THE MEDICINES AMENDMENT BILL 2014 PRESENTATION

RDG'S SUBMISSION TO THE PORTFOLIO COMMITTEE ON HEALTH: MEDICINES AND RELATED SUBSTANCES AMENDMENT BILL – BILL 6 OF 2014

THE PROPOSAL

In this proposal, RDG recommends changes to Clause 1 of Bill 6 of 2014, which aims to amend the Medicines and Related Substances Act. The definition for a complementary medicine is ill-conceived and misplaced and should be removed from the proposed legal changes. By increasing the definition's scope and reach, it finds a happy home in regulations or MCC's administrative policy guidelines. So, the deletion of the proposed definition is right and of little legal consequence. These are RDG's main concerns because of the potential damaging effects on the viability of the complementary medicines' industry and future availability of health and wellness medicines in South Africa. Similarly, the inclusion principles apply to a biological medicine.

Regulatory Discussion Group Proposal

October, 2014

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A. INTRODUCTION TO THE REGULATORY DISCUSSION GROUP (RDG)

1. The RDG is an Universitas[1], affiliated people interested in the regulatory mechanisms of control created for therapeutic products in South Africa.

2. Therefore, the RDG is not a trade organisation, nor is membership limited to any specific vocation. RDG engages informed role players from diverse disciplines to augment understanding and offer insight into the fundamental aspects under review at any one time.

3. Thus, RDG's aim is to inform role players about regulatory mechanisms that can assure South Africans have access to therapeutic and consumer products that are safe, efficacious and of acceptable quality, while respecting the constitutional imperative of freedom of choice, philosophical and cultural diversity.

[1]**LAWSA: 617 Common law origin The** following distinction between an *universitas personarum* and an unincorporated association was drawn in *Webb & Co Ltd v Northern Rifles*, *Hobson & Sons v Northern Rifles*: "An *universitas personarum* in Roman-Dutch law is a legal fiction, an aggregation of individuals forming a *persona* or entity, having the capacity of acquiring rights and incurring obligations to a great extent as a human being. An *universitas* is distinguished from a mere association of individuals by the fact that it is an entity distinct from the individuals forming it, that its capacity to acquire rights or incur obligations is distinct from that of its members, which are acquired or incurred for the body as a whole, and not for the individual members."

Nowhere in the Roman-Dutch sources is it mentioned that an *universitas personarum* is based on contract. It is one of the distinctions between the *universitas* and *societas* in Roman-Dutch law that the latter is based on a contractual relationship among its members, while an *universitas* is "an entity distinct from the individuals forming it. . . [with rights which] . . . are acquired or incurred for the body as a whole, and not for the individual members".

The view that an *universitas* is based on contract originated from a combination of Roman-Dutch principles and English club law. According to the English concession system, incorporated associations come into being as legal persons by royal charter or legislation only, while unincorporated associations are without legal personality and are contractually founded. The Roman-Dutch *universitas* acquires legal personality without statutory recognition or any form of charter (like the English club without legal personality) but it is not contractually founded. Therefore the principle established by South African case law that the *universitas* is based on contract is contrary to Roman-Dutch principles.

B. PURPOSE OF THIS PRESENTATION

4. The purpose of RDG's presentation is to recommend changes to Clause 1 of the Medicines Amendment Bill 6 of 2014 (the Bill), which aims to amend the Medicines and Related Substances Act, 101 of 1965 (the Medicines Act – principal Act).

5. The Bill's definition of a complementary medicine is inflexible, ill-conceived and misplaced and should be removed from the proposed legal changes to the principal Act.

6. Even more, the existing definition of a medicine in the Medicines Act should stay unchanged. The definition has stood the test of time and legal challenge – good law is tested law. It is broad in scope and suffices to serve the purposes of protecting public health and interests when reasonably interpreted and so, is justifiable in an open and democratic society based on freedom and equality.

7. The addition of the words to the medicine definition; "*and includes any biological medicine, complementary medicine and veterinary medicine;*" are unwarranted and superfluous. These medicines are only a species and sub-classification of the genus "medicine" and already included in the definition of a medicine.

8. By way of contrast, by increasing the definition's scope and reach to match current trading practices for "modern"[2] and traditional[3] complementary medicines, it finds a happy and flexible place in regulations or MCC's administrative policy guidelines. What is more, the definition can be easily changed as the regulatory controls mature over time without reverting to the principal Act which is a lengthy process and preventable in the circumstances.

[2] Vitamin, mineral and herbal containing preparations.
[3] Homeopathic, Ayurvedic and Traditional Chinese medicines, amongst others.

9. So, the deletion of the proposed definition from the principal Act is right and of little legal consequence. It can bear fruit in sub-legislation or in quasi-judicial administrative guidelines.

10. These are RDG's main concerns because of the potential damaging effects on the viability of the complementary medicines' industry and future availability of health and wellness medicines in South Africa for which there is a demand.

11. The legal reasoning applies to a biological medicine because it is misplaced and merely a species of the genus "medicine" as explained for a complementary medicine.

C. RDG SUPPORTS GOVERNMENT'S EFFORTS TO REGULATE CAM

12. RDG respects and supports the Minister and Director General of health's efforts to regulate complementary medicines coupled with the Business Day editor's view as expressed.

13. It is, therefore not surprising that the editor of Business Day articulates incisively as follows:[4]

> ***This product should not be on the shelves. The department is absolutely correct to be clamping down on such blatant violations of a law that is, after all, accepted practice the world over.***
>
> ***When people's lives are at stake, the government has a duty to protect the public from snake-oil salesmen. Apart from the risk that whatever is in the bottle may cause direct harm, false claims can result in patients forgoing prescribed medications in favour of an "alternative" that does nothing for them.***
>
> ***There are untested products on the shelves that claim to work as prophylaxis for malaria, for instance, and to control high blood pressure and elevated sugar levels. If they don't work — and who can say they do without conducting scientifically controlled research? — people could die.***
>
> ***Business Day's support for Health Minister Aaron Motsoaledi's bid to clamp down on such abuses should not be seen as an endorsement of the "nanny state". Where people are in a position to make informed choices they should be left alone to do***

[4] Business Day Live: EDITORIAL: Motsoaledi right to clamp down February 28 2014, 05:33 accessed http://www.bdlive.co.za/opinion/editorials/2014/02/28/editorial-motsoaledi-right-to-clamp-down.

so, even when those choices might be wrong. Genuine complementary medicines — those that are prescribed by homeopaths, for instance, or are traditional herbal remedies — should get a lighter regulatory touch.

They may or may not work. But as long as customers can be reasonably sure of what is in them, and it is made clear that there is no clinical research proving their efficacy in treating whatever they are intended for, people should be free to choose how to spend their hard-earned cash. The government has a duty to protect people from swindlers, but it cannot protect them from themselves.

14. With this intention, and in consideration of the comments in the **Complementary Medicines - Quality, Safety, And Efficacy guideline** and in particular; "*The administration and logistics of registration and regulation will be dealt with later in the form of further guidelines e.g. electronic registration possibilities and short and long applications arising from these latter processes*", RDG offers this presentation for consideration. [5]

15. In case we forget what the purpose of medicines' regulatory control is about:[6]

'It would be advisable to pause for reflection lest the wood become obscured by the trees. Manifestly the Act was put on the statute book to protect the citizenry at large. Substances for the treatment of human ailments are as old as mankind itself; so are poisons and quacks. The technological explosion of the twentieth century brought in its wake a flood of pharmaceuticals unknown before and incomprehensive to most. The man in the street - and indeed many medical practitioners - could not cope with the cornucopian outpourings of the world-wide network of inventors and manufacturers of medicines.

Moreover, the marvels of advertising, marketing and distribution brought such fruits within the grasp of the general public. Hence an Act designed, as the long title emphasises, to register and control medicines. The enactment created a tightly meshed screening mechanism whereby the public was to be safeguarded: in general any medicine supplied to any person is, first, subject to stringent certification by experts; then it has to be clearly, correctly and comprehensively packaged and labelled and may only be sold by certain classes of persons and with proper explanatory information; to round it out detailed mechanisms for enforcement are created and ancillary measures are authorised.'

1. Likewise, the Medicines Control Council has expressed itself on these aspects as follows:[7]

[5] Medicines Control Council (MCC) guideline 7.01 CAMS QSE Dec13 V2. My emphasis added.
[6] Administrator, Cape v Raats Rontgen and Vermeulen (Pty) Ltd 1992 (1) SA 245 (A) at 54B--E:
[7] Roadmap for Registration of Complementary Medicines; 15 November 2013.

> ***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.***

16. With this in mind, RDG's task is to find a solution for the immediate crisis in the healthcare and wellness sector of the pharmaceutical industry (complementary medicines) caused by the new and proposed regulatory controls for complementary medicines and other therapeutic goods.

D. SCOPE AND LIMITATIONS OF THIS PROPOSAL

17. RDG focuses its concerns on Clause 1[8] of the Medicines Amendment Bill 2014.[9] In particular the following sub-clauses are scrutinised:

> ***1. Section 1 of the Medicines and Related Substances Act, 1965 (hereinafter referred to as the principal Act), is hereby amended—***
>
> ***(c) by the insertion after the definition of ''Authority'' of the following definitions:***

[8] **MEMORANDUM ON THE OBJECTS OF THE MEDICINES AND RELATED SUBSTANCES AMENDMENT BILL, 2014:**

1. BACKGROUND
1.1 The Medicines and Related Substances Amendment Bill (''Bill''), seeks to amend the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) (''principal Act''), that has been recently amended by Medicines and Related Substances Amendment Act, 2008 (Act 72 of 2008) (''amendment Act''), so as to define certain expressions and to delete or amend certain definitions; to provide for the objects and functions of the Authority; to provide for the composition, appointment of chairperson, vice-chairperson and members, disqualification of members, meetings and committees of the Board of the Authority; to replace the word ''products'' with the word ''medicines'' and expression ''Scheduled substances'' in order to correctly reflect the subject matter of the said Act; and to effect certain technical corrections; and to provide for matters connected therewith.

2. OBJECTS OF BILL
Clause 1: Amendment of section 1 of principal Act, as amended by section 1 of Amendment Act 2.1 Clause 1 seeks to amend section 1 of the principal Act by—

a) the substitution in the definition of ''advertisement'' for the word ''product'' of the words ''medicine, Scheduled substance'';
b) the deletion of the words ''which contains a Scheduled substance'' in the definitions of ''cosmetic'' and ''foodstuff'';
c) the extension of the definition of ''medicine'';
d) the insertion of definition for ''Board''; and (e) the deletion of the definitions of ''advisory committee'' and ''product''.

[9] **Long title:** To amend the Medicines and Related Substances Act, 1965, so as to define certain expressions and to delete or amend certain definitions; to provide for the objects and functions of the Authority; to provide for the composition, appointment of chairperson, vice-chairperson and members, disqualification of members, meetings and committees of the Board of the Authority; to replace the word ''products'' with the word ''medicines'' and expression ''Scheduled substances'' in order to correctly reflect the subject matter of the said Act; and to effect certain technical corrections; and to provide for matters connected therewith.

'' 'biological medicine' means any substance or mixture of substances that contains a living organism, or that is derived from a living organism or biological process, including—

a) plasma-derived and animal products, for example clotting factors, immunosera and antivenoms;

b) vaccines;

c) biotechnology-derived medicines (rDNA products), for example rHu-antihaemophilic factors, hormones, cytokines, enzymes, monoclonal antibodies, erythropoietins and nucleic acids; and

d) products developed for human gene therapy;

(d) by the insertion after the definition of ''certificate of registration'' of the following definition:

'' 'complementary medicine' means any substance or mixture of substances that—

a) originates from a plant, mineral or animal;

b) ***is used or intended to be used for, or manufactured or sold for use, in assisting the innate healing power of a human being or animal to mitigate, modify, alleviate or prevent illness or the symptoms thereof or abnormal physical or mental state; and***

c) is used in accordance with the practice of the professions regulated under the Allied Health Professions Act, 1982 (Act No. 63 of 1982);'';

(h) by the substitution in the definition of "medicine" for the words following paragraph (b) of the following words:[10],[11]

"and includes any biological medicine, complementary medicine and veterinary medicine;".

E. RDG'S PRIOR RESEARCH ON THE TOPIC

18. RDG has researched for a workable solution to regulate the complementary medicines industry within an acceptable legal framework. RDG's finding are attached as **APPENDIX 1** and are part of this record.

19. The findings of the research and as submitted to the regulatory authorities are outlined in the Table I below:

Table 1:

RELIEVING THE TENSION
RDG'S REGULATORY PROPOSAL OUTLINE FOR HEALTHCARE AND WELLNESS PRODUCTS (HC&W) AND NON-INDIGENOUS TRADITIONAL MEDICINES

No.	ITEM	TASK DESCRIPTION
1.	**ISSUE:**	To find a solution for the immediate crisis in the healthcare and wellness sector of the pharmaceutical industry caused by the new regulatory controls.
2.	**WORKING METHODOLOGY:**	RDG has divided the task into two phases: 1) Find an answer for the immediate crisis to relieve pressure on the industry (based on the Bill definition for a complementary medicine); 2) Suggest an electronic administrative system that can register (licence) HC&W and non-indigenous traditional medicines – points 1 & 2 are not dependent; and

[10] **Medicines Amendment Act 2008 definition:** " '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 humans; or
b) restoring, correcting or modifying any somatic or psychic or organic function in humans, and includes any veterinary medicine;";

[11] Current definition:

		3) With the view of speeding up the product registration timelines but without detracting from quality, safety and therapeutic efficacy or efficaciousness.
3.	**ANALYSIS OF INTERNATIONAL REGULATORY SYSTEMS:**	The findings of the comparative analysis of international systems: 1) Health Canada's system surpassed all others – computer algorithm driven – pre-approved monographs – extensive database for active and inactive ingredients, product specifications and labelling, product and sire licensing database etc; 2) Australian system (TGA) failed – no therapeutic efficacy check- Medicines Act requirement; 3) Chinese system focused on pharmaceuticals, Chinese Traditional medicines and crude drugs, too staff intensive - paper based system; 4) EU countries fragmented, each country with its own nuances; and 5) Singapore - no premarket approval for traditional medicines or health supplements.
4.	**RDG PROPOSAL:**	The plan: 1) Delete the definition of a complementary medicine from the Regulations (and Bill) - it is superfluous and inflexible; 2) Include new classifications and sub-classification (discipline specific) in Regulation 25 – healthcare and wellness products and non-indigenous traditional medicines; 3) Call up new sub-classifications for registration over time, starting with high risk classifications and those aimed at vulnerable groups; 4) Licence all facilities in terms of Section 22C. of the principal Act
5.	**CORE REASONS:**	Reasons: 1) By creating new classifications for these medicines, existing marketed products meeting the rules can continue with sale until called up for registration (vested rights) – relieves current pressure on the industry and allows time to be integrated into the regulatory system; 2) Remove marketed products containing banned or Schedule 1 and higher substances – risk to public health and safety; 3) Licensing: RDG has made a proposal to ease the issuing of applicable Section 22C Medicines Act licences, so ring fence the industry and the RSA borders.
6.	**ZA CTD VERSUS HEALTH CANADA:- ADMINISTRATIVE HURDLES**	Comparative analysis: 1) There is a fundamental difference between the CTD/eCTD system and HC. They serve different purposes. The CTD system addresses <u>form</u> while HC addresses <u>function</u>. To achieve a rapid review of a product, functionality is paramount. The CTD format is a very poor fit – too human resource intensive and no instant feedback loop and not self-

		correcting. The decision driven pre-approved monographed HC system fits well with real-time user interaction, feedback and guidance is instant and part of the process.
7.	**INTERNATIONAL COOPERATION ENCOURAGED:**	Medicines Amendment Act flexibility: 1) Finally, nothing in law prevents the Authority from agreeing to cooperate with any regulatory authority to achieve the objects of the Medicines Act of which the regulatory control of healthcare and wellness products and non-indigenous traditional medicines are but one – The Authority may enter into agreements. (Medicines Amendment Bill 2014, when promulgated).

20. In deduction of RDG's research, it makes the following observations:

20.1. In sum, RDG's purpose in this proposal (RDG'S Regulatory Proposal for Healthcare and Wellness Products and Non-Indigenous Traditional Medicines) is to find a solution for the immediate crisis in the healthcare and wellness sector of the pharmaceutical industry caused by the new regulatory controls based on the definition in the Bill for a complementary medicine.

20.1.1. To that end, RDG has divided the task into two phases: Firstly, find an answer for the immediate crisis to relieve pressure on the industry and suggest an electronic administrative system that can register HC&W and non-indigenous traditional medicines with the view of speeding up the registration timelines but without detracting from quality, safety and therapeutic efficacy. The two phases are not co-dependent or inter-reliant.

20.1.2. Thus, the findings of the comparative analysis of international systems concluded that Health Canada's system surpassed all others for various reasons but efficiency was notable.

20.1.3. More importantly, RDG's plan is straightforward. Firstly, drop the definition of a complementary medicine from the Regulations and Bill - it is superfluous, Secondly, include new classifications for healthcare and wellness products and non-indigenous traditional medicines and call these up when necessary. Thirdly, call up new sub-classifications for registration systematically, starting with high risk classifications. Finally, licence all manufacturing and distribution facilities in terms of the Medicines Act

20.1.4. Furthermore, there is a fundamental difference between the CTD/eCTD system and HC. These are the forms needed to complete a medicines application for registration.

20.1.5. They serve different purposes as highlighted in a one-on-one comparative analysis. In contrast, the CTD system addresses form while HC addresses function. But to achieve a rapid review of a product, functionality is paramount. So, the CTD format is a poor fit – too human resource intensive and no instant feedback loop. On the other hand, the decision driven pre-approved monographed HC system fits the requirements with real-time user interaction, feedback and guidance.

20.1.6. Finally, nothing in law prevents the Authority from agreeing to cooperate with any regulatory authority to achieve the objects of the Medicines Act of which the regulatory control of healthcare and wellness products and non-indigenous traditional medicines are but one.

21. Inasmuch, RDG offers such a proposal that may help parties to find a common platform for productive discussions with the purpose of protecting public health and safety while developing a solid industry formed on legal certainty.

22. On the other hand, RDG's proposal does not include African traditional medicines as this topic extends beyond the scope of the current work. However, the proposal is written to accommodate such future demands.

23. Furthermore, RDG has used a drafting style to allow easy additions of product classes (sub-classifications) to cover SAHPRA's regulatory essentials. The drafting style is in line with the Medicines and Related Substances Amendment Bill 2014. RDG has pursued this drafting style when making proposals on the regulatory control of medical devices and IVD products. RDG's purpose is to offer a composite and easy to read General Regulations' set to the Medicines Act by eliminating duplication.

24. Finally, in this proposal, RDG motivates its thinking – searching and finding a legal solution for the immediate crisis to stabilise the industry and give time to explore suitable administrative alternatives to licence and control these products including manufacturing

and distribution facilities without harming the viability of the complementary medicines industry and the people it serves.

F. RDG'S THINKING ON THE DEFINITION OF A MEDICINE

25. Indeed, determining and establishing the classification of an article such as a medicine is not easy. Although the right freely to engage in economic activity is an important right in an open and democratic society based on freedom and equality, the purpose for which the right is limited by the Medicines Act is to achieve the widest and most efficient form of regulation and control of medicines in the interests of the public. The importance of such purpose speaks for itself - without proper regulation and control the health of the public is put in danger.

26. RDG'S thinking about the definition of a medicine finds its roots in international and case law. An article or substances qualifies as a medicine (classification) if it is used for a therapeutic or medicinal purpose.[12]

27. To illustrate, water to quench thirst may, in certain circumstances, also be used simultaneously for a therapeutic purpose, for instance if a patient who has become dehydrated is given water by a medical practitioner, it is clear that the water is used with two purposes in mind: Firstly, to quench a patient's thirst; and secondly for a therapeutic purpose, viz to cure the dehydration. Water used in such a case would fall under the definition of 'medicine'.[13]

28. It is clear from the "water" example that the classification of a substance is "use" driven in that it used to "*the diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof in humans*".[14]

[12] Reitzer Pharmaceuticals (Pty) Ltd v Registrar of Medicines and Another 1998 (4) Sa 660 (T) at various paragraphs.
[13] *Ibid*, at p 686
[14] *Ibid:* Further, applying some of the basic principles of statutory interpretation, that an adherence to the literal wording and meaning to include water used merely for drinking purposes within the definition of 'medicine' would give rise to an absurdity so glaring that it could not have been contemplated by the Legislature or would lead to a result contrary to the Legislature's intention by chap 3 of the

29. Furthermore, a complementary medicine and for that matter a biological medicine is a species of the genus "medicine" To enter the portals of the Medicines Act, a substance or article must comply with either of the two attributes necessary in the definition of a medicine. Either it must be used for a therapeutic purpose or mediate a physiological function, one or the other will do.

30. To summarise, RDG opinion is that a product is classifiable as a medicine in terms of the Medicines Act if it meets any of the following criteria provided each product is evaluated on its own merits and in context. If doubt exists whether a product is a foodstuff, cosmetic or a medicine at the borderline interface then the Medicines Act will prevail in the interests of public health and safety as the more restrictive interpretation is warranted – more control over the article:

30.1. A medicine is therefore a substance or mixture of substances used or purporting (whether express or implied claims) to be suitable for use or presented for:

30.1.1. The diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof;

30.1.2. Restoring, correcting or modifying any somatic or psychic or organic function;

30.1.3. An ingredient in the product is listed in Schedule 1 or higher to the Medicines Act;

30.1.4. A product with similar ingredients is registered as a medicine;

30.1.5. A product making similar claims or indications is registered as a medicine;

Constitution, that, although the 'therapeutic purpose' of the substance was more strongly pronounced in para (a) of the definition of 'medicine' than in para (b), both paragraphs were intended to refer to substances used for therapeutic or medicinal purposes. In that case, then, water used merely to quench thirst, although it might prima facie be included under para (b), would not be used for a therapeutic or medicinal purpose and would therefore not fall within the definition of 'medicine'..

30.1.6. An ingredient in the product has a known pharmacological action at the recommended doses according to the present state of scientific knowledge;

30.1.7. An ingredient in the product has a known immunological action at the recommended doses according to the present state of scientific knowledge;

30.1.8. An ingredient in the product has a known metabolic action at the recommended doses according to the present state of scientific knowledge;

30.1.9. Submitted documentation in terms of the 2002 call-up notice for so-called complementary medicines – complementary medicines audit;

30.1.10. A product, especially if presented in a pharmaceutical dosage form contains any of the following or derivatives, precursors, by-products, or extracts: vitamins, minerals, amino acids, alkaloids, glycosides, enzymes, co-enzymes, digestive enzymes, hormones, steroids, anabolic steroids, steroidal saponins, phytosterols, phytochemical, trimethylxanthine, phytoalexin, stilbenoid, flavonoids, phospholipids, pure chemical substance, herbs, probiotics, herbal extracts, animal extracts, natural oils from plant and animal origin;

30.1.11. Product supports a body function;

30.1.12. The product carries a health warning;

30.1.13. Product is recommended by healthcare professionals or sold through health shops or pharmacies;

30.1.14. Product is indicated for vulnerable groups[15];

[15] Vulnerable Groups will include, persons with disabilities, older persons, vulnerable women and orphans.

30.1.15. Product is used by allied practitioners or promoted to or by them;

30.1.16. Product contains a herbal substance at pharmacologically effective doses;

30.1.17. Contains a substances generally used for a therapeutic purpose whether claims are made or not – express or implied claims;

30.1.18. The product has a NAPPI code or Registry audit number.

31. Finally, Judge Zondi summarises the point as follows:[16]

> ***"The question whether or not any particular substance is a medicine must be determined with reference to the provisions of the [Medicines] Act and when its identity is being questioned. The attributes of the substance and the claims made in respect of the substance will determine if it is a medicine within the meaning of the Medicines Act".***

G. CURRENT CAM DEFINITION DIFFICULTIES

32. By way of contrast, the Bill's complementary medicines definition is problematic and fraught with complications.[17] The Bill's definition of a complementary medicine creates legal uncertainty, ambiguity and misses the mark. The definition is too restrictive and unrealistic when considering split trading practice as the scope covers "modern" and "traditional" paradigms. For this reason, living side by side is not easy under such circumstances. There is a potential incompatibility.

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[16] Treatment Action Campaign and another v Rath and others [2008] 4 All SA 360 (C).

[17] GNR.510 of 10 April 2003: General Regulations as amended – same as the Bill's definition:

"**complementary medicine**" means any substance or mixture of substances that—

a) originates from plants, minerals or animals;

b) is used or intended to be used for, or manufactured or sold for use in assisting the innate healing power of a human being or animal to mitigate, modify, alleviate or prevent illness or the symptoms thereof or abnormal physical or mental state; and

c) is used in accordance with the practice of the professions regulated under the Allied Health Professions Act, 1982 (Act No. 63 of 1982);

33. To illustrate, the terms “complementary medicine” or “alternative medicine” refer to a wide-ranging set of healthcare practices that are not part of a country’s own tradition or conventional medicine and are not integrated into the main health-care system.

34. Yet the World Health Organisation (WHO) merges the terms TM and CM (WHO - T&CM) encompassing products, practices and practitioners. This encourages obfuscation to a person not involved in the relevant discipline. Even the expert stands bewildered. Not only is this bad in law but likewise does not foster clarity for those regulated, a paramount requirement. The WHO for a complementary medicine definition is bad in law.

35. As a result, the umbrella expression (as expressed in the Bill as well) "complementary and alternative medicine" (CAM) resists easy legal definition because the health systems and practices are diffuse with imprecise boundaries. CAM is described as a wide-ranging domain of healing resources that encompasses health systems, modalities, practices, theories and beliefs, but excludes those intrinsic to the government’s main health system of a particular society or culture in a given historical period.

36. In fact, captured within these inhomogeneous disciplines are a group of diverse medical and health care systems, practices, and products that are not considered part of conventional medicine. Besides boundaries within CAM and between the CAM domain and that of the main system are not always sharp or fixed. Hence, this composite conceptual framework defies definition required for singularity, uniformity and legal certainty as it circumscribes such a broad domain of healing resources, as practices and beliefs are very diverse in their foundations and methodologies.

37. Furthermore, any statutory definition may only create restrictions that are not warranted and may lead to insurmountable problems necessitating further legislative revision. Proceed with circumspection and caution!

H. A CALL FOR FOR LEGAL CERTAINTY

38. Juxtaposed, a cardinal rule of law is that the meaning of any provision must be clear, unambiguous and decisive. Legal instruments must serve its purpose and not overreach but must address the mischief the Medicines Act envisages.

39. Moreover, the purpose of enacted law is to suppress mischief in the public interest and so protect health and safety. Objects of an Act and the intention of the legislature cannot be at odds nor allow dilution. Purposivism attributes meaning to a provision in the light of the purpose that it seeks to achieve in the context of the instrument of which it forms part. [18]

40. So, the office of judges is always to make such construction as must suppress the mischief and advance the remedy, and to suppress subtle inventions and evasions for continuance of the mischief, and for private or personal gain, and to add force and life to the cure and remedy according to the true intent of the makers of the Act for the public good. For that reason, purposivism allows for a deviation from the literal or clear and unambiguous language of a statute and considered a practical necessity and hence negating literalness of interpretation.[19] RDG supports this interpretation.

I. QUICK OVERVIEW OF RDG'S PROPOSAL

41. All is not lost. Given these points and in the interests of clarity and legal precision, RDG proposes each discipline has its own classification and sub-classifications in terms of the General Regulations because RDG's view is that an umbrella classification is not workable. It lacks legal certainty and may misdirect by introducing preventable complexities later. The umbrella of a complementary medicine definition sits uncomfortably in this very complex medical and regulatory environment.

[18] Or, in other words, the purposive approach (sometimes referred to as "purposivism", purposive construction, purposive interpretation, or the "modern principle in construction" is an approach to statutory and constitutional interpretation under which common law courts interpret an enactment (that is, a statute, a part of a statute, or a clause of a constitution) in light of the purpose for which it was enacted. Purposive approach. (2014, February 7). In Wikipedia, the Free Encyclopedia. Retrieved 16:54, May 24, 2014, from http://en.wikipedia.org/w/index.php?title=Purposive_approach&oldid=594377716

[19] LAWSA: Law of South Africa; Volume 25(1) - Second Edition Volume Statute Law and Interpretation Theories of Statutory Interpretation Theories of Interpretation In The Common-Law Tradition at para 316

42. While RDG is alive to the implications attached to this suggestion, excision of the complementary medicines definition may be cheap at the price because legal payback ahead could turn out to be expensive. Legal challenges are a possibility. In short, the definition is superfluous, restraining and therefore redundant. The current definition is broad enough to accommodate the various disciplines envisaged provided they comply with the general definition for a medicine which they do. There particular mode of action (how they work) is irrelevant in their classification as a medicine.

43. Accordingly, RDG considers it important not to disturb the central construction of the Medicines Act because this strategy serves no legitimate government purpose. RDG predicts that it will only lead to problems later if included in the principal Act.

J. OPPOSING WORLD VIEWS

44. Even more, captured in the current regulatory definition (with tension) are both "modern" and traditional approaches to healthcare. These stark differences do not fit together in law as "modern" claims are established in the biomedical sciences and do not have their own separate whole medical system as begins in traditional medicine.

45. These two different worldviews cannot be integrated holistically and legally. They appear far apart resulting in vagueness echoed in the Bill's definition. Simply, what fits and where? Controls cannot be founded on ambiguity by expecting people involved to second-guess the regulator's intention.

46. In particular, RDG agrees that modern health claims (healthcare and wellness products) depend on evidence from a range of sources, including (but not limited to) clinical studies, animal and *in vitro* studies, pharmacopoeias, textbooks, peer-reviewed published articles, and regulatory authority reports. This is similar to an evidence-based method for the registration of medicines.

47. Considering a health claim is a statement that indicates the intended useful effect of a product when used following recommended conditions of use. So, RDG proposes that these claims are practical provided the health and safety of South Africans are not at risk; this is consistent with a risk-based method where health claims are matched against the level of evidence presented to support the safe use of the products.

48. To illustrate, standards of evidence determine the permissible claims, based on the credibility, strength and quality of evidence available that supports the claim. Three types of claims are acceptable, as follows:

- **Treatment claims:** these relate to the diagnosis, treatment or mitigation, or prevention of a disease, disorder or abnormal physical state, or its symptoms in humans;

- **Risk reduction claims:** these claims describe the relationship between using a medicinal ingredient and reducing the risk of developing a chronic disease or abnormal physiological state, by significantly altering a major risk factor or factors recognized to be involved in its development; and

- **Structure-function claims:** these claims describe the effect of a medicinal ingredient on a structure or physiological function in the human body, or a product's support of an anatomical or physiological function. This category includes claims of maintaining or promoting health.

49. What is more, traditional health claims should be grounded on the knowledge, skills, and practices built on theories, beliefs, and experiences indigenous to a specific culture, used in the maintenance of health, as well as prevention, diagnosis, improvement, or treatment of physical and mental illness.

50. For a claim to be categorised as "traditional use," it must start in the theories, experiences and beliefs symbolising the respective ancient practice of medicine. There are multiple ways to support a long history of use and may include demonstrating a time span

representing two generations of safe traditional use. The labelling of these products should show the traditional usage along with the source of the mechanism of action of the remedy, which should be tradition specific.

K. ADMINISTRATIVE LAW DRIVEN SYSTEM AT THE DETAIL LEVEL

51. As is practice, RDG agrees that the regulator publish administrative policy guidelines for each pharmacological or therapeutic classification, where proper to back their thinking. These administrative guidelines will give stakeholders an opportunity to take part and contribute to the unfolding dynamic and scope each discipline within a structured legal framework.

52. As has been mentioned, RDG proposes it improper to use a collective umbrella definition for a very complex set of incompatible paradigms in which we try to cover both "modern" and "traditional" disciplines. Each discipline should have its own place linked to its set of administrative guidelines as this fits our constitutional equality imperatives and eliminates unfair discrimination through equal treatment.

L. THE PRESENT CRISIS AND THE ZONDI JUDGEMENT

53. It is RDG's interpretation, based on the Zondi judgement *(Treatment Action Campaign and another v Rath and others [2008] 4 All SA 360 (C))* that it was not the purpose of the 2002 call up notice to subject to registration the nutritional substances (so called complementary medicines) mentioned in the notice.

54. Arguably and some may, with merit disagree, the primary purpose of the 2002 call-up notice was to bring the substances about which medicinal claims are made to the attention of the Medicines Control Council for it to decide the correctness of the claims and whether the claims are a health hazard.

55. What is more, the notice states categorically that submission of an application in its response does not found product registration but is a primary step in the registration process. The 2002 notice does not make the substances identified subject to registration as medicines but to a call-up process instituted as a primary step towards registration as medicines. In other words, the substances identified in the 2002 notice do not automatically become registrable.

56. Even more, in 2010, the Registrar of medicines sent out a circular telling the industry that a registry number issued in terms of the 2002 audit did not entitle one to sell the product.

M. EFFECTS OF ZONDI JUDGEMENT ON THE CAM INDUSTRY

57. That being the case, this judgement together with the Registrar of medicines directive left the self-styled "modern" complementary medicines without a safe harbour and beached. By far, most products sold in South Africa fall within this class and so potentially in breach of various terms of the Medicines Act.

58. To return to the subject, we are faced with an industry carrying an unbearable legal burden that needs urgent attention. The regulations are onerous. Nevertheless, a place exists in South Africa for these healthcare and wellness products that act in the area of preventive and promotive healthcare because the public demands access to such products if safe, effective and of acceptable quality. For this reason, the industry needs legitimate urgent protection to survive and continue with its offering under regulatory surveillance.

59. Under the circumstances, the immediate solution is not to re-classify these products as "foods" or foodstuffs. This is short sighted and hollow. By re-classifying a host of "modern" complementary medicines as foodstuffs does not solve the problem nor does the dodge address the mischief that the Medicines Act seeks to prevent. Such a strategy is irresponsible, ill-considered and not supportable. Therefore, RDG seeks a defensible long-term solution to the predicament so consumers can use these products with confidence as part of their access to healthcare services and so secure commercial survival.

60. In fact, people do not use foodstuffs to treat diseases nor are foods consumed for the article's pharmacological, immunological or metabolic effects. If doubt exists concerning the product's classification then the regulatory pathway swings in favour of the Medicines Act in the interests of public health and safety. As an example, an applicant may not introduce new chemical entities that are not used in foodstuffs using a farfetched rationale as these substances are not typically eaten or drunk by man, the test.

61. In addition, high concentrations of food-based actives not found in foodstuffs place the product's classification in question. One gram of ascorbic acid is not present in a foodstuff when considering that 100 mg is required for nutritional purposes. Nevertheless, there is no final cut off point and each product must be assessed on its own merits, the product must speak for itself. On the positive side, wellness products are indicated for healthcare and wellness purposes and should be entitled to use applicable health claims to inform users. Likewise, RDG supports this stance in the public interest but then claims must not overreach.

N. TO EACH HIS OWN IS BEAUTIFUL

62. RDG's proposal is a tidy solution that will bring instant clarity and certainty to the current confusion by deleting the definition of a complementary medicine and replacing with individual therapeutic classifications for each discipline, modern and traditional while maintaining the statutory definition of a medicine. This is the simplest legal solution for the burning crisis.

63. Equally, RDG's suggestion provides each discipline, modern and traditional with the dignity, respect and cultural diversity it deserve and discards the mishmash that now confronts and confines the different disciplines – to each its own. Let alone, this submission enhances legal elasticity for a dynamic progressive enhancements when the systems unfold and matured by experience.

64. Even more, the changes required in law are minimal. Equally important, the amendment removes the restriction of the current regulatory definition of a complementary medicine and re-introduces the full scope and domain of the general definition of a medicine.

65. To explain, removal of parts of the definition of a medicine (structure function claim - *restoring, correcting or modifying any somatic or psychic or organic function in man*) is short sighted and negatively influences the scopes of practice of allied practitioners registered in terms of the Allied Health Professions Act, No. 63 of 1982. This limitation is unnecessary and unfortunate. We need these pharmacological actions for traditional medicines of herbal and other origins to explain their mechanisms of action.

66. Thus RDG view is that this feature (lacuna) requires thoughtful reappraisal. Why limit rights when unnecessary? The Constitution requires application of a benign interpretive approach when affecting or limiting fundamental rights. Under the circumstances, RDG offers a solution to the predicament and harmonises its method with the rest of the world. Remarkably, the change required in law is small as revisiting the statute is circumvented. This method provides flexibility, international synchronisation and harmonisation, which has the gain of promoting trade across borders coupled with the standards necessary to safeguard the integrity of healthcare products.

67. In contrast, RDG observes interested parties are wasting an inordinate sum of time on unimportant definitional arguments by creating artificial divides that are fiction in law and take the matter no further.

68. Finally, considering the objectives of the Medicines Act, the purpose of the amended regulatory framework is to guarantee South Africans have ready access to healthcare and wellness products (medicines) that are safe, effective and of high quality, while respecting the constitutional imperative of freedom of choice, philosophical and cultural diversity. This aim is praiseworthy and should be tamper free unless substantive reason exist to change. So said, the current Act has stood the tests of time and still stands firm today.

O. RDG'S PRAYER

69. In the circumstances and based on the reasoning in this presentation, RDG's respectfully asks the Parliamentary Portfolio on health not to include the Clause 1 definitions proposed in the Medicines Amendment Bill 2014 in the principal Act as there are more suitable regulatory places for these definitions if needed in regulations or the Medicines Control Councils administrative policy guidelines.

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Sunday, 19 October 2014

ATTACHMENT: APPENDIX 1

APPENDIX 1

RELIEVING THE REGULATORY TENSION

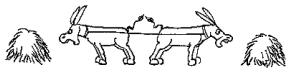
RDG'S REGULATORY PROPOSAL FOR HEALTHCARE AND WELLNESS PRODUCTS AND NON-INDIGENOUS TRADITIONAL MEDICINES

ABSTRACT

In this proposal, RDG motivates its thinking – finding a legal solution for the immediate crisis to stabilise the South African complementary medicines industry and give time to find suitable administrative procedures to licence and control these products in South Africa.

Regulatory Discussion Group Proposal

Sunday, June 1, 2014



RELIEVING THE TENSION

RDG'S REGULATORY PROPOSAL OUTLINE FOR HEALTHCARE AND WELLNESS PRODUCTS AND NON-INDIGENOUS TRADITIONAL MEDICINES

1.	**ISSUE:**	To find a solution for the immediate crisis in the healthcare and wellness sector of the pharmaceutical industry caused by the new regulatory controls.
2.	**WORKING METHODOLOGY:**	RDG has divided the task into two phases: 1) Find an answer for the immediate crisis to relieve pressure on the industry; 2) Suggest an electronic administrative system that can register HC&W and non-indigenous traditional medicines – points 1 & 2 are not dependent; and 3) With the view of speeding up the product registration timelines but without detracting from quality, safety and therapeutic efficacy.
3.	**ANALYSIS OF INTERNATIONAL REGULATORY SYSTEMS:**	The findings of the comparative analysis of international systems: 1) Health Canada's system surpassed all others – computer algorithm driven – pre-approved monographs – extensive database for active and inactive ingredients, product specifications and labelling, product and sire licensing database etc; 2) Australian system (TGA) failed – no therapeutic efficacy check- Medicines Act requirement; 3) Chinese system focused on pharmaceuticals, Chinese Traditional medicines and crude drugs, too staff intensive - paper based system; 4) EU countries fragmented, each country with its own nuances; and 5) Singapore - no premarket approval for traditional medicines or health supplements.
4.	**RDG PROPOSAL:**	The plan: 1) Delete the definition of a complementary medicine from the Regulations - it is superfluous; 2) Include new classifications and sub-classification in Regulation 25 – healthcare and wellness products and non-indigenous traditional medicines; 3) Call up new sub-classifications for registration over time, starting with high risk classifications; 4) Licence all facilities – Section 22C.
5.	**CORE REASONS:**	Reasons: 1) By creating new classifications for these medicines, existing marketed products meeting the rules can continue with sale until called up for registration (vested rights) – relieves current pressure on the industry and allows time to be integrated into the regulatory system; 2) Remove marketed products containing banned or Schedule 1 and higher substances – risk to public health and safety; 3) Licensing: RDG has made a proposal to ease the issuing of applicable Section 22C Medicines Act licences, so ring fence the industry and the RSA borders.
6.	**ZA CTD VERSUS HEALTH CANADA:**	Comparative analysis: 1) There is a fundamental difference between the CTD/eCTD system and HC. They serve different purposes. The CTD system addresses form while HC addresses function. To achieve a rapid review of a product, functionality is paramount. The CTD format is a poor fit – too human resource intensive and no instant feedback loop. The decision driven pre-approved monographed HC system fits the bill with real-time user interaction, feedback and guidance.
7.	**INTERNATIONAL COOPERATION ENCOURAGED:**	Medicines Amendment Act flexibility: 1) Finally, nothing in law prevents the Authority from agreeing to cooperate with any regulatory authority to achieve the objects of the Medicines Act of which the regulatory control of healthcare and wellness products and non-indigenous traditional medicines are but one – The Authority may enter into agreements. (Medicines Amendment Bill 2014, when promulgated).

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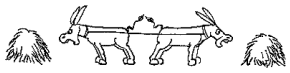


Regulatory Discussion Group

RELIEVING THE TENSION
RDG'S REGULATORY PROPOSAL FOR HEALTHCARE AND WELLNESS PRODUCTS AND NON-INDIGENOUS TRADITIONAL MEDICINES

A. BACKGROUND AND INTRODUCTION

1. The Regulatory Discussion Group (RDG) supports the Minister and Director General of health's view to regulate and control the sale of complementary medicines in South Africa. It is, therefore not surprising that the editor of Business Day expresses his views incisively as follows:[1]

> ***This product should not be on the shelves. The department is absolutely correct to be clamping down on such blatant violations of a law that is, after all, accepted practice the world over.***
>
> ***When people's lives are at stake, the government has a duty to protect the public from snake-oil salesmen. Apart from the risk that whatever is in the bottle may cause direct harm, false claims can result in patients forgoing prescribed medications in favour of an "alternative" that does nothing for them.***
>
> ***There are untested products on the shelves that claim to work as prophylaxis for malaria, for instance, and to control high blood pressure and elevated sugar levels. If they don't work — and who can say they do without conducting scientifically controlled research? — people could die.***

[1] Business Day Live: EDITORIAL: Motsoaledi right to clamp down February 28 2014, 05:33 accessed http://www.bdlive.co.za/opinion/editorials/2014/02/28/editorial-motsoaledi-right-to-clamp-down.

> ***Business Day's support for Health Minister Aaron Motsoaledi's bid to clamp down on such abuses should not be seen as an endorsement of the "nanny state". Where people are in a position to make informed choices they should be left alone to do so, even when those choices might be wrong. Genuine complementary medicines — those that are prescribed by homeopaths, for instance, or are traditional herbal remedies — should get a lighter regulatory touch.***
>
> ***They may or may not work. But as long as customers can be reasonably sure of what is in them, and it is made clear that there is no clinical research proving their efficacy in treating whatever they are intended for, people should be free to choose how to spend their hard-earned cash. The government has a duty to protect people from swindlers, but it cannot protect them from themselves.***

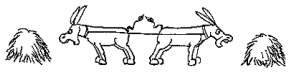
2. RDG supports the BD editor's view. With this in mind, in various public fora, including the complementary medicines workshop held in February 2014, the South African regulator asked for contributions from anyone to help find a solution and a way forward for the proper regulatory control of complementary medicines in South Africa. There is a place in South Africa for these products if well formulated, therapeutically effective, safe and of good quality.

3. With this intention, and in consideration of the comments in the Complementary Medicines - Quality, Safety, And Efficacy guideline and in particular; "*The administration and logistics of registration and regulation will be dealt with later in the form of further guidelines e.g. electronic registration possibilities and short and long applications arising from these latter processes*", RDG offers this proposal for consideration. [2]

4. In case we forget what the purpose of medicines' regulatory control is about:[3]

> ***'It would be advisable to pause for reflection lest the wood become obscured by the trees. Manifestly the Act was put on the statute book to protect the citizenry at large. Substances for the treatment of human ailments are as old as mankind itself; so are poisons and quacks. The technological explosion of the twentieth century brought in its wake a flood of pharmaceuticals unknown before and***

[2] Medicines Control Council (MCC) guideline 7.01 CAMS QSE Dec13 V2. My emphasis added.
[3] Administrator, Cape v Raats Rontgen and Vermeulen (Pty) Ltd 1992 (1) SA 245 (A) at 54B--E:



incomprehensive to most. The man in the street - and indeed many medical practitioners - could not cope with the cornucopian outpourings of the world-wide network of inventors and manufacturers of medicines.

Moreover, the marvels of advertising, marketing and distribution brought such fruits within the grasp of the general public. Hence an Act designed, as the long title emphasises, to register and control medicines. The enactment created a tightly meshed screening mechanism whereby the public was to be safeguarded: in general any medicine supplied to any person is, first, subject to stringent certification by experts; then it has to be clearly, correctly and comprehensively packaged and labelled and may only be sold by certain classes of persons and with proper explanatory information; to round it out detailed mechanisms for enforcement are created and ancillary measures are authorised.'

5. Likewise, the Medicines Control Council has expressed itself on these issues as follows:[4]

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,

[4] Roadmap for Registration of Complementary Medicines; 15 November 2013.

Chinese Pharmacopoeia monographs, or those monographs identified by the Council.

6. With this in mind, RDG's task is to find a solution for the immediate crisis in the healthcare and wellness sector of the pharmaceutical industry caused by the new regulatory controls.

7. Inasmuch, RDG offers such a proposal – a good faith discussion document – that may help parties in finding a common platform for productive discussions with the purpose of protecting public health and safety while developing a solid industry formed on legal certainty.

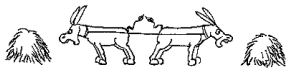
8. On the other hand, RDG's proposal does not include African traditional medicines as this topic extends beyond the scope of the current work. However, the regulations are written to accommodate future demands.

9. Furthermore, RDG has used a drafting style to allow easy additions of product classes to cover SAHPRA's regulatory essentials. The drafting style is in line with the Medicines and Related Substances Amendment Bill 2014. RDG has pursued this drafting style when making proposals on the regulatory control of medical devices and IVD products. RDG's purpose is to offer a composite and easy to read General Regulations' set to the Medicines Act by eliminating duplication.

10. Finally, in this proposal, RDG motivates its thinking – searching and finding a legal solution for the immediate crisis to stabilise the industry and give time to explore suitable administrative alternatives to licence and control these products including manufacturing and distribution facilities.

B. THE TASK – TWO PHASED APPROACH

11. Under these circumstances, RDG has divided the task into two phases. In the first place, find an answer for the immediate crisis to relieve pressure on the industry and so create legal certainty for their businesses – vested right creation. Secondly, evaluate the different regulatory procedures in the world to decide which best fits the South African regulatory environment, is compatible with our law and resource efficient. Human capacity and regulatory productivity are important features in this assessment and a key driver.



12. RDG proposes a straightforward solution for this problem. To start with, generate new classifications for these classes of medicines and so vest rights (permit continued sale until registered or rejected) by amending the General Regulations: Provided the suppliers immediately remove from the market banned and Schedule 1, and higher substances as these products pose a potential risk to public health and safety. Some of these products are spiked with dangerous ingredients, several life-threatening. This last action satisfies the MCC's resolutions while the first stabilises the industry by creating legal certainty for the continued sale of products presently on the market not containing hazardous substances – Schedule 1 and higher and banned substances.

13. Thus, RDG's aim is to assure South Africans have ready access to healthcare and wellness products that are safe, effective and of high quality, while respecting the constitutional imperative of freedom of choice, philosophical and cultural diversity.

14. If so and because of the low risk nature and marketing style of healthcare and wellness products in South Africa – preventive and promotive health, the adopted regulatory system calls for a cut of needless administrative burdens for companies trying to bring safe, effective products of acceptable quality to market. This, supported by an efficient, flexible regulatory mechanism without compromising public health and safety while enabling consumer access, industry innovation and growth.

15. Mostly, the current Medicines Act amended regulations support solutions that contribute to a broader vision of improved health and patient autonomy. RDG supports this initiative and suggests in this proposal a few improvements to take the process a step forward.

C. IS IT A MEDICINE BY EXAMPLE?

16. Determining the classification of a medicine is not easy. As an example, the applicant's case was that Florex (a dried yeast product) was a dietary supplement, not a medicine, and would therefore not have been subject to registration under the Medicines Act save for the over-broad definition of 'medicine' in s 1. Although at the time of the application no medicinal claims were being made in the advertising and packaging material, at the time of its launch the Florex label had indicated that it was intended 'for concurrent use with antibiotic therapy . . . or as prescribed by your doctor'. Further

indications that the applicant regarded Florex as an anti-diarrhoeal were, *inter alia*, that it regarded Inteflora, a product manufactured, sold and used for a similar purpose, as a competitor and the manner in which Florex had been marketed on the applicant's behalf. The applicant's attack on the definition of 'medicine' was primarily directed at the word 'used' in the introductory phrase on the grounds that, for example, even water would fall under the definition of 'medicine' if it were used to treat or cure thirst.

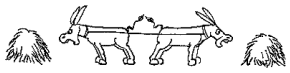
17. The court held: (*verbatim*)

17.1. Further, that, although the right freely to engage in economic activity was an important right in an open and democratic society based on freedom and equality, the purpose for which the right was limited by the Medicines Act was to achieve the widest and most efficient form of regulation and control of medicines in the interests of the public. The importance of such purpose spoke for itself - without proper regulation and control the health of the public would be endangered.

17.2. Further, that the limitation was not over-broad: the efficacy of the limitation lay in the control and regulation provided for in the Act. The limitation did not negate the essential content of the right in question. It was reasonable and justifiable that 'medicine' be widely defined.

17.3. Further, applying some of the basic principles of statutory interpretation, that an adherence to the literal wording and meaning to include water used merely for drinking purposes within the definition of 'medicine' would give rise to an absurdity so glaring that it could not have been contemplated by the Legislature or would lead to a result contrary to the Legislature's intention by chap 3 of the Constitution, that, although the 'therapeutic purpose' of the substance was more strongly pronounced in para (a) of the definition of 'medicine' than in para (b), both paragraphs were intended to refer to substances used for therapeutic or medicinal purposes. In that case, then, water used merely to quench thirst, although it might *prima facie* be included under para (b), would not be used for a therapeutic or medicinal purpose and would therefore not fall within the definition of 'medicine'.

17.4. Accordingly, given the provisions of s 35(2) of the Constitution, that the Act was reasonably capable of a more restricted interpretation which did not exceed the limits of any of the rights in chap 3 of the Constitution.



17.5. Further, as to the applicant's contention, which was conceded by the respondents, that Florex did not contain any ingredient which was inherently harmful, that this was not conclusive as it did not necessarily mean that the use of such product for certain purposes might not ultimately have serious harmful consequences. Furthermore, the mere fact that the applicant had not applied for the registration of Florex as a medicine had made it impossible for the Council to review its safety, quality and efficacy.

17.6. Further, that the respondents (MCC) were public authorities charged with the duty of promoting and protecting the public interest through the mechanisms of the Act by regulating and controlling medicines. The fact that Florex or the substances it contained might not appear to be directly harmful to the public was not conclusive because the respondents were charged not only with protecting the public against the use of unsafe or harmful substances, but also with protecting the public against ineffective substances of which the quality was not properly controlled.

17.7. Further, that in all the circumstances any alleged harm the applicant might suffer as a result of the enforcement of the Act was outweighed by the interest and the interests of the respondents (MCC). The application for a temporary interdict was accordingly dismissed.[5]

18. Furthermore, the court opined about the word "therapeutic" for the purposes of its interpretation of the word "medicine" in the Medicines Act:

> ***In s 35(1) (x) reference is made to 'the therapeutic suitability and effect' of any medicine. In my view, the concept of the 'therapeutic efficacy' of a medicine 'in relation to its effect on the health of man or any animal' (s 1(3)) is obviously closely tied to the purpose for which that medicine is used. To my mind, the Act envisages that 'medicine' is used for a therapeutic or medicinal purpose.***
>
> ***'Therapeutic', as an adjective, is defined in The Shorter Oxford English Dictionary as 'of or pertaining to the healing of disease'. Webster's Third New International Dictionary defines it as follows: 'of or relating to the treatment of disorders by remedial agents or methods'. (I refer to what Prof Folb has said above concerning***

[5] Reitzer Pharmaceuticals (Pty) Ltd v Registrar of Medicines 1998 9 BCLR 1113 (T).

dictionaries which limit the ordinary meaning assigned to 'medicine' to the treatment of illness and disease.)

The word 'geneeskundige', used in the Afrikaans text on two occasions as a translation of 'therapeutic', is defined by Bosman, Van der Merwe and Hiemstra Bilingual Dictionary as meaning 'medical, medicinal, therapeutic(al)'. 'Geneeskundige' indicates, to my mind, the broader concept of a substance used not only to treat illness and disease, but also to prevent it.

On a proper interpretation 'medicine' as defined in the Act is, to my mind, a substance used for a therapeutic or medicinal purpose.[6]

19. Similarly, Mr van Bennekom,[7] who is a wholesale dealer in health foods, vitamins and mineral products, is charged, *inter alia*, with possession for the purpose of supply, on 22 June 1981 in Amsterdam, of a large quantity of packed and unregistered proprietary medicinal products or medicinal preparations contrary to Article 3 (5) (b) of the Wet of de Geneesmiddelenvoorziening [Law on the Supply of Medicinal Products]. On that ground a large quantity of vitamin and multi-vitamin preparations which were in pharmaceutical form (tablets, pills and capsules) but were unaccompanied by any indication or recommendation within the meaning of Article 1 of the Wet op de Geneesmiddelenvoorziening were confiscated. The accused admits possession of the goods in question for the purpose of supply, but he denies that they are medicinal products.

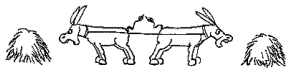
20. Under Netherlands law, any medicinal product in a pharmaceutical form must be registered by the public authorities before it may be marketed. Registration is designed to ensure that the medicinal product is subject to sufficient analysis before being put on the market in order, so far as possible, to exclude ineffective or harmful medicinal products.

21. The Wet op de Geneesmiddelenvoorziening assigns the following meaning to "medicinal product":

"Any substance or combination of substances which is intended to be used or which is in any way indicated or recommended as being suitable for:

1. Healing, treating or preventing any infection, disease, symptom, pain, wound or illness in human beings;

[6] *Ibid.*
[7] Case 227/82.



2. Restoring, correcting or modifying the function of bodily organs in human beings;

3. Making a medical diagnosis by its administration to or use upon human beings."

22. The court ruled as follows on the various questions:

22.1. **QUESTION 1:** In the first question the Court is asked, essentially, whether products such as the vitamin preparations at issue, not "indicated or recommended" expressly as being suitable for curing, treating or preventing an infection, may none the less be substances "*presented for treating or preventing disease in human being or animals*" within the meaning of the Community definition of "medicinal product" in Directive 65/65.[8]

ANSWER: ***Substances, such as the vitamin preparations at issue, which are not "indicated or recommended" expressly as being suitable for curing, treating or preventing an infection, may none the less constitute substances "presented for treating or preventing disease in human beings or animals" within the meaning of the Community definition of "medicinal product" contained in Directive 65/65.***

[8] **Article 1:** For the purposes of this Directive, the following shall have the meanings hereby assigned to them:
1. **Proprietary medicinal product:** any ready-prepared medicinal product placed on the market under a special name and in a special pack.
2. **Medicinal product:** any substance or combination of substances presented for treating or preventing disease in human beings or animals.
Any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings or in animals is likewise considered a medicinal product.
3. Substance: Any matter irrespective of origin which may be:
— human, e.g.
human blood and human blood products;
— animal, e.g.
micro-organisms, whole animals, parts of organs, animal secretions, toxins, extracts, blood products, etc.;
— vegetable, e.g.
micro-organisms, plants, parts of plants, vegetable secretions, extracts, etc.;
— chemical, e.g.
elements, naturally occurring chemical.

22.2. **QUESTION 2:** Seeks to ascertain whether a substance which may have curative or preventive properties in relation to human or animal diseases, but which is not presented as such and cannot be administered to a human being or an animal with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings or animals, nevertheless falls within the definition of a medicinal product for the purposes of Directive 65/65.

ANSWER: ***A product which falls neither under the first nor the second part of the Community definition of "medicinal product" cannot be considered a medicinal product within the meaning of Directive 65/65.***

22.3. **Question 3:** In its third question, the national court, proceeding on the assumption that vitamins in low concentrations may be regarded as foodstuffs, asks in substance whether a higher concentration should lead to their being regarded as medicinal products within the meaning of the directive, and, if so, on the basis of what criteria.

Answer: ***The classification of a vitamin as a medicinal product within the meaning of the second part of the definition in Directive 65/65 must be carried out case by case, having regard to the pharmacological properties of each of them, to the extent to which they have been established in the present state of scientific knowledge.***

22.4. **QUESTION 4, 5 AND 6:** The fourth, fifth and sixth questions ask, in substance, whether, where the certain vitamin or multi-vitamin preparations may:

a) Be regarded as medicinal products within the meaning of Directive 65/65, but are not covered by the legislation on medicinal products of one or more Member States, or

b) Are not covered by the Community definition of medicinal product, the law of one Member State may none the less prohibit the sale or the holding in stock for the purpose of supply of such preparations imported from another Member State.

ANSWER: ***Where certain vitamin or multi-vitamin preparations may:***

a) be regarded as medicinal products within the meaning of Directive 65/65, but are not covered by the legislation on medicinal products of one or more Member States, or

b) are not covered by the Community definition of medicinal products,

the law of a Member State may prohibit the sale, or the holding in stock for the purpose of supply, of such preparations imported from another Member State, in particular when they are presented in pharmaceutical form or when they are highly concentrated. However, such rules are justified only if authorizations for marketing are granted when they are compatible with the requirements of health protection.

23. To summarise, RDG opinion is that a product is classifiable as a medicine in terms of the Medicines Act if it meets any of the following criteria provided each product is evaluated on its own merits and in context. If doubt exists whether a product is a foodstuff or a medicine at the borderline then the Medicines Act will prevail in the interests of public health and safety:

23.1. Substance or mixture of substances used or purporting (express or implied claims) to be suitable for use or presented for:

23.1.1. The diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof;

23.1.2. Restoring, correcting or modifying any somatic or psychic or organic function;

23.1.3. An ingredient in the product is listed in Schedule 1 or higher to the Medicines Act;

23.1.4. A product with similar ingredients is registered as a medicine;

23.1.5. A product making similar claims or indications is registered as a medicine;

23.1.6. An ingredient in the product has a known pharmacological action at the recommended doses according to the present state of scientific knowledge;

23.1.7. An ingredient in the product has a known immunological action at the recommended doses according to the present state of scientific knowledge;

23.1.8. An ingredient in the product has a known metabolic action at at the recommended doses according to the present state of scientific knowledge;

23.1.9. Submitted documentation in terms of the 2002 call-up notice for so-called complementary medicines – complementary medicines audit;

23.1.10. Product contains any of the following or derivatives, precursors, by-products, or extracts: vitamins, minerals, amino acids, alkaloids, glycosides, enzymes, co-enzymes, digestive enzymes, hormones, steroids, anabolic steroids, steroidal saponins, phytosterols, phytochemical, trimethylxanthine, phytoalexin, stilbenoid, flavonoids, phospholipids, pure chemical substance, herbs, probiotics, herbal extracts, animal extracts, natural oils from plant and animal origin;

23.1.11. Product supports a body function;

23.1.12. The product carries a health warning;

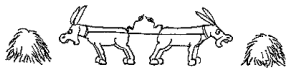
23.1.13. Product is recommended by healthcare professionals or sold through health shops or pharmacies;

23.1.14. Product is indicated for vulnerable groups[9];

23.1.15. Product is used by allied practitioners or promoted to or by them;

23.1.16. Product contains a herbal substance at pharmacologically effective doses;

[9] Vulnerable Groups will include, persons with disabilities, older persons, vulnerable women and orphans.



23.1.17. Contains a substances generally used for a therapeutic purpose whether claims are made or not – express or implied claims;

23.1.18. The product has a NAPPI code or Registry audit number.

24. Finally, Judge Zondi summarises the point as follows:[10]

> ***"The question whether or not any particular substance is a medicine must be determined with reference to the provisions of the [Medicines] Act and when its identity is being questioned. The attributes of the substance and the claims made in respect of the substance will determine if it is a medicine within the meaning of the Medicines Act".***

D. CURRENT CAM DEFINITION DIFFICULTIES

25. By way of contrast, the current regulatory complementary medicines definition is problematic and fraught with complications.[11] The current regulatory definition of a complementary medicine creates legal uncertainty, ambiguity and misses the mark. The definition is too restrictive and unrealistic when considering split trading practice as the scope covers "modern" and "traditional" paradigms. For this reason, living side by side is not easy under such circumstances.

26. To illustrate, the terms "complementary medicine" or "alternative medicine" refer to a wide-ranging set of healthcare practices that are not part of a country's own tradition or conventional medicine and are not integrated into the main health-care system.

[10] Treatment Action Campaign and another v Rath and others [2008] 4 All SA 360 (C).
[11] GNR.510 of 10 April 2003: General Regulations as amended

"**complementary medicine**" means any substance or mixture of substances that—

a) originates from plants, minerals or animals;

b) is used or intended to be used for, or manufactured or sold for use in assisting the innate healing power of a human being or animal to mitigate, modify, alleviate or prevent illness or the symptoms thereof or abnormal physical or mental state; and

c) is used in accordance with the practice of the professions regulated under the Allied Health Professions Act, 1982 (Act No. 63 of 1982);

27. Yet the World Health Organisation (WHO) merges the terms TM and CM (WHO - T&CM) encompassing products, practices and practitioners. This encourages obfuscation to a person not involved in the relevant discipline. Even the expert stands bewildered. Not only is this bad in law but likewise does not foster clarity for those regulated.

28. As a result, the umbrella expression "complementary and alternative medicine" (CAM) resists easy legal definition because the health systems and practices are diffuse with imprecise boundaries. CAM is described as a wide-ranging domain of healing resources that encompasses health systems, modalities, practices, theories and beliefs, but excludes those intrinsic to the government's main health system of a particular society or culture in a given historical period.

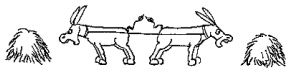
29. In fact, captured within these inhomogeneous disciplines are a group of diverse medical and health care systems, practices, and products that are not considered part of conventional medicine. Boundaries within CAM and between the CAM domain and that of the main system are not always sharp or fixed. Hence, this composite conceptual framework defies definition required for singularity, uniformity and legal certainty as it circumscribes such a broad domain of healing resources, as practices and beliefs are very diverse in their foundations and methodologies.

E. A CALL FOR FOR LEGAL CERTAINTY

30. Juxtaposed, a cardinal rule of law is that the meaning of any provision must be clear, unambiguous and decisive. Legal instruments must serve its purpose and not overreach but must address the mischief the Medicines Act envisages.

31. Moreover, the purpose of enacted law is to suppress mischief in the public interest and so protect health and safety. Objects of an Act and the intention of the legislature cannot be at odds nor allow dilution. Purposivism attributes meaning to a provision in the light of the purpose that it seeks to achieve in the context of the instrument of which it forms part. [12]

[12] Or, in other words, the purposive approach (sometimes referred to as "purposivism", purposive construction, purposive interpretation, or the "modern principle in construction" is an approach to statutory and constitutional interpretation under which common law courts interpret an enactment (that is, a statute, a part of a statute, or a clause of a



32. Consequently, the office of judges is always to make such construction as must suppress the mischief and advance the remedy, and to suppress subtle inventions and evasions for continuance of the mischief, and for private or personal gain, and to add force and life to the cure and remedy according to the true intent of the makers of the Act for the public good. For that reason, purposivism allows for a deviation from the literal or clear and unambiguous language of a statute and considered a practical necessity and hence negating literalness of interpretation.[13] RDG supports this interpretation.

F. QUICK OVERVIEW OF RDG'S PROPOSAL

33. Given these points and in the interests of clarity and legal precision, RDG proposes each discipline has its own classification and sub-classifications in terms of the General Regulations because RDG's view is that an umbrella classification is not workable. It lacks legal certainty and may misdirect by introducing unnecessary complexities later.

34. While RDG is alive to the implications attached to this suggestion, excision of the complementary medicines definition may be cheap at the price because legal payback ahead could turn out to be expensive. Legal challenges are a possibility. In short, the definition is superfluous, restraining and therefore redundant.

35. Accordingly, RDG considers it important not to disturb the central construction of the Medicines Act because this strategy serves no legitimate government purpose.

G. OPPOSING WORLD VIEWS

36. Even more, captured in the current regulatory definition (with tension) are both "modern" and traditional approaches to healthcare. These stark differences do not fit together in law as "modern" claims are established in the biomedical sciences and do not have their own separate whole medical

constitution) in light of the purpose for which it was enacted. Purposive approach. (2014, February 7). In Wikipedia, the Free Encyclopedia. Retrieved 16:54, May 24, 2014, from http://en.wikipedia.org/w/index.php?title=Purposive_approach&oldid=594377716

[13] LAWSA: Law of South Africa; Volume 25(1) - Second Edition Volume Statute Law and Interpretation Theories of Statutory Interpretation Theories of Interpretation In The Common-Law Tradition at para 316

system as begins in traditional medicine. These two different worldviews cannot be integrated holistically and legally. They appear far apart resulting in vagueness echoed in the regulatory definition.

37. In particular, RDG agrees that modern health claims (healthcare and wellness products) depend on evidence from a range of sources, including (but not limited to) clinical studies, animal and *in vitro* studies, pharmacopoeias, textbooks, peer-reviewed published articles, and regulatory authority reports. This is similar to an evidence-based method for the registration of medicines.

38. Considering a health claim is a statement that indicates the intended useful effect of a product when used following recommended conditions of use. So, RDG proposes that these claims are practical provided the health and safety of South Africans are not at risk; this is consistent with a risk-based method where health claims are matched against the level of evidence presented to support the safe use of the products.

39. To illustrate, standards of evidence determine the permissible claims, based on the credibility, strength and quality of evidence available that supports the claim. Three types of claims are acceptable, as follows:

- **Treatment claims:** these relate to the diagnosis, treatment or mitigation, or prevention of a disease, disorder or abnormal physical state, or its symptoms in humans;

- **Risk reduction claims:** these claims describe the relationship between using a medicinal ingredient and reducing the risk of developing a chronic disease or abnormal physiological state, by significantly altering a major risk factor or factors recognized to be involved in its development; and

- **Structure-function claims:** these claims describe the effect of a medicinal ingredient on a structure or physiological function in the human body, or a product's support of an anatomical or physiological function. This category includes claims of maintaining or promoting health.

40. What is more, traditional health claims should be grounded on the knowledge, skills, and practices built on theories, beliefs, and experiences indigenous to a specific culture, used in the maintenance of health, as well as prevention, diagnosis, improvement, or treatment of physical and mental

illness. For a claim to be categorised as "traditional use," it must start in the theories, experiences and beliefs symbolising the respective ancient practice of medicine. There are multiple ways to support a long history of use and may include demonstrating a time span representing two generations of safe traditional use. The labelling of these products should show the traditional usage along with the source of the mechanism of action of the remedy, which should be tradition specific.

H. ADMINISTRATIVE LAW DRIVEN SYSTEM AT THE DETAIL LEVEL

41. As is practice, RDG agrees that the regulator publish administrative guidelines for each pharmacological or therapeutic classification, where proper to back their thinking. These administrative guidelines will give stakeholders an opportunity to take part and contribute to the unfolding dynamic.

42. As stated before, RDG proposes it improper to use a collective umbrella definition for a very complex set of incompatible paradigms in which we try to cover both "modern" and "traditional" disciplines. Each discipline should have its own place linked to its set of administrative guidelines as this fits our constitutional equality imperatives and eliminates unfair discrimination through equal treatment.

I. TO EACH HIS OWN IS BEAUTIFUL

43. RDG's proposal is a tidy solution that will bring instant clarity and certainty to the current confusion by deleting the definition of a complementary medicine and replacing with individual therapeutic classifications for each discipline, modern and traditional while maintaining the statutory definition of a medicine. This is the simplest legal solution for the burning crisis.

44. Equally, RDG's suggestion provides each discipline, modern and traditional with the dignity, respect and cultural diversity it deserve and discards the mishmash that now confronts and confines the different disciplines – to each its own. Let alone, this submission enhances legal elasticity for a dynamic progressive enhancements when the systems unfold and matured by experience.

45. Even more, the changes required in law are minimal. Equally important, the amendment removes the restriction of the current regulatory definition of a

complementary medicine and re-introduces the full scope and domain of the general definition of a medicine.

46. To explain, removal of parts of the definition of a medicine (structure function claim - *restoring, correcting or modifying any somatic or psychic or organic function in man*) is short sighted and negatively influences the scopes of practice of allied practitioners registered in terms of the Allied Health Professions Act, No. 63 of 1982. This limitation is unnecessary and unfortunate. We need these pharmacological actions for traditional medicines of herbal and other origins to explain their mechanisms of action.

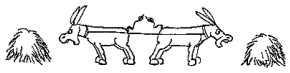
47. Thus RDG view is that this feature (lacuna) requires thoughtful reappraisal. Why limit rights when unnecessary? The Constitution requires application of a benign interpretive approach when affecting or limiting fundamental rights. Under the circumstances, RDG offers a solution to the predicament and harmonises its method with the rest of the world. Remarkably, the change required in law is small as revisiting the statute is circumvented. This method provides flexibility, international synchronisation and harmonisation, which has the gain of promoting trade across borders coupled with the standards necessary to safeguard the integrity of healthcare products.

48. In contrast, RDG observes interested parties are wasting an inordinate sum of time on unimportant definitional arguments by creating artificial divides that are fiction in law and take the matter no further.

49. Finally, considering the objectives of the Medicines Act, the purpose of the amended regulations is to guarantee South Africans have ready access to healthcare and wellness products (medicines) that are safe, effective and of high quality, while respecting the constitutional imperative of freedom of choice, philosophical and cultural diversity. This aim is praiseworthy and should be tamper free unless substantive reason exist to change. So said, the current Act has stood the tests of time and still stands firm today.

J. INTERNATIONAL COMPARATIVE ANALYSIS AND POTENTIAL SOLUTION

50. To change the topic, RDG has examined various existing international systems to regulate healthcare and wellness products and traditional medicines. RDG has come to the conclusion while taking into consideration



the South African regulatory framework and the marketing style of "modern" complementary medicines (Dietary Supplement Health and Education Act of 1994 - DSHEA styled products or "modern" complementary medicines) that Health Canada's system for the control of similar products offers a practical regulatory high-quality choice for our country. Natural health products (NHPs) marketed for sale in Canada are bound by their Food and Drugs Act and regulated as "medicines" in our parlance.

51. For the same reason, RDG has conducted a thorough comparative analysis of similar systems in the world to confirm the preferred Canadian choice. The nations' regulatory systems examined were Australia, Canada, China, European Union, Singapore and the UK. The findings RDG has compared with the South African system. That is to say, evaluation criteria were how each system tackles quality, safety, therapeutic efficacy and notably legal compatibility. Additionally, RDG checked product and site licensing rules and procedures. The aim was to show which system provides the necessary regulatory comfort that is human resource and time efficient.

52. The findings of the comparative analysis of various international systems for the control of healthcare and wellness products and non-indigenous traditional medicines confirmed that the Canadian system surpassed hands-down others reviewed. In the final analysis, the Australian system failed because the regulator does not check therapeutic efficacy claims, a need of the RSA Medicines Act. Besides, the Australians are re-designing their software system. By way of contrast, the Chinese system is focused on pharmaceuticals, Chinese Traditional medicines and Chinese crude drugs, also the regulator is a staff intensive body using a paper based system. Across the European Union countries, the regulatory control of products of this nature is fragmented, with each country having its own character. As an example, in the UK, there is no registration method for vitamins while traditional herbal products requires a paper submission. As a final point, in Singapore there is no premarket approval required for traditional medicines or health supplements. For these reasons, the Canadian system came out on top and what's more is legally compatible with South African law.

K. OVERVIEW OF THE CANADIAN SYSTEM

53. Yet, the Canadian system offers a comprehensive regulatory software package because it closely mimics the current trading practices for both modern and non-indigenous traditional medicines sold in South Africa. This is not surprising because of the US influence on the Canadian trading

practices and the influence of the US DSHEA styled modern complementary medicines.

54. Notably and on the positive side, the Natural Health Product Directorate was created to make sure Canadians have ready access to natural health products (NHPs)[14] that are safe, effective and of high quality, while respecting freedom of choice and philosophical and cultural diversity. Natural Health Products are a class of health products which include: vitamin and mineral supplements, herbal preparations, traditional and homeopathic medicines, probiotics and enzymes and cover the spectrum of "modern" complementary medicines sold in South Africa.[15]

55. Comparatively and furthermore, NHPs are regulated under their own specific regulations, the Natural Health Products Regulations, which came into effect in 2004 as indicated by their Food and Drugs Act R.S.C., 1985, c. F-27. These regulations take into account the unique nature and properties of these products. On the other hand, this is avoidable in South African law because the Medicines Act structural framework is flexible enough to accommodate these classes of products within existing regulations when considering that each county's statute is unique. The principles in law stand and definitely adaptable.[16]

56. To be legally sold in Canada, all natural health products must have a product licence, and the Canadian sites that manufacture, package, label and import these products must have site licences. Since 2004, Health Canada has authorized over 70,000 NHPs for sale and issued over 2,000 site licences.[17]

57. When the Natural Health Products Regulations came into effect in 2004, the large number of products that were on the market created an instant

[14] **Natural Health Product**
An NHP is a substance or a combination of substances described in Schedule 1 of the NHPR, a homeopathic medicine, or a traditional medicine, that is intended to provide a pharmacological activity or other direct effect in:

a) diagnosing, treating, mitigating, or preventing a disease, disorder, or abnormal physiological state or its symptoms in humans;
b) restoring or correcting organic functions in humans; or
c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

Schedule 2 of the NHPR sets out substances which do not fall within the meaning of an NHP.

[15] http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/prodnatur/nhp-psn-eng.pdf, accessed 2014-05-20 10:11:31 AM

[16] *Ibid.*

[17] *Ibid.*

number of unprocessed applications. Since then, NHPD has been working with stakeholders to create a steady and predictable regulatory environment for NHPs. NHPD has heard from stakeholders, consumers and parliamentarians on the need for increased access to products, while maintaining consumer safety. This calls for a reduction of unnecessary administrative burden for companies trying to bring safe products to market. A more flexible and efficient regulatory approach and system update came in 2012.[18]

58. Significantly, the improved system rests on three pillars driven by guidance documents (guidelines) for the licensing of "modern" complementary medicines, traditional medicines and quality control of these products.[19] The first two guidance documents outline the approach to how NHPs are reviewed in Canada, including standards for health claims, risk information and combination of NHPs. While the last, shapes the rules for ensuring high quality NHPs, while allowing for flexibility in how these requirements are met. Then, significant efforts have been made to increase the number of monographs available for applicants. To explain, NHPD has published over 250 monographs representing hundreds of ingredients. It capitalizes on earlier licensing decisions to create and update monographs so decreasing unnecessary red-tape in the review of well characterized products.[20]

59. Under the "New Approach to Natural Health Products", application review times depend on how much is known to NHPD about a product's benefits and risks, relying on information amassed from over 70,000 authorized NHPs. This means that products with the greatest level of certainty are subject to the shortest review time based on previous opinions.

60. A three-class system outlines the review targets, starting with Class I products attesting fully to a NHPD monograph, up to the more complex Class III products, which will need more review. Applicants are encouraged to use NHPD monographs to ensure the fastest review. As more monographs become available and as further process improvements are implemented, NHPD will continue redefining and expanding the three-class system criteria.[21]

CLASS	STANDARDS	TIMELINES

[18] *Ibid.*
[19] *Ibid.*
[20] *Ibid.*
[21] *Ibid.*

Class I: High level of certainty ➔ lowest level of pre-market review	Class I is comprised of products that can be indexed against an individual monograph. The level of certainty is higher, as the product has been licenced repeatedly due to its well established safety and efficacy profile.	Applications submitted using the electronic Product Licence Application form (ePLA), and meeting all parameters of the monograph will have the opportunity to attest using the embedded form and receive a licence within 10 days.
Class II: Medium level of certainty ➔ medium level of pre-market review	Class II is comprised of applications with safety and efficacy profiles of medium certainty. This includes products supported by a combination of NHPD monographs.	These products are subject to an expedited risk-based review, with a target of 30 days.
Class III: Low level of certainty ➔ higher level of pre-market review	Class III is comprised of applications with safety and efficacy profiles of higher uncertainty. Examples belonging to this class are: products with previously unlicensed claims for serious conditions, never before seen ingredients or combinations, and products with significant safety concerns.	For the novel portions of these applications, applicants will be required to submit supporting evidence. NHPD aims to complete the review of these applications in up to 180 days. When possible, NHPD will capitalize on previous licensing decisions and complete reviews in less than 180 days.

L. MODERN HEALTH CLAIMS

61. Primarily, most products sold in South Africa make modern health claims and so severely struck by the current regulatory definition of a complementary medicine. Estimates are around 60 - 80% of products sold fall into this class. As mentioned, the first Canadian guidance document applies to product licence applications for NHPs that make modern health claims and not to product licence applications for traditional medicines.

62. Modern Health Claims (biomedical claims) are claims based on evidence from a range of sources, including (but not limited to) clinical studies, animal and

in vitro studies, pharmacopoeias, textbooks, peer-reviewed published articles, and regulatory authority reports.[22]

63. Risks related to safety and efficacy includes potential risks due to an ingredient's physical or chemical form; the seriousness of the health claim and the conditions of use implied; and the health impact from lower than expected performance of the product. A risk-based assessment approach is used to categorize evidence recommendations into three levels of risk: low, medium, and high. These levels are proportionate to the standard of evidence necessary to support safety and efficacy of a product.[23]

M. RISK RATING OF MODERN HEALTH CLAIMS

64. **Low Level of Risk:** This level applies to those products/ingredients that, through their intended use, present a low risk to health. This category includes NHPs with wide safety margins, including:

64.1. NHPs used for treatment, cure, risk reduction or prevention of minor diseases or conditions (including symptoms or risk factors of those conditions), which naturally resolve in a timely manner or for which lower than expected performance of the product should not pose a major risk to the person taking it under the recommended conditions of use;

64.2. NHPs for the treatment of minor symptoms or risk factors of major conditions or the risk reduction of these conditions; and

64.3. NHPs for general health maintenance, support, or promotion that refer to modification of a biochemical or physiological function of a nutritional nature or imply benefit to a minor disease or health condition.

65. **Medium Level of Risk:** This level applies to those products/ingredients that, through their intended use, present a significant risk to health. This category includes NHPs used for treatment, cure, or prevention of major diseases or health conditions which are not naturally resolved within a timely manner or have undesirable effects that may persist or worsen if proper care is not

[22] Pathway for Licensing Natural Health Products Making Modern Health Claims accessed http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/prodnatur/legislation/docs/modern-eng.pdf; 2014-05-20 12:04:09 PM.
[23] *Ibid.*

pursued in a timely manner.[24] It also includes NHPs for the treatment of risk factors of serious conditions or the risk reduction of these conditions.

66. **High Level of Risk:** This level applies to those products/ingredients that, through their intended use, present a serious health risk. This category includes NHPs with the narrowest safety margin and effective dose range, as well as those used for treatment, cure, and prevention of serious diseases that require supervision by a health care practitioner, or are debilitating or potentially life threatening without effective treatment. High level of risk includes, but is not limited to Schedule A disease/conditions.

67. At any level of risk, additional evidence may be necessary to substantiate safety and efficacy for:

67.1. Vulnerable sub-populations (e.g., children, pregnant and breastfeeding women, elderly, amongst others);

67.2. Any known interaction among ingredients;

67.3. Any known interaction with any other product/medication; and/or

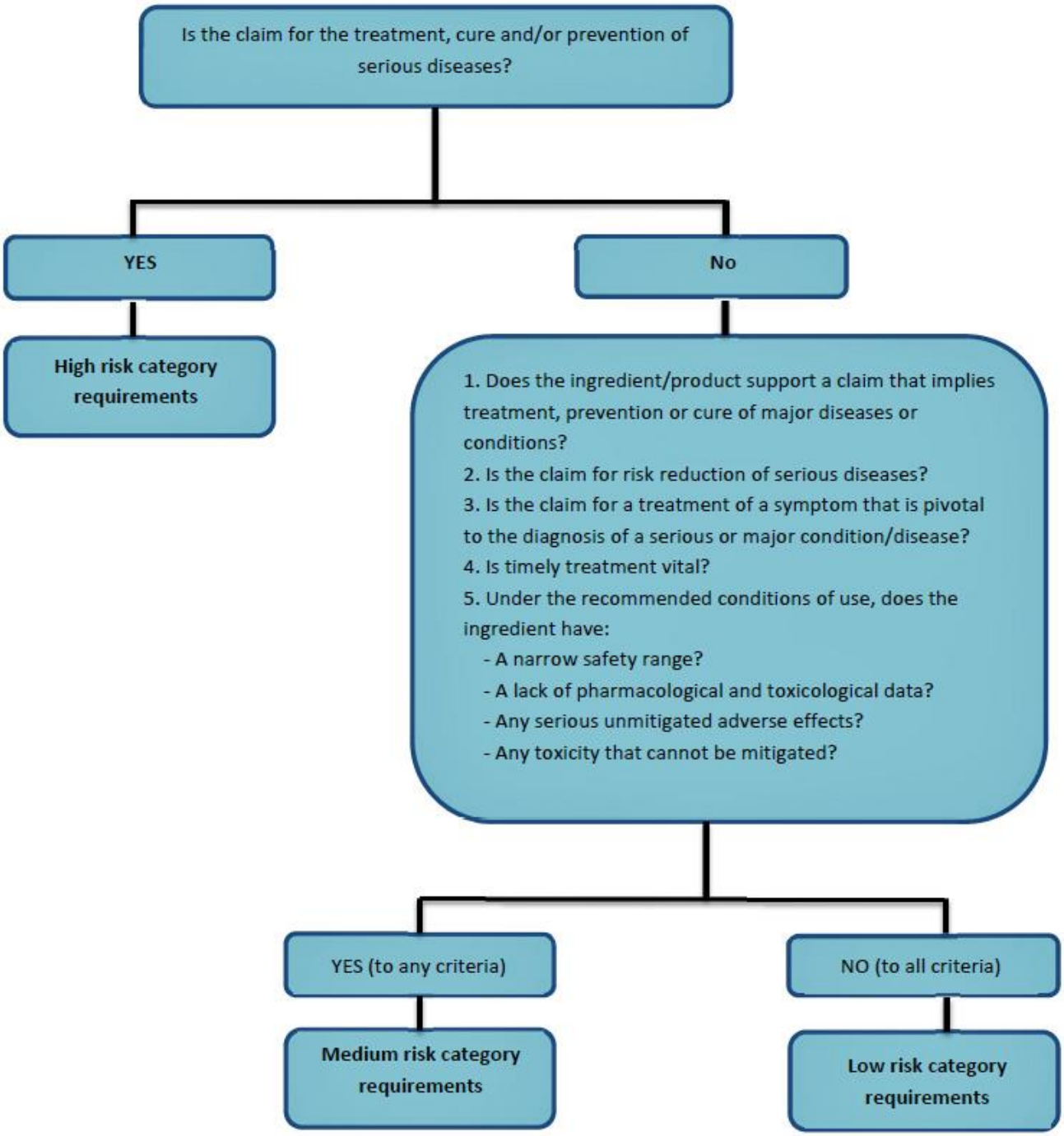
67.4. Any indication that the product/ingredient(s) may alter diagnostic testing.

68. **General Health Claims:** Products with general health claims include those that have low therapeutic impact and are therefore subject to the appropriate evidence requirements.

[24] **Claim by Health Condition:** NHP claims can be categorized into three main categories based on the characteristics of the health condition:

- **Serious disease/condition claims** are for products indicating treatment, prevention or cure of diseases/conditions that require supervision by a health care practitioner, or are debilitating or potentially life threatening without effective treatment. Treatment is vital to mitigate the health impact.
- **Major disease/condition claims** are for products indicating treatment, prevention, or cure of diseases/conditions that are not naturally resolved within a timely manner or have potentially undesirable effects that may worsen or persist if proper treatment or care is not pursued in a timely manner.
- **Minor disease/condition claims** are for products indicating treatment, prevention, risk reduction, or cure of diseases/conditions or symptoms that are expected to naturally resolve within a timely manner or for which lower than expected performance of the product should not pose a major risk to the person taking it under the recommended conditions of use.

Figure 1: Risk-Based Approach for Determining Safety and Efficacy Evidence for NHPs Making Modern Health Claims



Note: This decision process should be followed for each medicinal ingredient individually, for each claim individually, and for the product as a whole. Based on identified safety concerns for any ingredient, the evidence recommendations may be elevated to a higher category.

N. SAFETY EVIDENCE REQUIREMENTS FOR MODERN CLAIMS

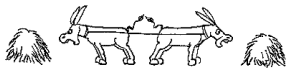
69. All products should be safe under their recommended conditions of use. Safety evidence recommendations are based on the identified risks, including but not limited to:

- Severity and seriousness of adverse effects;
- Probability or frequency of adverse effects;
- Severity and seriousness of the disease or condition for which the product is indicated for use;
- Health impact associated with a lower than expected performance of the product;
- Use by potentially vulnerable sub-populations (e.g., infants, children, pregnant and breastfeeding women, elderly); and
- Inherent risks of the medicinal ingredients in the product.

When necessary, safety evidence may also need to support:

- Chemistry and manufacturing information;
- Characterization of the disease implicated in the recommended use or purpose;
- Characterization of the risk factors associated with the disease implicated in the recommended use or purpose;
- Assessment of the potential for interactions;
- An independent causality assessment of adverse reactions;
- A description of the post-market surveillance program (for active surveillance data).

O. EFFICACY EVIDENCE FOR MODERN CLAIMS



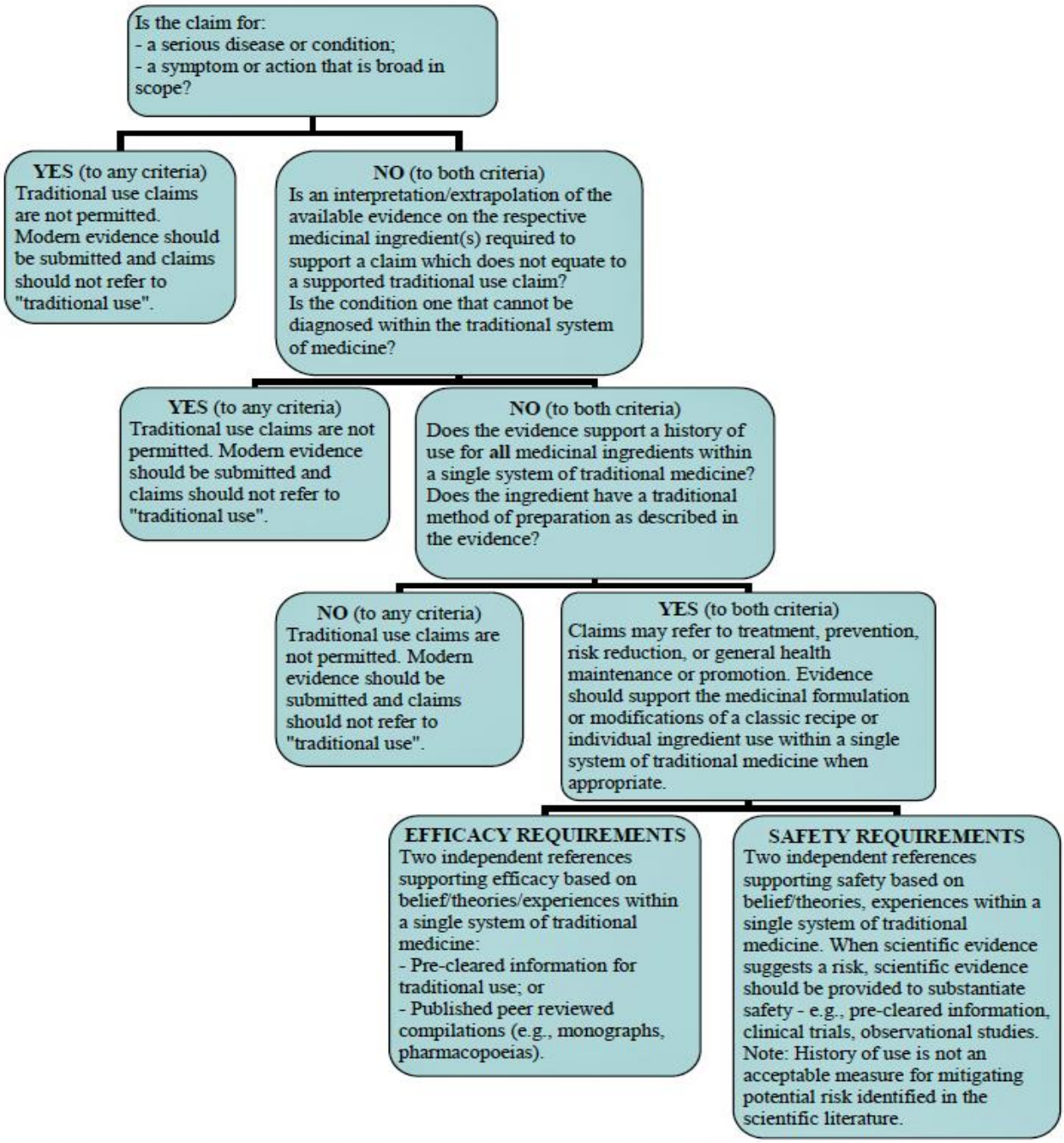
70. Products must have at least one health claim. Efficacy evidence should support the reasonable association of the medicinal ingredient(s) with the health claim(s) and show that therapeutic efficacy of the product will be supported by at least one medicinal ingredient or the combination of more than one. To do this, the evidence should support the claim for the specific target population intended, the specific directions of use and the specific system of medicine, when proper. Also, the efficacy evidence should be able to support the health context of the product and, when necessary, give enough background information to describe the characterization of the health condition implied by the claim and the health context of the recommended use.[25] Criteria for risk assessment are like those outlined in the MCC's QSE guideline, the details are not advanced here.

P. NON-INDIGENOUS TRADITIONAL MEDICINES

71. Traditional medicine is defined as medicine based on the sum total of knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures, used in the maintenance of health, as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness. This definition is one modified from the World Health Organization Traditional Medicine Program, recognizing traditional medicines at their core as ancient medical practice that existed in human societies before the application of modern science to health and that have evolved to reflect different philosophical backgrounds and cultural origins.

[25] *Ibid.*

Figure 1: Risk-Based Approach for determining when Traditional Use Claims are Appropriate for Traditional Medicines



Q. IMMEDIATE PLAN TO RELIEVE THE CURRENT CRISIS

72. To get back to the point, significant energy, over many years has gone into South African government's efforts to regulate the complementary medicines industry in South Africa. Indeed, RDG acknowledges, appreciates and supports the hard work of colleagues. In a like manner, RDG's purpose is to build on this foundation and augment this work in stakeholders' interests.

73. More importantly, the official MCC's complementary medicines regulatory plan is straight forward and clear:

73.1. Withdraw from the market products containing banned substances;

73.2. Withdraw from the market unregistered self-styled complementary products containing schedule 1 and higher substances;

73.3. Withdraw from the market misbranded products not fitting the regulatory definition of a complementary medicine; and

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

74. In reality, this robust directive has created the crisis as the object has significant bearing on the complementary medicines industry. When implemented, the nature and characteristic of this industry will change and be unrecognisable unless government intervenes. These changes and consequences are what RDG hopes to influence with stakeholders' help but then only if public safety stands supreme in this pursuit.

75. Granted, RDG acknowledges MCC's powers to regulate originate from the Medicines Act as well as our administrative law, underpinned by the Constitution. Notwithstanding the right freely to engage in economic activity is an important right in an open and democratic society based on freedom and equality, the Medicines Act limits this right. For its purpose is to achieve the widest and most efficient form of regulation and control of medicines in public interest. RDG supports this view but balance is required to find a suitable compromise between competing interests, freedoms and fundamental rights.

76. Besides, the test is to decide whether the registration or availability of a medicine is in the public interest. In so doing, the MCC may only consider the safety, quality and therapeutic efficacy's merits of the medicine. The significance of such purpose speaks for itself - without proper regulation and control the health of the public is threatened (*Reitzer Pharmaceuticals (Pty) Ltd v Registrar of Medicines and another 1998 (9) BCLR 1113 (1998 (4) SA 660) (T)*).

77. Admittedly, the industry does not take issue with the points outlined in sub-paragraphs 73.1 – *remove banned substances*, 73.2 – *remove listed S1 and higher substances* and 73.4 – *register new complementary medicines*. Since the issue is with 73.3 - *withdraw from the market misbranded self-styled complementary products not fitting the regulatory definition of a complementary medicine.*

78. Still RDG will concentrate on 73.3 that is driving the current crisis and the regulatory tensions assuming stakeholders agree with sub-paragraphs 73.1, 73.2 and 73.4. Without urgent intervention, the regulatory environment has the potential to destroy the existing wellness industry. The healthcare and wellness industry is reported with a turnover of R 8 billion and supports a noteworthy economic infrastructure. Destruction of the industry cannot be government's intention. As a result, RDG seeks immediate relief through a legally acceptable correction.

R. ZONDI JUDGEMENT

79. It is RDG's interpretation, based on the Zondi judgement (*Treatment Action Campaign and another v Rath and others [2008] 4 All SA 360 (C*)) that it was not the purpose of the 2002 call up notice to subject to registration the nutritional substances (so called complementary medicines) mentioned in the notice.

80. Arguably and some may, with merit disagree,[26] the primary purpose of the 2002 call-up notice was to bring the substances about which medicinal claims are made to the attention of the Medicines Control Council for it to decide the correctness of the claims and whether the claims are a health hazard.

[26] Some say it was a valid call-up of products for registration. There is evidence indicating it may be so. HPA however have for years held that this is not the case but may have recently changed its mind. Maybe a case of lost in translation?

81. What is more, the notice states categorically that submission of an application in its response does not found product registration but is a primary step in the registration process. The 2002 notice does not make the substances identified subject to registration as medicines but to a call-up process instituted as a primary step towards registration as medicines. In other words, the substances identified in the 2002 notice do not automatically become registrable.

82. Even more, in 2010, the Registrar of medicines sent out a circular telling the industry that a registry number issued in terms of the 2002 audit did not entitle one to sell the product.

S. EFFECTS OF ZONDI JUDGEMENT

83. That being the case, this judgement together with the Registrar of medicines directive left the self-styled "modern" complementary medicines without a safe harbour and beached. By far, most products sold in South Africa fall within this class and so potentially in breach of various terms of the Medicines Act.

84. To return to the subject, we are faced with an industry carrying an unbearable legal burden that needs urgent attention. The regulations are onerous. Nevertheless, a place exists in South Africa for these healthcare and wellness products that act in the area of preventive and promotive healthcare because the public demands access to such products if safe, effective and of acceptable quality. For this reason, the industry needs legitimate urgent protection to survive and continue with its offering under regulatory surveillance.

85. Under the circumstances, the immediate solution is not to re-classify these products as "foods". This is short sighted and hollow. By re-classifying a host of "modern" complementary medicines as foodstuffs does not solve the problem nor does the dodge address the mischief that the Medicines Act seeks to prevent. Such a strategy is irresponsible, ill-considered and not supportable. Therefore, RDG seeks a defensible long-term solution to the predicament so consumers can use these products with confidence as part of their access to healthcare services and so secure commercial survival.

86. In fact, people do not use foodstuffs to treat diseases nor are foods consumed for the article's pharmacological, immunological or metabolic effects. If doubt exists concerning the product's classification then the regulatory pathway swings in favour of the Medicines Act in the interests of public health and safety. As an example, an applicant may not introduce new chemical entities that are not used in foodstuffs using a farfetched rationale as these substances are not typically eaten or drunk by man.

87. In addition, high concentrations of food-based actives not found in foodstuffs place the product's classification in question. One gram of ascorbic acid is not present in a foodstuff when considering that 100 mg is required for nutritional purposes. Nevertheless, there is no final cut off point and each product must be assessed on its own merits, the product must speak for itself. On the positive side, wellness products are indicated for healthcare and wellness purposes and should be entitled to use applicable health claims to inform users. Likewise, RDG supports this stance in the public interest but then claims must not overreach.

T. SYNOPSIS OF RDG'S PROPOSAL

88. Above all, RDG suggests the first step to remedy the restrictiveness is to amend the Medicines Act's General Regulations to introduce legal clarity, flexibility and certainty. Equally, RDG proposes additions to accommodate both healthcare and wellness products and traditional medicines by stating so and with legal precision. No place exists for second-guessing what fits and what does not. This leads to mischief. People that work in this field must understand what the regulator permits and wants. Obligations must be frank. Regrettably, the definition of a complementary medicine fails because it is nebulous.

89. Thus, RDG's proposal is forthright and to illustrate:

89.1. Delete the definition of a complementary medicine from the General Regulations;

89.2. Delete Category D from Regulation 25 (1) (d) as it is superfluous;

89.3. Broaden the scope of General Regulation 25 - Categories and classification of medicines:

89.3.1. Amend subsection (2) by deleting reference to Category D and include the word "therapeutic" to accommodate traditional medicines: *"(2) Medicines in categories A are subdivided into the following pharmacological or <u>therapeutic</u> classifications—"*

89.3.2. (c) By insertion of the following items after item 32.16 of sub-regulation (2) –

"33. Aromatherapy medicine

34. Ayurvedic medicine

35. Biochemic tissue salts

36. Flower remedies

37. Gemmotherapy medicine

38. Healthcare and wellness products

38.1 Single ingredient

38.2 Combinations ingredients

38.2.1 Acne therapy

38.2.2 Anti-dandruff products

38.2.3 Antiseptic skin cleansers

38.2.4 Corn and callous remover

38.2.5 Counterirritants

38.2.6 Diaper rash products

38.2.7 Digestive enzymes

38.2.8 Joint health products

38.2.9 Laxatives – carbon dioxide releasing

38.2.10 Laxatives – hyperosmotic

38.2.11 Marigold extract and isolates – lutein and zeaxanthin

38.2.12 Medicated skin care products

38.2.13 Multivitamin/mineral supplements

38.2.14 Oil products, multiple ingredients

38.2.15 Oligotherapy

38.2.16 Oral health products

38.2.17 Organotherapy

38.2.18 Probiotics

38.2.19 Sunscreen

38.2.20 Wart remover

38.2.21 Whey products

38.2.22 Workout supplements

39. Homeopathic medicine

39.1 Nosodes

40. Homotoxicological medicine

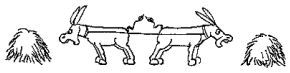
41. Traditional Chinese medicine

42. Traditional Tibetan medicine

43. Unani Tibb medicine

44. Other non-specified traditional medicines"

90. And, RDG proposes that both healthcare and wellness products and traditional medicines follow the classification system outlined by Health Canada for the regulatory control of "natural health products". Inasmuch, this is compatible with current thinking charted in the MCC's roadmap. Health Canada's monograph-based system serves the local South African



healthcare industry's purposes. Equally import, this procedure introduces significant flexibility into the call up process for these sub-classes of medicines over time. Monographs cover each of the sub-classifications recommended for the amendment.

91. The Compendium of Monographs can help speed the evaluation of the safety and efficacy of medicinal ingredients commonly used in natural health products. A monograph is a written description of particular elements on an identified topic.

92. The following are the parameters for the use of a monograph:

- **Proper name:** The proper name must be identical to the way it appears on the monograph.

- **Common name:** The common name must be chosen from one of the common names from the options provided in the monograph.

- **Source material:** The source material must be chosen from the options provided in the monograph. More than one source material is acceptable, providing that all source materials listed in the Product Licence Application form reflect the same dose and/or use or purpose on the referenced monograph.

- **Route of administration:** The route of administration must be chosen from the options provided in the monograph. There is a list of acceptable routes of administration.

- **Dosage form:** The dosage form must reflect the route of administration noted in the monograph and must be chosen from the list of recognized dosage forms. A number of dosage forms are unsuitable for compendial applications as they require quality assessment.

- **Use or purpose.** The uses have been identified for each monographed ingredient based on NHPD's evaluation of the safety and efficacy data. Applicants may choose from one or more claims provided in the monograph or create an alternative using a "statement to the effect of."

- **Dose:** The total daily dose must be either equal to that noted in the monograph, or, when a range is specified, fall within the range indicated in the monograph. Furthermore, to make a traditional use claim, the method of preparation must be one that was traditionally used. All monographs appertain to adults unless otherwise specified.

- **Potency:** Only when the monograph includes a potency, can a potency be included in the Product Licence Application form.

- **Frequency**: The frequency must be the same as the frequency on the monograph when specified. When the monograph specifies a divided dose the frequency must be more than once daily. If no frequency is specified, the applicant may select an appropriate frequency.

- **Directions of use:** Where specified, all directions of use must be included in the Product Licence Application form. The directions of use may be identical to that on the monograph or the applicant may choose to write a "statement to the effect of."

- **Duration of use:** When the monograph includes duration of use, it must be included on the Product Licence Application form.

- **Risk information:** All risk information contained in the monograph must be included in the Product Licence Application form. The risk information may be identical to that on the monograph, or the applicant may choose to write a "statement to the effect of."

- **Specifications:** The specifications must meet the minimum requirements outlined in the Compendium. Certain monographs will include additional specifications relevant to that ingredient or product.

- **Non-medicinal ingredients:** Only non-medical ingredients listed on the NHPD List of Acceptable Non-medicinal Ingredients may be used unless otherwise specified.

93. Natural Health Products Directorate's (NHPD) product licensing system allows applicants to reference the monographs below in support of the safety and efficacy of their product, rather than providing evidence for

ingredients that are already known to be safe and efficacious when used under the conditions specified in the monographs.

94. Given that, healthcare and wellness products may not contain banned substances or substances listed in Schedule 1 and higher to the Medicines Act because healthcare and wellness products may not contain poisonous substances, that is to say a contradiction in terms.

95. With this in mind, RDG proposes, in line with Health Canada's thinking that acceptable active substances for healthcare and wellness products with pre-approved health claims are:

95.1. A plant or a plant material, an alga, a bacterium, a fungus or non-human animal material, and certain listed isolates from these materials;

95.2. Carbohydrates;

95.3. Essential Fatty Acids;

95.4. Minerals;

95.5. Probiotics;

95.6. Proteins and amino acids; and

95.7. Vitamins.

96. In a like manner, traditional medicines must follow a similar regulatory path and have their own pre-approved list of substances sourced from official pharmacopoeias as outlined in the MCC guidelines.

97. In the final analysis, RDG reasons by creating the new classifications for these medicines, existing marketed products meeting the rules (removal of banned and Schedule 1 and higher substances) can continue with sale until called up for registration. Provided: The supplier removes marketed products, which contain banned or Schedule 1 and higher substances.

98. Undoubtedly, the legal relief that the industry needs and wants; the continued sale of existing products that do not contain banned and S1 and higher scheduled substance, properly made and labelled. In fact, achieving

this solution is straightforward for a simple reason; RDG's relief proposal is not reliant on a particular administrative (software) system the regulator chooses to evaluate and register these classes of products. Any administrative system will do in the short-term for immediate relief comes from the addition of the relevant classifications to the General Regulations.

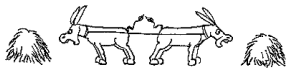
99. Most of all, RDG's proposal produces legal certainty for the industry and gives assurance to the public that these product classes are under regulatory scrutiny. Equally, such medicines must at once meet relevant Medicines Act terms and stay bound to it.

U. YOU CANNOT LIMIT THE RIGHTS OF THE REGULATOR

100. Importantly, RDG proposes that Regulation 48C be removed from the general Regulations because it prescribes when specified classes of medicines are to be call-up for registration. This is a decision that must be left to the regulator to decide as events unfold. Dictating specific timelines may not be in the best public interest during this uncertain time of regulatory fluidity.

101. The Medicines Act prescribes the procedure to follow when calling up a medicine for registration.[27] To clarify, Section 14 prescribes the procedure

[27] **14. Prohibition on the sale of medicines which are subject to registration and are not registered.**—(1) Save as provided in this section or sections 21 and 22A, no person shall sell any medicine which is subject to registration by virtue of a resolution published in terms of subsection (2) unless it is registered.
(2) (a) The council may from time to time by resolution approved by the Minister, determine that a medicine or class or category of medicines or part of any class or category of medicines mentioned in the resolution shall be subject to registration in terms of this Act.
(b) Any such resolution may also relate only to medicines which were available for sale in the Republic immediately prior to the date on which it comes into operation in terms of paragraph (c) or only to medicines which were not then so available.
[Para. (b) substituted by s. 7 (a) of Act No. 94 of 1991.]
Wording of Sections
(c) Any such resolution shall be published in the Gazette by the registrar and shall come into operation on the date on which it is so published.
(3) In the case of a medicine which was available for sale in the Republic immediately prior to the date of publication in the Gazette of the resolution by virtue of which it is subject to registration in terms of this Act, the provisions of subsection (1) shall come into operation—
(a) if no application for the registration of such medicine is made within the period of six months immediately succeeding that date, on the expiration of that period; or
(b) if application for the registration of such medicine is made within the said period, on the date one month after the date on which a notice in respect of such medicine is published in the Gazette in terms of section 15 (10) or section 17 (a).



the Registrar must follow. However, the power to call up a particular category or class of medicine is a discretionary right. In fact, discretionary powers are easily recognised by the permissive statutory language that confers them: They are signalled by words in empowering provisions such as '*may'* or *'it shall be lawful'*. Such powers are characterised by the element of choice they confer on the regulator. To explain, as Kenneth Culp Davis famously put it, *'a public officer has discretion whenever the effective limits of his power leave him free to make a choice among possible courses of action and inaction'. To say that somebody has a discretion 'presupposes that there is no unique legal answer*' to the problem.[28]

102. So, Regulation 48C is misplaced for two reasons. Firstly, call-up notices are issued by the Registrar in terms of Section 14(2) of The Medicines Act as the "*council may from time to time by resolution approved by the Minister, determine that a medicine or class or category of medicines or part of any class or category of medicines mentioned in the resolution shall be subject to registration in terms of this Act*". Secondly, because the Medicines Act is in flux and may change in the short-term, it is prudent not to bind the new regulator to terms to which it may not agree in future or turn out to be unsuitable should a new system be put in place to administer these medicines. In the circumstances, RDG suggests Regulation 48C be removed from the General Regulations and product classes called up for registration when fitting. Furthermore, there is latitude for the regulator to vary the call-up notices not in force. There is a window of opportunity to do just this task.[29]

[28] Kenneth Culp Davis Discretionary Justice, 2nd edition, 1971, 4.

[29] For instance, in Kruger v President of the Republic of South Africa, in which the President had issued a proclamation bringing into force an arbitrary selection of statutory provisions on a future date, the Constitutional Court found that the President would have been entitled to revoke the proclamation at any time before the date on which the relevant provisions were to come into force. 'The power to withdraw', Skweyiya J observed, 'accords with the nature of the power to issue and publish proclamations of this sort and the lawful exercise of this power will not be harmful to the rule of law'.

In relation to other administrative acts s 10(1) of the Interpretation Act provides that unless the contrary intention appears, where powers are conferred or duties are imposed, these may be exercised 'from time to time as occasion requires'. This enigmatic provision could be interpreted as allowing for the free variation or revocation of non-legislative acts, in accordance with the proposition that 'effective daily administration is inconceivable without the continuous exercise and re-exercise of statutory powers and the reversal of decisions previously made'. 162 But the better interpretation is that s 10(1) merely enables administrators to exercise their powers anew in different situations, and not to revisit or revoke their existing decisions whenever they like.

103. To clarify, when, if ever, does an administrator have the power to vary or revoke its own decisions? This is a question of great practical importance in administrative law, and it has received a good deal of attention from our courts over the years. It is addressed to by legislation — in this case, the Interpretation Act 33 of 1957 rather than the PAJA.

104. As far as legislative administrative acts are concerned, the answer to the question above is simple enough: at common law, legislation may generally be amended or repealed by the body that is empowered to make it (maxim: *cujus est instituere ejus est abrogare*).[30] Section 10(3) of the Interpretation Act mirrors this by providing that unless a contrary intention appears, a power to make *'rules, regulations or by-laws'* includes the power to *'rescind, revoke, amend or vary*' them. Today this public power would, however, have to be exercised following PAJA to the extent that rulemaking qualifies as administrative action, and at least it would have to comply with the principle of legality and the broader rule of law.[31] On the positive side, it seems unlikely that people will object to a regulation that suites their cause and creates rights for them.

105. In the circumstances, RDG thinks it prudent to administer the content of Regulation 48C in pertinent statutory provisions (Section 14) linked to administrative policy guidelines.

V. SITE LICENSING

106. Site licensing is an important part of any regulatory system to assure that healthcare products are produced in a high quality way according to sound good manufacturing and distribution practices. The licence holder is finally

There are good reasons for this. The rule of law holds that individuals should be entitled to rely on governmental decisions, and to be able to plan their lives around such decisions, insulated at least to some degree from the injustice that would result from a sudden change of mind on the administrator's part. There is also the fundamental principle that administrators must have lawful authority for everything they do — or undo. These considerations of certainty, fairness and legality help to explain why official decision-makers are said at common law to be functus officio once a decision has been made. 163 According to this doctrine, an official who has once 'discharged his official function' by making a decision is unable to change his mind and revoke, withdraw or revisit the decision. Extracted from Hoexter C, Administrative law in South Africa Juta 2013, p 276-7.

[30] *Ibid* p 277.

[31] *Ibid.*

responsible for product quality. As a result, RDG proposes that manufacturers of healthcare and wellness products and non-indigenous traditional medicines follow the current South African rules for good manufacturing and distribution practices qualified to the basket of products manufactured in the facility.

107. RDG proposes that unlicensed manufacturers of healthcare and wellness products and non-indigenous traditional medicines and applicants, without delay be issued with a manufacturing licence in terms of Section 22C of the Medicines Act. To ease this process, RDG has proposed that Regulation 19 to the General regulations be modified to accommodate this suggestion:

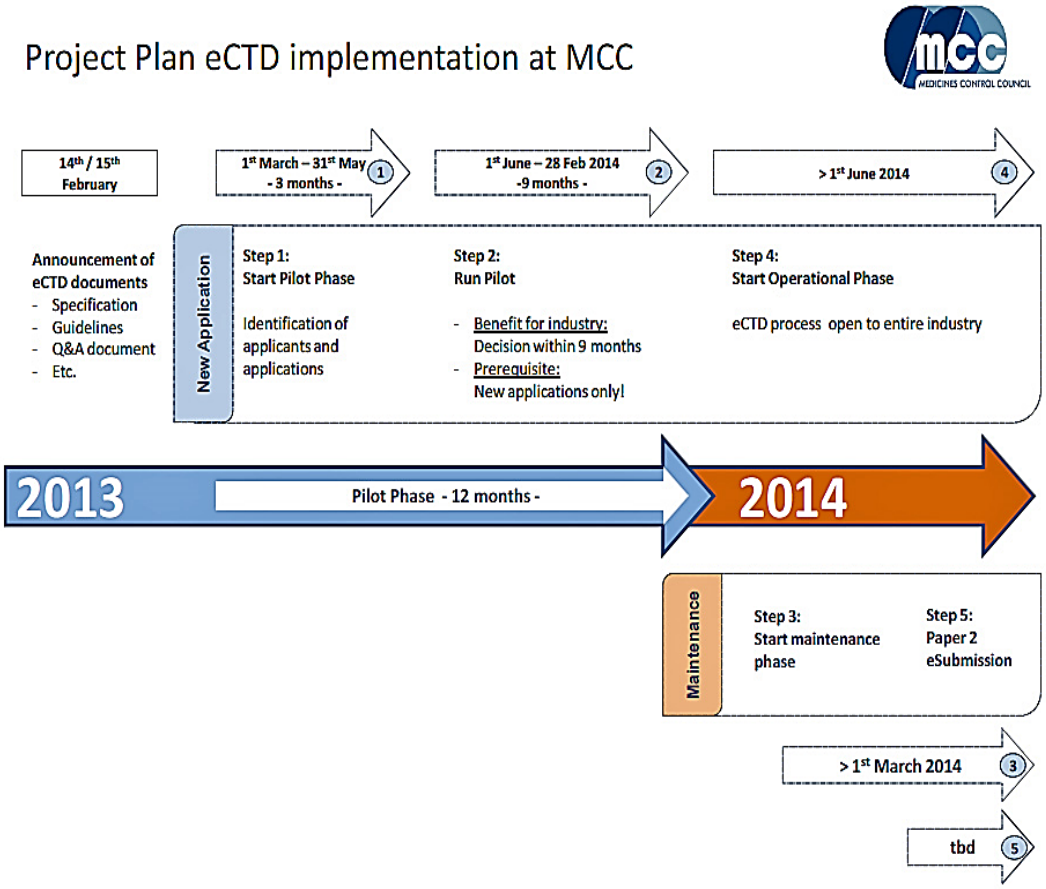
Regulation 19 (3) The Authority [Council] must where applicable, inspect the business premises specified in the application.

108. Compliance and enforcement activities are a key element to safeguard the medicines and health products to which South African have access. The Inspectorate is well-placed to watch compliance of these products. Where the inspectorate identifies or is notified of a potential non-compliance, they can take steps to prove whether a problem exists. Also, pharmaco-vigilance (PV) plays an important role as its purpose and activities relate to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem. Further, the aims of PV are to enhance patient care and safety with medicines; and to support public health programmes by providing reliable, balanced information for the effective assessment of the risk-benefit profile of medicines.

W. COMPARATIVE ANALYSIS - ZACTD AND HC SYSTEM

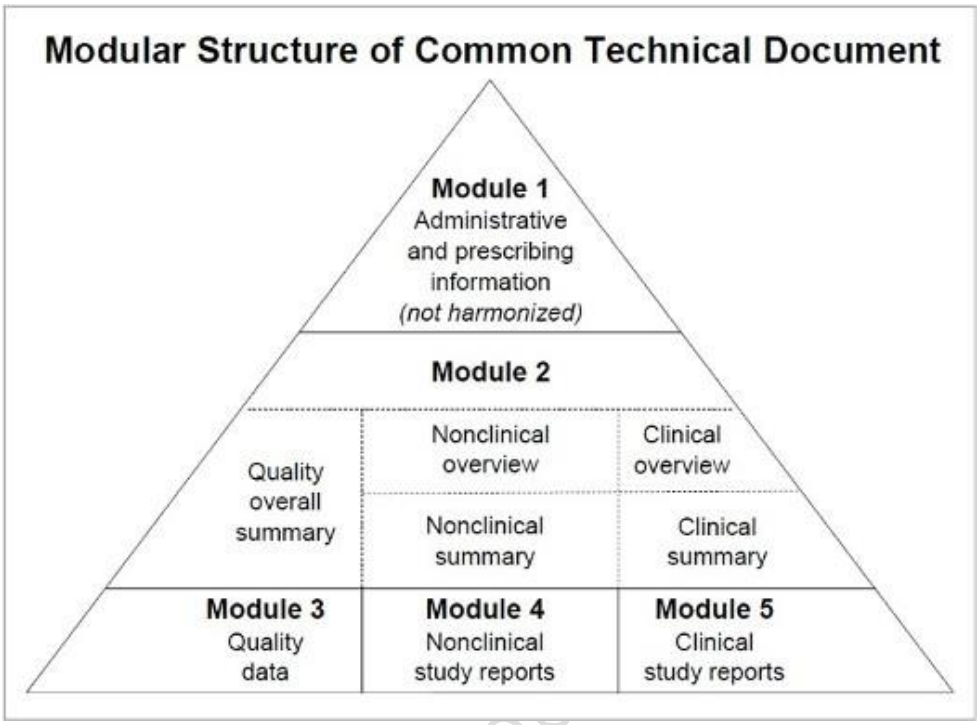
109. In June 2010, the Medicines Control Council (MCC) announced the intention to implement the South African Common Technical Document (ZA CTD) format which would replace the current MRF1 and any applications still in MBR1 format.

110. In brief, the Common Technical Document (CTD) is a set of specifications for an application dossier for the registration of medicines and designed to be used across Europe, Japan and the United States. It is an internationally agreed format for the preparation of applications on new drugs intended to be submitted to regional regulatory authorities in participating countries. It



was developed by the European Medicines Agency (EMA, Europe), the Food and Drug Administration (FDA, US) and the Ministry of Health, Labour and Welfare (Japan). To finish, the CTD is maintained by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

111. To illustrate, the Common Technical Document is divided into five modules:



1. Administrative and prescribing information

2. Overview and summary of modules 3 to 5

3. Quality (pharmaceutical documentation)

4. Preclinical (Pharmacology/Toxicology)

5. Clinical – efficacy (Clinical Trials)

112. The Electronic Common Technical Document (eCTD) is an interface for the pharmaceutical industry to agency transfer of regulatory information. Yet the Paper CTD is destined to be replaced by its electronic counterpart, the eCTD but the content remains based on the Common Technical Document (CTD) format.

113. Briefly, A CTD is a common harmonized FORMAT for applications for preparing marketing authorizations in various regulatory regions. A TEMPLATE for presenting data in the dossier. But is NOT a statement of data requirements for applications. Its purpose is to provide for a well-structured harmonized common format/template for the submission of technical

requirement to the regulatory authorities that is acceptable in ICH regions and facilitate exchange of regulatory information among regulatory authorities. Or, in other words, the CTD refers to an application format and not to an application type.

114. CTD does not indicate the studies required to support the application; it just indicates a suitable format for the representation of chemical-pharmaceutical, nonclinical and clinical data that have been acquired to support the application.

115. On the contrary, the CTD does not harmonise the technical content of the submission; it provides a common format in which the data must be submitted. And so the role of the eCTD is to offer the ability to transfer the CTD from industry to a regulatory authority.

116. In contrast, the Health Canada system is a software application programme driven across the internet. The Natural Health Products Online Solution is a suite of secure electronic tools that allow for quicker drafting and processing of natural health product licence (registration) applications. Through accurate data capture and product content validation for the applicant, the Natural Health Products Online Solution provides higher quality submissions requiring fewer clarifications and contributes to faster decision making and licencing.[32]

117. The suite of tools includes the Electronic Product Licence Application Forms (ePLAs), the Natural Health Products Ingredient Database (NHPID), the Electronic Submission Builder (eSB) and Trading Partner accounts:

- Related Guidance Documents and Forms;
- Natural Health Products Ingredients Database;
- Features and System Requirements;
- Forms and User Guides;
- Instructional Videos;

[32] http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/online-enligne/index-eng.php accessed 2014-05-21 10:00:05 AM.

- NHP Online Solution Frequently Asked Questions;
- Electronic Submission Builder (eSB) program; and
- Guidance document on how to interact with the Natural Health Products Directorate electronically.

118. To highlight, the Natural Health Products Ingredients Database is a repository of scientific terminologies and pre-cleared information approved by the Natural Health Products Directorate (NHPD). The NHPID is a database holding the NHPD's standards for validated NHP ingredient information and pre-cleared NHP information. Standardized information includes terminologies, ingredient roles and functions, and controlled vocabulary such as test methods and units of measurement. It also assists in populating selected portions of the ePLA based on the application type.

119. The information found inside the database, and then populating the ePLA, is seen as the most current information from the NHPD. Plus, the information within the database is constantly growing and evolving along with advancements in the knowledge of natural health products. As such, it houses information that has been reviewed and does not represent the final state of all NHP related items. This is why the NHPD encourages applicants to submit NHPID Issue forms to modify and add new information to the database when required.

120. The Natural Health Products Ingredients Database is designed to:

- capture and provide access to a scientific repository of approved medicinal and non-medicinal ingredient information as well as NHPD monograph and abbreviated labelling standards information;
- validate content of product license applications as they are prepared electronically; and
- serve as a world-class reference standard for internal assessment, and for the natural health products industry.

121. At present, there is no other internationally-known and/or agreed-upon list and/or primary reference that provides exhaustive details of substances or terms relating to natural health products in Canada.[33]

122. Furthermore, the Natural Health Products Ingredients Database contains:

122.1. Medicinal ingredients;

122.2. Non-medicinal ingredients;

122.3. Non-Natural Health Product (NHP) ingredients (not allowed as medicinal ingredients in natural health products or under specific restrictions);

122.4. Selected single-ingredient NHPD monographs and selected single-ingredient abbreviated labelling standards (AbLS);

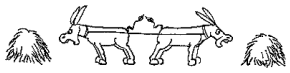
122.5. Ingredient details relevant to their type (for example, Chemical Abstracts Service (CAS) numbers for chemical substances, organism parts and preparations for organism substances, etc.);

122.6. Medicinal, non-medicinal, and non-NHP ingredient restriction details; and

122.7. Controlled vocabularies that represent a standard for the electronic transmission of core sets of natural health product information (e.g. lists for dosage forms, route of administrations, ingredient categories, organism parts, organism preparations, non-medicinal purposes, etc.)

123. Into the bargain, the Natural Health Products Ingredients Database includes a search engine that enables users to search and navigate easily through the defined ingredient terminology. The database is a dynamic information repository that is continuously updated to show the most recent findings within the NHP industry. Let alone, the Natural Health Products Ingredients Database Issue Form captures the details necessary to make a prompt and accurate decision of requests for potential improvements to the database.

[33] *Ibid.*



124. Still more, the ePLA is an electronic version of the NHPD's paper Product Licence Application Form with several key improvements to make sure that submitted applications are not missing information needed for processing. The ePLA will check required fields were not left blank and certain pieces of data are in the correct format. For instance, the ePLA connects with the NHPID to confirm only pre-validated ingredients and nomenclature are selectable from the electronic application. This ensures applications will contain less errors and be processed faster by the NHPD. Another key point is ePLA eliminates the need for paper, which expedites processing times and reduces costs.

125. Surprisingly, the computer requirements are modest. That is, most modern PCs running Windows XP or higher will work with the NHP Online Solution tools. For best results, you will want to run Microsoft Internet Explorer when using the NHPID and will want to ensure that you have the most recent version of both Adobe Reader and Java.

126. In the final analysis, there is a fundamental difference between the CTD/eCTD system and HC. The systems serve separate purposes. The CTD system addresses form while the HC speaks to function. To achieve a rapid review of a product, the need is functionality. In the circumstances, the CTD format is a poor fit for the job at hand as it lacks real-time interaction between the applicant and the regulator and is not self-correcting.

X. MCC'S GUIDANCE DOCUMENTS AND HEALTH CANADA

127. The Roadmap for the Registration of Complementary Medicines (December 2013) describes the pathway for the regulatory control of complementary medicines. The QSE guidance document[34] is compatible with the Canadian system which it mimics in many respects.

128. To illustrate, a licence application in terms of the HC regulations must contain the following information:

> ***5.*** *An application for a product licence shall be submitted to the Minister and shall contain the following information and documents:*

[34] 7.01 CAMs QSE Dec13 v2

(a) the name, address and telephone number, and if applicable, the facsimile number and electronic mail address of the applicant;

(b) if the address submitted under paragraph (a) is not a Canadian address, the name, address and telephone number, and if applicable, the facsimile number and electronic mail address of the applicant's representative in Canada to whom notices may be sent;

(c) for each medicinal ingredient of the natural health product,

i. its proper name and its common name,

ii. its quantity per dosage unit,

iii. its potency, if a representation relating to its potency is to be shown on any label of the natural health product,

iv. a description of its source material, and

v. a statement indicating whether it is synthetically manufactured;

(d) a qualitative list of the non-medicinal ingredients that are proposed for the natural health product and for each ingredient listed, a statement that indicates the purpose of the ingredient;

(e) each brand name under which the natural health product is proposed to be sold;

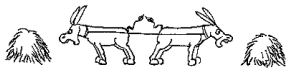
(f) the recommended conditions of use for the natural health product;

(g) information that supports the safety and efficacy of the natural health product when it is used in accordance with the recommended conditions of use;

(h) the text of each label that is proposed to be used in conjunction with the natural health product;

(i) a copy of the specifications to which the natural health product will comply; and[35]

[35] **Specifications:**
44. (1) Every natural health product available for sale shall comply with the specifications submitted in respect of that natural health product under paragraph 5(i) and with every change to those specifications made by the product licence holder.
(2) The specifications shall contain the following information:
(a) detailed information respecting the purity of the natural health product, including statements indicating its purity tolerances;
(b) for each medicinal ingredient of the natural health product, detailed information respecting its quantity per dosage unit and its identity, including statements indicating its quantity and identity tolerances;



(j) one of the following attestations, namely,

i. if the natural health product is imported, an attestation by the applicant that the natural health product will be manufactured, packaged, labelled, imported, distributed and stored in accordance with the requirements set out in Part 3 or in accordance with requirements that are equivalent to those set out in Part 3, or

ii. if the natural health product is not imported, an attestation by the applicant that the natural health product will be manufactured, packaged, labelled, distributed and stored in accordance with requirements set out in Part 3.[36]

129. To conclude, a comparative analysis of the RSA CTD document and HC are reproduced in Annexure 2. As a result of this, no relevant difference is obvious in the rules, even more so when considering the low risk nature of the products in question.

130. In the final analysis, the logical conclusion from the analysis indicates that the Canadian system serves the immediate needs of the complementary medicines industry because it is a legal and technical fit.

Y. INTERNATIONAL REGULATORY COOPERATION AND HARMONISATION

131. It should not shock anyone to hear that we are living in an increasingly interdependent world. International regulatory cooperation sometimes

(c) if a representation relating to the potency of a medicinal ingredient is to be shown on a label of the natural health product, detailed information respecting the potency of the medicinal ingredient, including statements indicating its potency tolerances; and
(d) a description of the methods used for testing or examining the natural health product.
(3) The specifications and every change to those specifications shall be approved by a quality assurance person.

[36] **PART 3 - GOOD MANUFACTURING PRACTICES**
Prohibition
43. (1) Subject to subsection (2), no person shall sell a natural health product unless it is manufactured, packaged, labelled, imported, distributed or stored, as the case may be, in accordance with this Part.
(2) A person may sell a natural health product that is manufactured, packaged, labelled, imported, distributed or stored, as the case may be, in accordance with requirements that are equivalent to those set out in this Part if the natural health product is imported.

makes sense but should not elevate business concerns over public protections. Nor should international regulatory harmonization be used as an excuse to limit public participation in the regulatory process.

132. However, international regulatory cooperation can be a force for good, if it means regulators from different nations are working together to enact common-sense standards that are clearer, more consistent and protect citizens no matter where they live. But if business interests are being prioritized over essential public protections, no one should cooperate with that object.

133. To explain further, it is significant that the Medicines and Related Substances Amendment Bill recognises the benefit of international cooperation. To illustrate, some functions of the envisaged Authority include: the efficient, effective and ethical evaluation and registration of medicines, medical devices and IVDs that meet defined standards of quality, safety and efficacy; ensure that the process of evaluating and registering medicines, medical devices and IVDs is transparent, fair, objective and concluded timeously; that compliance with existing legislation is being promoted and controlled through a process of active inspection and investigation.

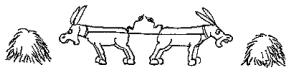
134. Inasmuch, the Authority may work with other regulatory authority or institution and may exchange and receive information from any authority or institution about matters of common interest and agree to co-operate with any regulatory authority to achieve the objects of this Act.[37]

Z. CONCLUSION

135. In conclusion, RDG's purpose in this proposal is to find a solution for the immediate crisis in the healthcare and wellness sector of the pharmaceutical industry caused by the new regulatory controls.

136. To that end, RDG has divided the task into two phases: Firstly, find an answer for the immediate crisis to relieve pressure on the industry and suggest an electronic administrative system that can register HC&W and non-indigenous traditional medicines with the view of speeding up the registration timelines but without detracting from quality, safety and therapeutic efficacy.

[37] Medicines Amendment Bill 2014, section 2B.



137. Thus, the findings of the comparative analysis of international systems concluded that Health Canada's system surpassed all others for various reasons.

138. More importantly, RDG's plan is straightforward. Firstly, drop the definition of a complementary medicine from the Regulations - it is superfluous, Secondly, include new classifications for healthcare and wellness products and non-indigenous traditional medicines and call these up when necessary. Thirdly, call up new sub-classifications for registration systematically, starting with high risk classifications. Finally, licence all facilities.

139. Furthermore, there is a fundamental difference between the CTD/eCTD system and HC. They serve different purposes as highlighted in a comparative analysis. In contrast, the CTD system addresses form while HC addresses function. But to achieve a rapid review of a product, functionality is paramount. So, the CTD format is a poor fit – too human resource intensive and no instant feedback. On the other hand, the decision driven pre-approved monographed HC system fits the bill with real-time user interaction, feedback and guidance.

140. Finally, nothing in law prevents the Authority from agreeing to cooperate with any regulatory authority to achieve the objects of the Medicines Act of which the regulatory control of healthcare and wellness products and non-indigenous traditional medicines are but one.

Best wishes and take care.

René Doms FPS
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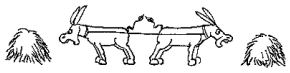
Attachment: Annexure 1
Annexure 2
Annexure 3



ANNEXURE 1:

EXAMPLE OF WHAT NEEDS TWEAKING IN THE GENERAL REGULATIONS IF RDG'S PROPOSAL IS ACCEPTED

GOVERNMENT GAZETTE, XX MONTH 2014 NO. XXXXX

Government Notice

DEPARTMENT OF HEALTH

No. R XXX **xx Month 2014**

GENERAL EXPLANATORY NOTE:

[ ] Words in bold type in square brackets indicate omissions form existing regulations.

_____ Words underlined with a solid line indicate insertions in existing regulations.

AMENDMENT TO THE GENERAL REGULATIONS MADE IN TERMS OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT NO. 101 OF 1965), AS AMENDED

The Minister of Health intends, in terms of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), as amended, in consultation with the Medicines Control Council, to amend the regulations in the Schedule.

The Minister's reasons for wanting to do so are as follows:

1. Notably, the purpose of the proposed amended regulations is to assure South Africans have ready access to healthcare and wellness products and non-indigenous traditional medicines that are safe, effective and of high quality, while respecting the constitutional imperative of

freedom of choice and philosophical and cultural diversity.

2. I mean health products like vitamin and mineral supplements, herbal preparations, traditional and homeopathic medicines, probiotics and enzymes, amongst others. The focus of this proposed regulatory change.

3. Considering a medicine is any substance or combination of substances used or presented as having properties for treating or preventing disease or for restoring, correcting or modifying physiological functions. That is to say, a medicine exerts its action through chemical, pharmacological, immunological or metabolic mechanisms or used to make a medical diagnosis.

4. Granted most medicines are identifiable as such and are subject to regulatory authorisation procedures. Yet some products are difficult to distinguish a medicine from, for example, cosmetics or food supplements. These are styled borderline products.

5. However, should any of these products contain a pharmacologically active substance or make medicinal or therapeutic claims directly or by implication to treat or prevent disease, or to interfere with the normal operation of a physiological role of the human body, then they must follow the more stringent medicines regulatory pathway in the interest of public health and safety.

6. Moreover, this legal procedure provides a licensing and post-marketing surveillance regulatory framework in which safe and useful health products are available, while ensuring that illegal products are removed from the market. Accordingly, this satisfies the need for increased access to health products, though maintaining consumer safety.

7. In particular, this calls for a cut of unnecessary administrative burden for companies trying to bring safe health products to market through a more efficient, flexible regulatory framework but without compromising public health while enabling consumer access and industry innovation and growth. Inasmuch, these amended regulations support solutions that contribute to a broader vision of improved health and patient autonomy.

8. As a result, the WHO Traditional Medicine Strategy 2014–2023 was developed and launched in response to the World Health Assembly resolution on traditional medicine. Across the world, traditional medicine (TM) either is the mainstay of health care delivery or serves as a complement to it. In some countries, traditional medicine or non-conventional medicine may be termed complementary medicine (CM). Furthermore, the strategy has two key goals: to support in harnessing the potential contribution of T&CM to health, wellness and people centred health care and to promote the safe and effective use of T&CM through the regulation of products, practices and practitioners.

9. In contrast, in many parts of the world, policy-makers, health professionals and the public are wrestling with issues about the safety, effectiveness, quality, availability, preservation and regulation of traditional and complementary medicine. South Africa is no exception because no internationally acceptable definition for a complementary medicine exists.

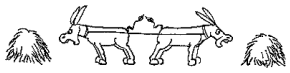
10. In fact, the terms “complementary medicine” or “alternative medicine” refer to a broad set of health care practices that are not part of a country’s own tradition or conventional medicine and are not integrated into the main health-care system. They are used interchangeably with traditional medicine in some countries. Traditional and complementary medicine (T&CM) merges the terms TM and CM, encompassing products, practices and practitioners. This promotes further obfuscation.

11. For this reason, the expression "complementary and alternative medicine" (CAM) resists easy definition because the health systems and practices to which it refers are diffuse and its boundaries ill defined. Described as a broad domain of healing resources that encompasses health systems, modalities, and practices and with theories and beliefs, other than those intrinsic to the main health system of a particular society or culture in a given period.

12. As an example, complementary medicines includes such practices and ideas self-defined by users as preventing or treating illness or promoting health and well-being. Healthcare practices categorized as alternative may differ in historical origin, theoretical basis, diagnostic technique, therapeutic practice and in relationship to the medical mainstream. Even though alternative therapies, including traditional Chinese Medicine (TCM) and Ayurveda, have antique, non-Western origins and are alternative medical systems, others, such as homeopathy, are native to the West and emerged in the eighteenth century.

13. As a result, captured within these inhomogeneous disciplines are a group of diverse medical and health care systems, practices, and products that are not thought part of conventional medicine. Boundaries within CAM and between the CAM domain and that of the main system are not always sharp or fixed. Hence, this composite conceptual framework defies definition required for singularity and legal certainty as the outline covers such a broad domain of healing resources, as practices and beliefs are very diverse in foundations and methodologies.

14. Yet a cardinal rule of law is that the meaning of any provision must be clear, unambiguous and decisive. The legal instrument must serve its purpose and not overreach and must speak to the mischief the Act envisages. The purpose of enacted law is to suppress



mischief in the public interest and conversely promote the public good.

15. To achieve the legislative objectives and to remove ambiguity, each discipline has been given its own classification in the suggested regulations. It is envisaged that modern health claims will be based on evidence from a range of sources, including clinical studies, animal and *in vitro* studies, pharmacopoeias, textbooks, peer-reviewed published articles, and regulatory authority reports. By the same token, traditional health claims will be grounded on the knowledge, skills, and practices based on theories, beliefs, and experiences indigenous to a specific culture, used in the maintenance of health, as well as prevention, diagnosis, improvement, or treatment of physical and mental illness. As an example, for a claim to be categorized as "traditional use," it should be founded upon the theories, experiences and beliefs embodying the respective ancient practice of medicine.

16. Additionally and as is practice, the Medicines Control Council will issue administrative guidelines for each pharmacological or therapeutic classification, where proper and so give stakeholders an opportunity to take part. Administrative guidelines are meant to offer help to industry and health care practitioners on how to follow governing statutes and regulations. These guidelines give support to officials how to carry out guidance in a way that is fair, consistent and effective. These administrative law instruments are so structured to allow flexibility. Even so alternate approaches to the principles and practices described in these documents may be acceptable.

Interested persons are invited to send, within XXX week/months after the date of publication of this notice, substantiated comments on or representations about the proposed regulations to the Minister of Health, Private Bag X828, PRETORIA (for the attention of the Chief Director: Medicines Regulatory Affairs).

SCHEDULE

Definitions

1. In this Schedule, "the Regulations" means the General Regulations as published under Government Notice No. R. 510 in GG 24727 of 15 April 2005, as amended. "the Act" means the Medicines and Related Substances Act, 1965 (Act 101 of 1965)

Amendment of regulation 1 of the Regulations

2. Regulation 1 of the Regulations is hereby amended by –

(a) the deletion of the definition of "complementary medicine".

Amendment of regulation 8 of the Regulations

3. Regulation 8 of the Regulations is hereby amended by –

(a) the substitution of items (bb) (i) and (ii) of sub-regulation (1) by the following item –

(bb) in the case of a **[complementary]** medicine—

(I) a statement identifying the discipline of the medicine; and if the medicine has not received registration with the Medicines Control Council the disclaimer "This medicine has not been evaluated by the Medicines Control Council. This medicine is not intended to diagnose, treat, cure or prevent any disease."

"(bb) in the case of a medicine that has not received registration from the Medicines Control Council the disclaimer "**CAUTION:** This medicine has not been evaluated by the Medicines Control Council and may not be suitable to diagnose, treat, cure or prevent any disease."

Amendment of regulation 9 of the Regulations

4. Regulation 9 of the Regulations is hereby amended by –

   (a) the substitution of items (t) (i) and (ii) of sub-regulation (1) by the following item –

   "(t) in the case of a medicine that has not received registration from the Medicines Control Council the disclaimer "**CAUTION:** This medicine has not been evaluated by the Medicines Control Council and may not be suitable to diagnose, treat, cure or prevent any disease."

Amendment of regulation 10 of the Regulations

5. Regulation 10 of the Regulations is hereby amended by –

   "(n) in the case of a medicine that has not received registration from the Medicines Control Council the disclaimer "**CAUTION:** This medicine has not been evaluated by the Medicines Control Council and may not be suitable to diagnose, treat, cure or prevent any disease."

Amendment of regulation 22 of the Regulations

6. Regulation 22 of the Regulations is hereby amended by the substitution in subregulation (5) (b) for item (vi) of the following item:

   "(vi) category, pharmacological or therapeutic classification,"

Amendment of regulation 23 of the Regulations

7. Regulation 23 of the Regulations is hereby amended by the deletion of the following paragraph:

   (a) the deletion of paragraph (m).

Amendment of regulation 25 of the Regulations

8. Regulation 25 of the Regulations is hereby amended by –

(a) the deletion of paragraph (1) (d).

(b) the substitution for the first sentence of subsection (2) of the following sentence:

"(2) Medicines in categories A are subdivided into the following pharmacological or therapeutic classifications—"

(c) By insertion of the following items after item 32.16 of sub-regulation (2) –

"33. Aromatherapy medicine

34. Ayurvedic medicine

35. Biochemic tissue salts

36. Flower remedies

37. Gemmotherapy medicine

38. Healthcare and wellness products

38.1 Single ingredient

38.2 Combinations ingredients

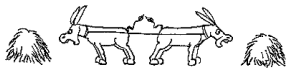
38.2.1 Acne therapy

38.2.2 Ant-dandruff products

38.2.3 Antiseptic skin cleansers

38.2.4 Corn and callous remover

38.2.5 Counterirritants



38.2.6 Diaper rash products

38.2.7 Digestive enzymes

38.2.8 Joint health products

38.2.9 Laxatives – carbon dioxide releasing

38.2.10 Laxatives – hyperosmotic

38.2.11 Marigold extract and isolates – lutein and zeaxanthin

38.2.12 Medicated skin care products

38.2.13 Multivitamin/mineral supplements

38.2.14 Oil products, multiple ingredients

38.2.15 Oligotherapy

38.2.16 Oral health products

38.2.17 Organotherapy

38.2.18 Probiotics

38.2.19 Sunscreen

38.2.20 Wart remover

38.2.21 Whey products

38.2.22 Workout supplements

39. Homeopathic medicine

39.1 Nosodes

40. Homotoxicological medicine

41. Traditional Chinese medicine

42. Traditional Tibetan medicine

43. Unani Tibb medicine

44. Other non-specified traditional medicines"

(d) the substitution for subregulation (3) of the following subregulation:

(3) Medicines in category C are subdivided into the following pharmacological classifications—

Deletion of regulation 25A of the Regulations

9. The following heading and regulation are deleted after regulation 25:

[(a) "DISCIPLINES OF COMPLEMENTARY MEDICINES
25A. Medicines in category D are subdivided into such disciplines as may be determined by the Council after consultation with the Allied Health Professions Council of South Africa.".]

Amendment of regulation 26 of the Regulations

10. The following regulation is hereby substituted for regulation 26 of the regulations:

"26. A certificate of registration substantially in the form shown below shall be issued by the Council in terms of section 15(3) after a medicine has been registered:

MEDICINES AND RELATED SUBSTANCES ACT 1965, (ACT 101 OF 1965): MEDICINE REGISTRATION CERTIFICATE

It is hereby certified that registration of the medicine described below has been approved by the Council in terms of Section 15(3)(a) of the Medicines and Related

Substances Act, 1965 (Act No. 101 of 1965), subject to the conditions indicated.

1. Proprietary name……

2. Registration number……..

3. Approved name of every active ingredient and quantities thereof per dosage unit or per suitable mass or volume or unit of the medicine ……

4. Dosage form……

5. Conditions under which the medicine is registered……..

6. Name of holder of certificate of registration……

7. Name and address of the manufacturer and the manufacturing facility……..

8. Name of the final product release control……..

9. Name of the final product release responsibility……

10. Date of registration……..

11. Category of medicine……

12. Pharmacological classification……..

_____

Registrar

Issued at…… on…….. 20…… "

Amendment of regulation 40 of the Regulations

11. Regulation 40 of the Regulations is hereby amended by –

(a) the substitution of items (t) (i) and (ii) of sub-regulation (1) by the following item –

"(t) in the case of a medicine that has not received registration from the Medicines Control Council the disclaimer "**CAUTION:** This medicine has not been evaluated by the Medicines Control Council and may not be suitable to diagnose, treat, cure or prevent any disease."

Amendment of regulation 45 of the Regulations

12. Regulation 45 of the Regulations is hereby amended by -

(a) the substitution of item (4) (c) (v) of subregulation (4) by the following -

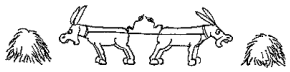
"(v) of an Aromatherapy medicine, Ayurvedic medicine, Biochemic tissue salts, Flower remedies, Gemmotherapy medicine, Homeopathic medicine, Homotoxicological medicine, Traditional Chinese medicine, Traditional Tibetan medicine, Unani Tibb medicine or Other non-specified traditional medicines whichever is applicable, an indication that the medicine must be used in accordance with the relevant disciplines' principles."

Amendment of regulation 48 of the Regulations

13. Regulation 48 of the Regulations is hereby amended by -

(a) the substitution of subparagraph (1) (w) by the following paragraph –

"(w) in the case of a medicine that has not received registration from the Medicines Control Council the



disclaimer "**CAUTION:** This medicine has not been evaluated by the Medicines Control Council and may not be suitable to diagnose, treat, cure or prevent any disease."

(b) the deletion of paragraph (4) (c) (vii).

Deletion of regulation 48C of the Regulations

14. Regulation 48C of the Regulations is hereby amended by –

(a) the deletion of regulation 48C.

DR ……

ANNEXURE 2

1.1 ZA Module 1: Administrative information

ITEM	RSA - MCC	RSA - MCC	HEALTH CANADA NHP – v 4.1 Dec 2013
1.0	**Letter of application**	Applicable	Yes
		Include a brief statement as to why the product meets the requirements for traditional use registration, specifically addressing the evidence of long standing use of the product or its ingredients	Yes
1.1	**Comprehensive table of contents**	Applicable	Easy to compile. Product information summary report created on successful completion of application.
1.2	**Application**		
1.2.1	**Application form**	Applicable	The ePLA Form is divided into five parts which are completed progressively. Form may be saved at any time on the workstation and resumed at a later time. Form interacts with a The ePLA dynamically connects with the Natural Health Products Ingredients Database (NHPID) to obtain information related to standard terminologies for natural health

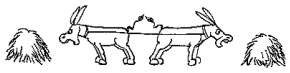
			products such as medicinal and non-medicinal ingredients, dosage forms, routes of administration, and units. The Natural Health Products Ingredients Database information on monographs is also accessed when applicable. Additional forms may be appended automatically to the ePLA.
1.2.2	**Annexes**		
1.2.2.1	Proof of payment	Applicable	As electronic attachment.
1.2.2.2	Letter of authorisation for communication on behalf of the applicant/PHCR	Applicable	As electronic attachment.
1.2.2.3	Dossier product batch information	Applicable	As electronic attachment.
1.2.2.4	Electronic copy declaration	Reserved for eCTD	-
1.2.2.5	Curriculum vitae of the person responsible for pharmacovigilance	Applicable	As electronic attachment.
1.2.2.6	API change control	Not Applicable	Not Applicable
1.2.2.7	EMA certificate for a Vaccine Antigen Master File (VAMF)	Not Applicable	Not Applicable
1.2.2.8	EMA certificate for a Plasma Master File (PMF)	Not Applicable	Not Applicable
1.3	**South African labelling and packaging**		
1.3.1	South African Package Insert	Applicable	As electronic attachment. Free text (consistent with the chosen monograph)

			Homeopathic medicines - Pre-determined list of four general claims.
1.3.1.1	Package insert	Applicable	As electronic attachment.
1.3.1.2	Standard References	Applicable	As electronic attachment, if not pre-approved monograph
1.3.2	Patient Information Leaflet	Applicable	As electronic attachment.
1.3.3	Labels	Applicable	As electronic attachment.
1.3.4	Braille	Reserved for later use	Reserved for later use
1.4	**Information about the experts**		
1.4.1	Quality	Applicable (person responsible for information included in Module 2.3)	As electronic attachment.
1.4.2	Non-clinical	Applicable (person responsible for information included in Module 2.4)	As electronic attachment, if not pre-approved monograph
1.4.3	Clinical	Applicable (person responsible for information included in Module 2.5)	As electronic attachment, if not pre-approved monograph
1.5	**Specific requirements for different types of applications**		
1.5.1	Literature based submissions	Applicable	As electronic attachment, if not pre-approved monograph
1.5.2	Amendments/Variations [38]	Applicable	Change management built into software system. Following issuance of a product licence, if any changes are

[38] Amendments guideline

			made, as stated in Sections 11 and 12 of the Natural Health Products Regulations, the ePLA can be used to submit the post-licence amendment or notification.
1.5.2.1	Tabulated schedule of amendments	Applicable	Change management built into software system
1.5.2.2	Medicines Register Details	Applicable	As electronic attachment.
1.5.2.3	Affidavit by Responsible Pharmacist	Applicable	As electronic attachment.
1.5.3	Proprietary name applications and changes	Applicable	As electronic attachment.
1.5.4	Genetically modified organisms	Not applicable	Not applicable
1.5.5	Package Insert / updates	Applicable	As electronic attachment.
1.6	**Environmental risk assessment**		
1.6.1	Non-GMO (genetically modified organisms)	Not required	Not required
1.6.2	GMO	Not required. However, there may be exceptional cases where further justification to the absence of an environmental risk assessment may be necessary	Not required or as electronic attachment
1.7	**Good manufacturing practice**		
1.7.1	Date of last inspection of each site	Applicable	As electronic attachment.
1.7.2	Inspection reports or equivalent document	Applicable	As electronic attachment.
1.7.3	Latest GMP certificate or a copy of the appropriate licence	Applicable	As electronic attachment.

1.7.4	Release	Applicable	As electronic attachment.
1.7.4.1	API	Applicable	As electronic attachment. All proper names are pre-populated from the Natural Health Products Ingredients Database. Common name: All common names in the pick list are pre-populated from the Natural Health Products Ingredients Database and are derived from authorized references. For probiotics and bacteria, an extra field entitled 'Strain' is provided to enter the bacterial strain number. This field is mandatory for probiotics and non-mandatory for bacteria.
1.7.4.2	IPIs	Applicable	As electronic attachment.
1.7.4.3	Finished Product Release Control (FPRC) tests	Applicable	As electronic attachment. Finished product specifications are extensive.
1.7.4.4	Finished Product Release Responsibility (FPRR) criteria	Applicable	As electronic attachment.
1.7.5	Confirmation of contract	Applicable	As electronic attachment.
1.7.6	CPP (WHO Certification scheme)	Applicable	As electronic attachment.



1.7.7	SAPC registration	Applicable	As electronic attachment.
1.7.8	Registration with Registrar of Companies	Applicable	As electronic attachment.
1.7.9	Other documents relating to the Applicant/PHCR	Applicable	As electronic attachment.
1.7.10	Sample and Documents	Applicable	
1.7.10.1	Confirmation of submission of sample		As electronic attachments.
1.7.10.2	Batch manufacturing record of the sample		
1.7.10.3	CoA of the sample		
1.7.11	Certified copy of a permit to manufacture specified Schedule 5, Schedules 6, 7 and 8 substances.	Applicable	As electronic attachment.
1.7.12	Inspection flow diagram	Applicable	As electronic attachment.
1.7.13	Organogram	Applicable	As electronic attachment.
1.8	**Details of compliance with screening outcomes**	Applicable	Monographs are all pre-screened.
1.9	**Individual patient data - statement of availability**	Applicable when relevant	Not applicable.
1.10	**Foreign regulatory status**		
1.10.1	List of countries in which an application for the same product as being applied for has been submitted	Applicable	As electronic attachment.
1.10.2	Registration certificate or marketing authorisation	Applicable	As electronic attachment.
1.10.3	Foreign prescribing and patient information	Applicable	As electronic attachment.
1.10.4	Data set similarities	Applicable	As electronic attachment.
1.11	**Bioequivalence trial information**	Applicable when relevant	As electronic attachment, if applicable

1.12	**Paediatric development programme**	Not applicable	Not applicable
1.13	**Risk management plan**	Reserved for future use	Reserved for future use

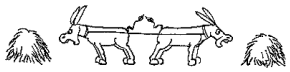
1.2 Module 2: Common Technical Document summaries

2.1	**CTD Table of Contents (modules 2 to 5)**	Applicable	As electronic attachment.
2.2	**Introduction**	Applicable	
2.3	**Quality Overall Summary (QOS)**	A description of the desired product and product related substances and a summary of general properties, characteristics, features and characterization data, as described in S.3.1, should be included. The QOS should summarise the data on potential contamination by micro-organisms, products of micro-organisms, pesticides, toxic metals, fumigants, etc. In some specific circumstances, the risk of radioactive contamination is to be considered	
2.3.S	Quality Overall Summary - Active Pharmaceutical Ingredient *(name, manufacturer)*		As electronic attachment if not pre-approved monograph. Finished product specifications and microbial pesticides etc contamination covered by system and a pre-condition of licensing. Specifications are extensive and a condition of licensing. As an example: Specifications Table 1: Finished product specifications template for a product containing a plant, plant material, alga, fungus or bacterium and/or their extracts or isolates+ Table 2: Finished product specifications template for a product containing a non-human animal material and/or their extracts or isolates+ Table 3: Finished product specifications template for a product containing enzymes+ Table 4: Finished product specifications template for a product containing vitamins+ Table 5: Finished product specifications template for a product containing amino acids+ Table 6: Finished product specifications template for a product containing essential fatty acid+ Table 7: Finished product specifications template for a product containing synthetic duplicates+
2.3.P	Quality Overall Summary - Finished Pharmaceutical Product *(name, dosage form)*		

			Table 8: Finished product specifications template for a product containing minerals+ Table 9: Finished product specifications template for a product containing probiotics+ Table 10: Specifications template for finished products containing synthetic duplicates for topical use Appendix 1: List of Unsuitable Dosage forms*:
2.3.A	Quality Overall Summary - Appendices		
2.4	**Non-clinical Overview**	A bibliographic review of safety data together with a summary report, and where required by the competent authority, upon additional request, data necessary for assessing the safety of the medicinal product. The report on safety data should take into consideration the agreed format for the organisation of the non-clinical overview in the CTD. The list of relevant references for non-clinical data can be included at the end of module 2.4	Electronic attachment if not pre-approved monograph.

2.5	**Clinical Overview**	A bibliographical evidence or expert evidence to the effect that the medicinal product in question, or its ingredients or a corresponding product, has a history of traditional medicinal use (as per the definition in the guideline) within the Republic of South Africa or within a country, the regulatory authority of which the MCC aligns itself with. In addition, the plausibility of pharmacological effects or efficacy of the medicinal product as well as information on the safety of use should be addressed in this section.	Electronic attachment if not pre-approved monograph.
2.6	**Non-clinical Written and Tabulated Summaries**		
2.6.1	Introduction	Tabulated non-clinical summaries are generally not required for well-known	
2.6.2	Pharmacology Written Summary [39]		Electronic attachment if not pre-approved monograph.

[39] *The CTD defines further heading levels and navigation should be provided within the document to the subheadings.*



2.6.3	Pharmacology Tabulated Summary (See Appendix B)	substances when a monograph or a pharmacopoeia entry has been established. When the applicant is requested to supplement the data supporting the monograph with additional safety data (e.g. tests on genotoxicity, reproductive toxicity and carcinogenicity) these data shall be presented in the tabulated nonclinical summaries in this section. When there is no monograph or pharmacopoeia entry, tabulated non-clinical summaries in Module 2 shall be provided.	
2.6.4	Pharmacokinetics Written Summary [2]		
2.6.5	Pharmacokinetics Tabulated Summary (See Appendix B)		
2.6.6	Toxicology Written Summary [2]		
2.6.7	Toxicology Tabulated Summary (See Appendix B)		
2.7	**Clinical Summary**	Tabulated clinical summaries are generally not required for well-known substances when a monograph or a pharmacopoeia	
2.7.1	Summary of Biopharmaceutic Studies and Associated Analytical Methods [2]		Electronic attachment if not pre-approved monograph.
2.7.2	Summary of Clinical Pharmacology Studies [2]		

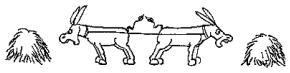
2.7.3	Summary of Clinical Efficacy – *Indication* [2]	entry has been established. When supplementing data concerning the plausibility of pharmacological effects or efficacy of the product as well as information on the safety of use are addressed in section 2.5, a tabulated summary shall be presented in this section 2.7.	
2.7.4	Summary of Clinical Safety [2]		
2.7.5	Literature References		
2.7.6	Synopses of Individual Studies		

1.3 Module 3 – Quality

Refer to the Guideline "Complementary Medicines – Quality, Safety and Efficacy"

3.1	**Table of contents of module 3**	Applicable	Electronic attachment if not pre-approved monograph.
3.2	**Body of data**	Applicable	Electronic attachment if not pre-approved monograph.
3.2.S	**Active Pharmaceutical Ingredient *(name, manufacturer)***		Electronic attachment if not pre-approved monograph.
3.2.S.1	General information (name, manufacturer)	Applicable	Electronic attachment if not pre-approved monograph.

3.2.S.1.1	Nomenclature *(name, manufacturer)*	Information on the naming of the substances should be provided.	Electronic attachment if not pre-



			approved monograph.
3.2.S.1.2	Structure *(name, manufacturer)*	Applicable	Electronic attachment if not pre-approved monograph.
3.2.S.1.3	General Properties *(name, manufacturer)*	Applicable	Applicable
3.2.S.2	Manufacture (name, manufacturer)	Applicable	Applicable
3.2.S.2.1	Manufacturer(s) *(name, manufacturer)*	Applicable	Applicable
3.2.S.2.2	Description of Manufacturing Process and Process Controls *(name, manufacturer)*	Applicable	Applicable
3.2.S.2.3	Control of Materials (name, manufacturer)	Applicable	Applicable
3.2.S.2.4	Controls of Critical Steps and Intermediates (name, manufacturer)	Applicable	Applicable
3.2.S.2.5	Process Validation and/or Evaluation (name, manufacturer)	Applicable	Applicable
3.2.S.2.6	Manufacturing Process Development *(name, manufacturer*)	Applicable	Applicable
3.2.S.3	Characterisation *(name, manufacturer)*	Applicable	Applicable
3.2.S.3.1	Elucidation of Structure and other Characteristics *(name, manufacturer)*	Applicable	Applicable
3.2.S.3.2	Impurities *(name, manufacturer)*	Applicable	Applicable
3.2.S.4	Control of active pharmaceutical ingredient *(name, manufacturer)*	Applicable	Applicable
3.2.S.4.1	Specifications *(name, manufacturer)*	Applicable	Applicable

3.2.S.4.2	Analytical Procedures *(name, manufacturer)*	Applicable	Applicable
3.2.S.4.3	Validation of Analytical Procedures *(name, manufacturer)*	Applicable	Applicable
3.2.S.4.4	Batch Analyses *(name, manufacturer)*	Applicable	Applicable
3.2.S.4.5	Justification of Specification *(name, manufacturer)*	Applicable	Applicable
3.2.S.5	Reference Standards or Materials *(name, manufacturer)*	Applicable	Applicable
3.2.S.6	Container Closure System *(name, manufacturer)*	Applicable	Applicable
3.2.S.7	Stability *(name, manufacturer)*	Applicable	Applicable
3.2.S.7.1	Stability summary and conclusions *(name, manufacturer)*	Applicable	Applicable
3.2.S.7.2	Post approval stability protocol and stability commitment *(name, manufacturer)*	Applicable	Applicable
3.2.S.7.3	Stability Data *(name, manufacturer)*	Applicable	Applicable

3.2.P	**Pharmaceutical Product *(name, dosage form)***		
3.2.P.1	Description and Composition of the pharmaceutical product *(name, dosage form)*	Applicable	Applicable
3.2.P.2	Pharmaceutical Development *(name, dosage form)*	Applicable	Applicable
3.2.P.2.1	Components of the Pharmaceutical Product *(name, dosage form)*	Applicable	Applicable
3.2.P.2.1.1	Active Pharmaceutical Ingredient(s) *(name, dosage form)*	Applicable	Applicable

3.2.P.2.1.2	Excipients *(name, dosage form)*	Applicable	Applicable
3.2.P.2.2	Final pharmaceutical product *(name, dosage form)*	Applicable	Applicable
3.2.P.2.2.1	Formulation development *(name, dosage form)*	Applicable	Applicable
3.2.P.2.2.2	Overages *(name, dosage form)*	Applicable	Applicable
3.2.P.2.2.3	Physicochemical and biological properties *(name, dosage form)*	Applicable	Applicable
3.2.P.2.3	Manufacturing process development *(name, dosage form)*	Applicable	Applicable
3.2.P.2.4	Container closure system *(name, dosage form)*	Applicable	Applicable
3.2.P.2.5	Microbiological attributes *(name, dosage form)*	Applicable	Applicable
3.2.P.2.6	Compatibility *(name, dosage form)*	Applicable	Applicable
3.2.P.3	Manufacture *(name, dosage form)*	Applicable	Applicable
3.2.P.3.1	Manufacturer(s) *(name, dosage form)*	Applicable	Applicable
3.2.P.3.2	Batch formula *(name, dosage form)*	Applicable	Applicable
3.2.P.3.3	Description of manufacturing process and process controls *(name, dosage form)*	Applicable	Applicable
3.2.P.3.4	Controls of critical steps and intermediates *(name, dosage form)*	Applicable	Applicable
3.2.P.3.5	Process validation and/or evaluation *(name, dosage form)*	Applicable	Applicable
3.2.P.4	Control of Inactive Pharmaceutical Ingredients *(name, dosage form)*	Applicable	Applicable
3.2.P.4.1	Specifications *(name, dosage form)*	Applicable	Applicable

3.2.P.4.2	Analytical procedures *(name, dosage form)*	Applicable	Applicable
3.2.P.4.3	Validation of analytical procedures *(name, dosage form)*	Applicable	Applicable
3.2.P.4.4	Justification of specifications *(name, dosage form)*	Applicable	Applicable
3.2.P.4.5	Excipients of human or animal origin *(name, dosage form)*	Applicable	Applicable
3.2.P.4.6	Novel excipients *(name, dosage form)*	Applicable	Applicable
3.2.P.5	Control of pharmaceutical product *(name,*	Applicable	Applicable

	dosage form)		
3.2.P.5.1	Specification(s) *(name, dosage form)*	Applicable	Applicable
3.2.P.5.2	Analytical procedures *(name, dosage form)*	Applicable	Applicable
3.2.P.5.3	Validation of analytical procedures *(name, dosage form)*	Applicable	Applicable
3.2.P.5.4	Batch analyses *(name, dosage form)*	Applicable	Applicable
3.2.P.5.5	Characterisation of impurities *(name, dosage form)*	Applicable	Applicable
3.2.P.5.6	Justification of specifications *(name, dosage form)*	Applicable	Applicable
3.2.P.6	Reference standards or materials *(name, dosage form)*	Applicable	Applicable
3.2.P.7	Container closure system *(name, dosage form)*	Applicable	Applicable
3.2.P.8	Stability *(name, dosage form)*	Applicable	Applicable
3.2.P.8.1	Stability summary and conclusion *(name, dosage form)*	Applicable	Applicable
3.2.P.8.2	Post-approval stability protocol and stability commitment *(name, dosage form)*	Applicable	Applicable

3.2.P.8.3	Stability data *(name, dosage form)*	Applicable	Applicable
3.2.A	Appendices	Not Applicable	Not Applicable
3.2.A.1	Facilities and equipment *(name, manufacturer)*	Not Applicable	Not Applicable
3.2.A.2	Adventitious agents safety evaluation *(name, dosage form, manufacturer)*	Not Applicable	Not Applicable
3.2.A.3	Excipients	Not Applicable	Not Applicable
3.2.R	**Regional Information**		
3.2.R.1	Pharmaceutical and Biological availability	Applicable if relevant	Applicable if relevant
3.2.R.2	Parent API manufacturer with various sites	Applicable	Applicable
3.2.R.3	Certificate(s) of suitability with respect to the Ph.Eur. (CEPs)	Applicable if relevant	Applicable if relevant
3.2.R.4	Multiple API manufacturers	Applicable	Applicable
3.2.R.4.1	Comparative API manufacturers study report	Applicable	Applicable
3.2.R.4.2.	Comparative results	Applicable	Applicable
3.2.R.4.3	Confirmation of compliance with guidelines	Applicable	Applicable
3.2.R.4.4	Certificates of analysis	Applicable	Applicable
3.2.R.5	Medical device	Not Applicable	Not Applicable
3.2.R.6	Materials of animal and/or human origin	Applicable	Applicable
3.2.R.7	Batch records of samples	Applicable	Applicable
3.2.R.8	Other	Reserved for future use	Reserved for future use
3.3	Literature references	Applicable	Applicable

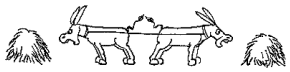
1.4 Module 4: Non-clinical study reports

4.1	**Table of contents of Module 4**	Applicable	
4.2	**Study reports**	If applicable. If data are available or have been requested these should be provided and summarised in Module 2.6, for which the corresponding non-clinical	As electronic attachment, if not pre-approved monograph

		overview would be included in Module 2.4	
4.3	**Literature references**	Such references should be indexed following the agreed format for the organisation of Module 4.	As electronic attachment, if not pre-approved monograph

1.5 Module 5: Clinical study reports

5.1	**Table of contents of Module 5**	Applicable	As electronic attachment, if not pre-approved monograph
5.2	**Tabular listing of all clinical studies**	If applicable	As electronic attachment, if not pre-approved monograph
5.3	**Clinical study reports**	If applicable. If data are available or have been requested these should be provided and summarised in Module 2.7 for which the corresponding clinical overview would be included in Module 2.5	As electronic attachment, if not pre-approved monograph
5.4	**Literature references**	Such references should be indexed following the agreed format for the organisation of Module 5.	As electronic attachment, if not pre-approved monograph



ANNEXURE 3

See below.

Regulatory Criteria for products termed

Complementary medicines/Dietary supplements/Food Supplements/ Natural Health Supplements as well as Traditional Medicines

	Requirements	EU - EFSA	EU - EMA
		http://www.efsa.europa.eu	http://www.ema.europa.eu/ema/
1	Term used for product category	Food supplements	Herbal
2	Health Care legislation applicable	Food	Medicine
3	Registration	No, if included in list of permitted substances otherwise yes.	Yes
3.1	Registration process	Food supplements are regulated as foods. The main EU legislation is Directive 2002/46/EC. Its Annex II contains a list of permitted vitamin or mineral substances that may be added for specific nutritional purposes in food supplements. The Directive sets out labelling requirements and requires that EU-wide maximum and minimum levels are set for each vitamin and mineral added to supplements. Vitamin and mineral substances may be considered for inclusion in the lists following the evaluation of an appropriate scientific dossier concerning the safety and bioavailability of the individual substance by EFSA (submit a technical dossier). Health Claims: EFSA has reviewed health claims related to vitamins and minerals and a database has been created. EFSA also reviews new health claims (based on new scientific data). For this, applications are transmitted to EFSA by competent authorities in Member States for evaluation.	Market access for herbal medicinal products in the European Union: Medicinal products containing herbal substances/preparations must fall within one of the following three categories to reach the market: 1. A product can be classified under traditional medicinal use provisions ('traditional use') accepted on the basis of sufficient safety data and plausible efficacy: the product is granted a traditional use registration (simplified registration procedure) by a Member State, 2. product can be classified under well-established medicinal use provisions ('well-established use'). This is demonstrated with the provision of scientific literature establishing that the active substances of the medicinal products have been in well-established medicinal use within the Union for at least ten years, with recognised efficacy and an acceptable level of safety. As a result the product is granted a marketing authorisation usually by a Member State or by the European Medicines Agency. (While both classification have specific requirements, both regulatory paths involve the assessment of mostly bibliographic safety and efficacy data) 3. A product can be authorised after evaluation of a marketing authorisation application consisting of only safety and efficacy data from the company's own development ('stand alone') or a combination of own studies and bibliographic data ('mixed application'). As a result the product is granted a marketing authorisation by a Member State or by the Agency via the centralised procedure if all requirements are met. Irrespective of the regulatory pathway to access the market, the quality of the herbal medicinal product must always be demonstrated.
3.2	CTD or Electronic registration format	Not CTD. 4 Part Technical Dossier (Submit as CD-ROM or equivalent) As per "GUIDANCE ON SUBMISSIONS FOR SAFETY EVALUATION OF SOURCES OF NUTRIENTS OR OF OTHER INGREDIENTS PROPOSED FOR USE IN THE MANUFACTURE OF FOODS"	CTD (as per the member state requirements)
3.3	Registration number	Not applicable.	Yes
3.4	Labelling	Labelling of food supplements must contain: - the names of the categories of the nutrients or substances that characterise the product or an indication of the nature of those nutrients or substances; - the portion of the product recommended for daily consumption and a warning of the risks to health if this is exceeded;- a declaration to the effect that the supplement is not a substitute for a varied diet; - the reference "This is not a medicinal product", where the presentation of the product is similar to that of a medicinal product; - a warning to the effect that the product should be stored out of the reach of young children. The labelling should not include: -any statement attributing to the product properties of preventing, treating or curing a human disease; -any mention stating or implying that a balanced and varied diet cannot provide appropriate quantities of nutrients in general. Health claims as per EFSA database/submit to EFSA for evaluation.	Labelling as per medicinal products as in Article 54 of the Directive 2001/83/EC. Label to include the following additional statement: "...this is a traditional herbal medicinal product for use in specified indication(s) exclusively based upon long-standing use; and the user should consult a doctor or a qualified health care practitioner if the symptoms persist during the use of the medicinal product or if adverse effects not mentioned in the package leaflet occur. "
3.5	Attestation	Foods do not require registration.	Each member country to determine the registration process.
4	Quality requirements	Include information regarding the Identity of the source (including characteristics, impurities etc), specifications, manufacturing process, methods of analysis, reaction/fate in foods to which source is to be added (i.e. stability).	Irrespective of the regulatory pathway to access the market, the quality of the herbal medicinal product must always be demonstrated. Information required includes: Description of the method of preparation of the herbal medicinal product, control of starting materials and herbal medicinal product, stability, qualitative and quantitative particulars of the active. GCP applies for starting materials of Herbal Origin. Multiple quality guidelines (on various topics) available on EMA website.
5	Safety requirements	Information of "need" and proposed uses, exposure, information on sources from genetically modified organisms, toxicological data, interactions with the source or other diet components, impact of source on the intestinal miliue and on absorption of nutrients.	Minimum requirements for non-clinical data for well-established herbal medicinal products in literature based applications: Reproductive Toxicity (only if there if a cause for concern of product is indicated during pregnancy), Genotoxicity, Carcinogenicity, Toxicokinetc data (mainly required for new products). (NOTE: If the minimum requirements cannot be fulfilled by published literature, additional non-clinical test may be required. Refer to EMA guideline for more comprehensive information on the non-clinical requirements.
6	Efficacy requirements	Bioavailability data: of the nutrient following oral consumption (from human data, in vitro or animal studies or from information on analogous substances).	Depends on the type of product (single entity or combination) and availability of literature (including Community Herbal monographs). If a combination product is not well established, data required is similar to that of a new product.
7	Category/Class definition	Food supplements means foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities.	Herbal medicinal product: Any medicinal product, exclusively containing as active ingredients one or more herbal substances or one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations.Herbal substances: All mainly whole, fragmented or cut plants, plant parts, algae, fungi, lichen in an unprocessed, usually dried, form, but sometimes fresh. Certain exudates that have not been subjected to a specific treatment are also considered to be herbal substances. Herbal substances are precisely defined by the plant part used and the botanical name according to the binomial system (genus, species, variety and author). Herbal preparations: Preparations obtained by subjecting herbal substances to treatments such as extraction, distillation, expression, fractionation, purification, concentration or fermentation.
8	Product presentation or format	Capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities.	These include comminuted or powdered herbal substances, tinctures, extracts, essential oils, expressed juices and processed exudates.
9	Authorised/accepted nutrients	As per Annex II of Directive 2002/46/EC	
9.1		Minerals	Herbal
9.2		Vitamins	
9.3			
9.4			
9.5			
9.6			
9.7			
9.8			
9.9			
9.10			
9.11			
9.12			
9.13			
9.14			
10	General Overview	Foods do not require registration and claims are very limited.	Community herbal monographs are prepared by the Committee on Herbal Medicinal Products (HMPC) at the Agency and are relevant for the traditional use registration as well as the well-established use marketing authorisation.

	Requirements	UK - MHRA	AUS - TGA	CA- Canada Health
		http://www.mhra.gov.uk/index.htm	http://www.tga.gov.au	http://www.hc-sc.gc.ca/dhp-mps/index-eng.php
1	**Term used for product category**	**Food supplements and Traditional Herbal Medicines**	**Complementary medicine**	**Natural Health Product**
2	**Health Care legislation applicable**	**Food and Medicine**	**Medicine**	**Medicine**
3	**Registration**	**Foods no , Herbals yes**	**Yes**	**Yes**
3.1	**Registration process**	Foods are not registered. Manufactured herbal medicines placed on the UK market are required to have either a Traditional Herbal registration (THR) or a Marketing Authorisation (MA). THR take 210 days to approve.	Must be registered or listed on ARTG before sale. Most complementary products are listed. Listed ingredients are considered low risk.	Two guideline for natural health products: 1) Products making a traditional claim. 2) Products making a modern claim. 3 Tier product registration process. Class I: High level of certainty - lowest level of pre-market review (10 days). Class II: Medium level of certainty - medium level of pre-market review (30 days). Class III: Low level of certainty -higher level of pre-market review (180 days). All products must have a product licence and be linked to a site (manufacturing) licence.
3.2	**CTD or Electronic registration format**	No registration process for vitamins. Traditional herbal products required a paper submission.	Electronic submission for listed substance (TGA eBS framework). Listed products are not evaluated by regulator. Non-listed substance must either first be listed (paper submission) or product must be registered (paper submission). Application will not pass electronic validation if ingredient restrictions are not met. True homoeopathic medicines more dilute than 1000x do not need to be listed on the ARTG unless high claim, from animal products, contains poison substances or is a sterile product.	ePLA electronic submission for Natural Health Products. All products to be submitted for registration prior to marketing. All registered products are displayed on the Natural Products Database displaying the formulation, strength, dose, approved claims and is freely available. This allows for self regulation where companies not complying with their registration particulars to be reported.
3.3	**Registration number**	Foods not registered. THR certification mark provided for registered products.	Yes AUST L number (except true homoeopathic - not listed on ARTG)	NPN or NPN-HM
3.4	**Labelling**	Only health and nutrition claims are allowed to be used on food supplement labels, and they must not be false, misleading or exaggerated. Medicinal claims are not permitted to be used on food supplement labels. THR medicines are required to include the following statement "this is a traditional herbal medicinal product used in specified indication(s) based on traditional use only' and to include the registration number.	Labels not submitted at listing and therefore not approved by TGA. Registration number and discipline must be stated (homoeopathic -only discipline needed for those not listed on the ARTG). Label must clearly state the tradition followed.	Copy of the label content to be submitted with the product licence application. All labels to display the registration number.
3.5	**Attestation**	Not required for foods. THR medicines require a formal application process.	Sponsor legally certifies that QSE legislative requirements are met	Applicant signs an attestation form attesting to meet particulars of the product application and the monograph requirements.
4	**Quality requirements**	Codex Alimentarius qualify processes are promoted but seem to be voluntary. Not clear if fascilities need to be registered for vitamins. THR required registered manufacturers and distributors and GMP is applied.	PIC/S guide for GMP. Homoeopathic medicines do not need to be manufactured in GMP facility (excludes sterile products)	Independent on-site audit: NHP manufacturers, packagers, labellers and importers may elect to undergo an independent on-site audit to demonstrate compliance with Good Manufacturing Practice (GMP) standards. Alternatively, the NHPD may request that a site licence applicant undergo an audit by a Health Canada recognized third party, when critical quality issues are identified, or when activities involving higher risk product types are being conducted. Majority of site licenses are issued through a paper based system whereby applicants submit a QAR (quality assurance report) and supporting documentation.
5	**Safety requirements**	The Regulations provides for a "positive list" of vitamins and minerals permitted to be used in food supplements. The Regulations also allow for a derogation period so that nutrients/substances not on the "positive list" can continue to be used provided that they satisfy certain conditions. It is also likely that the EU directive on food supplements will extend to cover other health food products in the future. There are legal stipulations governing general labelling requirements such as the list of ingredients, conditions of storage or use and the place of origin. Food supplement labels are also required to bear cautionary and warning statements. THR require registration before marketing. This is a very resource intensive process requiring high levels of expertise from both the regulator and applicant. THR requires a 30 year history of traditional use.	Only listed substances allowed. Non listed substances must first be added to list or the product registered. Evidence of safety and efficacy must support either application. EMA guidelines for herbal medicines followed.	Shortened review time does not change the current tools in place to assess health product safety. The level of evidence required to demonstrate safety remains the same, and health products will continue to be labelled with required cautionary statements, e.g. reported adverse reactions and potential interactions with other health products; duration of use; warnings for certain populations like pregnant women etc. All ingredients must be listed in the Natural Products Ingredient Database and appropriateness will be assessed based on safety and efficacy.
6	**Efficacy requirements**	Only health and nutrition claims are allowed to be used on food supplement labels, and they must not be false, misleading or exaggerated. Medicinal claims are not permitted to be used on food supplement labels. The responsibility for ensuring the validity of claims rests with the manufacturer, importer, distributor and local authorities. THR requires efficacy claims to be based on traditional use of at least 30 years with 15 years use in the EU.	Efficacy claims not evaluated by the regulator. However claims are limited to self-diagnosable and self-manageable by average consumer and ber managed safely without medical supervision. High level treat claims require registration. Note: The TGA is finalising new evidence required to support indications for listed substances that will replace the current guideline.	Health Canada has preapproved monographs with preapproved claim. Products that contain substances on the natural health product ingredient list that do not have a monograph are required to submit evidence of efficacy for the claim intended to be marketed. Required evidence is ingredient based, not product based. There are lists of prohibited diseases and conditions.
7	**Category/Class definition**	Food supplement means any food the purpose of which is to supplement the normal diet and which— (a) is a concentrated source of a vitamin or mineral or other substance with a nutritional or physiological effect, alone or in combination; and (b) is a concentrated source of a vitamin or mineral or other substance with a nutritional or physiological effect, alone or in combination; and is sold in dose form. Traditional Herbal Medicines require a 30 year history of use with at least 15 years history of use in the EU. The Certification Mark indicates that the herbal medicine has been registered under the Traditional Herbal Registration (THR) scheme; and meets the required standards relating to its quality, safety, evidence of traditional use.	Complementary medicine means a therapeutic good consisting wholly or principally of 1 or more designated active ingredients, each of which has a clearly established identity and a traditional use.	Natural health products
8	**Product presentation or format**			The acceptable pharmaceutical dosage forms include, but are not limited to capsules, chewables (e.g. gummies, tablets), liquids, powders, strips or tablets.
9	**Authorised/accepted nutrients**			
9.1			Amino acids	1. A plant or a plant material, an alga, a bacterium, a fungus or a non-human animal material
9.2			Charcoal	2. An extract or isolate of a substance described in item 1, the primary molecular structure of which is identical to that which it had prior to its extraction or isolation
9.3			Choline salt	3. Any of the following vitamins :biotin, folate, niacin, pantothenic acid, riboflavin, thiamine, vitamin A, vitamin B_6, vitamin B_{12}, vitamin C, vitamin D, vitamin E, vitamin K_1, vitamin K_2.
9.4			Essential oil	4. An amino acid
9.5			Plant or herbal material (or a synthetically produced substitute for material of that kind), including plant fibres, enzymes, algae, fungi, cellulose and derivatives of cellulose and chlorophyll	5. An essential fatty acid
9.6			Homoeopathic preparation	6. A synthetic duplicate of a substance described in any of items 2 to 5
9.7			Microorganism, whole or extracted, except a vaccine	7. A mineral
9.8			Mineral including a mineral salt and a naturally occurring mineral	8. A probiotic
9.9			Mucopolysaccharide	
9.10			Non-human animal material (or a synthetically produced substitute for material of that kind) including dried material, bone and cartilage, fats and oils and other extracts or concentrates	
9.11			Lipid, including an essential fatty acid or phospholipid	
9.12			Substance produced by or obtained from bees, including royal jelly, bee pollen and propolis	
9.13			Sugar, polysaccharide or carbohydrate	
9.14			Vitamin or provitamin	
10	**General Overview**	Food supplements fall under foods which means formulations and ingredients are not preapproved before marketing and that the responsibility for QSE falls on the manufacturer. This system is difficult to regulate and open to the possibilty of abuse. Novel foods being launched are difficult to regulate. Traditional Herbal Medicines requires onerous application process. 300 products were approved in 3 years.	Listing system - efficacy claims not checked by regulator. TGA to replace current guidelines with new evidence required to support claims (undergoing change). Regulatory system does not verify efficacy claims and therefore falls short of the MCC mandate of ensuring QSE.	The online monograph system reduces the regulatory resource requirements. If a product meets the monograph requirements registration is expedited. All NHP are classified as medicines requiring registration. Each product has a registration number and the approved label showing claims, warning, formulation etc. are listed on the website. GMP is a requirement in licenced facilities. The system is self regulating as competitors, consumers or interest groups can report companies not meeting their registration requirements.

	Requirements	CHINA-CFDA	Singapore - HAS / HPRG
		http://eng.sfda.gov.cn/WS03/CL0755/	http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/about_cda.html
1	Term used for product category	Drugs and Health food	Health Supplement
2	Health Care legislation applicable	Medicine and Food	Medicine or Food
3	Registration	Yes	No
3.1	Registration process	Article 31 For production of a drug admitted by national drug standards, an application shall, in accordance with the provisions of the drug regulatory department under the State Council, be submitted to the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government or to the drug regulatory department under the State Council, and the relevant technical data and supporting documents shall be provided. The drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government shall, within 30 working days from the date it receives the application, review and make comments, and report the matter to the drug regulatory department under the State Council for review while notifying the applicant of its comments. If all the requirements are fulfilled upon review, a drug approval number shall be issued by the drug regulatory department under the State Council.	Separated into Health Supplements, Chinese Medicines and Traditional Medicines (Malay & Indian). No premarket approval required for Traditional Medicines or Health Supplements. Onus for ensuring safety and efficacy is on the marketer. There are limits on certain ingredients (vitamins, minerals) above which products must be registered and licensed for import and sale. There is a premarket system for Chinese Medicines. HSA will assist in classifying a product as either a health product (medicine) or a "supplement of food nature" (food).
3.2	CTD or Electronic registration format	CTD: The Requirements comprise 7 chapters, 59 articles and 5 attachments. It focuses on the confirmation of the authenticity, accuracy and integrity of the application materials in accordance with relevant requirements on on-site verification for drug registration in Provisions for Drug Registration, and ensures that the on-site verification for drug registration can be carried out legally, orderly, standardised and efficiently in terms of lawful content, clear procedure, uniform standards and clear division of labour.	Electronic classification system (pdf based)
3.3	Registration number	Any drug substance used by a drug manufacturer to produce a drug products shall have a drug approval number or an import drug license or a pharmaceutical product license issued by the drug regulatory department under the State Council upon examination, with the exception of Chinese crude drugs and the prepared slices of Chinese crude drugs over which no control by approval number is exercised.	
3.4	Labelling	Article 54 A label shall be printed or stuck on the drug package together with an insert sheet, as required by regulations. In the label or insert sheet shall be indicated the adopted name of the drug in China, its ingredients, strength, manufacturer, approval number, product batch number, production date, date of expiry, indications or functions, usage, dosage, contraindications, adverse drug reactions, and precautions. Specified marks shall be printed in the label of narcotic drugs, psychotropic substances, toxic drugs for medical use, radioactive pharmaceuticals, drugs for topical use, and non-prescription drugs.	There are general labelling requirements. Labels can be submitted for review.
3.5	Attestation	Article 1 To ensure drug quality and safety for human beings, to protect the health of people. Article 2 All institutions and individuals engaged in research, production, distribution, use, or drug administration shall abide by this Law. Article 3 The State develops both modern and traditional medicines to give full play to their role in prevention and treatment of diseases and in maintenance of health. Article 79 Any drug manufacturer, distributor, institution for non-clinical safety study, or institution for drug clinical trial that does not implement the GMP, GSP, GLP or GCP according to regulations shall be given a disciplinary warning and shall be instructed to rectify within a time limit. If it fails to do so, it shall be instructed to suspend production or business operation or other work for rectification and shall also be fined. If the circumstances are serious, the Drug Manufacturing Certificate, Drug Supply Certificate or the qualifications of the institution for drug clinical trial shall be annulled. Article 86 Where the drugs with labels or marks are not in conformity with the provisions of Article 54 of this Law, except for those treated as counterfeit or substandard drugs, an instruction for rectification and a disciplinary warning shall be given. If the circumstances are serious, the approval documents for the drugs shall be withdrawn.	Only required for those products that must be registered.
4	Quality requirements	Any newly-established drug manufacturer or manufacturer with newly –built drug manufacturing workshops or newly-added dosage forms for production shall, within 30 days from the date it obtains the approval documents for manufacturing drug or from the date its formal production is approved, apply to the drug regulatory department for GMP certification as required. Good Clinical Practice (GCP) certification for drug clinical trials Good Manufacturing Practice (GMP) Good Supply Practice (GSP) certification for the drugs distributions. All necessary requirements	No licensing requirements. Onus is on the marketer, manufacturer, importer. There is a list of quality specifications which include heavy metals and microbial contaminants.
5	Safety requirements	Article 15 The State adopts a classification system for prescription drugs and non-prescription drugs. The State subdivides non-prescription drugs into Class A drugs and Class B drugs according to the level of safety. Any drug retailer distributing prescription drugs or Class A non-prescription drugs shall have licensed pharmacists or other pharmaceutical technicians whose qualifications are legally recognized. Any retailer distributing Class B non-prescription drugs shall have pharmacy staff members who have passed the examination organized by the local drug regulatory institution of the municipality divided into districts or by the local drug regulatory institution at the county level which is directly set up by the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government. Article 34 The drug regulatory department under the State Council may, based on the needs for protection of public health, set an observation period of not more than five years for a new drug produced by a drug manufacturer; and no approval shall be given to any other manufacturer to produce or import the said drug during the observations period.	No registration process. Onus is on the marketer. There is a list of prohibited substances. A registration process exists for vitamins and minerals above certain limits.
6	Efficacy requirements	Article 29 Clinical trials, manufacturing or importation of drugs shall be in conformity with the provisions in the Drug Administration Law and in the Regulations, and shall be reviewed and approved by the drug regulatory department under the State Council. The drug regulatory department under the State Council may authorize the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government to conduct site inspection of research and development conditions of the drugs being applied, to conduct preliminary review of the submitted dossier, and to test the pilot samples. The specific measures therefore shall be formulated by the drug regulatory department under the State Council. Article 30 Any clinical trial to be conducted for research and development of a new drug shall be subject to the approval by the drug regulatory department under the State Council in accordance with the provisions in Article 29 of the Drug Administration Law	Claims are permitted. Onus is on the marketer to ensure all claims are truthful and supported by evidence which may be requested by the authority at any time. Required evidence is ingredient based, not product based. There are lists of prohibited claims and diseases and conditions. Some vitamins, minerals and herbs are subject to medical advertisement control.
7	Category/Class definition	1) Use for different purposes: A health food is used to regulate body functions, enhance the body's ability to resist disease and improve a health condition, reduce the risk of disease, and not to prevent or treat disease. Drug means for the prevention, treatment and diagnosis of human diseases, purposefully regulate physiological functions, and provides for indications or functions, usage and dosage. (2) in accordance with the provisions of health foods, a health food cannot contain any substances which could cause any acute, subacute or chronic harm to the human body. Drugs can have toxic side effects. (3) Using different routes of administration, Health foods for oral route only , Medicine administration includes but is not limited to oral, injectable, topical application, (4) Different types of raw material: Toxic and Hazardous Substances shall not be used as raw material for health foods	Health Supplement includes the following categories of products: 1. Quasi-medical products: vitamins and nutritional preparations from natural sources, traditional medicines, homeopathics, other substances. 2. Traditional Medicines: other than Chinese medicines, Jamu, ayurvedics, homeopathics. Includes herbal preparations. 3. Health Foods with vague and general medicinal claims.
8	Product presentation or format		Are presented in any of the following dosage forms to be administered in small unit doses; capsules, softgels, tablets, liquids, syrups, and any other dosage forms as may be approved by the licensing authority.
9	Authorised/accepted nutrients		
9.1			Substances derived from natural sources, including non-human animal and botanical materials in the forms of extracts, isolates and concentrates; and
9.2			Vitamins, minerals, amino acids (natural and synthetic)
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10	General Overview	China's main focus are, Pharmaceuticals, Chinese Traditional and Chinese crude drugs. All of these fall under drugs. The Chinese regulator is a staff intensive body using a paper based system.	Signapore uses a combination of food and medicine approach. Onus falls on the marketer to ensure claims are truthful and supported by evidence. This can lead to abuse of the system.