THE SELF MEDICATION MANUFACTURERS ASSOCIATION OF SOUTH AFRICA (SMASA)

Latest Gazetted Regulations and Guidelines : SMASA Concerns/Comments

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SMASA Self-Medication Manufacturers Association of South Africa

Who we are

- SMASA was formed in 1999 and represents the interests of the manufacturers of non-prescription medicines (OTC)
- We serve to promote responsible self-medication to the public
- SMASA **welcomes and supports the introduction of SAHPRA, Bill 6 and the Health Supplement QSE guidelines.**
- We recognize the authorities **two distinct objectives** to
  - Protect patients against harmful or ineffective medicines (Gatekeeper)
  - Protect patients against the consequences of untreated disease (Enabler)

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SMASA members

Full Members

- Adcock Ingram Healthcare
- Aspen Pharmacare
- Bayer Consumer Care
- Boehringer-Ingelheim SA
- FDC SA
- GlaxoSmithKline SA
- iNova Pharmaceuticals
- Johnson & Johnson Consumer
- Merck Consumer Healthcare
- Norgine
- Novartis SA
- Pfizer Consumer Healthcare
- Procter & Gamble
- Reckitt Benckiser
- Sandoz SA
- Smith & Nephew
- Takeda
- Vital Health Foods
- Winthrop Pharmaceuticals (Sanofi Consumer Healthcare)

Associate Members

- Clicks Holdings
- Dischem Pharmacies
- Imperial Health Sciences
- MediRite Pharmacies SA
- (Shoprite Checkers)
- MRA Regulatory Consultants
- X-Procure Software SA

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Discussion points

1. **Matters of Principle**
   - Rationalisation required
   - Alignment and harmonization required
   - Main areas of concern

2. **Specific Comment**
   - Bill 6
   - Health Supplements QSE Guideline

3. **Recommendation and Final Conclusion**

4. **Developments and Changes to Bill 6**

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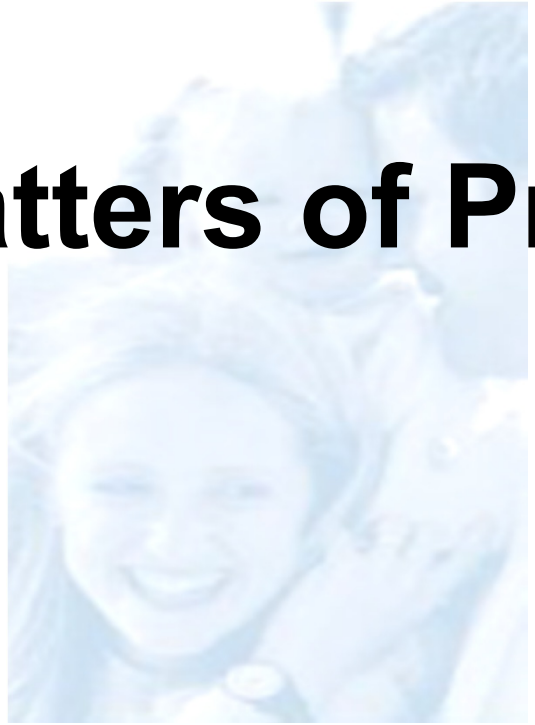
1. Matters of Principle



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Rationalization

- **One size does not fit all**
  - Create structures within SAHPRA that are appropriate for each product type e.g. medicines, cosmetics, medical devices, CAMs (**SAHPRA Business Plan**)
  - Ensure adequate and fair representation of all products within SAHPRA board, committees and technical structures
  - Create registration flows and criteria appropriate to the type of product in question – **utilizing a risk based approach in regulations.**
  - Registration timelines need to be practical and efficient – General Regs. (Act 72 Section 35(1) (xl iii) and 15 (2)b makes provision for this.

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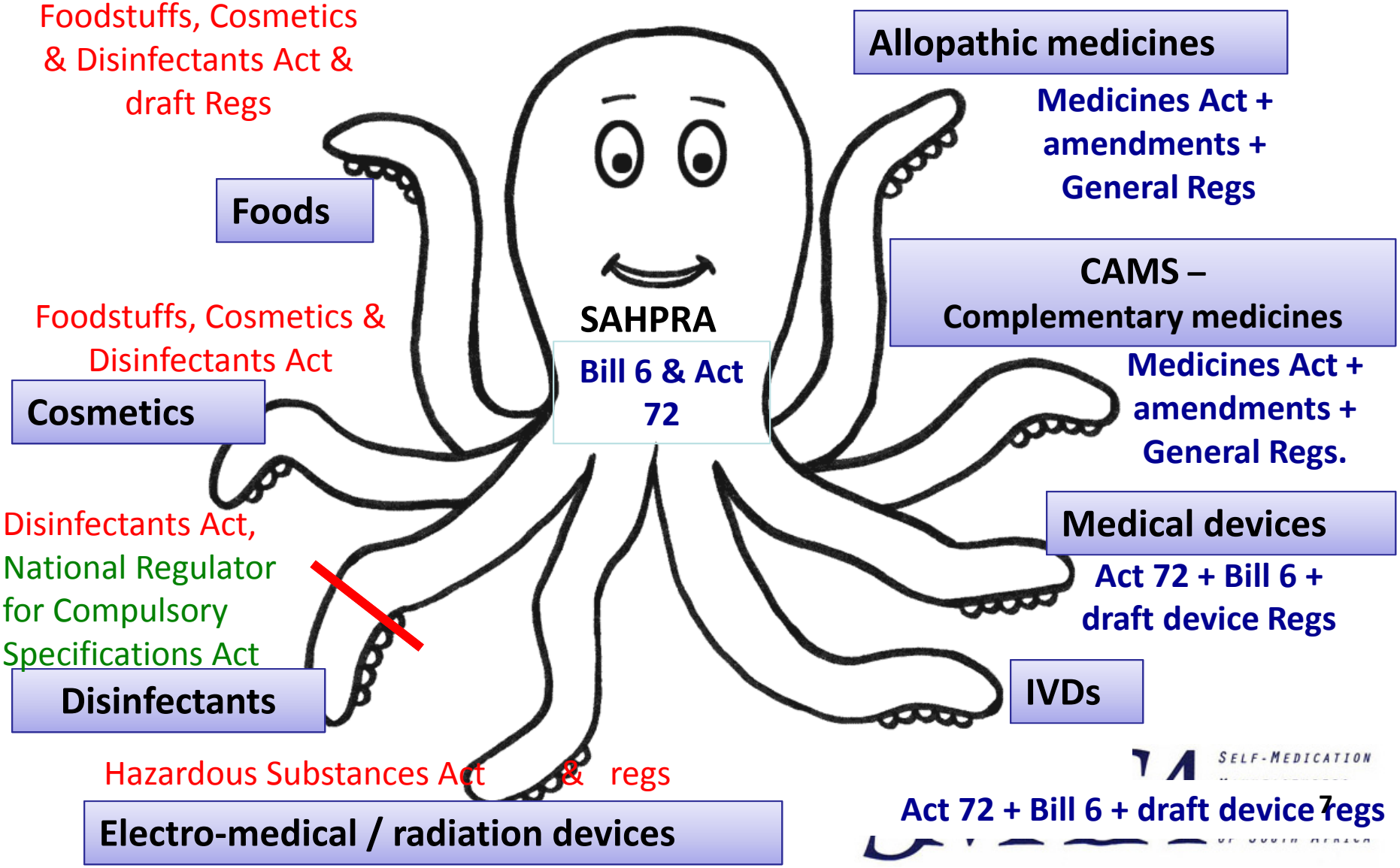
Rationalisation and Complexity

Key:

Law gives powers to NDoH / DG

Law gives powers to MCC / SAHPRA



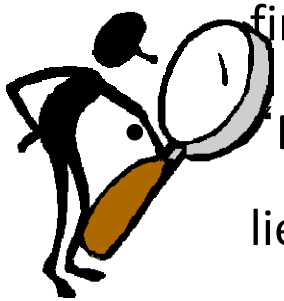
Alignment and harmonization

Section 2B(2)a pg 4 line 20 (Functions of Authority) addresses the recognition of other authorities.

- Reciprocal registration for OTC, medical devices and CAMs based on risk and where they are registered through reputable structures such as EU, FDA, TGA etc.
  - Supported that SAHPRA enter into recognition agreements with reputable regulatory authorities for medical devices and IVDs, some of which are so-called **borderline devices** (denture, contact lens solutions)
  - This will be a necessity given the regulatory scope and magnitude of numbers of products.

Main Areas of Concern for SMASA

- Structure and formation of SAHPRA – skills resources and capacity to achieve the widest and most efficient form of regulation and control. - **one size (one regulatory model) will not fit all**
- Timelines associated with registrations and handling of backlog
- SAHPRA as a PFMA entity – assurance of financial independence AND financial sustainability



- "**Regulatory oversight**" of Foodstuffs and Cosmetics – Legislative control lies with the Foodstuffs, Cosmetics and Disinfectant Act 54 of 1972. Can mere amendments to the Medicines Act change this?

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Main Areas of Concern for SMASA

- Lack of legal certainty in many areas e.g. vested rights of products previously exempted in terms **of Government Gazette Notice R43 of 9 January 1996**. The QSE guideline subjects products in pharmaceutical dosage forms to registration.
- Expansion of **Regulation 25** – Pharmacological classification which will influence the call up for registration in line with Section 14 (2a) and 14 (3)
- The current overlap of regulations has resulted in erroneous categorization and registration of foods, food/health supplements, disinfectants, cosmetics and medical devices as medicines

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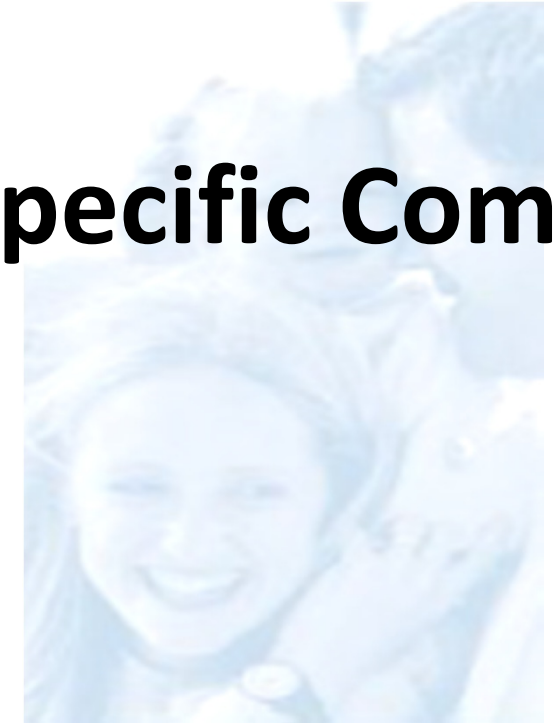
2. Specific Comments



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Definitions – Bill 6

- Definition of a complementary medicine Section 1 (d) **“Complementary Medicine”**

- Inflexible and misplaced

- Should be moved from Principal Act to Regulations

- Existing definition of a medicine should stay unchanged

- At most the following words should be added:
  - and includes any veterinary medicine;
  - **biological medicine** and
  - **complementary** medicine

- Definition needed for ‘food supplement’

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Definition of Complementary medicine – Bill 6

- We propose the below definition to be adopted in the regulation

"Complementary medicine" means any substance or mixture of substances that-

(a) originates from, but not limited to plants, ***fungi, algae, seaweed, lichens, minerals***, *animals* ***and includes one or more substances included in the substance list as determined by the Council;*** ~~or other substance as determined by Council~~

(b) is used or purporting to be suitable for use or manufactured or sold for use—

(i) in maintaining, complementing, or assisting the innate healing power or physical or mental state, or

(ii) to diagnose, treat, mitigate, modify, alleviate or prevent disease or illness or the symptoms or signs thereof or abnormal physical or mental state of a human being or animal, and

(iii) restoring or correcting organic functions in humans, or

(c) is used-

(i) as a health supplement

(ii) in accordance with those disciplines as determined by Council, or

(d) is declared by the Minister, on recommendation by the Council, by notice in the Gazette to be a complementary medicine

Note: Disciplines are problematic… e.g. rooibos products relate to which discipline?

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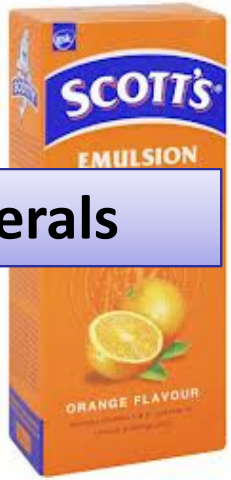
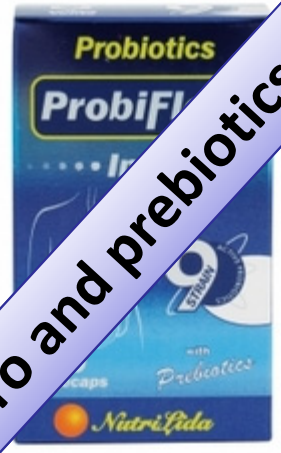
“Complementary Medicine”

Vitamin and minerals



Homeopathic products

Pro and prebiotics



Glucosamine

Plant extracts

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Definition of Advertisement – Bill 6

'advertisement' in relation to any [product] medicine, Scheduled substance, medical device or IVD, means any written, pictorial, visual or other descriptive matter or verbal statement or reference-

(a) appearing in any newspaper, magazine, pamphlet, ***electronic media*** or other publication;

(b) distributed to members of the public; or

(c) brought to the notice of members of the public in any manner whatsoever,

which is intended to promote the sale of [product] medicine, Scheduled substance, medical device or IVD, and **'advertise'** has a corresponding meaning;

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Definitions

Should be included in the Medical device guidelines - Examples of Borderline Medical Devices

Non corrective contact lens and contact lens solutions - includes daily disposable, daily wear and continuous or extended wear are medical devices	
Therapeutic clothes e.g. stockings – medical device	
Certain eye drops - specifically intended to be used for disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses are medical devices.	
Teeth whiteners e.g. toothpaste, whitening strips – cosmetics.	
Personal protective equipment e.g. masks, shoe covers – medical devices	

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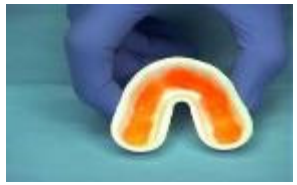
Scheduled substances are not products

Fluoride (Scheduled substance)

- Cosmetic (Toothpaste)

- Medical Device (fluoride trays)



- Complementary medicine (Multivit with Fluoride)

- Medicine (Fluoride tablets)

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Scheduled substances are not products

Vitamin A (Scheduled substance)

- Cosmetic (Cream)

- Complementary medicine (Supplement)

Food supplement definition?

- Medicine (Vitamin A injection)

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Complementary Medicines Health Supplements QSE Guideline - Comments

- The South African population suffers from a double burden of nutrition-related diseases with about a **third of children** being under nourished*

- Health Supplements play an important role in healthcare - should this guideline be implemented in its entirety, Health Supplements in South Africa will be subjected to some of the **strictest controls internationally**.

- Majority of Health Supplements are imported and meet the international rules of classification and registration.

- As the Bill, regulations and many guidelines are not finalized - recommend that the MCC roadmap in the regulations be amended. We propose three to five years post the finalisation of the guidelines.

* South African Department of Health Strategic Plan for the Prevention and Control of Non-Communicable Diseases (2013).

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Health Supplements QSE Guideline – Comments

SectionS	Comments	Rationale
General	Pharmacological Classification be handled in regulation 25	Influence the call up timelines in Regulation 48 and 14(2) and 14(3)
S 1.1. Definition of Health Supplement	Products such as Garlic and Tumeric ***have a nutritional physiological effect ...***	*recommend that the list in Annexure named "**Other**" make provision for these substances.*
S 1.2. Compliance with Good Manufacturing Practice	Inclusion of US Hazard Analysis and Critical Points (HACCP) and food safety certificate requirements.	Many of the products being imported into South Africa by applicants are manufactured in terms of EU and FDA food safety requirements
S 2.1 API (3.2.S)	Quality requirements for API's need to be amended in line with what is acceptable - based on risk . Acceptance of Monographs.	A DMF for nutritional API's is not a requirement in, for example, the EU, Canada and the United States hence DMF's do not exist for these ingredients.
S 2.2.1.3 Additives	We recommend this must be in a regulation not in a guideline.	Sweeteners must be aligned to Foodstuffs Act and *Codex Alimentarius*

Health Supplements QSE Guideline – Comments

SectionS	Comments	Rationale
S 2.2.1.6 Overages	There needs to be clarity on stability overage	Provide clarification on whether this overage is present in the formulation or assayed in the final product at start or end of shelf-life.
S 2.2.2. Product Development (3.2.P.2)	Waiver from this requirement is requested.	Product development expert reports do not exist for "old HS medicines"
S 2.3. Amendments	Based on our request for consideration of reduced requirements for API's, we propose that only the relevant sections of the Amendments Guidelines be applicable	Sections of the current Amendments Guideline are not entirely appropriate for Health Supplements.

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Complementary Medicines
Health Supplements Guideline – Proposal

- A **risk based approach** for the regulation of Health Supplements whereby low risk products follow a notification process (meeting requirements of quality, safety and efficacy as outlined in approved Monographs)

- We also recommended that an **abridged dossier format** (ZA-CTD) for Health Supplements, as was done previously for homeopathic medicines and galenicals (packed lines).

- The final date for the submission of dossiers as per the MCC roadmap in the regulations be amended. We propose three to five years post the finalisation of the guidelines.

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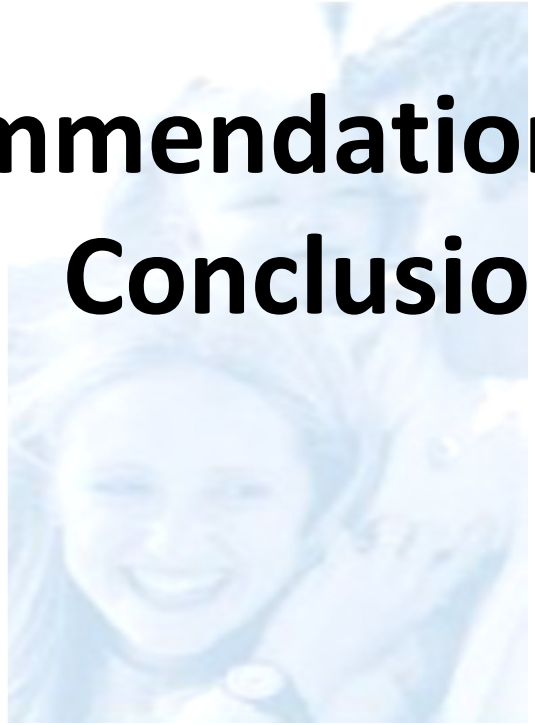
3. Recommendation and Final Conclusion



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Recommendations and final conclusions

- SMASA welcomes and supports an enhanced regulatory framework and urges the NDoH to consider existing frameworks in authorities experienced with regulating CAMs, medical devices and food/health supplements.
  - For example, Health Canada's approach to the regulation of Natural Health Products use of monographs
  - UK MHRA's approach to the regulation of medical devices and borderline medical devices such as **EU Manual on Borderline and Classification in the Community Regulatory framework for MD** (July 2016)

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4. Developments and Changes - Bill 6

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Bill 6 – Developments in Parliament

Section of Act	NDOH Change	Rationale
Definition: Adverting	Amended in the Act	Agreed . To include “electronic media including radio and television”
Definition: Complementary medicine and Biological medicine	Amended and removed from Bill	Agreed to keep in regulations.
Section 2B [3] Foodstuffs and Cosmetics	Removed from the Bill, DOH - find other ways to regulate and have policy development around foodstuffs and cosmetics (Schedule Substances)	Conflict between Principle act and Act 54 of 1972, which regulates the toxicity of foodstuffs and cosmetics

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Bill 6 – Developments in Parliament

Section of Act	NDOH Change	Rationale
Section 18 and Pricing Matters	Not in agreement. Included Medical Devices, IVD and complementary products	MPs greed that it was necessary for the MoH to consult with the Pricing Committee on sections 18A, B and C. Currently still to be debated.
Long Title of Bill	Inclusion in long title, viz. *that the MoH must consult the Pricing Committee when prescribing acceptable and unacceptable acts in relation to bonusing*.	It is proposed that section 18A and section 22G (medicines pricing) refers to the Pricing Committee and It also now is proposed to include scheduled substances within the ambit of section 18A.

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Bill 6 – Developments in Parliament

Section of Act	NDOH Change	Rationale
Section 22C Licensing	Amended in Bill	As some distributors who deal with S0 or unscheduled medicines as they operate as retailers dealing with bulk products.
Section 22 H - Purchase and sale of medicines by wholesalers	No changes made to this section	Allopathic supply chain route "as is" applies to all other products, i.e. only manufacturer can supply to wholesaler and there can only be one importer / manufacturer and wholesalers may not sell to each other
Schedule Substances	Deleted only the requirement of Schedule substance register	Allows for different levels of regulatory control over substances, whether in the form of naturally-occurring products, APIs, or finished pharmaceutical products (medicines).

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Thank you

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