## Introduction to Proposed Regulations for Health Foods, Dietary Supplements & Complementary Medicines

a) First World medicinal regulatory systems are generally inappropriate for South Africa, whose demographics, for all practical purposes, places the country between the First and Third World, with the majority of its health care resources firmly in a Third World classification and highly likely to remain so.

b) Only two categories of medicine represent a significant threat to consumers, namely Orthodox and Traditional African. Potential risks may occasionally arise from Traditional Chinese, Ayurvedic, Western Herbal, and Homoeopathic as well as Nutritional Supplements and Health Foods, in decreasing risk order.

c) Foods, their nutrients, and related constituents are not medicines and accordingly should not be regulated as such. If these factors positively influence conditions, then their action is food corrective, not medicinal in action. Only non-food remedies to which resistant conditions alone will yield are medicinal.

c) Orthodox medicines are best regulated by the current First World model, which evolved with problems of high toxic potential in mind. Traditional African medicines, least evaluated of all, are best dealt with via accelerated research, concurrent with educational programmes to minimise use of harmful substances.

d) The remaining potential risk categories are best dealt with primarily on the basis of their toxicological potential, secondarily according to claims and indications and thirdly, according to quality criteria. In all instances, complementary medicine criteria cannot legally exceed that for Traditional African medicines.

e) The essential difference between orthodox and complementary medicines are the synthesised and novel and hence possibly toxic nature of the former, without natural correlate and widespread traditional use capable of confidently rendering them reasonably safe, based on existing epidemiological information.

f) Arising from the orthodox model, at least as far as products evaluated on the basis of Randomised Controlled Trials are concerned, are specific safety and efficacy data. These medicines accordingly will generally be true to manufacturer's claims for pharmacological effects, side-effects and contraindications.

g) Complementary, (incl traditional) medicines, on the basis of their existing in nature and including the possibility of already being in the public domain, are not patentable and hence are not financially viable to undergo the five to ten year and R3000 million drug development, evaluation and registration process.

h) Complementary medicines accordingly require different evaluation / regulatory criteria. On one hand, whilst they are less likely to be toxic, their efficacy may, on the other hand, not have been definitively proven. The most practical means of regulating these is on the basis of their safety and indications/claims.

i) Complementary and traditional medicines, dietary supplements, health foods and miscellaneous natural health substances are acknowledged as being valuable in contributing to the health of consumers, subject to reasonable controls in terms of quality, safety and efficacy, appropriate to their specific classification.

j) Regulations are for the protection and benefit of the consumer but must not unduly restrict public access so as to be in accordance with their constitutional rights to "security in and control over their body and not to be deprived of freedom arbitrarily, without just cause" and "to receive information and ideas".

k) Regulations affecting mainly service providers, must be in accordance with their constitutional rights "not to be discriminated against on the basis of ethnic origin, conscience, belief or culture", "not to have possessions seized", and "to freedom of expression and of the media, to impart information and ideas".

l) The purpose of these proposals are 3-fold: 1) to ensure appropriate food or pharmaceutical GMP Quality Criteria; 2) to ensure appropriate food and medicines Safety Criteria; and 3) to ensure appropriate Efficacy and Promotional Claim Criteria, the latter according to the basis of their natural classification.

**Outline of Regulatory Proposals for Health Foods, Dietary Supplements & Complementary Medicines.**

**(To be presented on rejection in principle of the Listing System)**

(We have elected to use layman's rather than technical / legal terminology, to retain essential simplicity.)

1) A **complementary medicine is** differentiated from orthodoxy by its broad definition **as defined in the SAMMSDA Act, subject to the following circumscribing guidelines and applicable regulations.**

2) **If a natural product bears a disease indication or claims to treat or prevent disease, it shall be evaluated as a complementary medicine for quality, safety and efficacy** on the **preponderance of scientific evidence**, with quality set at appropriate good manufacturing practice and stability standards.

3) **If a product bears no disease indication or claim and is not toxic, it shall be exempt from medicines regulations** and **subject only to quality and safety criteria applicable to the most similar foods**, in the case of processed products, to criteria appropriate to the most similar processed foods.

4) **If a product claims to assist in the reduction of risk or the recovery from disease, it shall on proof of long and wide usage as a natural foodstuff or beverage, and substantiation of all claims by the preponderance of available scientific evidence, qualify as and be subject only to food regulations.**

5) If any product **fails to meet the required "preponderance of scientific evidence" iro claims** in terms of its classification as a food or a complementary medicine, then **it shall be considered to be an illegal unapproved medicine** and hence subject to notice / withdrawal / confiscation / prosecution, in that order.

6) **Indications and claims shall be evaluated on the basis of** text, symbols or pictures on labels, package inserts, pamphlets, articles, books, **audio and visual promotional material**, but if on a strict **individual patient basis**, shall **exclude all means directly to practitioners or verbally to patients.**

7) **Practitioner information** shall comprise only **one copy of any individual issue** and bear both **names** and the current practice and postal **addresses** marked legibly and indelibly on the front page of each individual document/price list, the initials on each 10th page and both names on pages 1, 5, 20, 100 & 500.

8) Any **promotional material not bearing** or **duplication of** the required **identifying information** shall be the **responsibility of the manufacturer** and or **distributor**, and shall **constitute** the making of **illegal medicinal claims**, and the holder liable to **confiscation** of any corresponding **product** in their possession.

9) **Independent information** in any of the mentioned media dealing with **non-proprietary substances** and **not bearing the name of a proprietary product, shall not be construed as making a claim** for such substances, with the **exception** of direct or virtually direct **correlation product formulations.**

10) **Structure - function and risk reduction claims for "foods"** shall **not** be construed as **medicinal**, **provided** they are **not novel** substances **without epidemiological safety record, are substantiable via the preponderance of the available scientific evidence, are strictly in context, and are contained in viable quality, quantity, stability and form. Unsubstantiable claims render the marketer** responsible for publicising the claim**, liable for an admission of guilt fine or prosecution and any product with packaging bearing unsubstantiable claims shall be confiscated and subject to complete withdrawal.**

11) **Structure - function "dietary supplement" claims, if substantiable on the preponderance of available scientific evidence, shall not constitute medical claims, provided the claims do not address non self-limiting conditions** and the **doses are substantiable as safe and dose and period effective.**

12) **Structure - function "dietary supplement" claims addressing non self-limiting conditions**, shall **constitute medicinal claims** and be deemed illegal and subject to **registration as a complementary medicine, if substantiable as safe and effective for the specific conditions, dose and period of use, based on the preponderance of available scientific evidence. Unsubstantiable claims shall render the product illegal** until the **product name** has been suitably **changed to effect disassociation between the claim and the product. Both products shall be subject to confiscation and the manufacturer / distributor shall be liable for product withdrawal and for an admission of guilt fine or prosecution.**

13) If a product is in advance deemed to be a health food, dietary supplement or complementary medicine by its manufacturer/distributor by virtue of its indications/claims, then **a corresponding dossier of the scientific original papers/abstracts** to be used as educational material **and all other substantiating data must be submitted** to the appropriate Food or Medicines authority **to render the product legal.**

14) A **grace period of 3-months shall apply following promulgation** of the final regulations, during which **dossiers shall be required to be filed with the respective authority. All products on the market without dossiers after this period shall be illegal and may be confiscated without notice.**

15) **Dossiers filed** with each authority shall on receipt of a **nominal administrative fee** commensurate with each category of product, plus **for the number of pages** filed, be **allocated a unique dossier number** which shall be added **in a visible position on each product within one month of allocation.**

(It is suggested that administrative fees be set at a level of market related consultancy fees by an appropriate qualified natural scientist so that the authority is able to remain self-sustaining in its administrative evaluation of product dossiers under its jurisdiction. These fees shall of necessity be considerably higher for **complementary medicines**, which shall require a **formal scientific evaluation and approval or rejection process** within a prescribed period [3-months after filing], relatively lower for **dietary supplements**, which shall require a **formal scientific evaluation process without an approval, but possibly a rejection or re-categorisation referral process** to the alternative authority. The lowest fee structure pertains to **health foods and beverages**, which merely require **a formal monitoring evaluation, and possibly a rejection or referral to an internal re-categorisation process.**)

16) **If authorities encounter a products making** structure - function / risk or medicinal **claims without corresponding dossier or registration numbers**, these may be confiscated by the respective authority until resolved, but **if current dossiers have been filed, confiscation may only follow prosecution.**

17) **Products which** as a result of usage recommendations or by virtue of the product itself is **considered by the authority to represent an unacceptable risk**, shall be subject to **emergency powers of confiscation** to protect consumers, but **must be urgently prosecuted to determine the matter in court.**

18) In the case of **products with dossiers without rejection, manufacturers / distributors must be given legal notice and a reasonable opportunity (1-3 weeks) to voluntarily withdraw the product** from the market. In the case of **no, or rejected dossiers, confiscation** shall proceed **without notice.**

19) **Prosecution shall always follow emergency confiscation** so that the matter may be deliberated and settled on the merits in court, and punished if appropriate. **For non-emergency confiscation or voluntary withdrawal, a prescribed fine shall be levied by the Authority on admission of guilt.**

20) **Prosecution shall always follow non-emergency confiscation, which is not settled out of court by admission of guilt. Non-emergency confiscation for products without dossier** shall also be **subject to voluntary withdrawal of any remaining products following admission of guilt** and the levy of a fine.

21) **Fate of non-emergency confiscated products shall be return to the manufacturer / distributor at 25 % of wholesale value, but only if the purchaser contracts with the authority to fulfil all legal obligations** in terms of the applicable regulations. **Compliance shall be monitored** by the authority.

22) Each **authority shall compile and maintain an electronic register of dossier receipt comfirmation and allocated reference numbers**, compiled in order of filing and searchable by name of applicant and product (which corresponding information must be visible on the external product for official inspection).

23) Each **authority shall electronically post and regularly update the registers** for each category on an **official Department of Health Web-page**, instantly **accessible via the internet**, including portable **access to the inspectorate via a cell-phone linked laptop for a detailed check on product legality.**

24) All three **sectors are encouraged to assist their respective authority by self-regulating their and neighbouring sectors by alerting** the authorities to known transgressions of the spirit of the regulations.

25) **Monitoring, evaluation, rejections, and registrations by the authorities shall proceed in the order of the date of filing, interrupted only by the monitoring of complaints pertaining to products with dossiers, and non-dossier products separately in order of complaint and random inspections.**

To be completed on MCC compliance with PHARMAPACT demands for "levelling of the laying field".

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**P**eople's **H**ealth **A**lliance **R**ejecting **M**edical **A**uthoritarianism, **P**rejudice **A**nd **C**onspiratorial **T**yranny

**http://pharmapact.tsx.org**

**POSTSCRIPT:**
These proposals pre-suppose that all commercial substances intended for ingestion are equally evaluated for and regulated according to their toxicity potential, according to and in order of their relative risk / benefit potential, ie non-health-benefiting toxics first, followed by health beneficials, if necessary / at all.