THE SUPREME COURT OF APPEAL OF SOUTH AFRICA
JUDGMENT

REPORTABLE
Case No: 197/2014

In the matter between:

MEDIRITE (PTY) LIMITED Appellant

and

SOUTH AFRICAN PHARMACY COUNCIL First Respondent

THE MINISTER OF HEALTH Second Respondent

Neutral citation: *Medirite v South African Pharmacy Council* (197/2014) [2015] ZASCA 27 (20 March 2015)

Coram: Mpati P, Maya, Leach, Pillay and Zondi JJA

Heard: **16 February 2015**

Delivered: **20 March 2015**

Summary: Administrative law – amendment to general rules of pharmaceutical practice neither rational nor reasonable – amendment set aside on review.

ORDER

On appeal from: Gauteng Division, Pretoria (Mabuse J sitting as court of first instance):

1 The appeal succeeds with costs, such costs to include the costs of two counsel.
2 The order of the court a quo is set aside and is substituted with the following:
'(a) The first respondent's amendment of s 1.2.2 of Annexure A to the *Rules Relating to Good Pharmacy Practice*, published in Government Gazette No 35095 on 2 March 2012 under Board Notice 35/2012, insofar as it introduced subsecs (b), (c) and (d) to s 1.2.2.1, is set aside.
(b) The first respondent is to pay the applicant's costs, including the costs of two counsel.'

JUDGMENT

Leach JA (Mpati P, Maya, Pillay and Zondi JJA concurring)

[1] For obvious reasons of public interest, the pharmaceutical industry is heavily regulated. Amongst other controls the first respondent, the South African Pharmacy Council, a juristic person established under s 2 of the Pharmacy Act 53 of 1974 (the Act), is empowered under s 35A(*b*)(ii) of that Act to make rules relating to 'good pharmacy practice' that are binding upon all persons licensed to provide pharmacy services.[1] On 17 December 2004, the first

[1] Regulation 20(1) of the 'Regulations Relating to the Practice of Pharmacy, GN R1158, *GG* 21754, 20 November 2000; regulation 7(1) of the 'Ownership and Licensing of Pharmacies, GN R553, *GG* 24770, 25 April 2003; regulation 18(8)(b) of the 'Regulations Relating to the Period and Manner of Appeal Against Decisions of the Medicine Control Council, GN R906, *GG* 14826, 28 May 1993'.

respondent published rules relating to good pharmacy practice (the GPP Rules).[2] An amendment to those rules, published by the first respondent on 2 March 2012,[3] lies at the heart of the present dispute. As more fully set out below, the appellant was aggrieved by certain provisions introduced by the amendment and sought to have them reviewed and set aside by the high court, citing the first appellant and the Minister of Health as respondents in its application. No relief was sought against the Minister who was joined solely as a potentially interested party but who has played no part in the proceedings, either in the high court or in this appeal. In any event, the appellant's application was dismissed on 20 December 2013. The appeal to this court is with leave of the court a quo.

[2] Pharmacies situated within the precincts of other business premises such as supermarkets and hospitals, but run as separate businesses, have become fairly commonplace in this country as they are elsewhere in the modern world. Since 2003 the appellant, a wholly owned subsidiary of Shoprite Checkers (Pty) Ltd, operating under the brand name of *Medirite*, has conducted separate pharmacy businesses within Shoprite, Checkers and Checkers Hyper supermarkets. Capitalising on the free flow of foot traffic between the supermarket in which it is situated and the pharmacy itself, its business model proved so successful that when the present proceedings were instituted in the court a quo, the appellant was operating 129 licensed pharmacies in this way and planned to expand that number considerably within a few years.

[3] Typically, the appellant's pharmacies are organised as follows:

(a) The pharmacy itself consists of a dispensary in which scheduled medicines are kept and stored out of public reach, an office or consultation room, a waiting area for patients or customers, and a service counter between the dispensary and the shop floor.

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[2] Rules Relating to Good Pharmacy Practice, GN R129, *GG* 27112, 17 December 2004.
[3] Rules Relating to Good Pharmacy Practice, GN R35, *GG* 35095, 2 March 2012.

(b) Members of the public deal with the pharmacist across the service counter, with the patient being provided with the necessary degree of privacy and confidentiality by partitioning that create a booth-like structure. The counter is directly accessible from the supermarket floor but the dispensary behind it may be accessed solely through a door between it and the office or a private consultation room.

(c) The space between the counter and the dispensary is fitted with a retractable and lockable vertical shutter that is closed and locked whenever the pharmacy is not open for business. In this way no-one other than the responsible pharmacist, who retains the keys, has access to the scheduled medicines stored in the pharmacy.

(d) Situated immediately adjacent to, but in front of the service counter, are both the waiting area (usually near the door that leads to the office and dispensary, and furnished with chairs) and the so-called 'front shop' which is not part of the licensed pharmacy premises. (I should mention that the owner of a pharmacy is obliged to hold a license issued by the Director-General of the Department of Health for the premises where the pharmacy business is conducted.)[4] The front shop is stocked with health and beauty products, experience having shown that there are valuable synergies to be exploited between the provision of pharmacy services and the sale of these products.

(e) The stock offered for sale in the front shop also includes certain so-called 'schedule 0' medicines, such as headache tablets. Unlike other scheduled medicines, these may be sold by any retailer, including supermarkets, spaza shops (tuckshops) or liquor stores, and therefore do not have to be processed and paid for at the pharmacy counter. However, as certain schedule 0 medicines are often included in doctors' prescriptions, a range of these are also stocked within the dispensary for convenience in order to be dispensed together with other prescription medicines.

[4] Reg 8 of the Regulations Relating to the Ownership and Licensing of Pharmacies, supra, fn 1.

[4] As at May 2011, s 1.2.2(b) of Annexure A to the GPP Rules provided that 'the pharmacy premises must be clearly demarcated and identified from the premises of any other business or practice'. However, on 27 May 2011 the first respondent published for comment a draft amendment thereto that envisaged not only revising the wording of that rule (but not its import) but the introduction of additional requirements as to the method of demarcation of pharmacy premises, including the construction of a wall. Alarmed by this, the appellant submitted detailed written representations to the first respondent on 25 July 2011 in an attempt to persuade it not to effect the proposed amendment. The appellant also met with the registrar of the first respondent on 29 September 2011 to voice its concerns. These representations had no effect and, on 2 March 2012, the first respondent published the amendment.

[5] The amendment introduced a new s 1.2.2.1 that in its entirety reads as follows:

'(a) The pharmacy premises must be clearly identified and demarcated from the premises of any other business or practice.

(b) The demarcation must be permanent, solid and closed-off at all times, which demarcation may be inter alia brick and mortar, aluminium, steel, glass, dry wall or wood partition.

(c) The demarcation must be from floor to the ceiling height and must enclose all areas attached to the pharmacy viz: the waiting area, the clinic, the semi-private area and the private area.

(d) The pharmacy must have a single point of entry and a single point of exit in compliance with the Occupation Health and Safety Act 85 of 1993 (OHSA).

(e) In order to comply with the requirement of accessibility to pharmaceutical services, a pharmacist must have an unfettered 24 hour access to the pharmacy.'

[6] The appellant has calculated that in order for members of the public not to feel physically restricted and to enjoy a sense of confidentiality when consulting with the pharmacist, the proposed wall should be about four metres

from the service counter. As the length of a pharmacy is typically about eight metres, the wall will create a 'box' jutting out and enclosing an area in excess of 30 square metres of floor space in front of the counter. Not only will this entail substantial construction expenditure (the appellant estimates the cost of building a wall meeting these requirements at approximately R200 000) but the presence of such a wall will in all likelihood have a profound negative impact on the supermarket business model, interfering as it must with the free flow of customers between the host supermarket and the pharmacy. The further requirement that the wall must extend from floor to ceiling is in itself problematic, not only as many of the host supermarkets are in buildings that have either extremely high ceilings or, in many cases, no ceilings at all, but the erection of a wall of this nature may adversely impact on the lighting and ventilation design of the buildings in which the pharmacies are situated.

[7] Consequently, on 22 March 2012, relying upon s 5 of the Promotion of Administrative Justice Act 3 of 2000 (PAJA), the appellant asked the first respondent to provide its reasons for passing the amendment. In its reply of 26 April 2012, the first respondent stressed the need to ensure that the profession provides excellence for the benefit of those they serve, and went on to say:

'(I)t is imperative to ensure that the premises defined as a "pharmacy" is clearly demarcated which demarcation needs to be clearly identified and permanent. This has proved to be problematic where a pharmacy is situated within another business, and has in practice given rise to the colloquial, yet arbitrary, "white line" concept to demarcate the area registered as the pharmacy. This is evident in pharmacies situated within healthcare facilities or group practices, institutional pharmacies which have a section directly accessible by members of the public and pharmacies situated within an ordinary retail environment eg "supermarket model".

The absence of a permanent demarcation of the pharmacy premises has led to a lack of definitive jurisdiction for the Council and in some circumstances definitive jurisdiction *vis a vis* other statutory health councils in the application of Ethical Rules. In addition the "white line" can be moved without notice and may at the extreme even vary from day to day.

It is common cause that owners/responsible pharmacists and the Office of the Registrar are aware of the demarcation of the pharmacy premises due to the fact that floor plans have to be provided for purposes of pharmacy licenses and the recording of such pharmacies. However, when a pharmacy is situated within another business and in the absence of a permanent demarcation these premises lines/boundaries/borders are unknown to 3rd parties, in particular the members of the public, other healthcare professionals and Council's inspectors (should they not have access to or be in possession of floor plans).

At the highest level, the lack of a permanent, visible, therefore known demarcation brings into question where does the pharmacy begin and end and thus where do the rules and laws begin and end in terms of pharmacies and pharmaceutical services. In addition the Council identified specific areas of concern in regulating the pharmacy in the absence of a permanent business demarcation:

(a) Confidentiality issues, in terms of record keeping and potential access to patient records;

(b) Access to scheduled substances;

(c) Stock control;

(d) Access to the pharmacy but unregistered/unauthorized; and

(e) In contrast to point (d) above, the lack of access to the pharmacy when the main business is closed or inaccessible.

Based on the abovementioned details the Council identified the need to simplify the minimum standards pertaining to the demarcation, accessibility of a pharmacy situated within construction of a permanent "structure" must incorporate the entire pharmacy.'

[8] On receiving these reasons, the appellant attempted to persuade the first respondent to withdraw the amendment. When its efforts were unsuccessful, the appellant decided to challenge the amendment and launched review proceedings in the court a quo. As appears from its reasons of 26 April 2012, and repetitively repeated in its answering affidavits, the first respondent's primary concern in effecting the amendment appears to have been to ensure that pharmacy premises are clearly identifiable and demarcated from the host businesses in which they are situated. Certain of its expressed reasons for that view are somewhat difficult to appreciate, but nothing turns on this as the

appellant accepted that it is necessary for pharmacies to be both identifiable and clearly demarcated from the supermarkets in which they are to be found. The appellant's challenge on review related solely to the provisions of subsecs (b), (c) and (d) of s 1.2.2.1 introduced by the amendment ie the requirements relating to a permanent wall extending from floor to ceiling with restricted points of entry and exit. As already mentioned, its challenge was dismissed by the court a quo and is now before this court on appeal.

[9] It is necessary to record at the outset that both sides were agreed, correctly, that the first respondent's amendment of the GPP Rules constituted administrative action taken by an administrator as envisaged by PAJA. Section 33(1) of the Constitution requires such administrative action to be 'lawful, reasonable and procedurally fair' and PAJA is designed to ensure the achievement of that end. It provides that administrative action may be set aside, inter alia, if irrelevant considerations were taken into account or relevant considerations were not considered,[5] if it was not rationally connected to either the information before the administrator[6] or the reasons given for it by the administrator,[7] or if it was an action that no reasonable decision-maker could take.[8] The requirement of rationality is to ensure that the action is not arbitrary or capricious and that there is a rational connection to the facts and the information available to the administrator taking the decision and the decision itself.[9]

[10] Whether an action may be impugned on any of these grounds involves a fact driven inquiry having regard, inter alia, to the information available to the administrator, the considerations relied on, the ends that were sought to be

[5] Section 6(2)(*e*)(iii).
[6] Section 6(2)(*f*)(cc).
[7] Section 6(2)(*f*)(ii)(dd).
[8] Section 6(2)(*h*). See further *Bato Star Fishing (Pty) Ltd v Minister of Environmental Affairs* 2004 (4) SA 490 (CC) para 44.
[9] *SA Predator Breeders Association v Minister of Environmental Affairs and Tourism* [2011] 2 All SA 529 (SCA) para 28.

achieved and the effect the proposed action would have upon interested parties. But in considering the lawfulness of the action sought to be impugned, it is important for a court to remember that it is engaged in a review and not an appeal, and that it is not for it to usurp the administrator's function. Accordingly, as long as the administrative action is rational or reasonable it cannot be impugned, even if it is not an action the court would have taken. But of course questions such as reasonableness and rationality involve the making of a value judgment that cannot be tested in isolation, so to speak, without considering the so-called 'merits' of the action and why it was taken.[10]

[11] A consideration of the merits of the decision in the present case is bedevilled by a singular lack of information as to why the first respondent decided that a wall meeting the prescribed requirements was necessary. As already mentioned, the GPP Rules prior to the introduction of the amendment also required pharmacy premises to be 'clearly demarcated and identified from the premises of any other business or practice', and the first respondent had never complained that any of the appellant's pharmacies breached this rule despite having regularly inspected them. The inference is that the appellant's premises were in fact clearly demarcated and identifiable. Nor for that matter is there any suggestion that any complaint, of any nature whatsoever, had been made arising out of the adoption of any similar business model by other pharmacy owners. Significantly, when the draft amendments were published for purposes of comment, it was done without any motivation as to why the existing rule had been inadequate or why it had been felt necessary to effect changes thereto.

[12] Nor does the first respondent's motivation in effecting changes to the existing rule appear from the documents it furnished under Uniform rule 53 in response to the institution of review proceedings. What does appear from those

[10] See eg, C Hoexter *Administrative Law in South Africa* (2ed) (2012) at 351-352.

documents is that, in April 2008, the first respondent had established a task team to develop a discussion paper in regard to various aspects of pharmaceutical practice. Thereafter the first respondent's registrar wrote to various foreign pharmaceutical regulators, inquiring about their respective requirements relating to pharmacies in supermarkets. The first respondent's records show no response to any of these enquiries. All one knows is that in the minutes of a teleconference of the task team conducted on 25 June 2009 it was noted that corporate pharmacies should be advised to have 'a white line demarcation separating the pharmacy from the rest of the business'(the 'white line model' is a system which uses markings on the floor of the premises to indicate the boundary between the pharmacy and the host business), and that members of the task team were to 'engage with a few corporate pharmacies regarding the white line model'. These minutes must be construed as an indication that the task team favoured the introduction of such a method of demarcation. Significantly, they make no mention of a permanent enclosure.

[13] The first respondent alleged in its answering affidavits that during the teleconference there had in fact been a vigorous debate about the efficacy of the 'white line model' as it was regarded as being problematic. It also alleged that the white line model 'has rarely been properly observed' and suggested that the line might be moved on a daily basis, something that with its limited resources it could not police. However, not only did the first respondent give no details of this ever having happened, but even if one accepts that there was a perception that this could occur, there is no mention in the minutes of any discussion concerning the necessity of providing a box-like enclosure of the nature of that ultimately prescribed by the amendment.

[14] So why did the first respondent introduce subsecs (b), (c) and (d) requiring a permanent wall extending from floor to ceiling, with restricted access, in order to demarcate and identify a pharmacy's premises? The answer

to this question is shrouded in mystery. As already mentioned, the main issue the first respondent addressed in resisting the review was the necessity to adequately demarcate and identify the premises of a pharmacy, but nowhere in the papers did it explicitly set out its reason why it felt that it was necessary to build a wall of this nature in order to achieve this end. The closest it has ever come to an explanation is the suggestion in its reasons of 26 April 2012 that it had identified the need 'to simplify the minimum standards pertaining to the demarcation' of a pharmacy. This is quite simply no reason at all. Whilst there can be no doubt that the prescribed wall would certainly achieve the end of demarcating and identifying the premises of a pharmacy, it can hardly be suggested that it is the simplest solution to achieve that end.

[15] The fundamental difficulty facing the first respondent is, thus, that it has neither explained what considerations it took into account nor provided any motivation for its introduction of a rule requiring a wall envisaged in the introduced subsecs, the building of which is likely to impinge heavily upon the appellant's business model. Had it had any facts justifying the need for such a wall, it can be presumed they would have been forthcoming. As they were not, the matter must be decided on the basis that there were none.

[16] In these circumstances, accepting that there was no information before the first respondent or factual foundation that demonstrated any existing mischief that needed to be addressed by way of a wall of the nature specified, the decision to oblige pharmacy owners to build such a wall was arbitrary and irrational in the sense that it lacked any logical justification.

[17] Faced with this difficulty, counsel for the first respondent argued that once it was accepted that it was rational and reasonable to require a demarcation of the pharmacy premises, it was not for a court to question the means by which it decided to achieve this end – namely, by erecting the wall in compliance with

the subsecs. However, although the first respondent was empowered by s 4 of the Act to generally 'do all such things as the council deems necessary or expedient to achieve the objects of this Act', it does not have carte blanche to do just as it likes. Instead its discretion is fettered by the obligation to exercise its administrative powers lawfully. Sub-sections (b), (c) and (d) relating to the nature and extent of the envisaged wall were made by it in purporting to exercise those powers, and it is its action in doing so that may be challenged on review. Accordingly, even if a demarcation is justifiable, the administrative action amending the GPP Rules to introduce the requirement of a wall of the nature envisaged is liable to be set aside under PAJA if it was not properly taken. And as that decision lacked rationality for the reasons already given, it does not withstand scrutiny under PAJA.

[18] Of further importance is the first respondent's failure to indicate why it felt that a less onerous demarcation would not have sufficed. Although it is not for a court to determine on these papers what would have been an adequate albeit less restrictive method of demarcation, it takes little imagination to envisage various ways in which the premises of a pharmacy in a supermarket or other business premises could easily be clearly identified and demarcated at little cost and without causing significant interference with the free flow of customer traffic between the two businesses.

[19] The first respondent argued that the onerous practical implications the appellant would bear in giving effect to the amendment were irrelevant as the amendment was not specifically targeted at the appellant but at all pharmacies located in other businesses, and that persons who do business in a highly regulated field must proceed on the basis that, from time to time, the regulatory landscape will change. It further argued that although the appellant had made much of the adverse implications of the floor-to-ceiling model, it would have been amenable to considering a workable alternative that was less invasive.

[20] Of course persons doing business in a regulated profession cannot expect that the regulations under which they operate will remain static. But that is no reason for the consequences of any proposed changes in the regulations upon those affected to be regarded as irrelevant and not to be taken into account before they are implemented. As already mentioned, s 6(2)(*h*) of PAJA requires an administrative decision to be reasonable in the light of the circumstances of each particular case. As O'Regan J stressed in her seminal judgment in *Bato Star Fishing*,[11] factors relevant to the determination of whether a decision is reasonable or not will include the reasons given for the decision (which as I have stressed are singularly lacking in this case) as well as 'the nature of the competing interests involved and the impact of the decision on the lives and well-being of those affected'.[12] It has been stated that 'proportionality is a constitutional watchword'[13] and as was observed by Plasket J in *Ehrlich*,[14] quoting with approval the views of Prof Jowell, unreasonable administrative action includes 'those that are oppressive in the sense that they "have an unnecessarily onerous impact on affected persons or where the means employed (albeit for lawful ends) are excessive or disproportionate in their result"'.[15]

[21] Accordingly, in seeking to achieve a clear demarcation between pharmacy and supermarket, the first respondent was obliged to weigh up the effect of its rules on those affected thereby, particularly as the implementation of the new subsecs was likely to have a substantial adverse effect on the basic business model being used not only by the appellant but by other pharmacy owners using the supermarket model countrywide.

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[11] *Bato Star Fishing (Pty) Ltd v Minister of Environmental Affairs* 2004 (4) SA 490 (CC).
[12] Paragraph 45.
[13] *City of Johannesburg Metropolitan Municipality v Blue Moonlight Properties 39 (Pty) Ltd* 2011 (4) SA 337 (SCA).
[14] *Ehrlich v Minister of Correctional Services* 2009 (2) SA 373 (E).
[15] Para 42 quoting, J Jowell 'Judicial Review of the Substance of Official Decisions' (1993) 13 *Acta Juridica* 117 at 120.

[22] Moreover, implicit in the recognition that the first respondent was amenable to a less invasive alternative than the wall it had prescribed, is an acknowledgement that the floor-to-ceiling wall was not necessary in order to achieve the objective to ensure a clear demarcation between the pharmacy and the host business. This is a telling concession. By seemingly ignoring any other option the first respondent failed to consider less drastic but surely available means to accomplish the desired result of a clear demarcation. A floor-to-ceiling wall would indeed be an absolute demarcation, but without the first respondent providing any reason for requiring such a wall, the adverse consequences to the supermarket business model and the costs flowing therefrom appear to have been wholly disproportional to the end it sought to achieve. Instead it used 'a sledgehammer to . . . crack a nut'.[16] As the first respondent has failed to attempt to justify the use of a sledgehammer, its action must be regarded as unreasonable.

[23] Consequently, the first respondent's administrative action in making the subsecs in question ought to have been set aside as having been both irrational and unreasonable. For these reasons alone the court a quo erred in concluding otherwise, and its order cannot stand. This renders it unnecessary to consider the various further issues debated in this court.

[24] The following order will therefore be made:

1 The appeal succeeds with costs, such costs to include the costs of two counsel.
2 The order of the court a quo is set aside and is substituted with the following:
'(a) The first respondent's amendment of s 1.2.2 of Annexure A to the *Rules Relating to Good Pharmacy Practice*, published in Government Gazette No 35095 on 2 March 2012 under Board Notice 35/2012, insofar as it introduced subsecs (b), (c) and (d) to s 1.2.2.1, is set aside.

[16] A somewhat hackneyed but graphic idiom used, inter alia, *in S v Manamela* 2000 (3) SA 1 (CC) para 34.

(b) The first respondent is to pay the applicant's costs, including the costs of two counsel.'

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L E Leach
Judge of Appeal

Appearances:

For the Appellant:	J J Gauntlett SC (with him M W Janisch) Instructed by: Werksmans C/o Van der Merwe Du Toit Inc, Pretoria Phatshoane Henney, Bloemfontein
For the Respondent:	A P H Cockrell SC (with him A B Friedman) Instructed by: Potgieter-Marais Attorneys, Pretoria J L Jordaan Attorneys, Bloemfontein