The Complementary Medicine Challenge

Mandisa Hela

SARI 2014
Legislative Framework

- Medicines and Related Substances Act
- Pharmacy Act
- Consumer Protection Act
- Regulations to these statutes
- Bill of Rights in the Constitution
Overview

- Legislative framework
- Implications of Legislative Mandates
- Regulations for CAMs
- Implementation plan and road map
- Grandfathering
- Challenges
- Vitamins, minerals, probiotics, dietary supplements
- Way forward
Implications of Legislative Mandates

• The Medicines and Related Substances Act defines a medicine. That implies all medicines are regulated within the ambit of this statute.

• The Medicines and Related Substances Act defines a medicine (Category A) as “any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in:
  
  ➢ The diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof
  
  ➢ Restoring, correcting or modifying any somatic or psychic or organic function
  
  ➢ Includes veterinary medicines (Category C).
Category D Medicines

• Complementary medicine means any substance or mixture of substances that:
  – originates from plants, minerals or animals
  – Is used or intended to be used for, or manufactured or sold for use in assisting the innate healing power of a human or animal to mitigate, modify, alleviate or prevent illness or the symptoms thereof or abnormal physical state; and
  – Is used in accordance with the practice of the professions regulated under the Allied Health Professions Act
Implications of Legislative Mandates

• Licensing of manufacturing premises and compliance with Good Manufacturing Practice

• Licensing of Distributors/Wholesalers and compliance with Good Distribution and Wholesaling Practice

• Compliance with labelling requirements

• Compliance with scheduling, names, ports of entry
Implications of Legislative Mandates cont.

- Compliance with advertising standards
- Licensing of testing and release laboratories
- Access to any medicine is linked to a person who demonstrates competency to handle that particular medicine

The Pharmacy Act defines a pharmacy

- Licensing of premises by the Department of Health
- Appointment of a Responsible Pharmacist where pharmaceutical activities are conducted
- Responsible Pharmacist accountable to the Pharmacy Council
The Consumer Protection Act is intended to protect consumers.

It specifically protects the **Right to know**

Though the Bill of Rights promotes the right to trade, there are limitations when it comes to protecting the public.

The Medicines Act’s primary mandate is to protect the public from harm.
Regulations for Complementary and Alternative Medicines (CAMs)

• On the 15\textsuperscript{th} November 2013 Regulations to guide the regulation and control of CAMs for the first time in RSA were published
• The implementation of these regulations is phased and a risk-based approach is followed
• Introduce Category D medicines
• Provide linkage between categories of medicines and disciplines of complementary medicines.
Implementation Plan

• Withdraw banned substances from the market, e.g. Yohimbine, Kava-kava, Senecio species which were already declared undesirable, immediately

• Withdraw scheduled substances

• Withdraw products not fitting the definition of a CAM from the market

• Submit all “new” CAMs for evaluation by the MCC
Roadmap

Dec 2013
- Withdraw banned substances
- Withdraw scheduled substances
- Withdraw medicines not fitting definition of CAMS
- Submit new CAMS

15 Feb 2014
- All labelling to comply

May 2014
- 20.2.8 Antiviral agents
- 21.2 Oral hypoglycaemics (Diabetes)
- 6 Cardiac medicines
- 26 Cytostatic agents

Nov 2015
- 32.3 Slimming preparations (weight reduction products)
- 7.1, 21.7, 21.8, 21.9 Male and Female hormones and Sexual stimulation products

May 2016
- 32.16 (Other) Immune boosters
- 17 Medicines acting on muscular system (body building products)
- 22 (Vitamins) Sport supplements containing vitamins and minerals exceeding the upper limit allowed

Nov 2019
- All remaining pharmacological classifications
Grandfathering

• Section 14(3) of the Medicines Act makes provision for medicines that were available for sale immediately prior to the date of publication to continue to be sold until they are called in.
• Provision is made for called in products that are under evaluation to be sold.
• Grandfathered medicines that are not submitted during the call-in period will be declared illegal.
• These provisions only apply to medicines that fit in the CAMs definition.
Challenges

• CAMs have no global common definition. Regulation and licensing of these medicines and health care providers varies from country to country.

Efficacy Evidence - Ranges from long historical use, pharmacopoeiae, monographs, citations from other studies, independent histories to clinical trials

• What is regarded “traditional” in one geographic area does not have a long history of use in other areas

• Education standards for the professionals vary greatly from area to area

• Scopes of practice vary greatly across the globe
Challenges cont.

- The Foodstuff and Medicine divide. Definitions in the Foodstuffs, Cosmetics and Disinfectants Act and the Medicines Act are however quite clear. Amendments of levels of vitamins in the schedules have been gazetted.

- Misbranding CAMs - these include multivitamin preparations, HRT, bio-identical hormones, probiotics etc.

- Vitamins and minerals are not prescribed according to any specific, exclusive traditional CM philosophy or principle.
Vitamins, Minerals and Probiotics

• High dose food products (including vitamins and minerals) will be best evaluated by a category A registration where claims are associated with their use in full evaluation of safety, quality and efficacy

UNLESS:

Vitamin, Mineral (and Probiotic) prepared and shown to be of use and origin in a specific discipline with DIRECT relation to the identified discipline in the form presented and used medicinally. Identified schedule status will still apply.
Vitamins and Minerals
Summary

AMENDED SCHEDULES
Define minimum oral dose that qualifies vitamins, minerals as a medicine.

If (all) below these levels with food based claims

If part of a “combination product”:
MEDICINE CATEGORY D

FOODSTUFF
OR
MEDICINE S0

MEDICINE >S1
CATEGORY A

If (any) above these (or qualifying) levels, or make medicine claims
Dietary supplements

• Dietary supplements which make medicinal claims fit a category A classification

• Statutes from elsewhere in the world e.g. the US Dietary Supplements, Health and Education Act (DSHEA) are not law in South Africa

• Adulteration of these is quite common and tight vigilance is required (e.g. Sibutramine, steroids, sildenafil)
Way forward

• Many comments have been received at the information workshops
• There may be holes that need to be plugged as we plod along
• It is however not business as usual
• The MCC is willing to engage with all parties
Conclusion

• The area of Complementary and Alternative is complex as there are no common international standards as in orthodox medicines

• The mandate of regulators is to protect citizens in their countries within the framework of existing laws

• Globalisation is a reality and efforts towards harmonisation should be strengthened

• Efficiency through information sharing is desirable.
WHICH TRAIN? WHICH TRACK?
The train has left the station........

Now I really wish I had started focusing on the Regulations much sooner!!
Acknowledgements

1. Doms R; 2014: Commentary Plan to clean up the complementary medicines industry in South Africa
2. Gouws J; 2014: Presentation at CAMs workshops
3. Gower N; 2014: Presentation at CAMs workshops