Welcome to our first newsletter of 2017. Some of you are probably wondering what happened to our January edition. The reason for us holding back first edition for the year was in order to report back on important events which tied us up in the first weeks back in office. **This year is going to be a ‘make or break’ year for the Complementary Medicines sector, as well as for African Traditional Medicines in South Africa.** There are three new pieces of legislation in the pipeline which are being steamrolled by our government, and threaten to restrict the public’s access to traditional and natural health practices and products.

First there is the Protection, Promotion, Development and Management of Indigenous Knowledge Systems Bill (Bill 6 of 2016), which threatens the livelihoods of thousands of African traditional healers, and can lead to the expropriation of indigenous traditional medicines by the pharmaceutical and biotechnology sectors with the help of government.

Secondly, government intends simultaneously promulgating two Medicines and Related Substance Amendment Acts (Act, 14 of 2015 and Act, 72 of 2008) to facilitate the dismantling of the Medicines Control Council, and to establish a semi-private drug regulatory institution called the South African Health Products Regulatory Agency (SAHPRA). The SAHPRA has been described as similar in model to the U.S. Food and Drug Administration (FDA). It is intended that this new agency will regulate all complementary medicines, health supplements and skincare products containing schedules substances (pretty much everything), despite there being no enabling clause in the legislation to do so.

Thirdly, the Traditional Health Practitioners Act (Act 22 of 2007) has been earmarked by government for major amendments this year. Despite the Act having been signed into law sixteen years ago, a permanent Council has not been appointed and there is no Council House or mechanism for traditional healers to register as Traditional Health Practitioners. Traditional healers and their associations are intensifying their campaigns to keep government to its promises in recognising healers as health practitioners. This year we intend digging in our heels as an organisation, and will be following a far more vigorous approach to protect the public’s constitutional right to choose the healthcare modalities of their choice, including non-drug therapies.

**WE NEED YOUR SUPPORT TO DEFEND YOU AND YOUR BUSINESS THIS YEAR**

In order for the TNHA to battle on and to lobby for more appropriate regulatory systems for natural health practitioners and traditional and natural health products, **WE NEED YOUR SUPPORT.** To safeguard your right, and the rights of future generations to natural health modalities, **WE NEED YOUR SUPPORT.** This year will require all stakeholders, including manufacturers, retailers, practitioners and the public to join the TNHA as members, so we can help you. There are intended legal challenges we need to launch this year which must be adequately funded.

If your company, practice or retail shop is not a member of the TNHA you are vulnerable to harassment and prosecution. You are not protected. Without your support in 2017, the TNHA, YOUR ONLY VOICE will soon be lost, along with your businesses and future health choices. Show your support by becoming a member, by visiting [www.tnha.co.za](http://www.tnha.co.za)

**Anthony Rees**  
(National Chairman)
LETTER TO THE EDITOR

I attended Parliament on 26 January 2017 during the public hearings held with regards to the Indigenous Knowledge Systems Bill. I attended as a member and supporter of the Traditional and Natural Health Alliance. I also saw this as an opportunity to first hand take part in our democratic system other than just going to cast my vote.

At first I was overawed with the history and tradition that the buildings exuded, and the fact that history was made there and was being added to every day. This feeling was soon replaced with disappointment at the obvious disconnect that was evident between the real world and those that strode those halls, their arrogance and sense of self-importance only exceeded by their obviously inflated salaries when judged by the trappings of wealth that were flashed around.

Once the work began in the Old Assembly Hall, the attitude of arrogance and disinterest from the chosen committee members was even more evident. Wait, here I must mention ONE exception, Nazier Paulsen from the EFF. Despite indicating his relative lack of knowledge with regards to matters of the IKS Bill in a previous statement, Mr Paulsen was the only member that seemed to have hit the books, asking questions that were both highly relevant and indicative of his actual interest and understanding of the subject matter.

In contrast, the other members seemed disinterested, just going through the motions to justify their salaries, with Juanita Terblanche of the DA more interested in her laptop than the proceedings. And Mr Koornhof of the ANC that was Chair for the morning session? Well, what can I say? Disdain for the people, or at least those that indicated their opposition to the IKS Bill?

Basically everybody in opposition was allocated to the 3rd day of oral representation intermixed with some unscheduled presentations that I still fail to find relevant to the subject matter. Perhaps a bit of misdirection? Those in full or partial support were scheduled for days 1 and 2, with each having his allotted 50 minutes. Those on the 3rd day? Not so much.

25 Minutes to cram a prepared 50 minute presentation into allows for little, if any, of the message to fall on the ears of those present. If it was not for the questions asked by Mr Paulsen, most of the TNHA message would have been diluted due to the new time constraints.

What was extremely disappointing to me was the lack of representation of those that would most be affected if this Bill should become law. There were a few representatives of what would classically be described as Indigenous people representing their cultural knowledge, but the fact of the matter is that this Bill describes any and all local knowledge, including that from European ancestry. So everything from that self-developed game played by stock herders, to ouma’s new doily pattern, to that magic herb you have growing in the window for stomach aches is covered, and will become the property of the government if not claimed. And the most obvious sector that was missing was that of the small company manufacturing natural products from proprietary and unpatentable recipes.

In order to stay updated with any current progress on these oral representations, and to read the transcripts of that which I could not attend, I would check on https://pmg.org.za/committee/23/ on a daily basis. What I found surprising is that the minutes of the 1st and 2nd sessions were published on the parliamentary website. The 3rd day with the representations made by people opposing the Bill? STILL WAITING after 3 weeks.

I would not be surprised if the eventual final day transcript is never published in order to state that there was NO opposition to the Bill.

In my opinion these public hearings were just instituted to satisfy legal conditions for this Bill to be approved, and in no way will our voices be counted in the final decisions. From the official transcripts and the atmosphere in the hearings, the decision has already been made.

Ronald Gibson
Western Cape

If you would like to send us your feedback or opinions on any topical issues, free to write to our Editor at contact@tnha.co.za
THE INDIGENOUS KNOWLEDGE SYSTEMS BILL UPDATE

On the 24th of January the TNHA submitted written comments to the Parliamentary Portfolio Committee on Science and Technology on the Protection, Promotion, Development and Management of Indigenous Knowledge Systems Bill (Bill 6 of 2016). On the 26th our National Chairman Anthony Rees and Nomsi Madlamini of the Traditional Doctors Union (TNHA alliance partner) presented oral submissions to the Committee (right).

This bill in its current form, threatens the on-going practice of African Traditional Medicine by an estimated 200,000 traditional healers by restricting their accreditation criteria for registration to practice legally, and could potentially create a new government bureaucracy called the National Indigenous Knowledge Systems Office (NIKSO) under the Department of Science and Technology.

The NIKSO, if established by law, will technically own all historical indigenous plant usage rights for either medicinal or biotechnology use in South Africa, and create a mechanism for it sell off these novel plant uses to the highest bidding pharmaceutical and the biotechnology industries currently lining up at the back door.

We do not believe the State can be the regulator, arbitrator, trustee and licensee of the majority of indigenous knowledge and plant-based usage rights. It has a direct conflict of interest, and prejudices indigenous communities who should be the beneficiaries of benefit-sharing when commercial interests exploit our natural plant and knowledge resources.

You can download a copy of our written submission to the Parliamentary Portfolio Committee on Science & Technology HERE.

For further background information on our analysis of the Bill, read our August 2016 article titled PROTECTION OR ETHNOPIRACY? HERE.

NEW DRAFT GENERAL REGULATIONS FOR MEDICINES

The long awaited draft General Regulations which will accompany the new Medicines and Related Substances Amendment Act towards mid-year this year, and which will create the legal mechanism to launch the new South African Health Products Regulatory Authority (SAHPRA), were gazetted for comment by the Department of Health on the 27th of January.

The SAHPRA will replace the Medicines Control Council (MCC) which has existed for over half a century. The SAHPRA will no longer fall directly under the National Department of Health’s control and will become a Section 3(A) public entity in terms of the Public Finance Management Act (Act 1 of 1999).

Section 3(A) Companies are governed by a Board just like any other private listed company. The SAHPRA will need to impose licence fees over the economic sector it regulates in order to cover its operational costs and expansion. They will also be responsible for all their own legal costs, and can no longer use the State Law Advisers and attorneys to defend or to prosecute cases they become involved in.

As a transitional arrangement the SAHPRA will have to generate 70% of the funds required for its operations (through company licencing and product registration fees), and government will supplement the 30% balance.
The MCC had a limited in-house staff of approximately 100 people up until 2015 and has relied on various expert committees under the MCC Council and part-time experts from academic institutions, including medical doctors, pharmacists, pharmacologists, veterinarians, agriculturalists, and lawyers to do its job mandated by the Medicines and Related Substances Act. It will now have to attract experts from the private and academic sector as permanent employees.

According to the current MCC Registrar of Medicines, the MCC hired 52 new staff members over the last two years and intends employing a further 30 staff members when the SAHPRA is established. This will bring the staff complement to just over 180 full-time members.

The MCC has a massive historical medicine registration backlog and the pace of assessing medicines for registration has become a major crisis for both the pharmaceutical and complementary medicine industry. It currently receives between 1,200 and 1,600 new product applications a year.

Complaints from the pharmaceutical industry and even patient organisations compelled previous Health Minister Manto Tshabalala Msimang to launch an investigation into the workings of the MCC in 2006, which revealed in 2008 that the reasons for the registration backlogs are related to poor infrastructure, insufficiently trained staff, high staff turnover and lack of financial resources. Little has changed in the last ten years, and the queue of products waiting to be authorised for sale is getting longer.

The MCC has an estimated backlog of 1,200 novel medicines (new chemical entities), 2,900 generic medicines, 9,500 grandfathered medicines which have never been assessed for their safety or effectiveness despite being allowed to be sold to the public (going all the way back to the 1970’s), and an additional 120,000 complementary medicines and health supplements on record requiring registration applications to be in by the end of 2019.

That’s a potential 133,000 products awaiting assessment for their safety, quality and efficacy. In that last 50 years since the MCC begun registering medicines +/- 13,000 medicines have been fully assessed and registered.

In April last year, the MCC published a list of six (6) complementary medicines in the government gazette which have been given the ‘Right of Sale’, pending their further assessment towards registration. To date, none of these six products have been registered and the MCC is remaining tight lipped over their application status, or how many other applications they have received since 2014 when the registration of complementary medicines begun.

Currently the MCC can only register approximately 120 new medicines a year. Despite intending to increase the SAHPRA workforce by 30 staff, the current registration backlogs will take generations to clear.

When the SAHPRA is established it will also have the added burden of assessing and registering thousands of medical devices which have never been registered before, as well as all skincare products containing ‘scheduled substances’.

We already know that the MCC wants all natural health product ingredients to be scheduled.

There are potentially thousands of natural and synthetic skincare products which may have to meet strict registration criteria as medicines in the near future.
THE DEFINITION OF A COMPLEMENTARY MEDICINE HAS CHANGED ONCE AGAIN

It seems the MCC can’t settle on a legal definition for ‘complementary medicine’.

Already we have seen five different definitions in government gazettes since 2002. Once again the MCC is making the erroneous inclusion of the ‘complementary medicine’ definition in the sub-legislation (regulations) instead of the principal Act itself.

Complementary medicines and health supplements are NOT pharmaceutical drugs which were defined in the Medicines Act fifty years ago, without amendment. They are a totally new class of health products, requiring their own definition in the Act. If there are already separate statutory health councils for the regulation of allopathic medicine and complementary medicine practitioners, surely, the same separations should exist in the Medicines and Related Substances Act. The MCC cannot legislate by regulation!

The new ‘complementary medicine’ definition in the draft General Regulations reads:

“complementary medicine” means any substance or mixture of substances that –

(a) originates from plants, fungi, algae, seaweeds, lichens, minerals, animals, or other substances as determined by the authority;

(b) is used or purported to be suitable for use or manufactured of sold for use –
   (i) in maintaining, complementing, or assisting the physical or mental state; or
   (ii) to diagnose, treat, mitigate modify, alleviate, or prevent disease or illness or the symptoms or signs thereof or abnormal physical or mental state,

   of a human or animal; and

(c) is used –
   (i) as a health supplement; or
   (ii) in accordance with those disciplines as determined by the Authority; or

(d) is declared by the Authority, on approval of the Minister by notice in the Gazette, to be subject to registration as a complementary medicine in terms of Section 14.

Health Supplements are a sub-category of ‘complementary medicine’ and are defined as follows:

“health supplement” means any substance, extract or mixture of substances as determined by the Authority, sold in dosage forms used or purported for use in restoring, correcting or modifying and physical or mental state by –

a) complementing health;

b) supplementing the diet; or

c) a nutritional effect

and excludes injectables or substances classified as schedule 1 or higher.

From the proposed definition above, ALL natural health products will be deemed ‘complementary medicines’, or a sub-set of called ‘health supplements’. All these definitions are excessively broad and may even include foods marketed as ‘healthy’ or to promote wellness.

By deleting the previous references to complementary used by the disciplines of the Allied Health Professions Council of South Africa, and replacing it with any disciplines determined by the Authority (SAHPRA) in future, manufactured African Traditional Medicines will be ensnared into the definition of complementary medicines. The SAHPRA, in consultation with the Minister, may even declare skin products or super foods containing natural ingredients ‘complementary medicines’, if they are ‘purported’ to have health-giving properties.

# The word ‘purport’ in the Mirriam-Webster Dictionary means – “meaning conveyed, professed, or implied”.

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5 | TNHA February 2017 Newsletter
WHERE ARE THE NEW COMPLEMENTARY MEDICINES REGULATIONS?

There has been no sign of the proposed amendments to the complementary medicines regulations promised in July last year. We suspect the delay is due to the Medicines Control Council being unable to decide whether the existing regulations which came into being in November 2013 should be scrapped or redrafted from scratch. We have been reliably informed that applications received for complementary medicines thus far, have been placed on ice, pending a decision from the Department of Health and Council on how to proceed.

The fact remains that the current regulatory regime for complementary medicines has been mired in controversy, legal entanglements and a lack of coordination on behalf of the Medicines Control Council since inception.

We have learned that the current assessment procedures and supportive documentation required to register complementary medicines are incompatible with the current system in place to assess pharmaceutical drugs, leaving assessors unable to motivate products for registration.

Most natural products are combination products, and not single chemical drugs that can be tested and re-tested to have uniform results.

Natural health products are complex by nature. Stability tests and tests for marker ingredients in herbal products are highly variable due to them being organic and being harvested at different times of the year and from different regions with different soils. The tools and tests available to test drugs are not appropriate from many complementary medicines.

The majority of manufacturers and importers have also boycotted and rejected the entire process thus far, making it difficult for the Medicines Control Council to force anyone to comply. In the past the TNHA have warned the MCC that if they enforce any of the existing regulations on any of our members, we come to their defence and vigorously oppose their actions on constitutional, legal and procedural grounds.

TNHA CONSIDERING LEGAL ACTIONS

WE DEMAND THE REPEAL OF ALL COMPLEMENTARY MEDICINE REGULATIONS AND CALL-UP NOTICES

We will soon be serving official notice on the Minister of Health, Department of Health and Medicines Control Council, demanding the repeal of ALL complementary medicine regulations going back to 2002. The current regulations are inappropriate and unlawful.

WE WILL SHUT DOWN THE SAHPRA BY HAVING ACT 14 OF 2015 DECLARED INVALID

We are also currently requesting the nine provincial legislatures and National Council of Provinces to furnish us with the dates and times of public hearings held on the Medicines and Related substances Amendment Bill (Bill 6 of 2014), that was signed into law in January 2016, but not yet promulgated. We have also requested the schedule of Public Notices placed in the media preceding these meetings, along with copies of the ads. This is being done in terms of the Promotion of Access to Information Act (Act 2 of 2000).

We have already established that in some provinces, public hearings on this Bill were first advertised just two working days before the public hearings, and that these hearings were held in obscure locations. Once we have completed our research on this legislative error, we intend petitioning the President to not promulgate the Act 14 of 2015, and
effectively stop the establishment of the SAHPRA. If this fails, we will petition the Constitutional Court directly, to declare the Act invalid, due to lack of public engagement. In recent years other national legislation has been struck down by the president and Constitutional Court for the very same issue.

2017 MEMBERSHIPS ARE DUE

JOIN THE TNHA IN TWO EASY STEPS

1. Fill in and submit the online Membership Application Form found at: www.naturalhealthalliance.co.za/membership.htm

2. Pay your annual membership fee and send us proof of payment to our membership coordinator at: membership@naturalhealthalliance.co.za

2017 MEMBERSHIP FEES

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Trilogy contains the 3 most highly recommended supplements together in one package.

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- **20 Billion probiotics** from 12 strains.
- **1000mg Omega 3** fish oil (100% mercury free) providing 360mg EPA and 270mg DHA in triglyceride form. The oil is sourced from anchovies and is molecularly distilled for purity and potency.

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- Two formulas: MEN (added chromium), WOMEN (added iron)
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