



PLAN TO REGULATE THE COMPLEMENTARY MEDICINES INDUSTRY IN SOUTH AFRICA

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South African's regulator's plan

- › Plan is straight forward and clear
- › Considerable impact on the complementary medicines industry
- › MCC's powers to regulate originate from the Constitution and the Medicines Act

Number 1: Banned substances

- Withdraw products containing banned substances

Number 2: Schedule 1 and higher

- Withdraw unregistered self-styled complementary products containing schedule 1 and higher substances

Number 3: Misbranded self-styled CAM

- Withdraw misbranded products not fitting the regulatory definition of a complementary medicine

Number 4: Pre-registration of new CAM

- Submit new complementary medicines complying with the regulatory definition for registration prior to sale – no sale before registration





Regulator's plan

- › Withdraw products containing banned substances
- › Hazardous to health
- › Risk to public health and safety
- › MCC administrative law decision

Banned substances

- Apiol
- Damiana
- Kava-kava
- Senecio plant species - pyrrolizidine alkaloids
- Yohimbine





Regulator's plan

- › Withdraw scheduled substances
- › Hazardous to health
- › Risk to public health and safety
- › MCC administrative law decision

Scheduled substances

- Milk thistle (silymarin)
- Red yeast rice (lovastatin)
- Slimming preparations (sympathomimetics),
- Vitamins, minerals
- Probiotics in high doses
- Proteolytic enzymes
- Melatonin
- Phospholipids



Regulator's plan

- › Medicines not fitting definition of cams
- › Category A medicines
- › Registration prior to sale
- › Risk to public health and safety
- › Criminal law

Misbranded – self-styled

- Misbranded - branded or labelled falsely and in violation of statutory requirements
- Self-styled - as claimed by and for yourself often without justification
- Complementary medicine
- Regulatory definition





A Category D complementary medicine (edited definition – “allied practitioner medicine”) means any substance or mixture of substances that:

- a) Originates from plants, minerals or animals;**
- b) Is used in assisting the innate healing power of humans to mitigate, modify, alleviate or prevent illness or the their symptoms or abnormal physical or mental state; and**
- c) Is used in accordance with the practice of the professions of Ayurveda, Chinese medicine and acupuncture, chiropractic, homeopathy, naturopathy, osteopathy, phytotherapy and therapeutic aromatherapy and Unani Tibb.**





A Category A medicine (“general medicine”) means any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in—

- a) The diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof in man; or**
- b) Restoring, correcting or modifying any somatic or psychic or organic function in man,**

and includes any veterinary medicine.





Category A medicine - general medicine:

- a) diagnose, treat, mitigate, modify or prevent a disease;
- b) affect a physiological function – structure/function claim.**

Category D complementary medicines - allied practitioner medicine:

- a) natural origin
- b) assist the innate healing powers of the body in illness management
- c) within allied practitioner's scope of practices.



BN 129 OF 17 DECEMBER 2004: RULES RELATING TO GOOD PHARMACY PRACTICE (GOVERNMENT GAZETTE NO. 27112)

22 MINIMUM STANDARDS FOR THE PROVISION OF COMPLEMENTARY MEDICINE

- a) Where complementary medicines are offered for sale, staff involved must be **trained** in the use thereof.
- b) The pharmacy must stock only those complementary medicines, which are judged by the pharmacist to be **effective** and appropriate for the treatment of stated conditions.
- c) The client must be given appropriate **information** about the use and effectiveness of complementary medicine sold to them.
- d) The client must be informed of possible **adverse reactions** and **drug/drug** and **drug/food** interactions.
- e) **Medicines acquired and sold must comply with MCC requirements.**

Guidance

Information about complementary medicine must be suitable for the needs of specific groups of clients and must not make claims, which in the pharmacist's judgement, are misleading or speculative.





DSHEA and the modern South African complementary medicines industry

- › Majority of CAM brands built on the US DSHEA model
- › No similar statute in RSA
- › No “food” safe harbour
- › DSHEA entitles “foods” to make structure/function claims - restoring, correcting or modifying any somatic or psychic or organic function in man
- › Make therapeutic or medical claims without being classified as a medicine.

Fundamental false assumption

- Medicines Act has no such exemption
- Classified as Category A medicines
- Require registration before sale
- Sale unlawful





DSHEA and the modern South African complementary medicines industry continued...

- › The Medicines Act is “use” based
- › Seller’s intention is not the only consideration
- › Evasive or deceptive tactics not acceptable
- › A product promoted as a medicine unexpectedly does not become a foodstuff because it suits the seller.
- › Estoppel - precludes a person from denying the truth of some statement previously made by himself

Classification test

- Use
- Evasive tactics
- What consumers were lead to believe
- Estoppel





NOTE:

- **Structure/function claims (DSHEA model) are not exempted from the Medicines Act provisions.**
- **Products bearing such claims are unregistered Category A medicines**
- **Each product must be assessed on its own merits**
- **Do not apply in a vacuum.**
- **If uncertain, discuss with the regulator**





Call-up of all new complementary medicines

› Regulation 48C 2 (d) (ii):

- Complementary medicines falling in category D and in all pharmacological classifications not presently on the market on 15 November 2013 are subject to registration prior to sale.

CAM Call-up notice

- 15 February 2013
- No new complementary medicines marketed unless registered.
- Must comply with the regulatory definition for a complementary medicine.





Call-up of all new complementary medicines

- Judge Zondi: 2002 call-up notice is a regulatory audit and not call-up notice
- Registry number did not create a right of sale for the product – no vested right
- Onus rested on the seller to ensure that they were not in breach of any of the provisions of the Medicines Act
- Registrar warns in 2010

MCC's concern

- Claims of safety, quality and efficacy made without MCC's approval
- Response to audit only a primary step in registration process
- Compile audit and decide on way forward
- Determine potential public health hazard
- Superseded all previous call up notices for preparations of this nature





Bertelsmann judgement – North Gauteng High Court

- MCC's resolution stipulated that the product should be withdrawn as it was considered a risk to public safety.
- Counter-argument was to continue with sale pending outcome of the administrative Medicines Act appeal
- A decision taken by the MCC, in its specialist professional capacity, regards as essential, as necessary and in the public interest, cannot thereafter be revoked.
- Any person aggrieved by a decision of the MCC must appeal that decision in terms of Section 24 of the Medicines Act.

Medicines Act administrative appeals

- Not appeal in terms of the common law of a judicial nature
- Did not suspend an order against which it is launched
- Decision of the MCC remains effective until it has been set aside,
- Either by the appeal process or
- By order of a competent court or
- Is effectively overruled by a successful new application for the registration of a similar or the same medicine.





“Grandfathering”

- “Grandfathering” is an exemption that allows persons to continue with an activity they were engaging in before it became illegal through a change in regulation
- An exception to a restriction

“Grandfathering”

- No complementary medicines submitted after 1990 are grandfathered.
- Do not have a vested right of sale
- 2002 call up notice was an “audit” process
- No moratorium
- Warning from Registrar in 2010





What is left and what may be sold?

- Surprisingly, more than one expects
- Multivitamin preparations
- Health claims
- “True” complementary medicines

Exemption requirements

- That the percentage of the recommended dietary allowance (RDA), of each ingredient per dosage unit on the label
- Claims and health statements to inform the public as to the rational use of the preparation
- Compliance with Good Manufacturing Practices
- Inform Registrar of manufacturing facility packaged and where quality control testing is done





Food/medicine divide

- “foodstuff” means any article or substance (except a medicine as defined in the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965)) ordinarily eaten or drunk by a person... for human consumption, AND includes any part or ingredient of any such article or substance, or any substance used or intended or destined to be used as a part or ingredient of any such article or substance.

Borderline products

- It must be ordinarily eaten or drunk by a person
- “Ordinarily” means under normal conditions or most of the time
- “Foodstuff” means consumer goods sold by a grocer or a substance that can be used or prepared for use as food
- Once a given product has been classified by a regulatory authority as a medicine, it follows that closely related products similarly classified
- Pharmacological, metabolic or immunological effect
- Supply on a medical prescription by regulation
- Medical diagnosis





- **By re-classifying a host of “modern” complementary medicines as foodstuffs does not solve the problem nor does it address the mischief that the Medicines Act seeks to prevent.**
- **A foodstuff is not generally used to treat a disease nor is it consumed for its pharmacological, immunological or metabolic effects.**
- **Not introduce new chemical entities that are not generally used in foodstuffs using a farfetched rationale**
- **High concentrations of food based actives not normally found in foodstuffs**





What may be sold

- 1) Registered medicines
- 2) Grandfathered medicines called up for registration including vitamin and homeopathic preparations which have a valid application number issued by the MCC but remain unregistered
- 3) Vitamin preparations that are exempted from the registration requirement that are below the 1985 call up notice as outlined in the table above
- 4) Complementary medicines presently on the market that comply with the regulatory definition for a complementary medicine as defined in the regulations until registered or rejected by the MCC after due process



What may not be sold

- 1) Products that contain banned substances
- 2) Misbranded unregistered non-grandfathered products without a valid application number substances listed in Schedule 1 and higher
- 3) Misbranded self-styled complementary medicines that do not comply with the regulatory definition for a complementary medicine - Category A medicines, previously called up for registration
- 4) All new complementary medicines meeting the regulatory definition for registration not presently on the market (15 November 2013)





Thank you