

TNHA Newsletter

Traditional & Natural Health Alliance



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September 2016 Edition

From the Editor

We're moving forward steadily, and we're discovering what we always suspected: the 2013 regulations for natural products are flawed in more ways than one. We have long known that these regulations are unfair, impossible to implement and drawn up with no understanding of the way natural products are formulated or used. Whether that was deliberate or not, it has placed our right to healthcare of our choice in jeopardy.

That is unacceptable to the millions who use and rely on these products for our health and wellbeing.

Apart from being unfair, the regulations are unlawful in our opinion.

Our chairman Anthony Rees has been putting his investigative skills to good use, and has come up with some startling finds. Read his report this month, and his conclusions, and then join us as we launch our membership drive to gather our supporters into the TNHA family.

We have to stand together in this if we are to challenge the regulations in a meaningful way, so please sign up and get your friends, your family, your practitioners, your clients, your health shop – whoever! – to do so too.

Thanks in advance. And many thanks to those who have supported us thus far, we appreciate it.

Jeanne Viall



THE COMPLEMENTARY MEDICINE REGULATIONS MUST FALL!

Anthony Rees (TNHA Chairman)



In last month's newsletter we announced that the long awaited draft regulatory amendments for natural health products had been gazetted on the 25th of July, and that we would provide you with our official comments on them.

After reading them closely we have concluded that the Medicines Control Council (MCC) have not listened to any of the comments raised by stakeholders over the past two and a half years, and that they have again attempted to widen their net to capture the CAM sector.

Despite many warnings from the TNHA and other organizations to the MCC about their unconstitutional, unlawful and irrational conduct to date, they have forged ahead with their pharmaceutical expropriation of the natural health product sector and continue to threaten the public's access to the majority of safe, affordable and efficacious natural health products.

LITTLE OR NO PROGRESS

In November 2013, the MCC set an ambitious five-year Road Map for the registration of natural health products. They expect applications for registration for all natural health products to be lodged by November 2019.

We are now almost three years into this five-year registration window period and the MCC have only considered 6 (six) out of the 120 000 natural health products audited by them prior to the regulations coming into effect.

It is clear to us that the drug evaluation regime imposed on these products is incompatible with natural health products, and cannot continue without a scrapping of the current regulations.

What is needed is going back to the drawing board with an open mind and evaluating them with the health supporting paradigm with which they are formulated and used.

MCC INSIDERS SAY CAM REGULATIONS ARE IRRATIONAL AND UNLAWFUL

Over the past month the TNHA consulted with a former senior official of the MCC and a current medicines evaluator dealing with CAM applications before Council (whistle blowers names withheld). Both have serious doubts about whether the MCC has the capacity or legal jurisdiction over this sector.

Both have indicated their willingness to testify in any legal application to have the regulations repealed.

NO REGULATORY IMPACT ASSESSMENTS CONDUCTED BEFORE THE CAM REGULATIONS

On the July 20 we wrote to the MCC and requested copies of the Regulatory Impact Assessments (RIAs) which the MCC and the National Department of Health should have commissioned and published prior to the November 2013 CAM regulations.

A week later we received a response from the Registrar of Medicines, Joey Gouws, stating that the MCC had not conducted any Regulatory Impact Assessments. All of the serious legal, procedural and implementation issues we

currently face can be attributed to the MCC and DoH not doing their homework prior to the drafting and passing of the regulations.

Since 2006 all National Departments and organs of state (including the MCC) have been required to conduct comprehensive RIAs for new legislation or regulations based on the input from broad-based consultation and risk assessment to identify potential stumbling blocks in their implementation and enforcement.

In May 2013, the Presidency issued a Proclamation Notice to all government departments specifying the framework in which the RIAs must be conducted. The National Department of Health and MCC have failed to adhere to this administrative imperative prior to passing the CAM regulations.

ILLEGAL IMPORTATION BLOCKADE

We have known for a while now that the Port Health Authorities, which fall under the National Department of Health, have been instructed by the Medicines Control Council not to allow any natural health products into the country without importers producing MBR 20.8 Registry Letters for them issued pursuant to the 22 February 2002 regulatory call-up notice (R.204).

The notice described complementary medicine disciplines which are not the same as those currently listed in the regulations for CAM products.

Furthermore, the MCC were only legally entitled to issue MBR 20.8 Registry Letters for six months after it was gazetted. The MCC ignored the provisions of their own notice and continued to illegally issue MBR 20.8 Registry Letters prior to the 2013 regulations. In this time period approximately 120 000 MBR 20.8 Registry Letters were issued.

Therefore, the withholding of natural health product imports by Port Health Authorities in South Africa without supportive MBR 20.8 Registry Letters is illegal.

The TNHA have called for the immediate withdrawal of this unlawful instruction to Port Health Authorities and for them to release products being held back.

On the August 30 the TNHA raised these issues with the MCC and await their official response.

ALL CAM REGULATIONS GAZETTED SINCE FEB 2002 MUST BE REPEALED

On the August 24 the TNHA officially demanded that the Feb 2002 call-up notice (R.204) be rescinded, and that all regulations for CAM products gazetted after 15 November 2013 (R. 870, R.716 and R.837) be repealed without delay. The MCC and Department of Health have been placed on notice that if they continue to unconstitutionally and unlawfully proceed in the manner they have been for the last fourteen years, they will be challenged.

Read our official call for the repeal of the CAM regulations here:

<http://www.naturalhealthalliance.co.za/Commentson2016CamRegs.pdf>

TNHA MEMBERSHIP ANNOUNCEMENT

WE HAVE LAUNCHED NEW MEMBERSHIP CATEGORIES AND INVITE YOU TO FORMALISE YOUR TNHA MEMBERSHIP

The TNHA is the only broad-based natural health organization in South Africa preparing to legally challenge the current CAM regulations on behalf of the CAM value chain, including the public.

OUR MISSION: To promote access to all health care information, services, treatments and products that people deem beneficial for their own health and survival; to promote an understanding of the laws and factors impacting the right to access; and to promote the health of the people of South Africa.

OUR VISION: A healthy nation, with empowered people, making informed healthcare decisions.

We are currently negotiating with various law firms to spearhead the TNHA's intended legal challenge, and therefore need your support to capacitate ourselves for this next phase, and to raise the funds required to take the appropriate action.

We call on ALL CAM manufacturers, importers, wholesalers, retailers, practitioners and consumers who are affected by the current CAM regulations to support the TNHA by becoming official members in our new membership categories.

We also call on all national associations involved in natural health to become alliance partners of the TNHA so they can keep up to date with regulatory developments which affect their members.

NEW MEMBERSHIP CATEGORIES

From May 2014 until now becoming a member of the TNHA was open to anyone with an interest in natural health. We did not have structured membership categories or levy annual membership fees.

We have done considerable lobbying and education on a shoestring budget derived solely from generous donations and sponsored adverts carried in our newsletters which reach over 24 000 monthly readers.

Our social media platform has reached over 125 000 unique monthly visitors and still growing. (www.facebook.com/naturalhealthalliance)

Because our work has become more proactive and specialised, the time has come to formalise and broaden our membership structures, and intensify our campaigns.

To raise the funds necessary to operate more efficiently we will now be levying affordable annual membership fees.

To this end we are restructuring our organization to be more efficient and responsive to the needs of our members. In order that each sector of the natural health value chain to be represented going forward, we have split the TNHA's membership register into four segments.

MANUFACTURERS

Product Manufacturers
Importers
Wholesalers
Raw Ingredient Suppliers
Direct Selling Companies

RETAILERS

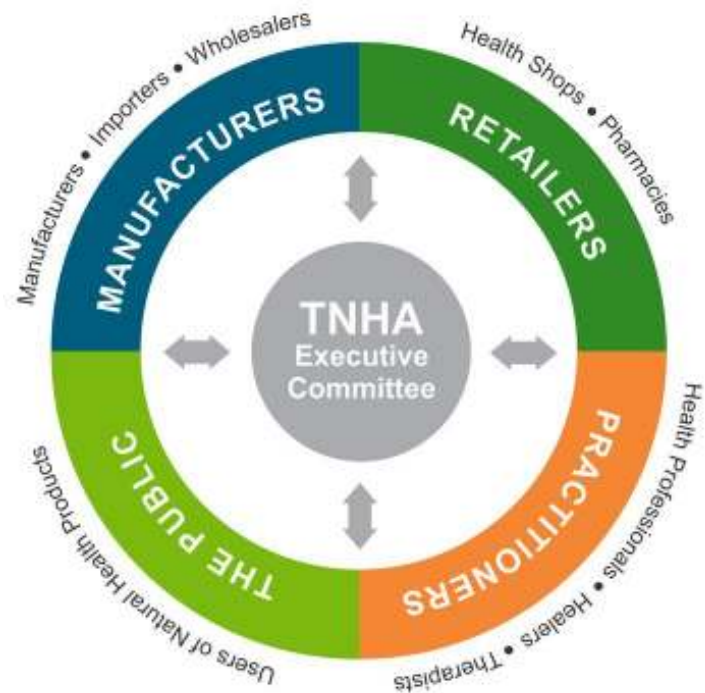
Health Shops
Pharmacies

PRACTITIONERS

Integrative Medical Doctors
Traditional Health Practitioners / Healers
Allied Health Practitioners
Nutritional Therapists

THE PUBLIC

Consumers & Patients who use
natural health products



PLEASE NOTE: We do not accept membership applications from MANUFACTURERS that manufacture Category A medicines (pharmaceutical drugs). Only companies which manufacture or import natural health products exclusively may apply.

Upon receipt of your application forms and the clearance of your annual membership fees, the TNHA will enter you or your company into the appropriate membership category registers and send you a membership certificate which is valid for one calendar year from date of issue.

As official members you will receive invitations to upcoming meetings we intend hosting in the future, and be encouraged to assist us in better understanding your current challenges as we pave the way towards more appropriate regulation of natural health products.

If you have any queries regarding membership call us on 072 377 7598.

JOINING THE TNHA IN TWO EASY STEPS

To join the TNHA in one of the new membership categories please fill in and submit our online application form found at: http://naturalhealthalliance.co.za/Application_Form.htm

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

ANNUAL MEMBERSHIP FEES FOR THE NEW CATEGORIES

MANUFACTURERS

TYPE OF BUSINESS	NUMBER OF PRODUCTS	ANNUAL MEMBERSHIP FEE
SMALL BUSINESS	1 - 10 products	R5 000.00
MEDIUM BUSINESS	11 - 20 products	R7 500.00
LARGE BUSINESS	21 and more products	R10 000.00
WHOLSALERS	All wholesalers	R5000.00

RETAILERS

TYPE OF BUSINESS	ANNUAL MEMBERSHIP FEE
HEALTH STORES AND PHARMACIES (per store)	R1 500.00

PRACTITIONERS

TYPE OF BUSINESS	ANNUAL MEMBERSHIP FEE
ALL PRACTITIONERS	R500.00

THE PUBLIC

CONSUMERS	ANNUAL MEMBERSHIP FEE
MEMBERS OF THE PUBLIC	R200.00

OUR BANKING DETAILS

Account name: Natural Health Alliance

Bank: Nedbank

Account Number: 1077025629

Branch Code: 101009

International SWIFT Code: NEDSJJ
