IN THE HIGH COURT OF SOUTH AFRICA
GAUTENG DIVISION PRETORIA

CASE NO: 11203/2018

(1) REPORTABLE: YES
(2) OF INTEREST TO OTHER JUDGES: YES

E.M. KUBUSHI **DATE: 01-10- 2020**

In the matter between:

THE ALLIANCE OF NATURAL HEALTH PRODUCTS IN SOUTH AFRICA	APPLICANT
and	
MINISTER OF HEALTH	FIRST RESPONDENT
SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY	SECOND RESPONDENT

JUDGMENT

KUBUSHI J

This judgement is handed down electronically by circulating to the parties' representatives by email and by uploading on Caselines.

INTRODUCTION

[1] This opposed application concerns the regulation of complementary medicines including health supplements by the second respondent, the South African Health Products Regulatory Authority ("the Authority"). The applicant, the Alliance of Natural Health Products in South Africa, seeks to review and set aside certain aspects of the General Medicine Regulations promulgated on 25 August 2017 under General Notice 859 in Government Gazette 41064 ("the impugned Regulations"), which empowers the Authority to regulate complementary medicines. The said impugned Regulations have been promulgated by the first respondent, the Minister of Health ("the Minister"), in terms of section 35 of the Medicines and Related Substances Act[1] ("the Medicines Act") in consultation with the Authority.

[2] In essence the review concerns a dispute regarding the ambit of the impugned Regulations which seek to regulate complementary medicines and health supplements in the same way as conventional medicines.

CONDONATION

[3] Both parties have applied for condonation for various instances of non-compliance with time periods. The parties are not opposing each other's application for condonation and accept that the applications be granted. On consideration, I am of the view that it ought to be granted.

THE PARTIES

The Applicant

[4] The applicant is a voluntary association whose mission is said to be to ensure that South Africans have access to safe and high quality natural health products, while respecting freedom of choice and philosophical and cultural diversity. Its members are said to be operating across the complementary medicine, traditional medicine and

[1] 101 of 1965.

health supplement sectors and include traditional healers, natural health advocates, manufactures and retailers. In terms of the applicant's Constitution,[2] which was signed on 14 February 2018, the applicant was constituted two (2) days before the institution of this application.[3] The applicant brings this application in its own interest and in the public interest.

[5] The applicant's case is grounded mainly on what it refers to as the 'quintessential *ultra vires* question'. The contention being that, in making the impugned Regulations, the Minister acted *ultra vires* in that he seeks, by means of the impugned Regulations, to regulate all supplementary medicines whilst the Medicines Act does not empower him to do so. If this argument is not accepted by the court, then in that event, the applicant contends that the impugned Regulations should in any event be set aside for procedural irregularities in that the process was vitiated by the final drafting process because the information that served before the Minister at the time he decided to promulgate the impugned Regulations was limited and inadequate as it did not include some of the material public comments sent in, in relation to the previous iterations of the draft Regulations; and/or on the ground of irrationality and/or unreasonableness in that the decision to promulgate the impugned Regulations was made with undue haste resulting in the failure to undertake the regulatory impact assessment which would have determined the impact, in taking on an additional task of regulating complimentary medicines, on the Authority's serious existing backlog in the registration of conventional allopathic medicines, and any financial impact such task may have on the Authority.

The Respondents

[6] The application is opposed by the Minister who is cited herein in his capacity as the Cabinet member responsible for the administration of the Medicines Act, which office empowers him under section 35 of the Medicines Act to make Regulations.

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[2] Annexure AR 10.
[3] See further paragraph 211 of the Replying Affidavit.

[7] The Minister in opposing the application is supported by the Authority as the second respondent herein.

[8] The Authority is an organ of state established in terms of section 2 of the Medicines Act. The Authority's objects, as provided for in the Medicines Act, are to provide for the monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines, scheduled substances, clinical trials and medical devices, IVDs and related matters in the public interest. The Authority is cited in this matter because it must, in terms of section 35 of the Medicines Act, be consulted by the Minister before regulations are made. For convenience, I shall in the judgment refer to the Minister and the Authority collectively as the respondents.

[9] The respondents oppose the application on the ground that the impugned Regulations are not *ultra vires* when viewed on a proper construction of the legislation. They submit further that the making of the impugned Regulations was neither procedurally unfair, nor irrational and/or unreasonable. The crux therefore is whether the making of the impugned Regulations was *ultra vires* or procedurally unfair, irrational or unreasonable.

[10] Besides the defences raised in opposing the application on the merits, two other points of defence, namely, the abstract nature of the applicant's case and the applicant's lack of standing, are raised by the respondents as preliminary issues. I intend to deal with these two points before I come to the merits part of the application. If I find in favour of the respondents, in any one of the two points, it will not be necessary that I deal with the merits part of the application as either of the two points may be dispositive of the applicant's case.

The *Amicus*

[11] By agreement, and after a case management meeting before Poterill J, the parties agreed to admit the Treatment Action Campaign NPC (TAC) into the proceedings as *amicus curiae* ("*amicus*"). TAC is a non-profit company and non-profit organisation which advocates for increased access to treatment, care and support services for persons living with HIV and/or tuberculosis (TB), and campaigns to reduce new HIV and TB infections.

[12] The *amicus* does not seek any specific relief in respect of the substantive and procedural attacks on the impugned Regulations. The *amicus* has, however, raised an issue on the standing of the applicant to bring this application. The applicant, on the other hand, disputes the *amicus'* entitlement to raise the question of standing, which according to the applicant is not an issue between the parties. Notwithstanding that it does not seek any specific relief in respect of the substantive and procedural attacks on the impugned Regulations, TAC has made submissions which it seeks the court to take into consideration when considering the merits. The applicant submits, however, that TAC's legal submissions fall outside the permissible bounds and should not be considered by the court. If necessary, I shall deal more fully with these issues later in the judgment.

[13] However, before I do so, I find it necessary that I set out the salient facts leading to the institution of this application.

THE SALIENT FACTS

[14] The purpose of the Medicines Act is stated in the Preamble thereof as, amongst others, to provide for the registration of medicines and related substances intended for human and for animal use. The Medicines Act also empowers the Minister to prescribe any medicine or other substance as a 'scheduled substance'.[4] The Medicines Act's purposes also include the control of medicinal substances.

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[4] Section 22A.

[15] The Minister's regulation-making power in terms of section 35 of the Medicines Act includes, amongst others, providing for the classification of medicines into classes or categories for the purpose of the Medicines Act.[5] The regulatory scheme classifies medicine into four broad categories, namely, category A to D, with 'complementary medicines' falling under category D.[6] 'Complementary medicines' are classified further into two sub-categories, namely, discipline-specific medicines (which are not relevant for purposes of this judgment) and 'health supplements'.[7] The upshot is that 'complementary medicines' are a category of 'medicines' (Category D) whilst 'health supplements' are a subset of 'complementary medicines'.

[16] The issues in this application revolve around the definitions of complementary medicines and health supplements as contained in the impugned Regulations in that the definitions are said to be too wide, as a result of which the definitions incorporate products that are complementary medicines and health supplements, that do not fall within the ambit of medicine as defined in the Medicines Act.

[17] The impugned Regulations constitute an attempt by the Government to regulate, amongst others, complementary medicines in the interest of the general public. Regulation became necessary because, complementary medicines, in the form of health products, herbal medicines and health supplements have become widely available over the counter and the numbers and variety of available health products have grown exponentially in recent years. It is said that in South Africa alone, there are 130 corporate entities in the health supplement industry with an annual revenue stream of R10 billion.

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[5] Section 35 (1)(ii)
[6] Regulation 9(1).
[7] Regulation 9(2).

[18] Most of these products, so it is said, generally make claims about quality, efficacy, safety and contents. The impugned Regulations, as such, reflect an attempt by Government to ensure that members of the public who are able to purchase these products off the shelves, are fully informed of those claims of safety, efficacy and quality. The impugned Regulations are also an attempt to ensure that such products are registered so that the public have recourse should this be necessary and are a basis for the subsequent detailed registration guidelines issued by the Authority to guide the industry and associated stakeholders towards compliance.

[19] The gravamen of the applicant's complaint, in this matter, is not that the Minister does not have the power to regulate complementary medicines or that complementary medicines should not be regulated as envisaged by the impugned Regulations, but that such regulation should not be in respect of all complementary medicines. Critically, what the applicant disputes is the over-breadth of the impugned Regulations which, according to the applicant, seek to regulate products that are not covered by the definition of medicines, as contained in the Medicines Act, and those that do not contain scheduled substances as required by the Medicines Act. As the applicant states, the majority of complementary medicines including health supplements do not fall within the ambit of medicine as defined in the Medicines Act.

[20] According to the respondents the need to regulate complementary medicines and health supplements as medicines was identified many years ago. As far back as 2002. Over the years, the Department of Health attempted to regulate these products in different ways. These attempts included a number of call ups of different products like old herbal drugs in 1973, special foods of which medicinal claims were made in 1974, substances which purported to be medicines in 1978, the oral preparations containing vitamins alone or in combination with other pharmacologically active ingredients in 1985, and in 2002 the notice for medicines frequently referred to as complementary medicines.

[21] The call up notice of 2002 is said to have been an attempt by the Medicines Control Council ("MCC") – the precursor of the Authority, and the Minister to ascertain what complementary medicines existed in the market. This operation revealed a significant increase in the number of new complementary medicines which were on the market without review of quality, safety and efficacy. Having determined the extent of complimentary medicines in the market, the Government thereafter embarked on a consultative process in various forms from 2011. The consultative process is said to have entailed the solicitation of views and comments on the best possible means to regulate complementary medicines, in keeping with the objects and purpose of the Medicines Act.

[22] Following these consultations and on 22 July 2011, draft amendments to the General Regulations were published by the Minister for public comment. It was proposed in the draft amendments that a category D (complementary medicine) be established as a category of medicine. The Director General for Health invited comments on the Draft Regulations and many industry bodies obliged. A number of drafts ensued from the comments received and eventually a set of draft Regulations emerged and were published under Government Notice 50 in Government Gazette 40577 of 27 January 2017. Finally, the impugned Regulations were promulgated on 25 August 2017 replacing the previous set of General Regulations which were published under Government Notice 510 in the Government Gazette 24727 of 10 April 2003.

POINTS *IN LIMINE*

Abstract Challenge to the Application

[23] The respondents have taken the point that the applicant's case is flawed because its challenge to the impugned Regulations, being entirely abstract in nature, is impermissible simply because the applicant conceded that there are some complementary medicines and health supplements that are medicines as defined in the Medicines Act or contain scheduled substances as provided for in the Medicines

Act and are, thus, subject to regulation. The point is taken squarely in the papers and addressed in the heads of argument.

[24] This abstract challenge is raised mainly on the basis that the applicant does not, in its case, challenge the classification of any particular product. The respondents' argument is that there is actually no particular set of facts advanced by the applicant in its papers, relating to a particular complimentary medicine or health supplement, against which the court can assess the validity of the impugned Regulations. The argument is that, notwithstanding that on its own version some complementary medicines and health supplements are liable to be regulated as medicines, the applicant does not in its papers provide any evidence of products that fall within the purview of the impugned Regulations and those that do not fall within the impugned Regulations' ambit. Evidence of this nature, according to the respondents, will assist the court to assess the validity of the impugned Regulations. The suggestion, therefore, is that such a failure by the applicant to provide that evidence renders its challenge abstract and thus impermissible.

[25] In support of this argument, the respondents are relying on the unreported judgment of the High Court, Gauteng Division, Pretoria, in *Amabhungane Centre for Investigative Journalism NPC v Minister of Justice and Correctional Services*,[8] where it was held that only abstract challenges where the constitutionality of legislation is at issue or where the particular circumstances of the case demand it, may be entertained by our courts.

[26] The respondents' submission is that this is not a case that justifies an abstract challenge. The proposition is that the applicant's complaint should have been resolved through the internal grievance mechanisms provided for in the Medicines Act. The respondents' counsel asserts, in this regard, that the Medicines Act provides a tailor

[8] [2019] ZAGPPHC 384 at para 22.

made mechanism for challenging individual decisions of aggrieved persons. As a matter of principle, so counsel contends, the scheme of the Medicines Act is such that an aggrieved party is limited only to the remedies provided for in the Act. In support of this argument Counsel referred to the provisions of sections 24A[9] and 36[10] of the Medicines Act, which provide for mechanisms in a form of a mediation process through the Chief Executive Officer of the Authority,[11] a specialist appeal committee set up by the Minister[12] on failure of the mediation process and an exemption mechanism at the recommendation of the Authority to the Minister. Two authorities were also referred to, namely, *Steenkamp and Others v Edcon Limited* [13] and *South African Maritime Safety Authority v McKenzie,*[14] in support of this argument.

[27] The respondents rely specifically on the finding of the court in *McKenzie* where the court expressed itself as follows:

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[9] "**24A. Appeal against decision of Authority** —
(1) Any person aggrieved by the decision of the Authority may appeal against such decision by notifying the Chief Executive Officer within 30 days of becoming aware of such decision of his or her intention to appeal and setting out the full grounds of appeal.
(2) Upon being notified the Chief Executive Officer shall meet with the appellant within 30 days of being notified in the absence of legal representatives to try to resolve the matter, especially if the appeal involves administrative matters.
(3) Should the Chief Executive Officer and the appellant fail to resolve the matter as contemplated in subsection (2), the appellant shall within 30 days of being notified by the Chief Executive Officer of the failure to resolve the matter and upon payment of the prescribed fee, request the Minister in writing to convene an appeal committee.
(4) The appeal committee contemplated in subsection (3) shall –
(a) Comprise the chairperson who shall have the knowledge of the law and four other persons who shall have knowledge of the subject matter of appeal but with no financial or business interests in the affairs of the parties to the appeal, two of them nominated by the appellant and the other two by the Chief Executive Officer; and
(b) Conduct the appeal hearing and make a decision within 30 days from the day when it first meets to hear the appeal.
(5) A party aggrieved by the decision of the appeal committee may approach the High Court for a judicial review.

"**36. Exclusion of any medicine, Scheduled substance, medical device or IVD from operation of the Act** —
(1) The Minister may, on the recommendation of the Authority, by Notice in the Gazette exclude, subject to such conditions as he or she may determine, any medicine, Scheduled substance, medical device or IVD from the operation of any or all of the provisions of this Act, and may in like manner amend or withdraw any such notice."

[11] Section 24A (2) of the Medicines Act.
[12] Section 24A (3) and (4) of the Medicines Act.
[13] 2016 (3) SA 251 (CC) at para 145.
[14] 2010 (3) SA 601 (SCA) at paras 15 – 16.

"A relevant feature of some legislation of this type is that it not only confers rights but also provides a mechanism for the enforcement of those rights. Where that happens the question arises whether those means are exclusive and provide the sole means of enforcement or whether it is open to the beneficiary of the right to use the ordinary processes of the courts in order to enforce them. Another question that arises is whether the beneficiary of the right enjoys not only the benefit of the right itself but also a right to claim damages if the right is infringed. Our courts have frequently grappled with these questions and the jurisprudence in that regard casts light upon the present problem.

Where a statute creates both a right and a means for enforcing that right the position is that:

> 'We must look at the provisions of the Act in question, its scope and its object, and see whether it was intended when laying down a special remedy that that special remedy should exclude ordinary remedies. In other words, we have no right to assume, merely from the fact that a special remedy is laid down in a statute as a remedy for a breach of a right given under statute, that other remedies are necessarily excluded.'

If on a proper interpretation of the statute in question the legislature has confined a person harmed by a breach of the right conferred therein to the statutory remedy, then resort to other means of enforcement is excluded. Accordingly, both the scope of the right itself and the means of enforcing that right are determined by the intention of the legislature as ascertained on a proper interpretation of the legislation. . ."

[28] The respondents' argument that in terms of the scheme of the Medicines Act, an aggrieved party is limited to the mechanisms provided for in sections 24A and 36 of the Medicines Act before approaching court for relief, is correct. This argument by the respondents' counsel, however, misses the point of the applicant's case.

[29] The applicant' case to me is very clear. As it has been earlier stated, the applicant's case is grounded on the fundamental question of *ultra vires* which, according to the applicant, renders the impugned Regulations unlawful. The alleged unlawfulness attacks the root of the impugned Regulations and not the classification of a particular product that is inappropriately regulated. The applicant in its case does

not complain about whether or not a particular product (whether complimentary medicine or health supplement) should not fall under the ambit of the impugned Regulations, as the respondents seem to be arguing in their point *in limine*. Quite the contrary argument to what the respondents are arguing, the applicant argues that the ambit of the impugned Regulations is too wide and renders the impugned Regulations unlawful hence the impugned Regulations should be reviewed and set aside.

[30] The applicant, correctly so in my view, concedes that its case is abstract, in the sense that it is not based on specific attempts by the Authority to regulate or control a particular complementary medicine or health supplement. Its concern is that the scheme of the impugned Regulations is such that the Minister seeks to automatically regulate all complementary medicines and health supplements even though the majority of those products make no claim to a therapeutic benefit and do not contain scheduled substances. Therefore, its argument that a case-by-case challenge would be inappropriate in the circumstances of this case does stand critical scrutiny. This argument, by the applicant, accords with its stance that not all complementary medicines and health supplements should be subject to regulation under the Medicines Act.

[31] I beg to differ with the argument by the respondents' counsel that evidence based on a case-by-case basis would have assisted the court to assess the validity of the impugned Regulations. It is my view that evidence of this nature would only assist in assessing the validity of a particular product that would have been placed before the court. It would not address the challenge of the fundamental question of the unlawfulness of the impugned Regulations raised by the applicant. What is sought to be reviewed by the applicant is not the validity of a particular product but the impugned Regulations, in particular, the definitions of complementary medicines and health supplements, contained in the impugned Regulations. Therefore, the evidence as provided in the applicant's papers suffices.

[32] I am also in agreement with the proposition by the applicant's counsel that the point taken by the respondents in regard to the alleged abstract nature of the challenge can be readily resolved by the interpretation given by the court to the definition of complementary medicine and health supplement as contained in the impugned Regulations. The resolution of the question whether the definition of complementary medicines and health supplements in the impugned Regulations includes products that are excluded in the definition of medicine in the Medicines Act will provide an answer to whether the applicant should have followed the grievance mechanisms of the Medicines Act or approached a court on a case-by-case basis. For, if I find that the definitions of complementary medicines and health supplements in the impugned Regulations include products that are medicine as defined in the Medicines Act, the applicant must succeed in its case as the impugned Regulations would be unlawful and there would have been no need for a case-by-case approach. However, if I make a contrary decision, the applicant's case must fail and its members must follow the mechanisms provided for in sections 24A and 36 of the Medicines Act or approach a court on a case-by-case basis.

[33] In emphasis, I would say that the applicant's approach that the *ultra vires* question, therefore the question of unlawfulness, can only be determined by the court, is correct. Section 24A of the Medicines Act provides for mechanisms in respect of individual persons aggrieved by the decision of the Authority. In my understanding, it means that such an aggrieved person would be a person who had already applied for registration of a product and is not satisfied with the decision of the Authority. Such a person, as argued by the applicant's counsel, would have already accepted that the impugned Regulations are lawful. This will be a similar situation with regard to a person who requires exemption in terms of section 36 of the Medicines Act. Therefore, in order for me to decide whether the abstract nature of applicant's challenge is permissible or not, the question of whether the definition of complementary medicines as contained in the impugned Regulations apply to all complementary medicines must be answered first.

[34] The case of *Koyabe*[15] to which the respondents' counsel referred in order to strengthen his argument that internal remedies ought to be exhausted first before a judicial challenge can be undertaken, does not assist the respondents' case or take it any further. The judgment does not assist the respondents in the sense that the facts in the applicant's case are distinguishable from the facts in that judgment. In *Koyabe* the court dealt with the right to just administrative action, more particularly about the circumstances in which internal remedies must be exhausted before applications for judicial review can be made. In this instance, I did not understand the applicant to be saying that internal remedies should not be followed where it is appropriate to do so but instead its submission is that this is not the case where internal remedies should be followed. And the applicant is correct. The finding in *Koyabe* is nor proposition that a duty to exhaust internal remedies must be followed blindly and rigidly without considering the circumstances of the case. I find the law as enunciated in *Koyabe* more supportive of the applicant's case than that of the respondents.

[35] The following was stated in *Koyabe*:

> "The duty to exhaust internal remedies is therefore a valuable and necessary requirement in our law. However, that requirement should not be rigidly imposed. Nor should it be used by administrators to frustrate the efforts of an aggrieved person or to shield the administrative process from judicial scrutiny." . . . Thus, where an internal remedy would not be effective and or where its pursuit would be futile, a court may permit a litigant to approach the court directly. So too where an internal appellate tribunal has developed a rigid policy which renders exhaustion futile."[16]

[36] The mechanisms the respondents' counsel is arguing for do not find application in the circumstances of this matter. It is my view that the issue of unlawfulness can only be determined by the court as argued by the applicant.

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[15] *Koyabe and Others v The Minister for Home Affairs and Others* 2010 (4) SA 327 (CC).

[16] *Ibid* at paras 38-9.

[37] This point *in limine* stands to be dismissed.

The Applicant's Lack of Standing

The Respondents

[38] Although the respondents support the argument advanced by the *amicus* on the absence of standing (as shall be discussed later in the judgment), the respondents' counsel, however, attacks the point of the applicant's lack of standing on a narrower argument of the regulation process. The submission being that the applicant is an outsider to the process as it never made representations concerning the impugned Regulations and can, therefore, not challenge that process. As a stranger to the regulation making process, the applicant has no standing to challenge that process, so counsel argues. The applicant presents itself as being a voluntary association whose members operate across the complementary medicine and health supplement space, thus, the argument attacks its failure to respond to the invitation for public comments leading to the publication of the impugned Regulations, which it now seeks to challenge.

[39] A further argument that counsel raised is that since the applicant had no involvement at all in the Regulation making process, it could not challenge any particular decision by the Authority in relation to a particular product, as earlier argued. And as a body that did not exist at the time of that process of Regulation making, it does not have standing to challenge the process it did not participate in.

[40] In support of this argument counsel for the respondents relies on the decision of two judgments, namely, *Freedom Under Law v Acting Chairperson: Judicial Service Commission and Others* [17] where at para 29 the following was stated:

> "It follows that it cannot be said that the decision taken on 22 July 2009 was taken on the basis of a mistaken view as to what had been decided on 5 July 2008. The applicant submitted that the JSC in any event had to afford the parties to the complaint and counter-complaint a hearing before reversing its earlier decision

[17] 2011 (3) SA 549 (SCA).

whatever it may have been. I will assume without deciding that the parties should have been afforded a hearing before the decision was taken. However, although the judges of the Constitutional Court indicated that they were reserving their rights they did not take the matter any further but attended the interviews conducted by the sub-committee as did Hlophe JP. The parties concerned, therefore, accepted the decision of the JSC. In these circumstances it is not for the applicant, an outsider to the proceedings, to complain about the JSC's failure to give them a hearing."

[41] And *Doctors for Life International v Speaker of the National Assembly and Others*[18] where the court at paras 216 – 219 expressed itself as follows:

"Standing

In this case the applicant actively sought to obtain an opportunity to be heard on the Bills both at the NCOP and in the provincial legislatures, as I have described above. The attempts though repeated and persistent, were in vain. As soon as possible after the Bills had been promulgated, the applicant approached this Court for relief. In my view, this Court will consider an application to declare legislation invalid on the grounds set out in this judgment only in circumstances where the applicant has sought and been denied an opportunity to be heard on the Bills and where the applicant has launched his or her application for relief in this Court as soon as practicable after the Bills have been promulgated.

It is true that such a standing requirement is different to that contemplated by s 38 of the Constitution in respect of the alleged infringement or threatened infringement of rights in the Bill of Rights. We are not, of course, in this case directly concerned with the provisions of the Bill of Rights but with s 72 of the Constitution. There are powerful reasons why a restricted approach to standing of litigants is appropriate in cases such as this.

The Court has to find a balance between, on the one hand, avoiding improper intrusions into the domain of Parliament, and, on the other, ensuring that a constitutional provision which requires Parliament to facilitate public involvement in the law-making process is sufficiently justiciable to ensure that the commitment to facilitating public involvement that it represents is not rendered nugatory. In my

[18] 2006 (6) SA 416 (CC).

> view, only those applicants who have made diligent and proper attempts to be heard by the NCOP should be entitled to rely on any failure to observe s 72 of the Constitution. Similarly, applicants who have not pursued their cause timeously in this Court may well be denied relief.
>
> Rules of standing of this sort will prevent legislation being challenged on the ground of non-compliance with s 72 many years after the event by those who had no interest in making representations to Parliament at the time the legislation was enacted. It will thus discourage opportunist reliance by those who cannot show any interest in the duty to facilitate public involvement on that duty. In my view, this restricted form of standing further reflects this Court's concern to protect the institutional integrity of Parliament, while at the same time seeking to ensure that the duty to facilitate public involvement is given adequate protection."

[42] Based on the two judgments counsel contends that the applicant lacks standing to challenge the impugned Regulations and that on this point alone, the application should be dismissed.

[43] In opposition to the argument on lack of standing, the submission by the applicant is that the respondents' stance that it should not be allowed to raise the question of standing at all because it never took part in the regulation making process, it without merit. The applicant submits that it has standing to challenge the impugned Regulations simply because its complaint is that comments were ignored during that process.

[44] The applicant contends further that the evidence on record shows that the Minister did not consider relevant comments on the apparent understanding that the work of reviewing comments would be done by the people within the Department and others from outside it, which approach by the Minister was, in itself, irregular.

[45] In my view, the applicant cannot be said to be an outsider to the process because it was not in existence at that time. It has a valid reason why it did not comment or participate in the process. The applicant did not comment on the draft because it was only formed afterwards. Its Constitution was signed on 14 February 2018 after the comment period on the final version of the draft Regulations had closed and after the promulgation of the impugned Regulations by the Minister on 25 August 2017. It is common cause that this application was launched on 16 February 2018, two days after signature of its Constitution.

[46] It is also not in dispute that the applicant was established mainly as a body to bring this litigation on behalf of its members. The applicant's counsel explains that its members were afraid to approach the court individually and wanted to hide behind the applicant, for whatever fears they might have had. The respondents' reliance on *Doctors for Life* in this regard, does not assist its case. I am in agreement with the argument by the applicant's counsel that *Doctors for Life* is distinguishable from the current application. In *Doctors for Life*, the comments were completely ignored whereas in this instance, the applicant was not in existence.

[47] It is my opinion that the applicant has standing to raise a process argument particularly where that argument is that comments were ignored. Perhaps it can be said that the applicant cannot make procedural arguments but, an argument that the process that was followed was a sham because comments were ignored is, to me, perfectly valid and the applicant should be allowed to raise it. It is not necessary that the applicant should have contributed to the comments for it to have standing to challenge the regulation making process, and, as argued by the applicant's counsel, the applicant's comments would have been one more comment on the pile of comments submitted and ignored.

[48] It is acceptable that the public-comment process was particularly important because of the significance of the amendments in the last draft of the Regulations

circulated in 2017. It was at this stage that the scope of the impugned Regulations increased to include complementary medicines and health supplements. The applicant's complaint is that the latter end of the process was rushed hence some material comments were ignored, that is, neither of those comments nor a summary of the comments made at that time served before the Minister.

[49] That the applicant did not comment on the draft Regulation because it did not exist at the time, does not, in my view, bar it from challenging the lawfulness of the impugned Regulations since it was formed in opposition to the effect of the impugned Regulations.

[50] This point *in limine* by the respondents also falls flat.

The Amicus/ TAC

[51] When it comes to the *amicus* or TAC, there are two preliminary points that have been brought to my attention and require determination before I deal with the merits part of the application. The first point has been raised by the applicant to the effect that the *amicus* should not be allowed to raise the question of standing. The second point is raised by the *amicus* that the applicant lacks standing to institute this application. I deal first with the point raised by the applicant, for if I find in its favour it will not be necessary to deal with the *amicus'* point. Should the *amicus* not be allowed to raise the point of lack of standing of the applicant?

[52] As already stated, it is the applicant's stance that the *amicus* should not be allowed to make the point of lack of standing. In its answering affidavit to TAC's intervention application, the applicant states that it allowed the intervention without accepting that the intervention was properly motivated or TAC had anything helpful to offer the court.

[53] The applicant submits that TAC misunderstands its rights and duties as an *amicus*. According to the applicant, TAC has been offered the privilege to participate in the proceedings as *amicus* and, thus, has a special duty towards the court to provide cogent and helpful submissions by raising new contentions based upon the material already before court and not to raise new factual disputes. Like, for instance, it is not the role of an *amicus* to challenge standing, and by so doing, TAC has strayed beyond the limits of its role as an *amicus*. For that reason, the applicant proposes that the submissions TAC wishes to advance in this regard not be accepted by the court.

[54] The contention is that TAC seeks to introduce new evidence on the issue of standing in circumstances where the standing is not seriously disputed by the respondents. An *amicus*, according to the applicant, is not an opposing party in the conventional sense and is not entitled as a matter of course to impugn the standing of a party on its own accord. Its role is to draw the attention of the court to relevant matters of law and fact to which attention would not otherwise be drawn. In turn for the privilege of participating in the proceedings without having to qualify as a party, an *amicus* has a special duty to the court.

[55] The applicant's further submission is that the role of an *amicus* does not extend to a defence like standing, which should have been raised by the parties, as such, TAC's attack is misplaced. The contention being that, raising the issue of standing is an attempt by TAC to resuscitate the issue that the respondents seem to have abandoned or not vigorously pursued. This issue should have been raised and pursued by the respondents and it is not appropriate that it be raised by the *amicus*. In any event, so the argument goes, by raising this issue, TAC does not add a distinctive perspective to assist the court to correctly decide the substantive issues before it, but wants to ensure that the issue is not heard at all.

[56] In support of this argument, the applicant relies on the case of *Ex parte Goosen and Others (Legal Practice Council and Others as amici curiae) (Recusal Judgment)*[19] wherein the court was confronted with a recusal application. The *amicus* in that judgement had applied for the recusal of one member of the specially constituted Full Court. It did so to avoid the perception of bias arising from a conflict of interest derived from the Judge's membership of another *amicus* appearing in the matter. The question that that court had to determine was whether the *amicus* had standing to seek recusal. The question as formulated by the court was whether an *amicus* who is invited to participate by a court has standing to apply for the recusal of a member of that bench [court]. In deciding the issue, the court stated as follows:

> "There would seem to be sound policy considerations that confine standing in regard to recusal of a judge to a party and not extend standing to *an amicus of the kind who appeared in this matter*. No example of such an application on behalf *of an amicus, invited by a court to offer assistance*, has been found in the researches undertaken for the purposes of this judgment."[20] (own emphasis)

[57] That court held further that: 'it was doubtful that an "*amicus*" whose presence in a case was the result of an invitation by the court to participate in order to assist the court had standing to move for the recusal of a member of the Court that invited it'.

[58] *Ex parte Goosen*, in my view, is not a good case in support of the applicant's argument in this instance. In that judgment the court dealt with an *amicus* who had been invited by the court and it is to that particular *amicus*, that is, an *amicus* invited by the court, that the judgment refers. This is what would distinguish *Ex parte Goosen* from the current matter, as argued by TAC. As such, the applicant's proposition that a similar approach should be adopted in respect of the *amicus* before this court, who is raising a point on standing, is farfetched. It is common cause that the *amicus* in this

[19] 2020 (1) SA 569 (GJ).
[20] *Ibid* at para 20.

instance was admitted to the proceedings on application by it to the court, it was not invited.

[59] Another reason that would distinguish *Ex parte Goosen* from the present matter is that *Ex parte Goosen* focused specifically on the apprehension of bias. It is thus correct that if the parties to the litigation cannot open the question of bias it must follow that it cannot be open to the *amicus* to raise it. The question of standing, as correctly argued by TAC's counsel, is different in that either a party has standing or does not have standing.

[60] I am in alignment with TAC's argument that standing is a matter of law. A question of standing, as a matter of law, can be raised by a court. There is, therefore, no reason why such an issue cannot be raised by the *amicus* as well. The role of an *amicus* has been held to be to draw the attention of the court to relevant matters of law and fact to which attention would not otherwise be drawn.[21] As it has been said, the core role of an *amicus* is to help the court to reach a decision in making factual and legal submissions including matters of law. The question of standing is a matter of law relevant for the determination of this matter, and can, thus, be raised by an *amicus*. The next question that arises is whether it is permissible for the *amicus* in this instance to raise the question of standing.

[61] TAC submits that having already been admitted as *amicus*, its evidence is on record. The issue of standing is one of the issues that it raised in its intervention application which issue the applicant chose not to oppose, and thus, TAC is entitled to raise it.

[21] *Minister of Health & Others v Treatment Action Campaign & Others* 2002 (10) BCLR 1033 (CC).

[62] The question now, is whether TAC, having been admitted unopposed as *amicus* in these proceedings, should be allowed to proceed to raise the issue of the applicant's standing without much ado?

[63] As already stated, TAC was admitted as *amicus* in a meeting held with the ADJP. In paragraph 3 of the minutes of that meeting, dealing with TAC's admission the following is stated:

> "3. TAC is admitted as *amicus curiae*.
>
> 3.1 TAC's legal submissions are confined to novel issues.
>
> 3.2 The applicant and the respondents may deliver supplementary heads of argument, in which –amongst others – they address whether TAC's heads of argument are indeed confined to novel issues.
>
> 3.3 If necessary, the presiding judge may determine the extent of any impermissible overlap in the main parties' and TAC's heads of argument."

[64] Based on the content of the paragraph of the minutes alluded to above, the upshot is that, even though TAC was admitted in the proceedings on the basis of the issues it raised in the application for intervention, one of them being the applicant's lack of standing, it did not necessarily mean that the issues raised therein were permissible. Hence, firstly, the applicant and the respondents were given an opportunity to file supplementary heads of argument, in which –amongst others – they address whether TAC's heads of argument are indeed confined to novel issues. Secondly, the judge presiding over the review proceedings was afforded the discretion to determine the extent of any impermissible overlap in the main parties' and TAC's heads of argument. Meaning that the judge presiding has the discretion to determine whether any of TAC's legal submissions fall outside the permissible bounds. The applicant, having raised this issue in its supplementary heads of argument, it is left to this court to make the decision whether the issue of standing as raised by TAC is permissible.

[65] An *amicus* is required to raise something new. The Constitutional Court in *Fose v Minister of Safety and Security*[22] refused to permit the intervention of the SAHRC as an *amicus curiae* because it "did not raise any substantially *new contentions* which might have been useful for the court."(emphasis added)

[66] Thus, in essence, TAC as *amicus* should be limited to raising novel issues in its arguments. Are the issues raised by TAC in its argument novel?

[67] TAC's stance is that the submissions it seeks to make – both factual and legal– have not been advanced by any of the parties to the review proceedings and are therefore distinguishable.

[68] The new evidence, according to TAC, will assist the court by providing a basis for TAC's challenge to the applicant's standing. The legal submissions will on the other hand help determine whether the challenge to the impugned Regulations should be entertained and locate the matter in its constitutional context, which sees appropriate regulation as a constitutional obligation and not a policy opinion.

[69] It need first to be said that the question of the standing of the applicant was raised initially by the respondents in their answering affidavit. In raising the said issue, the respondents question the fact that the applicant, having presented itself as being a voluntary association whose members operate across the complementary medicines and health supplements sectors, did not respond to the invitation for public comments leading to the publication of the impugned Regulations, which it now seeks to challenge.

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[22] 1997 (3) SA 786 (CC) at para 10.

[70] In light of the absence of any details about the membership of the applicant and the fact that the applicant appears to have come into existence only two days before the launch of this application, the respondents deny that the applicant acts in the interest of its members or in the public interest. This was the basis upon which the respondents initially challenged the applicant's standing.

[71] It is worthy to note that the respondents do not challenge the applicant's standing on the basis that it can act in its own interest. The basis of the respondents' challenge is that the applicant cannot act in the interest of its members or act in the public interest. Interestingly enough, the applicant does not raise a ground of acting in its members' interest as a basis to challenge the impugned Regulations, it relies on own interest and public interest. TAC, on the other hand, attacks the applicant's standing both on own interest and public interest.

[72] Standing, to the extent challenged by the respondents in the answering affidavit, is challenged on the narrow basis that the applicant does not act in the public interest. This argument is not aggressively pursued by the respondents either in the heads of argument or their counsel's oral argument. The respondents dedicate only one line to this argument in the heads of argument and their counsel, in passing during oral argument, mentions that he supports the argument of TAC's challenge to the applicant's standing. In its oral argument counsel attacks the applicant's standing on another narrow ground of process, as already discussed in this judgment above.

[73] The applicant's contention is that in challenging the applicant's standing, TAC attacks the membership of the applicant on the back of the respondents' denial that the applicant is acting in the public interest because the applicant failed to provide details of its members and names of its office bearers, although unlike the respondents, TAC challenges the applicant's standing to prosecute the review in the public interest as well as in its own interest.

[74] By so doing, it is the applicant's argument that TAC steps into an environment where issues have been clearly defined and wants to bring new evidence on an issue that neither of the main parties regard as central to the real issues of the review. This, according to the applicant, operates against applicable law in the sense that TAC in its role as *amicus* must only draw the attention of the court to relevant matters of law and fact to which attention would not otherwise be drawn. The *amicus* must not repeat arguments already made but must raise new contentions, and generally, these new contentions must be raised on the evidence already before the court. Thus, the proposition is that TAC is not entitled as a matter of course to impugn the standing of the applicant on the basis of the applicant's public interest ground, as it was already raised by the respondents.

[75] The issue of standing itself is not novel, as it had already been raised by the respondents. However, TAC says it seeks to introduce new evidence in respect of the evidence furnished in support of the allegation that the applicant lacks own interest and public interest standing.

[76] As I have earlier stated, the respondents attack the applicant's standing on the ground that the applicant lacks public interest standing. This question appears to have already been settled between the parties. The answer provided by the applicant in the answering affidavit seems to have satisfied the respondents because, as the applicant contends, the point was not seriously pursued in the respondents' heads of argument. The respondents, dedicating only one line to it in the heads of argument and in oral argument and its counsel, without elaborating further, stated that he supports the arguments of TAC on this point and instead argued on a different ground of process. Any new evidence by TAC, in this regard, seeks to bolster the respondents' argument which they chose not to pursue. And, this is not permissible.

[77] The reply proffered in the replying affidavit by the applicant that its membership list is irrelevant in that the applicant is a universitas entitled to sue and be sued in its

own name, and it can and is, acting in the public interest, is to me an equally satisfactory response to the negative inference TAC wishes to draw from the fact that the identity of the applicant's membership and office bearers are not disclosed.

[78] A universitas, as pointed out by the applicant, is distinguished from a mere association of individuals by the fact that it is an entity distinct from the individuals forming it. Likewise, its capacity to acquire rights or incur obligations is distinct from that of its members, which are acquired or incurred for the organisation as a whole, and not for individual members.

[79] The improper regulation of complementary medicines and health supplements not only affects manufacturers of these products, but also suppliers and customers. In particular, consumers will take the brunt of absorbing the costs of inappropriate and unlawful regulation of products as medicines, thus severely restricting access to these products. It is also likely that many products may be withdrawn from the market. As such, this case is correctly brought in the public interest.

[80] I would, in this regard, hold that TAC is not entitled to raise this ground of standing. What then remains is whether TAC can pursue its challenge on standing on the basis of the applicant's own interest standing.

[81] TAC says it wants to advance legal submissions aimed at assisting the court to determine whether the applicant has shown enough to be afforded own interest standing.

[82] The applicant submits, correctly, that although TAC's contention about the applicant's own interest standing is a contention raised on the material already before

court it, however, seeks to sustain the point with fresh evidence which raises factual disputes. This should not be allowed.

[83] To this end, TAC adduces new evidence in support of its challenge to the applicant's own interest standing in an attempt to resuscitate the issue of standing. Raising new evidence in this regard, is overreach by TAC as it is supposed to constrain itself to novel issues. Therefore, TAC's submission on standing stands to be rejected.

THE MERITS

[84] On the merits part of the claim, as already stated earlier herein, the applicant's case is based on the quintessential *ultra vires* question. It is the applicant's claim that the definition of complementary medicine and health supplements in the impugned Regulations is too wide and includes products that do not fall within the definition of medicine as defined in the Medicines Act. This overreach, as argued by the applicant, is not permissible and, thus, the impugned Regulations are *ultra vires* when measured against the empowering statute.

[85] This averment is denied by the respondents who insists that, in promulgating the impugned Regulations as they stand, the Minister did not act *ultra vires*, but was empowered to do so by section 35 of the Medicines Act.

International Best Practice

[86] In support of their respective claims the parties referred to various practices relating to complementary medicines followed in different countries as a guide that should be followed when deciding whether the impugned Regulations are *ultra vires* or not. Mostly, reference to the international practices was to confirm the need for regulation of complementary medicines which is not in dispute in these papers.

[87] Having perused and considered the submissions on foreign practices, I am inclined to agree with the applicant's argument that there is, actually, no benchmark of good practice that can be followed by South Africa. Different regulatory options apply in different countries Like for instance:

87.1 In Australia, complementary medicines, including dietary supplements, fall within the medicine directorate, but they have a separate listing system. The Australian Therapeutic Goods Administration works directly with industry, regulating the safety and quality of lower-risk medicines by limiting these medicines to pre-approved low-risk ingredients and pre-approved low-risk or minor health conditions, and by requiring quality manufacturing.

87.2 In Canada, natural health products are regulated under medicines but have their own regulations, directorate and standards.

87.3 In the USA, dietary supplements are regulated by the Federal Food and Drug Administration, under the food legislation. There is a separate directorate (dietary supplements) with separate regulations and a separate registration system/process.

87.4 In the European Union, nutritional food supplements are regulated as foods, as is the case in the United Kingdom.

[88] From the above it can be readily ascertained that complimentary medicines and health supplements are regulated differently in the various countries quoted by the parties. The approach to regulation of complimentary medicines and health supplements by South Africa need not necessarily follow anyone of those foreign practices. In this judgment the practice South Africa seeks to follow, that of regulating complementary medicines and health supplements as medicines under the Medicines Act, should be considered on its own merits.

The Applicant's Argument

[89] The applicant's case is premised on the assertion that aspects of the impugned Regulations are *ultra vires* when measured against the Medicines Act. At the heart of

the applicant's argument is the legal question concerning the interpretation of the word 'medicines' as used in the Medicines Act. The applicant's contention is that this is an objective, legal issue, and not one that can be altered by claims to government policy or how the respondents choose to read the Medicines Act.

[90] According to the applicant, the starting point in this case must be the Act and its correct interpretation. If on a proper interpretation of the Act, more particularly the definition of medicines, it is found that the concept of complementary medicines (as defined in the impugned Regulations) includes products and substances that are not medicines (as defined in the Medicines Act), then the impugned Regulations are unlawful to that extent and the declaratory relief set out in the notice of motion should be granted.

[91] In essence, the applicant's complaint is that there are products which should not be included in the ambit of the Medicines Act and should not be regulated as envisaged by the impugned Regulations. These products, according to the applicant, are now defined as complementary medicines and health supplements as defined in the impugned Regulations, whilst in effect they do not contain scheduled substances, and make no therapeutic or curative claims. These products only claim to promote well-being and good health, or promote relaxation. In this sense, they are qualitatively different from medicines, which are designed and dispensed solely to target therapeutic purposes or to treat or cure maladies. The impugned Regulations, as they stand, treat all these complementary medicines and health supplements – and regulate them – as if they are medicines. The applicant accordingly contends that the impugned Regulations are *ultra vires* and unlawful because the Medicines Act does not permit the regulation of products and substances that are not medicines or that do not contain scheduled substances.

[92] In trying to assist in the interpretation of the Medicines Act, the applicant states the following:

[93] The Act regulates medicines, scheduled substances, medical devices and IDVs as defined in the Act. Only medicines and scheduled substances are relevant for purposes of this judgment.

[94] The applicant goes on to state that medicines are defined on the basis of objective facts. A substance or mixture of substances is only medicine if it is used, purports to be used or is manufactured for use or sale in relation to the matters set out in subsections (i) and (ii) of the definition of medicine in section 1 of the Medicines Act. Each constituent element of the definition is satisfied by objectively determinable criteria. The implication, clearly, is that there is no room for opinion in resolving the question whether something is a medicine or not.

[95] To qualify as medicine, so it is argued, it is not necessary for the substance or mixture of substances to perform the functions set out in subsections (a) (i) and (ii) of the definition of medicine. The substance or mixture of substances is a medicine if it is (a) used for those functions, (b) purports to be suitable for those functions, or (c) marketed by the manufacturer or the seller to be used for those functions. In other words, something does not have to work to be a medicine. If it is thought to work, or marketed to work, it is a medicine.

[96] According to the applicant, a sensible contextual approach to the interpretation of subsections (a) (i) and (ii) of the definition of medicine is required to avoid absurd results. Subsection (a) (i) poses few difficulties: to qualify as a medicine in terms of the subsection, the substance or mixture of substances must be used or marketed to be used for the prevention, diagnosis, treatment, mitigation or modification of physical or mental disease. This is consistent with the conventional understanding of the purpose and use of medicines. However, the functions in subsection (a) (ii) appear at first blush to be broader. Read literally, they could include anything that has almost any effect (restoring, correcting, or modifying) on the body or mind. This would, according to the applicant, include water, which is used to restore hydration levels in

the body. But clearly, such an expansive reading is not what is intended, so the argument continues. In its submission, the applicant argues that a more sensible approach would be to regard something as medicine only if it is used, or purports to be suitable for use, or manufactured or sold for use for a "therapeutic purpose". In other words, for the prevention or treatment of a malady, but not the meeting of ordinary human nutrition or sustenance.

[97] The impugned Regulations, according to the applicant, are not a model of clarity and are often difficult to follow. The applicant contends that the regulatory scheme contained currently in the impugned Regulations would not attract controversy were it not for the fact that the impugned Regulations introduce expansive definitions of the concepts of complementary medicines and health supplements as analysed below.

[98] A substance or a mixture of substances must satisfy each of the three conjunctives criteria set out in sub-regulation (a) to (c) of the definition of complementary medicines to qualify as a complimentary medicine. Sub-regulation (a) identifies the ingredients from which the complementary medicine must be derived. This, as argued by the applicant, is expansive and would cover almost any natural or synthetic product, including all ordinary foodstuffs. Regulations (b) and (c) are designed to hone and restrict the definition by focussing on uses which render a substance a complementary medicine.

[99] The contention is that the impugned Regulations attempt to ratchet open the already wide definition of medicine in the Medicines Act. The applicant contends that subsection (a) (ii) of the definition in the Medicines Act restricts itself to substances which have a positive impact in cases in which the body is malfunctioning, by restoring, correcting and modifying. The impugned Regulations on the other hand goes on to also include substances that have only a secondary role in contributing to the ordinary proper functioning of the body by maintaining, complementing or assisting.

[100] The argument goes further that when courts have been asked to interpret subsection (a) (ii) of the definition of medicine in the Medicines Act, they have interpreted the definition purposively to avoid the countless absurdities that would arise if the definition was read to include substances that merely contribute to normal physical or mental functions.

[101] The applicant submits, further that the definition of medicines in the Medicines Act cannot be ratcheted open based on an understanding of the concept in the impugned Regulations. The interpretation of the Medicines Act (and more specifically the definition of medicines) is a legal question and cannot draw its cue from the subordinate Regulations.

[102] In this regard the applicant relies on the judgment in *Sebola and Another v Standard Bank of South Africa Ltd and Another* [23] wherein the Constitutional Court confirmed the principle that a regulation cannot be used to interpret the Act from which it derives. In that sense, the applicant argues that to accept the respondents approach of interpreting the Medicines Act from their understanding of the definition of complementary medicines in the impugned Regulations, would be to interpret the Act based on its interpretation in the Regulations.

[103] The applicant's proposition is that, ultimately, the Medicines Act only applies to substances which fall within the ambit of "medicines" or "scheduled substances," which are both terms defined in the Medicines Act. The Minister's regulation-making power is similarly restricted to such substances. Conversely, the Minister has no power to regulate products that are not medicines, or do not contain a scheduled substance. It follows that the Minister can only regulate complementary medicines and health supplements to the extent that these fall within the definitional ambit of medicines, or contain scheduled substances. Anything else the impugned

[23] 2012 (5) SA 142 (CC) at para 62.

Regulations seek to control will fall outside the Medicines Act's ambit and consequently be *ultra vires* the empowering legislation, so the applicant argues.

The Respondents' Argument

[104] The respondents' submission is that the Minister is empowered to make the Regulations by the wide power provided to him in section 35 of the Medicines Act. These powers include: providing for classification of medicines, medical devices or IDVs into classes or categories for the purposes of this Act. The powers are wide enough to include complementary medicines within its ambit and empowers the Minister to regulate complementary medicines as he had done.

[105] The contention is that, if one of the objects of the legislation is to protect the public and ensure safe, effective and quality products, then making Regulations which regulate complementary medicines is generally for the efficient carrying out the objects and purpose of the Medicines Act. Once it is so, then the Minister was empowered to make the impugned Regulations and did not act *ultra vires* in doing so.

[106] The respondents' proposition is that, in interpreting the Medicines Act and the definition of medicine, the court is required to adopt a purposive and contextual construction. The respondents submit that purposively construed, there is no basis for the narrow interpretation contended for by the applicant. Nor is there any suggestion that the broad definition means that all foodstuffs is included in the definition of 'medicine' in the Medicines Act. Properly construed, the definition applies to all products which purport to diagnose, treat, mitigate, modify or prevent disease. Those products which purport to do so will be regarded as medicines under the Medicines Act, whether they are complementary medicines or traditional ones.

[107] According to the respondents this is a sensible and purposive construction of the Medicines Act which gives effect to the obligation of the Authority to ensure the

safety of the public. This is also the way in which the respondents have always interpreted the definition of medicine. The example that the respondents make in this regard is that while water might fall within the definition of medicine, the respondents have not interpreted it to do so nor have they attempted to regulate its use.

[108] It is submitted further that the broad definition of medicines is sufficiently wide to include complementary medicines to the extent that they address diagnosis, treatment, mitigation, modification or prevention of disease. Those products that do not do so are not complimentary medicines and will, therefore, not be regulated. The contention being that benefits of regulation of a product as a medicine (even when indicated for supplemental use or as a health supplement) would allow registration review, oversight of the product quality as well as safety of the product for use as intended.

[109] The respondents, in an attempt to assist in the interpretation of the Act, proffer the following argument: The definition of medicine in the Medicines Act, read with the definitions of the words "sell"[24] and "advertisement",[25] envisage three different circumstances which may result in a substance being a medicine. These are if the substance: is used for the defined purpose; purports to be suitable for use for such purpose; or is manufactured or sold for use for such purpose. The defined purposes, according to the respondents, are widely stated and include the diagnosis, treatment,

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[24] "1.Definitions.—(1) In this Act, unless the context otherwise indicates—
"sell" means sell by wholesale or retail and includes import, offer, advertise, keep,expose, transmit, consign, convey or deliver for sale or authorize, direct or allow a sale or prepare or possess for the purposes of sale and barter or exchange or supply or dispose of any person whether for consideration or otherwise; and "sale" and" sold have corresponding meanings: .

[25] 1.Definitions.—(1) In this Act, unless the context otherwise indicates— "advertisement", in relation to any medicine, Scheduled substance, medical device or IVD, means any written, pictorial, visual or other descriptive matter or verbal statement or reference –
(a) appearing in any newspaper, magazine, pamphlet, electronic media (including radio and television) or other publication;
(b) distributed to members of the public; or
(c) brought to the notice of members of the public in any manner whatsoever, which is intended to promote the sale of that medicine, Scheduled substance, medical device or IVD, and "advertise" has a corresponding meaning; . . .

mitigation, modification or prevention of disease or its symptoms and they also include restoring or correcting or modifying any somatic or physic or organic function in humans.

[110] This, according to the applicant, means that the definition hits both substances which in fact are used for any of the defined purposes as well as those which purport or claim to be suitable for such purposes. A substance may be a medicine if it purports to be suitable for one of the purposes or if it is manufactured or sold for one of the purposes even if it does not or cannot achieve such purpose.

[111] The respondents contend that, based on the interpretation they propose, the definition of complementary medicines and health supplements as contained in the impugned Regulations is not overboard and does not contain products that fall outside the definition of medicine as defined in the Medicines Act. Thus, on that contention, they argue that the *ultra vires* question raised by the applicant ought to be dismissed.

Analysis

[112] From my understanding of the aforementioned arguments, it is common cause that something is a medicine if it falls within the definition in section 1 of the Medicines Act and that something is a scheduled substance if it is scheduled by the Minister, on recommendation of the Authority, under section 22A (2) of the Medicines Act.

[113] It also appears that the parties are agreed on what the definition of medicine in the Medicines Act should entail. They are agreed that the purposive and contextual approach to the interpretation of the Act should prevail as well. Of significance is that they are agreed that the interpretation of medicine in the Medicines Act is wide enough to include complementary medicines in its ambit and that section 35 of the Medicines Act empowers the Minister to regulate complementary medicines.

[114] Where the parties differ is whether the Medicines Act empowers the Minister to regulate *all* complementary medicines. It is the applicant's stance that not all complementary medicines make therapeutic claims – there are complementary medicines that make therapeutic claims and those that do not. The applicant contends, for the reasons advanced above, that the Medicines Act does not empower the Minister to regulate those complementary medicines that do not make therapeutic claims. Whereas, it is the respondents' argument that the Medicines Act empowers the Minister to regulate all complementary medicines. Meaning that the definition of 'medicines' in the Medicines Act is wide enough to include all complementary medicines in its ambit.

[115] There is no material factual dispute in the arguments raised. What remains is a legal dispute regarding the correct interpretation of the concept of a medicine as defined in the Medicines Act. The main issue being whether the interpretation should be wide or narrow. In essence the question at issue is whether complementary medicines and health supplements as defined in the impugned Regulations fall within the ambit of the definition of medicines in the Medicines Act. In order to resolve the issue, it is useful to juxtapose the definitions of complementary medicine and health supplements with the imperative language of the definition of 'medicine' in the Medicines Act.

[116] There are a number of consequences (which the applicant seeks to avoid) that ensue if a substance falls within the ambit of the definition of medicine which are contained in the following sections of the Medicines Act:

116.1 section 14(1) prohibits the sale of any medicine which the Authority has declared subject to regulations under section 14(2) unless it has been registered.

116.2 section 18(1) prohibits the sale of any medicine unless its container or packaging 'bears a label stating the prescribed particulars'.

116.3 section 18(2) prohibits the advertising of any medicine unless the advertisement 'complies with the prescribed requirements'.

116.4 section 18 A (1) prohibits supplying any medicine according to a bonus system, rebate system or any other incentive scheme.

116.5 section 18 B (1) prohibits providing a free sample of medicines.

116.6 section 18 C (1) empowers the Minister to regulate the marketing of medicines, and to provide for Codes of Practice for relevant industries.

116.7 section 19(1) prohibits the sale of any medicines unless it complies with prescribed requirements.

116.8 section 20 (1)(a) prohibits the publication or distribution of any false or misleading advertisement concerning any medicine.

116.9 section 20 (1)(b) prohibits the publication or distribution of an advertisement that claims that a registered medicine has an effect other than what is stated in its registration notice.

[117] The Act also attaches consequences to scheduled substances under the following provisions:

117.1 to the extent that a scheduled substance is not also a medicine, it is bound by the labelling/packaging, and advertising requirements in section 18(1) and (2) of the Act.

117.2 the main consequences of any substance being scheduled is that the Act imposes onerous restrictions on its possession, sale and manufacture. These restrictions increase from those in Schedule 0 to the severe restrictions attached to Schedule 8 substances.

117.3 all medicines that must be registered automatically fall within Schedule 0. This is relatively anodyne, as no real restrictions apply to the possession or sale of these substances (sections 22A (3) and (16) (a)).

[118] I set out these consequences in order to indicate why it is that the applicant finds it necessary to differentiate between complementary medicines that make

therapeutic claims and those that do not do so. In essence, the applicant seeks to avoid these consequences in respect of complementary medicines and health supplements that it contends do not make therapeutic claims.

[119] The Constitutional Court in *Affordable Medicines*,[26] when dealing with the question of whether the Minister's actions were *ultra vires* or not, expressed itself as follows:

> "In exercising the power to make regulations, the Minister had to comply with the Constitution, which is the supreme law, and the empowering provisions of the Medicines Act. If, in making regulations the Minister exceeds the powers conferred by the empowering provisions of the Medicines Act, the Minister acts *ultra vires* (beyond the powers) and in breach of the doctrine of legality. The finding that the Minister acted *ultra vires* is in effect a finding that the Minister acted in a manner that is inconsistent with the Constitution and his or her conduct is invalid. What would have been *ultra vires* under common law by reason of a functionary exceeding his or her powers, is now invalid under the Constitution as an infringement of the principle of legality. The question, therefore, is whether the Minister acted *ultra vires* in making regulations that link a licence to compound and dispense medicines to specific premises. The answer to this question must be sought in the empowering provisions." (footnotes left out)

[120] When coming to the interpretation of the Medicines Act, the definition of the term medicine is important. The definition itself is contained in section 1 of the Medicines Act which provides that:

> "**"medicine"** —
>
> (a) means any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in —

[26] *Affordable Medicines Trust and Others v Minister of Health and Another* 2006 (3) SA 247 (CC) at para 50.

(i) the diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof in humans; or

(ii) restoring, correcting or modifying any somatic or psychic or organic function in humans; and . . .'

[121] This is to be juxtaposed with the definitions of complementary medicines and health supplements in the impugned Regulations. The definitions are stated as follows:

'"**complementary medicine**" means any substance or mixture of substances that –

(a) originates from plants, fungi, algae, seaweeds, lichens, minerals, animals or other substance as determined by the Authority;

(b) is used or purporting to be suitable for use or manufactured or sold for use –

(i) in maintaining, complementing, or assisting the physical or mental state; or

(ii) to diagnose, treat. mitigate, modify, alleviate or prevent disease or illness or the symptoms or signs thereof or abnormal physical or mental state, of a human being or animal; and

(c) is used –

(i) as a health. supplement; or

(ii) in accordance with those disciplines as determined by the Authority; or

(d) is declared by the Authority, on approval of the Minister by notice in the Gazette, to be subject to registration as a complementary medicine in terms of section 14;'

and

> "**health supplement**" means any substance, extract or mixture of substances as determined by the Authority, sold in dosage forms used or purported for use in restoring, correcting or modifying any physical or mental state by
>
> a) complementing health
>
> b) supplementing the diet; or
>
> c) a nutritional effect,
>
> and excludes injectables or substances classified as schedule 1 or higher".

[122] The proper approach to interpretation has been recently enunciated in the judgment in *Natal Joint Municipal Pension Fund v Endumeni Municipality*.[27] The court in that judgment stated as follows:

> "The present state of the law can be expressed as follows. Interpretation is the process of attributing meaning to the words used in a document, be it legislation, some other statutory instrument, or contract, having regard to the context provided by reading the particular provision or provisions in the light of the document as a whole and the circumstances attendant upon its coming into existence. Whatever the nature of the document, consideration must be given to the language used in the light of the ordinary rules of grammar and syntax; the context in which the provision appears; the apparent purpose to which it is directed and the material known to those responsible for its production. Where more than one meaning is possible each possibility must be weighed in the light of all these factors. The process is objective and not subjective. A sensible meaning is to be preferred to one that leads to insensible or unbusinesslike results or undermines the apparent purpose of the document. Judges must be alert to, and guard against, the temptation to substitute what they regard as reasonable, sensible or businesslike for the words actually used. To do so in regard to a statute or statutory instrument is to cross the divide between interpretation and legislation. In a contractual context it is to make a contract for the parties other than the one they in fact made. The 'inevitable point of departure is the language of the provision itself', read in context and having regard to the

[27] 2012 (4) SA 593 (SCA) at paras 18-9.

purpose of the provision and the background to the preparation and production of the document.

All this is consistent with the 'emerging trend in statutory construction'. It clearly adopts as the proper approach to the interpretation of documents the second of the two possible approaches mentioned by Schreiner JA in *Jaga v Donges NO* and another [1950 (4) SA 653 (A) at 662G – 663A], namely that from the outset one considers the context and the language together, with neither predominating over the other. This is the approach that courts in South Africa should now follow, without the need to cite authorities from an earlier era that are not necessarily consistent and frequently reflect an approach to interpretation that is no longer appropriate."

[123] The interpretation of the first part of the definition of medicine in the Medicines Act, that is, subsection (i) thereof, is not problematic; both parties are agreed on it. The problem appears to be with the second part of the definition, that is, subsection (ii). This is where the applicant seeks a narrow interpretation which will exclude the incorporation of all complementary medicines even those that do not make therapeutic claims; whilst the respondents argue for a broader interpretation which will include all complementary medicines.

[124] I am inclined to agree with the applicant on its point that the Medicines Act does not empower the Minister to regulate all complementary medicines. For complementary medicines to fall within the proper contextual definition of medicine in the Medicines Act, only those that purport to be suitable for use, manufactured or sold for use for a therapeutic purpose, that is, for the prevention and treatment of a malady, may be regulated. Hence, only those complementary medicines and health supplements that purport to be used or manufactured for use or sale to address the prevention, diagnosis, treatment, mitigation or modification of physical or mental diseases ought to be regulated.

[125] Subsection (ii) of the Medicines Act, which provides for 'restoring, correcting or modifying any somatic or psychic or organic functions in humans' should, as proposed by the applicant, be read and/or interpreted in its narrow sense, in order to give meaning to its purposive objective of products that purport to be suitable for use, manufactured or sold for use for a therapeutic purpose, that is, for the prevention and treatment of a malady. To give it a broad meaning as suggested by the respondent will lead to a number of absurdities.

[126] The respondents, in their argument in support of the contention that subsection (ii) ought to be given a broader interpretation, provide an explanation in the contrast between the alternative component of "medicine" which relates to restoring, correcting or modifying somatic or psychic or organic function in humans; and, the definition of complementary medicines which refers to maintaining, complementing or assisting the physical and mental state. The explanation is that the applicant, in its interpretation, ignores the definition of health supplements in the alternative definition of complementary medicines which imposes the additional restriction that the 'maintenance, complementing or assisting' as referred to therein, is used as a health supplement. Health supplements, according to the respondents, are defined in a way which tracks the definition of medicine, namely, a substance used or purported for use in restoring, correcting or modifying any physical or mental state by, *inter alia*, complementing health.

[127] When the definitions of complementary medicines and health supplements are read in the sense that the respondents seek that they be accepted as the proper interpretation, they, however, confirm the applicant's submission that the alternative definition of complementary medicines read with the definition of health supplements have a secondary role in contributing to the ordinary proper functioning of the body by maintaining, complementing or assisting the physical and mental state. This is far more acceptable than the interpretation the respondents are contending for.

[128] The respondents' further argument that in any event, the concepts of "restoring, correcting or modifying" cover and include "maintaining, complementing or assisting" when read with the dictionary definitions of those words (which are provided in the 'References to Respondents Argument'). The definitions of the words as provided by the respondents give a literal construction which is not helpful when so construed. In *Cool Ideas 1186 CC v Hubbard and Another*,[28] the Constitutional Court considered the proper approach to statutory interpretation. The court stated the following:

> "A fundamental tenet of statutory interpretation is that the words in a statute must be given their ordinary grammatical meaning, unless to do so would result in an absurdity. There are three important interrelated riders to this general principle, namely:
>
> (a) that statutory provisions should always be interpreted purposively;
>
> (b) the relevant statutory provision must be properly contextualised; and
>
> (c) all statutes must be construed consistently with the Constitution, that is, where reasonably possible, legislative provisions ought to be interpreted to preserve their constitutional validity. This proviso to the general principle is closely related to the purposive approach referred to in (a)."

[129] The interpretation sought by the respondents is not a natural interpretation of the statutory provisions in question let alone that it is one that vindicates the object of the Medicines Act. The contextual approach, as suggested by the applicant, is rather more persuasive. The contextual interpretation vindicates the purposive object of the Medicines Act which is to treat and prevent maladies.

[130] To a certain extent, the respondents seem to have conceded to this point in their submission, in the answering affidavit, when they say that the broad definition of medicines is sufficiently wide to include complimentary medicines to the extent that they address diagnosis, treatment, mitigation, modification or prevention of disease, those products that do not do so are not complementary medicines and will, therefore,

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[28] 2014 (4) SA 474 (CC) at 484.

not be regulated. Having made a finding that the narrow interpretation is more acceptable this argument ties with such finding.

[131] The applicant is correct, therefore, when it says that the impugned Regulations (in particular the definitions of complementary medicines and health supplements) seek to ratchet open the definition of medicine in the Medicines Act. The proper interpretation of the term 'medicine' in the Medicines Act shows that the Medicines Act restricts itself to substances which have a positive impact in cases in which the body is malfunctioning by diagnosing, treating, mitigating, modifying or preventing maladies.

[132] Once the respondents have conceded that 'those products that do not diagnose, treat, mitigate, modify or prevent disease, are not complementary medicines and will, therefore, not be regulated', it is the end of the story. The impugned Regulations' introduction of any other product renders them *ultra vires* to that extent. This is what the applicant's complaint is and this is what the definition of complementary medicines and health supplements in the impugned Regulations does. Consequently, to that extent, the impugned Regulations are *ultra vires* and the applicant should be granted the declaratory order it seeks.

[133] Nevertheless, the respondents make a further proposition to the effect that contrary to the applicant's claim that all forms of health supplements are now going to be regulated as medicines, the MCC has carefully sought to ensure that only those particular substances that may be associated with health claims and/or potentially risk the health and safety of the citizenry if not appropriately prepared, dosed or reviewed are regulated in line with international trends.

[134] This the respondents contend they have maintained by first establishing a Category D (complementary medicine) as a category of medicine. The establishment of this category was intended to enable the regulator to deal with complementary

medicines separately. To ensure that there was no confusion as to which medicines fell under this new category.

[135] A routine administrative practice of the MCC was to provide guidance to stakeholders on the various administrative actions of the regulator in the form of guidelines. They provide guidance on the types of information sought by the regulator and generally seek to harmonise regulatory requirements as prescribed with the required technical information that may, for example, seek to satisfy any application requirement. Guidelines are not intended to dictate exclusive approach to compliance, but simply provide the current approach of the regulator on any matter and are subject to change based on interaction with stakeholders and the execution of regulatory oversight.

[136] The purpose of the guidelines, with respect to complementary medicines was, and remains, to offer guidance to those wishing to submit applications for assessment of quality, safety and efficacy of their products so as to register them as complementary medicines as defined. The guidelines provide details on how the product attributes will be assessed (in line with section 1(3) of the Act) in determining whether the registration/availability of any product is in the public interest and therefore what is required from the applicants. The guidelines are said to be based on the regulations. They are the Authority's interpretation of the product registration requirements in the regulations and are aimed at assisting manufactures to comply with the regulations.

[137] Following an extensive public comment process and the review of all comments received, the MCC decided to simplify the guideline by separating it into different documents addressing specific topics as follows:

137.1 Guideline 7.01 – safety and efficacy data for discipline-specific medicines;

137.2 Guideline 7.04 – safety and efficacy data for health supplements; and

137.3 Guideline 7.05 – quality data for all complementary medicines.

[138] Attached to Guideline 7.04 are annexures which list substances that may typically be considered to be health supplements. It is worth noting that these annexures were prepared following an extensive research, investigation and consultation process which also included international comparisons with countries such as Australia and Canada. The annexures detail which substances will be considered as health supplements and under what circumstances and provide specific guidance on warnings and formulations where required. It is expected that the industry will follow the prescribed annexures in future for new product development, thus providing a *de facto* listing system for that found in Australia or Canada, but providing for sufficient assurance of quality of products.

[139] Additional guidelines are said to have been developed and published for public comments to assist those wishing to register complementary medicines. Stakeholders and members of industry do not only get to comment on these annexures prior to implementation but may also (at any time) motivate for the inclusion (or removal) of a substance on any of the annexures of health supplements as set out in the Guidelines.

[140] These Guidelines the respondents are contending for do not assist their case. I say so on the strength of *Sebola*, a judgment of the Constitutional Court which confirmed the principle that a regulation cannot be used to interpret the Act from which it derives. Similarly, in this instance, the interpretation of the Medicines Act (and more specifically the definition of medicines) is a legal question and cannot draw its cue from the subordinate Regulations as the respondents seek to do. The process of issuing the Guidelines referred to by the respondents all happens in the Regulations. The process confirms the applicant's argument that the respondents seek to interpret the Act in terms of their understanding of the impugned Regulations.

[141] The starting point, as always, is the Act and not the Regulations.

Amicus

[142] Based on my findings above, TAC's case must fall flat. There is nothing new that could be gleaned from its papers to persuade me otherwise. The applicant was, thus, correct to find it not necessary to deal with TAC's argument about the proper interpretation of the Medicines Act.

[143] TAC's further argument on the constitutional perspective does not take its argument any further. Having found the Regulation to be wide and thus *ultra vires*, TAC's perspective canvassed in relation to section 27(1)(a) of the Constitution cannot remedy this default.

CONCLUSION

[144] In *Affordable Medicines*,[29] the court stated the *ultra vires* principle in the following terms:

> "In exercising the power to make regulations, the Minister had to comply with the Constitution, which is the supreme law, and the empowering provisions of the Medicines Act. If in making regulations, the Minister exceeds the powers conferred by the empowering provisions of the Medicines Act, the Minister acts *ultra vires* (beyond the powers) and in breach of the doctrine of legality. The finding that the Minister acted *ultra vires* is in effect a finding that the Minister acted in a manner that is inconsistent with the Constitution and his or her conduct is invalid."

[145] Section 35 of the Medicines Act, as it has been said, empowers the Minister, in consultation with the Authority, to make Regulations. The Minister may make different Regulations in relation to different medicines or scheduled substances, or different

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[29] *Supra* n 26 at para 50.

categories of medicines or scheduled substances. The upshot is that the regulatory scheme only permits the regulation of substances that are 'medicines' or contain 'scheduled substances'. Any regulation promulgated under the Act that purport to regulate substances that are neither 'medicines' nor contain 'scheduled substances' should not be permitted.

[146] Having come to the conclusion I have of the *ultra vires* question, it follows that the abstract nature of the applicant's case is permissible under the circumstances of this matter.

APPROPRIATE RELIEF

[147] Following on a finding of unlawfulness in the impugned Regulations, the court has a wide discretion to consider appropriate relief which is just and equitable – pursuant to section 172(1) of the Constitution. In this regard, the applicant in the heads of argument proposes three possible formulations, namely:

147.1 The first is, to strike down the impugned Regulations *in toto* as prayed for in paragraph 4.1 of the notice of motion. This, according to the applicant, would not leave any *lacunae* as the result of this is merely to return to the regulatory scheme before the impugned Regulations were promulgated. The Minister and the Authority could fast-track new draft Regulations.

147.2 The second is for the court to 'read in' words into the definition of complementary medicines and health supplements, to limit their application to substances that are also medicines in terms of the Medicines Act as prayed for in paragraph 4.2 of the notice of motion. This solution, according the applicant, is less desirable in the sense that it involves the court in the polycentric task of drafting Regulations. The contention is that if the court does find this feasible, it should be as interim relief, applying in a determined period until the Minister can promulgate new Regulations.

147.3 The third is for the court to strike down the impugned Regulations only to the extent that they apply to complementary medicines and health supplements that are not medicines as defined in section 1 of the Medicines Act, or do not contain scheduled substances. This would have the benefit of leaving the rest of the Regulations in place. This is if the problematic definitions could be removed without leaving the rest of the Regulations senseless.

[148] Of the proposals suggested by the applicant, I find the first and second suggested proposals not feasible. Striking down the Regulations *in toto* is too drastic a step to take. The portion of the Regulations that is not affected by the unlawfulness ought to be left intact as long as it does not affect the construct of the Regulations. As already argued by the respondents, a lot of work has gone into the drafting of the impugned Regulations and should not go to waste. Whatever is salvageable or is not affected by the unlawfulness should be retained.

[149] As argued by the respondents, appropriate deference ought to be afforded to the respondents in recognition of their particular expertise in drafting Regulations and the complex nature of the issues at hand.[30] In that regard I find it not appropriate to grant the relief prayed for by the applicant in paragraph 4.2 of the notice of motion, that is, the proposal of reading in words into the definitions of complementary medicines and health supplements to limit their application to substances that are also medicines in terms of the Medicines Act. As accurately submitted by the applicant, this would involve the court in the polycentric task of drafting Regulations which should be afforded to the administrator being the respondents in this instance.

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[30] *Kolbatschenko v King N.O.* 2001 (4) SA 336 (C) at 356D - G.

[150] I would rather grant the third suggestion proposed by the applicant, that of striking down the impugned Regulations only to the extent that they apply to complementary medicines and health supplements that are not medicines as defined in section 1 of the Medicines Act, or do not contain scheduled substances. This would have the benefit of leaving the rest of the Regulations in place and give the respondents an opportunity to come up with the best way of regulating complementary medicines and the appropriate alternative categorization thereof. The relief is just and equitable under the circumstances.

[151] Although it is the applicant's proposition that the relief to be granted should not be suspended as prayed for by the respondents, I am, however, inclined to grant such suspension. I am loath to leave the regulation of complementary medicines without a specific timeframe within which the respondents must finalise the correction of the faulty Regulations.

[152] The regulation of complementary medicines, as argued by all the parties, is vital. It should, therefore, not be left to chance and a timeframe within which to finalise any Regulations pertaining thereto must be set of necessity. The suspension as such will afford the required timeframe.

[153] I, therefore, intend to suspend the striking down of the impugned Regulations only to the extent that they apply to complementary medicines and health supplements that are not medicines as defined in section 1 of the Medicines Act, or do not contain scheduled substances, for a period of twelve (12) months as requested by the respondents. The period of twelve (12) months will allow the Authority time to take steps to determine how best to regulate complementary medicines and the appropriate alternate categorization thereof.

COSTS

[154] The applicant prayed for costs including costs of two counsel. Being the successful party in these proceedings, the applicant is entitled to the costs as prayed for in the notice of motion, such costs to include costs of two counsel.

[155] Ordinarily, *amicus curiae*, is neither awarded costs nor ordered to pay costs of the successful opposing party. Even though the basis on which I have decided the matter did not require much of the arguments presented by the *amicus* I intend to follow that principle here as well.

THE ORDER

[156] As a result, I make the following order:

1. The parties' respective applications for condonation are granted.

2. The definition of 'medicine' in section 1 of the Medicines and Related Substances Act, No. 101 of 1965 is declared to apply only to substances that are used or purport to be suitable for use or are manufactured or sold for use in the diagnosis, treatment, mitigation, modification or prevention of maladies, in order to achieve a medicinal or therapeutic purpose, in human beings and animals.

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.

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.

5. The first and second respondents are ordered, jointly and severally, to pay the applicant the costs of this application, such costs to include costs of two counsel.

E.M KUBUSHI

JUDGE OF THE HIGH COURT

APPEARANCES

Applicant's Counsel	: Adv. D. Borgstrom SC Adv. M. Seape
Applicant's Attorneys	: **CLIFFE DEKKER HOFMEYR INC.**
First Respondents' Counsel	: Adv. G. Marcus SC Adv. N. Rajab-Budlender
First Respondents' Attorneys	: **THE STATE ATTORNEY, PRETORIA.**
For the *Amicus Curiae*	: Adv. J. Berger Adv. T. Pooe
Date of hearing	: 26 & 27 May 2020
Date of judgment	: 01 October 2020