COMPLEMENTARY MEDICINE REGULATION – Navigating the Path Forward

self-care association
OF SOUTH AFRICA

Disclaimer

The views expressed herein are those of the Self Care Association of South Africa and its members. It is not meant to be a direct reflection of any measures to be taken or discussed with the South Africa Regulator.

self-care association
OF SOUTH AFRICA

History of Complementary medicines (CM) in SA: Looking Back – The Roadmap

self-care association
OF SOUTH AFRICA

Timeline:

2002 — MCC gazetted a call up for CM's (Audit purposes):
- Abbreviated MRF1 (Admin info, label and/or PI, formulation) – Review safety & efficacy
- MBR20.8 – Nappi code & import purposes
- 6 Months vs 11 years

2004 — Proposed Regulations for CM's published by MCC – Never promulgated

2008 — Proposed Regulations for CM's published by MCC – Never promulgated

2011 — Proposed Guidelines for CM's published by MCC – Never implemented
- MCC applies more intense review of MRF1's

15 Nov 2013 — General Medicine Regulations – Updated to include CM's (Discipline specific)
Road map for CM compliance
Guidelines on CM's published for implementation

Sept 2014 — Proposed amendment of 2013 Regulations published (to include Health supplements)

Jul 2016 — 2nd Proposed amendment of 2013 Regulations published (to include Health supplements)

Jan 2017 — Proposed amendment of General Medicines Regulations (including proposed changes relevant to CM's)

25 Aug 2017 — Amended General Medicines Regulations promulgated - Health supplements officially included in Act 101

01 Oct 2020 — High court judgement – Alliance of Natural Health Products SA vs SAHPRA & MOH
- August 2017 General Regulations invalid for certain CMs

11 April 2022 — Supreme Court of Appeal judgement - Alliance of Natural Health Products SA vs SAHPRA & MOH
- August 2017 General Regulations invalid for certain CMs

07 May & 27 May 2022 — SAHPRA response:
- Considered approaching Constitutional court for leave to appeal
- Final decision – No appeal

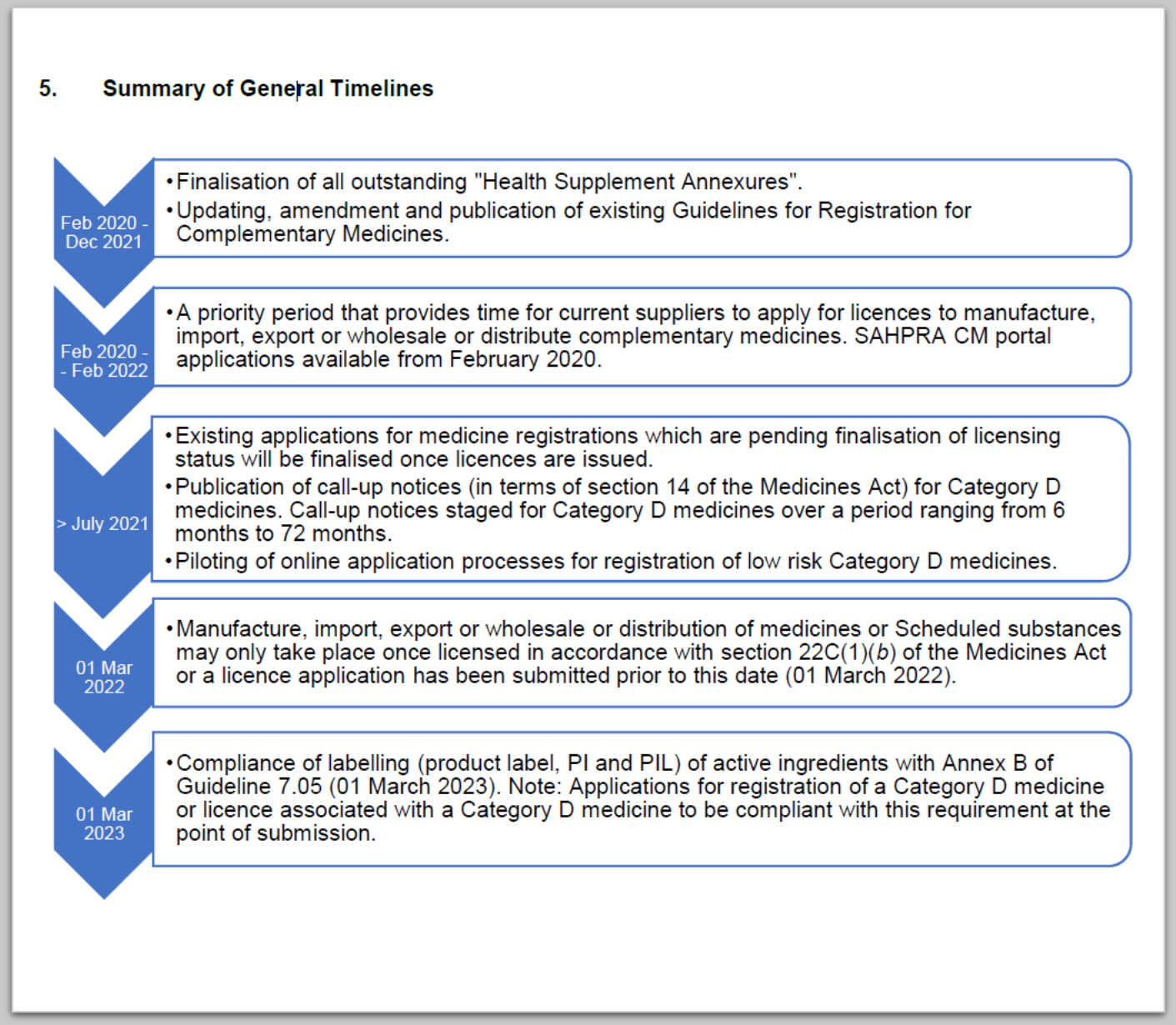
self-care association OF SOUTH AFRICA

What is the current status?

self-care association
OF SOUTH AFRICA

Guideline 7.02 - Road map for Complementary Medicines

Road map provides transitional requirements



Requirements for right of sale of CM's:

3.3.2 Rights of sale

All Category D medicines (complementary medicines), as defined, will be permitted continued rights of sale, provided that:

- An application is submitted for their registration by the prescribed deadlines of the applicable call-up notice;
- they are manufactured, imported, exported, wholesaled or distributed by a holder of or applicant for a relevant licence contemplated in section 22C(1)(*b*) of the Medicines Act at the end of the timeframe specified herein;
- they are specifically compliant with the requirements of section 20 and regulations 10, 11, 12 and 42 as prescribed, and are compliant with any other relevant provisions of the Medicines Act and its regulations; and
- they are indicated based on LOW RISK, which includes:
  i. General health enhancement without any reference to specific diseases;
  ii. Health maintenance; or
  iii. Relief of minor symptoms (not related to a disease or disorder).

self-care association OF SOUTH AFRICA

Requirements for right of sale of CM's:

- **Licensing**
  - Applies to CM manufacturers, importers, exporters, distributors & wholesalers
  - 3 Types of SAHPRA Category D licences:

    - Type DL01 - Licence to manufacture, import or export Complementary Medicines (Category D) [manufacturers only]
    - Type DL02 - Licence to import or export Complementary Medicines (Category D) [holders of certificate of registration]
    - Type DL03 - Licence to act as a wholesaler of or distribute Complementary Medicines (Category D) [wholesalers or distributors]

  - Process - Involves DOH, SAPC and SAHPRA
  - 3D Product Listing – Required as part of licensing process
    - 3D Product list templates (HCR's, 3rd Party manufacturers and Wholesalers & Distibutors)
    - Tutorial video – SAHPRA CM's Portal

self-care association OF SOUTH AFRICA

Requirements for right of sale of CM's:

Guideline 7.02 Roadmap for CM's

- **Licensing**
  - Process described in Annexure C of Guideline 7.02 (Flow diagram & narrative)

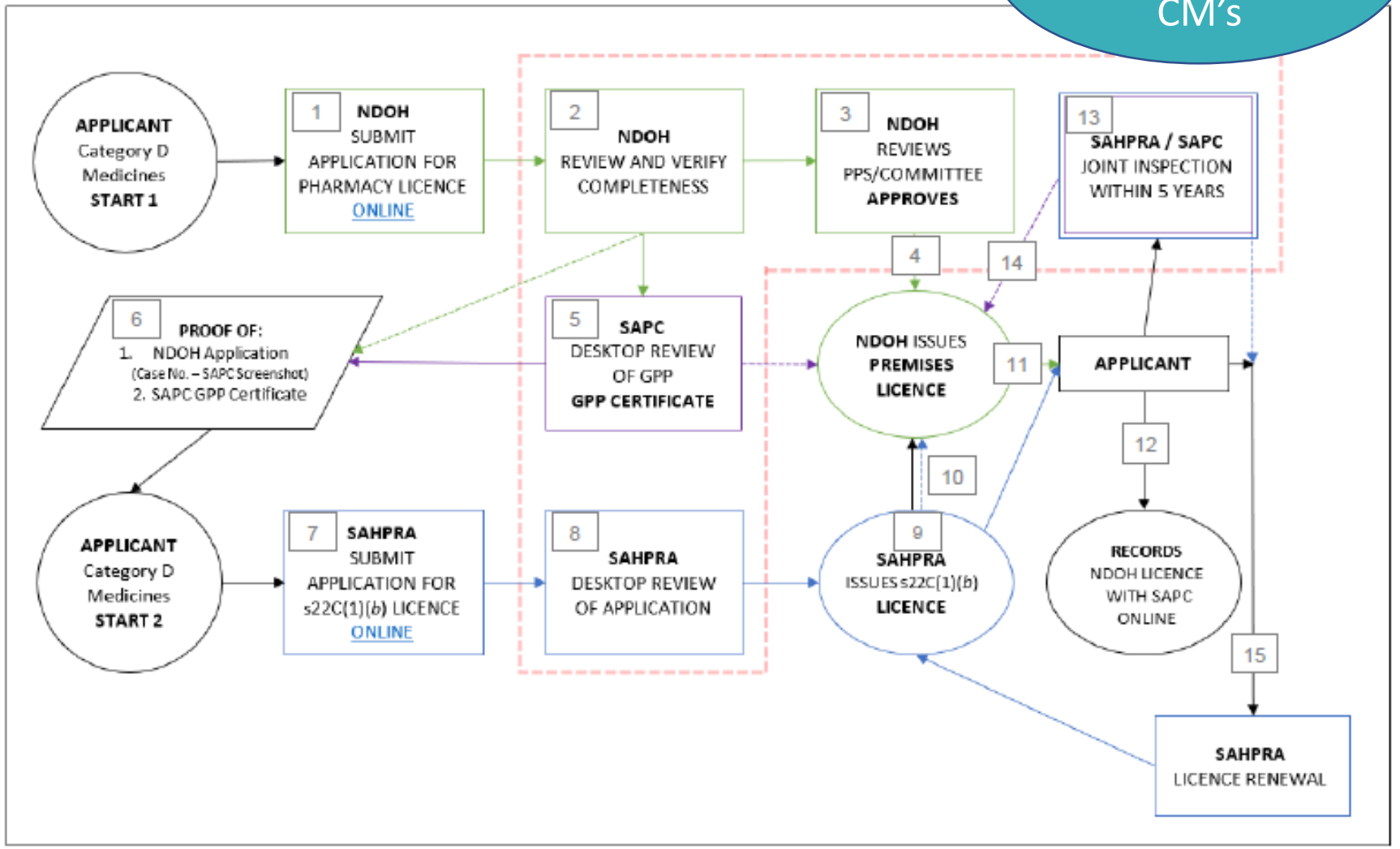


FIGURE 1: PROCESS FLOW FOR NEW APPLICATIONS FOR LICENCES LIMITED TO COMPLEMENTARY MEDICINES

Requirements for right of sale of CM's:

- **Marketing & Advertising**
  - Section 20 (Act 101 of 1965)

20. Publication or distribution of false advertisements concerning medicines, medical devices or IVDs.

(1) No person shall—

(a) publish or distribute or in any other manner whatsoever bring to the notice of the public or cause or permit to be published or distributed or to be so brought to the notice of the public any false or misleading advertisement concerning any medicine, medical device or IVD; or

(b) in any advertisement make any claim to the effect that the therapeutic efficacy and effect of any medicine, medical device or IVD is other than that stated by the Authority in terms of section 22(1)(a)(ii) or state or suggest that any medicine, medical device or IVD should be used for a purpose or under circumstances or manner other than that stated by the Authority in terms of section 22(1)(a)(ii).

(2) It shall be a sufficient defence in any prosecution for an offence under paragraph (*a*) of subsection (1) if it is proved to the satisfaction of the court that the accused, not being a person selling the medicine, medical device or IVD to which the false or misleading advertisement which is the subject of the prosecution relates, did not know, and could not reasonably be expected to have known, that the advertisement was in any respect false or misleading.

  - Challenge – No registered claims / Indications
  - Keep aligned with Guideline requirements to support claims (High risk vs Low risk)
  - Keep aligned with intended use specified in 3D Product List

self-care association OF SOUTH AFRICA

Requirements for right of sale of CM's:

- **Labelling**

  Must comply with:

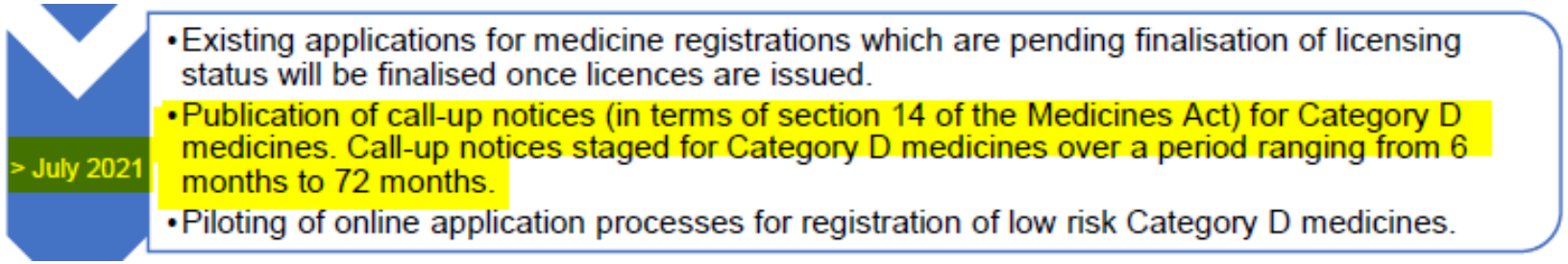
  - Regulation 10 – Label information
  - Regulation 11 – Professional Information
  - Regulation 12 – Patient Information Leaflet

- **Naming convention for active ingredients in CM's**
  - Annexure B of Guideline 7.05 – CMs – Registration Application ZA-CTD – Quality
  - Deadline for compliance:
    - Amended in Dec 2021 to 28 February 2023 (1 year extension)
    - Applies to CM's available for sale prior to implementation of Annexure B
    - Newly launched CM's expected to comply with this requirement

self-care association OF SOUTH AFRICA

Requirements for right of sale of CM's:

- **Call-up for product registration**
  - Products must be submitted for registration when called up by SAHPRA



Guideline 7.02 – Road map for CM's

  - What we know:
    - Online product registration process still to be developed and tested
    - Format will be CTD (Common Technical Document)
    - Extent of information required – Risk related (High risk vs Low risk)
    - Online registration process – more specific guidance on requirements
    - Call-up will start at Low risk single substance CM's
    - Call-ups to be staggered over 72-month period

self-care association OF SOUTH AFRICA

Requirements for right of sale of CM's:

- **Low risk vs High Risk claims**
  - Unregistered CM's currently marketed – should have Low risk indications

Table 1. Risk Level, type of claim and evidence required

Risk Level	Type of Claim	Evidence required to support claim
LOW RISK	• General health enhancement without any reference to specific diseases [1] • Health maintenance, including nutritional support. • Relief of minor symptoms (not related to a disease or disorder) [2]	• Clinical data to be evaluated [3] AND/OR: • Two of the following four sources that demonstrates adequate support for the indications claimed: 1 Recognised Pharmacopoeia [4]; 2 Recognised Monograph [4]; 3 Three independent written histories of use in the classical or traditional medical literature. [5,6], or 4 Citations from other *in vivo, in vitro* studies, case reports or others.
HIGH RISK	• Treats/cures/manages any disease/disorder. • Prevention of any disease or disorder. • Reduction of risk of a disease/disorder. • Aids/assists in the management of a named disease/disorder or sign/symptom of a named disease/disorder. • Relief of symptoms of a named disease or disorder [2] • Treatment of proven vitamin or mineral deficiency diseases.	• Clinical data to be evaluated [3]. AND • Two of the following four sources that demonstrates adequate support for the indications claimed: 1 Recognised Pharmacopoeia [4]; 2 Recognised Monograph [4]; 3 Three independent written histories of use in the classical or traditional medical literature, or 4 Citations from other *in vivo, in vitro* studies, case reports or others.

Guideline 7.01: Complementary medicines - Discipline-specific safety and efficacy

self-care association OF SOUTH AFRICA

Alliance of Natural Health Products SA (ANHP)
vs
SAHPRA & MOH

self-care association
OF SOUTH AFRICA

April 2022 - Supreme Court of Appeal (SCA) ruling

- **What did the court rule?**
  1. Certain products/CMs does not fit the definition of a medicine and cannot be regulated under the Medicines Act - 2017 General Medicines Regulations invalid for these CMs
  2. The order of PARTIAL invalidity – suspended for 12 months
- **Implications of the ruling**
  - MOH/SAHPRA must rectify the deficiency within 12 months to align with the judgement
  - Current regulations will apply and must be followed until regulations are amended
- **Key Points for consideration:**
  - Which products fall under the ruling? – CMs not claiming any therapeutic purpose
  - Partial invalidity – CM's claiming therapeutic purpose will remain under current regulations & SAHPRA
  - The role of "Therapeutic purpose" in determining which products falls within the judgement – To Be Confirmed

self-care association OF SOUTH AFRICA

CM regulatory challenges faced by industry

self-care association
OF SOUTH AFRICA

Licensing process

1. **Responsible pharmacist, NDOH Pharmacy licence & SAPC registration**
   - Cost & Feasibility
   - Long & time-consuming process
   - Only 42 approved category D licences – CM's Portal
2. **GMP vs Food Safety certification**
   - Pharmaceutical GMP processes / SOP's (e.g. Product release, recall, stability, etc.)
   - Finished product manufacturers currently hold food safety certifications
3. **3D Product Listing**
   - Compliance with current CM requirements (Formulation, classification, risk classification vs intended use)
   - Several reverts & long delays
   - Request for reformulations and Cat. A applications

self-care association OF SOUTH AFRICA

Labelling compliance

1. **PI's and PIL's**
   - Challenging for multi-ingredient products
   - Format is challenging, e.g. "Pharmacological action" in PI
   - Resource & cost
2. **Dual language**
   - Space constraints
   - Resource & cost
3. **CM specific requirements**
   - Disclaimer, class & category, discipline, words "Complementary medicine"
   - Often lacking
4. **Annexure B compliance (Naming convention for actives)**
   - Inaccurate interpretation
   - Space constraints
   - Resource & cost

self-care association OF SOUTH AFRICA

CTD Registration format & quality related requirements

- Extensive information required
- Not practical for CMs (mostly multi-ingredient products)
  - e.g. Multivitamin product:
    - 12 API's
    - 2 x alternative suppliers for each API
    - **= 24 x Module 3.2.S**
- Information often not available for CM ingredients
- Extremely costly to implement requirements
- Current CM manufacturers often Food safety certified and not GMP
- SAHPRA - Online product registration process
  - to provide more specific guidance on requirements
  - Pilot planned with industry – ITG-CM WG

self-care association OF SOUTH AFRICA

ANHP vs SAHPRA & MOH

- Court ruling has created a period of uncertainty and sense of anxiety
  - No clarity on “Therapeutic purpose” definition
  - List of products falling under the “non-therapeutic” ruling?
  - How and whom will “Non-therapeutic” products be regulated?
  - Current “Status quo” for “Non-therapeutic” products - not practical for industry
    - Labelling changes costs and resource intensity
    - Reformulation costs
    - Costs for dossier preparation

self-care association OF SOUTH AFRICA

How do we collaborate with SAHPRA to ultimately benefit patients in the long run?

self-care association
OF SOUTH AFRICA

Industry involvement

- **Proactive interaction with SAHPRA CM's Committee**
  - SCA CM's committee
  - ITG CM's Working Group
- Identifying practical and appropriate regulatory systems / requirements which are mutually acceptable to both industry and our regulator
- **Selfcare Association:**
  - Supports SAHPRA as the regulator of all CMs under the Medicines Act
  - Current regulatory framework for non-therapeutic products - irrational and not fit-for-purpose. SAHPRA to find a middle ground.
  - Not supportive of non-therapeutic products moving under the Foods Act
  - Championing a 2-step approach:
    - Task group 1 - Short term transitional plan – next 12 months
    - Task group 2 - Long term – after 12 months.

self-care association OF SOUTH AFRICA

SCA Approach

- **Task Group 1 (Short term proposal) – Transitional Plan – Next 12 months?**
  - Completed and submitted via ITG CM Working group:
    - Clearly defined “therapeutic purpose” vs “non-therapeutic purpose”
    - For non-therapeutic products place a “transitional freeze” on:
      - Licensing and 3D product listing
      - Registration process / registration obligations
      - Specific labelling requirements (Regulation 10), e.g. bilingual requirement, Category & Class of medicine, Disclaimer etc.
      - Regulation 11 - Professional information (PI)
      - Regulation 12 - Patient information leaflet (PIL)
      - Regulation 42 - Marketing and advertising
    - Permit sampling of non-therapeutic products - interim 12-month period directly to consumers
  - ITG received a letter from SAHPRA stating that they are busy going through the process and comments will be considered when correcting the Regulations.

self-care association OF SOUTH AFRICA

SCA Approach

- **Task Group 2 (Long term proposal) – After 12 months**
  - Researched other markets (adopting an international system)
    - Singapore
    - Asia
    - UK
    - Netherlands (EU)
    - Canada
  - Little harmonization between different markets
  - Food supplements / health supplements regulated in several markets under foods legislation
  - Food legislation – not considered for SA
  - **Next steps:**
    - Propose a definition for “Therapeutic purpose”
    - Scrutinize Guideline 7.05 CM’s – Quality to identify pragmatic requirements for listing of low risk CM’s

self-care association OF SOUTH AFRICA

Contact Us

nicola@selfcareassocation.co.za

+27(0) 82 410 5859

www.selfcareassociation.co.za

self-care association
OF SOUTH AFRICA