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Play it again (and again): A new regime for complementary medicines

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The Minister of Health has published certain amendments to the General Regulations ("the Regulations") made in terms of the Medicines & Related Substances Act No. 101 of 1965 as amended ("the Medicines Act"). The amendments were published in the *Government Gazette* on 24 March 2023. The public has one month to comment on the regulations as of 24 March 2023.

The amendments concern primarily the treatment of complementary medicines in the Regulations. Centrally, the definition of "complementary medicine" has been amended from its current rambling version into a definition that simply defines a complementary medicine as "a Category D medicine." In turn, a Category D medicine is to be defined as "medicines classified in sub-regulation [9(2)], intended for use in humans or animals which are, without further manipulation, ready for administration, including packaged preparations where only a vehicle is added to the effective medicine."

Regulation 9(2) as it is to be amended will refer to medicines "identified in class 33 of Annexure 1 and class 28 of Annexure 2" and "medicines identified in class 34 of Annexure 1 and class 29 of Annexure 2, excluding medicines or substances listed as Schedule 1 or higher in the Act." Therefore, the existing discipline-specific criteria, which are set out in classes 33 and 28, respectively, remain with only a shift in the textual relationship between the Regulations and the annexures to the Regulations. Class 33 of annexure 1 refers to various allied professions and class 28 of annexure 2 refers to complementary medicines used for veterinary purposes. Class 34 of annexure 1 refers to health supplements and class 29 of annexure 2 refers to supplements used for veterinary purposes.

Therefore, the proposed amendments now endeavour to introduce a classification system for complementary medicines as set out in the annexures to the Regulations. Accordingly, the list in class 34 of annexure 1 includes amino acids, "animal extracts, products and derivatives", enzymes, fats, oils and fatty acids, minerals, probiotics, vitamins and a category of simply "other", the meaning of which is unknown. A relatively wide range of substances are therefore potentially included in the proposed definition.

Additional amendments are also proposed so as to bring Category D medicines squarely into the Regulations in so far as –

- the labelling of complementary medicines is concerned (regulation 10);
- the professional information to be supplied about complementary medicines (regulation 11);
- the patient information leaflet that must accompany a complementary medicine (regulation 12);
- applicable regulations relating to the use and sale of veterinary complementary medicines (regulations 13 and 14).

Other amended defined terms include "health supplement", which is simply defined as a Category D medicine along with "discipline-specific medicine", which is also defined as a Category D medicine. Obviously, it is not apparent from the Regulations how one is to deal with a substance that is used in more than one discipline where that information is required for purposes of labelling the medicine concerned.

The amendments to the Regulations presumably follow on from the decision of the Supreme Court of Appeal in *Minister of Health and Another v Alliance of Natural Health Products (South Africa)* (neutral citation: (Case no. 256/2021) [2022] ZASCA 49

(11 April 2022)) that upheld a judgement by the Pretoria High Court striking certain parts of the existing Regulations down as being unconstitutional. That judgement fundamentally held that the Regulations, as currently drafted, cast the net too wide and include a number of products or substances that are not medicines:

"To qualify as a medicine, a substance (or a mixture of substances) must: be used; purport to be suitable for use; or be manufactured or sold for use for a purpose set out in subparas (a)(i) or (a)(ii) of the definition. It was rightly common cause between the parties that on a sensible contextual interpretation of the definition these are limited to therapeutic or medicinal purposes. The heads of argument of the appellants therefore aptly state that medicines 'must always have or claim to have a therapeutic purpose'. This makes eminent sense. On this interpretation, drinking water is clearly not a medicine under the Act, but water that is claimed to have the ability to cure a disease, would be one." (paragraph 20)

Such an assessment was based on the currently applicable definitions of "complementary medicine" and "health supplement", respectively. However, with the amendments now proposed, where focus shifts from the Regulations to the annexures to the Regulations, will the constitutional flaws in the current Regulations be remedied?

The classes in the annexures to the Regulations, and which relate to complementary medicines, do little to introduce the clarity that is needed about what is or is not a complementary medicine for purposes of the Medicines Act and the application of the law. Bearing in mind that the regulation of complementary medicines is currently being pursued by guideline, with there being no formal call-up for registration of any particular category of complementary medicines, a number of products have been corralled into becoming listed as complementary medicines at the instance of the regulator.

How one is to reconcile the current listings of products with the proposed amendments to the Regulations and what those amendments will mean for the lawful registration of products and substances as complementary medicines, remains a source of frustrating policy and regulatory uncertainty.

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