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

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Attention: **Dr. Kaizer Thembo**

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cc: The Honourable Dr. Mathume Joseph Phaahla (Minister of Health)
Prof. Helen Rees (Board Chair, SAHPRA)
Dr. Boitumelo Semete-Makokotlela (CEO, SAHPRA)
Dr. Kenneth Leonard Jacobs (Chair, Portfolio Committee for Health, Parliament)

08 OCTOBER 2023

COMMENTARY ON SAHPRA's *GUIDELINE ON A ROADMAP AND TRANSITIONAL PROCESS FOR THE REGULATION OF CATEGORY D MEDICINES (16 JULY 2023)* BY THE TRADITIONAL AND NATURAL HEALTH ALLIANCE (TNHA)

INTRODUCTION:

1. On 16 July 2023 SAHPRA published a guideline on a roadmap and transitional process for the regulation of category D medicines. It is important to note that it is only on SAHPRA's website that it is clearly stated that this document is open for comment until 17 October 2023. It is usual practice for SAHPRA expressly to state upfront in the proposed new Guideline itself that it is published for public comment and when the deadline for comments is. In this instance, this was not done. (These facts are hidden in a table).

2. The TNHA does not intend commenting in detail on the contents of the said Guideline and Roadmap for the reasons set out below, namely that the Guideline is invalid and unlawful.

3. Section 9(1) (d) and (2) (a) and (b) of the 2017 General Regulations (published in General Notice 859 of *Government Gazette* 41064 on 25 August 2017) to the Medicines and Related Substances Act 101 of 1965 (the Medicines Act) for the first time introduced so-called category D medicines as follows:

> (d) Category D = Complementary medicines intended for use in humans and animals which are, without further manipulation, ready for administration, including packaged preparations where only a vehicle is added to the effective medicine.
>
> (2) Medicines in Category D shall be classified into the following sub-categories:
>
> (a) discipline-specific medicines with such disciplines as determined by the Authority; and
>
> (b) health supplements.

4. The Alliance for Natural Health South Africa ("ANHPSA"), of which the TNHA is a founding member, took SAHPRA and the Minister of Health to Court on the 19th of February 2018 for seeking to change primary legislation (which is a statute), by way of secondary legislation (which are regulations). Regulations are promulgated to give effect to matters contained in a primary statute (or Act). Where the primary statute is silent on an issue, regulations can clearly not be promulgated to deal with issues on which the primary statute is silent. This is exactly what SAHPRA and the Minister of Health sought to do by referring to a category D which does not exist in the Medicines And Related Substances Act (Act No. 101 of 1965), hereafter referred to as the 'Medicines Act', and to 'complementary medicines' which do not exist in the Medicines Act.

5. The main argument put forward by the ANHPSA was therefore very simple: SAHPRA and the Minister of Health were not authorised to introduce issues into regulations not dealt with by the primary statute. Such conduct was *ultra vires* (beyond SAHPRA and the Minister of Health's powers). Both Judge Kubushi in the North Gauteng Division of the High Court in *Alliance of Natural Health Products in South Africa v Minister of Health and Another* (11203/2018) [2020] ZAGPPHC 731 (delivered on 01 October 2020) and later the full bench of the Supreme Court of Appeal, (when SAHPRA and the Minister of Health took the matter on appeal) in *Minister of Health and Another v Alliance of Natural Health Products (South Africa)* (256/2021) [2022] ZASCA 49; 2022 (5) SA 392 (SCA) (delivered on 11 April 2022) did not hesitate to declare all references to complementary medicines in the regulations invalid. Thus, all regulations dealing with complementary medicines were declared invalid including the regulations purporting to create a category D relating to complementary medicines.

6. It was unsuccessfully argued by SAHPRA and the Minister of Health that the definition of a medicine in the Medicines Act included complementary medicines. Of interest is that counsel for the Minister of Health and SAHPRA - namely G Marcus SC - argued before the Supreme Court of Appeal on a previous occasion that a natural product (Florex) does not fall within the definition of a medicine as set out in the Medicines Act.
Reitzer Pharmaceuticals (PTY) Ltd v Registrar of Medicines (South Africa) (10842/98) 1998 (4) SA 660 (T).

7. Both Judge Kubushi and the Supreme Court of Appeal gave SAHPRA and the Minister of Health a year to remedy this defect. Given that Judge Kubushi rendered her judgment on 01 October 2020 and that SAHPRA and the Minister of Health knew that there was a fifty percent chance of losing their appeal, both SAHPRA and the Minister of Health knew for 18 months and 11 days that the inclusion of complementary medicines in the regulations were problematic. Apparently, they did absolutely nothing about the situation.

8. The Medicines Act stipulates in section 35 (2) 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.

9. Thus, SAHPRA and the Minister of Health knew for more than a year and a half that they:

9.1. had to remedy the defect;

9.2. that regulations, if drafted, had to be published three months in advance in order to give interested persons the opportunity to comment thereon;

9.3. had to give themselves sufficient time to study all comments and representations made in respect of the proposed regulations; and

9.4. had to give themselves time to amend the proposed regulations in line with the public comment and representations.

10. Furthermore, given the fact that both Judge Kubushi J and the Supreme Court of Appeal made it clear beyond any doubt that a principal act cannot be amended by regulations, both SAHPRA and the Minister of Health knew that complementary medicines could not be sought to be introduced by way of regulations and that an amendment to the Medicines Act or a completely new act dealing with complementary medicines were called for.

11. The Supreme Court of Appeal judgment was handed down on 11 April 2022. The grace period of a year afforded to SAHPRA and the Minister of Health therefore lapsed on 12 April 2023. Note that dates are calculated by following the Interpretation Act 33 of 1957:

4. Reckoning of number of days

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.)

12. Notwithstanding the above, the Minister of Health published allegedly "amending" regulations on 24 March 2023 in *Government Gazette* No. 48358 (NO. R. 3258). This was shocking for the following reasons:

12.1. The Minister of Health had expressly been told by Kubushi J and the Supreme Court of Appeal that no principal statute may be amended by way of regulations. This legal rule constitutes the express reasoning of the courts to declare the 2017 regulations invalid as far as the introduction of complementary medicines is concerned. To do that which was expressly declared invalid and *ultra vires* by the courts, constitutes a total and flagrant disregard of the courts' reasoning and orders and hence constitutes utter contempt of the courts' judgments and orders.

12.2. The Minister of Health disregarded section 35(2) of the Medicines Act and gave interested parties only a month in which to make representations whereas 3 months are prescribed by the Medicines Act.

12.3. The Minister of Health simply disobeyed a court order instructing it to complete the process of rectifying its error before 12 April 2023. A party who disobeys a court order is severely penalised and can be ordered to pay fines and/or be given a prison sentence. Such a party may also not approach a court for any relief whilst still in contempt of court save if it seeks condonation for its contempt. It has to give a comprehensive and true account for its contempt of court.

12.4. Furthermore, the only purported amendment which was envisaged to the 2017 regulations was to refer to complementary medicines as category D medicines. The futility of such an alleged amendment is self-evident – category D was struck down along with complementary medicines by the courts. One is also left to wonder how regulations which were struck down because of being invalid can be sought to be amended.

12.5. In short, the entire attempted amendment is so defective as to constitute a nullity in and of itself.

13. On 25 May 2023, an extension (published in *Government Gazette* No. 48658 (NO. 3454)) of two months was given for commentary (thus until 25 July 2023) after interested parties sought an extension of time within which they could comment. This extension did not assist the Minister of Health in the slightest as far as its disobedience of a court order was concerned. As set out above, the rectification of the Minister's error was ordered by the Supreme Court of Appeal to take place **before 23 April 2023.**

14. To make matters even worse (if this was even possible) on 16 July 2023, as is clear from the heading of this document SAHPRA published a guideline named GUIDELINE ON A ROADMAP AND TRANSITIONAL PROCESS FOR THE REGULATION OF CATEGORY D MEDICINES. This publication defies credulity.

15. The completely invalid amending regulations of 23 March 2023 have not even been promulgated in final format and yet, in anticipation, the Minister of Health deems it fit to publish a Guideline as to how the proposed (and unamended regulations after the input of interested parties) should be interpreted and implemented. Such conduct is not only illogical but leads to the conclusion that the Minister of Health does not envisage taking any commentary on the proposed regulations of 24 March 2023 into

consideration. Clearly a Regulatory Authority which has to regulate an industry in the public interest cannot act in such a reckless and authoritarian way.

16. As a result, no commentary regarding the contents of the illegal "GUIDELINE ON A ROADMAP AND TRANSITIONAL PROCESS FOR THE REGULATION OF CATEGORY D MEDICINES" are required or called for by law. The "GUIDEINE ON A ROADMAP" is invalid and *ultra vires.*

17. It should further be noted that a special, separate "category D'' website (https://sahpracm.org.za/catd/) was created by SAHPRA with the result that an interested person who consults the SAHPRA website will not readily find this website. On its website for so-called category D medicines SAHPRA is bold enough still to maintain that complementary medicines fall under the Medicines Act (notwithstanding the two adverse court orders) that:

Category D medicines are a category of **medicine** (and as such, those substances subject to regulation are either a "medicine" or "scheduled substance" defined in terms of section 1 of the Medicines Act).

Category D medicines may be identified as "complementary medicines", defined by way of the General Regulations made in terms of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), published under Government Notice 859 in *Government Gazette* 41064 of 25 August 2017 **(this definition is currently under review):**

18. On the same website it is stated that the definition of a health supplement is also currently under review.

19. Thus SAHPRA makes it clear that it is defying the Supreme Court of Appeal's judgment and order and still insists that complementary medicines are medicines as defined in the Medicines Act. Its allegation that the definitions of complementary medicines and health supplements are under review constitutes an admission that these definitions are in a state of flux.

CONCLUSION:

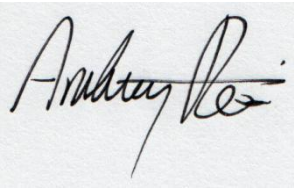
20. The conduct on the part of SAHPRA and the Minister of Health set out above does not behove a Regulatory Authority which has been mandated to act in the public interest and is regrettable.

21. What the Minister of Health and SAHPRA should be doing is to:

    21.1. Seek to amend the Medicines Act, but, as has been demonstrated by various previous attempts to do this, it is unfeasible as one cannot shoehorn complementary medicines and health supplements into an Act for the regulation of allopathic (orthodox) medicines. Furthermore, the amendment of an Act necessitates a comprehensive consultative period;

    21.2. Draft a new regime/ Act for complementary medicines.

    21.3. SAHPRA simply does not have the authority to regulate complementary medicines.



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Traditional & Natural Health Alliance

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