

**The Registrar of Medicines**  
**National Department of Health**  
**Private Bag X828**  
**Pretoria**  
**0001**

By: Post and email [GouwsJ@health.gov.za]

20 January 2015

**CLARIFICATION SOUGHT ON THE REGULATORY STATUS**  
**OF AFRICAN TRADITIONAL MEDICINES**

**Dear Dr Joey Gouws**

The TNHA would like to congratulate you on your appointment as Interim Registrar.

With your many years of experience as Director of Law Enforcement, and being fully versed in the Medicines and Related substances Act (Act 101 of 1965), plus its regulations, our organization seeks clarity from you on the regulatory status of marketed 'African Traditional Medicines' in the Republic on behalf of our seventy thousand (70,000) African Traditional Health Practitioner alliance partners.

As you are aware, 'Category E' medicines, or Traditional African Medicines, were earmarked for regulation under the Act almost a decade ago. Recommendations to Council were to be made by an expert sub-committee of the Medicines Control Council (MCC), namely the African Traditional Medicines Committee. <sup>[1]</sup>

It appears this committee is still active, as evidenced in the Department of Health's recent presentation to the Parliamentary Portfolio Committee on Health on the 3<sup>rd</sup> of September 2014. <sup>[2]</sup> In this presentation, motivations for

the current Medicines and Related Substances Amendment Bill (Bill 6 of 2014) included 'poorly regulated' and unregulated products, *vis-à-vis* 'Complementary Medicines' and 'African Traditional Medicines'.<sup>[2]</sup>

According to the National Reference Centre for African Traditional Medicines, this expert committee's scope of work has been to advise the MCC on the proposed regulation, registration and control of finished traditional medicines.<sup>[3]</sup>

Various non-indigenous traditional medicines in the form of traditional Chinese Medicines, traditional Western Herbal Medicines, traditional Ayurvedic Medicines and traditional Unani-Tibb Medicines were recently categorised as 'Category D', Complementary Medicines in terms of Regulatory Notice R. 870, published on the 15<sup>th</sup> of November 2013. As a result, a phased registration period has been imposed which ends in 2019.

I recently had a chat with Ms. Precious Matsoso, the Director General of the Department of Health, and previous Registrar of Medicines. She indicated that indigenous African Traditional Medicines were far removed from Complementary Medicines, and that the World Health Organization's current Traditional Medicines Strategy makes a distinction between indigenous Traditional Medicines and non-indigenous Complementary Medicines. I looked this up and confirmed this fact.<sup>[4]</sup> She alluded to the SA government adopting the WHO strategy in this regard.

I asked her about the intended regulatory approach to mass produced African Traditional Medicines, now competing directly in with 'Category A' and 'Category D' medicines in health stores, pharmacies, supermarkets and more recently, online. As you are aware, over the last few years there has been significant growth in this increasingly formalised sector of indigenous African Traditional Medicines in the form of herbs and mixtures thereof. These products are bottled, labelled and sold in the retail environment sporting a myriad of health claims and in many cases indistinguishable from complementary medicines and pharmaceutical drugs. Without prejudice and wishing to bring undue pressure on any companies, I attach a few photo examples of the hundreds of African Traditional Medicines we are cataloguing at the end of this letter.

Ms. Matsoso either did not understand my question, or merely attempted to confuse the issue by intimating that African Traditional Medicines cannot be regulated in the same fashion as Complementary Medicines because they are formulated and compounded on an individual basis by Traditional Health Practitioners for their individual patients. What Ms. Precious Matsoso did not address in my question is the commercialisation of African Traditional Medicines sold in multiple units in the retail sector, and in modern medicine delivery formats such as tinctures, capsules, pills etc.

Because of the apparent lack of clarity on the legal status of these 'African Traditional Medicines', would you be kind enough to answer the following:

1. Under what legal category do indigenous African Traditional Medicines currently fall, which are:
  - (a) sold with health claims (or inferred claims) in mass by manufacturers?;
  - (b) sold in modern formats? (e.g. capsules, pills, tinctures etc.); and / or

(c) sold among other 'Category D' and 'Category A' products?

2. When did the 'African Traditional Medicines Committee' of the Medicines Control Council last meet?
3. Who are the persons currently appointed to the 'African Traditional Medicines Committee', and what are their qualifications and vested interests in the manufacture and sale of medicines (if any)?
4. Does the Medicines Control Council still intend to bring under its control, the quality, safety and efficacy of 'African Traditional Medicines'?
5. Has the Medicines Control Council begun collating data on the risks (if any) of 'African Traditional Medicines' sold in South Africa?

I look forward to your timeous response, as we will be presenting our follow-up submission to the Parliamentary Portfolio Committee on Health with reference to the Medicines and Related substances Amendment Act in the coming weeks.

Yours sincerely



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**Anthony Rees**

General Secretary: TNHA

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The Hon. Minister of Health

Members of the Parliamentary Portfolio Committee on Health

References:

1. Mayeng BI. Linking African Traditional Medicines with the Medicines Control Council – Workshop on Traditional Medicine and Intellectual Property Rights, July 2011 (slide 4)  
<http://www.nstf.org.za/ShowProperty?nodePath=/NSTF%20Repository/NSTF/files/Workshops/2011/linkingafrican.pdf>
2. Dept of Health - Briefing on the Medicines and Related Substances Amendment Bill, Sep 2014 (slides 11 & 15)  
<http://www.samed.org.za/Filemanager/userfiles/140903medicenesBill6DoHslides.pdf>
3. National Reference Centre for African Traditional Medicines – A South African Model (pg. 18)  
<http://www.sahealthinfo.co.za/traditionalmeds/traditionalpart1.pdf>
4. World Health Organization – WHO Traditional Medicines Strategy: 2014-2023. (pg. 15)  
[http://apps.who.int/iris/bitstream/10665/92455/1/9789241506090\\_eng.pdf?ua=1](http://apps.who.int/iris/bitstream/10665/92455/1/9789241506090_eng.pdf?ua=1)



**PRODUCT NAME:** SUTHERLANDIA  
**MANUFACTURER:** PHYTO NOVA  
**MEDICINE FORMAT:** CAPSULES  
**HEALTH CLAIMS (on label):** NATURAL IMMUNE BOOSTER AND ANTI-OXIDANT.  
**HEALTH CLAIMS (associated marketing materials):** Anti-inflammatory, Reduces Stress, eases joint and muscle pain.



**PRODUCT NAME:** AFRICAN GINGER  
**MANUFACTURER:** PHYTO NOVA  
**MEDICINE FORMAT:** CAPSULES  
**HEALTH CLAIMS (on label):** Symptomatic relief from flu, headaches and sinusitis.  
**HEALTH CLAIMS (associated marketing materials):** Pain of sinusitis.



**PRODUCT NAME:** WARBURGIA  
**MANUFACTURER:** PHYTO NOVA  
**MEDICINE FORMAT:** CAPSULES  
**HEALTH CLAIMS (on label):** Symptomatic Relief of Candida and Cystitis  
**HEALTH CLAIMS (associated marketing materials):** 'Effective for vaginal infections, mouth infections or throat infections.'



**PRODUCT NAME:** NATURAL ANTI-BIOTIC  
**MANUFACTURER:** HERBAL AFRICA  
**MEDICINE FORMAT:** TINCTURE  
**HEALTH CLAIMS (on label):** Treatment of acute ear, nose and throat infections.  
**HEALTH CLAIMS (associated marketing materials):** 'alleviates the effects of insect bites and stings, sores, cuts and infections'



**PRODUCT NAME:** HYPERTENSION FORMULA  
**MANUFACTURER:** HERBAL AFRICA  
**MEDICINE FORMAT:** CAPSULES  
**HEALTH CLAIMS (on label):** Reduce diastolic and systolic blood pressure.  
**HEALTH CLAIMS (associated marketing materials):** Lessens hypertension's debilitating end organ damage. Assists the liver and digestive system. Recommended for diabetes.



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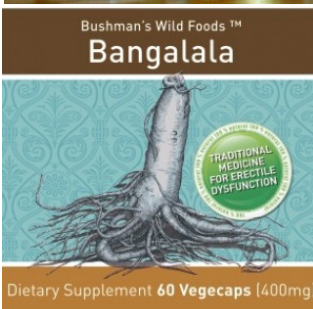
**PRODUCT NAME:** MATEMA  
**MANUFACTURER:** HERBAL AFRICA  
**MEDICINE FORMAT:** TINCTURE  
**HEALTH CLAIMS (on label):** N/A  
**HEALTH CLAIMS (associated marketing materials):** Cancer of the colon, intestine, liver, lung, prostate, breast and skin. Cysts. Tumours.



**PRODUCT NAME:** SCELETIUM 100  
**MANUFACTURER:** AFRICAN BOTANICALS  
**MEDICINE FORMAT:** CAPSULES  
**HEALTH CLAIMS (on label):** N/A  
**HEALTH CLAIMS (associated marketing materials):** Low mood, winter-blues, mood swings, Anxiety, stress, nervous tension, Hot flushes and irritability in menopause, Alcoholic rehabilitation support, Irritability in smoking-cessation, Supports libido.



**PRODUCT NAME:** HYPOXIS - AFRICAN POTATO  
**MANUFACTURER:** MEDICINE FORMAT: LIQUID & CAPSULES  
**HEALTH CLAIMS (on label):** N/A  
**HEALTH CLAIMS (associated marketing materials):** An important breakthrough in the fight against cancer, HIV+, TB, arthritis, reduction of side effects of chemotherapy and radiation.



**PRODUCT NAME:** BANGALALA  
**MANUFACTURER:** BUSHMAN'S WILD FOODS  
**MEDICINE FORMAT:** CAPSULES  
**HEALTH CLAIMS (on label):** N/A  
**HEALTH CLAIMS (associated marketing materials):** For treatment of erectile dysfunction or as a sexual performance enhancer. It improves blood flow to the penis and helps promote stronger and longer lasting erections.



**PRODUCT NAME:** UGAZI – CORRECTIVE FOR WOMEN

**MANUFACTURER:** BEGUM MANUFACTURERS

**MEDICINE FORMAT:** LIQUID

**HEALTH CLAIMS (on label):** N/A

**HEALTH CLAIMS (associated marketing materials):** Helps remedy urinary tract infections, water retention and reduces discharge. Restores the ladies normal bodily state.



**PRODUCT NAME:** UGAZI – PAIN AND FEVER TABLETS

**MANUFACTURER:** BEGUM MANUFACTURERS

**MEDICINE FORMAT:** TABLETS

**HEALTH CLAIMS (on label):** N/A

**HEALTH CLAIMS (associated marketing materials):** To relieve aches and general body pain.



**PRODUCT NAME:** PHILA - DIABETES

**MANUFACTURER:** PHILA HEALTH

**MEDICINE FORMAT:** LIQUID & CAPSULES

**HEALTH CLAIMS (on label):** N/A

**HEALTH CLAIMS (associated marketing materials):** Phila Diabetes will help regulate the sugar levels in your body and alleviate the problems and symptoms that are associated with diabetes.



**PRODUCT NAME:** UVUKAHLALE RELIEF

**MANUFACTURER:** UVUKAHLALE

**MEDICINE FORMAT:** LIQUID

**HEALTH CLAIMS (on label):** For all manner of aches and pains.

**HEALTH CLAIMS (associated marketing materials):** It will assist with reducing swelling and inflammation, help reduce mental stress and anxiety.



**PRODUCT NAME:** PHAKISANI

**MANUFACTURER:** UVUKAHLALE

**MEDICINE FORMAT:** LIQUID

**HEALTH CLAIMS (on label):** Phakisani Helps The Phagocytes To Engulf Any Virus Related To HIV/AIDS. It Is An Immune Tonic And Alleviates Burning Urine.

**HEALTH CLAIMS (associated marketing materials):** As above.



**PRODUCT NAME:** DIABETIC WELL BEING

**MANUFACTURER:** TOUCH LIFE

**MEDICINE FORMAT:** LIQUID

**HEALTH CLAIMS (on label):**

**HEALTH CLAIMS (associated marketing materials):** Treats: Thirst, Excess Urine Sleepless Nights Weight Loss Poor Vision Cold Legs/Hands Weakness Tiredness Poor Concentration Night Sweats



**PRODUCT NAME:** THUSO'S CHOICE

**MANUFACTURER:** PHILA HEALTH

**MEDICINE FORMAT:** LIQUID

**HEALTH CLAIMS (on label):** N/A

**HEALTH CLAIMS (associated marketing materials):** Immune Boosting, Constipation, Swollen Glands, Liver Problems, Stomach Ulcers, Cancer, Kidney Problems, Diabetes, High Blood Pressure, Rheumatism, Asthma, Boils, Chronic Bronchitis, Wasting In AIDS, Swollen Feet