantity e.g. per 100mls	
Recommended Shelf Life	
Recommended shelf life (for multi-dose after first opening of container)	
Recommended shelf life (after reconstitution, where applicable)	
Storage conditions	
Container closure	
Special user instructions and pre-cautions (where applicable)	
Intended use of the product	
Category of Distribution	☐ General Sale ☐ Pharmacy

Have there been any of the following:	☐ Previous recalls ☐ Reportable adverse incidents ☐ Banning in other countries ☐ Post-market surveillance studies ☐ Any other relevant safety information
Please provide details on each item you have ticked (attach any relevant documentation)	
International or national standards with which the product complies (enclose a copy)	
List of SADC states where the product has obtained marketing approval (Attach documentation)	

PART III: PRODUCT COMPOSITION

List of all components of the finished products and their amounts on a per unit, batch and percentage basis including individual components of mixtures prepared in-house and overages, if any					
Ingredients and quality standard	**Function (reason for inclusion)**	**Strength (Label Claim)**			
		Quantity per unit dosage form (e.g. mg/Tablet)	**% per unit dosage form**	**Quantity per batch**	**% per batch**
Contents					

Subtotal 1					
NA					
Subtotal 2					
Total					

Attachments to accompany the application:

1. **Mock -up of the packaging and labeling of the product.**
2. **Product information i.e product descriptions, indications, methods of use, etc**
3. **A complete dossier prepared in compliance with the guidelines for grant of marketing authorization of cosmetics.**

PART IV: DECLARATION AND SIGNATURE

I declare that all the information I have stated in this application is correct and truthful to the best of my knowledge and belief. I understand that submission of false information shall render the application void and that if approval is granted, the market authorisation may be revoked.

Particulars of the Person Signing on Behalf of the Applicant

c) Name: ……..

e) Signature: …… d) Date: …/…/……. *(dd/mm/yyyy)*

The Medicines and Allied Substances Act, 2013(Act No.3 of 2013)

GRANT OF MARKETING AUTHORISATION FOR COSMETICS FOR HUMAN USE IN ZAMBIA

(ABBREVIATED PRODUCT DOSSIER FORMAT)

<table>
<tr><td>No.</td><td>PRODUCT INFORMATION</td></tr>
<tr><td>1.</td><td>Brand name of Cosmetic</td></tr>
<tr><td></td><td></td></tr>
<tr><td>2.</td><td>Generic name of Cosmetic</td></tr>
<tr><td></td><td></td></tr>
<tr><td>3.</td><td>Cosmetic Description
Provide a general description of the Cosmetic. The description should also include the following:
a) Product description:White
b) Container Closure System:Lami Tune
c) Pack sizes:20ml;50ml;100ml</td></tr>
<tr><td>4.</td><td>Quantitative and Qualitative Composition
<table><tr><td>SN</td><td>INN NAME</td><td>Chemical Name</td><td>Reference Standard</td><td>Quantity Per Unit (g/mg)</td><td>Quantity Per Batch (g/kg)</td><td>% Proportion</td><td>Reason for Inclusion</td></tr><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table></td></tr>
<tr><td></td><td></td></tr>
<tr><td>5.</td><td>Certificates
Provide:
a) original Free Sale Certificate specifically address to Zambia (notarized copies are acceptable)
b) Manufacturing Licence of the manufacturer
c) Documentary proof of compliance to ISO 22716
d) Documentary proof of registration for the product in other countries specifically those in the SADC region</td></tr>
</table>

6.	**State the intended use of the Cosmetic**
7.	**Intended User**
8.	**Cosmetic Shelf-life (in months)**
9.	**Directions for Use**
10.	**Sample label (mock -up)**
11.	**Storage conditions**
12.	**Name and address of Applicant**
13.	**Name and address of authorised local distributor** *(Provide original letter of authorisation)*
14.	**Name, contact details and address of appointed local responsible person** *(include valid power of attorney)*
15.	**Complete name(s) and address(es) of the manufacturing site(s) of the Cosmetic**
16.	**Contract of manufacture (where applicable)**
17.	**Two (2) samples of the product in the smallest commercial pack size**

ZAMBIA MEDICINES REGULATORY AUTHORITY

MARKETING AUTHORISATION SECTION

ALLIED SUBSTANCES UNIT

Dossier Submission Checklist – COSMETICS

A completed copy of the checklist should be included in the dossier.

1. Supporting documents

Supporting documents	**Yes (Y)/ No (N)/ Not applicable (N/A)**	**Comment**	***For ZAMRA Use Only***
Letter of application (cover letter)			
Proof of payment			
Samples (2)			
Samples CoA			
Free Sale Certificate			
GMP Certificate and Manufacturing License			
Package insert(where applicable) /Directions for use			
Product Label (Mock up cartons)			

2. Dossier

SECTIONS	Description	Yes (Y) No (N)	Comment	*For ZAMRA Use Only*
SECTION 1	Administrative information on duly completed and signed Application form			
SECTION 2 Subsections 2.1 – 2.13	Product Details			
Part I	Administrative Documents and Product Summary			
Part II	Raw Materials Quality Data (Specification)			
Part III	Quality Data of Finished Product			
Part IV	Safety Data			
Part V	Labelling and Packaging			

For official use

Date of Submission: _____ **Application number:** _____

Number of Binders: _____ **Payment Receipt number:** _____

Application Complete (Proceed for Evaluation) ☐

Application Deficient (Refer to applicant for additional information) ☐

DECLARATION

I declare that all the information I have stated is correct and truthful to the best of my knowledge and belief.

Particulars of the person signing on behalf of the applicant

a) Name:

……

b) Designation:

……

Signature: …… d) Date: …/…/……. *(dd/mm/yyyy)*

SUPPORTING DOCUMENTS – IMPORTATION OF COSMETICS

FOLLOWING THE EFFECT OF THE REGULATION OF COSMETICS, THE FOLLOWING ARE THE SUPPORTING DOCUMENTS TO ACCOMPANY AN IMPORT PERMIT APPLICATION.

1. **SIGNED DECLARATION ON RESTRICTED AND PROHIBITED SUBSTANCES NOT BEING CONTAINED IN PRODUCT(S) TO BE IMPORTED**

2. **WHERE AVAILABLE, THE MATERIAL SAFETY DATA SHEET (MSDS) FOR RESPECTIVE INGREDIENTS**

3. **INVENTORY LIST OF PRODUCTS STATING QUANTITATIVE COMPOSITION OF INGREDIENTS**

4. **DETAILS OF MANUFACTURER AND MANUFACTURING SITE ADDRESS**