

ROADMAP FOR REGISTRATION OF COMPLEMENTARY MEDICINES

Dr Kaizer Thembo
thembk@health.gov.za

INTRODUCTION

- Amendment to the General Regulations published 15 November 2013 allow for *inter alia* control of CAMs
 - Regulation 1 : Defined Complementary medicine
 - Regulation 25 : Added Category D complementary medicines intended for human and animal use
 - Regulations 8, 9, 10, 40, 48 deal with the label, PIL, PI require a notice to the public if the medicine is unregistered:
 - “This medicine has not been evaluated by the MCC.
 - This medicine is not intended to diagnose, treat , cure or prevent a disease”

INTRODUCTION cont....

- Definition of Complementary medicine:
 - originates from plants, minerals or animals
 - use....for assisting the innate healing power of a human or animal to mitigate, modify, alleviate or prevent illness or the symptoms.....; and
 - used according to practice of the professions under the Allied Health Professions Act
- Important to note a CAM does not intend to diagnose treat, cure or prevent a disease

INTRODUCTION cont....

- Intention of the MCC is to consider Complementary medicine:
 - On a Risk-Benefit approach
- MCC will identify the different Disciplines after consultation with the Allied Health Professions Council

WAY FORWARD

- Evaluate the existing CAMs against the definition
- Medicine not fitting the definition
 - Is not a CAM and must be removed from the market
 - Submit an application for registration
- Medicine fitting the definition
 - may stay on the market provided that the indication / claim is in line with the definition
 - Need to submit an application for registration when the pharmacological class is being called in
 - Need to correct the label, Package Insert and PIL as required by 15 February 2014

WAY FORWARD cont...

- Licensing in terms of Section 22C
 - Apply for licence to Import
 - Apply for licence to Manufacture

CALLING IN OF MEDICINES and SUBMISSIONS

- Medicines fitting the definition of a CAM and falling in pharmacological classifications and currently on the market
 - 6 (Cardiac medicines)
 - 20.2.8 (Antiviral agents)
 - 21.2 (Oral Hypoglycaemics)
 - 26 (Cytostatic agents)
- Submission within six (6) months (15 May 2014)

CALLING IN OF MEDICINES

cont....

- Pharmacological classification
 - 32.3 *Slimming preparations / weight reduction*
 - 7.1, 21.7, 21.8, 21.9 *Male and Female sex hormones and sexual stimulations*

Submission within twenty four (24) months
[15 November 2015]

CALLING IN OF MEDICINES

cont....

Pharmacological classification

- 17 *Medicines acting on muscular system*
 - Sports supplements making medicinal claim
- 22 *Vitamins*
 - Sports supplements containing supplements in excess of identified upper limits
- 32.16 *Immune stimulation*

Submission within 30 months [15 May 2016]

CALLING IN OF MEDICINES cont....

- **Due to risk to patient safety**
 - Products containing banned substances (i.e. Yohimbe etc)
 - Remove from the market immediately
 - Products containing Scheduled substances (S1 and higher)
 - Glucosamine when used for arthritis
 - Vitamin D > 500 I.U. etc
 - Methylhexanamine (body building products)
- Remove from the market immediately

NON-MEDICINAL PRODUCTS

Products falling outside the definition of a medicine

- Foodstuffs, Cosmetics and Disinfectant Act, 1972
(Act 54 of 1972)
- Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies, 1947 (Act 36 of 1947)

CLOSURE

- All CAMs to be called in for registration by December 2019

SUMMARY / CONCLUSION

