COMPLEMENTARY MEDICINES REGULATORY SCAM

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DEPT HEALTH: DRAFT REGULATIONS IN TERMS OF ACT 101 OF 1965, AS AMMENDED

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Whilst we have little or no objection to the bulk of these draft regulations, other than the appalling fact that they will do little or nothing to reduce or prevent the avoidable several hundred thousand adverse events and several thousand annual deaths from allopathic iatrogenesis via Medicines Control Council approved drugs, **we certainly do have very strong reservations, indeed condemnation, of the manner in which so-called "complementary medicines" have deliberately been tagged onto these allopathic amendments, with a view to going unopposed against expected support for the main regulations. Given the unprofessionalism and unconstitutionality of the previously failed medicines amendment bill (72/1997) and act (132/1998), we assume that any unpublished "specific" regulations, ominously escaping scrutiny by strategically avoiding the usual public participatory parliamentary hearings, will be as diabolical as, if not more so than the predecessors from which these have been developed.**

These "General Regulations" as far as they concern so-called "complementary medicines", are so absurdly general and devoid of any detail sufficient to comment on their merit, that this attempt to usher in regulations, which the Department is not prepared to subject to critique, must be rejected with contempt. We assume that this relates to gross incompetence, as with the failed SAMMDRA Act and earlier Amendment Bill, and/or to **a deliberate strategy to bypass public scrutiny / input into said regulations, which in respect "complementary medicines", amounts effectively to empowering the Medicines Control Council with carte blanche authority to regulate by resolution as they see fit, including imposition of the so-called "listing system" being promoted by vested financial interests.** This is view is exemplified by **the blatant substitution of details in the "general regulations" for unacceptably nebulous provisions** such as in Section 22, APPLICATION FOR THE REGISTRATION OF A MEDICINE**.** Subsection (3) for example, states: *"An application ... shall be accompanied by ... g. **any other information as the Council may from time to time, by guidelines …determine**".* Subsection (6) for example states: *"A medicine in respect of which an application for registration is made must comply with **technical requirements as determined by the Council**".* Subsection (9) for example, states: *"The provisions of regulation 22 shall, **with the necessary changes**, apply to the application for the registration of a. veterinary medicines, b. biological medicines, and c. complementary medicines".*

Act 101 in many respects clearly remains unconstitutional, especially regarding the powers of the Inspectorate. In particular, Section 28 (1) (search and seizure) of Act 101/65 is inconsistent with the Privacy clause 14 of the Constitution and has been declared invalid (Constitutional Court Case 13/97). Also, the non-representative composition of the Council is so completely allopathically dominated and biased that it is clearly incapable of any essential neutral objectivity. That the MCC are not up to the task, is evidenced by the fact that, besides having **failed to control iatrogenesis** via their registration system, they have **formally allowed "quack medicines" to be misrepresented in the marketplace via the allocation of registration application numbers for eg homoeopathic products, which are permitted to bear absurd medicinal indications without a shred of acceptable evidence of such efficacy** (the only country to do so). The result is **irresponsibly denying patients effective remedies and thereby actively contributing to the development of chronic disease by perpetuating the myth of efficacy for homoeopathic remedies** and strategically **creating a false impression that the authorities are embracing natural remedies, whereas they are in fact actually supporting quackery.**

In reality, **authentic natural health substances, which are pre-manufactured by the supreme chemist, the Almighty Creator, for our healthy sustenance, are to be subjected to ridiculously stringent manufacturing and marketing criteria in order to suppress their ready availability to consumers,** whilst fraudulent products will conveniently escape the universal medicinal criteria of evidence for efficacy, due to legislated perpetuation of the absurd illusion of eg nothing (so-called homoeopathy / flower essences / energy medicines) posing as something (remedies with indications), and conveniently escaping the excessive criteria being promoted by the very same interests which themselves are incapable of equal scrutiny by virtue of their quack products containing essentially nothing, which is therefore obviously easily made to such high manufacturing standards, but which will be difficult, if not impossible, to be met by the purveyors of true natural health substances, who will be prejudiced thereby.

Internationally, medicines regulation is based on the triple criteria of Quality, Safety and Efficacy (Effectiveness). The planned regulations will focus on pharmaceutically based quality criteria, but by a double-standard, in collusion with certain quack interests, will not require scientific evidence of efficacy for these, yet will demand a higher degree of such evidence for true natural substances, eg nutrients and herbs, so as to allow quack interests to regain lost market dominance held prior to the dissolution of trade sanctions against South Africa and the opening up of the free market to high standard evidence-based natural products, which threatened pharmaceutical interests, not similarly threatened by the quack remedies, which simply presented no effective competition at all. This expose' is not intended to belittle anyone's belief system; it merely exposes **the unacceptable reality of statutory health fraud.**

The "general regulations", as they pertain to so-called "complementary medicine", and providing no detail whatsoever, by all accounts from previous attempts to introduce **the so-called "listing procedure"**, which this amendment conveniently fails to delineate, **is seriously at variance with the National Drug Policy for South Africa** (Department of Health, January 1996). The numerous concerns set out above and to follow, are for example, significantly inconsistent with the "**Health Objectives**" set out on page 4:

- ***To ensure the safety, efficacy and quality of drugs****;*
- *To ensure good dispensing and prescribing practices;*
- ***To promote the rational use of drugs*** *by prescribers, dispensers and patients through the provision of the necessary training, education and information;*
- ***To promote*** *individual responsibility for health, preventive care and* ***informed decision-making****.*

It is absurd that the blunders of the past are about to be repeated without attempting to correct serious flaws in the proposals as identified by us, now even more absurdly so, by affording public comment on non-specific "general regulations" on the only basis available to interested non-privileged role-players, namely the pathetic track record of the failed Amendment Bill 72 of 1997 and SAMMDRA Act 132 of 1998, which was based on the Duke's report: "The Medicines Regulatory System in South Africa", Dept of Health, 24 March 1998, and the "Report of the Medicines Regulatory Authority Transformation Task Team, Dept of Health, 17 July 1998, **in addition to mere snippets of legislative proposals coming indirectly to our attention, in spite of repeated requests for specifics.**

In particular, the regulations pertaining to the "Expedited Registration Procedure" (listing system) **eg, as set out in Chapter V: "Regulations Pertaining to Complementary Medicines"**, Dept of Health, 1999, under SAMMDRA, being **the most specific viewed by the public to date, are at variance with the "aim" of the National Drug Policy for South Africa**, Department of Health, January 1996, as set out in **Section 3: Legislation and Regulations**, namely: ***"To ensure that drugs reaching patients are safe, effective and meet approved standards and specifications".*** Specifically, 3.2 states: ***"The current drug registration procedure will be adapted to meet needs within the policy framework. Formal procedures for registration, based on quality, efficacy and safety will be upgraded …".*** No. 3.3 states: ***"The conditions pertaining to the retail sale of pharmaceuticals will be adapted to local conditions to meet the requirement of rational, effective and safe drug supply".*** No**.** 3.6 states: ***"Marketed*** *(see dictionary definition of marketed)* ***traditional medicines will be investigated for safety and quality".***

The **National Drug Policy,** sets out in Section 7: **Rational Use of Drugs,** the AIM: ***"To promote the rational prescribing, dispensing, and use of drugs by medical, paramedical and pharmaceutical personnel and to support the informed and appropriate use of drugs by the community".*** Subsection 7.7 **Advertising and Marketing of Drugs**, states: *"The objective is to ensure that* ***advertising and marketing of drugs shall be in keeping with the NDP****, and in compliance with national regulations, as well as voluntary industry standards.* ***All promotional making claims shall be reliable, accurate, truthful, informative, balanced, up-to-date, capable of substantiation and in good taste. They shall not contain misleading or unverifiable statements or omissions likely to induce medically unjustifiable drug use or to give rise to undue risks. Promotional material shall not be designed to disguise its real nature".*** **The registration of eg homoeopathic remedies, bearing medicinal claims and indications, is absurd and it makes a mockery of the NDP and the legislative process which it purports to guide.**

"Act 101/1965 provides for the establishment of the Medicines Control Council for the control of medicines". (Medicines and Related Substances Control Act No.101 of 1965) ***"The Council was created by Parliament for the purpose of ensuring the quality, efficacy and safety of medicines available to the public".*** (Folb P, Schlebusch J, "The regulation of medicines in South Africa", SAMJ 1989, 16 Dec; 76); ***"In terms of the Act, the Council has the mandate to ensure that the medicines available to the South African public are safe and in the public interest. The Council may take into account only the scientific data available"!*** **(Folb P, "The registration and control of medicines in SA", Med Law 1991; 0(6)) Current science has determined that there is no evidence of efficacy for any homoeopathic remedy for any single clinical condition, so how can these be registered for any indications or conditions?** I presented a series of research articles exposing homoeopathic fraud (non-efficacy and toxicological data) to the full MCC on 23 July 1999. This is posted at: <http://www.gaiaresearch.co.za/homeopathy.html>.

Far more serious than even these charges of fraud and quackery however, is the fact that whilst the legislative process is being abused by administrators and regulators to illegally secure market share for the pharmaceutical companies (both allopathic and complementary), at great expense to the public and smaller traditional purveyors of natural health products, **a blind eye is being turned to several hundred thousand avoidable adverse events and several thousand avoidable annual deaths from allopathic iatrogenesis via Medicines Control Council approved drugs**. **Even more tragically, in terms of this amendment to Act 101, some 10-20,000 preventable deaths per annum from traditional African medicines are being callously ignored**, in spite of earlier recognition that: ***"The Council is mandated to serve the public interest in the regulation and control of the quality, safety and efficacy of medicines"***, and that: ***"Because most of South Africa's population lives in conditions more akin to the developing world, it is important to examine whether the country is optimally served by the established system"***. (Folb P et al, "Drug regulation in South Africa", J Clin Phamacol, 1988 Sep; 28(9)) **How can the Dept of Health / MCC justify all the effort to the listing system if it fails the masses?**

Attempts to pervert semantics to change the word "marketed" to mean only First World methods, is gross administrative and regulatory abuse of the legislative process. Supply of eg "unlabelled" traditional African medicines, remains by definition "marketed". In this context it means to *"buy or sell in market / sell (goods) in market or elsewhere"* (Oxford Dictionary)**. Act 101 itself defines "sell" as: *"retail, wholesale, import, offer, advertise, keep, expose, transmit, consign, convey or deliver for sale or authorize, direct or allow a sale or prepare or possess for purposes of sale, and barter or exchange or supply or dispose of to any person whether for a consideration or otherwise"*. We morally and constitutionally challenge this double standard where two norms are arbitrarily culturally applied.** Subsection 9 (3) of the Constitution (Equality), reads: ***"The State may not unfairly discriminate against anyone on one or more grounds…, including ethnic origin or culture"***. Subsection (5) moreover, states: *"Discrimination on one or more grounds in subsection (3) is unfair, unless it is established that the discrimination is fair."* **To enforce compliance, the onus will fall on the party wishing to discriminate and hence the State would have to convince the Constitutional Court that discrimination in these circumstances is fair, which is clearly impossible, given the presented facts.**

The **National Drug Policy** in Section 11, **Traditional Medicines**, clearly states the AIM to be: ***"To investigate the use of effective and safe traditional medicines at primary level"*** and that: ***"marketed traditional medicines will be registered and controlled".*** The MCC / Dept of Health however, have gone to great lengths to convince traditional African healers and medicinal vendors that their drugs will not be registerable. An entire public meeting, the only ever legally called by public notice, on 27 February 1999, to brief role-players on proposed regulations for complementary medicines, when it was learned that PHARMAPACT had invited traditional African medicine role-players to join their protest, was instead dedicated to convincing these deliberately uninvited role-players that their own medicines would be exempt from the regulations. The **National Drug Policy** of the Dept of Health concludes: ***"Its successful implementation depends on a commitment to its principles by all role players and stake holders. This commitment must go beyond lip service to include active participation in the process of initiation, review and modification to ensure that the people of South Africa receive the drugs they need at a cost that they and the system as a whole can afford".*** **Clearly the regulators have lost touch with the NDP.**

"Trade in traditional medicines is a multi-million Rand "hidden economy" in southern Africa, where a high level of urbanization generates high demand for traditional medicines, particularly to mining towns or large urban centres." (Cunningham, A.B. 1993. Imithi isi Zulu: the traditional medicine trade in Natal/KwaZulu. MSc. thesis, University of Natal.) (Williams, V.L. 1996. The Witwatersrand muti trade. Veld and Flora 82: 12-14.) The **African National Congress's National Health Plan** states: *"**Guiding Principles**: **Every person has the right to achieve optimum health, and it is the responsibility of the state to provide the conditions to achieve this. The ANC is committed to the promotion of health through prevention and education. All racial and ethnic discrimination will be eradicated. There will be a priority focus on the prevention and control of major risk factors and diseases". Drugs Policy: Only drugs shown by analysis to be safe and of acceptable quality and efficacy will be marketed. A special committee will investigate the safety of traditional drugs. A regulatory body for traditional medicine will be established."* (A National Health Plan for South Africa, ANC, Johannesburg, May 1994) All we have witnessed in this regard is shallow window dressing and extensive procrastination. **Clearly the government has lost touch with the guiding principles in its own National Health Plan.**

All State proposed medicine regulations in recent years have cowardly tackled only soft targets whilst avoiding the toxicity issue of traditional African medicines, in spite of this most widely used category being responsible for the death of an estimated 10-20,000 South Africans every year, not necessarily at the fault of the purveyors of these substances as much as the indirect fault of the authorities, who are aware of which substances are the main culprits, but for some perverse reason refuse to disseminate such knowledge and regulate such substances at their major points of sale. **This inaction amounts to the callous culling of thousands of our citizens via poisoning and also involuntary population control of hundreds of thousands via sterility, infertility and physical incapacity to procreate, a strategy dating from the apartheid era, yet perpetuated by the present regime for reasons one can only speculate on, but which facts render the pretence that these regulations are "in the public interest", to be a shameful act of fraud, indeed genocide, via gross dereliction of duty.**

These facts are extensively documented in the writer's 23,000 word **"Genocide and Ethnopiracy" Report**, which has been served on the South African Government in various forms and on various forums over the past few years. The most recent October 2000 edition is downloadable in PDF format at: <http://www.gaiaresearch.co.za/trads.html>, following a synoptic abstract on that page, as is also the full printed version of this writer's recent co-authored, peer-reviewed published article, which introduces the 10-20,000 deaths per annum from traditional African medicines in South Africa estimate into the international scientific medical literature, also downloadable in PDF format at the abovementioned URL, following the abstract appendiced to the document before you. For several years, PHARMAPACT have formally attempted to bring these mortalities, morbidities and also the grossly undemocratic monopolistic bias of natural medicines regulation in South Africa under appropriate review, but to no avail. These efforts are extensively documented on our website at <**http://www.gaiaresearch.co.za/pharmapact**>.

APPENDIX
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(ORIGINAL PUBLISHER'S ABSTRACT)

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The toxicity of *Callilepis laureola*, a South African traditional herbal medicine

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Abstract

Objectives: To review the literature on the toxicity of *Callilepis laureola,* and to assess the cytotoxicity of *C. laureola* in human hepatoblastoma Hep G2 cells *in vitro.*

Design and methods: Cells were incubated for up to 48 h in the presence of increasing concentrations of an aqueous extract of *C. laureola* (0.3-13.3 mg/mL). Cytotoxicity was quantitated spectrophotometrically by the metabolism of the tetrazolium dye MTT. Cytoviability of the control cells was considered to be 100%.

Results: *C. laureola* produced cytotoxicity in a concentration-dependent manner. Cytotoxicity was significant at all concentrations tested (0.3-2.5 mg/mL, $p < 0.05$ vs. controls and 3.3-13.3 mg/mL, $p < 0.0001$ vs. controls). After 6 h, 100% toxicity was observed at a concentration of 6.7 mg/mL.

Conclusion: *C. laureola* causes significant cytotoxicity in Hep G2 cells *in vitro.* These findings are in accordance with the observed hepatotoxicity in clinical cases of *C. laureola* poisoning.

Keywords: Callilepis laureola; Impila; African; Traditional herbal medicines; Hep G2 cells; Hepatotoxicity

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(INTRODUCTORY EXTRACT)
(From the published text, with added emphasis by contributing author, Stuart Thomson, for this forum)

Introduction

There is a mythical yet predominant view that herbal medicines are harmless and free of side effects because they are "natural". There have been several cases, however, of hepatic injury and even death associated with their use. The effective and safe use of medicinal herbs has therefore been identified as a top research priority; and the implementation of regulatory procedures and investigations on safety are currently underway in *developed* countries.

While not addressed as frequently in the literature, the safety of herbal medicines used in *underdeveloped* countries is also a major concern. In South Africa, it is estimated that between 60 – 85% of the native population use traditional medicines, usually in combinations. Cases of acute poisoning due to traditional medicines are not uncommon, many of which have resulted in significant morbidity and mortality (18), with mortality estimated to be as high as 10,000-20,000 per annum (19).

Venter and Joubert analyzed cases of acute poisoning admitted to Ga-Rankuwa Hospital, Pretoria over a 5 year period (1981-1985). Overall, poisoning with traditional medicines resulted in the highest mortality, accounting for 51.7% of all deaths that were due to acute poisoning. Patients were predominantly male and the majority of admissions were children between the age of 1-5 years. **Traditional healers were the main source of the medicines, and in some cases substances were bought at a shop for African remedies (21)**. The majority of poisonings were accidental, only 4% were due to deliberate self-poisoning. **A study by Stewart *et al.* analyzed the Johannesburg forensic database over 5 years (1991-1995) and found that** *(African)* **traditional remedies were involved in 43% of poisoning cases (22).**

While these studies have provided estimates, it is suspected that the true number of poisoning cases from traditional medicines is far greater (23). Medically certified information on the mortality among native South Africans is lacking, especially for rural areas where deaths are not always registered (19, 23). Many poisoning cases are thought to remain undiagnosed since patients residing in rural areas may die before reaching a hospital (23). Furthermore, autopsies are not routinely conducted, and the cause of death is not always determined or documented on the certificate, thus many poisoning cases may go unrecognized.

Detection of traditional medicine poisoning is further complicated due to the lack of analytical techniques required to make a confident diagnosis. Due to a shortage in resources, diagnostic tools are either limited or have not yet been developed. Moreover, the plant component of the traditional remedy responsible for the observed toxicity may not be known. In some cases, the culprit plant has been identified through direct questioning. People are generally very reluctant to admit the use of herbal remedies, however, often because hospitals tend to hold a negative view toward traditional medicines, **and also because of the cultural secrecy surrounding their use.**

In the present study, we investigate the *in vitro* hepatotoxicity of one known toxic herb: *Callilepis laureola*. *C .laureola* is a traditional remedy commonly used by the Zulu who are predominantly located in the KwaZulu-Natal region in the northeast of South Africa. *C. laureola*, a member of the family Compositae, is a herbaceous perennial plant found commonly in grassland habitats of eastern South Africa. *C. laureola* is known to be "very poisonous and has even been responsible for several deaths among the Zulu". **It has been estimated that the plant is responsible for up to 1500 deaths per annum in KwaZulu-Natal alone**, one of nine provinces in South Africa (27, 32). **The plant is commonly known as *Impila*, which ironically is the Zulu word for "health".**

Although there are no approved medical uses of *Impila* from a health regulatory standpoint, the plant is widely used among the Zulu and appears to serve as a multi-purpose remedy (22). Reports indicate it is used to treat stomach problems, tape worm infestations, impotence, cough, and to induce fertility. *Impila* is also administered to pregnant women by traditional birth attendants to "ensure the health of the mother and child" and to facilitate labour. A tonic made from the root is also taken by young girls in the early stages of menstruation. The greatest and most valued attribute of this plant, however, appears to lie in its "protective powers" in warding off "evil spirits". For example parents who have lost previous children to illness may administer *Impila* enemas to their current children for the belief it will "protect" them. **It is suspected that these magical beliefs are the primary reason for the common use of *Impila* in young children, and the high *Impila*-related mortality in children under the age of 5 years (22).**

Impila is most often prepared using the tuberous rootstock of the plant, while the leaves are reputed to have minimal curative properties. The tuber may be harvested and collected in the winter, and dried and crushed into a powder. Alternatively, a fresh piece of the tuber, the size of a forefinger, may be chopped and bruised. The resultant powder is boiled for approximately 30 minutes to 1 hour in a suitable volume of water and the decoction is administered either orally or as an enema. It has been estimated that each dose of the herbal remedy is prepared from approximately 10 grams of plant material (32).

The danger of *C. laureola* was first documented in 1909. Numerous cases of *Impila*-induced hepatic and renal toxicity emerged in the medical literature during the 1970s and since this time there have been regular reports of fatal *Impila* intoxications. The toxicity of *Impila* appears to be very sudden in onset, and it is suspected that many patients do not reach a hospital before death (22). **The fatalities due to *C. laureola* toxicity are significant. As reported by various investigators, it is estimated that 63% of patients die within 24 hours, and a further 28% die within 5 days, thus bringing the total mortality to 91% (23).**

Despite it's reputed toxicity, *Impila* continues to be a very popular and commonly used traditional remedy in South Africa (23). If the toxicity of *C. laureola* is so well established, why then is the plant still being used significantly in South Africa? There appears to be several complex answers to this question. Currently there is no legislation controlling traditional medicines in South Africa, and the regulatory standards and public education required to ensure their safe use have yet to be implemented (19). In rural areas, traditional healers are the primary source for obtaining such medicines, whereas in towns and cities, traditional medicines are readily available in African medicine shops where they are sold over-the-counter.

Another issue to consider is the cultural context in which traditional medicines are used. *Impila* is most commonly used for the magical properties it is believed to possess. While some illnesses are attributed to natural causes, others are thought to be the result of an "evil spell", or the consequence one must suffer for violating the ancestral spirits. The respect for traditional healers and the belief in the curative properties of traditional medicines is so deep-rooted, that often a fatality resulting from a toxic herb will wrongfully be blamed on the underlying "illness" for which the herb was taken. Other points of consideration are the factors that affect the toxicity of the herb itself. The toxicity of some plants is known to vary with season.

The lack of safety regulation and the ease at which herbal medicines may be obtained likely increase the occurrence of fatal errors among traditional healers, vendors and the public in regards to the strict "ancient rules" regarding the use of *Impila* as an herbal remedy: "*impila* is never given to a child under the age of 10; it is never given by way of an enema; it is never used in arbitrary doses nor in any but the weakest solution; when swallowed, it must never be allowed to be absorbed; in other words, it is used exclusively in the form of treatment known as *phalaza* (i.e. swallowing a large volume of a weak decoction, followed by immediate inducement of complete or near-complete catharsis). There is little doubt that a lack in knowledge and awareness of these strict rules has contributed to the numerous cases of *Impila*-induced fatalities.

Although clinical cases of *C. laureola*-induced toxicity are well documented in the literature, the mechanism by which the plant produces hepatic and renal toxicity is not completely understood. Cases of human poisoning with *C. laureola* have been researched by various investigators in South Africa and are well documented in the literature. Diagnostic methods to confirm such poisonings are in the process of development (22). The mechanism by which *C. laureola* produces hepatotoxicity is still not known, and to date there are no published data available on the plant's effects *in vitro*. Therefore, as a starting point, we report preliminary results of the hepatotoxic effects of *C. laureola in vitro* using the human hepatoblastoma Hep G2 cell line.

Our results suggest that the principle target of *C. laureola*-induced toxicity is the mitochondria. The mechanism appears to involve a metabolite-induced opening of the mitochondrial permeability transition pore (MPTP), release of cytochrome c, and caspase activation. Whether apoptosis or necrosis is the predominant mode of cell death involved in *C. laureola* intoxication will have clinically important implications for treatment interventions and the development of antidotes. The *in vitro* model used in the present study will be a useful tool to study the mechanism of *C. laureola*-induced hepatocyte death, and further investigations in this direction are currently in progress.

(For the full technical aspects of this paper, see the full text PDF version associated with this introductory extract.)

(Abstracted) **References**

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