Peoples Health Alliance Rejecting Medical Authoritarianism, Prejudice And Conspiratorial Tyranny

PHARMAPACT

PHARMAPACT IS THE HEALTH FREEDOM LOBBYING ARM OF THE GAIA RESEARCH INSTITUTE

PHARMAPACT SAYS NO! TO THE LISTING SYSTEM,
PHARMACEUTICAL EXPROPRIATION OF NATURAL HEALTH PRODUCTS
& GOVERNMENT GENOCIDE THROUGH GROSS DERELICTION OF PUBLIC DUTIES!

EXTENSIVE DOCUMENTATION http://www.gaiaresearch.co.za/pharmapact ON THE WORLD WIDE WEB
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The Honourable Minister of Health **By Registered Mail**
The Republic of South Africa **24 August, 2001**
For Attention: Chief Director: As Addressed
Pharmaceutical Services
Private Bag X 828
Pretoria

Dear Madam

PUBLIC COMMENT ON DRAFT GOVERNMENT NOTICE NO. 480: 1 JUNE 01
DEPT HEALTH: DRAFT REGULATIONS IN TERMS OF ACT 101 OF 1965, AS AMMENDED

Herewith my humble contribution iro proposed amendments to Act 101 of 1965, in the form of a ***critique*** insofar as it concerns those aspects pertaining to ***complementary medicine.***

Please afford these earnest comments your serious attention, including drawing attention of the Honourable Minister of Health hereto, since surely she will wish to be informed hereof, given the gravity of these concerns (and failing which task you will be held accountable).

Thanking you in advance for your kind and responsible co-operation to this noble end.

Yours sincerely

Stuart Thomson
Director, Gaia Research Institute
National Co-ordinator, PHARMAPACT

COMPLEMENTARY MEDICINES REGULATORY SCAM

PUBLIC COMMENT ON DRAFT GOVERNMENT NOTICE NO. 480: 1 JUNE 01

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

- By Stuart Thomson, National Co-ordinator, PHARMAPACT, Director, Gaia Research Institute-

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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>.