ctfa
COSMETIC TOILETRY & FRAGRANCE ASSOCIATION OF SOUTH AFRICA

28 July 2020

To:
Mr Alex Gisagara
cc: Dr Charles Karangwa
Rwanda Food and Drugs Authority
P. O. Box 85, Kigali

To Whom it May Concern

Re: CTFA's specific comments on the commencement of Rwanda :
FDA Law No 003/2018 of 09/02/2018, Article 8 - Regulations No CBD/TRG/011 Rev_0 Governing Control of Medicated Cosmetics and Guidelines on Submission of Documentation for Registration of Medicated Cosmetic Products

Further to our letter dated 21 April 2020 and our virtual engagement on 15 July 2020, please find specific commentary from the South African cosmetic industry on the regulations mentioned above. We thank you for your kind consideration for an extended commentary period to accommodate the South African cosmetic industry's comments.

Cosmetic Toiletry and Fragrance Association of South Africa (CTFA) is a national trade association representing over 80% of cosmetic companies in South Africa. These range from major multi-national cosmetic manufacturers and brands to medium and small companies. Industry members include companies who import and export products internationally, including to Rwanda. As the industry association in South Africa, CTFA has overseen the self-regulatory system for cosmetics for 25 years. Our industry members are committed to the continued development of safe, innovative and efficacious products both for the local market as well as for products destined for export.

As mentioned in our engagement the South African cosmetic industry is in support of the Rwanda Food and Drugs Authority's proposal for regulatory reform. This will facilitate the promotion of safe products for consumers, both locally and internationally. We raised and discussed the over-arching concerns that we identified as potential trade barriers for the South African export market and this submission includes commentary to the specific regulatory requirements included in the proposed regulations.

General comments:

1. The adoption date of the regulations requires clarity for international trade with due consideration of a compliance and transition period. We are cognisant of RFDA's mandate to protect consumer health and safety as well as to protect the integrity and safety of products that enter the Rwandan market. However, without such a consideration the South African exporters will be affected as immediate compliance will not be possible from a supply chain perspective. Stock of labels and packaging components planned for export may be rendered unusable and will need to be destroyed which has a huge cost impact for SMME's which have already experienced a strained business environment due to the pre-existing economic environment in South Africa, perpetuated as a result of the Covid-19 pandemic, which I am sure is a similar challenge Rwanda is facing currently.

2. As a country on the African continent and one that is currently in the process of reforming, we understand first-hand the challenges faced by our markets. We believe we are well positioned to offer proposals on a harmonised approach to enable free trade on the continent that will allow the Rwandan market to thrive as well as facilitate trade with African and international countries and simultaneously function to ensure safe and efficacious products for the local consumer. South Africa's recent draft Regulations relating to Labelling, Advertising and Composition of Cosmetics, R 1469, 22 December 2017, may be considered as an example of regulatory reform. This regulation allows a phased approach to reform that may be adapted in promoting compliance through compliance and transition periods that will consider Rwanda's specific local market requirements.

Specific comments:

1. Medicated cosmetics – this term creates confusion to an already clearly defined and internationally recognised product category of "cosmetics". In South Africa and internationally, medical products have a distinctly different and separate regulatory oversight due to the nature of product composition and permitted ingredient levels as well as label claims and physiological benefits or effects of the product. Cosmetic products may in some instances share the same ingredient composition as medical products, but the levels of use and the benefits are distinctly different. Cosmetics do not provide physiological benefits but rather provide a temporary benefit and effect. This is clearly indicated in the definition of a cosmetic, "means any substance or preparation intended to be placed in contact with the various external parts of the human body (including epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance or correcting body odours, protecting them or keeping them in good condition."
   I would further like to draw your attention to the statement below which supports the global view on cosmetics vs medicines or medicinal products: *Demarcation between the Cosmetic Products Directive 76/768 and the Medicinal Products Directive 2001/83 as agreed between the Commission Services and The Competent Authorities of Member States*[1]). The Demarcation states: "The Council and the Commission agree that the expression "protecting or keeping in good condition does not cover prevention of disease or protection against contamination […].". Preventing or treating diseases is limited to the medical product definition.

   With reference to the list of medicated cosmetics in clause 1.2.1 Medicated cosmetics, of *FDA Law No 003/2018 of 09/02/2018, Article 8 - Regulations No CBD/TRG/011 Rev_0 Governing Control of Medicated Cosmetics,* toothpastes, anti-dandruff products, anti-perspirant products. These products meet the definition of cosmetics as mentioned above in the underlined text. Furthermore, the active ingredient level in these products is premised on Scientific Committee on Consumer Safety (SCCS) reports which provides scientific evidence of ingredient safety at prescribed levels of use in regulations. In all these products the product claims made remain within the requirements of cosmetic regulations and the safety of such products are determined through safety assessments as prescribed in regulations. The below provides specific information on the categories deemed as medicated cosmetics in this regulation:

[1]Guidance document on the demarcation between the cosmetics products Directive 76/768 and the medicinal products directive 2001/83 as agreed between the commission services and the competent Authorities of member states

- Toothpastes promote oral hygiene and are not medicinal in nature. The fluoride content and product claims are restricted to cosmetic regulatory requirements. Cosmetic toothpastes focus mainly on improving oral hygiene such as breath freshening and acid neutralisation whereas medicated toothpastes treat severe oral health conditions, such as gum bleeding, and may contain active ingredients at levels beyond those permitted for cosmetic toothpaste use.

- Anti-dandruff products are everyday products that fight the causes of (mild to moderate) dandruff versus products sold in the pharmacy which treat severe dandruff/psoriasis (medical conditions) which require drug status and specific prescribed directions for use to obtain a medical benefit. Anti-dandruff is a well-established cosmetic product category, helping consumers for decades to cope with the annoyance of dandruff (visible flakes). Further substantiation is provided by the active ingredient entry in international and South African cosmetic regulations, which includes the term "anti-dandruff" which confirms that such products are cosmetic in nature. In addition, the SCCS has recently published their opinion on Zinc Pyrithione as safe for use up to 1% as an antidandruff agent in rinse-off hair products.

- The primary function of antiperspirant products is to correct body odours by temporarily blocking the skin's surface pores to minimise sweat flow which odour-causing bacteria feed on. There is no physiological or metabolic action and all active ingredients used (i.e. aluminium salts) are in line with the cosmetic regulatory restrictions. Furthermore, aluminium compounds have recently been favourably reviewed by SCCS as safe for use at specific levels in cosmetic antiperspirants.

Based on the above examples, cosmetic products do not require registration as medical or medicinal products would. The function of cosmetics is temporary and does not claim to treat any medical condition which will require a controlled approval/registration process prior to being placed on the market as a means of ensuring consumer safety. This would place an unnecessary and administrative burden on the authority for products that have been proved to be safe through cosmetic regulatory requirements that prescribe the use of ingredients, (of which the use level and safety has been predetermined) and compulsory safety assessment of the final product prior to placing the product on the market. This ensures that only responsible product manufacturers and suppliers qualify to access the market. Furthermore, product claims are prescribed in cosmetic regulations and are restricted to a non-medical nature. In this way the regulator can further protect the consumer from misinformation.

The South African cosmetic industry has made substantial submissions to other African countries indicating a similar action for reform and increased control to ensure that safe and efficacious products are placed on the market. These include Kenya, Mozambique, Tanzania and Botswana. At an international level, the South African cosmetic industry has made submissions to China, European Union, Russia, and USA to promote local industry growth and trade between our countries. Some of these submissions are supported by the South African Department of Trade and Industry (the Dti,) especially when there is a risk of introducing trade barriers.

[2]OPINION on Zinc pyrithione COLIPA no P81. SCCS/1512/13 Revision of 18 June 2014. Scientific Committee on Consumer Safety SCCS.

We would like to reiterate our gratitude for this opportunity to make a submission outside of the commentary period. I look forward to hearing from you so that we can engage further on the details included in this letter.

CTFA remains available to discuss this letter at your convenience and look forward to your positive response.

Yours sincerely

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CTFA Head: Regulatory & Policy Affairs

Adelia Pimentel
CTFA Executive Director

Cc: Ms Lorenci Klopper SA High Commission (Counsellor: Political)
Mr Kola High Commission SA High Commission (First Secretary)