Title of Document:	**MEDICINES AND RELATED SUBSTANCES ACT 2025**
Document Type:	**ACT**
Deadline for Submission of Comments:	**20 May 2026 (extension requested although this was not for formal comments)**
Name of Individual or Organization providing comments	**Cosmetic, Toiletry & Fragrance Association of South Africa**

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SECTION 1: COMMENTS ON EXISTING PROVISIONS (Amendments or Changes to what you see)

Section	Comment/Proposed Change	Justification for the Change
General comment	If the intention is to make the Act applicable to cosmetics, then "cosmetics" needs to be added to the definition of "regulated product". However, this will also result in confusion as many of the Sections applicable to "regulated products" must not apply to cosmetics. It is proposed that the definition of "cosmetics" in the Act is reconsidered (refer to next comment) and that the Act is then reviewed word by word to ensure that only those sections applicable to cosmetics refer to cosmetics. In this way minimal changes will be require to the Act to clarify these matters. This will in effect result in regulated products and cosmetics being two separate principles and they can each be regulated accordingly. CTFA has not included a detailed review of the changes that would be required to accomplish this, but is happy to provide such input if requested by BoMRA.	The applicability of the Act should be verified. It is understood that the Act should cover cosmetics and does so in certain Sections, but there is a great deal of confusion because "cosmetics" do not form part of the definition of "regulated products" or "related substances". Most of the powers and functions given by the Act apply to "regulated substances" so it brings the whole Act's relevance to cosmetics in question, even if there are dedicated sections for cosmetics. Given that there is a dedicated Part for cosmetics, does this mean that if that Part applies then the rest does not apply?
Part I – Preliminary - "cosmetic"	The definition of cosmetics in the Act is different to that in the draft Cosmetic Regulations. They should be identical. The definition in the Act has some differences compared to the draft Cosmetic Regulations, as well as to the European Union; South African; and African Organisation for Standardisation	It is proposed to use the ARSO definition to achieve the objective of harmonisation among African countries, to result in easier trade both within and outside of Africa.

	(ARSO) definitions. Through the African Union's objectives, ARSO has a large focus on harmonisation amongst African member states. It has recently been agreed at the ARSO cosmetics technical committee that a definition close to that of the EU will be adopted. For comparison, below, please find the five definitions. EU: any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips, external genital organs) or with the teeth and mucous membranes of the oral cavity. Its purpose must be exclusively or mainly to clean, perfume, change appearance, protect, keep in good condition, or correct body odors. Draft Cosmetic Regulations: means any substance or mixture intended to be placed in contact with the external parts of the human body, including the epidermis, hair system, nails, lips, external genital organs, teeth, or mucous membranes of the oral cavity, for the exclusive or principal purpose of cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition, or correcting body odours, but does not include a medicine as defined in the Act; MRS Act (2025):	

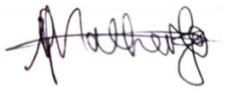
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	"cosmetic" means — (*a*) any substance or mixture of substances manufactured, sold or represented for use by rubbing, pouring, spraying, or applying by any other means to the external parts of the human body, including — (i) epidermis, (ii) hair system, (iii) nails, (iv) lips, (v) external genital organs, (vi) teeth, or (vii) the mucous membranes of the oral cavity, for the purpose of — (*aa*) cleansing, (*bb*) beautifying or alteration of appearance, (*cc*) protecting, or (*dd*) correcting body odours; or (*b*) any article intended for use as a component of a cosmetic; SA definition (to consider for alignment to ARSO definition in the future): "cosmetic" means any article, preparation or substance (except a medicine as defined in the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965)), intended to be rubbed, poured, sprinkled or sprayed on, or otherwise applied to the human body, including the epidermis, hair, teeth, mucous membranes of the oral cavity, lips and external genital organs, for purposes of cleansing, perfuming, correcting body odours, conditioning, beautifying, protecting, promoting attractiveness or improving or altering the appearance, and includes any part or ingredient of any such article or substance; ARSO definition: substance or mixture intended to be placed in contact with the external parts of the human body (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,	

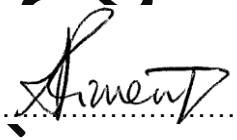
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	changing their appearance, protecting them, keeping them in good condition or correcting body odours	
87(3)	Only a subset of the information provided to BoMRA during the notification process could be made publicly available. The information that is made publicly available must not be sensitive or CBI. Please discuss the particular information that could be released, with stakeholders.	The development and maintenance of the register of notified products is supported. However, it should not be made publicly available as there is Confidential Business Information (CBI) included.
88	The classification of cosmetics into two classes – special use and general use is likely to result in avoidable lengthy debates about cosmetics that could be argued to be either. Is it the correct understanding of the intention that general use cosmetics will be subject to notification while special use cosmetics will be subject to registration? It is not clear what the difference in the end result will be besides the initial scrutiny that all cosmetics should be subjected to – are they safe under normal use?	Remove this provision from the Act and have a single category for cosmetics. They can still be assessed in the same manner during the notification process. It is currently understood that the cosmetics being notified are not subject to any scrutiny, but will be in the future. Is this correct or are they already being checked before a notification number is assigned?
89(1)	During the BoMRA stakeholder meeting, it was mentioned that safety assessments may be required. Could you please clarify whether safety assessments will need to be submitted during product notification in the future?	Clarity required in the regulations.
89(1)(c)	Disposal activities are not within the ambit of "normal or reasonably foreseeable conditions of use".	Waste management activities are usually seen as separate to the normal safety considerations of products, often regulated in its own right. Delete "disposal".
89(3); 90(3)	Do penalties apply per product/shipment, or any other basis?	Please provide further information.
90(1)(c)	The principles of adverse events and undesirable effects (etc.) for cosmetics require further clarification in the regulations.	Clarity required in the regulations.
95(2)	Proposal: "A person who deals in a cosmetic product shall not make a claim about a property that a cosmetic product does not possess" Furthermore, the regulation should stipulate further guidance on the matter of claims.	There are typographical errors. Further clarity is required on this broad "claim" provision.

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