THE TRADITIONAL & NATURAL HEALTH ALLIANCE

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**2nd PRESENTATION TO THE PARLIAMENTARY
PORTFOLIO COMMITTEE ON HEALTH**

IN REALATION TO PUBLIC HEARINGS ON THE

THE MEDICINES AND RELATED SUBSTANCES AMMENDMENT BILL (Bill 6 of 2014)

25th February 2015

**TNHA PRESENTERS**

**
Dr. Bernard Brom**Chairman: TNHA

**
Anthony Rees**
Secretary General: TNHA

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**Phephsile Maseko**Executive Committee Member: TNHA

\* Slide presentations of presenters are available on request.

**The Traditional & Natural Health Alliance**PostNet Suite 141
Private Bag X1
Vlaeberg
8018
Rep. of South Africa

Tel: 072 3777598 / 021 789 2682
Email: contact@naturalhealthalliance.co.za

**GLOSSARY OF ABBREVIATED TERMS**

* **ADRs** Adverse Drug Reactions
* **AHPCSA** Allied Health Professions Council of South Africa
* **ATM** African Traditional Medicine
* **ATMs** African Traditional Medicines
* **CAMs** Complementary & Alternative Medicines (interchangeable with ‘Natural Health Products’)
* **ELS**  Electronic Listing System
* **GMP** Good Manufacturing Practice
* **NDoH** National Department of Health
* **NHPs** Natural Health Products (interchangeable with ‘Complementary Medicines’)
* **MCC** Medicines Control Council
* **PICS GMP** Pharmaceutical Inspection Co-operation Scheme : Good Manufacturing Practice
* **PPC** Parliamentary Portfolio Committee on Health
* **SAHPRA** South African Health Products Regulatory Authority
* **THO** Traditional Healers Organization
* **THPICSA** Traditional Health Practitioners Interim Council of South Africa
* **TNHA** The Traditional & Natural Health Alliance
* **TNHPs** Traditional & Natural Health Products
* **WHO** World Health Organization

**The Separation of Health Paradigms**

**Creating an appropriate framework for both the Biomedical and Traditional & Natural Health Products sectors to co-exist**

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**Presented by: Dr Bernard Brom**

**PORTFOLIO COMMITTEE PRESENTATION**

PROBLEM 1:

**TWO FUNDAMENTALLY DIFFERENT PARADIGMS OF HEALTH CARE CANNOT BE REGULATED BY ONLY ONE PARADIGM**

**Definition of paradigms: Models of medicine with their own basic philosophy and understanding of health, ill health and disease.**

**PARADIGM ONE**

The **Biomedical Paradigm,** also known as the conventional medical paradigm (allopathic) is currently the dominant model of medicine in South Africa. It derives its power from “science” and the ability to diagnose disease.

It is heavily reliant on synthetic, chemical drugs and surgery to treat pre-defined disease labels.

Health ---------------------------- 🡪 disease

**PARADIGM TWO**

This paradigm has many names including Integrative Medicine , Traditional Medicine, Functional Medicine and Natural Medicine.

They are connected by a common thread that runs through them:

* Their focus is not on treating disease labels, but on the person who is ill.
* Their focus is also placed on healthy people, and not just the sick. (Preventative Medicine)
* Their focus is not on the disease but on supporting the system’s own innate self-regulating (homeostatic) system and it's healing potential.
* There is the understanding that ill-health, and especially chronic disease, arises when the body’s own innate intelligence weakens, and that by strengthening this weakness the body’s healing system can then heal. Synthetic drugs are generally not required for this, but natural remedies, which can support these healing processes, are.
* This paradigm also recognizes that all illnesses have an underlying cause, which in theory is well known. These causes include nutritional and phytonutrient deficiencies, inappropriate lifestyles, emotional stress and psycho-spiritual imbalance.

**Biomedicine: focus on disease and using drugs and surgery**

**Health------------------------ 🡪 disease**

**Uses powerful drugs and surgery to treat the disease.**

**Integrative & Traditional and Natural Health Products: focus on supporting health using natural approaches.**

**Health--------🡪 dysfunction ------------- 🡪 increasing dysfunction -------- 🡪 disease**

**This paradigm returns ill-health to health. Only health can heal.**

**Uses natural products to help body return to health.**

Drugs invariably block particular biochemical or metabolic pathways in the body in order to treat symptoms. This interference with normal metabolism and biochemistry contributes to the high risk and commonality of serious adverse events associated with pharmaceutical medicine. Drug poisoning (Adverse Drug Reactions) is the 3rd or 4th most common cause of ill health .

In the USA 16 000 deaths are recorded every year from one group of drugs - the anti-inflammatory drugs and 100 000 people end up in American hospitals from bleeding ulcers.

Natural Health Products do not block or interfere with function, but support the innate intelligence of the body to heal, and therefore work differently: less powerful by comparison (don’t need power), supportive in their role, have mild to moderate side effects, if any, and rarely cause death..

**MORE PEOPLE DIE FROM LIGHTNING STRIKES THAN NATURAL REMEDIES!**

There is such a vast gap regarding toxicity (risk) between drugs and natural medicines that they should not fall under the same regulatory process.

Why would any authority want to place green tea, in its leaf form, or encapsulated and placed in a bottle with claims of being an antioxidant, in the same category as aspirin or paracetamol (Panado) ? It surely has much more in common with a a cup of black or rooibos tea than it does with paracetamol? The latter drug is the most common cause of liver transplants in children.

Why would any authority want to ban an extract from the Milk Thistle herb (Silybum marianum), containing the phytonutrient ‘sylimarin’, one of the most popular herbal extracts for liver support and used by millions of people around the world, with absolutely no adverse risks to health when used in accordance with traditional recommendations (200-600 mg/day silymarin)?

By contrast, dangerous drugs like sleeping pills, which kill people and cause serious addiction and long-term problems, are prescribed with just a warning on the label or patient information leaflet.

Clearly there is something seriously wrong in the way natural products are regulated. There is a major bias against natural products, and the regulators involved in drawing up the regulations do not have the best interests of the public’s health in mind, or understand these remedies *at all.*

As a medical doctor who has used both pharmaceutical drugs and natural health products for decades, I am aghast at the manner in which our MCC is trying to influence the way these substances and products are regulated. It is unfair, unwise and unconstitutional.

Why would any government want to place one group of experts in control of remedies that they have no knowledge of how to use, have never used and are clearly biased in their decisions?

I would challenge any of these regulators to demonstrate to me how they would manage a serious chronic disease in an Integrative way without the use of drugs.

I have practiced for 35 years and regard myself as one of South Africa’s foremost experts in the non-drug treatment of ill health.



**THE REMEDY**

**A separate regulatory body, which separates Biomedical, Pharmaceutical Drugs and Traditional & Natural Health Products, is required in South Africa.**

The MCC’s Complementary Medicines Committee (CMC), of which I was a member, continues to have little control over the substances under it’s mandate. In the past it was nothing more than an advisory group to the MCC, with no power. We believe little has changed in this regard.

We need a new Directorate with members who represent all traditional and natural medicines that are available in South Africa. This should include members from the Traditional African Medicine, Integrative and Natural Health Product sectors.

We accept the principle of Good Manufacture Practice (GMP), but the level of GMP must be proportionate to the product type in question. For most natural health products, the relevant level would be food grade, as opposed to pharmaceutical grade GMP.

Traditional and Natural Health Products are generally regarded as safe as a whole, and should not be required to extraneously prove safety. Accordingly the ‘presumption of safety’ principle is key and should be used in the main, to avoid placing the burden for proof of safety on manufacturers prior to products being placed on the market. This represents an unfair and unconstitutional burden for produces that have been long been consumed by the South African population with no significant evidence of harm.

In many other countries, the onus is on the regulators to prove that these products are unsafe, based on reports or good science and a good pharmacovigilance programme.

The present regulatory process which started in November 2013 is too expensive, unnecessarily difficult and complex and therefore acts as a barrier for the vast majority of small- to medium-sized manufacturers and suppliers of for Natural Health Products.

A simple **Electronic Listing System (ELS),** as has been suggested in the past, can easily be used by both manufacturers and the regulator and can be setup within months at minimal cost, in comparison to the slow paper-based system currently in place.

Mr Peter Kreft, who was instrumental in setting-up and developing an Electronic Listing System in the past, which was accepted by the MCC (but never implemented) says the system will cost about R140,000 to set up, requires minimal personnel to administer, and allows for a rapid registration process.

Similar systems are successfully implemented in Australia and Canada.

Why is South Africa, with its budgetary constraints, choosing an extremely expensive and over-stringent regulatory process for Natural Health Products, which have been used in this country for many years without any serious reports of toxicity or risk? Especially when there are good studies and acceptance of these products in many countries in the world.

The Australian Therapeutic Goods Administration (TGA) has a two-tier system for the regulation of medicines, including what they call complementary medicines. This is a risk-based approach: Within the Australian regulatory framework, medicines are classified as either **registered drugs** or **listed products.**

* Higher-risk medicines must be registered on the Australian Register of therapeutic goods (ARTG), which involves individually evaluating the quality, safety and effectiveness of the product.
* Lower-risk medicines containing pre-approved, low risk ingredients and that make limited claims can be listed on the ARTG.

**Registered medicines** (high risk) are assessed by the TGA for quality, safety and efficacy.

* All prescription medicines are registered
* Most over-the-counter medicines are registered
* Some complementary medicines are registered

**Listed medicines** (low risk)are assessed by the TGA for quality and safety but not efficacy

* Some OTC medicines are listed
* Most complementary medicines are listed

Some complementary medicines are exempt from the requirements to be included on the ARTG, such as certain preparations of homeopathic medicines.

**Australian Government Definition of a Complementary Medicine:**

*“Medicinal products containing such ingredients as herbs, vitamins, minerals, nutritional supplements, homeopathic and certain aromatherapy preparations are referred to as ‘complementary’ under the Therapeutic Goods Act 1989”*

A complementary medicine is defined in the Therapeutic Goods Regulations of 1990, as a therapeutic good consisting principally of one or more designated active ingredients mentioned in Schedule 14 of the regulations, each of which has a clearly established identity and traditional use:

Adverse Events to Natural Health Products

The TGA has a strong pharmaco-vigilance programme, which involves the assessment of adverse events that are reported to the TGA by consumers, health professionals, the pharmaceutical industry, international medicines regulators or by the medical and scientific experts on TGA advisory committees.

**Innovative Natural Products**

Innovative natural products are modern innovative combinations of natural herbs, vitamins, minerals and other nutrients recognized to be important in supporting healthy functions. They are of special interest to doctors of Integrative Medicine who specialise in supporting health rather than treating disease.

In terms of the present regulations and guidelines these products will be erroneously classified as ‘Category A’ pharmaceutical drugs and not ‘Category D’ complementary medicines.

Most Traditional and Natural Health Products (TNHPs) cannot be patented because they use natural ingredients and most have large, high power, randomised controlled (double-blind) studies to support traditional and empirical health claims.

What they do have is many years use by thousands of Integrative doctors and traditional and natural health practitioners around the world, along with use by hundreds of thousands of patients over decades. Small clinical (human) studies have often been carried out for many natural health ingredients and traditional formulations and may be found via itnernational databases such as Natural Medicines (naturalmedicines.therapeuticresearch.com).

Under the new regulatory system, innovative natural health products are required to have similar registration to pharmaceutical drugs, despite the fact that the absence of any significant harmfulness toxicity for the the vast majority of them.

Most non-indigenous products associated with integrative or functional medicine have GRAS (Generally Recognised As Safe) status as dietary supplements in the USA and have long and safe histories of use in the USa, EU, Australia and Canada.

On the opposite side of the spectrum of risk, many conventional pharmaceutical drugs have known to be toxicity and risks, simply treat symptoms of disease, rather than the cause, and are still registered for patient use following their approval based on a subjective weighing of risks and benefits by regulatory authorities.

Innovative natural products, at recommended dose ranges, have long histories of safe use, with abundant scientific evidence of intended function to support homeostatic mechanisms in the body, therefore they should not be required to go through the same requirement for proof of safety and efficacy as required for pharmaceutical drugs.

**AFRICAN TRADITIONAL MEDICINES**

African Traditional Medicines should be controlled by an separate committee, made up of registered African Traditional Practitioners and other experts in the field of African Traditional Medicine, and not only by academics (who are by and large pharmacologists) with little experience of these herbs in a clinical setting.

Both experience and science needs to have a voice in this process of registration.

More Detail

Each country has its own specific subset of traditional medicines that have been used for thousands of years. Many of these herbs require specific preparation and use, and used I accordance with these traditional practices, traditional medicines have a spectacular history of safe use. A very small number of instances of harm from ‘traditional medicines’ has generally been the result of misuse of the traditional medicines or failure to follow traditional preparation or dispensing requirements.

Most modern pharmaceutical drugs have been used for less than 100 years (many far shorter than that), and yet within this time period the toxic effects have become obvious. It sometimes takes between 10 to 20 years for any serious toxic effect to become attributed to these drugs, and for the regulator to recall them .

The toxic African (and other traditional) herbs are generally well known to practitioners and are not used, or used carefully by experts with experience.

Traditional Health Practitioners should be allowed to use the same criteria that other medical doctors use in deciding about their herbs, i.e. risk vs benefit. The risk for most herbal products is extremely small. The risks associated with drugs, even among the least toxic categories, are much higher than the majority of indigenous plant medicines used today. This of course also applies to all Natural Health Products.

Drug Toxicity Examples

*Panado,* for example, is the most common cause of liver failure in children.

*Aspirin: "The FDA has concluded that data does not support the use of aspirin as a preventive medication by people who have not had a heart attack, stroke or cardiovascular problems, a use that is called 'primary prevention.' In such people, the benefit has not been established, but risks — such as dangerous bleeding into the brain or stomach — are still present."* [FDA Consumer Update May 5, 2014](http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm390539.htm)

*Vioxx* caused 27 785 deaths before being pulled off the market.

The diabetic drug *Avandia,* a $3 billion-a-year blockbuster drug, has been linked to a 43% increase in heart attacks compared with other medication or placebo (New England Journal of Medicine). According to FDA whistle-blower Dr David Graham, Avandia has caused 47 000 diabetics to suffer heart failure, strokes or death. It remains on the market with an increased warning only, which doctors don’t talk about and most patients are not even aware of.

Use of *Benzodiazepines* (sedatives and tranquilizers) for just 3 months or more have been linked to Alzheimer’s disease. (References available)

*Cancer drugs* with serious toxic effects are approved just because they can shrink tumours, but they don’t prolong life by more than weeks or a few months.

These are just a few examples of drug toxicity from single drugs or one family of drugs.

In contrast, all natural products combined do not come anywhere close to such toxicity. Instead we can say that natural products cause fewer deaths than deaths caused by lightning.

PROBLEM 2

**The public’s right to medicines** of their choice, especially if these medicines are generally safe and have appropriate GMP and support health rather than treat disease. Natural products are generally far safer than cigarettes and even many foods such as peanuts.

PROBLEM 3

**THE EFFICACY ISSUE**

The efficacy (power to produce intended results) issue: Efficacy takes on a different meaning in the Integrative and Traditional & Natural Health medical paradigm. In the biomedical paradigm efficacy has to do with a single synthetic drug producing a clear intended result by blocking a biochemical process, e.g. antihistamine, beta blocker, serotonin-reuptake inhibitor. The intended result is built into the drug.

Natural medicines cannot be classified in such simplistic terms. Even a relatively simple molecule like magnesium participates in more than 300 enzymatic reactions in the body, is critical to many cellular functions, including energy production, protein formation, and cellular replication. (40% of the American population consume less than 2/3 of the RDA for magnesium.)

With such widespread complex effects within the body’s metabolism, it is impossible to talk about cause-effect conditions. Magnesium is prescribed rather to improve health and not produce an interfering effect in the body, which can be easily measured.

The same applies to herbal products. These are also comprised of extremely complex families of active and (assumed) inactive ingredients. Herbs are also not prescribed or used to block a biochemical reaction in order to change particular symptoms and signs. Herbal function is the experience of thousands of herbalists over thousands of years who have identified key actions of the herb in supporting the body’s own innate capacity and intelligence.

While the efficacy of drugs can be measured by using single drugs to reduce symptoms within a relatively short period of time, e.g. pain management, inflammation reduction, cancer shrinkage etc., the efficacy of Traditional and Natural Health Products can only be considered over the long term, with effects of better health, the reduction in diseases (symptom pictures), as healthy functions return.

More Detail

**Drug efficacy:**  A single drug given to treat a symptom with the intended reduction of that symptom.

Comparison can easily be made with other drugs.

Natural medicine efficacy: must take into account the way Integrative Medicine Doctors, Allied Health Practitioners and Traditional Health Practitioners actually use their remedies in a real world practice. Single natural remedies are generally never given alone. The patient is treated as a whole with lifestyle changes and numerous products/substances to support health.

**The only measure that is important regarding efficacy for natural medicines would be outcome studies in which practitioners would be allowed to include lifestyle plus a range of supplements to improve health over time, and allow the natural innate intelligence of the body to heal the disease.** This latter approach is not permitted in medical studies, which places the practice of natural health approaches at an enormous disadvantage.

PROBLEM 4

The Allied Health Professions Council of South Africa (AHPCSA) is neither the voice of Integrative Medicine or African Traditional Medicine, yet all these paradigms and groupings utilise Natural Health Products and substances. These other sectors must be represented in the SAHPRA structures.

PROBLEM 5

**Medical Devices** used by this natural paradigm should also be regulated by its Directorate.

PROBLEM 6

**Conflict of interest within SAHPRA if it becomes semi-private.**

The FDA in the USA has run into the same problems. It is also semi-private, but its freedom is undermined by Big Pharma which pays the bills, and places enormous pressure on getting drugs through the regulatory process quickly and slowing down the process of drug withdrawal.

More Detail

Editorial by Dr Daniel Ncayiyana in the South African Medical Journal (July 2010, vol100,No7):

*“The power and influence of drug companies in the registration process is a continuing source of much disquiet among honest clinical researchers and medical journal editors. The clinical trials used to support drug registration are almost always funded and directed by the manufacturer, with huge financial interest in the outcome. More often than not, such evidence is shrouded in secrecy on the excuse of protection of intellectual property.”*

*And further he notes: “There is a crying need for greater transparency, integrity and independence from big pharma if the regulators are to earn the complete trust of the practitioner and the consumer.”*

A semi-private body like SAHPRA can vey quickly become, like the FDA in America, driven by big businesses which pay for their own registration process.

PROBLEM 7

**Definition of a natural medicine** is so inclusive, that it could limit the range and increase the cost of many natural products that support the health of the community. Experts from one paradigm, especially those who have been especially vocal against natural medicines, should not be allowed to also regulate this industry. These individuals have no personal experience of using natural medicines, and come from a theoretical and very biased viewpoint.

PROBLEM 8

Integrative medical doctors who use complex, mixed innovative remedies should not have those medicines limited by the company’s inability to pay for expensive studies here is South Africa, when those studies have already been done in other countries. Many of these are small companies

PROBLEM 9

**Belief and Public Interest**

The present biomedical paradigm of medicine, regulated by Act 101 of 1965, was for a westernized allopathic medical system, which did not include African Traditional Medicines and other Natural Health Products. This medical system, ‘Biomedicine’ is still the official medical system used in South Africa and excludes the majority of our population, who use African Traditional Medicine.

More details

Biomedicine is regarded as ‘modern medicine’ free from the magic, superstition and unscientific language of the past. Traditional systems are regarded as unscientific and primitive, and in South Africa traditional healers have been referred to as the perjorative “withdoctors”. Healing with herbs and divination has been dismissed as “just a placebo effect”.

The same arrogant attitude is also present for the power of prayer, laying on of hands and any form of healing such as homeopathy, where the parameters of healing are not explainable within the scientifically-known methodology. If it can’t be explained by science, the thinking goes, then it is not scientific, not real and can be dismissed.

It is important to broaden our understanding of science, to include traditional knowledge systems. Traditional African Medicine is backed by the science of experience.

Modern science dismisses God, and we are expected to bow down instead to the god of science.

The “human being” can’t be measured, only some of the body’s functions. Thus the human being as a whole becomes less important when it comes to ill health, and only “the disease” is focused on.

Messages from the Ancestors are seen to be delusions of the healer, but scientists’ inspiration and intuitive knowing are respected.

We choose what we want to believe in and disregard the belief systems of others. This is arrogant and discriminatory.

South Africans need to re-examine their attitude to its African Traditional Practitioners, who have a line of transferring of knowledge that stretches back hundreds if not thousands of years. There is much to learn from this experience. The science of measurement and the science of experience are required to discover each other’s limits and possibilities.

We need a new African Medicine that respects and grows within all cultures of South Africa.

PROBLEM 10

**Terminology**: The use of the word ‘medicine’ is confusing and is regarded differently in different paradigms of medicine. Synthetic drugs should be called ‘drugs’, which will clarify their difference with African herbs and other natural products. These products should be called ‘Traditional and Natural health Products’ and while this does require some further definition, as a whole the distinction between a drug and a natural product is clear.

PROBLEM 11

**Medical Devices**

There are a range of medical devices which are part of the Integrative Medical paradigm. The Biomedical paradigm uses very powerful instruments which can do serious harm (like their drugs). The Integrative/Traditional medicine paradigm uses instruments of a very different nature and intent. The intent is not to harm, even when used in a therapeutic way.

Example: laser light, when used by the Biomedical paradigm, can be used as a surgical knife. On the other hand Integrative doctors use ‘low-energy lasers’, which stimulate healing.

**Medical devices belonging to another paradigm should fall under a separate regulatory authority.**

PROBLEM 12

**Health education and advertising**: The public have a right to be educated about health and the maintenance of health. Health claims should therefore not be overly restricted.

Education on health matters is urgent. The treatment of disease can be left to doctors, but health is the right of each individual. It makes no sense that natural health products should be over-restricted in their health claims. This penalizes the consumers’ right to knowledge and to take responsibility for their own health.

Appropriate information around Traditional and Natural health Products, including superfoods and natural skin care products (cosmetics) should be allowed.

More details

Many regulatory authorities, including our own have been over restrictive around health claims.

There is very little we can know for certain: each person is a unique individual, and in the end must take responsibility for his or her own health. The more information around health that can be provided, the better they can look after their own health.

Health products are for health. The most prevalent diseases today have been shown in one way or another to be related to lifestyle and food choices (for example diabetes and heart disease). It is imperative that the public be given as much information possible regarding the value of the food they eat and the nutrients they need. There is no evidence at all that the information which has appeared on natural health products has caused any serious problems. Claims which are incorrect can easily be detected by specialists who understand how the products are used. The benefits of more information clearly outweigh the risks. The public is not stupid, and it is condescending and patronizing to say that people cannot make up their own minds about what they ingest.

PROBLEM 13

Medical science’s double-blind, randomized, placebo-controlled trials held up as the gold standard, however they is limited in their application to Traditional and Natural health Products. Yet medical scientists tend to get their way when it comes to defining and regulating Traditional and Natural health Products, and expect the research on natural medicines to meet the inappropriate standards of their paradigm.

More Detail:

Medical science is losing its lustre. Please consider the following:

* A publishing bias against studies with negative or inconclusive findings exists. Clinical studies in which the results show a significant difference are three times more likely to be accepted, and are likely to be published more rapidly, than those with insignificant findings. Unpublished data skews the results and findings of any meta-analysis.

*Stern J et al BMJ 1997;315(7109):640. Montori VM et al 2000;75(12):284*

* One review found that 51% of studies funded by for-profit organizations were in favour of the trial drug, compared with only 16% of studies sponsored by non-profit organisations.

*Als-Neilsen B et al JAMA 2003;290(7):921*

Dr Angell, editor of the New England Journal of Medicine for two decades, said: “Physicians can no longer rely upon the medical literature for valid and reliable information”.

She reluctantly concluded that prescription drugs are not nearly as effective as the publications on randomised trials suggest.

She also said that “it is often possible to make clinical trials come out pretty much any way you want, which is why it’s so important that investigators be truly disinterested in the outcome of their work.”

*Angell, M Industry sponsored clinical research: A broken system. JAMA 2008;300(9):1069*

* There is increasing concern about data fabrication. A recent analysis found that 2% of scientists admitted to fabricating or modifying data at least once, and one third confessed to questionable research practices. Interrogating colleagues revealed more alarming figures of 14% data fabrication and 72% debatable scientific behavior.

*Fanelli D Plos ONE 2009(5)*

* There is a big difference between statistical significance and clinical relevance that is generally not taken into account. The statistics are thrown around in the press and used by drug companies PR agencies, but this may not have clinical relevance in terms of the big picture for the patient. Taking the drug, for example, may decrease the risk of another heart attack but increase the risk of a stroke.

**Osler, a great physician once said: “Variability is the law of life, and no two individuals react alike and behave alike under the abnormal conditions which we know as disease. The good physician teats the disease, the great one treats the patient.”**

*\* The information above was extracted from a Forum article in the SAMJ July 2013, vol 103, No7 by Associated Professor David Muckart and entitled “ Evidence-based medicine - are we boiling the frog”.*

PROBLEM 14

**Loss of Small and Medium Sized Business**

The present regulations, once fully rolled out, will perpetuate the system of big business dominating health, in which small businesses (which are often the place of innovation and creativity) disappear, as has already occurred in Germany. Multinational drug companies are more interested in profit than in the business of health. The large companies can afford to pay their way in the new regulatory process, and will potentially sell inferior products.

More Detail

The regulatory process is driven by the paradigm of pharmaceutical drugs, which because of their toxicity, are generally sold as single agents.

Natural products, however, are often mixed products and provide a synergy of effects which support healthy function. The registration process as it stands for these mixed products will be enormously expensive. Large companies will simply choose single products which can be easily registered for sale at high prices once the market share has dwindled to a few big companies.

This is an unfair business practice, placing small companies at a disadvantage. We have no argument with appropriate GMP, and these products are generally regarded as low risk, so why should a country like South Africa place such a heavy burden on small business, when the benefits are great?

South Africa should not be pandering to big business. The current regulations are excessively onerous for small companies and only serve monopoly capital.

PROBLEM 15

**Belief**

Belief is not generally recognized as an important component within the Biomedical model and yet is extremely important within African Traditional Medicine and other Traditional health systems in the realm of Natural Health Products.

Beliefs can be powerful forces that affect our health and capacity to heal.

Understanding how social, structural, psychological and cultural factors affect physical health and being sensitive to these factors can make an important difference in health outcomes. Beliefs affect how and from whom a person will seek care, how self-care is managed, how health choices are made, and often, how a patient responds to a specific therapy.

Cultural beliefs are also reflected in a society’s health care system. It is not surprising, for example, that a dominant theme in Western medicine has been to fight or vanquish disease, while in the traditional medical system, the prevailing image in health care is one of balance.

**Believe is a medicine** and when it is packed in a bottle, bone throwing ,package of herbs or a message from ancestors it needs to be acknowledged and valued for what it is i.e. a way of supporting health of the person, their family and their community.



CONCLUSION

This Bill and the recent Regulations passed for ‘Complementary Medicines’ have not taken into account that we are dealing with two very different paradigms of medicine.

The conventional Biomedical paradigm which treats disease using drugs and surgery and the Traditional/Integrative medical paradigm which supports health using natural medicines and lifestyle changes.

An editorial in the British Medical Journal (BMJ) defined Integrative Medicine in the following way:

*“Integrative medicine is not simply a synonym for complementary medicine. Complementary medicine refers to treatments that may be used as adjuncts to conventional treatment and are not usually taught in medical schools. Integrative medicine has a larger meaning and mission, its focus being on health and healing rather than disease and treatment. It views patients as whole people with minds and spirits as well as bodies and includes these dimensions into diagnosis and treatment. It also involves patients and doctors working to maintain health by paying attention to lifestyle factors such as diet, exercise, quality of rest and sleep, and the nature of relationships.”*

In that same journal, the editor says that even this definition does not capture the full richness of what might be achieved through the growth of Integrated medicine and that this medicine could ‘restore the soul to medicine’.

China is the only country in the world where Western medicine (Biomedicine) and Traditional and Natural Medicine are practiced alongside each other at every level of the health care system. They are gradually developing a unique ‘Integrative Medicine’ for that country.

We believe that the Western based pharmaceutical driven system of medicine practiced in this country is not sustainable because it does not heal people but increases the burden of chronic disease.

Recognizing the value of this submission by the Traditional & Natural Health Alliance, and the value which it brings to the SAHPRA debate can allow a unique African medicine to emerge for the common good of every ill person in our land.



SUMMARY

**1. Drugs are generally high risk products and Traditional and Natural health Products are generally of low risk.**

**2. There should be separate regulatory Directorates under the SAHPRA for Pharmaceutical Drugs and for Traditional and Natural health Products.**

**3. Each Directorate must be governed by their own experts who represent the full spectrum of their respective paradigms.**

**4. African Traditional Medicine and Natural health Products are sister categories, falling into the same health paradigm.**

**5. An Electronic Listing System which can rapidly implemented at minimal cost is appropriate for Traditional and Natural health Products.**

*“It is easier and cheaper to prevent the onset of a disease
than it is to treat it once the disease has developed.”***— From the IOM Summit on Integrative Medicine and the Health of the Public**



**TNHA REGULATORY PROPOSAL**

Balancing Consumer Choice & Safety in
Traditional & Natural Health Products

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**Presented by: Anthony Rees**

**INTRODUCTION**

We would like to take this opportunity to thank this Committee, and especially the Chair of the Committee, the Hon. Mary-Ann Lindelwa Dunjwa, for extending an invitation to our organization to return to the legislature, so that we can make appropriate proposals to the Medicines and Related Substances Amendment Bill (Bill 6 of 2014).

We sincerely hope that the proposals contained in this submission will be duly considered in the final structure, scope and mandate of the South African Health Products Regulatory Authority (SAHPRA).

The African Traditional Medicine (ATM) and Natural Health Product (NHP) industry is a multi-billion-rand enterprise in South Africa, and manufacturers and distributors have enjoyed unfettered access to consumers throughout the country for hundreds of years.

At least 30 million people ingest African Traditional Medicines each year, with 75-80% of South Africans utilizing them before seeking biochemical, medical interventions.

There is now a growing market of indigenous ATMs in the formal sector, with indigenous plants being marketed singularly and in mixtures in pharmacies, formal retail stores and even informal Spaza shops.



A recent TNHA survey identified over 150 African ATMs available in formal and informal retail outlets in the greater Cape Town metropolis. We suspect there are a great deal more being sold in different regions across South Africa.

The African Traditional Medicine sector was last estimated to enjoy a R4 billion annual market share in 2008, while the more formalised Natural Health Product (Complementary Medicine) sector stood at R8.5 billion rand per annum when last assessed in 2014.

There are approximately 24,000 plant species found in South Africa, with +/- 3,000 of them used as ATMs. At the last count, there were +/- 14,000 different Natural Health Products being sold in South Africa, according to an audit by the Medicines Control Council conducted between 2002 and 2013.

This is a exceedingly large, parallel health sector in South Africa, which until recently had been left unregulated, and with little government interference.

On the 15th of November 2013, the Department of Health published Regulations for Natural Health ‘Complementary Medicines’ (NHPs) , which were categorised according to the substances prescribed in the Scopes of Practice of the five prescribing professions of the Allied Health Professions Council of South Africa (AHPCSA), namely **Western Herbal Medicines, Chinese Traditional Medicines, Ayurvedic Medicines, Unani-Tibb Medicines and Homeopathic Medicines**. Some categories were omitted initially, however the Department of Health has published amendments, which now include natural health substances defined as ‘Health Supplements’, which are made up of vitamins and minerals.

The TNHA was recently informed by the Directorate of Food Control that further amendments are in the pipeline, which will bring more categories of Natural Health Products (NHPs) under the control of the MCC and SAHPRA, including, but not limited to probiotics & prebiotics, amino acids, essential fatty acids and other innovative, isolated plant extracts.

African Traditional Medicines remain unregulated in South Africa, however recent official statements by the former Deputy Minister of Health, **Dr. Gwen Ramakgopa**, and the Director General of the Department of Health, **Ms. Precious Mtsoso** have indicated that the SAHPRA will control the manufacture and sale of these products.

A slide presentation to this Committee, delivered by the National Department of Health on the 3rd of September 2014, which preceded this round of public submissions stated unequivocally, that among the main reasons for this Amendment Act was the “Accommodation of poorly regulated and unregulated products e.g., complementary and alternative medicines [NHPs] and African Traditional Medicines.”







In a follow-up consultation between this Committee and the Department, after the public submissions at the end of last year’s Parliamentary sitting, the Parliamentary Monitoring Group reported that both the ANC and EFF members of this Committee demanded to know why the Department of Health had not expressly stated their intentions to regulate African Traditional Medicines under the SAHPRA.

The Director-General, Ms. Precious Mtsoso responded by stating that the Department intends regulating ATMs under the new Act (after the passing of this Bill), and that a booklet had been published which outlines the process for bringing ATMs under MCC/SAHPRA control. (See: <https://pmg.org.za/committee-meeting/17906/>)

***Ms Malebona Matsoso, Director General: DoH, replied that the Department had published a booklet that explained how it planned to carry out regulations for traditional medicines, and would distribute the booklet to the Committee's research team. SAHPRA would regulate all products which had been mentioned in the Bill -- those that were processed in laboratories, as well as the plants that were used during the process of making medicines.***

***Ms Matsoso explained that the Department had been working with universities in South Africa to regulate products. For example; the University of Cape Town (UCT) had professionals that dealt with the safety of medicines. There was also the Drug Information Unit, and the monographs that had been developed by the World Health Organisation (WHO) were supplied by the University of the Western Cape (UWC). The monographs were used for both the traditional and complementary medicines. The University of North West (NWU) had been at the forefront in regulating the quality of products, and the University of Pretoria (UP) and Rhodes University had been largely involved in biomedical research. The professionals were situated in the universities, so it was important that SAHPRA be developed to get permanent staff.***

The TNHA have spent the last six weeks attempting to obtain this alleged ‘booklet’ from the institutions she mentioned. The Heads of Department at these institutions all deny any knowledge thereof. The TNHA would have liked to study this ‘booklet’ prior to this submission being made, so that we could comment appropriately.

It is also spurious that this booklet will only be distributed to this Committee’s research team, and not the elected officials who are responsible for the decision-making.

In the interim, we have written an urgent letter to the new Registrar of Medicines, **Ms. Joey Gouws**, on the 20th of January 2014, requesting clarification on the official status of marketed African Traditional Medicines which are currently sold on the open market. We have received neither reply nor acknowledgment thereto.

The Natural Health Product regulations, although gazetted a little more than a year ago, have been rejected by the majority of stakeholders in the Natural Health Product industry. Our organization and a growing amount of consumers also reject these regulations as they are irrational, discriminatory, arbitrary, disproportionate, and literally impossible to comply with.

In a year, since the publication and inception of the said regulations, not one single product has been registered; utilizing the ZACTD application procedure mandated by the regulations and guidelines.

The manner in which the regulations for NHPs were drafted under a shroud of secrecy, and then promulgated without notice has resulted in confusion and chaos, which has resulted in a stalemate between industry and the MCC.

There is currently a High Court challenge against the regulations before the Gauteng High Court, brought by the Health Products Association of South Africa (a TNHA Alliance partner).

Our organization has drafted a Constitutional challenge to the Act and Regulations; however we would hope that a last ditch dialogue with this Committee may bring sensibility and accountability to the fore, so we can all avoid further legal entanglements. Our first presentation to this Committee on the 29th of October 2014 outlined these numerous issues, therefore we will not expand on them in this document.

From observing the manner in which the NHP sector has been threatened by the overzealous and inappropriate regulatory regime forced on it, our African Traditional Health Practitioner alliance partners have taken notice of the many challenges its sister natural health sciences are faced with post-regulation, and have joined the TNHA as alliance partners to:

1. monitor regulatory policies on all traditional medicines products in South Africa,
2. create a unified Traditional and Natural Health sector, comprised of similar paradigms and philosophies,
3. work proactively in proposing a new regulatory framework under SAHPRA, which separates the biomedical and traditional and natural health paradigms under an appropriate statutory system.
4. collaboration to assist African Traditional Health Practitioners with further education and training the appropriate harvesting, storage, manufacture and dispensing of TAMs.

The TNHA recognises that all traditional medicines, whether indigenous or non-indigenous, should be appropriately regulated under the same regulatory prescripts in terms of achieving equality in terms of the Bill of Rights.

The current thinking of the Department of Health is that NHPs and ATMs must be regulated under separate structures, which is discriminatory.

This Committee may believe that the creation of regulations for Traditional & Natural Health Products (TNPs) are delegated exclusively to the Medicines Control Council (MCC) / SAHPRA, in terms of its broad vested powers to publish sub-legislation in terms of Section 35 of the Medicines and Related substances Act (Act 101 of 1965), and that it is not in the scope of this Committee to interfere in the functions of the Council and Minister in this regard.

We contend that regulating of a whole new sphere of health substances which had until recently not been regulated, encompassing an entirely new paradigm of health, should never be relegated to sub-legislation and a statutory body that is inherently ignorant of the use Traditional and Natural Health Products, is biased towards the medical paradigm, or a sub-committee made up of only one of many stakeholders.

The Medicines and Related Substances Act was never envisaged by this Parliament to regulate Traditional & Natural Health Products half a century ago. The spirit and intent of the legislature was for a regulatory body to assess, regulate and control novel pharmaceutical drugs which proliferated unchecked, along with their associated risks over the last century.

We contend that the publishing of Regulations for NHPs in November 2013 was *ultra vires*, and should have been a process born of this Committee, and though amendments to the principal Act. This process should have taken place with broad based stakeholder engagement, in a transparent and fair manner, as has happened everywhere else in the world where regulations for Traditional & Natural Health Products have been adopted.

What has resulted is ‘Legislation by Regulation’, which has had many unforeseen consequences and made the current model unworkable.

Simply patching the Act *post facto* though this Bill, with an inclusion of ‘Complementary Medicines’ in Section 1 (Definitions) will not suffice. Section 35 of the Act, was never intended to create new categories of medicines on this scale or for this paradigm. The classes and categories described in Section 35, were for existing pharmaceutical products exclusively.

The SAHPRA requires fundamental structural reorientation, and unambiguous terms of reference to bring about a meaningful regulatory environment for Traditional & Natural Health Products.

Stakeholders have lost trust in the MCC’s ability to conform to basic constitutional obligations, and to make regulations in a non-biased manner. There has been a total lack of transparency in the decision-making process of the MCC and its ‘expert’ Complementary Medicines Committee (CMC). The CMC was established by selective invitation to only one stakeholder group, namely the Allied Health Professions Council of South Africa (AHPCSA).

The Traditional & Natural Health Alliance requests that this Committee exercise its legislative mandate and steer a policy shift towards a more sustainable, constitutional, inclusive and transparent regulatory framework for Traditional & Natural Health Products under the SAHPRA.

This will include the repeal of the existing regulations for NHPs and the disbanding of the non-representative Complementary Medicines and African Traditional Medicines Committees of the Medicines Council as a matter of urgency.

The TNHA propose a more appropriate and rational regulatory system for Traditional & Natural Health products, which balances the rights of consumer choice and public safety.



**A NEW REGULATORY SYSTEM FOR TRADITIONAL & NATURAL HEALTH PRODUCTS IS NECESSARY TO PROTECT THE PUBLIC AND TO GUARANTEE CONSUMER ACCESS.**

The TNHA wish to be part of an ongoing dialogue between this Committee, the Department of Health and the SAHPRA in co-creating an appropriate, transparent and culturally sensitive regulatory system for Traditional & Natural Health Products.

Traditional & Natural Health Products must be regulated under equal terms under the Medicines and Related substances Act as a matter of priority, in order to address the inequality of the current status quo, or be wholly expunged from the Act and Regulations by a capable court.

Hopefully the latter can be avoided if this Committee recognises that simple structural amendments to the SAHPRA can remedy most of the issues experienced by stakeholders.

**SUGGESTED STRUCTURAL CHANGES TO THE SAHPRA**

Considering all the facts presented in this presentation, the TNHA would like to see Traditional and Natural health Products separated from the Biomedical sector completely.

Two Directorates are envisaged under the SAHPRA. Each Directorate shall function autonomously, and under the leadership and supervision of personnel of the relevant paradigms represented.

We would like the SAHPRA Board having proportional representation from the Traditional and Natural Health Product sector. Section 2 of the Bill does not include any Traditional & Natural Health Product representatives despite their substances being regulated. Only representatives of the biomedical paradigm are currently included. We would like proportional representation based on the number of products registered.

**The Traditional & Natural Health Product Directorate.**

This Directoratewill be staffed by a minimum of 8 and maximum of 12 full-time employees who are trained experts in the categories represented. It will act as a decision-making body and secretariat for all matters related to the Traditional and Natural Health Product sector. It will liaise with the SAHPRA on macro policy issues affecting human medicines.

It shall also enter into cooperative agreements and joint ventures with regulators in foreign jurisdictions, research institutions and relevant Health Professions Councils in all matters pertaining to Traditional and Natural health Products.

**Category Sub-Committees**

There will be two Committees which control both African Traditional Medicines and Natural Health Products respectively. These Committees will approve the inclusion of African Traditional and Natural Health substances to the ELS database, which have been submitted by the Modality-Specific Sub-Committees. This committee will act as arbitrator in disputes related to decisions of the Modality-Specific Sub-Committees under it’s control.

**Modality-Specific Sub-Committees**

These will be expert working groups, representing expertise in each modality represented by Traditional and Natural Health Products.

They shall collate data from various local and international sources relating to the dosages (safe daily limits), risks and health claim substantiation for individual substances which will be submitted for inclusion into the ELS database.

They shall also assess novel and integrative health products, through long form applications (if required).

All recommendations of these committees shall be forwarded to the relevant Category Sub-Committees for ratification.

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**MOVING FORWARD - GUIDING PRINCIPLES FOR A REGULATORY SYSTEM FOR TRADITIONAL & NATURAL HEALTH PRODUCTS**

This is a list of Guiding Principles for a new legislative framework for Traditional & Natural Health Products under the SAHPRA.

**NATURE OF TRADITIONAL & NATURAL HEALTH PRODUCTS (TNHPS):**

TNHPs are different in nature from, and must not be treated strictly as either foods or pharmaceutical drugs. They are collectively, a new category of health products, to be managed under a new, separate Directorate.

**SAFETY:**

Safety of TNHPs is a primary concern.

**QUALITY:**

The TNHP industry must meet clearly defined and established standards of quality assurance (GMP), which are appropriate to the individual substances used, based on individual risk profiles.

**EFFICACY:**

Health claims may be supported by health outcomes criteria, based on, but no limited to established traditional use, empirical data and appropriate clinical studies to be determined by the TNHP Directorate in consultation with its sub-committees.

**ACCESS:**

TNHP regulations must not unduly restrict access by consumers.

**INFORMED CHOICE:**

TNHP consumers must be provided with pertinent information about the products they purchase thorough appropriate labelling regulations and being able to obtain information about their ‘listed’ product choices online.

**COST:**

TNHP regulations must not place inappropriate cost on industry, consumers and government.

**DECISION-MAKING:**

Decision-making power must be given to a separate regulatory body (Traditional AND Natural Health Product Directorate), staffed by individuals who have established expertise and experience with TNHPs.

**AVAILABILITY OF APPEAL:**

An open and transparent process of appeal must be available to TNHP stakeholders.

**TRANSPARENCY:**

Information regarding decisions and the regulatory system must be readily available to all TNHP stakeholders. An online registration application lodging system must be accessible to track the status of applications to finality.

**CULTURAL DIVERSITY:**

TNHP regulations must respect diverse cultural traditions and not discriminate among them.

**BIODIVERSITY & INTELLECTUAL PROPERTY:**

The TNHP regulations must fulfil the requirements of the Biodiversity Ac (Act 10 of 2004), Patents Amendment As (Act 20 of 2005) and Regulations on Bioprospecting, Access and Benefit-Sharing (2008).



**SUGGESTED TERMS OF REFERENCE FOR THE PARLIAMENTARY PORTFOLIO COMMITTEE ON HEALTH TO ESTABLISH A NEW REGULATORY FRAMEWORK FOR TRADITIONAL & NATURAL HEALTH PRODUCTS.**

* **That the Parliamentary Portfolio Committee on Health consult, analyse and make recommendations regarding the legislative and regulatory regime governing African Traditional Medicines and Natural Health Products, including, but not limited to African Traditional Medicines, Western Traditional Herbal Medicines, Traditional Chinese Medicines, Ayurvedic Medicines, Unani-Tibb Medicines, Homeopathic Medicines, Integrated Medicines and Health Supplements, and including innovative plant-based chemical isolates.**

**COMMENTRY:**

The creation of a level playing field in the regulation of African Traditional Medicines and Natural Health Products in terms of the Equality Clause referred to in Chapter 2, Section 9 of the Constitution Act. (Act 108 of 1996) must be effected.

A Constitutional crisis has developed as a result of the publication of recent Regulations for the control of non-indigenous Natural Health Products (Complementary Medicines) published on the 15th of November 2013 in terms of Section 35 of the Medicines and Related Substances Act (101 of 1965).

The Regulations and provisions carried over in the Medicines and Related Substances Amendment Bill (Bill 6 of 2013), allow the Medicines Control Council and Minister of Health to continue to discriminate between non-indigenous Traditional Medicines and indigenous African Traditional Medicines.

The current regulations discriminate on the basis of tradition, race, ethnicity, culture, belief and social origin. This discrimination is unfair, and the State must provide compelling reasons why the current discriminatory regulatory regimes for Natural Health Products (Complementary Medicines) and African Traditional Medicines is fair.

We are aware that a decision was made to separate non-indigenous Traditional Medicines (complementary medicines) and indigenous African Traditional Medicines as far back at 2008 by the then Minister of Health, Dr Manto Thabalala Msimang.

This decision was influenced by the World Health Organizations ‘*Traditional Medicines Strategy*’ document of 1995 and the more recent ‘*Framework for Traditional Medicines : 2014-2023*’ published in 2013, which irrationally and erroneously creates duplicitous regulatory regimes for these sister traditions.

In recent years the Director General of the Department of Health, Ms. Precious Mtsoso and the previous Registrar of Medicines, Ms. Mandisa Hela, have continued to unconstitutionally discriminate in their policy directives in this regard. This is simply not acceptable, as the Constitution is the supreme law of the Republic, law or conduct inconsistent with it is invalid, and the obligations imposed by it must be fulfilled.

* **That the Parliamentary Portfolio Committee on Health consult broadly with stakeholders, including, but not limited to, the Allied Health Professions Council, the Traditional Health Practitioners Interim Council, national health practitioner and natural health product sector associations and individuals representing, growers, importers, manufacturers, wholesalers, distributors, exporters, retailers and consumers.**

**COMMENTRY:**

This provision will create openness, transparency, accountability, and procedural fairness, where there has been little to none thus far. This will fulfil the requirements of Section 31(1) and (2) of the Constitution (Act 108 of 1996) and provisions of the Promotion of Administrative Justice Act (Act 3 of 2000).

The non-transparent and non-inclusive manner in which the Medicines Control Council promulgated the Regulations for Natural Health Products (Complementary Medicines) in terms of Regulatory Notice 870 of 15 November 2013; and subsequent the amendments to these regulations were born from decisions made by a Medicines Control Councils’ expert sub-committee, namely the ‘Complementary Medicines Committee’ (CMC).

The CMC was appointed by a selective invitation, and without public notice for nominations or due application process. This Committee does not represent the Natural Health Product sector, being constituted exclusively by staff members of the Medicines
Control Council and selected members of the Allied Health Professions Council.

We contend CMC is not a legitimate, properly constituted body of the MCC charged to deliberate and make recommendations for the regulation of Natural Health Products (Complementary Medicines).

The CMC has conducted it affairs in secrecy, with no record of decision making being available. The TNHA therefore rejects all decisions and recommendations of the CMC, and by extension Regulatory Notice R870 of 15 November 2013, and any/all further amendments thereto.

* **That the Parliamentary Portfolio Committee on Health consider the objectives of providing consumers freedom of choice in health care in terms of and access to TNHPs while ensuring the quality and safety of such products with appropriate methodology and controls;**

**COMMENTRY:**

The Committee and SAHPRA must acknowledge the Freedom of Choice consumers and patients must continue to enjoy while choosing Traditional & Natural Health Products to achieve and maintain wellness.

**PERSONAL SOVEIGNTY OVER HEALTH CHOICES**

This will create a balance between the primary statutory obligation of the SAHPRA to ensure public safely with respect to all medicines and health substances sold in the Republic, and the Freedom and Security of the Person, in terms of Section 12 (2)(b) of the Constitution (Act 108 of 1996).

This section guarantees the unalienable right of each person to make decisions over the security and control over their own bodies, including exercising health choices to achieve the same.

**BELIEF, CONSCIENCE AND RELIGIOUS ACCESS RIGHTS**

These choices must be acknowledged and guaranteed by virtue of the public’s unalienable right to freedom of religion, belief and opinion, in terms of section 15(1) of the Constitution. (Act 108 of 1996).

Many consumers and patients who choose and utilise Traditional & Natural Health Products, do so in terms of their religious, cultural and belief systems. Regulations which impede on the above rights are unconstitutional.

**ENSURING QUALITY, SAFETY AND EFFICACY**

**APPROPRIATE ASSESSORS**

The appropriate regulation of Traditional & Natural Health Products can be achieved as part of an ongoing process, and be assessed and monitored by appropriately qualified professionals and experts from the Traditional & Natural Health Product professions and manufacturing sector exclusively.

**The Medicines and Related Substances Control Act (Act 101 of 1965) was never intended for the control of African Traditional Medicines and Natural Health Substances, but rather novel synthetic, man-made molecules, after the thalidomide tragedy.**

Traditional & Natural Health Products were largely ignored by the MCC over the last half a century, since the inception of the Act in 1965. There were some small attempts to regulate some product categories over the last twenty years, with sporadic call-ups (vitamins, minerals, homeopathic medicines and some herbs), however these products were grandfathered with no further assessment of their quality, safety or efficacy.

The MCC’s current biomedical assessors are neither sensitive nor appropriately trained in the philosophies and practice Traditional & Natural Health medicines and therefore they are not appropriately qualified personnel to assess these products.

Broad-based expert sub-committees must be established, made up of experts in Traditional & Natural Health Products, and the disciplines making up the array of products in the categories represented.

These committees will assess certain applications where data is lacking, and make recommendation to the inclusion and removal of information relating to the data core of the Electronic Listing System (ELS).

**ELECTRONIC LISTING SYSTEM**

An Electronic Listing System (ELS) can run off a ‘positive list’ of pre-authorised Traditional African medicines natural health substances which may be sold singularly or in combination products. The ELS will be owned by the SAHPRA, administered by a Traditional & Natural Health Product Directorate, and substances and products assessed by expert sub-committees made up of data assessors and researchers.

The ELS enables the rapid, cost-effective, and appropriate control of Traditional & Natural Health Products. Approximately 80% of registration applications could be assessed by means of the ELS Procedure. The remainder would need to be assessed manually through a separate long application procedure by expect sub-committee assessors.

Such a system has been developed to an advanced level locally and abroad, and can be implemented in the matter of months after the establishment of the SAHPRA and our recommended controlling sub-structure.

Substance, dosage, health claims, appropriate GMP requirements and label warning data on the electronic list can be imported from similar systems utilised effectively by regulatory authorities abroad (e.g. Australia and Canada)

The list of African Traditional Medicines (mainly plants) can be collated from several hundred existing monographs of indigenous herbs which have been completed by various research and education institutions in South Africa over the past two decades. This list may not yet cover all the 3,000 medicinal plants used by traditional health practitioners in South Africa, but can be expanded on an ongoing basis, as new research comes to the fore.

Appropriate traditional health claims should be allowed to be included on list, as long as they are historically documented. They can be expanded upon or withdrawn as the appropriate evidence-base catches up.

**SAFETY**

Where the safety of a natural health substance is documented by an overseas regulatory authority, and this authority uses rational criteria, these will be added to the list. Similarly, where the safety of individual African Traditional Medicines (herbs) is documented, these will be added to the list.

Substances which, according to risk/benefit studies are identified as being potentially toxic or cause adverse reactions can be limited by daily dosage limits, scheduled for use under practitioner supervision only, or placed on a ‘negative’ (undesirable product list).

**Buyer Beware! *Caveat Emptor***

Most substances are considered to be safe for OTC use (not scheduled), and shall carry applicable warnings on labels with respect to and known side effects, contra-indications and warnings.

**Scheduling:** Products that need to be prescribed and used under the care and follow-up of health practitioners may be scheduled according to risk.

**QUALITY**

Manufacturing regulations will contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of these products.  The must ensure that Traditional & Natural Health Products will be safe for use, and that they contain the ingredients and strengths stipulated on product labels.

Substances can be quality assured on a sliding scale, based on a substances-by-substance basis. Substance/Category specific guidelines may be published accordingly.

This will allow many current manufacturers to continue trading, with a small percentage having to upgrade their facilities and analytical capacity accordingly. The current inappropriate regulations and guidelines shift the majority of natural health products into the pharmaceutical drug category ‘Category A’.

Most Traditional & Natural Health Products manufacturers cannot afford the financial outlay in order to conform to the pharmaceutical GMP requirements for pharmaceutical drugs. This will result in the majority of Natural Health Product manufacturers withdrawing their products from the market in the next four years, or having to pass on these compliance costs to consumers, making the products unaffordable.

For vitamins, minerals and other food factors, appropriately modified food GMP will suffice, as is the case under the US Dietary Supplement Health and Education Act of 1994.

For herbal ingredients which are common across Traditional & Natural Health Products, PICS GMP requirements can be appropriately applied.

A Manufacturing and/or Distribution License must be a prerequisite for being able to complete an ELS Application.

Health Store retailers and direct marketers should be exempt from licencing if they sell unscheduled OTC Traditional & Natural Health Products exclusively.

**EFFICACY**

Traditional & Natural Health Products are used differently to the way that pharmaceutical drug are used:

The efficacy of a product is closely linked to the question of health claims. A product will

only be efficacious if it produces the outcome indicated by its health claim. Thus, efficacy

requires that a product "does what it says it will do."

Health claims, meanwhile, are statements of the effect of a product on the health of an

individual made by the manufacturer or distributor, and displayed on the product label or

literature. TNHPs make three different categories of health claims which a defined as follows.

**Structure-function claims** report the effect of a product on a structure or physiological function in the human body and are based on the maintenance or promotion of good health.

**Risk-reduction claims** relate consumption of a product to significant reduction in the risk of developing a disease or abnormal physiological state. Risk reduction may occur in two ways. One, the product may alter a recognized major health risk factor or factors of a disease or abnormal state. Two, it may affect a body function or system so as to improve the body's capacity to resist the disease or abnormal state.

**Therapeutic or treatment claims** report the effects of a product on the actions of a specific disease or its symptoms. Treatment can include the cure or alleviation of either the disease or its symptoms.

**Traditional health claims.** The efficacy of many TNHPs have been demonstrated over centuries through their use by a large number of people. Therefore, experience, clinical practice and empirical verification must be considered as *prima facia* evidence for TNHPs' efficacy.

TNHPs should be eligible to make all four types of claims above, if sufficient or reasonable evidence supports such claims. What constitutes "sufficient" or "reasonable" evidence should be left to the expert sub-committees to decide.

Most TNHPs claim to support health as opposed to treating illness. For example, they do not ‘kill’ bacteria as antibiotics do, but rather they improve the ‘innate forces’ in the body to overcome the bacteria.

While it is appropriate for broad sections of the population to use them, individual states of health start at individually differing baselines.

In order to not have mis-branding, appropriate wording is relevant.

Therefore, health claim wording such as: ‘***Assists in the treatment of...***’ or ‘***This substances has traditionally been used for ….***’ should be acceptable claims attached to individual substances listed in the ELS.

**Products with no demonstrated efficacy.** Products meeting requirements for safety and quality, but unable to demonstrate efficacy, should continue to be made available to the public, but without health claims. They should carry prominent text on all labels with a disclaimer stating something like “*This product has not been assessed for its efficacy by the Directorate of Traditional & Natural Health Products*.”

**POST MAREKTING SURVEYLENCE**

Post-market surveillance monitoring of TNHP’s is crucial, as there is currently no standardized reporting system for TNHPs in the event of adverse reactions occurring.. Products should be easily tracked through their life cycle and their quality, safety and efficacy should be regularly monitored by the Directorate of Traditional & Natural Health Products.

As with the pre-market assessment, the level of post-market monitoring and surveillance should be based on the level of safety of the product. A TNHP adverse event reporting system would be an important part of this post-market assessment as long as the reports are **verifiable** and **not anonymous**.

Manufacturers should be required to maintain and analyse post-market data of their products. For products that are of lower safety (higher risk), more extensive reporting of adverse reactions would be required.

* **That the Parliamentary Portfolio Committee on Health considers the legislative and regulatory regimes governing TNHPs in other countries.**

**COMMENTRY:**

There are progressive countries in the world, where conscientious law makers have recognised the fact that the control of Traditional & Natural Health Products cannot be simply relegated to the same regulatory framework as pharmaceutical drugs. Among the examples are examples are China, Cuba, Canada and Australia.

These jurisdictions have created a dividing line between the paradigm of Traditional & Natural Health Products and the paradigm of Biomedicine and it’s pharmaceutical products.

We call upon this Committee to investigate these regulatory systems and implement an African regulatory solution, and not merely a cut and paste system derived from the EU (present regulatory framework).

For the TNHA, a primary objective of any new regulatory framework for Traditional & Natural Health Products must take into account the well-being of consumers. On the whole, our desired outcome is a regulatory framework for Traditional & Natural Health Products that:

(a) protects the health of consumers
(b) respects consumers' access to products and
(3) guarantees product safety, quality efficacy.

* **That the Parliamentary Portfolio Committee on Health considers the appropriate cost recovery of a regulatory system for TNHPs.**

**COMMENTRY:**

The Medicines Control Council and envisaged SAHPRA charges three types of fees to manufacturers of medicines. These include site licencing (manufacturing) fees, product registration fees (application and assessment) and thirdly annual product licencing fees.

Cost recovery for services under SAHPRA will be aimed at full cost recovery, owing to it new semi-private status.

Many companies, which currently sell Natural Health Products carry extensive product lines to meet consumers' needs. Although the current fees for the evaluation and registration of these products under the ‘Category D’ classification cost R12,400 per product application, this cost will inevitably be passed on to consumers.

A large percentage of products are earmarked to be denied registration under ‘Category D’ because of the draconian system currently imposed. They will be forced to pay the same application fees as for pharmaceutical drugs. Small and medium sized companies will therefore be prevented from registering, and as a result will close down. This will severely limit the consumer’s choice of products.

We believe that fees should reflect the higher safety (lower risk) nature of TNHPs, in contrast to pharmaceutical drugs.

Any cost recovery program for TNHPs should be fair and reasonable and not result in unnecessary restriction of access to TNHPs. Further, we believe that the right balance must be established between the cost to be borne by the regulator and that of the final consumer.

On the one hand, appropriate levels or structure of fees must not unduly restrict access to products by consumers. On the other hand, the industry must participate in the cost of public services that enhance the safety, quality and image of its products on the market.

The Electronic Listing System (ELS) we propose relieves the human capacity burden on the regulator, as the majority of TNHPs applications can be pre-approved electronically, using few physical resources and considerably less man hours than the current paper-based, dossier procedure (ZACTD).

The ELS will allow for reduced human assessment needs and registration fees, the continuity of business for manufacturers and foster an environment where consumers continue to enjoy choices in products at reasonable prices.

* **That the Parliamentary Portfolio Committee on Health oversee the drafting of regulations that guarantee the public have informed choices when choosing TNHPs.**

**COMMENTRY:**

Informed choice is fundamental to all medicine. The TNHA believe that a growing amount of South African TNHP consumers are intelligent, independent, and capable of making responsible choices with respect to their health. When it involves their own bodies, people have the right to make decisions, provided that such decisions do not cause serious harm to themselves or others.

To ensure successful decision-making, we feel that people must have both knowledge and

authority. We believe that both are essential for individual autonomy, empowerment, and

meaningful health judgements.

For us, individual knowledge and authority have two prerequisites: first, ready availability of relevant and comprehensive information about various options and their implications; second, accountability on the part of regulators which make decisions about the products and the practitioners who use the products in practice. In relation to TNHPs, consumers need access to information from the beginning to the end in order to understand what they are and which ones are appropriate for health.

LABELING

To this end, appropriate labelling regulations for TNHPs must contain responsible health claims, appropriate warnings and safe daily dosage recommendations. Consumers should also be provided with a time period on the label where if the health condition does not diminish or reverse, they should seek professional advice from an appropriately trained health practitioner.

PUBLIC WEBSITE

The SAHPRA should also make information on all individual approved substances and authorised products listed on the ELS available on website, and in layman’s language which is understandable to the man of the street.. Search results should contain the labelling information listed above,, so that consumers can make informed choices before committing to purchasing TNHPs.

* **That the Portfolio Committee on Health allow for a fair and reasonable transition period for the TNHPs to conform to the Electronic Listing System.**

**COMMENTRY:**

Because of the wide scope of the ELS and the time period envisaged to establish the structures required in setting up a Directorate of Traditional and Natural Health Products, this new regulatory system cannot be accomplished overnight. We thus suggest that the existing regulations for Complementary Medicines be rescinded (repealed) and current enforcement policies regarding TNHPs put on hold until the framework and structure is in place.

The public must continue to be protected from unsafe products, while industry must be in a position to market their products while the new framework is implemented.

In addition, there will be a need to appoint an interim transition team for say two years. This team would be responsible for ensuring that the steps required for establishing this new framework be undertaken in a timeous manner. This team should consist of experts in the field on TNHPs and with the assistance of appropriate personnel from the Department in advisory capacities.



**African Traditional Medicines and SAHPRA**

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**Presented by: Phephsile Maseko**(Executive Committee Member: TNHA)
(National Coordinator: Traditional Healers Organization)

**PREAMBLE**

In response to the call for input on the Medicines and Related Substances Amendment Bill (Bill 6 of 2014), the Traditional Healers Organisation (THO) has work shopped its view and proposals based on:

* National Reference Centre for African Traditional Medicines - A South African Model (2010),
* The World Health Organisation (WHO) Traditional Medicine Strategy (2014 - 2023),
* The Traditional Health Practitioner’s Act (Act 22 of 2007),
* The Medical Schemes Act and its Regulations (Act 131 of 1998),
* The National Health Act (Act 61 of 2003),
* The National Health Charter (2011),
* The current BB BEE Charters,
* The Pharmacy Act (Act 53 of 1974),
* Health Professions Act (Act 56 of 1974),
* The Children’s Act (Act 38 of 2005),
* The Medicines and Related Substances Act (Act 101 of 1965), and
* This Medicines and Related Substances Amendment Bill (Bill 6 of 2014).
* The THO formed an alliance with the Traditional and Natural Health Alliance last year in recognition of our shared interests and vision for traditional and natural health.

**BACKGROUND**

Having studied the Amendment Bill, our organisation would first like to commend the efforts of this Parliament in endeavouring to create equality in medical practice in the Republic. The Act we are amending, which was drafted to control allopathic (pharmaceutical) drugs such as thalidomide, comes from the dark era of apartheid, the same era that proposed the Medicines Control Council (MCC), an institution that lacked fairness, respect for dignity of Africans, the right to choice, right to information, right to cultural, linguistic and religious practice and treatment with dignity and freedom of association.

This body was implemented to control allopathic (pharmaceutical) drugs and its manufacturers – ‘Big Pharma’ - as opposed to all forms of medicines consumed by our people. In seeking redressing for this historical injustice, the Traditional Healers Organisation (THO) feels that we must at all costs avoid replacing the MCC with a similar monster.

This Bill and its resulting new structure, the SAHPRA, must demonstrate transformation and an understanding of the existence of all healing systems as used by our people and their respect their autonomous status. Importantly, this new structure must open up the sovereign right of individual South Africans to choose their health system and medicines of their choice.

Consequently, we note with displeasure that a meeting held on the 15th of March 2012, only a group of 12 previously advantaged institutions (pharmaceutical drug affiliated groups) were invited to make presentations on this new body, and thereby unconstitutionally ignoring the interest of about 72 percent of South Africans that consume African Traditional Medicines (refer to page 19 of the Medicine and Related Substances Amendment Bill (Bill 6 of 2014).

To us this demonstrates how unfairly biomedical bias has entrenched itself within the structures of our government.

Our understanding is that this proposed Act should include a new, separate Directorate under SAHPRA to regulate African Traditional Medicines. This authority must be made up of specialists within our sector and accountable to the public and practitioners.

We are therefore of the view that for redress to happen, such an authority must account to the public (through their representatives in government) to avoid a master servant relationship with the allopathic (pharmaceutical) regulatory body.

What is confusing is that there is not much difference between this newly proposed regulatory body and the previous problematic MCC, at least in principle.

**COMPOSITION OF THE SAHPRA BOARD**

• Section 2(C) of the Bill establishes the SAHPRA board. However, what is not clear is whether this new body will have a Registrar. Or perhaps, the duties of the registrar will be subsumed by the new Chief Executive Officer. Our humble view is that this is problematic as the Registrar was previously responsible for registering medicines and without this office, this essential job will be lost in the office of the CEO who in the main is a political figure charged with the responsibility of overall leadership of the administrative arm of the board.

• We contend strongly that the new SAHPRA board must retain a Registrar who must, however, not be a pharmacist but a person with a greater understanding of all medicine sciences who can therefore act neutral at all times. The board itself continues to affirm allopathic medical system as the only and best medical model/system. This is because 85 percent of the people to be appointed are pro west and the allopathic medicine. A separate regulatory board for ATMs’ should have autonomy to ensure that all ATMs’ value-chain phases are represented. The appointment of regulatory committees should be comprised of experts who have a proven track record on developing ATMs – as a country, we can go as far as recruiting international experts. This is the only way ATMs will be fully supported from the regulatory perspective.

• The organisation is of the view that clinical trials and research methodologies should demonstrate an understanding of the uniqueness of African Traditional Medicine and its application. To save government resources, research must appreciate that some plants have already gone through vigorous investigation and trials and should be uplifted to monographs stage. When conducting African Traditional Medicine (ATM) trials we must look to the empirical evidence, disciplines and research methodology without undermining ATM development. The same would go for Complementary Medicine (CAMs). We must hasten to add that we are alive to the fallibility of Allopathic Scientific Research as evidenced by the recent-years contrasting strong oppositional views amongst ‘some of the world's great scientists’ about what a healthy diet is.

• The Traditional Health Practitioners Act No. 22/2007 anticipates the establishment of regulations to affirm the latter. This begs the question therefore; how will these regulations anticipated by the THP Act find expression within SAHPRA?

**SAHPRA Authority Functionaries**

• If parliament is unable to disassociate African Traditional Medicine from other healing systems we believe it should at least design the authority in this way;

1. At the political level we expect to have SAHPRA executive which will be responsible for political directives and total leadership of all the healing systems. Such a body will be represented by all the key industry executives from the sub committees.
2. At the administrative level the THO is of the view that every industry must have its own executive committee with experts that reflect that industry’s interest. Such a sub-committee will be responsible for performing all administrative functions including registration of industry medicines in liaising with industry Councils.

**General Comments**

The following are some of our inputs to the amendment Bill.

Definitions:

1. Section 1: Include ‘African Traditional Medicine’ on definitions. (Refer to THP Act). Definitions 1: “An African healing system utilised or administered to human beings or animals to diagnose and treat/manage diseases, prevent or reverse a disease state and to maintain a good health or good look and (b) used for sanitation (insecticides)”.

2. Definition 2: Traditional Medicine means an object or substance used in Traditional Health Practice for—(a) The diagnosis, treatment or prevention of a physical or mental illness; or (b) any curative or therapeutic purpose, including the maintenance or restoration of physical or mental health or wellbeing in human beings but does not include a dependant—producing or dangerous substance or drug. And (C) is used in accordance with the practice of the professions regulated under the Traditional Health Practitioners Act 22/2007.

**General Comments on Complementary Medicine**

2. Section 1 (d): Replace with WHO definition.

3. Section 2B: Insert "as long as it does not undermine our sovereignty

4. Section 2C (2A): Board too skewed in favour of allopatic medicine. ...Clinical trials should be considerate of the history, disciplines and research methodology of both ATM and CAMs....Insert ATM and CAMs on the group of experts

5. Section 16C: Insert the board will have to consult with the relevant expert committee