

REF: MRA1/8/5 Vol II (153)

17 March 2021

ATT: All Cosmetics Stakeholders

RE: UPDATE ON COSMETIC REGULATION

Reference is made to the above subject matter.

The Botswana Medicines Regulatory Authority (BoMRA) communicated in the press release issued on the 3rd September 2019, Ref MRA 1/8/5 Vol 35 that there are no applicable regulatory requirements to clear, import or distribute cosmetics.

The Medicines & Related Substances Act, 2013 (MRSA) and its regulations of 2019 mandates that cosmetics be regulated for their safety. BoMRA is starting the regulatory process with a listing process for all cosmetics. The process will be rolled out at the first stakeholder engagement at a date to be advised. Stakeholder feedback of the process will further inform BoMRA of the appropriate regulatory measures to be applied to cosmetics.

However, in preparation for the regulation of cosmetics, BoMRA has adopted the following Botswana Standard on Cosmetics:

- Classification of cosmetics raw materials and adjuncts — Part 1 Dyes, colours and pigments **BOS 688 – 1b**
- Classification of cosmetics raw materials and adjuncts — Part 2 — List of raw materials generally not recognized as safe for use in cosmetics **BOS 688-2b**

BOS 688-2b contains four (4) annexes. These are

1. Annex A - List of substances which shall not form part of the composition of cosmetic products
2. Annex B - Substances not to be contained in cosmetic except subject to restrictions and conditions set
3. Annex C - Permissible preservatives in cosmetic products
4. Annex D - Permitted UV filters in cosmetic products

Applicants are strongly advised to ensure that their cosmetic products comply with the standard. Products not adhering with these standards will be deemed non-compliant and regulatory action may be instituted on them.

Applicants are advised to procure the said standards from Botswana Bureau of Standards (BoBS) for list of cosmetics prohibited substances.

Furthermore, BoMRA has noted that there are certain products that are marketed and distributed as cosmetics but contain prohibited substances (Annex I above) and/or make medicinal/therapeutic claims. BoMRA advises stakeholders that products that suggest any medicinal claim are not regarded as cosmetics.

For any further inquiries, please contact info@bomra.co.bw.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Sinah Selelo', written over a dotted line.

Dr Sinah Selelo

For/Chief Executive Officer.