LEGAL PRACTITIONERS

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LEGAL ALERT

GUIDELINES ON THE APPLICATION FOR GRANT OF MARKETING AUTHORIZATION OF COSMETICS IN ZAMBIA

Introduction

On 22 March 2023, the Zambia Medicines Regulatory Authority ("**ZAMRA**") published the Guidelines on the Application for Grant of Marketing Authorization of Cosmetics in Zambia (the "**Guidelines**"). The Guidelines are issued pursuant to section 68 of the Medicines and Allied Substances Act No. 3 of 2013 ("**MASA**") and came into effect on 9 September 2024. This article outlines the key processes an applicant must follow when applying for marketing authorization for cosmetic products in Zambia.

Marketing Authorization for Cosmetic Products

The MASA defines a "cosmetic" as any substance manufactured or sold for use in cleansing, beautifying, or altering the hair, eyes, teeth, nails, or complexion of the skin. This includes deodorants and perfumes. Section 39(1) of MASA prohibits any person from placing on the market, advertising, marketing, manufacturing, selling, importing, supplying, administering, or dealing with any medicine or allied substance (including cosmetics) without a marketing authorization issued by ZAMRA. Section 39(2) further mandates that anyone intending to undertake such activities must apply to ZAMRA for marketing authorization in the prescribed manner and form provided under the Guidelines.

Categories of Cosmetics Recognized under the Guidelines

The Guidelines recognize a wide range of cosmetic products, including but not limited to:

- Creams, emulsions, lotions, gels, and oils for the skin;
- Face masks, including chemical peeling products;
- Tinted bases (e.g., liquids, pastes, powders);
- Make-up powders and after-bath powders;
- Pure glycerin;
- Toilet soaps and deodorant soaps;
- Perfumes, toilet waters, and eau de Cologne;
- Deodorants and anti-perspirants;
- Hair products;
- Shaving products (e.g., depilatories, creams, foams, lotions, waxes);
- Aftershave products;
- Make-up and make-up removers for face and eyes;
- Products for care of the teeth and mouth;
- Nail care and makeup products;
- Products for external intimate hygiene;
- Sunbathing products and self-tanning products;
- Anti-wrinkle products;
- Sunscreen products; and
- Cosmetic glue (for hair, eyelashes, and nails).

General Requirements

Applicants must submit their application using the form indicated in Annex II of the Guidelines (the "**Application Form**"). The Application Form requires the following details:

- Applicant name, contact person, and local responsible persons;
- Brand name and generic name of the cosmetic;
- Product description, including container closure system and pack sizes;
- Quantitative and qualitative composition.
- The application must also be accompanied by a product dossier.

Product Dossier

A product dossier is the collection of the various documents and data (including

Regulatory Data and Regulatory Documentation) concerning the research, development, manufacture, safety, quality and efficacy of a product submitted for marketing authorisation. It is divided into five parts:

1. Administrative Documents and Product Summary:

- Administrative documentation;
- Qualitative and quantitative composition;
- Product presentation;
- Summary of safety report;
- On-pack product claim support.

2. Raw Materials Quality Data:

- Specifications and analytical test methods of raw materials;
- Safety data of raw materials;
- Colorants, preservatives, and UV filters.

3. Quality Data of Finished Product:

- Product composition;
- Manufacturing details;
- Quality specifications and analytical test methods of the finished product;
- Container closure system specifications;
- Stability data.

4. Safety Data:

- Safety assessments;
- Declarations on freedom from transmissible spongiform encephalopathies (TSE), bovine spongiform encephalopathy (BSE), and asbestos;
- Safety claims;
- Efficacy assessments.

5. Labelling and Packaging:

- Compliance with Section 50 of the Competition and Consumer Protection Act No. 24 of 2010 and ISO 22715 standards for cosmetics.

Application Requirements

A complete application must include:
Cover letter from the applicant;

- Duly completed and signed application form;
- Proof of payment of the prescribed application fee;
- At least two samples of the cosmetic in the smallest commercial pack with English labelling;
- Duly completed checklist (Annex 1);
- Product dossier.

Applicants must submit their applications electronically in a selectable or editable PDF format through the ZAMRA online portal. Product variants such as fragrance, color, or flavor require separate applications. The registration cost for marketing authorization is USD 500 per product.

Deficiencies in applications must be rectified within 60 days of receiving a request for additional information, failing which the application will be rejected. Marketing authorizations are valid for five years, after which amendments require ZAMRA approval.

Retention Fees

Marketing authorization holders must pay an annual retention fee by 31 December each year. The fees are **ZMW 1,333.20** (approximately **USD 50.31**) for locally manufactured cosmetics and USD 200 for imported products. Failure to pay may result in suspension or revocation of the authorization.

Renewal of Marketing Authorization

Renewals must be applied for at least six months before the expiration of the authorization. Fees are **ZMW 1,600** (approximately **USD 61.54**) for locally manufactured products and USD 350 for imported products.

Appeals

Aggrieved applicants may appeal ZAMRA decisions under Section 56 of the MASA. Appeals must be made to the Minister within 30 days of the decision.

Conclusion

The Guidelines provide a structured framework for ensuring the safety and quality of cosmetics on the Zambian market. By adhering to these requirements, applicants can facilitate compliance and support the regulation of cosmetics for consumer protection. It is imperative for stakeholders in the cosmetics industry to familiarize themselves with these procedures to ensure seamless application and adherence to Zambian regulatory standards.

We hope you found this alert useful. Please contact our Corporate Advisory Partner and Associate, Jacqueline Jhala at JJhala@corpus.co.zm and Dalitso Ng'ona at DNg'ona@corpus.co.zm respectively, if you have any questions relating to this alert.

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