MEDICINES CONTROL COUNCIL

DEPARTMENT OF HEALTH
Republic of South Africa

MEDICINES CONTROL COUNCIL

ROADMAP FOR REGISTRATION OF COMPLEMENTARY MEDICINES

This document has been prepared to serve as a recommendation to applicants wishing to register complementary medicines for which claims of safety, quality and efficacy are being made and which have been called up for registration. It represents the Medicines Control Council's current thinking on the safety, quality and efficacy of medicines. It is not intended as an exclusive approach.

Version 1 – Implementation in accordance with Government Gazette Notice R. 870 of 15 November 2013	15 November 2013

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REGISTRAR OF MEDICINES

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1 Introduction

The Medicines Control Council has noted that there are increasing numbers of medicines frequently called complementary or alternative medicines (CAMs) being sold in South Africa for which claims of safety, quality and efficacy are being made without the products being registered by the Council.

On 22 February 2002 the Council published a notice in Government Gazette No. 7282, R. 204 solely for the purpose of an audit of products already on or about to enter the market at that time, for a period of 6 months. The intention was that the audit should have been completed in respect of those products available on the market by 22 August 2002. Nevertheless, submissions dealing with the subject matter of the 2002 notice continue to be made to the Medicines Control Council.

In addition, the 2002 notice indicated that the submissions made should provide limited information in respect of the said medicines.

Subsequently, the Minister of Health published during July 2011 an amendment to the Regulations to the Medicines and Related Substances Act, 1965 (Act 101 of 1965) that calls for the regulatory control of all complementary or alternative medicines.

2 Scope of the Document

This document lays down the roadmap for the regulatory control of complementary medicines following the publication of the General Regulations as amended by Government Gazette No. 37032 Notice R. 870 and applies equally to products for human and for veterinary use.

3 Legislative control of Complementary medicines

The 2002 notice was intended to enable the Department of Health and the Medicines Control Council to gain an understanding of the number and types of complementary or alternative medicines that were already on the market or about to enter the market by August 2002. Although this objective was achieved, submissions of notification of new products continued to be made to the Department and the Medicines Control Council.

The 2002 notice has led to much uncertainty amongst importers, manufacturers, wholesalers, retailers and consumers regarding the legal status of these products, as companies who submitted such applications were often under the misconception that these submissions were serving as applications for registration rather than simple notifications. Government Gazette Notice R. 870 of 15 November 2013 calls for the legislative control of all these complementary or alternative medicines. In terms of the Notice all medicines falling in Category D shall comply with the regulatory requirements as per the notice. In addition, in terms of Government Gazette Notice R. 870 the medicines falling in Category D and in the following pharmacological classifications 20.2.8 (Antiviral agents), 21.2 (Oral hypoglycaemics), 6 (Cardiac medicines), 26 (Cytostatic agents) are subjected to registration from the date of the said publication.

In terms of the legislative amendment to the Regulations addressing the control of complementary medicines, the following regulatory requirements should be adhered to:

(i) Licensing of Manufacturers and Wholesalers:

In terms of the provisions of Section 22C(1)(b) of the Medicines and Related Substances Act, 1965 all manufacturers and wholesalers of complementary or alternative medicines should be licensed.

3 Legislative control of Complementary medicines - continued

(ii) Labelling of Complementary medicines

In terms of the provisions of Regulations 8, 9 and 10 of the Medicines and Related Substances Act, 1965 all medicines falling in Category D must comply with the labelling requirements in so far as the product label, the Package Insert and the Patient Information Leaflet are concerned.

(iii) All other requirements in terms of the Medicines and Related Substances Act, 1965.

4 Registration of Complementary medicines

The Medicines Control Council acknowledge that a significant number of medicinal products, the so called complementary or alternative medicines, despite their long tradition, do not fulfil the requirements of a well-established medicinal use with recognised efficacy and an acceptable level of safety and are not eligible for registration. Having regard to the particular characteristics of these complementary or alternative medicinal products and taking in consideration their long tradition it is desirable to provide a special simplified registration procedure for certain of these traditional complementary or alternative medicinal products.

However, even a long tradition does not exclude the possibility that there may be concerns with regard to the medicine's safety. The Council shall therefore ask for all necessary data for assessing safety. In addition, as the quality aspects of the medicinal products are independent of the traditional use, no derogation should be made with regard to the necessary physico-chemical, biological and microbiological tests. Products should comply with quality standards in the relevant European Pharmacopoeia monographs, WHO Pharmacopoeia monographs, Indian Pharmacopoeia monographs, Chinese Pharmacopoeia monographs, or those monographs identified by the Council.

The simplified registration process shall be acceptable only where the complementary or alternative medicinal product may rely on a sufficiently long medicinal use within the European Community, India, and China or within South Africa as per the specific discipline.

Products that fall outside of the statutory definition of a medicine (non-medicinal complementary products, fulfilling the criteria of the food legislation) remain regulated by the Foodstuffs, Cosmetics and Disinfectants Act 54 of 1972 ("the Foodstuffs Act") and/or the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act 36 of 1947 and may remain on the market.

At the Medicines Control Council meeting of April 2012 (MCC52), the Council resolved that, based on a risk assessment, complementary or alternative medicines making claims for and purporting to treat, diagnose and modify conditions of HIV and AIDS, diabetes, hypertension and cancer should submit an application for evaluation to the Council in accordance with the requirements of the General Guideline on Complementary Medicine registration. In terms of the Government Gazette 37032, Notice R. 870 of 15 November 2013, the following complementary medicines, resorting in any one of the complementary medicine disciplines and falling within the following pharmacological classifications 20.2.8 (Antiviral agents), 21.2 (Oral hypoglycaemics), 6 (Cardiac medicines), 26 (Cytostatic agents) are subjected to registration from the date of the said publication.

Such complementary medicines that were available for sale in the Republic before or are so available on the date on which the aforementioned Government Gazette Notice comes into operation shall submit for registration within six (6) months from the date of publication and complementary medicines that become so available after the said date shall submit for registration prior to the sale thereof.

4 Registration of Complementary medicines - continued

Similarly, Council has resolved that all slimming / weight reduction products and sexual stimulation medicines (so-called "Life-style" products) will be called in for assessment within 24 months after the publication of the regulations. This will also apply to all complementary or alternative medicines currently on the market as well as all new CAMs products. All immune-boosters, medicines acting on muscular system (pharmacological classification 17) and sports supplements making any medicinal claim and in the case of sport supplements, containing supplements in excess of the identified upper limit of Vitamins or Minerals will be called in for evaluation assessment within 30 months of the publication of the Regulations.

Products that contain "banned" substances – such as yohimbine, damiana, kava kava and apiol – should be withdrawn from the market with immediate effect.

In addition, those that contain Scheduled substances that are currently listed in the schedules to the Act should be withdrawn from the market with immediate effect. These include glucosamine when used for arthritis (S3), silymarin (as contained in "milk thistle" (S3), Vitamin D in amounts greater than 500 I.U. a day (S3), phenylephrine (m-synephrine, contained in Citrus aurantium or Bitter Orange (S1)), dehydroepiandrosterone (DHEA, prasterone (S5)), dimethylaminoethanol (DMAE) and deanol (S5) to mention a few. The aforementioned call up of products will continue until such time as all the pharmacological classifications for complementary medicines have been called in.

Any applicant not able to submit the required data as called for by the Council will have to remove the product from the market and cease the sale thereof.

In respect of a product that satisfies the definition of a medicine and has been called up for registration in terms of section 14(2) of the Medicines Act, importers, manufacturers, wholesalers and/or retailers may exercise one of two options at the point the rescission notice comes into effect:

- They may choose to remove such a medicine from the market until such time as the medicine has been registered by the MCC; or
- They may choose to keep such a product on the market on condition that they refrain from making any medicinal claim in any form that is reasonably capable of being understood as referring to the product in question – this applies to any form of published information, including but not limited to product labels, package inserts and advertisements.

It is the intention of the Medicines Control Council to apply the provisions of the registration of complementary medicines to all such medicines by November 2019.

5 Licensing of Manufacturers and Wholesalers

In terms of the provisions of Section 22C (1)(b) of the Medicines and Related Substances Act, 1965 all manufacturers, manufacturing, importing and exporting and all wholesalers, wholesaling and distributing complementary or alternative medicines shall be licensed. All companies dealing in complementary or alternative medicines that have not yet submitted any application for a licence as provided in terms of Section 22C(1)(b) of the Act need to submit an application for the appropriate licence without delay. The Council will start with the inspections of these sites and will issue a licence where appropriate. The Council will inspect against the SA Guide to GMP with a lower expectation than required for Allopathic medicines**.**

6 Labelling of Complementary medicines

In terms of the provisions of Regulation 8 of the Medicines and Related Substances Act, 1965 all medicines falling in Category D must comply with the labelling requirements. All complementary or alternative medicines not yet called up for evaluation by the Medicines Control Council must comply with the labelling requirements within 6 months from the date of the Gazette publication. This implies that the label of each complementary medicine shall

- be written in English and at least one other official language
- state on the product label:
  - the category of medicine
  - the pharmacological classification of the medicine
  - the discipline of medicine
  - the words "This medicine has not been evaluated by the Medicines Control Council. This medicine is not intended to diagnose, treat, cure or prevent any disease"
- no other information not called for by Regulation 8 except when Council has authorised the inclusion of any such additional information

7 Enforcement

The Medicine Control Council does not have the statutory power to enforce the Medicines Act and the said call-up for registration. This resides with the Department of Health. With this in mind, the Council has requested that the Department takes all reasonable steps to ensure that those tasked with enforcing the Medicines Act, including but not limited to its Law Enforcement Unit and Port Health officials, are aware of the rescission and its implications for their work.

In cases of uncertainty as to whether a particular product is a medicine, the Registrar of Medicines should be contacted for assistance. It must be noted that so-called "dietary supplements" which make medicinal claims, including those of "supporting" or "assisting the body", satisfy the statutory definition of a medicine. It should also be noted that foreign statutes such as the United States Dietary Supplements, Health and Education Act 1994 (DSHEA) are not law in South Africa and thus have no bearing on the conduct of bodies such as the Medicines Control Council.

Please note that as per previous publications, the Minister of Health has published a number of exclusion criteria for products that may be sold in terms of the Foodstuffs Act. The rescission notice does not affect these exclusion criteria:

(i) Slimming agents

Low calorie based or natural food, without any recognised medicinal substances, together with a printed energy balanced diet approved by a registered dietician.

(ii) Vitamins

Permissible health messages allowed as per Government Gazette Notice 16930, number R.43 provided that the vitamin levels of the products do not exceed the maximum vitamin levels as previously called up by the various Government Gazette Notices.

(iii) Herbals

Products allowed to be used for the purpose of nutrition, garnishing, flavour or smell.

7 Enforcement - continued

(iv) Minerals / Electrolytes

Supplement inadequate diet provided that products do not exceed 200 % of the RDA (See MCC Circular 8/81).

(v) Aromatherapy

All preparations intended for aromatherapy for which no medicinal claims are made are excluded from registration, with permission being granted to make use of certain descriptive wording in the advertising of these products. (Government Gazette No. 16930, Notice No. R. 44)

8 General advice to consumers

Consumers must remember that all complementary or alternative medicines are medicines. As with any other medicine they should be used with care. When intending- to use a complementary or alternative medicine, make sure it is the correct product for you. Consumers must remember that "natural" does not mean safe. Many plants can be poisonous to humans. Many pharmaceutical medicines have been developed from plants because of the powerful compounds they contain.

Herbal remedies can interact with other medicines. This could result in the other medicines having reduced or enhanced effects, including side-effects. When consulting your doctor or pharmacist about your health always tell them about any complementary medicines you are taking. As with all medicines, keep complementary or alternative medicines out of the sight and reach of children.

9 Contact details

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Road map for Complementary Medicines