TNHA
Traditional & Natural Health Alliance
Protecting, educating and empowering the natural health industry and consumers across South Africa.

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COMMENTS ON THE DRAFT GENERAL REGULATIONS AMENDMENT (R. 3258), IN TERMS OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965

Monday, July 24, 2023

The Traditional & Natural Health Alliance (TNHA) hereby submits its comments on the draft amendments gazetted on the 24th of March 2023, regarding the General Regulations for Medicine of 2017 (Notice No. 859 of 25 August 2017), under the Medicines and Related Substances Act (Act No. 101 of 1965).

The TNHA is a prominent voluntary association that represents a diverse group of stakeholders in the natural health products sector, including manufacturers, importers, distributors, retailers, practitioners, and consumers.

Established in 2013, our association covers the entire value chain of the natural health product sector, providing a comprehensive representation of the industry.

In addition to our role as the TNHA, we proudly serve as founding members of the Alliance of Natural Health Products [South Africa] (the “ANHP”).

We sincerely appreciate the extension of the lawful comment period from one month, as initially stipulated, to three months, in line with the provisions of section 35(2) of the Act. This extension has allowed us ample time to conduct a thorough evaluation and provide feedback on the proposed amendments.

THE CURRENT STATUS OF THE REGULATIONS PERTAINING TO COMPLEMENTARY MEDICINES (CAMs)

1. There are two important recent and specific judgments related to the subject of complementary medicine that will be discussed below: the Kubushi J (*Alliance of Natural Health Products in South Africa v Minister of Health and Another* (11203/2018) [2020] ZAGPPHC 731), and the Supreme Court of Appeal ("the SCA") (*Minister of Health and Another v Alliance of Natural Health Products (South Africa)* (256/2021) [2022] ZASCA 49; 2022 (5) SA 392 (SCA)).

2. Kubushi J held as follows in paragraphs [3] and [4] of her order:

> 3. The General Regulations promulgated on 25 August 2017 under General Notice 859 in Government 41064 are declared unlawful to the extent that they apply to 'complementary medicines' and 'health supplements' that are not 'medicines' or 'Scheduled substances' as defined in section 1 of the Medicines and Related Substances Act, No. 101 of 1965.
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> b4. The declaration of invalidity is suspended for a period of twelve (12) months to allow the South African Health Products Regulatory Authority an opportunity to correct the defect.

3. The SCA stated the following in its judgment:

> [11] The court a quo rejected the argument that the application constituted an impermissible abstract challenge and found for the Alliance on the *ultra vires* ground. In the result it found it unnecessary to consider the other review grounds. It considered that the partial declaration of invalidity in respect of the regulations should be suspended for a period of 12 months and made the following order on the merits:

4. Furthermore, the SCA stated the following in paragraph [26]:

> [26] In sum, the regulations purport to regulate substantial numbers of substances that are not medicines under the Act. The court a quo correctly concluded that, to this extent, the regulations are *ultra vires* and invalid. Paragraph 3 of its order cannot be faulted. It follows that the appeal must fail on the *ultra vires* ground and that it is unnecessary to make a final determination of the other review grounds.

5. The SCA however, ordered the Minister of Health, and not SAHPRA, to remedy the defect, as it was put by Kubushi J.

6. Section 35(2) of the Medicines and Related Substances Act 101 of 1965 states that:

> (2) The Minister shall, not less than three months before any regulation is made under subsection (1), cause the text of such regulation to be published in the *Gazette*, together with a notice declaring his or her intention to make that regulation and inviting interested persons to furnish him or her with any comments thereon or any representations they may wish to make in regard thereto.

7. The SCA judgment was delivered on 11 April 2022. Thus, the 12-month suspension period lapsed on 12 April 2023. Note that dates are calculated by following the Interpretation Act 33 of 1957:

> **4. Reckoning of number of days**
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> When any particular number of days is prescribed for the doing of any act, or for any other purpose, the same shall be reckoned exclusively of the first and inclusively of the last day, unless the last day happens to fall on a Sunday or on any public holiday, in which case the time shall be reckoned exclusively of the first day and exclusively also of every such Sunday or public holiday.

(A month is defined as a calendar month.)

8. Yet the only attempt made by the Minister of Health to "remedy the defect", as it was put by Kubushi J, was to publish regulations *"amending"* regulations pertaining to complementary medicines. <u>One cannot amend something which has been declared unlawful and *ultra vires*.</u> <u>Neither could the Minister publish any regulations which did not first, comply with the three-month period laid down in section 35(2) of the medicines Act nor second, nor within a time frame which would not be completed before the lapse of the 12-month period.</u> Yet this is exactly what the Minister of Health did. It published regulations purporting to amend the impugned regulations on 24 March 2023 *Government Gazette* No. 48358 (NO. R. 3258) and gave the public only one month in which to comment thereon. On 25 May 2023, an extension of two months was given for the proposed regulations issued on 24 March 2023 in *Government Gazette* No. 48658 (NO. 3454).

9. Although the Minister, at the behest of interested parties, including our association, extended the commentary period, this still did not cure the Minister's:

   a) Contempt of the Court order of the SCA, nor

   b) The fact that the Minister was seeking to amend regulations which were declared null and void due to the principles of unlawfulness and *ultra vires,* which attempt at amendment is therefore also null and void.

10. In fact, the allegedly "amended" regulations merely parroted the impugned regulations and the only difference was that complementary and alternative medicines were now referred to as Category D medicines.

11. Section 14 (2)(a) of the Medicines Act states that:

> (2) (a) The Authority may from time to time determine that a medicine, medical device or IVD, or class or category of medicine, medical device or IVD or part of any class or category of medicine, medical devices or IVDs mentioned in the declaration, shall be subject to registration in terms of this Act.

12. No Category D has ever been officially promulgated. There were various prior abortive attempts. Only in the 2017 General Regulations a Category D was promulgated. This category referred solely to complementary medicines and were thus held to be *ultra vires* and unlawful by both Kubushi J and the Supreme Court of Appeal. The proposed amendment of the impugned regulations is therefore *ultra vires* and unlawful.

13. In any event, the Medicines Act does not cater for complementary medicines save if they make therapeutic claims which then bring them under the aegis of a 'medicine' as defined in Section 1 of the Medicines Act. Further, and in any event, a statute cannot be amended by way of regulations. What the Minister should have done is to seek to amend the definition of a medicine. This has been attempted in Parliament with dismal results on numerous occasions.

14. The primary reason that such a solution is not viable is because it was attempted before with egregious consequences. The Medicines Act caters for synthetic, orthodox / allopathic medicines formulated from scratch from chemicals. We fail to see how a third (actually a fourth if one takes into account the impugned regulations) attempt can bear fruit and why the South African Health Products Regulatory Authority (the "SAHPRA") and the Minister would seek to repeat a disastrous history.

The previous denouement:

15. In 1998, the Medicines Control Council (the "MCC") and the Minister effected an amendment to the Medicines Act called the South African Medicines and Medical Devices Regulatory Authority Act (the "SAMDRA Act") (Act No. 132 of 1998). The SAMDRA Act was repealed by the Medicines and Related Substances Amendment Act No. 59 of 2002. This constituted the nascent concept of a SAHPRA type of body. Chapter 2 thereof dealt with the *Establishment of South African Medicines and Medical Devices Regulatory Authority*. It was established for a year and contained a definition for complementary medicine, including African Traditional Medicine within

section 1 (the definition section of the Act). There were no regulations for medicines or schedules associated with the SAMDRA Act for a period of a year. The Authority in control of the SAMDRA Act was working *in vacuo*, and, as a result, the SAMDRA Act was repealed and there was a reversion to the original Act prior to the amendment.

16. The SAMDRA Act had a definition for CAMs in its definition section:

> "complementary medicine" means any substance or mixture of substances, which-
>
> (a) originates from a plant, mineral, or animal, and which may be, but is not limited to, being classified as herbal, homeopathic, ayurvedic or nutritional; and
>
> (b) is used or intended to be used for, or manufactured or sold for use in, or purported to be useful in, complementing the healing power of a human or animal body or for which there is a claim regarding its effect in complementing the healing power of a human or animal body in the treatment, modification, alleviation or prevention of disease, abnormal physical or mental state or the symptoms thereof in a human being or animal; and
>
> (c) is used in, but not limited to, the disciplines of Western herbal, African traditional, traditional Chinese, Homeopathy, Ayurveda, Unani, Antroposophy, Aromatherapy and Nutritional supplementation; or
>
> (d) because of its origin, intended use or use in a discipline, is determined by the Authority, by notice in the Gazette, to be a complementary medicine;

17. This state of affairs endured until 2014 when a new Bill served before Parliament (Bill 6 of 2014) which included medical devices and veterinary medicines. Pressure groups including our association, interjected at every level both in written comments, oral presentations, and at the Parliamentary level in the Portfolio Committee for Health because there was yet another endeavour to include complementary medicines into section 1 of the first version of the Bill as tabled.

18. After public representations before the Portfolio Committee for Health it was decided by the said Committee that they would remove the definition for complementary medicine from the statute (and subsequent versions of the Bill which went through Parliament) and the final gazetting of the Amendment Act never included any such definitions again, as demonstrated by the Medicines Act in its current format.

19. The pressure groups, including our association, were very successful in Parliament in fending off a definition of complementary medicines being added. African traditional leaders and traditional health practitioners, in particular, believed strongly that their Constitutional rights were being trampled on. The argument stands that

non-indigenous traditional medicines listed in the definition of 'complementary medicine' (*vis a vis* traditional Chinese medicine, Unani-Tibb, Ayurveda, Western Herbal etc) cannot be divorced from indigenous African Traditional Medicines. In fact separate development of regulation in this regard is violation the Founding Provision of Clause 1 of Chapter 1 of the Constitution, namely the Supremacy of the Constitution (Act No. 98 of 1996, as amended),

Supremacy of Constitution

2. This 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.

and further violates the Equality Clause of Chapter 9 of the Bill of Rights, as the regulations discriminate on the basis of ethnic and social origin, belief, culture and in some instances, religion.

Equality

9. (1) Everyone is equal before the law and has the right to equal protection and benefit of the law.

(2) Equality includes the full and equal enjoyment of all rights and freedoms. To promote the achievement of equality, legislative and other measures designed to protect or advance persons, or categories of persons, disadvantaged by unfair discrimination may be taken.

(3) The state may not unfairly discriminate directly or indirectly against anyone on one or more grounds, including race, gender, sex, pregnancy, marital status, ethnic or social origin, colour, sexual orientation, age, disability, religion, conscience, belief, culture, language and birth.

(4) No person may unfairly discriminate directly or indirectly against anyone on one or more grounds in terms of subsection (3). National legislation must be enacted to prevent or prohibit unfair discrimination.

(5) Discrimination on one or more of the grounds listed in subsection (3) is unfair unless it is established that the discrimination is fair.

20. For the Minister and SAHPRA to ignore and neglect the need to regulate African Traditional Medicine, which for intents and purposes is not dissimilar to the other forms traditional medicine listed in the definition of complementary medicine, is discriminatory and inconsistent with the Bill of Rights. Therefore the draft amendment, which excludes African Traditional Medicine, is unconstitutional and therefore invalid. The Minister and SAHPRA are obligated to fulfill their constitutionally bound duty by including African Traditional Medicine into the definition of complementary medicine forthwith, or demonstrate to us why such continued discrimination is both rational and fair as explicitly outlined in Section 9(5) of the equality clause.

21. The Minister should also be aware that the SAHPRA have attempted in the past to justify the exclusion of African Traditional Medicine from the complementary medicine regulatory framework on the basis that the continued exclusion adheres to harmonization efforts contained in the '***Guidelines for Registration of Traditional Medicines in the African Region***', published by the WHO regional office for Africa in 2010. This guideline fell under the stewardship of the Directorate for Technical Cooperation for Essential Drugs and Traditional Medicine of the WHO (Geneva), and which was directed and influenced at the time by our former Registrar of Medicines of the Medicines Control Council, and former Director-General of our National Department of Health, Mrs Malebona Precious Matsoso. These Guidelines classify indigenous and non-indigenous traditional medicines as separate categories without explanation or just cause. This Guideline, adhered to by our National Department of Health and the SAHPRA, was the genesis of the erroneous exclusion of African Traditional Medicine from our complementary medicine regulatory framework. If any traditional medicine modality requires urgent attention in terms of regulating safety and protecting the public it is African Traditional medicine, where many deaths have been recorded as a result of acute adverse effects from muti ingestion from unlabeled concoctions of potentially poisonous plants sold on our streets. Sadly most of these deaths are among children and babies. The supremacy of our Constitution and the application of our Equality Clause invalidates such discriminatory categorizations. All traditional medicines must be regulated on an equal basis simultaneously with the most regulatory fervour aimed at that modality which poses the highest individual and societal risk base. It is both irrational and unethical to impose stringent regulations on demonstrably low-risk complementary medicines, while continuing to turn a blind eye on the modality which has shown demonstrable harm for decades. As an illustration, it is noteworthy to mention that during her tenure as the Interim Chair of the Medicines Control Council, Prof Helen Rees, the current Chair of the SAHPRA (South African Health Products Regulatory Authority) Board, was apprised of morbidity statistics concerning specific poisonings related to African Traditional Medicine in the late 1990s. This information was brought to her attention by Mr. Stuart Thomson of PHARMAPACT, who conveyed the matter through written representations and a hearing before the full Council. Mrs Malebona Precious Matsoso was present at the time, in her capacity as Registrar.

22. The question as to whether to introduce CAMs into the Medicines Act has been thoroughly debated and discarded. SAHPRA then decided, without any definition of CAMs in the Medicines Act – to introduce CAMs by the backdoor via regulations which were illegal and unanimously held by our Courts to be illegal in the judgments of Kubushi J and the SCA.

23. For this very reason there cannot be a fourth attempt at changing the definition of a medicine in the Medicines Act. It is simply not feasible given the background set out above.

24. In the recent case of the *South African Veterinary Association v Speaker of the National Assembly and Others (CCT27/18) [2018] ZACC 49; 2019 (2) BCLR 273 (CC); 2019 (3) SA 62 (CC) (5 December 2018)* the importance of the public consultative process was emphasised. The Medicines Act cannot be amended without following the prescribed consultative process. This can take years.

25. New regulations seeking to deal with complementary medicines will, per definition, be illegal. Trying to schedule complementary substances higher than schedule 0 in one fell swoop will create considerable blow-back.

26. When Kubushi J stated that the "defect" be cured, she meant that only medicines as defined by her and in the Medicines Act fell under the purview of the Medicines Act. Hence all Guidelines pertaining to complementary medicines were implicitly declared null and void by Kubushi j and the SCA.

27. Nothing daunted, SAHPRA published a new Guideline pertaining to Complementary medicines on 17 April 2023 but called it a "General Information Guideline". The scope of the 17 April 2023 SAHPRA General Information Guideline was stated only to be relevant to human medicines and (unbelievably!) complementary medicines. All the references to complementary medicines in this Guideline are illegal.[1]

Legislation pertaining to African Traditional Healers: The Traditional Health Practitioners Act 22 of 2007

28. The Traditional Health Practitioners Act which treats African traditional medicines differently from CAMs, also means that section 9(3) of the Bill of Rights which places the onus on the Minister, in terms of section 9(5) to prove that people are not being treated unequally, is being breached. It might, in any event be treated as as *pro non scripto.* Save for its existence in the statute books it might as well not have been promulgated. Nothing has changed. Why African Traditional Healers are dealt with in a separate statute and CAMs not, is difficult to justify. It at least serves as an acknowledgement of the fact that the Medicines Act only encompasses allopathic / orthodox medicines.

29. To add insult to injury, on 16 July 2023, SAHPRA has buckled down and published an entire guideline entitled the "GUIDELINE ON A ROADMAP AND TRANSITIONAL PROCESS FOR THE REGULATION OF CATEGORY D MEDICINES". The extent of the Minister and SAHPRA's contempt of court is breath taking in its insouciance.

30. Given the extent of the contempt of court, we believe the Minister of Health and the officials of SAHPRA are acting *mala fides* and should be held personally liable if the draft amendments are carried into law.

CONCLUSION

31. Instead of consulting the industry subsequent to the High Court and SCA judgments referenced above, SAHPRA has, myopically, clamped down in enforcing the illegal regulations instead of easing off and seeking resolutions. The Minister has similarly, and sadly, been remiss.

    The salient points:

    A. The regulations can not be amended *ex post facto*, after the courts has struck them down, and after the suspension of invalidity terminated by way of the order of the SCA.
    B. The mere substitution of the words 'complementary medicine and 'health supplement' with a prefix word 'Category D' in the draft amendment is *ultra vires*, as Category D was struck down in the same fatally flawed regulations.
    C. The continued exclusion of African Traditional Medicine is unconstitutional in terms of Section 9 of the Bill of Rights, namely the Equality Clause.

The Traditional & Natural Health Alliance (TNHA) firmly advocates for a distinct regulatory framework outside the scope of the Medicines Act to govern traditional and natural health products. We believe it is essential to establish a new, purpose-written statute (Act) that comprehensively encompasses all forms of traditional medicine while being regulated based on their demonstrated low-risk profile.

This presents a unique opportunity to create a constitutionally sound regulatory framework that caters to both indigenous and non-indigenous traditional medicines and health supplements. Countries like Australia and New Zealand have successfully implemented such all-encompassing frameworks.

The current practice of assimilating complementary medicine into the pharmaceutical regulatory framework, devoid of adequate representation, has proven highly problematic and financially burdensome for our industry. It has impeded growth and adversely

affected the sector's performance. Instead, we propose that such products be regulated in a manner akin to food products rather than pharmaceutical drugs, in alignment with international practices.

Our government has already demonstrated the importance of separate regulatory bodies for orthodox / allopathic health practitioners and allied health practitioners, including Homeopaths, Naturopaths, Chinese Medicine Practitioners, and African Traditional Medicine Practitioners. We acknowledge the value of self-determination in their unique paradigms of practice and the importance of safeguarding public health. Similarly, we contend that traditional and natural health products should be regulated independently from pharmaceutical drugs, with a dedicated statutory authority led by competent experts in complementary and traditional medicine.

The recent SCA judgment has presented an opportune moment for a reset in this regard. We advocate for the abandonment of the current ineffective complementary medicine regulations and the exploration of a new, all-inclusive path forward. If we do not set a new course and continue to act as if its business as usual, we may be beset with more litigious actions in our courts.

We extend our gratitude for considering our proposal and reiterate our commitment to engaging constructively with the Ministry of Health to advance the interests of the traditional and natural health products sector and the public.

If you require any further information or have any inquiries, please do not hesitate to contact us.

Sincerely,

Anthony Rees
National Chairman
Traditional & Natural Health Alliance.