IN THE HIGH COURT OF SOUTH AFRICA

(GAUTENG DIVISION, PRETORIA)

Case No: 15758/2018

(1) REPORTABLE: NO
(2) OF INTEREST TO OTHER JUDGES: NO
(3) REVISED. NO

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SIGNATURE **DATE:** 13 December 2021

In the matter between:

ACPSA (THE ASSOCIATION OF COMPOUNDING PHARMACISTS OF SOUTH AFRICA) **Applicant**

and

THE MINISTER OF HEALTH **First Respondent**

SAHPRA (THE SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY) **Second Respondent**

DIRECTOR-GENERAL: HEALTH **Third Respondent**

SOUTH AFRICAN PHARMACY COUNCIL **Fourth Respondent**

JUDGMENT

MANOIM J

[1] This is an application to review and set aside certain regulations that pertain to the applicant's profession that the respondents published in the Government Gazette on 25 August 2017(the 2017 regulations).

[2] The applicant is a voluntary association that represents pharmacists who engage in pharmacy compounding.

[3] The respondents are variously the Minister of Health, the Director General of Health, SAHPRA and the South African Pharmacy Council. It is only the Minister and the Director General of Health (the first and third respondents) who oppose the application.

[4] What constitutes pharmacy compounding is not well defined. It involves a pharmacist combining, mixing, or altering ingredients catering to the need of an individual patient. But compounding pharmacists also prepare medicines for animals and here they overlap with the functions of veterinarians.[1]

[5] The applicant does a poor job of explaining the need for compounding. A better explanation comes from the deponent for the respondents who explains how the need for compounding arises. Some patients have difficulty swallowing pills or capsules; children may require different doses which are not readily available in manufactured

[1] In its founding affidavit the applicant defines it in this way: "*Pharmacy compounding involves the acts of preparing, mixing, combining. packaging and labelling a medicine by a pharmacist, pharmacist intern or pharmacists assistant for an individual patient or an animal as a result of a prescription issued by a veterinarian or by a person licensed in terms of section 22C(1)(a) of the Medicines and Related Substances Act 101 of 1965 as result of a prescription*." Case Lines page 006-13 paragraph 2.3

form. Other patients may need medicines delivered via tubes inserted through the nose or the stomach.

[6] The manufacture of medicines is highly regulated in terms of the Medicines and Related Substances Act, 101 of 1965 (the Medicines Act). Registered medicines are tested for quality, safety, and efficacy. However, since compounding involves altering the ingredients of a medicine it falls outside of this form of regulation. Hence the need, and the applicant accepts this, for specific regulations to fill this lacuna.[2]

[7] The 2017 regulations have a wide application. Only seven out of fifty-six provisions deal with compounding and of those seven, only five are the subject of this review.

Legal basis for the review

[8] The review is not confined to the contents of the regulations but also the process of how they were made.

[9] The applicant relies on both the principle of legality and Promotion of Administrative Justice Act, 3 of 2000 (PAJA) to base its review.

[10] The respondents argue correctly that it matters whether the review is under PAJA or the principle of legality. For process purposes the test under PAJA is fairness. In terms of a legality review the test is more confined – it is whether a rational process was followed. Similarly, the test for the substantive content is more confining in a legality review that it would be under PAJA. In this matter if the review is judged under the legality standard the relevant test would be rationality.

[11] The respondents have argued that when the Minister makes regulations this is not an administrative act and thus reviewable under PAJA but a legislative function which falls outside of PAJA

[12] The case law makes this distinction but is less helpful in establishing a precise test for when a regulation is one or the other. [3]

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[2] See paragraph 8 of the founding affidavit where the applicant states it *" wholeheartedly supports the principle that compounding medicines should be regulated."*

[3] The genesis of the debate were the remarks by Chaskalson CJ in what is referred to as the *New Clicks* case (*Minister of Health and Another NO v New Clicks South Africa (Pty) Ltd and Others* 2006 (2) SA 311 (CC)) where he held that price setting regulations by the Minister of health constituted administrative action and hence were reviewable under PAJA. But these remarks were distinguished in some later cases, one of which was *Mostert NO v Registrar of Pension Funds and Others A 2018 (2) SA 53 (SCA) ([2017] ZASCA 108*) where the court held "*The final word on regulation-making and the applicability of PAJA to it may*

[13] Indeed, it is entirely possible that some of the regulations here are closer in the spectrum of possibility to the legislative side whilst others tend to the administrative.

Process

[14] The regulations were first published on 27 January 2017 for public comment. Several parties made comments including the applicant. But then after first round of comments the final regulations were published on 25 August 2017. The applicant complains that the Minister did not allow a further round of comments despite the regulations having been redrafted. There is no dispute that with the exception of one, all the regulations that are the subject of the review were redrafted. The dispute is whether the changes were substantial. For the respondents it was contended that they were not and having had a first round of comments to which the drafters were responsive, there was no obligation on the Minster to open up the next draft for further comments less this process continues ad infinitum.

[15] However, I do not need to decide this point as far as the process is concerned because of the conclusion I have taken about the content of the regulation. Since I have decided this based on rationality, I will assume without having to come to a definitive conclusion about this, that the principle of legality is the appropriate standard of review in this matter.

The policy differences between the two parties

[16] In order to decide whether the regulations pass a rationality scrutiny, one has to understand what policy goal the Minister is seeking to advance. The fact that the applicant and the Minister do not agree on the policy is not a sufficient ground for establishing that they are not rational.

[17] But before I take that further I consider what that difference concerns. It revolves around a practice called anticipatory compounding.

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therefore not have been spoken. And as this matter shows, not all the provisions of PAJA, and particularly s 7, are tailored for the review of a regulation." Mostert was later followed in *Equal Education and another v Minister of Basic Education and Others* 2019 (1) SA 421 (ECB) where the court observed:*" The fact of the matter is that there is no general rule that, when a Minister makes regulations, they exercises administrative action. Mostert has made it clear that what Chaskalson CJ said in New Clicks is no authority for such stance."*

[18] What it means is that the pharmacist produces a surplus based on her knowledge of the expected demand for a compounded product. If for instance the pharmacist knows that 20 customers order the same compounded product each month, she will produce an amount to meet this demand and not just the single quantity that the immediate customer who has placed an order needs.

[19] For the applicant's members anticipatory compounding makes practical sense. They can benefit from economies of scale and economise on the time spent on compounding. Less clearly articulated, but clearly the dominant motive, is the expanded business opportunity afforded to them by producing a surplus in anticipation of future sales.

[20] The respondent is wholly opposed to this practice. This is because the respondent considers this a backdoor for mass production of a product. Since these products are not subject to the same strict requirements for compliance that registered medicines are this creates a potential safety threat to the consumers of compounded medicines.

[21] The two parties are thus coming from diametrically opposed points of departure. Whilst the applicant recognises that there is a legitimate need for regulation it does not believe it needs to inhibit the ability of its members to engage in anticipatory compounding. The respondents consider the production of unregistered medicines a problem but recognise the need for some patients to require compounding. Thus, their point of departure is minimalist circumstances for permitting production not minimalist regulation.

[22] This difference in objectives has a bearing on the interpretation of rationality. Much of what the applicant says about the alleged irrationality of the regulations comes from the fact that starts from a different premise to the respondents.

Which regulations

[23] The 2017 regulations deal with compounding in seven different places. The review is confined to five of them. The complaints can be divided into two issues; a problem with the scope of the definition of compounding and the impact of the remaining regulations on the potential for engaging in anticipatory compounding.

[24] At the outset one of the difficulties facing anyone drafting regulations in terms of the Medicines Act is that instead of the Act ceding the field for specific detail to the regulations, the Act in many places is highly detailed.

[25] Section 14(1) is the general prohibition provision which states:

"Prohibition on the sale of medicines, medical devices or IVDs which are subject to registration and are not registered

[26] 14(1) Save as provided in this section or sections 21 and 22A, no person shall sell any medicine, medical device or IVD which is subject to registration by virtue of a declaration published in terms of subsection (2) unless it is registered."

[27] But in section 14(4) an exception is created for compounding in these terms:

"(4) The provisions of subsection (1) shall not apply in respect of the sale of any medicine-

(a) compounded in the course of carrying on his or her professional activities by a pharmacist, veterinarian or person who is the holder of a licence contemplated in section 22C (1) (a), for a particular patient in a quantity not greater than the quantity required for treatment as determined by the medical practitioner, pharmacist, practitioner or veterinarian; or

(b) compounded by a pharmacist in a quantity not greater than that prescribed by regulation for sale in the retail trade, subject to the conditions likewise prescribed or in a quantity for a particular person or animal as prescribed by a medical practitioner or a dentist or a veterinarian or a practitioner or a nurse or other person registered under the Health Professions Act, 1974, and referred to in section 22A, as the case may be,

if such medicine does not contain any component the sale of which is prohibited by this Act or any component in respect of which an application for registration has been rejected and is not or has not been advertised: Provided that the active components of such medicine appear in another medicine which has been registered under this Act."

[28] This led to suggestions by the applicant that in some places the regulations are ultra vires the Act. The respondents contend on the contrary that the Minister is given

powers to make regulations in terms of section 35 of the Act and the express reference to "*prescribed by regulation*" in section 14(4)(b). In this sense the Minister fills in the gaps left open by the empowering legislation.

[29] One of those gaps is the definition of compounding. Although the Act refers to compounding it does not define it. This is the challenge the Minister has assumed in the regulations and leads me to consider the first challenged regulation that defines compounding

(i) Definition of compounding

[30] The relevant regulation is regulation 1. Here the definition states:

"Compound means to prepare, mix, combine, package and label medicine-

(a) By a pharmacist, pharmacist intern or pharmacist's assistant practising in terms of the Pharmacy Act for-

(i) An individual patient; or

(ii) An animal as a result of a prescription issued by a veterinarian practising in accordance with the Veterinary and Para- Veterinary Professions Act, 1982; or

(b) For dispensing as a result of a prescription for a patient by a person licensed in terms of Section 22C(1)(a) of the Act (the Medicines Act) and practising in accordance with the relevant scope of practice."

[31] In its founding affidavit the applicant says the problem arises with paragraph (b) of the definition. Specifically, it queried whether the reference to a patient only applies to humans or includes humans and animals.

[32] This was met with a response in the answering affidavit that the *"the use of the word patient ..must have been intended to refer to both an individual person* [read human] *and an animal"* The deponent then suggests that she accepts there was an error in the drafting and the phrase individual patient should have read *"individual person"*

[33] Of course, this is no solution. Replacing the word 'patient" with 'person' simply adds to the confusion. If the respondents intend to reference animals, they should do

so specifically, as they do in subparagraph (a)(ii). This removes room for ambiguity and has the virtue of consistency.

[34] But even this concession to some minor tweaking of the definition does not seem to have satisfied the applicant who then raised another issue of concern in a supplementary affidavit.

[35] Here the problem with the definition was the reference to *"individual"*. This is a new complaint although it is consistent with the applicant's main objection that the regulations serve to prohibit anticipatory compounding. If compounding is defined with reference to individual humans, or animals if they are to be included, then anticipatory compounding gets outlawed at the first hurdle.

[36] But then, unexpectedly, the debate over the proper interpretation of the definition ran into a further difficulty. The organisation that represents veterinarians known as SAVCA, brought a challenge concerning the Medicines Act to the Constitutional Court. The basis was that they had not been sufficiently consulted during the drafting phase of the Act about their inclusion. The Court ruled in their favour on this point and the relief provided was that the word veterinarian should be severed from where it appears in section 22C (1) (a of the Medicines Act.[4] This is of course the same section that gets referred to in sub-paragraph (b) of the definition. This judgment came out after the regulations had been published and the parties did not deal with its consequences in the original papers but only in their heads of argument. The applicant now relies on this as an added bow to its quiver to justify the review.

[37] It is unclear, it contends, whether post *SAVA,* veterinarians are covered by the regulation.

[38] The respondents in their heads state that there is a simple answer to the consequences of the *SAVA* judgment for the veterinarians – they are not covered by the regulation and there is therefore no need, based on this outcome, to return the regulation to the drawing board. The respondents further make the point that if the veterinarians were concerned about this they would have intervened on their own behalf – it is not for the applicant to act to assert another profession's interest.

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[4] *South African Veterinary Association v Speaker of the National Assembly and others* [2018] JOL 40630 (CC).

[39] This is of course correct. But the real reason the applicant is concerned about the status of the regulation vis a vis vets is that they compete with them in the sale of compounding medicines for use by owners of animals. This concern was not apparent in the earlier filings but manifests itself in one remark in the supplementary heads of argument where counsel for the applicant states:

"With respect arguing that the… exclusion of vets from the provisions of regulation 3 simply means that the provisions of regulation 3 do not apply to vets and not consequent with the empowering legislative provisions and would make no sense why vets that compound medicines can or should be excluded from being subject to the same regulatory controls equally with other compounders of medicines."[5] (my emphasis)

[40] Put at its simplest the applicant is concerned that post *SAVA,* veterinarians, with whom it competes, are subject to a less onerous regulatory control than its members are. Although not stated directly the implication is that if the pharmacists are not allowed to engage in anticipatory compounding, but veterinarians can, the former is at a competitive disadvantage to the latter.

[41] There are two problems with the regulation that render it reviewable on grounds of rationality. From the concession in the answering affidavit, it is clear that the drafter intended to make clear what was not clear – that the regulation applied to animals in subparagraph (b). But if this was the case then this on its own justified redrafting the regulation. But post, *SAVA* admittedly a problem not made by these regulations, it appears that veterinarians are not subject to the compounding regulations, when the clearly the original intention was they were to be.

[42] Thus, if the purpose of the regulation was to have all professionals who do compounding for animals subject to the same regulatory scheme, then that outcome has not been achieved both as a result of a drafting error and the knock-on effect of the *SAVA* decision. It is not a solution to say that the outcome is that veterinarians are no longer subject to the regulation. That is regulating by accident. If the original

[5] See Points of Argument, paragraph 52 Case Lines 75-17. The points of argument document was filed on the date of the hearing by new counsel and thus after the respondents had filed their heads.

intention of the regulation was that they should be, then the respondents need to give attention to remedying the lacuna that has been created

[43] This means that the present regulation does not serve the purpose for which it was intended. It therefore does not meet the test of rationality and is reviewable on under the doctrine of legality.

(ii) Regulation 3

[44] Both parties agree that the difference between them on these regulations is the issue of anticipatory compounding. For this reason, I do not need to burden the decision by reproducing each regulation as I did with regulation 1. Instead, I will give a precis of each one.

[45] They provide as follows-

a. Regulation 3(1) provides that the compounder can only compound a medicine for use by a patient within 30 days of the date of the compounding. The date of compounding and the statement *"use within 30 days*" must be included in a label on the product.

b. In an earlier draft there was a reference to a 30-day period, but this ran from the date of dispensing (i.e., not the earlier date of compounding) and had no requirement for a label to be put on the product. The draft also referred to animals; the regulation only refers to a patient. Hence, a repeat of the problem discussed in relation to the definition section.

c. Both parties agree that the effect of the regulation as it is drafted now is to disincentivise anticipatory compounding. Making the 30 days run from the earlier date will have this effect.

d. Regulation 3(3)(a) makes it unlawful to compound contrary to the provisions of section 14 of the Medicines Act. The applicant is concerned that the regulation is too vague and thus in conflict with the rule of law. The applicant would prefer that instead the regulation would create a list of what conduct might be contrary to the provisions of section 14. For instance, the applicant gives as an example a particular product might not be available commercially and hence compounding should be justified in those circumstances. The respondents do not agree. Their deponent states if it is not commercially available in one centre

then the customer should be making use of courier services to get delivery. In heads of argument the respondents offer a softer approach, suggesting that if it is not reasonable to obtain the medicine elsewhere then there would be no contravention.

e. Regulation 3(3)(f) prohibits the exportation of compounded medicines. Here the argument again turns on the different positions on anticipatory compounding with the applicant considering this unnecessarily restrictive whilst the respondents consider that it is necessary to restrict compounding to precisely prevent that.

f. Regulation 3(3)(g) prohibits the practice of compounding unless it is done in compliance with good practice as determined by the SAHPRA, the second respondent in this case. The objection here is that firstly no code of good practice has been produced and this will create industry uncertainty. The applicant suggests in the founding affidavit that the issue is referred back to the Minister to draw up a code based on internationally recognised industry standards for compounding. No code has been proposed yet for the industry to comment on despite the regulations having been in force since 2017.A process point is also made because this regulation was not part of the original draft, and hence is entirely new.

g. The respondents first say the code cannot have retrospective effect so concerns here are unfounded, although I do not consider this to be the major concern of the applicant. Second, on process that in the Notice of Motion no relief was sought to have the matter referred back. I do not consider this point has much substance. As between reviewing and setting aside or putting the respondents on terms to draft new regulations both require a return to drawing board to rectify regulations. In any event in the answering affidavit the respondents deponent concedes that at a minimum the second respondents' proposed code would need to be published for public comment.[6] It is not apparent why this has yet to happen.

[6] Answering affidavit paragraph 33.3.

[46] The respondents have a credible answer to most of the complaints about the four sub-regulations in regulation three. This is because the respondents stoutly defend their position that anticipatory compounding is not in the best interests of public health as it is, unlike manufacturing of medicines, not adequately regulated. For this reason, whilst compounding is justified for certain classes of patients it must be on a limited basis. Hence the regulations have been crafted in this fashion – the adherence to compliance with the Act, the limited time period, and the prohibition on exports and the need for a good practices standard; are all in their view logically consistent with this identified public interest and hence since the means and ends are connected, rational.

[47] But there is a major problem for the respondents which detracts from this otherwise stout defence of the regulations. This is the concession made in the respondents deponent's answering affidavit to the following effect

[48] "I accept that in certain limited circumstances, anticipatory compounding may be required, and accordingly, ought to be permitted. Thus, to the extent that regulation 3 makes no provision whatsoever for the practice, I concede that it falls to be reviewed and set aside and remitted for SAHPRA's and the Minister's reconsideration."[7]

[49] The respondents in their heads of argument seeks to distance themselves from this concession on the basis that it is a legal concession and hence can be withdrawn. It relies on the authority this proposition on *Dengetenge Holdings (Pty) Ltd v Southern Sphere Mining & Development Co Ltd and Others* where the court held: [8]

"It is true that a concession made by counsel on a point of law may be withdrawn if the withdrawal does not cause any prejudice to the other party. However, in my view what counsel for Dengetenge did was not just to make a concession on a point of law. He effectively withdrew Dengetenge's opposition to the application. The court needs to do justice to all the parties in this regard."[9]

[50] In this case the concession has not been made by counsel nor is it a concession on a point of law. The concession is made by the deponent who is well qualified to

[7] Answering affidavit paragraph 88 Case Lines 011-45
[8] 2014 (5) SA 138 (CC) 5
[9] Supra, paragraph 55.

make it, given she is both a legal advisor to the second applicant and is a qualified pharmacist with many years of regulatory experience according to her affidavit.

[51] But most importantly the concession is made in respect of a policy issue. This is, as the deponent states, an acceptance that anticipatory compounding may be required, albeit that she qualifies this by stating that this would be in limited circumstances. But the fact she concedes that to the extent that the regulation makes no provision for it *"… falls to be reviewed and set aside"* defeats all the valiant attempts made in the respondents heads of argument to defend the rationality of the regulations.

[52] This because the concession serves to remove the foundation from the rationality argument that might otherwise have been made. Once the respondents have conceded the regulations go too far in preventing anticipatory compounding, then on their own version, they are conceding that the final product is irrational.

[53] In relation to regulation 3(3)(a) and 3(3)(g), whilst neither directly references anticipatory compounding they both could impact upon that practice. If anticipatory compounding is outlawed, in the respondents view, in terms of the Act, then a pharmacist would by virtue of the regulation contravene the Act. Nor is it clear why the regulation is necessary. Pharmacists know they must comply with the Act. They do not require a regulation to tell them that. But if its purpose is to tell them in a more specific way, what conduct would be compliant and what would not, then more detail is required. If that was the purpose of this regulation, then it serves a rational purpose if it sets out content so as to provide guidance; a generalised provision serves the opposite purpose – it furthers confusion. Similarly with 3(3)(g), a code of good practice is a good idea. But then there needs to be a code readily available so that compliance is possible Not providing one especially after all this time is irrational.

Conclusion

[54] I am satisfied that the applicant has made out a case to have the impugned regulations reviewed. This is because in the passages I have cited above, on the respondents own version in the answering affidavit, what they have wished to state in the regulations and what they do state are at variance. Hence the conclusion that they are not rational.

[55] Nevertheless, the relief I have provided for, is on more limited terms to that sought in the Notice of Motion. It allows the respondents to reconsider certain issues in relation to the definition of compounding and its application to animals and veterinarians, without being overly prescriptive, and second to assess how the remaining regulations can be recrafted to allow for the limited anticipatory compounding, envisaged in the answering affidavit. Finally in regard to regulations 3(1) and 3(3)(g), more specificity will cure any suggestion they are irrational by providing guidance over what practices are considered to be lawful and/or desirable and those which are not.

[56] What I have not done is to take a view on whether a total prohibition on anticipatory compounding is irrational. It is the applicant's version that it is, but this is, as I stated earlier, because it starts from a different premise to the respondents. The respondents premise that anticipatory compounding is harmful and must be limited by regulation is not in itself irrational. The reason I have found the regulations irrational is because it is the respondents deponent who opened the window to accept a need for a limited form of anticipatory compounding. Yet this limited opened window is not reflected in the current regulations sought to be reviewed, where it remains shut.

[57] What the extent of the limited form takes will be left up to the respondents to determine. Nevertheless, publishing a new draft for further comment from stakeholders would be prudent although I do not make provision for this in the order, save for the guidance or code of good practice contemplated in 3(3)(g). Here I have ordered that this code be published by the second respondent for comment since, unlike the other regulations, no code has been published to date.

Costs

[58] Given that the applicant has been successful it is entitled to its costs. However, it does not justify the award of the costs of two counsel (counsel for the applicant were used sequentially not simultaneously) or the costs of Professor Du Toit as the case turns essentially on the legal argument.

ORDER

I make the following order:

1. The following Regulations of the General Regulations published under Government Notice 859 in Government Gazette no. 41064 dated 25 August 2017 (the General Regulations) in terms of section 35 of the Medicines and Related Substances Act, 101 of 1965 (the Medicines Act") are reviewed and set aside to the extent indicated in paragraph 2:
    a. In Regulation I the definition of "Compound".
    b. Regulation 3(1).
    c. Regulation 3(3)(a).
    d. Regulation 3(3)(f). and
    e. Regulation 3(3) (g)
2. The review and setting aside of the above Regulations of the General Regulations are suspended for a period of seven (7) months and the matter is referred back to the First Respondent to, in accordance with the provisions of section 35 of the Medicines Act, within the said period, amend and publish the said Regulations listed above to achieve the following:

    a. That Regulation 1 must be redrafted to clarify
        i. whether it applies to animals, and whether veterinarians are subject to the regulation; and
        ii. Whether or not it applies only to individual persons and / or individual animals;
    b. That Regulation 3(1) be redrafted so that it provides clarity as to what conduct might be deemed to circumvent section 14(4) (a) and 14(4)(b) of the Medicines Act;
    c. That Regulations 3(1),3(3)(a), and 3(3)(f)) must be redrafted to clarify the limited circumstances to which they apply to anticipatory compounding; and
    d. That first Respondent procures that second respondent publish a draft of the Code/ Guidlines of Good Practice, contemplated in terms of regulation 3(3)(g), for public comment.
3. That the first respondent is liable for the costs of the applicant.

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JUDGE OF THE HIGH COURT

GAUTENG LOCAL DIVISION, PRETORIA

This judgment was handed down electronically by circulation to the parties' and/or parties' representatives by email and by being uploaded to CaseLines. The date and time for hand-down is deemed to be 10h00 on 13 December 2021.

Date of Hearing: 3 August 2021

Date of Judgment: 13 December 2021.

Appearances:

Counsel for the Applicant:	Adv J.M Barnard (with initial heads prepared by Advocate W. Gibbs)
Instructed by: VFV Attorneys	
Counsel for first and second respondents:	Adv. J Berger
Instructed by	State Attorney (Pretoria)