THE SUPREME COURT OF APPEAL OF SOUTH AFRICA

JUDGMENT

Reportable

Case no: 256/2021

In the matter between:

THE MINISTER OF HEALTH **FIRST APPELLANT**

THE SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY **SECOND APPELLANT**

and

THE ALLIANCE OF NATURAL HEALTH PRODUCTS (SOUTH AFRICA) **RESPONDENT**

Neutral citation: *Minister of Health and Another v Alliance of Natural Health Products (South Africa)* (Case no 256/2021) [2022] ZASCA 49 (11 April 2022)

Coram: VAN DER MERWE, SCHIPPERS AND NICHOLLS JJA and TSOKA and MOLEFE AJJA

Heard: 7 March 2022

Delivered: This judgment was handed down electronically by circulation to the parties' legal representatives by email. It has been published on the Supreme Court of Appeal website and released to SAFLII. The date and time for hand-down is deemed to be 09h45 on 11 April 2022.

Summary: Medicine – regulations under Medicines and Related Substances Act 101 of 1965 (the Act) – *ultra vires* to extent that they purport to regulate substances that are not medicines as defined in the Act.

ORDER

On appeal from: Gauteng Division of the High Court, Pretoria (Kubushi J sitting as court of first instance):

1 The order of the court a quo is varied by deleting para 2 thereof and by substituting the words 'South African Health Products Regulatory Authority' with the words 'Minister'.

2 The appeal is dismissed with costs, including the costs of two counsel.

3 The cross-appeal is dismissed with costs, including the costs of two counsel.

JUDGMENT

Van der Merwe JA (Schippers and Nicholls JJA and Tsoka and Molefe AJJA concurring)

[1] The Minister of Health (the Minister) is the first appellant in this matter. The second appellant is the South African Health Products Regulatory Authority (the Authority). It was established as an organ of state and juristic person by s 2 of the Medicines and Related Substances Act 101 of 1965 (the Act). The respondent is The Alliance of Natural Health Products (South Africa) (the Alliance), a voluntary association with the capacity to sue or be sued in its own name.

[2] After a public consultative process that had stretched over several years and in consultation with the Authority, the Minister, acting in terms of s 35 of the Act, made the regulations that are the subject of this appeal. They are the General Regulations published on 25 August 2017 under GN 859, in *GG* 41064 (the regulations). The Alliance sought declaratory orders as well as the review and setting aside of the regulations, in

whole or in part, in the Gauteng Division of the High Court, Pretoria. As I shall explain, Kubushi J partly upheld the challenge to the regulations, hence the appeal. Broadly stated, the issue in the appeal is whether any review ground of the Alliance was good.

[3] In essence, the Act is aimed at regulating four types of things. They are: medicines; scheduled substances; medical devices and *in vitro* diagnostic devices (IVDs). The Act defines each type in comprehensive terms. For the said purpose, the Act affords functions and powers to both the Minister and the Authority. In terms of s 22A, the Minister may prescribe scheduled substances on the recommendation of the Authority. The section provides for the scheduling of prescribed substances on different levels (Schedules 0 to 6). The manner in which the availability of these substances to the public is controlled, depends on the level of scheduling.

[4] Section 14 of the Act provides that the Authority may from time to time determine that a medicine, medical device, IVD or any class or category of any of them, shall be subject to registration. The procedure for registration is set out in s 16. Section 1(3) provides:

'In determining whether or not the registration or availability of a medicine is in the public interest, regard shall be had only to the safety, quality and therapeutic efficacy thereof in relation to its effect on the health of man or any animal, as the case may be.'

[5] It appeared from the evidence that there is a substantial market worldwide and in South Africa for complementary medicines and health supplements. There was no dispute that this market should be regulated in the public interest. That, in the main, was the purpose of the replacement of the previous General Regulations under the Act, with the current ones. The regulations therefore introduced a new category, namely complementary medicines (Category D). They are subcategorised into discipline-specific medicines and health supplements. Complementary medicines in each of the two subcategories that are intended for use in humans, consist, in terms of Annexure 1 to the regulations, of the following:

'**33. Complementary Medicines: Discipline-Specific Traditional Claims**

33.1 Aromatherapy
33.2 Homeopathy
33.3 Phytotherapy
33.4 Traditional Chinese Medicine
33.5 Unani Medicine
33.6 Western Herbal Medicine
33.7 Combination Product
33.8 Other Herbal

34. Complementary Medicines: Health Supplements

34.1 Amino acids
34.2 Aminosaccharides
34.3 Animal Extracts, Products and Derivatives
34.5 Carotenoids
34.5 Enzymes
34.6 Fats, Oils and Fatty Acids
34.7 Minerals
34.8 Polyphenols (including Bioflavonoids)
34.9 Probiotics
34.10 Saccharides (including prebiotics)
34.11 Vitamins
34.12 Multiple substance formulation
34.13 Other'

[6] The regulations attach a number of obligations to complementary medicines and, where applicable, health supplements. These include obligations in respect of: the labelling of containers (reg 10(1)(cc) and 10(3)(b)); furnishing of professional information in hard copy or electronically (reg 11(2)(t)); providing a patient information leaflet (reg 12(2)(n)); and advertising (reg 42(5)(c)(ii)). There can be no doubt that compliance with these obligations requires significant effort and costs.

[7] The review ground relied upon in the Alliance's founding affidavit was that the scope and ambit of the regulations exceeded the rule-making powers of the Minister in

terms of the Act. In essence, the contention was that the Minister was only empowered to regulate medicines and scheduled substances within the meaning of the Act. However, so it was contended, the regulations purported to regulate substances that were neither medicines nor scheduled substances and, to that extent, they were *ultra vires* (the *ultra vires* ground).

[8] In its supplementary founding affidavit in terms of Uniform rule 53(4), the Alliance put forward two additional review grounds. These were firstly that despite having published draft regulations for public comment on 27 January 2017, the Minister failed to consider the comments received in response thereto (or a summary thereof). The contention was that this tainted the regulations with procedural unfairness under the Promotion of Administrative Justice Act 3 of 2000 (PAJA), or with procedural irrationality under the principle of legality (the procedural ground). In the second place, the Alliance relied upon the substantive irrationality of the regulations. This was principally based on evidence that the Authority was faced with a considerable backlog of applications for the registration of substances, that had built up over a number of years. In the light hereof, the Alliance averred that in the absence of evidence that the Authority would have the capacity to cope with additional demands that the regulations placed on it, the regulations were irrational.

[9] In the answering affidavit on their behalf, the Minister and the Authority (collectively the appellants) contended that the application raised an impermissible abstract challenge. They denied that the regulations were *ultra vires* in any respect, on the basis that the definition of ‘medicine’ in the Act was sufficiently wide to include all complementary medicines and health supplements as defined in the regulations. These definitions lie at the heart of the dispute between the parties and I shall reproduce them shortly.

[10] With regard to the procedural ground, the Minister confirmed on oath that he had considered the comments received in response to the 2017 draft regulations. The alleged substantive irrationality was similarly disputed on the basis of factual allegations that

could not be rejected out of hand. In sum they were: that when the Authority was established during 2015, it inherited a backlog of applications for registration that had built up under the auspices of its predecessor; that the focus had since shifted from the drafting of the regulations and guidelines thereto to implementation; that the budget and resources of the Authority had been increased; that its structural organisation had been improved; and that therefore it had the capacity to administer the regulations.

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

'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.

4. 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.'

[12] The court a quo granted leave to appeal to the appellants. It also gave leave to the Alliance to cross-appeal against para 4 of its order. The Alliance supported paras 2 and 3 of the order before us on all the aforesaid grounds. I find it expedient, however, to first consider the *ultra vires* ground.

[13] The appellants persisted with the argument that the challenge to the regulations on the *ultra vires* ground was impermissibly abstract. The Alliance readily conceded the

abstract nature of this part of its application on the basis that it did not relate to a particular set of facts. If the regulations, or part thereof, are beyond the powers of the Minister, they are invalid under the Constitution. It follows that the judgment in *Savoi and Others v National Director of Public Prosecutions and Another* [2014] ZACC 5; 2014 (5) BCLR 606 (CC); 2014 (1) SACR 545 (CC); 2014 (5) SA 317 (CC) at paras 9-13, is in point. It tells us that the abstract nature of an application brings two factors to the fore. The first is standing, that is, whether the applicant is entitled to challenge the validity of the provisions in question. If so, the second factor is the application of the heavy burden on the applicant to show that the provisions are constitutionally unsound or invalid merely on their face.

[14] The Alliance acts on behalf of its members, which include manufacturers and retailers of complementary medicines and health supplements. Their rights are directly affected in an adverse manner by what they perceive to be invalid regulatory measures. The Alliance therefore clearly had standing to attack the regulations on this ground and the appellants did not contend otherwise.

[15] I deal below with whether the regulations are *ultra vires* merely on their face. Before I do so, I need to say something about the applicability of PAJA to the making of the regulations. I intend to follow the approach of this court in *Esau and Others v Minister of Cooperative Governance and Traditional Affairs and Others* [2021] ZASCA 9; [2021] 2 All SA 357 (SCA); 2021 (3) SA 593 (SCA) at paras 77-84. In *City of Tshwane Metropolitan Municipality v Cable City (Pty) Ltd* [2009] ZASCA 87; [2010] 1 All SA 1 (SCA); 2010 (3) SA 598 (SCA) para 10, Maya JA, writing for the court and with reference to the judgment of Chaskalson CJ in *Minister of Health and Another NO v New Clicks South Africa (Pty) Ltd and Others (Treatment Action Campaign and Innovative Medicines SA as Amici Curiae)* [2005] ZACC 14; 2006 (2) SA 311 (CC); 2006 (1) BCLR 1 (CC) para 113, expressed agreement with the contention that the making of regulations by a Minister constitutes administrative action within the meaning of PAJA. We are bound by this *dictum* unless we are convinced that it is clearly wrong. No attempt at all was made to convince us of that. In the result the matter had to be decided under PAJA.

[16] Section 35(1) of the Act provides for no less than 45 topics in respect of which the Minister is empowered to make regulations. Most of them relate directly to medicines, scheduled substances, medical devices or IVDs. The few that do not, are not applicable to substances that are not medicines. What remains is s 35(1)(xlv), which provides for the making of regulations:

'[G]enerally for the efficient carrying out of the objects and purposes of this Act, and the generality of this provision shall not be limited by the preceding paragraphs of this subsection.'

[17] The Act does not tabulate its objects and purposes and they have to be gathered from its provisions as a whole, including the objects of the Authority in terms of s 2A, namely:

'**Objects of Authority** – The objects of the Authority 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.'

I am prepared to accept, therefore, that the objects and purposes of the Act include matters related to the regulation and control etc of medicines and scheduled substances.

[18] It is important to note that the Act does not in this regard refer to substances related to medicines but to matters related to the regulation, registration and control of medicines. Therefore, despite the wide wording of s 35(1)*(xlv)*, it is difficult to comprehend that it encompasses a power to regulate substances that are not medicines in terms of the Act. In any event, it was clear from the answering affidavit and reaffirmed before us, that the case for the appellants was that the regulations purport only to regulate medicines within the meaning of the Act. Whether that is so, as I have said, is the nub of the case.

[19] The definition of 'medicine' in the Act is the following:

'(a) . . . any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in—

(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

(b) includes any veterinary medicine.'

The appeal does not concern para *(b)* of the definition.

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

[21] The regulations define 'complementary medicine' as 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.'

[22] Thus, to qualify as a 'complementary medicine', a substance must comply with each of paras (a), (b) and (c) of the definition. Paragraph (a) sets a requirement of origin, in wide terms. Paragraph (b) departs from the definition of 'medicine' in the Act. The addition of the word 'alleviate' in subpara (b)(ii) is not material. The same does not, however, apply to the phrase 'maintaining, complementing or assisting the physical or mental state' in subpara (b)(i). It does not restrict complementary medicines to substances that have or claim to have a therapeutic purpose. On the contrary, on its plain meaning subpara (b)(i) has nothing to do with somatic, psychic or organic malfunctioning,

but refers to contributing to (maintaining, complementing or assisting) the normal functions of the human body or mind (the physical or mental state).

[23] As I have said, in terms of para (c) a complementary medicine must also be used as a health supplement or 'in accordance with those disciplines as determined by the Authority'. In terms of the regulations 'as determined by the Authority' means as determined by it in guidelines published from time to time. The evidence did not reveal anything in that regard.

[24] However, 'health supplement' is defined as follows:

'. . . 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 injectable preparations, medicines or substances listed as Schedule 1 or higher in the Act.'

[25] It is true that this definition echoes the phrase 'restoring, correcting or modifying' in subpara (a)(ii) of the definition of 'medicine' in the Act. But the definition of 'health supplement' does not end there. It proceeds to state the additional requirement that the restoring, correcting or modifying has to be achieved by: complementing health; supplementing a diet; or a nutritional effect. Clearly therefore, this third element of the definition of 'complementary medicine' takes it even further away from substances that have or claim to have a therapeutic purpose. Whilst some complementary medicines and health supplements as defined in the regulations would be medicines under the Act, many would not.

[26] In sum, the regulations purport to regulate substantial numbers of substances that are not medicines under the Act. The court a quo correctly concluded that, to this extent, the regulations are *ultra vires* and invalid. Paragraph 3 of its order cannot be

faulted. It follows that the appeal must fail on the *ultra vires* ground and that it is unnecessary to make a final determination of the other review grounds.

[27] In my view, however, para 2 of the order cannot stand. That is so for two reasons. The first is that the judgment of the court a quo demonstrated that there had been no dispute as to the proper interpretation of the definition of 'medicine' in the Act before it. It is trite that a court should not issue a declarator in answer to a hypothetical or academic question. Secondly, this part of the order impermissibly departed from the language of the Act. It not only introduced the word 'maladies', but failed to give due recognition to subpara *(a)*(ii) of the definition of 'medicine'. As the propriety of para 2 of the order was raised *mero motu* by this court, setting it aside should not entitle the appellants to costs.

[28] It remains to consider the cross-appeal against the suspension of the declaration of invalidity. The Alliance contended that there was no justification for the suspension. However, it appeared not to have recognised that the court a quo had in this regard exercised a true or strict discretion that may not lightly be interfered with. See *Trencon Construction (Pty) Ltd v Industrial Development Corporation of South Africa Limited and Another* [2015] ZACC 22; 2015 (5) SA 245 (CC); 2015 (10) BCLR 1199 (CC) paras 88-90. I find no reason in principle to interfere with the suspension order. It was at least justified on the following basis. As I have said, it is widely accepted that there is a public interest need to also regulate complementary medicines and health supplements that are not medicines under the Act. Therefore, it is in the public interest to regulate these substances under the regulations during the interim period of consideration of the appropriate regulation thereof. The cross-appeal must therefore fail. However, para 4 of the order should be altered to refer to the Minister and not to the Authority.

[29] For these reasons the following order is issued:

1 The order of the court a quo is varied by deleting para 2 thereof and by substituting the words 'South African Health Products Regulatory Authority' with the words 'Minister'.

2 The appeal is dismissed with costs, including the costs of two counsel.

3 The cross-appeal is dismissed with costs, including the costs of two counsel.

_____

C H G VAN DER MERWE

JUDGE OF APPEAL

Appearances:

For appellants:	G Marcus SC (with him N Rajab-Budlender SC)
Instructed by:	State Attorney, Pretoria
	State Attorney, Bloemfontein
For respondent:	D Borgström SC (with him M Seape)
Instructed by:	Cliffe Dekker Hofmeyer Inc., Sandton
	Webbers Attorneys, Bloemfontein