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SAYS NO !

To The Tyranny Of Monopolistic
PHARMACEUTICAL EXPROPRIATION
Of Natural Health Substances.

Peoples Health Alliance Rejecting Medical Authoritarianism, Prejudice And Conspiratorial Tyranny.

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REGULATORY PROPOSALS FOR NATURAL HEALTH & THERAPEUTIC SUBSTANCES

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MEDICINES REGULATORY AUTHORITY/ DEPARTMENT OF HEALTH TRADITIONAL AFRICAN MEDICINE GENOCIDE AND ETHNOPIRACY AGAINST THE AFRICAN PEOPLE

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Whilst we have no desire to bring African traditional healers and medicinal vendors under any undue regulatory pressure, preferring education to suppression, the blatant traditional African medicine (TAM) regulatory double-standard exercised by the State, amounting to protracted genocidal negligence by the Medicines Regulatory Authority and ethnopiracy by the Department of Health, are unacceptable to us. It is ludicrous that these authorities, entrusted with public safety, intend that new regulations for complementary medicines, at tremendous burden to role-players and taxpayers alike, will only address marketed labelled medicines, and not those supplied by sangomas, nyangas and other informal vendors, when the latter are the sources of the very high rates of morbidity and mortality from traditional African medicines, eclipsing even the excessive allopathic iatrogenicity and thereby aiming at the wrong target while discriminating against the internationally established relatively innocuous herbals and nutritionals.

This report is structured in 5 parts: 1) Traditional African Medicines (TAM) Toxicity Double-Standard, incorporating 2) *Estimated TAM Mortality Burden*; 3) TAM Ethno-piracy by the State and the Pharmaceutical Industry, incorporating 4) *TAM Working Group (Nat Ref Centre♣)*; and 5) Cultural Notes.

TRADITIONAL AFRICAN MEDICINES TOXICITY REGULATORY DOUBLE-STANDARD

"The SAMMDRA Bill makes provision for different procedures to be applied when registering orthodox (science-based, allopathic) medicines and complementary (herbal, traditional, or homeopathic) medicines. In the case of traditional medicines, issues of safety and quality will take precedence over demonstrations of efficacy. Thus, while the National Drug Policy might have been intended for application to all medicines, including traditional medicines, this Bill leaves many issues perhaps as muddy as before. Given the number of unresolved issues, the possibility of a court challenge after passage through Parliament cannot be ruled out." (Andy Gray, "Registration of traditional medicines- new bill", Healthlink, Issue No 37, October 1998)

We are impressed by how perceptively the public are regarding **natural health suppression**, often remark *"but what about traditional African healers, herbs and multi-medicines?"* In the past, the African tradition was "apparently" exempt from Act 101/65 regulation and now under Act 132/98, the MRA proposes that the Expedited Registration Procedure not extend to these medicines. We challenge constitutionally this double-standard. Section 9 of the Constitution (Equality), subsection (3), states "The State may not unfairly discriminate against anyone on one or more grounds..., including ethnic origin or culture".

Significantly **subsection (5)** moreover, specifically states that "Discrimination on one or more grounds listed in subsection (3) is unfair, unless it is established that the discrimination is fair". The onus is uniquely on the party wishing to discriminate, and hence to enforce compliance, the regulatory authority would have to, at their initiative, convince the Constitutional Court that the discrimination in these circumstances is fair, which is clearly impossible, given the facts presented hereunder. We note that recent MCCψ/MRA propaganda statements indicate that the authorities are determined to avoid this dilemma by creating false divisional categories by strategically differentiating products to be regulated via the defining concept of "market", via the restrictive misapplication of the WHO criteria of "bulk", "finished" or "labelled" products, so as to attempt to exempt medicines used by African traditional healers and vendors from the SAMMDRA regulations, apparently due to a lack of heart or will to deal with this traditional medicine toxicity crisis.

Consider the political hot potato issues which the regulatory proposals fail to adequately address, if at all:

Medicines regulation, in the public interest, comprises of 3 integral aspects: quality, safety and efficacy. The first aspect is only meaningful to the extent that it relates to the latter aspects. There is no point in ensuring quality if it does not interact with, positively impact on and enhance safety and efficacy. The authorities however, appear to be prepared to allow erosion of the latter in a compromise for adherence to the former, which suits the pharmaceutical complementary medicines industry but fails all consumers. This is clearly exemplified by inadequacies which will accommodate useless homoeopathic products with serious unsubstantiated indications and ignore a clear category of deadly traditional African substances.

In terms of “quality”, the hygienic and contamination situation relating to the pavement on which these wares are displayed in the urban setting are of legitimate concern, being as they are, often tainted with sputum, urine and faeces etc from human, animal and pedestrian traffic, plus a fair measure of vehicular combustion petrochemical deposits. We must however, be careful not to pursue purity to absurdity, as with the GMP pharmaceutical manufacturing standards insisted on for natural health substances, which we insist ought logically to be maximally set at those for food standards, which latter are consumed in far more significant quantities, ironically also responsible for thousands of equally preventable deaths annually.

Regarding “efficacy and safety” aspects, it is imperative to evaluate the relative risk from traditional African herbs and substances, since some 75% of the African population are estimated to use traditional substances, usually in combinations. According to the electronic database established by Noristan Laboratories, now with TramedΦ, of the 350 plant extracts assayed, some 79 % showed definite pharmacological activity, and 12 % definite toxic effects. (Hughson L, Pharmaceutical & Cosmetic Review, Jul / Aug 1995) How can these now ideologically escape the claimed need for urgent appropriate scheduling and safety controls?

Professors Folb and Schlebusch, past chairman and registrar of the MCC_ψ respectively, opinioned internationally a decade ago that “*the issues of traditional medicines need to be addressed*” (Folb P et al, J Clin Pharmacol 1988: 28), yet apparently a moratorium exists iro traditional medicines, in spite of Folb again writing, under the heading “Traditional drugs and indigenised pharmaceuticals”, that “*some give rise to serious adverse reactions, and others contain chemicals that have long term effects such as carcinogenicity and hepatotoxicity.*” (Folb P, SA Jour Sci, Vol. 85. 1989 Aug) Why no urgent action here?

PHARMAPACT and its allies consider it ludicrous that these professors and now their successors, Dr Helen Rees (chair), Precious Matsoso (registrar) and especially Prof Eagles (vice-chair) claim jurisdiction over exotic herbal and other natural health substances as medicines when it is clear that these are impacting positively on health and negatively on medical profits, but not to have jurisdiction when some of the indigenised medicines are impacting negatively on health and positively on medical profits, whilst hypocritically using public safety as a red herring to suppress public access to those improving health. Tobacco and alcohol are relatively freely available, yet are both strongly pharmacologically active and are responsible for more deaths than any other substances, the most addictive, merely bearing a warning. Some serious reprioritisation is called for and the authorities are obliged to honestly face this dilemma. Toxicity is an adverse effect on health. In the final analysis, regulatory authorities deal not with toxicity, but with risk. Risk is the probability that the toxic properties of a substance will be produced in populations of individuals under their actual conditions of exposure. We can prove that there is no real risk from the natural substances about to be regulated, but exceptional risk from those which will not be.

Whilst there is little difference between an African medicinal and the exotics, all of which except for the former are currently the target of such vicious regulatory fervour by the regulatory authorities, the only difference we have identified, is that the latter have had their problematically toxic items excluded from international commerce for fear of litigation, whereas this process has not occurred with the indigenous substances, but for very few items. With current budget constraints, we cannot conceive of bureaucratic systems receiving the disproportionately high priority afforded it for relatively safe products, when an urgent traditional medicines Toxics List and educational programme are the only practical ways to truly act in the consumer's interest and save several thousand lives each year, not to mention untold suffering.

Whilst researching an earlier report, we assumed that the morbidity and mortality incidence for South Africans using indigenous medicines would be minuscule, but we were stunned to uncover the shocking scientifically recorded and published clinical observation that "in South Africa, the major cause of death (from acute poisoning) among black South Africans are traditional medicines."!!!! To reassure the reader that this was not a typographical error, the editor, a Clinical Professor of Medical Toxicology, added in brackets "(about 50 % of deaths)". (Ellenhorn's Medical Toxicity: Diagnosis and Treatment of Human Poisoning, Williams & Wilkins, 2nd. Edn.1997) That this situation could have escaped the authorities and has not received swift remedial action, is not only unacceptable, it is clearly criminal.

Dr. P.H. Joubert, M.D., author of the internationally published article referenced in the above-mentioned textbook has, as Professor with the Dept. of Pharmacology & Therapeutics at the Medical University of South Africa (Medunsa) been responsible for most of the epidemiological work in the shamefully neglected field of local indigenised medical toxicology. In spite of Joubert (and others) attempting for almost three decades to draw attention to this serious problem, practically nothing has been done to address this highly suspect apartheid oversight. Who needs a Third Force, when muti-medicine and a MCC ψ blind-eye to the problems, known to them for decades, will suffice as a silent tool for racist population control?

Joubert's successors and the medical press have played down this problem, eg. Dr. D.H Brand is mentioned in an article referring to follow-up work at Medunsa, 1987-1993, but both the title of the article, "Accidental poisonings rare in herbals" and the theme, contrary to the facts, suggested a small percentage of overdose or poisoning from traditional medicine, whereas Dr Brand's research had actually determined that "while only a small number of plant species were involved, these resulted in high mortality". (Medical Chronicle, Nov / Dec 1993); Brand also reported that "toxicity levels of Urginea sanguinea and some Drimia species are currently being investigated at Medunsa, following the observation of toxic symptoms in patients who had taken herbal medicines". (Brand pers comm with Anne Hutchings); Dr E Osuch, Joubert's current successor, in a recent thesis, confirmed that "The same traditional medicines (24 different plants) tended to recur as causes of hospital admissions...responsible for more than half of all acute poisoning deaths". (Thesis Summary)

Noteworthy is that this work continues at [Medunsa, Department of Pharmacology and Therapeutics] but now in determining the toxicity of traditional medicines in the "scientific marketplace". (S Afr J Sci 1997 Nov-Dec; 93(11/12)); The current department head, Prof W.J. du Plooy plays down the Medunsa statistics by deliberately interpreting them in the most meaninglessly favourable light, in an effort to trivialise the problem. (pers comm 16 Feb 1998, & "Analysing the Epidemiology of Traditional Medicine Poisoning", delivered at the Complementary Health Care Summit, 25 August 1998, and advertised as "Determine how your organisation can capitalise from this unique opportunity in the market". Entrance fee: R2000+ per day for the 3-day event).

Other scientists are even more directly in denial, eg Professor Drewes, ex Head of Chemistry, Natal University, clearly stated "What is certain, is that the nyangas are not going to poison their patients." Professor Laing, of the same department agreed, claiming that "no one dies from nyanga's prescriptions. It doesn't hurt them." (Muti: Myth, Magic or Medically Sound?, Peta Lee, Longevity, May 1996); Is it pure coincidence that Prof Drewes has done commercial drug investigative work on indigenous traditional medicinal plants, including the "African potato", Hypoxis rooperi, now on the commercial market in synthesised form, as have so many of his colleagues at universities throughout the country? It is our contention that most scientists and policy-makers/administrators so deeply in denial have seriously vested interests, financial and / or otherwise.

Urgent telephonic and e-mail requests made a year ago for specific research documents lodged in Du Plooy's Dept at Medunsa, to focus priority attention on this unacknowledged problem, have gone 90% unheeded. Du Plooy in his August presentation volunteers a grand total of one additional botanical name: Boophane disticha. Significantly, Du Plooy is a member of the NRC $\clubsuit$ and a MRC $\diamond$ funding recipient for "Traditional medicines as part of the national drug policy" and "Toxicology of traditional medicines", so neither he nor the authorities can claim ignorance or obscure research. Paradoxically, du Plooy hypocritically concludes: "The public should be protected against compounds that have harmful properties. How? It is impossible for medicines." Even more hypocritically: "AT LEAST THE PUBLIC SHOULD BE WARNED! ie awareness."

THE ESTIMATED MORTALITY BURDEN FROM TRADITIONAL AFRICAN MEDICINES

What then are the facts? *"Information on cause of death among adults in sub-Saharan Africa is essentially non-existent."* (Kaufman J, et al Bull World Health Organisation, 1997; 75(5)), yet we can definitely confirm that a phenomenal problem exists, beyond the worst-case scenario expectations of most scientists and policy-makers. The author of this report estimates that **annually several thousand deaths from traditional African medicines occur**, far in excess of those dying of AIDS and significantly **Dr M Stewart, Department of Chemical Pathology, SA Institute for Medical Research, concurs with this assessment, having recently determined "70 traditional African medicine deaths in 8 months at Coronation Hospital, Johannesburg, and this just the few that made it to the hospital alive, only to die there, not to mention those who were/are extremely close to death."** (pers comm, 31 March, 1999) **It is significant that the major poisoning symptoms and causes of death from traditional African medicines closely mirror the major symptoms and causes of death (besides infectious) among the black population: diarrhoea, fetal distress, hypoglycaemia, renal / hepatic failure, respiratory distress, and cardiac failure.**

"In the developing world, medically certified information is available for less than 30% of all deaths that occur and 98% of deaths in children younger than 15 years and 83% and 59% of deaths at 15-59 and 70 years, respectively occur there. The probability of dying from a non-communicable disease is higher in sub-Saharan Africa (and other developing countries) than in other market economies. This is at odds with popular perception. The paradox of higher non-communicable death rates in the adults of the developing world must be attributable to other (non-communicable) major determinants of mortality that are more common in these regions. The estimates that are most uncertain are those for sub-Saharan Africa, particularly for the exact composition of non-communicable and injury mortality. As more regions undergo epidemiological transition, particularly premature death among adults will increasingly become a major public-health concern. Surveillance and research to measure and monitor mortality must anticipate this trend." (Murray C, Lopez A, Mortality by cause for 8 regions of the world: Global Burden of Disease Study, Lancet 1997; 349)

"Information on cause of death among adults in sub-Saharan Africa is essentially non-existent, mostly extrapolations and outright guesses. Non-communicable diseases account for a significant portion, yet the empirical bases for public health policies and interventions are essentially absent." (Kaufman J, et al, Bull World Health Organisation, 1997, 75(5)); *"Data on mortality and morbidity in South Africa are inadequate. The absence of a comprehensive national health information system, poses problems for an analysis of mortality."* (White Paper on Population Policy, RSA, March 1998); *"Estimating specific causes of death in South Africa is difficult, the last detailed information being almost a decade old, with no chance of an update, since the law was changed at that time to exclude the necessity of recording the details of the actual cause of death. The data collection system makes no provision for gathering the type of data needed to determine how many deaths might be attributable to traditional medicines. The overall figures must all be considered to be vast underestimates. Not all deaths in rural areas are registered and many are in the ill-defined category where it was not specified on the certificate."* (pers comm. Dr Debbie Bradshaw, Centre for Epidemiological Research in Southern Africa, MRC♦, 6 April 1999); *"There is an urgent requirement for development of diagnostic methods in order to reduce the number of (cases, and) cases in which the death certificate refers only to the final pathology and not the causative agent."* (Stewart M et al, Ther Drug Monit, 1998, Oct, 20(5))

The crude death rate in South Africa is 8.9 per 1 000 (1995 United Nations estimates, & RSA Stats in Brief, Aug 1996; 9.4/1000 according to DoH), meaning that approximately 400,000 of 40 million South African's die each year. In the RSA **20% of all deaths are of unknown causes**, (according to Stats South Africa: 13.71 ill-defined (15.2, DOH), 4.24 undetermined, and 1.61 other external). (Bradshaw D, Estimated Cause of Death Profiles SA, Based on 1990 Data, CERSA, MRC, 1991); **Deaths from traditional African medicines could constitute a large portion of this 80,000 and it is not unrealistic to assume that traditional medicine poisoning deaths are responsible for at least 10% of the 80,000 annual deaths from unnatural causes, (excluding homicide, violence, accidents and self-inflicted), ie 8,000 traditional medicine mortalities would be conservative, confidently doubled to 15,000 and taking into account a percentage of deaths attributed to natural causes such as cardiac failure, 5000 additional of which may be traditional medicine induced, 20,000 is a conservative estimate for annual preventable deaths from traditional medicine.**

Prof Pieter Joubert, ex Medunsa, whose work is widely respected, published and cited internationally, has determined that "in developing countries, besides infectious conditions, acute poisonings with pesticides, paraffin (kerosene) and traditional medicines are the main causes of morbidity, whilst acute poisonings with traditional medicines is the main cause of mortality." (Joubert P, Mathibe L, Acute poisoning in developing countries, Adverse Drug React Acute Poisoning Rev 1989;8(3)); This assessment accurately pertains to local circumstances where "amongst black South Africans, the poisoning category is the second in order of importance in the five main causes of death (second only to contagious and parasitic diseases), whereas it is only the third and fourth category amongst the other groups." (Van Rensburg H, Mans A, Profiles of Disease and Health Care in South Africa, R&H Academica, 1982) This is confirmed by the 1990 MRC data.

Joubert, the internationally recognised authority on South African indigenous medical toxicity, in his earliest published work on the subject of traditional medicine poisonings, undertook a retrospective comparative epidemiological study of acute poisonings at teaching hospitals of the University of the Orange Free State, Bloemfontein, 1970-1976, which revealed that "among whites, medical drug poisonings predominated", but "among the black developing community, was responsible for few poisonings, priorities being prevention of pesticide, paraffin, carbon monoxide (indoor fires) and traditional medicine poisonings." (Joubert P, "Toxicology units in developing countries: different priorities?" J Toxicol Clin Toxicol 1982 Jul;19(5))

In a subsequent project covering 1981-1982 at Ga-Rankuwa Hospital, Pretoria, Joubert determined that "whilst 18 % of all acute poisonings were due to traditional medicines, most (86.58 %) of all deaths from acute poisoning were as a result of poisoning with traditional medicines" and concluded that (First World) "toxicology services, primarily geared towards the management of cases of drug poisoning, are inappropriate to the needs of developing communities." (Joubert P, Sebata B, "The role of prospective epidemiology in the establishment of a toxicology service for a developing community." S Afr Med J 1982 Nov 27; 62(23))

In a continuing project covering 1981-1985, also at Ga-Rankuwa Hospital, Joubert once again determined that "the main poisoning causes were paraffin (59 %), but with low mortality (2.1 %), whilst poisoning with traditional medicine resulted in a high mortality of 15.2 % and accounted for 51.7% of all deaths, always accidental". Furthermore, "Vomiting, diarrhoea, and abdominal pains were the most frequently encountered symptoms, while lungs, liver and central nervous system were commonly affected. The traditional healer was the main source, 83.4 %, while 11.3 % was bought from African medicine shops. Questioning patients and traditional healers facilitated the identification of a number of etiological agents". (Venter C, Joubert P, "Aspects of poisoning with traditional medicines in southern Africa". Biomed Environ Sci 1988 Dec;1(4))

The main paper referenced in the above-mentioned textbook is Prof. Joubert's **"Poisoning admissions of black South Africans"** (Joubert P, J Toxicol Clin Toxicol 1990; 28(1)), also dealing with acute poisoning admissions to Ga-Rankuwa Hospital, 1981-1985. This study determined that "Overall, the major causes of mortality were traditional medicines, responsible for 51.7 % of the deaths that occurred, followed by pesticides (23%). Of the patients who died, 62 % were poisoning by traditional medicines of which none were deliberate self-poisoning". Joubert concluded: "the main issues were the extremely high mortality" and "prevention of poisoning by traditional medicines merits high priority in the health care of the indigenous population of South Africa". Are labelled, finished, "marketed" medicines to blame here? Absolutely not.

"The 'traditional healer' was the main source, 83.4 %, while 11.3 % was bought from African medicine shops. In only 0.6% of cases were medicines collected by the patients themselves and in 4.4% the substances were obtained from other sources. The traditional healer is an integral part of African culture and many South Africans make use of traditional African medicines, mostly of plant origin, but also minerals or animal. In most instances these medicines are "crude watery extracts". Most towns and cities have "African medicine shops" where traditional medicines can be bought over the counter. There is currently no legislation controlling traditional African medicines. The traditional African medicine mortality is extremely high. If poisoning due to these substances can be eliminated, the overall mortality will decrease by about 50%". Most frequently implicated were *Jatropha curcas*, *Ricinus communis* and *Datura stramonium*. (Joubert, J Tox Clin Tox 1990;28(1))

This study described "traditional medicines" as "a particularly important and interesting aspect of the local poisoning pattern" and pointed out that "the major cause of fatal poisoning pattern at Ga-Rankuwa appears to be very similar to that reported from Bloemfontein", and also "is similar to mortality reported from Zimbabwe" (ref above) & (Nyazema NZ, Trans R Soc Trop Med Hyg 1986;80) & (Chitsike I, Cent Afr J Med 1994 Nov;40(11)) Researchers at the University of Zimbabwe have reported that "poisoning by traditional medicines are the biggest single group of all cases." (Kasilo O, Nhachi C, S Afr Med J 1992 Sep;82(3)); "The main agents associated with acute poisoning were traditional medicines." (Nhachi C, Kasilo O, J Appl Toxicol 1992 Dec;12(6); and "Zimbabwe has a big poisoning problem, especially with regard to treatments recommended by the traditional healer." The conclusion: "Education and information dissemination on toxic agents are vital and much remains to be done. The report confirms the importance of toxicology information to the Southern African (SADCC) region as a whole". (Kasilo O, Froese E, A 10-year review of the Teaching Hospital-Based National Drug and Toxicology Information Service. Clin Pharm Ther 1989 Oct; 14(5))

Further vindicating Prof. Joubert's concerns, in spite of attempted down-playing propaganda, are the summary conclusions of Joubert's current successor, **Dr. E Osuch**, who extended his work as a thesis covering the subsequent period 1987-1992. Dr Osuch concluded that "Traditional medicine ingestion was responsible for more than half of all acute poisoning deaths." Also of interest is that "Eight remedies have been identified which were associated with haematuria and renal failure. One of the most common causes of acute poisoning admission to the Ga-Rankuwa hospital was ingestion of the watery extract of Urginea sanguinea." Even more recently Osuch et al stated: "A large percentage of acute poisonings in black South Africans is due to traditional medicines." (Foukardis G, Munting G, Osuch E, Toxicological aspects of some traditional medicines used by patients admitted to Ga-Rankuwa Hospital. J Ethnopharmacol 1994 Feb;41(3)); "Used as a blood purifier, clinical symptoms affect the, gastro-intestinal & urinary tract, central nervous system, or the splanchnic system." (Foukaridis G, Osuch E, Mathibe L, Tsipa P, J Ethnopharmacol 1995 Dec; 49(2))

Du Plooy confirms our position by clinically summarising the work of Joubert, Brand, Osuch and Foukaridis: "A solid is less harmful. Extractions are more harmful. It could be life saving if the material is identified, which may take too long. Clinically, longer than 6-24 hours after poisoning is too long. (Activated charcoal must be given within 1-hour of ingestion.) Typical clinical features include kidney failure (haemolytic anaemia), heart failure, arrhythmia and a variety of infections. In children the most common problem is dehydration and eventual kidney failure. The incidence of poisoning is high in patients who are old and go for blood purification; patients with fertility problems (male and female); for abortion; and for male STDs". ("Analysing the Epidemiology of Traditional Medicine Poisoning", Compl Health Care Summit. 25 Aug 1998)

We have also identified and independently profiled what is **probably the major traditional African medicine "killer plant"**, again from a lead originating from Joubert, namely *Callilepis laureola*, known as **Impila**, which ironically means **"health"** in Zulu. (Hutchings A, Terblanche S. S Afr Med J 1998;75.); "Toxic plants are used for medicinal purposes by the Zulu population." (Foukardis G, Joubert P, Forte M, Clin Toxicol 1992;30); "With approximately 50% of the population using Impila in Natal, it is the second most widely used and has been reported on extensively."(Ellis M. Medicinal Plant Use-A Survey, Veld and Flora 1986 Sept), eg:

IMPILA: Byrant A, Zulu Medicine and Medicine Men, Centaur, 1966 – "without doubt a virulent poison", •Seedat Y, Hitchcock P, S Afr Med J Jul 31;45(30) – "acute renal failure"; •Wainwright J, Schonland M, Candy H, S Afr J Med 1977 Aug 13;52(8) – "found to cause fatal liver necrosis, widely used as a herbal medicine, nephrotoxic, hypoglycaemic, hepatotoxic"; •Watson A, Coovadia H, Bhoola K, S Afr Med J 1979 Feb 24;55(8) – "administration of Impila is common, the practice can and does cause poisoning, hepatic and renal tubular necrosis, hypoglycaemia, alteration of consciousness, hepatic and renal dysfunction"; •Veale D, S Afr Pharm J 1987;(54) – "rootstock is toxic and can be fatal if ingested in small quantities; confusion, vomiting, diarrhoea, convulsions, hypoglycaemia and liver and kidney failure"; •Savage A, Hutchings A, "Poisoned by herbs". Br Med J 1987;295 – "clinical symptoms of Impila intoxication are abdominal pain, jaundice, hypoglycaemia, disturbed hepatic and renal function"; •Dehrmann F et al, J Ethnopharmacol 1991 Sep; 34(2-3) – "used extensively as a medicament, nephrotoxic"; •Bye S, Dutton M, In: Oliver J, ed. Forensic Toxicology. Scottish Academic Press, 1992 – "hepatotoxic, nephrotoxic, hypoglycaemic".

What would the relative risk/benefit ratios be for Impila? (which would have to be comparatively higher for the latter than for the former for such a toxic drug to be tolerated by any self-respecting regulatory authority) Since there are no approved uses, we have to assess the popular uses against the above-mentioned risks, and clearly this plant would never be registered for and on the basis of these: a) "Roots are taken as tonics by young girls in the early stages of menstruation." (Doke C, Vilakazi B, Zulu-English Dictionary, 2nd edn. Witwatersrand Univ Press 1972); b) "Ground roots taken for snakebite and administered as enemas and in baths to protect the children of parents who have already lost many children." (Valley Trust [HST Ω], pers comm Hutchings); c) "Roots also used as protective charms placed under the pillow to stop bad dreams." (Cunningham 2669 NU, in Hutchings A, et al, Zulu Medicinal Plants: An Inventory. Univ Natal Press 1996)

Even more dangerous is Impila's traditional use during pregnancy and childbirth, likely the biggest killer of all, eg: "Roots are sometimes an ingredient in *"inembe"*, taken regularly during pregnancy to ensure an easy childbirth, and to make an infusion for fertility." (Gerstner J, Bantu Stud 15 (3) (4), 1941); "They are sometimes included in medicines known as *"isihlambezo"*, which are used by traditional birth attendants to ensure the health of both mother and baby during pregnancy." (Gumede M, Traditional Healers, Skotaville Publishers 1990); Dr Mike Stewart, Dept of Chemical Pathology, SAIMR, has focused on Impila as a priority, yet his entire annual budget for all his analytical work is a mere R50,000, with not a cent from the MRC♦.

"Many black South African women use traditional African herbal remedies as antenatal medications or to induce or augment labour. Very little is known about the pharmacology and potential toxicity of plants used in these herbal remedies. Several of these plants are poisonous." (Veale, et al, J Ethnopharmacol 1992 Jun; 36(3)); "Some of the herbs are toxic in large doses. According to Joy Veale, a lecturer in pharmacology at the University of Witwatersrand, there are about 36 plants in South Africa used to induce labour, of which 15 are toxic." (Pantanowitz D, Alternative Medicine: A Doctor's, Perspective. Southern Book Publishers, 1994) "African traditional herbal medication is commonly used in pregnancy by women attending King Edward VIII Hospital, Durban. Its use may lead to fetal distress effecting pregnancy outcome." (Mabina M, Pitsoe S, Moodley J [MRC♦, Univ Natal, Dept Obstetrics and Gynaecology] S Afr Med J 1997; 87(8)); "Though some evidence exists suggesting negative effects of its ingestion, the maternal-fetal health impact and toxicity of isihlambezo have not been adequately studied. Pharmacological analysis suggested both therapeutic and harmful consequences of isihlambezo." (Varga C, Veale D, Soc Sci Med, 1997 Apr, 44(7))

Paediatric use is also seriously problematic. (Bodenstein J, S Afr Med J 1977 Nov 5;52(20)); More specifically eg at Habisa Hospital, Kwazulu Natal: "We have observed a distinct clinical syndrome amongst acutely unwell children frequently associated with the administration of a traditional medicine enema. Admission was frequently prompted by sudden, marked clinical deterioration following enema administration (68% within 24 h). Clinico-pathological features of this enema syndrome:- respiratory distress/insufficiency with tachypnoea, abdominal distension, hypotonia and loss of consciousness occurred frequently. In-hospital mortality was 28% and higher in those receiving herbal (43%) rather than chemical (21%) enemas. Hyperkalaemia, leucocytosis (> 15,000 mm³) and respiratory distress/insufficiency occurred more frequently in those who died." (Moore D, Moore N, Ann Trop Paediatr, 1998 Jun, 18(2)); Pediatric enemata are a problem in other provinces, eg: "herbal intoxication regularly occurs, with high mortality in infants, especially under 1 year of age." (pers comm, Dr Baker, ICU, Livingstone Hospital, PE, 26 Mar 1999)

Besides the above-mentioned subsets, the following represent further confirmation of this enormous problem. "In the treatment of measles, a variety of indigenous medications are used, some of which are potentially dangerous." (Ijsselmuiden C, S Afr Med J 1983 Mar 5;63(10)); "Although widely recognised by physicians, the acute renal failure resulting from the use of herbal preparations obtained from witch-doctors has not been fully described." (Gold C. Clin Nephrol 1980 Sep;14(3)); "In cancer of the oesophagus, traditional medicines are a significant risk factor." (Sammon A, Cancer 1992 Feb 15;69(4)) "The potent effects of their herbal medicines can result in damage to any part of the gastro-intestinal tract, and may be fatal. Diseases caused by witch-doctors constitute an important facet of the disease spectrum of blacks." (Segal I, Tim L, S Afr Med J 1979 Aug 25;56(8)); "The inappropriate use of traditional medicines results in numerous fatalities, invariably in children." (Bye S, Dutton M, J Ethnopharmacol 1991 Sep; 34(2-3))

Traditional African medicines also have **psychiatric usage**. Dr Thomas Lambo, a champion of traditional African medicine, a Nigerian psychiatrist, dean of the Medical School, vice chancellor of the University of Idadan, and **Deputy Director-General of the WHO** for many years, in response to a question as to whether the traditional African healers sometimes harm their patients, answered **"They have an extensive pharmacopoeia of herbal psychotropic drugs. A lot of damage has been done, there is no doubt"**. (Bass T, Reinventing the Future: "Conversations with the World's Leading Scientists". Addison-Wesley Publishers, 1994) Prof D Oberholzer, Department of Psychiatry, Pretoria University, had **traditional healer's psychiatric herbs** analysed at the university laboratories and determined that **"many potentially harmful agents were discovered in the therapeutic plant material"**. (Oberholzer D, J S Afr Institute of Psychotherapy, 1985, Mar, Issue 36)

"Traditional medicines can be beneficial, dangerous or useless in a pharmacological or psychological capacity, their dangers being mainly as direct irritants or as hepatic or renal toxins. Mild to moderate toxicity from short or long term use is difficult to separate from the original illness. Greater absorption from enemas coupled with irritant proctitis and perforation indicate that enemata have a high mortality". (Ellis G, Medicinal Plant Use, Veld & Flora, Sept 1986) **"Traditional medicines (or mutis) are usually administered orally or as an enema by a traditional healer. Gastro-intestinal irritation was the most common syndrome (54%) experienced after traditional medicine administration. Cardiac glycosides are often found (44%) in autopsies [Jhb Forensic Chem Lab] where death was presumed to be caused by herbal medicine. It is concluded that in patients with gastro-intestinal symptoms, traditional medicine cardiac glycosides should be suspected."** (Mc Vann A, Havlik I, Joubert P, Monteagudo F, S Afr Med J 1992 Feb 1;81(3))

"Herbal medicine may be directly responsible for harmful or fatal results, and frequently cause especially gastro-intestinal disorders, which may certainly be ascribed to the witch-doctor and his medication." (Van Rensburg H, Mans A, Profiles of Disease and Health Care in South Africa, Academica 1982); Dr Desmond Pantanowitz, Professor of Surgery, University of Witwatersrand writes: **"Many dangerous substances have been isolated from nyanga concoctions, including the orange crystals of potassium dichromate, which can cause liver failure. Cantharides (Spanish fly) is often used to treat impotence; the side-effects of this poison are irritation of the gut and urethral mucosa, as well as kidney failure. Some nyangas even add battery acid to their concoctions to give them some 'body'. The concoctions are administered via various routes: oral, anal, and through the skin. Damage may occur along the entire gut, from the oesophagus all the way through to the anus. Ritual enemas are a favourite method used. Many infants receive up to 100 enemas age two. Enemas may be prescribed for ritual purposes and for the treatment of complaints as diverse as impotence, dysmenorrhoea, fever, diarrhoea, constipation, abdominal pain and headache. The traditional healer can be a danger to society"**. (Pantanowitz D, Alternative Medicine: A Doctor's Perspective. Southern Book Publ 1994)

"In the rural setting, a truncated cow horn is often used to dispense the enema; this may mechanically damage the rectum, causing anorectal laceration or rectal perforation. Complications are seen regularly at academic hospitals, particularly Baragwanath. Conditions that are repeatedly diagnosed are gut necrosis with perforation, peritonitis, gram negative endotoxic shock, disseminated intravascular coagulation, adult respiratory distress syndrome and hepatorenal failure, which can all result in the death of the patient. While the rural individual is given mainly herbal enemas, such as the poisonous milkweed species Aesclepias physocarpa, the sophisticated urban dweller is given additional exotics such as Dettol, vinegar, copper sulphate, potassium permanganate, hydrochloric acid, sodium hydroxide, and the favourite, battery acid. To my knowledge patient's families have never charged murder against a traditional healer in this country. No evidence can be obtained in a court of law. There is a code of secrecy and silence governed by a fear of retribution." (Pantanowitz D, Alternative Medicine: A Doctor's, Perspective. Southern Book Publishers, 1994)

Besides poisonous plants, **other toxic agents controversially used by traditional healers are: battery acid, chloroxylenol, potassium permanganate / dichromate, and copper sulfate**. (Ellenhorn's Medical Toxicity: Diagnosis and Treatment of Human Poisoning, Williams & Wilkins, 2nd Edn. 1997). **"Renal failure may occur with potassium dichromate"**. (Wood et al, S Afr Med J, 1990 Jun 16;77(12); (Michie et al, Hum Exp Toxicol, 1991;10) Potassium dichromate is used primarily for its colouring rather than disinfection action. (Bye S, Dutton M. Proc Int Assoc Forensic Toxicol, Scottish Academic Press, 1992); Du Plooy: **neon colourants**. (Analysing the Epidemiology of Traditional Medicine Poisoning, Compl Health Care Summit. 25 Aug 1998)

Dr Steven Toovey, Director of Medinfo, says: "We know, from experience, that some traditional medicines are toxic". The reporter continues: "Dr Toovey ran independent tests in two laboratories on a traditional mud remedy to "strengthen the blood, eaten mainly by pregnant women with anaemia. Both laboratories found arsenic and mercury in the samples. Among the test tubes filled with indigenous roots and herbs at Groote Schuur Hospital's department of pharmacology (Folb-Ed), researchers have encountered problems that move beyond the diseases and ailments they set out to cure. Toxic chemicals in muti remedies have raised alarm in the scientific community." The photo caption: "TRADITIONAL WEAPON: a researcher (African-Ed.) runs a test on local muti" (Emily Osinoff, "Indigenous plants could provide real muti", Sunday Argus, May 30 1999)

A very recent report is further confirmatory: "Toxicity related to traditional African medicines is becoming more widely recognised. Accidental herbal toxicity occurs not only as a result of a lack of pharmaceutical quality in harvesting and preparation, but also because these remedies are believed to be harmless. Treatment in most cases of plant poisoning remains symptomatic, with few antidotes available. The recent commercialisation of the traditional medicine scene is leading to the depletion of many species as their dispensing moves from the traditional village setting to the more lucrative markets in the cities and towns." (Stewart M et al, "The toxicology of African herbal medicines." Ther Drug Monit, 1998, Oct, 20(5)); The further significance of this latter statement is that the expertise and responsibility towards the patient of the healer in dealing with the potentially toxic among these substances is being eroded by this type of commercialisation, and whilst this raises the likelihood of far more accidental mortalities, it also presents a golden opportunity for more efficient centralised preventive educational programmes to be instituted.

The Department of Health initiated a project on the safe handling and storage of pesticides with the aim of increasing community awareness towards potentially hazardous pesticides. (Health - Government Yearbook Government Communications GCIS 1998) Why no corresponding programme for more widely used traditional medicines? Additional problems not being adequately addressed for awkward political considerations are eg, "traditional healer's may cause dangerous delays." (Smyth A, et al, South Africa's Health, Letter, BMJ 1995;47(3)); "a potential route (incisions) for viral disease transmission." (Hepatitis, HIV) (Jolles S&F, Letter, African Traditional Medicine, Lancet, 1998 Jul 4, 352(9121)); Forensic medicine: "Ritual or muti murders by a traditional healer are a form of human sacrifice. The murder is carried out after body parts are removed while the victim is still alive." (Scholtz H, et al, Forensic Sci Int, 1997 Jun 6, 87(2)) Education now!

We have mentioned the openly identified poisonous species implicated in the Ga-Rankuwa sub-sets, but these are only 5 out of 24, and neither du Plooy, as custodian of Joubert, Brand, and Osuch's Medunsaø toxicological data, nor Folb, as custodian of the UCT Tramedø data, have complied with our repeated requests for information access to compile and release an urgent educational African botanical toxics list. PHARMAPACT are singly campaigning for the necessary reform, via this and earlier efforts. We are trying to prepare an urgent toxics short-list, but are not receiving any co-operation from the authorities nor the data custodians in this regard. PHARMAPACT will refrain from publishing a compromise list, insisting on rightful access to the Tramed database, which was again denied us on 24 May 1999 by professor Folb, claiming that this aspect still had to be developed, yet declined our offer to undertake this work. (Pers comm, T/Dr A Rees)

In the meantime, besides this document, the following remain the only detailed but very limited sources of such information, but none in a form readily accessible or meaningful to the traditional healer / medicine fraternity: a) **Watt J, Breyer-Brandwijk M**, The Medicinal and Poisonous Plants of Southern and Eastern Africa, 2nd Edition, E & S Livingstone Ltd, 1962; b) **Hutchings A**, Zulu Medicinal Plants, Univ of Natal Press, 1996. It is interesting to note that Watt, like Folb, was a Professor of Pharmacology (Univ of Witwatersrand), but unlike the latter, cared enough about the African people to use the institution at his disposal to laboriously collate the existing toxicological information and make it widely available, including to all hospitals for the treatment of herbal poisonings. On the other hand, Folb leader of the Traditional Medicines Programmeø and handed public custodianship of an electronic database 20 years under development, cannot 5 years later provide a toxics list, nor is he willing to grant access to those volunteering to undertake this priority work. Folb, as Chair of the MCC for 18 years, had a mandate to ensure the protection of the public from toxic medicines, yet instead of using the database to identify and alert healers to the risks, only lucrative new drug leads were sought. We will press charges of genocide, and complicity thereto against all perpetuating officials.

AFRICAN MEDICINE ETHNOPIRACY BY THE STATE AND PHARMACEUTICAL INDUSTRY

None of the above-mentioned identified toxics are at all covered in the South African Traditional Healer's Primary Health Care Handbook, based on the TramedΦ database and produced by the Medical Research Council and the Traditional Medicines Research Group (TMRG)♣ of the Universities of Cape Town and of the Western Cape. Prof Eagles, Head of the Pharmacy School, UWC, as one of three tiers of the TMRG and who was and is again the vice Chairperson of the MCCΨ/MRA, is also, with du Plooy, an influential member of the Traditional Medicines Working Group, National Reference Centre (NRC)♣.

We have to protest, that the forgoing facts having been determined, and the regulatory authorities repeatedly exposed thereto, as well as to that which follows, they who were/are mandated to protect the public from toxic medicines were/are presented with a golden opportunity to educate prescribers, suppliers and consumers regarding which plants were/are most seriously implicated, as well as dose, contra-indications, precautionaries, early and advanced poisoning symptoms etc, a golden opportunity squandered by all concerned, especially the MCCΨ, via access to the Traditional Medicines Project (TRAMED)Φ/TMRG♣ with Folb / Schlebusch / Bruchner, and now Eagles / Rees / Matsoso at the helm.

Shockingly little or nothing has been done about this unacceptable situation, least of all by those who over the period that this information has been directly available to them and who have been directing MCCΨ policy under the shallow guise (at least to us), repeated ad nauseam, of being the custodians of public safety from toxic medicines and insisting that they have been empowered to control all substances fitting their enacted definition of a medicine. The new transitional authority inherits legal responsibility.

We are presently engaged in ongoing culpability investigations for gross dereliction of public duty and genocide against Professors Schlebusch and especially Folb and in the latter's case, a further enquiry into ethnopiracy, since Folb has directorship at the University of Cape Town of the Dept. of Pharmacology, the World Health Organisation Collaborating Centre for Drug Policy (WHOCDDP); and the Traditional Medicines ProgrammeΦ and so was better positioned than anyone to be aware of these shocking circumstances and especially as chairman of the MCCΨ, to have been doing something meaningful about them. Eagles also faces similar investigation, now approximating the position previously held by Folb.

Instead of using the 60,000 entry TRAMEDΦ database available to the WHOCDDP to "monitor all adverse reactions to medicines in South Africa, investigate national problems of drug toxicity, recommend policy in this regard and encourage the rational and safe use of medicines, including traditional medicines, to address an important and comparatively neglected scientific research and public health field, and to establish the rational and safe use of traditional medicines", the facilities are "presently engaged in large amounts of research based upon the extraction and isolation of active compounds from plants used by traditional healers in the treatment of disease." (Homepage:University of Cape Town, Dept of Pharmacology)
Students from indigenous backgrounds are now pushing for proper codes of conduct. (Sunday Times, 2/2/99)

Ethnopiracy projects at TramedΦ include: "*Natalie Brine* – anti-malarial compounds from plants; *Sandra de Klerk* anti-malarial activity present in plant mixtures used by traditional healers; *Motalepula Gilbert Matsabisa* – ethno-pharmacology in drug development; investigation of the anti-malarial activity of indigenous Southern African plants; *Siyabulela Calvin Ntutela* – efficacy of plants used in traditional treatment of tuberculosis; *Portia Rachaka* - potentiation of immune response by traditional herbal remedies (Homepage: University of Cape Town, Dept of Pharmacology); also "Malaria is the focus of research UCT's Pharmacology Department, where Dr Pete *Smith* has examined plants used by traditional healers for treating fever." (Diana Streak, Fair Lady, Sept 1995); *Matsabisa* is testing plants discovered by traditional healers in KwaZulu-Natal in treating malaria." (Sunday Times, 21 March 1991); More recently: "*the Traditional Medicines Research Group* at UCT sent a Masters student to a hi-tech laboratory in *Barcelona* that can analyse plant material much faster than in SA. One was obtained from the *Durban herb market* and the other is widely used throughout South Africa." (Claire Bisseker, Financial Mail, 19 Mar 1999); "Dr *Karen Barnes*, a clinical pharmacologist (?) supervised clinical trials of the drug in a high-risk area in KZN. *Sibongile Pefile's* area of research involves the use of plants to treat viral skin disorders." Laurice Taitz, Sunday Times, 2 May 1999)

The **Traditional Medicines Project (Tramed)Φ** is based on a **database** donated by **Noristan Laboratories** to the University of Cape Town's Pharmacology Department to be incorporated into a national database to which all interested parties can have access. (Lindy Hughson, editor, *Pharmaceutical and Cosmetic Review*, July/August 1995); The project has since 1995 been assisted by Dr T Felhaber, supported by a **Fellowship from SA Druggists**, and since 1991, **Isaac Mayeng**, supported by a grant from the **Medical Research Council (MRC)♦**. Mayeng is now employed full-time as senior medicines control officer with the MCCΨ/MRA, in serious vested interest conflict with his commercial ventures. This project had its genesis at a the 28th Annual Congress of the South African Pharmacology Society on the 24 September, 1994, at which most of the ethnoprates mentioned here were present. (Nigel Gericke, *Tramed, Indigenous Plant Use Newsletter*, November, 1994); **Noristan Laboratories**, who originally donated the database to UCT have subsequently been acquired by **Hoechst**, giving the global drugs cartel right of access to the vastly expanded database.

The database has had added, a substantial collection of information on traditional medicine donated by the Hans Snyckers Institute of the Medical School, Univ Pretoria. Further collaboration exists with Dr Anne **Hutchings** (ex-Univ Zululand), Prof Wimpie **du Plooy's** Dept of Pharmacology at MedunsaΦ, Dr Carl **Albrecht** at the Dept of Pharmacology and Dr Michael **Becker** at the Dept of Virology, both at the Medical School, Univ Stellenbosch. Dr David **Gammon**, **Dept of Chemistry, UCT**, is "collaborating with the Dept of Pharmacology in the investigation of the biological activity of medicinal plants found in the southern African region, identified through traditional medicine." (UCT Dept of Chemistry homepage) Central to the TramedΦ programme from an early stage has been T/Drs **Solomon Mahlaba and Isaac Mayeng**. Both are major sell-outs, benefiting only themselves, as the ancestral knowledge of the nation is raped by commercial interests, whilst scientific feedback to the traditional healers as a whole has been negligible. As reward, both have enjoyed virtually proprietary access to the database for their own medicines businesses.

The statutory **Medical Research Council (MRC)♦** are the logistical and funding backbone for these ventures, thereby directly implicating the State in these suspect ethnopiracy activities. Further projects elsewhere of which we are aware, besides Tramed and TMRG are: *"MRC♦-supported researchers at the Department of Pharmacology and Therapeutics (du Plooy's Department) at MedunsaΦ have analysed Devil's Claw, and compared its anti-inflammatory properties to fluticazone, a powerful cortisone-based anti-inflammatory."* (MRC Annual Report, June 1998); Professor Olivier and colleagues are involved in an indigenous medicine database at the **University of the North** and especially the **Rand Afrikaans and Free State Universities** are networking closely with the TMRG♣. More recently a consortium has been formed, comprising the **CSIR**⊗(specifically the Division of Food Science and Technology – Foodtek), **MRC♦**, and the **Universities of Cape Town, Western Cape and the North**. Eddie Koch writes: *"Almost every university now has research relating to traditional medicines in the pharmacy or other departments."* (Electronic Mail&Guardian, undated)

Nigel Gericke, a medical practitioner, a member of the **CMC**, and the **founder of TRAMEDΦ** whilst working as phytomedicines development manager for SA Druggists, states in his CV that he continues to serve as consultant to **TRAMED**, including "ongoing research into side-effects" and "to encourage the safe use of indigenous medicinal plants, and the development of a database, including toxicology." In late 1995, at the request of Folb, as the **MCCΨ**, a study and recommendations were made by Gericke for the development of a South African approach, yet ironically no urgent regulatory action is being imposed on this sector, which by far represents the major, if not sole risk to public safety from natural health substances against which the MCCΨ/MRA claim to act when witch-hunting the international natural health substance traditions.

Dr. Gericke in the meantime developed his own commercial range of ethnoprated indigenous medicines (**Healer's Choice** brand) and with his senior at SAD, Bosch van Oudtshoorn, co-authored a new book (**Medicinal Plants of South Africa**, Briza, 1997), (to make medicinal claims "independently" of the product?) developed from the **TRAMEDΦ** database, to which it gives no acknowledgement, nor to the traditional healers. Most irresponsibly this book does not even begin to address the above-mentioned vast toxicological problem, since for the majority of the 132 plants featured, in spite of significant toxicities, the book treats these as if they did not exist, except for occasionally mentioning that this or that isolate has toxicological potential, but more from a pharmacists perspective. There is however the obligatory publisher's indemnity.

A shockingly similar situation inexplicably exists with the recently published South African **Traditional Healer's Primary Healthcare Handbook** (UCT, 1997), also a product of the **TRAMEDΦ** Project, which, although it provides short token precautionaries for those toxics among the 55 plants featured, **simply does not do justice in addressing the enormous problem of acute poisonings and fatalities arising from traditional African medicines. We have to question and protest the deliberate exclusion of an educational Toxics List**, especially considering Folb's above-mentioned statements regarding toxicity, and more recently, those of **Eagles**: *"In favour of muti is that the cost is lower than that of allopathic medicines. **Against it stands the risk of poisons, toxicity, counterfeits and chemical pollutants. If people aren't enlightened about the dangers of mixing a handful of leaves together, the results can be uncontrollable**". (Lee P, undated, Independent Online)*

Some 3000 plants are in use, 10 % in major use, and of which **the most toxic or those responsible for most of the serious poisonings and fatalities are not even featured or identified in these two publications, especially curious considering that they both have their genesis from within TRAMEDΦ, and against the claimed public safety interest**, much of which is hypocritically regurgitated by Folb in the first paragraph of his forward to the manual. **The authorities have no excuse to plead ignorance in defence of their callous inaction in the face of so much innocent human suffering and loss of life, since this is the primary responsibility of the Medicines Control Council, and the traditional African healers and sellers of herbal medicine are not directly to blame. The MCCΨ/MRA / DOH upper hierarchy bear legal responsibility, prior to and hereafter for every one of the many thousands of preventable deaths occurring from traditional medicine poisonings every year.** This author will not rest until this has been achieved.

In addition to **TRAMEDΦ**, is a **Traditional Medicines Research Group (TMRG)♣** which is a broader joint venture between the **Medical Research Council, the Department of Pharmacology at UCT and the School of Pharmacy of the University of the Western Cape**, which is **also engaged in ethnopiracy testing of plant extracts at UCT, according to Dan Ncavivana, Deputy Chancellor of UCT: "to isolate active compounds to develop new drugs."** (Electronic Mail & Guardian, 19 Oct 1997); *"The University of the Western Cape is testing plants for anti-tuberculosis properties"*. Dr Leng, chairperson of the Department of Pharmaceutical Chemistry says *"The plants we have selected for screening are ones already used by traditional healers."* (Diana Streak, Back to our roots, Fair Lady, Sept 1995); It is no surprise that the person who was preferred by the **MCCΨ** to take over as Chairman in June 1998 was **vice chairman, Professor P. Eagles, head of the UWC School of Pharmacy, who is currently expanding on Folb's ethnopiracy operation,** and has taken over his role as a major influence (vice chair) on the Council. **Eagles is also the influential chairperson of the NRC♣.**

The Traditional Medicines Research Group (**TMRG**)♣ was formed in 1997, after **PHARMAPACT** embarked on a concerted expose' of Folb's MCC regulatory double-standard in the light of his **piracy TramedΦ Project**, at which point center stage was shifted to UWC, with the strategic transfer of **Mayeng** to Eagle's School of Pharmacy. The promotional media propaganda borders on the obsequious, but reading between the lines again reveals the phoney social rhetoric and cheap window-dressing, behind which the blatant ethnopiracy still festers, eg: *"The **TMRG**♣ intends to glean information for the health benefit of all South Africans."* **The plot:** *"The group will use modern scientific and biomedical knowledge to investigate medicinal plant extracts and isolate bioactive compounds for developing more effective drugs."* (The Monday Paper, UCT, February 24, 1997); **The lie:** *"Researchers hope to collect information on Southern African medicinal plants and to use this knowledge to set safety standards regarding herbal remedies."* (Electronic Mail & Guardian, March 4, 1997)

"Traditional healers seek recognition and scientific verification of their remedies. We want to gain their trust. What we will not do is use their intellectual property to make profits which do not benefit them. (Mahlaba and Mayeng?) An important objective will be to create a comprehensive traditional medicines database for use by traditional healers, policy makers, drug regulatory authorities, the pharmaceutical industry and the public." (See the lie!) **"We are committed to making the database universally accessible."** (MRC Press Release, 6 February 1997) Both the author, as a representative of the Western Cape Traditional Healers and Herbalists Association, and his research associate, T Dr Anthony Rees, as chairman of the South African Herbalists Association, have been denied access to the database. **Dr Phillip Kubukeli, President of the Western Cape Traditional Healers and Herbalists Association** is recorded on a televised documentary (SABC, Options, 1998), as having never had access to the **TramedΦ** database to which he and his colleagues have so freely contributed.

Kubukeli has naively been collaborating with TramedΦ for years, handing over indigenous knowledge for an occasional hand-out and in the hope of recognition for the healer's work. Kubukeli has stated that he "support(s) the idea of published research, since some herbs can be a hazard, so researching them will make us more sure that our medicine is safe, and our medicine will be acknowledged by the government, but fear(s) that by exposing too much, healers will be made redundant." (Diana Streak, Back to our roots, Fair Lady, Sept 1995); Sadly the Tramed collaboration has contributed more to the latter aspect, yet the naivety persists: "In my collaboration, we are working closely with Pharmacology departments in the study of the safety of our traditional medicines." (Presentation to PHARMAPACT's Health Freedom SA Indaba, Knysna, June 1998)

It is not possible to reconcile the false promotional rhetoric with the unequivocal facts: **Professor Eagles:** "Our brief (National Drug Policy) was to investigate traditional medicines for toxicity, efficacy, safety and quality to incorporate them in the health care system, and be able to register and control them." It is quite clear that the MCC (TramedΦ via Folb, and now Eagles) and in particular in their "brief to establish a Complementary Medicines Committee (CMC), including all experts" for the aforementioned purpose have not succeeded, not in spite of, but because of the domination on this committee by the likes of Gericke, Mayeng and Mahlaba. Neither Mayeng, nor Mahlaba have true representative mandate by the majority of traditional healers, nor should they, because of their obvious financial vested interests be qualified for any policy or decision-making process, yet nevertheless both hold influential positions on the Traditional African Medicines Committee of the CMC and the Traditional Medicines Working Group of the National Reference Centre (NRC)♣, Dept of Health. Mayeng furthermore, since late 1998, is Senior Medicines Control Officer, Medicines Registration, and heads the transitional Complementary Medicines Section at MCCψ/MRA.

T/Dr Solomon Mahlaba manufactures and markets his own extensive range of "finished, labelled and marketed" traditional African medicines, branded "UMUTI AMANDLA", which is known to the MCCψ, this matter and that of traditional medicines manufactured by "Guideline Products" having been brought to the attention of the Registrar, Precious Matsoso and the Inspectorate. T/Dr Isaac Mayeng, in a recent book confirms his vested interest as follows: "I also have my own private herbal medicines production and supply business." Proof of his two-facedness is in his own words: "Some healers think that if they cooperate with the medicinal side, the government will pay them a salary. Well that can never happen. There needs to be (bank?) checks (cheques?) and balances. At the national level, the element of power and greed comes into play quickly." (Susan Schuster Campbell, "Called to Heal", Zebra Press, 1998)

Earlier self-prophetic truisms from Mayeng: "The companies are positioning themselves with the healers. These groups are interested in the markets the healer's represent, not necessarily the healers themselves. Traditional healers have become sceptical of sharing their information, experience and data. Some healers have found their work published in journals under the name of their medical colleagues. Many healers feel, and rightly so, that their work has been stolen. Whenever there is a natural plant growing freely which improves a given disease, the pharmaceutical and scientific industries will prevent this herb from being widely distributed. The rules of the game demand that the active ingredients be isolated, synthesised, then packaged in such a way to sell to a mass market at great cost for the very medicine that was given in nature." (Schuster Campbell, 1998) As Eagles has stated: "A stumbling block in moving forward is apprehension among traditional healers about the benefits." (Gustav Theil, "Harvesting the curing power of plants". Mail&Guardian, March 4, 1997)

Hypocritically in February 1998, Mayeng advised the Parliamentary Portfolio Committee on Health that "traditional medicine had to be regulated to ensure standardisation of herbal medicine, a code of conduct and ethics, the passing on of invaluable knowledge, and patenting" (Vuyo Mvoko, News, Business Day, 19 February, 1998), and in February 1999, Mayeng presented the fruits of this stolen heritage, the "TramedΦ Monographs" to the WHO in Geneva for the rest of the pharma-world to plunder, while South African consumer's are poisoned to death in their thousands for lack of toxicological information. Mayeng now heads the section of the MCCψ/MRA which aims to engage in both this and all the preceding activities he so hypocritically warned readers about in the preceding interview. (Susan Schuster Campbell, 1998); Mayeng was recently exposed as a fraud, when in response to a query whether the ICCØ had been informed of the pending 26 February meeting, he claimed that the traditional healer's were not interested, and that he had no contacts for them (a lie), only to pretend the next day to be taking the initiative in informing the ICCØ of a critical meeting.

*"Almost every African city, town and village has a thriving market for the tools of the (traditional) healer's trade. In 1978, a United Nations-sponsored conference called for governments to look at incorporating traditional medicines into national health plans for the poor. Almost two decades later, growing awareness of benefits from traditional knowledge has affected the **global pharmaceutical industry**. New realities and a global shift toward natural remedies are bringing increased attention. Sometimes the "cure" is worse than the ailment. Throughout Africa, health officials and healers cite accidental poisoning as the biggest problem with traditional remedies. Governments seek to register and regulate their medicines. "All those words for (healers) are wrong", said Folb, chairman of the South African Medicines Control Council. A history of failed deals and unkept promises make African healers wary of foreigners promising big money for their secrets. Obstacles abound in getting the herbal remedies out of the African bush. Western pharmaceutical companies seek to test every known healing plant." (Tom Cohen, nando.net, Associated Press, October 18, 1997)*

Traditional healers have accused the pharmaceutical industry of trying to muscle in on their lucrative natural herbal market. Witness Nigel Gericke: *"There has been a huge swing to natural remedies and the potential for (industry in?) this country is enormous."* Says **Roger Stewart**, new product development manager at **SA Druggists**, already involved in traditional herbal remedies and who are researching new product opportunities: *"We believe that all medicines of this nature should comply with WHO guidelines."* (Diane Streak, Fair Lady, September, 1995); **Pharmacare**, alias **South African Druggists**, was told by the Medicines Control Council (MCC) to stop making four cure-all herbal remedies sold as **"Healers Choice"** because of legislative constraints. The company refused. Meanwhile the MCC admits it has reached an impasse with SAD, which had failed to register the ingredients used in Healers Choice, as required by the national drug policy. *"The natural-remedy market is worth some \$16,5-billion world-wide and is growing at a phenomenal rate,"* says Rodney Hesketh-Mare, general manager of **Pharmacare**. *"Local healers do not have a monopoly on these remedies. It may be that some healers will feel threatened, but we are approaching the market from a different angle, complementary to what is sold on the streets."* (Angella Johnson, Electronic Mail&Guardian, May 11, 1998)

This did not satisfy Sipho Mndaweni, president of the **Interim Co-ordinating Committee of Traditional Practitioners in South Africa (ICC)** who complained that *"traditional healers and vendors may end up being squeezed out of the market"* and who insisted that *"South African Druggists is just testing the water before marketing more traditional medicines to be sold over the counter"*. Mndaweni says, *"We won't see a cent of the vast profits they will make, even though people will buy these goods thinking it's the same as what we do."* His committee has made submissions to Parliament for *"some control over the trademark 'traditional medicines' and to stop this kind of abuse."* (Angella Johnson, "Inyanga rage as drug groups muscle in!" Electronic Mail&Guardian, May 11, 1998); **PHARMAPACT** are in strategic alliance with the **ICC**, monitoring, recording and reporting developments to our best ability with the documentation at our disposal.

"In the last few months at least four pharmaceutical companies have visited the downtown Johannesburg offices of the Traditional Doctor's Association to ask for help in identifying plants that can be used to manufacture new drugs and medicines. This sudden interest in the pharmacopeia that South Africa's healer's have gathered over the centuries is part of a multi-billion dollar research drive by drug companies to learn the secrets of traditional healers around the world." (Eddie Koch, undated electronic Mail&Guardian article, "The allure of the traditional cure: Multinational pharmaceutical companies scrambling to tap wisdom") This is nothing new; the process having been started by the multinational companies, (including Noristan) some 20 years ago. (Safowora A, Medicinal Plants and Traditional Medicine in Africa, John Wiley & Sons, 1982)

Worst of all is that this ethnopiracy is happening in our own back yard, with State support via the Dept of Health and Medical Research Council. Witness the following report-back from one of these meetings and then an example of the rape of the traditional African medicine heritage by a consortium of most of the above-mentioned names and institutions, **spearheaded by the statutory Council for Scientific and Industrial Research (CSIR)**, headed by Dr M Horak, team-leader of the Database Working Group of the **Traditional Medicine Working Group of the NRC**, with the full co-operation of Eagles, Matsoso, Makhambene, de Wet and Mayeng, all of the **MCC**, Walters of the **MRC**, Bannenberg and Peteni of the **DoH**, and du Plooy of **Medunsa**, plus Mahlaba and others. **Nothing is being done about the tens of thousands of fatal poisonings and untold morbidities, fearing non-co-operation by healers on the "claims for cures" scam.**

TRADITIONAL MEDICINES WORKING GROUP: NATIONAL REFERENCE CENTRE

At the first meeting it was decided that *"Different rules and regulations would apply or be needed to address differences in the supply of traditional medicines to patients. 1) Traditional medicines commercially available (manufactured, and packaged to be sold in retail outlets); 2) Traditional medicines prepared by a healer for a specific patient on an individual name basis."* At the next meeting, *"the involvement of the MCCψ centred on claims of a cure for some conditions. The moment a plant is claimed to cure a disease it can be legislated as a medicine. Current definitions of safety and efficacy will be revisited. Safety and some efficacy have partially been addressed by the fact that it has been given to patients for years. The major difference is between the individual use of a product and the bulk distribution and sale thereof. Safety needs to be addressed if a product is sold in bulk."* (NRC♣ 4 June 1997); *"The MCCψ is concerned with medicines of plant origin being pre-packed and sold in shops and not with one-on-one treatment of a patient. It also concerns the issue of herbs being sold on the pavement in certain cities."* (NRC♣ 11 Sept 1997)

REPORT-BACK REGARDING THE LEGAL ISSUES WORKING GROUP OF THE NATIONAL REFERENCE CENTRE ♣ FOR TRADITIONAL MEDICINES, NATIONAL DRUGS POLICY, HALLMARK BUILDING, DEPARTMENT OF HEALTH, PRETORIA. 2 JUNE 1998. By Stuart Thomson.

(This report was prepared for PHARMAPACT, the Interim Co-ordinating Committee of Traditional Medical Practitioners of South Africa (ICC)Ø, and the Western Cape Traditional Healers and Herbalists Association)

The NRC♣ for Traditional Medicines is a facilitating initiative of the Department of Health, arising out of the National Drug Policy for South Africa. The stated aim is to *"investigate the use of effective and safe traditional medicines at primary level."* As per the WHO, *"traditional medicines will be investigated for efficacy, safety and quality with a view to incorporate their use in the health care system"*. Quite clearly, *the traditional healers are not central to the plan in the long term, only their medicines are of real interest.* Most revealing of all is the unequivocal statement that *"Marketed medicines will be registered and controlled"*. A further insight is obtained from the outline of the functions of the reference centre which these working group meetings are busy establishing and which will include: *"development of a national database of indigenous plants screened for efficacy and toxicity; testing for efficacy and toxicity."*

Who exactly is running the show? Certainly not the traditional healers, though there are a fair share of non-representative opportunists and naïve stooges providing the obligatory window dressing, including in this instance: T/Drs. Simon Mhlaba (Natal Nyanga's Assoc.), Seth Seroka (African National Healer's Assoc.), and Isaac Mayeng (Tramso - Trad Med Syst Org), Prof. Folb's stooge as strategic liaison person for the traditional healers. Significantly all are on the equally non-representative and non-democratic African Traditional Medicine Sub-Committee of the Complementary Medicines Committee of the MCCψ. This concentration of influence on both forums illustrates either the deliberate selective nature of the canvassing for participants, or lack of support by the majority. There are otherwise only a handful of collaborating traditional healer opportunists, all in all, in about 20% minority to the academics and others.

Having lined-up the window dressing, the reminder of non-traditional healer Europeans at the meeting ensured that the group-leader would be Dr. Nico Walters of the Medical Research Council♣, Cape Town (speciality: indigenous technology), who acknowledged to me prior to the meeting that he was part of Professor Folb's team (and one of the tiers in the Traditional Medicines Research Group (TMRG)♣, including Folb's UCT Pharmacology Dept. and Prof. Eagles UWC Pharmacy Dept.). The MRC♣ are closely involved with the WHO Collaborating Centres for Drug Policy and actively support the ethnopiracy operations of Professors Folb, Eagles and du Plooy by way of financial grants. The MRC♣ pride the TMRG♣ with *"using modern scientific and biomedical knowledge to investigate medicinal plant extracts and to isolate bioactive compounds for developing safer and more effective drugs"*.

Also prominently involved was the Council for Scientific and Industrial Research's (CSIR) Ø Dr. R. Marthinus Horak, who quite frustrated, informatively pointedly reminded all that *"the focus was not intended to be traditional healers, but rather traditional medicines"*. Dr. Horak is the Manager of the Chemical and Microbial Products (CMP) Programme of Foodtek at the CSIR Ø. *"The CMP Programme (in their own words) recently launched a major bioprospecting project that is aimed at investigating most of the 23,000 South African indigenous plants for pharmaceutically active compounds, which plant extracts are to be tested by the by the CMP Programme."* (Bulletin of the Pl. Pr. Res. Inst. Autumn 1998).

Seeing this hopeless trend following that of the selective CMC nominations debacle, I, for the record, formally protested that the proceedings constituted a sham of representativeness and democracy and a set-up favouring vested interests, since those accepting nomination to a steering committee to decide the fate of millions were not public representatives, nor did they have a mandate to represent all, or most traditional healers. The convening Chairperson, Lulu Peteni, Deputy Director, Essential Drugs Programme, ruled me out of order, claiming that the only mandate given this group by the earlier group meeting was to elect the steering committee and to establish terms of reference for the future work of that committee which would meet frequently and the present work group which would meet infrequently, the usual autocratic top-down approach.

I protested that none of the meetings were truly representative, or democratic, since they were not called by public notice. Peteni replied that the 1996 National Drug Policy publication represented public notice, which I protested was absurd and was left no alternative other than to withdraw from the unconstitutional proceedings and merely observe. Before the close of the meeting, I protested the fact that the toxicity issues were being ignored, and requesting that my written submission be officially entered into the record and next agenda, to which I was advised that I should take up my objections with the Dept. of Health and that since my submission did not bear a signature, (just my name), it did not constitute a legal document.

Similar objections were recorded in the minutes of the June 97 Reference Centre meeting. At the recent meeting, members of Chief Gcaleka's group in particular, expressed concerns that their ancestor's gifts would be exploited, if not suppressed by the medical institutions, and T/Dr. Simon Mhalaba expressed his wariness of the database. Mayeng, Folb and Eagle's main collaborator, who has unique proprietary access, simply dismisses these issues with unsubstantiated assurances that "all the healer's fears will be taken care of". Most of the healers are naïve as to the money driven ruthlessness of the academic and pharmaceutical interests which are herding them and their ancestral wisdom and knowledge into a system established to prostitute these and expropriate their collective 2 billion Rand crude market in indigenous herbs.

The plan is clearly not to serve the healer, contrary to common belief. The minutes of the initial meeting state that "the Centre will concern itself with the study of plants with medicinal properties" and that "other issues concerning traditional healers do not fall within the mission of the Centre". It is generally not appreciated that these initiatives were conceived and instigated by the old regime in precisely the way which would cause the least suspicion, and were strategically implemented at the time of political transition, so that when the process started, it would appear to be a trustworthy initiative of the people's government.

The aim for the traditional healers is to have them willingly part with their knowledge, previously via "database collaboration", and now via the new trap of "registering claims for cures". There is nebulous talk of protecting intellectual property rights, non-disclosure documents, and contracts to deal with claims, but these are rendered clearer by the necessary talk of "financial incentives for drug leads given to companies", "contracts between companies and healers" and "claims at universities to constitute claims". Peteni revealed that "the function of the Centre was to acquire good quality information and to act as a clearing-house, leaving the rest up to the institutions". Besides the MCC, MRC and CSIR, virtually every university has representation, usually their pharmacology and / or pharmacy departments.

The further aim is to expropriate and pharmaceuticalise the local market and exploit the active principles internationally via patented synthesised derivatives, with little or no return for the African people. The June 97 minutes acknowledges that "traditional medicines are of economic importance and are seen as an important source of drug leads for pharmaceutical companies". The key to understanding the take-over is contained in statements such as "only widely accepted plants will be accepted into the formulary", "safety needs to be addressed if a product is sold in bulk", "once the chemical research is done, new intellectual property rights can be registered", "discoveries need to be patented to ensure that the discoverer benefits from further development by pharmaceutical companies", and "patenting is a costly process". These issues raise the hurdles to the extent that only pharmaceutical interests with their resources and not the healers / vendors can legally participate in prospering from their ancestral legacy.

Also from the minutes of the Traditional Medicines Working Group is a direct reference to vested interests: "The centre will not only encompass the MCC but other organisations like the CSIR and MRC will be included as partners. The CSIR is currently in a consortium with other institutes, busy with "bioprospecting". In 10 years the group wants to scrutinise 80% of indigenous medicinal plants. There was a concern that the CSIR has a financial interest and could take over the market. The CSIR is a national research institute, owned by the government and is as such not profit orientated." (NRC 11 September, 1997)

Let us briefly investigate this totally fraudulent concept and claim of "non-profit bioprospecting". The CSIR's Bioprospecting project aims to "investigate most of SA's indigenous plants for commercially valuable properties. We will strive to add value to indigenous knowledge through scientific investigation of eg traditional medicines derived from plants, in close collaboration with traditional healers, legal advisors and policy-makers, to develop equitable collaboration, subject to agreements which define confidentiality, intellectual property rights and reciprocity". Please bear in mind that traditional ancestral knowledge belongs to no one individual or group of individuals, but to whole communities! To claim such information for oneself and sell it is clearly theft and fraud and should be punishable by both civil and traditional court. Legitimately only a unanimous community can make such a decision. Foodtek, the CSIR department where the Bioprospecting project is resident, claims that "throughout this process, we will ensure the equitable sharing of benefits between all parties involved, the intellectual property of participants, in particular sharers of indigenous knowledge, is respected and safeguarded". (Foodtek Homepage 1998) Clearly however, if the true owner's are not participants, the thief (healer) is not only paid for stolen property, but has their identity and knowledge of their crime safeguarded by the receiving accomplice (CSIR).

Claims to "take account of the rights and interests of indigenous peoples and provide partnerships which will permit communities to benefit from their indigenous knowledge" (Foodtek Homepage 1998), are clearly just false public relations rhetoric, being as they are, irreconcilable with the facts, eg: "The discovery, development, world-wide patenting and licensing of an appetite suppressant derived from an indigenous plant by Horak and his colleagues at CSIR-Foodtek gave impetus to the establishment of the Bioprospecting consortium. The product is to be commercialised as a prescription medicine. A licensing agreement for development and commercialisation has been signed between the CSIR and the UK-based company, **Phytopharm**. Pfizer, is funding the construction of a FDA-approved clinical supplies unit at CSIR for the manufacture of P57, to be used in clinical trials". ("Bioprospecting breakthrough", Pharmaceutical & Cosmetic Review – Nov/Dec 1998)

"Under the agreement, Pfizer has acquired an exclusive world-wide licence to develop and market P57. Phytopharm will receive up to 32 million Dollars in license fees and milestone payments based upon the achievement of specific objectives. In addition, Pfizer will make at least 7 million Dollars in contributions in an early development programme to be carried out by Phytopharm, who will also receive royalties on sales of P57 by Pfizer. Financial Advisors: NM Rothchilds & Sons Ltd." (Press release, Phytopharm Homepage, Aug 1998); "The company did not name the plant to protect "its" intellectual property. Financial terms of the deal with the CSIR were also not disclosed". (Cape Times, Business Times, 24 Jun 1997); "CSIR scientists refused to divulge the species of the miracle indigenous plant code-named P57. American drug company Pfizer bought exclusive rights to market P57 in an estimated R 240 million deal". (A Baleta, Sunday Argus 3/4 Oct 1998); "Neither company was prepared to name the herb, which has been dubbed P57. Stuart Thomson: These companies come here, flash their money around, and for a few measly bucks, convince traditional healers to hand over ancestral knowledge." (L Taitz, "SA flower power for Viagra giant: Accusations of 'ethno-piracy' as Northern Cape plant is targeted for use in weight-loss drug", Sunday Times, Aug 1998)

This herb, **ghaap** (Asclepiadaceae) has for centuries been used by the African, Bushman, Hottentot, Nama, settler and colonist for diverse medicinal purposes, and for the assuage of both hunger and thirst. Horak claims that "When we deal with the custodians of this information we see them as peers and we respect their knowledge." Note the double-speak as Horak cannot resist grabbing all the glory for himself, when he goes on to state: "In South Africa you are at the top of your field in science when you publish 25 journal articles and a few books. In Europe the top scientists have frames on the wall with the drugs 'they' discovered behind glass. That's what I am looking forward to." (Laurice Taitz, Sunday Times, 2 May 1999) People such as this, including those mentioned in industry, academia and the government are plagiarists, frauds and thieves.

"The **Bioprospecting Programme** is supported by the activities of a South African based consortium. The Programme is managed by CSIR-Foodtek under its Chemical and Microbial Products Programme (CMP), which Dr Marthinus **Horak** heads up. Consortium members currently include the **Medical Research Council**, National Botanical Institute, Agricultural Research Council, and the universities of Cape Town (Folb), The North and Western Cape (Eagles), in collaboration with government departments and policy makers." This is, given the foregoing evidence, clearly a case of State genocide and ethnopiracy against the African people.

Let us examine the State's mandate regarding health, from their principal official guidance documents:

While *"Act 101/1965 provides for the establishment of a The Medicines Control Council for the control of medicines"* (Medicines and Related Substances Control Act No.101 of 1965), the specifics are internationally established as *"The Council is mandated to serve the public interest in the regulation and control of the quality, safety and efficacy of medicines. 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 Pharmacol, 1988 Sep; 28(9)); *"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))

The ruling African National Congress party's National Health Plan states as follows: *"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, ethnic, tribal and gender 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 and efficacy and potential benefit of traditional drugs. A regulatory body for traditional medicine will be established."* (A National Health Plan for South Africa, African National Congress, Johannesburg, May 1994)

The National Drug Policy for South Africa has as it's stated *"Health Objectives: To ensure the safety, efficacy and quality of drugs; ensure good dispensing and prescribing practices; promote the rational use of drugs by prescribers, dispensers and patients through the provision of the necessary training, education and information; promote individual responsibility for health, preventive care and informed decision making. Legislation & Regulations: To ensure that drugs reaching patients are safe, effective and meet approved standards and specifications. Only drugs, which are registered in South Africa, may be imported, produced, stored, exported and sold. 'Marketed' traditional medicines will be investigated for safety and quality. 'Marketed' traditional medicines will be registered and controlled. Rational use of Drugs: To promote rational prescribing, dispensing and use of drugs by personnel and to support the informed and appropriate use of drugs by the community."* (National Drug Policy for South Africa, Department of Health, January 1996) Oxford Dictionary definition of the word "market": n. Be offered for sale; v. Buy or sell in market; v.t. Sell (goods) in market or elsewhere. (The Concise Oxford Dictionary, Oxford University Press, 6th Edn 1975)

"The National Drug Policy (NDP) is the South African Government's plan for the rational and economic use of drugs in the country." (National Drug Policy for South Africa 1996) *The South African Drug Action Programme (SADAP) was envisaged to ensure the implementation of the NDP, (including) major changes to legislation such as to the Medicines and Related Substances Control Act. (Summers R, Suleman F. Drug Policy and Pharmaceuticals, in South African Health Review 1996, HST, HJKFF 1996); "The NDP aims to promote rational prescribing, dispensing and use of drugs by all health workers and the public. Emphasis is on education, training, and the provision of drug information and appropriate prescribing and dispensing. Dr W Bannenberg was appointed SADAP Director from 1997. The WHO Collaborating Centre on Drug Policy, Information and Safety Monitoring at the UCT (Department of Pharmacology) and UWC (School of Pharmacy) run courses promoting Rational Drug Use."* (Gray A, Eagles P, CH 10, "Drug Policy", in The South African Health Review 1997, Health Systems Trust and the Henry J Kaiser Family Foundation, 1997)

Professors Folb and Eagles who are the most informed and influential scientists and policy makers as far as medicines regulation and the toxicity of traditional African medicines are concerned of course run these departments. Educational courses for traditional healers? No way. They are not interested in the thousands of annual deaths and morbidities from medicines under their jurisdiction, they are more focussed on the academic prestige and millions of Rands to be made from ethnopirated traditional African medicinal substances for the patent and synthesis of mass-market First World drugs.

The **Medicines Regulatory Review**, rather than strengthening the public safety mandate in it's recommended overhaul of the regulatory system, actually furthers the erosion of the above-mentioned lofty, albeit never realised mandate of "public interest", by not stating strongly enough the problem of traditional African medicines toxicity, in spite of its recognition that ***"South Africa is faced with many purely national issues, including the massive challenge of African traditional drugs."*** (The Medicines Regulatory System in South Africa: Review and proposals for reform. Dept of Health, 24 March 1998); This report was prepared by Prof Dukes and Dr Hill from Norway and Australia, from whence the Listing System originated and mutated to an electronic form, and from whence it was exported to South Africa, in spite of it being hopelessly inadequate to address the traditional African medicines toxicity crisis which we strongly brought to the attention of the team, which once again included Summers and Bannenberg, as well as the Director-General, Health, Dr Ntsaluba.

Significantly, the Review never recommended that only ***"marketed"*** medicines be regulated, but it appears that this rather weakly stated aspect has been deliberately capitalised on by the **Medicines Regulatory Authority Transformation Task Team** who, too timid to exercise bold responsibility, **continue to promote the culturally and demographically inappropriate Listing System**, and which team included, not surprisingly, Summers and Eagles, but also Rees, Matsoso and Makhambene. (Report of the Medicines Regulatory Authority Transformation Task Team, 17 July / 23 September 1998); The **SAMMDRA** Act also **makes no distinction on the basis of the concept of only *"marketed"* medicines being subject to regulation** (RSA. South African Medicines and Medical Devices Regulatory Authority Bill, B 114-98), so the distinction appears to be merely a cop-out by the regulatory authorities to avoid having to handle this political hot potato.

Consider the conclusions reached in the recent paper titled ***"The toxicology of African herbal medicines": "There is a need to explode the myth that all of these are safe. In South Africa there exists a window of opportunity for a serious examination and publication of the facts concerning the risks of using traditional herbal remedies. In addition, there needs to be a coming together of those interested in the toxic, as opposed to the beneficial aspects of traditional medicines."*** (Stewart M et al, Ther Drug Monit, 1998, Oct, 20(5)) Whilst PHARMAPACT have clearly taken the initiative regarding the former aspects, it is now up to the State to facilitate the remaining obligations of this recommendation, heretofore so shamefully neglected.

With some 10-20000 annual preventable deaths from traditional African medicines in South Africa, why have these often ***"fatally poisonous medicines"*** not been given toxicological precautionaries at every opportunity and ***"called-up"*** to protect consumers? # Many of these substances cross our borders from as far afield as Mozambique, Malawi, Swaziland and Tanzania, so why are the MCCψ/MRA not similarly instructing the Customs officials to embargo these medicinal drugs at point of entry as with the relatively innocuous international health substances? # Why are MCCψ/ MRA inspectors not exercising their functions within the arena of the traditional African healers, herbal / muti shops and markets? # ***Toxic medicines used by other practitioners, even individually, are scheduled and/or registerable. Why should SAMMDRA complementary regulations exempt and perpetuate the biggest killer category of all?***

Are our African citizens not entitled to equal protection under SAMMDRA, or is genocide via deliberate inaction still alive and well through a sinister apartheid era plot to allow the poisoning of the unsuspecting African traditionalist, awkwardly exposed but allegiance to pharmaceutical ideology still taking preference over the mandate of ***"health for all"***?

The bottom line is that for the Expedited Registration Procedure (Listing System) or any other regulatory policy to be implemented, it will have to include the African traditional medicines, or face constitutional challenges, criminal charges and civil action against the enforcing authority, in addition to charges of genocide. If on the other hand, the African traditionalists are forced into such an oppressive system, it would involve the expropriation of a 2 billion Rand market from thousands of people who have traditionally earned their sustenance this way, severely restrict free public access to and escalate the cost of these substances to the very people who rely on them most and who the authorities purport to serve. A bold, equitable alternative to the industry-driven monopolistic Listing System is an urgent imperative. PHARMAPACT's proposals equitably satisfy the most pragmatic quality, safety and efficacy criteria.

The following are the most introductory articles of the:

Convention on the Prevention and Punishment of the Crime of Genocide

Adopted by Resolution 260 (III) A of the United Nations General Assembly on 9 December 1948.

Genocide is a crime under international law, contrary to the spirit and aims of the United Nations and condemned by the civilised world; At all periods of history genocide has inflicted great losses on humanity; In order to liberate mankind from such an odious scourge, international co-operation is required.

Article 1

Genocide, whether committed in time of peace or in time of war, is a crime under international law, which we undertake to prevent and to punish.

Article 2

Genocide means any of the following acts committed with intent to destroy, in whole or in part, a national, ethnical, racial or religious group, as such:

- (a) **Killing members of the group;**
- (b) **Causing serious bodily or mental harm to members of the group;**
- (c) **Deliberately inflicting on the group conditions of life calculated to bring about its physical destruction in whole or in part;**
- (d) **Imposing measures intended to prevent births within the group;**

Article 3

The following acts shall be punishable:

- (a) **Genocide;**
- (b) **Conspiracy to commit genocide;**
- (c) **Direct and public incitement to commit genocide;**
- (d) **Attempt to commit genocide;**
- (e) **Complicity in genocide.**

Article 4

Persons committing genocide or any of the other acts enumerated in Article 3 shall be punished, whether they are constitutionally responsible rulers, public officials or private individuals.



This report has been researched and prepared by:

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Appendix

CULTURAL NOTES CENTRAL TO THE AFRICAN CONCEPT OF TRADITIONAL HEALING

*"In **Bantu "Theory of Causation"**- ie their entire body of ideas on the causes of illness, death, and adversity; the spirits of the departed, the ancestors, hold a prominent and central place, the supreme arbiters of good and evil. The Bantu peoples therefore do not worry about physical disease, however painful, but are deeply concerned about its origin. Their treatment, ie the rituals, traditional practices and ceremonials are mainly directed towards the reconciliation with the ancestors and towards neutralising the magical and malevolent influences which have caused the illness. Their use of **herbal remedies** is based on the same premise, of disposing of the evil at work in the body of the afflicted person, which is the cause of the trouble."*

*"The term **witchdoctor** means the doctor who **renders witches harmless**, not the doctor who is a witch. The **isangoma** is thus the **exposer of evil and the diviner of causes**. The **second influence used against evil is the inyanga or herbalist**. He does not traditionally divine the source of evil, but treats it with herbs and various rituals and ceremonies. In the setting of these belief-systems, Western medicine is merely the painkiller, the analgesic as it were. The untutored person cannot conceive that the body is subject to disease processes which can progress unbeknown to them. It is not only the untutored among the Bantu who hold these views, the half-educated and even some educated people are often influenced by their age-old beliefs." (Walker M, in Aspects of Community Health in South Africa, Searle C, Ed. The South African Nursing Association, 1973)*

*"Africans believe that certain of their illnesses can only be cured by their own inyanga, that it is useless to go to the hospital if a person has contracted one of these. About half of the illnesses diagnosed by the inyanga today are attributed to witchcraft. The inyanga gives medicine to protect the patient and the family from a person's evil intentions. It is believed that the inyanga can prevent almost any adversity in life. Since they do not relate disease to organs, they cannot understand, recognise or treat disease by scientific observations. Thus **treatment is mystical and herbs are prescribed haphazardly.**" (Geland M, "An African Culture in relation to Medicine", in Mankind and Medicine in the Third Millennium, Tygerberg Hosp/Univ Stellenbosch, Sept 1976)*

There are two principal types of Zulu Traditional practitioners. The **Isangoma**, usually female is a diviner and is said to be chosen by her ancestors who bestow upon her a clairvoyant diagnostic powers. The "doctor" or **Inyanga** is usually male and has a comprehensive knowledge of Zulu medicines, usually passed from father to son. The medicines employed are often ground from a variety of leaves, barks, stems, bulbs, fruits, flowers, seeds and parts of animals. They may be given as purgatives, enemas, rubbed into the skin, breathed in, administered via small cuts in the skin etc. Traditionally in cases of diarrhoea, for example, purgatives were given in the belief that it was essential to clean out the cause of diarrhoea from the system.

The pharmacopoeia is extensive and contains powerful chemical substances with both potentially useful as well as toxic properties. In addition to the pharmacological properties, it is also believed that the colour of a medicine is related to its power, which therefore act at a metaphysical as well as a physical level. Treatment modalities, however, are not restricted to the use of medicines. The support and advice of protective ancestors can be elicited through adherence to complex rituals including animal slaughter. Scarification is a common treatment, analogous to immunization. (Friedman I, Healthlink, Issue No. 37, October 1998)

-----End of Cultural Notes-----

Postscript

A colour-coded word and symbol MS Word copy of this report is electronically available on request from gaia.research@pixie.co.za. Please specify the precise file type required. Comments are elicited for corrections and or additions to the final report, the publication form/fate of which will be determined by the reader's feedback and finally the MRA's committed response or absence thereof hereto. This pre-publication report, dated May 1999 comprises 23 pages (15,508 words) exclusive of covering documentation and postscript. Circulation of this edition has been limited to staff, the Chairperson and Councillors of the MRA, the ICC and PHARMAPACT reps.



The WHO Collaborating Centre for Drug Policy was established in the Department of Pharmacology during 1996, jointly with the School of Pharmacy at the University of the Western Cape.

The activities of the WHO Collaborating Centre for Drug Policy are to:

- monitor all adverse reactions to medicines in South Africa, investigate national problems of drug toxicity, and recommend policy in this regard;
- provide medicines information to all levels of health professionals in the country, thus encouraging the rational, safe and cost-effective use of medicines, including traditional medicines;
- provide a national medicines formulary for students, doctors, nurses, dentists, veterinarians and community health workers to promote the WHO concept of essential medicines which are simple, effective, good quality, affordable, and required for prevention and treatment of common conditions in the country;
- monitor the way in which medicines are used nationally and internationally, and develop policy based upon these trends, with special attention to the costs of medicines;
- develop a primary health care manual for 'traditional healers' in conjunction with the healers and with persons trained in botany, toxicology and medicine, and to organise a data base of more than 60 000 reported accounts of traditional medicines and their effects that are already available in the WHO Centre;
- collaborate with international health agencies in the education and training of pharmaceutical support personnel in developing countries;
- provide graduate programmes in chemical and pharmaceutical analysis of herbal medicines, and in screening activity. (Ethnopharmacy)



"I think you've crossed the line from seasoning to herbal medicine."



Traditional medicines being sold at a market in the Durban area.