



Summary: Pharmacy Act 53 of 1974 – Pharmacy Council’s power to expand the scope of practice of pharmacists to provide pharmacist-initiated management of antiretroviral therapy services – procedural fairness and rationality of Council’s decision.

ORDER

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

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

JUDGMENT

Makgoka JA (Nicholls, Hughes, and Unterhalter JJA and Chili AJA concurring):

[1] This case concerns primary health care for people living with human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS). The appellant, the Independent Practitioners Association Foundation (the IPA), appeals against certain orders of the Gauteng Division of the High Court, Pretoria (the high court). The court dismissed its application to set aside two decisions of the respondent, the South African Pharmacy Council (the SAPC). The appeal is with the leave of the high court.

The parties

[2] The IPA is a non-profit company that is wholly owned and controlled by its members, who are family medical practitioners in private practice. The SAPC is a statutory body and regulator of the pharmacy profession, established in terms of s 2 of the Pharmacy Act 53 of 1974 (the Pharmacy Act). The SAPC's objectives include promoting the health of the South African population and enhancing pharmaceutical care for patients. In pursuing these objectives, the SAPC is obliged to oversee the training and education of pharmacists, enabling them to fulfil their professional responsibilities in providing healthcare to the

public. The SAPC is also the *custos morum* (the custodian of morals and ethics) of the pharmacy profession.

The impugned decisions

[3] The two decisions of the SAPC that the IPA sought to review and set aside are these. First, the SAPC's approval of the implementation of the scope of practice for pharmacists who provide pharmacist-initiated management of antiretroviral therapy (PIMART) services. This initiative allows accredited pharmacists to administer first-line therapy for the treatment and management of HIV/AIDS. The implementation of PIMART required amendments to the Pharmacy Act to expand the scope of practice for specifically qualified pharmacists providing PIMART services. Such pharmacists would be able to, among other things, conduct consultations with HIV patients at a pharmacy or at an approved healthcare setting.

[4] The second decision, linked to the first, is the SAPC's publication of Board Notice 101 of 2021 (Board Notice 101) in the *Government Gazette* (the *Gazette*) dated 13 August 2021. This notice outlined: (a) the implementation of PIMART services; (b) the competency standards for such pharmacists; and (c) the criteria for approving a curriculum for a PIMART course. The publication of Board Notice 101 was preceded by Board Notice 71 of 2021, published in the *Gazette* on 22 March 2021 (Board Notice 71). Although the IPA does not challenge this notice, it contends that it is related to Board Notice 101 of 2021.

Factual background

[5] In 1995, the SAPC, in accordance with s 33(1) of the Pharmacy Act, issued regulations concerning pharmacist-initiated therapy (PIT) that could be obtained through supplementary or continuing professional development courses for pharmacists already registered in terms of the Pharmacy Act. These regulations

allowed pharmacists to provide services such as HIV testing, emergency post-coital contraception, pregnancy testing, urine test analysis, sexual health advice, and occupational post-exposure HIV prophylaxis for healthcare workers at a pharmacy. In 2000, antiretrovirals (ARVs) were first introduced in the private sector for people living with HIV/AIDS. Only specialists were permitted to initiate treatment. Therefore, the initiation of ARVs could only be carried out by healthcare providers and was predominantly hospital-based.

[6] In 2010, Nurse-Initiated Management of Antiretrovirals (NIMART) was introduced in the public health sector, allowing nurses to screen people living with HIV/AIDS and initiate antiretroviral therapy at primary healthcare clinics across the country. In December 2020, the Department of Health (the department) granted special authorisation that permitted nurses in private pharmacies to prescribe ARVs at pilot sites, provided these nurses had completed the NIMART training.

[7] Despite all these initiatives, the number of HIV infections remained persistently high. For example, in 2010, the number had increased from 5.7 million to 8.2 million, despite improved access through NIMART. This high rate of new HIV infections underscored the necessity for intensified prevention efforts. As infections continued to rise, the HIV-related budget grew substantially over the years. The department spent more than R20 billion, on HIV alone, in the 2019/2020 financial year. Consequently, there was a need to explore different methods to curb the rising number of new HIV infections.

[8] In light of the above, the department requested the SAPC, as the regulator of the pharmacy profession, to investigate an intervention aimed at increasing patients' access to antiretroviral medicines for Pre-Exposure Prophylaxis (PrEP) and Post-Exposure Prophylaxis (PEP). The department's initial proposal was for

the SAPC to ‘petition the South African Health Products Regulatory Authority (SAHPRA) to potentially [reclassify] certain medicines used for treating HIV, for the purposes of PrEP and PEP’.

[9] Ordinarily, pharmacists are only permitted to dispense Schedule 1 and 2 medicines without a prescription from an authorised prescriber. The aim was to reclassify some of the medicines under Schedules 3 and 4, to Schedule 2, allowing pharmacists to prescribe and dispense them without a prescription from another authorised prescriber. This would form part of pharmacist-initiated therapy, which involves diagnosing, treating, and managing illnesses and minor ailments by pharmacists under ss 22A(5) and 22A(6) of the Medicines and Related Substances Act 101 of 1965 (the Medicines Act).

[10] The SAPC investigated the matter and consulted, among others, the Southern African HIV Clinicians Society (HIV Clinicians Society). On 15 August 2018, the SAPC informed the Director-General of the department (the Director-General) of the department that it had decided against the department’s proposal for reclassifying certain medicines under Schedule 2. Instead, it selected PIMART, considering, among other things, the issue of accessibility. It stated that many community pharmacies offer HIV screening and have extended opening hours, which allow for timely access to HIV prevention tools such as PrEP and PEP.

[11] Regarding the qualification to offer PIMART services, the SAPC envisioned that practising pharmacists would need to undertake supplementary training. The training would include understanding global HIV trends, recognising the scale of the HIV epidemic in South Africa, understanding transmission risks per exposure, and grasping the aims and objectives of the treatment.

[12] Upon completing such training, pharmacists would need to apply for a PIMART permit, which would be issued by the Director-General under s 22A(15) of the Medicines Act. This permit would allow the accredited pharmacists ‘to prescribe and dispense [antiretroviral therapy] ART medicines for PrEP, PEP and, where appropriate, first line ARV therapy’. Concerning the competency standards for the pharmacists’ supplementary training, the SAPC consulted with the Southern African HIV Clinicians Society (the Clinicians Society), which provided the recommended competency standards that a pharmacist should meet to deliver PIMART services. These standards were developed by medical experts and subsequently submitted to the North-West University School of Pharmacy ‘to assess the competencies obtained in the Bachelor of Pharmacy and the additional training that would be required for pharmacists to provide PIMART services’.

[13] On 22 March 2021, the SAPC published Board Notice 71 in the *Gazette* for public comment and stakeholder engagement regarding its proposed adoption of PIMART. The schedule attached to the notice outlined: (a) the scope of practice of a pharmacist who provides PIMART services; (b) competency standards for a pharmacist offering PIMART services; and (c) criteria for accreditation or approval by the SAPC of a curriculum leading to the awarding of a PIMART course.

[14] Interested parties and stakeholders were invited to submit, within 60 days of publication, substantiated comments or representations concerning PIMART. The prescribed notice period ended on 21 May 2021. It is common ground that the IPA did not submit any comments within the specified period. However, the SAPC received comments from interested parties within the same period, all of which, in principle, supported the implementation of PIMART.

[15] On 30 June 2021, the SAPC met with the Director-General to brief her on its plan to implement PIMART and related matters. On 13 and 14 July 2021, it held meetings to consider the comments received in response to Board Notice 71, and a decision was made to introduce PIMART. On 12 August 2021, the Director-General approved the issuance of permits to pharmacists qualified to provide PIMART services.

[16] On 13 August 2021, the SAPC announced its decision to introduce PIMART in Board Notice 101. The SAPC informed interested parties of the services a PIMART-accredited pharmacist would be entitled to offer and how it would approve institutions providing the required supplementary training that pharmacists must complete to apply for PIMART accreditation. Regarding the decision, a pharmacist who has completed the PIMART supplementary training would be permitted to conduct consultations with people living with HIV/AIDS at a pharmacy or an approved healthcare setting, which includes the following:

- ‘(a) history taking, performing of screening and confirmatory tests, ordering, conducting and interpretation of diagnostic and laboratory tests in line with [the department’s] guidelines (for diagnosis, clinical staging and assessment of an HIV infected patient or those at high risk of contracting HIV);
- (b) assess and manage the HIV-infected patients or those at high risk of contracting HIV who require [PrEP and PEP], who are not pregnant or under 15 years of age;
- (c) a decision on safe and appropriate therapy;
- (d) initiate antiretroviral treatment limited to PrEP, PEP and first line [ART] plus initiation of TB-Preventative Therapy (TPT) in line with [the department’s] guidelines;
- (e) adjustment of ART (where necessary) which has been prescribed previously;
- (f) monitoring of the outcomes of therapy;
- (g) referral to another health care provider where necessary, e.g., discordant results; and
- (h) confidential and adequate record keeping.’

[17] On 8 September 2021, following the publication of Board Notice 101, which introduced the implementation of PIMART, the IPA submitted its

comments and objections to the SAPC regarding the implementation of PIMART. On 27 September 2021, the Forum of Statutory Health Professional Councils (the Forum) held a meeting to discuss, among other things, Board Notice 101. The Forum comprises the Health Professions Council of South Africa (HPCSA), the South African Nursing Council (SANC), and the Allied Health Professions Council of South Africa (APCSA). These health bodies raised some concerns. The SAPC delivered a presentation in which it responded to the comments and endeavoured to address the concerns raised. The Forum agreed to further engage on Board Notice 101, through a subcommittee. No subsequent resolutions seem to have been made by the Forum in this regard.

[18] On 11 October 2021, the IPA requested the SAPC to provide reasons under s 5 of the Promotion of Administrative Justice Act 3 of 2000 (the PAJA) for implementing the amendments to the Pharmacy Act, which expanded the scope of practice for pharmacists to include PIMART services. The SAPC did not respond to the request.

In the high court

[19] On 8 February 2022, the IPA lodged a review in the high court. The application was based on s 3 and s 6 of the PAJA, alternatively by way of a legality review. The IPA claimed that the publication of Board Notice 71, in March 2021, only in the *Government Gazette*, did not provide adequate notice of the nature and purpose of the proposed administrative action, namely the implementation of PIMART. It also contended that the notice, which led to the publication of Board Notice 101 in August 2021, did not provide its members with a reasonable opportunity to make representations regarding the implementation of PIMART.

[20] This was particularly true, the IPA contended, considering PIMART's supposed adverse effect on its members and the 'particular circumstances at the time'. The IPA alleged that the notice violated s 3 of the PAJA. Accordingly, the IPA argued that the implementation of PIMART lacked procedural fairness. Furthermore, the IPA argued that both the decision by the SAPC to adopt the notice and to publish it for implementation violated various provisions of s 6(2) of the PAJA.

[21] In its replying affidavit, the IPA attached supporting affidavits from several professional associations opposing PIMART. It listed nine professional associations in this regard. The SAPC objected to this. Among the grounds for its objection was that the IPA sought impermissibly to make out a new case in reply. It accordingly applied to have those parts of the replying affidavit struck out.

[22] The high court observed that the professional associations mentioned in the replying affidavit were not parties to the litigation, and the supporting affidavits accompanying the replying affidavit had not been submitted to the SAPC for consideration, nor did they form part of the record. Consequently, the high court struck out these affidavits in the replying affidavit as new matter.

[23] Regarding procedural fairness, the high court found that the SAPC had provided sufficient notice of its intention to adopt PIMART; that the nature and purpose of PIMART were clearly explained; and that the IPA and other interested parties were given a reasonable opportunity to comment or make representations. The high court therefore concluded that the SAPC's administrative action was procedurally fair.

[24] As to the substantive grounds of review under s 6(2) of the PAJA, the high court held that the decision to utilise PIT as a vehicle for PIMART and to enable

adequately trained pharmacists to provide PIMART services was rationally connected to: (a) the purpose for which it was made; (b) the information before the SAPC; and (c) the reasons given by the SAPC. The high court found that this decision was rationally connected to the SAPC's objectives to assist in the fight against HIV/AIDS. On these grounds, the high court dismissed the IPA's review application.

The issues in this Court

[25] The parties persisted with the arguments they had advanced in the high court. In addition, the IPA challenged the decision of the high court to strike out material from its replying affidavit. Accordingly, the four issues for determination, which I will consider in turn, are whether:

- (a) the high court correctly granted the SAPC's strike-out application;
- (b) the IPA had standing to bring the application;
- (c) the publication of Board Notice 71 was procedurally fair;
- (d) the introduction of PIMART was rational, generally, and in terms of s 6 of the PAJA.

The strike-out application

[26] The IPA contended that the high court erred in striking out annexures contained in its replying affidavit. It argued that these were attached in rebuttal of the SAPC's defences, and sought to rely on *Drift Supersand (Pty) Ltd v Mogale City Local Municipality (Drift Supersand)*¹ and *Lagoon Beach Hotel (Pty) Limited v Lehane N O and Others (Lagoon Beach Hotel)*.²

¹ *Drift Supersand (Pty) Ltd v Mogale City Local Municipality* [2017] ZASCA 118; [2017] 4 All SA 623 (SCA) para 10.

² *Lagoon Beach Hotel v Lehane* [2015] ZASCA 210; [2016] 1 All SA 660 (SCA); 2016 (3) SA 143 (SCA).

[27] Neither of these cases supports the IPA's position. In *Drift Supersand*, this Court found that the appellant's replying affidavit did not introduce new grounds for the application but instead clarified and elaborated on its original claims regarding its standing and the effect of the municipality's decision. In *Lagoon Beach Hotel*, the amplification of the appellant's case in reply was permitted because of the urgency of the matter and the absence of a deponent. The Court considered the practical difficulties faced by the appellant in gathering evidence in a short space of time.

[28] In the present case, the IPA aimed to bolster their grounds of review in its replying affidavit. By including affidavits from several associations that had not been mentioned in the founding papers, it sought to support its review application with new evidence and arguments that were not part of its initial case. The affidavits were introduced to strengthen the IPA's case. The supporting affidavits contained substantive arguments in favour of the primary relief claimed in the founding affidavit, rather than by way of rebuttal of the averments in the answering affidavit. They, therefore, constituted new material introduced for the first time in the replying affidavit. It is trite that an applicant must stand or fall by the averments made out in its founding affidavit. It was therefore impermissible for the IPA to make out a new case in the replying affidavit.³

[29] IPA also submitted that the high court did not exercise its discretion properly. It argued that the court should not have struck out the material in its entirety but should have examined it paragraph by paragraph to identify those parts that were offensive and those that could be justified. There is no merit in this contention. It is not a court's duty to sift through affidavits to determine

³ *Director of Hospital Services v Mistry* 1979 (1) SA 626 (A) at 636A; *National Council of Societies for the Prevention of Cruelty to Animals v Openshaw* [2008] 4 All SA 225 (SCA); 2008 (5) SA 339 (SCA); [2008] 4 All SA 225 (SCA) paras 29-30; *Mostert v FirstRand Bank t/a RMB Private Bank* [2018] ZASCA 54; 2018 (4) SA 443 (SCA) para 13.

which parts are offensive. It is the IPA that should have undertaken this exercise if it wished to argue that certain portions were severable. Even in this Court, the IPA has not distinguished between the portions that should be retained and those that should be discarded. For all the reasons stated above, the high court was correct to strike them out.

The IPA's standing

[30] The IPA relied on s 3(1) of the PAJA, which provides that 'administrative action which materially and adversely affects the rights or legitimate expectations of any person must be procedurally fair.' The SAPC contended that s 3(1) of the PAJA required the IPA to show that Board Notice 101 affects the rights or legitimate expectations of the IPA's members and, consequently, it should be non-suited if it fails to do so. I disagree. The reach of s 3(1) was explained by the Constitutional Court in *Joseph v City of Johannesburg (Joseph)*,⁴ as follows:

'... The structure of section 3(1) is important as it indicates the broad application of the procedural fairness provisions under PAJA. In *Walele*,⁵ in considering a procedural fairness claim based on an alleged legitimate expectation, this Court emphasised that section 3 of PAJA must be interpreted generously to give proper effect to section 33(1) of the Constitution.⁶ O'Regan J, writing for the minority, observed that "[w]e must be careful, in construing section 3(1), to bear in mind that it is the key provision in PAJA that gives effect to the right entrenched in section 33(1) of the Constitution."⁷

[31] The Court held further that the rights under s 3(1) of the PAJA should be construed not only to refer to private law rights, 'but also legal entitlements that have their basis in the constitutional and statutory obligations of government'.⁸ Furthermore, the IPA has standing to bring the review application under s 38 of

⁴ *Joseph and Others v City of Johannesburg and Others* [2009] ZACC 30; 2010 (3) BCLR 212 (CC); 2010 (4) SA 55 (CC) (*Joseph*).

⁵ *Walele v City of Cape Town and Others* [2008] ZACC 11; 2008 (6) SA 129 (CC); 2008 (11) BCLR 1067 (CC).

⁶ Section 33(1) of the Constitution provides: 'Everyone has the right to administrative action that is lawful, reasonable and procedurally fair.'

⁷ *Joseph* para 40.

⁸ *Ibid* para 42.

the Constitution,⁹ and in this context, our courts have adopted a broad approach to standing in matters such as these. In *Giant Concerts v Rinaldo Investments*,¹⁰ the Constitutional Court referred, with approval, to the assertion by Hoexter that where a review application is brought under the PAJA, s 38 of the Constitution should be read into the PAJA.¹¹

[32] The Constitutional Court also held, in *Mkhize v Premier of the Province of KwaZulu-Natal*,¹² that where review of public power is challenged under the PAJA, a broad approach to standing under s 38 should apply. In *Kruger v President of the Republic of South Africa*,¹³ the Constitutional Court recognised the standing of an attorney who applied in his own interest, and in the public interest, for a proclamation to be declared invalid in circumstances where s 38 was not of direct application. The Court explained:

‘... Where the practitioner can establish both that a proclamation is of direct and central importance to the field in which he or she operates, and that it is in the interests of the administration of justice that the validity of that proclamation be determined by a court, that practitioner may approach a court to challenge the validity of such a proclamation. . .’¹⁴

[33] In the present case, PIMART concerns public health, specifically focused on increasing access to therapy for people living with HIV/AIDS. This is the field

⁹ This section provides:

‘Enforcement of rights

Anyone listed in this section has the right to approach a competent court, alleging that a right in the Bill of Rights has been infringed or threatened, and the court may grant appropriate relief, including a declaration of rights. The persons who may approach a court are-

- (a) anyone acting in their own interest;
- (b) anyone acting on behalf of another person who cannot act in their own name;
- (c) anyone acting as a member of, or in the interest of, a group or class of persons;
- (d) anyone acting in the public interest; and
- (e) an association acting in the interest of its members.’

¹⁰ *Giant Concerts CC v Rinaldo Investments (Pty) Ltd and Others* [2012] ZACC 28; 2013 (3) BCLR 251 (CC) para 29.

¹¹ C Hoexter *Administrative Law in South Africa* 2 ed (2012) at 494.

¹² *Mkhize NO v Premier of the Province of KwaZulu-Natal and Others* [2018] ZACC 50; 2019 (3) BCLR 360 (CC).

¹³ *Kruger v President of the Republic of South Africa and Others* [2008] ZACC 17; 2009 (1) SA 417 (CC); 2009 (3) BCLR 268 (CC).

¹⁴ *Ibid* para 25.

in which the IPA's members operate. It is therefore necessary and in the interests of the administration of justice to subject PIMART's conceptualisation and implementation to judicial scrutiny at the instance of the IPA, given the impact of PIMART upon the professional work conducted by the members of the IPA. I am therefore satisfied that the IPA has established the necessary standing.

Procedural fairness

[34] Hoexter and Penfold describe the importance of procedural fairness as follows:

'Procedural fairness . . . is concerned with giving people an opportunity to participate in the decisions that will affect them, and – crucially – a chance of influencing the outcome of those decisions. Such participation is a safeguard that not only signals respect for the dignity and worth of the participants, but is also likely to improve the quality and rationality of administrative decision-making and to enhance its legitimacy.'¹⁵

[35] The IPA argued that the publication of Board Notice 71 did not provide sufficient notice to its members because: (a) it was issued at an inconvenient time when members were busy dealing with the COVID-19 pandemic; and (b) it was only published in the *Government Gazette*, a publication that, according to the IPA, is not generally read. Therefore, the IPA claimed that the publication of Board Notice 71 was procedurally unfair in terms of s 3 of the PAJA.¹⁶

¹⁵ C Hoexter and G Penfold *Administrative Law in South Africa* 3rd ed (2021) at 502. Footnote omitted.

¹⁶ Section 3 of the PAJA, in relevant parts, reads:

'Procedurally fair administrative action affecting any person

(1) Administrative action which materially and adversely affects the rights or legitimate expectations of any person must be procedurally fair.

(2)(a) A fair administrative procedure depends on the circumstances of each case.

(b) In order to give effect to the right to procedurally fair administrative action, an administrator, subject to subsection (4), must give a person referred to in subsection (1) –

- (i) adequate notice of the nature and purpose of the proposed administrative action;
- (ii) a reasonable opportunity to make representations;
- (iii) a clear statement of the administrative action;
- (iv) adequate notice of any right of review or internal appeal, where applicable; and
- (v) adequate notice of the right to request reasons in terms of section 5.'

[36] The Constitutional Court has held that fairness must be determined in light of the specific circumstances of a particular case.¹⁷ As mentioned, the IPA complained about the *timing* of the publication of Board Notice 71. It said that it was inopportune, as it occurred during the Covid-19 pandemic, when its members were engaged in the fight against the pandemic. The IPA also lamented the *method* of publication, ie only in the *Government Gazette*.

[37] As to the timing argument, it is worth noting that the IPA was not the only interested party to whom Board Notice 71 was directed. Despite the timing of the notice, other interested bodies were able to review and comment on its contents. The SAPC specifically mentioned responses from Clicks Retailers (Pty) Ltd, the Western Cape Department of Health, the Independent Community Pharmacy Association, the Pharmaceutical Society of South Africa National Office, and S Buys Academy (Pty) Ltd. The IPA criticised the quality of some of the comments. However, this does not detract from the fact that these entities responded to the notice, and nothing about the timing of the notice prevented them from doing so.

[38] The high court correctly observed that the IPA is a juristic person separate from its members. There is no suggestion that the COVID-19 pandemic also paralysed its administrative functions such that it could not respond to the invitation in Board Notice 71 to make representations. The period within which comments and representations were to be made was 60 days, which, to my mind, was adequate. The IPA conceded that its comments were submitted well after the

¹⁷ *Zondi v MEC for Traditional and Local Government Affairs and Others* [2004] ZACC 19; 2005 (3) SA 589 (CC); 2005 (4) BCLR 347 (CC) para 114; *Janse van Rensburg and Another v Minister of Trade and Industry and Another* [2000] ZACC 18; 2001 (1) SA 29; 2000 (11) BCLR 1235 (CC) para 24. *Minister of Public Works and Others v Kyalami Ridge Environmental Association and Another (Mukhwevho Intervening)* [2001] ZACC 19; 2001 (3) SA 1151 (CC); 2001 (7) BCLR 652 (CC) para 102; *Premier, Province of Mpumalanga, and Another v Executive Committee of the Association of State-Aided Schools, Eastern Transvaal* [1998] ZACC 20; 1999 (2) SA 91 (CC); 1999 (2) BCLR 151 (CC) para 39; and *President of the Republic of South Africa and Others v South African Rugby Football Union and Others* [1999] ZACC 11; 2000 (1) SA 1 (CC); 1999 (10) BCLR 1059 (CC) para 219.

prescribed period, and after the publication of the board notice through which PIMART was implemented.

[39] There is no suggestion that the notice only came to the attention of IPA or its members after the 60 days allowed for comments. The fact is that the IPA and its members, like all the other interested role players, were given sufficient notice of the introduction of PIMART through publication in the *Gazette*. Remarkably, the IPA does not suggest that the notice did not come to its attention or its members. As the Constitutional Court explained in *Law Society of South Africa v President of the Republic of South Africa*,¹⁸ procedural fairness requires that a party likely to be disadvantaged by the outcome of a decision be given an opportunity to be properly represented and fairly heard before a potentially prejudicial decision is made.

[40] The IPA called in aid *Joseph*. In that case, a municipality disconnected the electricity supply to a block of flats without giving the tenants any notice or an opportunity to make representations before the disconnection. The court found that this lacked procedural fairness, which directly affected the tenants' access to a basic service vital for their daily lives and dignity. The circumstances are different here. The SAPC demonstrated procedural fairness by publishing Board Notice 71 for public comment within 60 days. The process included adequate notice and an opportunity for stakeholders to participate, meeting the requirements of procedural fairness under s 3 of the PAJA.

[41] Regarding the method argument, the SAPC published Board Notice 71 on its website and in the *Gazette*. It seems undisputed that these are the methods by which the SAPC usually publishes new regulations. While publication on its

¹⁸ *Law Society of South Africa and Others v President of the Republic of South Africa and Others* [2018] ZACC 51; 2019 (3) BCLR 329 (CC); 2019 (3) BCLR 329 (CC); 2019 (3) SA 30 (CC) para 64.

website appears to be discretionary, publication in the *Gazette* is legislatively required by s 49 of the Pharmacy Act. The section authorises the Minister, in consultation with the SAPC, to make regulations on various matters related to the pharmacy profession. Of relevance, for present purposes, is s 49(4), under which Board Notice 71 was published. It reads:

‘The council shall, not less than two months before any rule is made in terms of this Act, cause the text of such rule to be published in the *Gazette* together with a notice declaring the council’s intention to make such a rule and inviting interested persons to furnish the council with comments thereon or any representations they may wish to make in regard thereto.’

[42] Thus, by publishing Board Notice 71 in the *Gazette*, the SAPC fulfilled its statutory obligation under s 49(4). However, according to the IPA, this was not enough. It contended that compliance with s 3 of the PAJA ‘compels procedural fairness, which, given the facts and circumstances [of the case], exceeded mere compliance with a minimum statutory requirement in a post-constitutional era’. The IPA suggested that to achieve its stated goal of ‘broad-based stakeholder consultation’, the SAPC should have taken more comprehensive steps to consult with medical practitioners. Board Notice 71 should, for example, have been published in a doctor’s journal for it to ‘reach the broadest possible readership of medical doctors’.

[43] The IPA has not challenged the validity of the Pharmacy Act or the provisions of s 49(4) on the ground that its notification procedure is inadequate or inconsistent with the PAJA. Therefore, in the absence of a challenge to the underlying legislation, it is not open to the IPA to argue that the introduction of PIMART by publication, pursuant to s 49(4) was insufficient. In the result, once the SAPC complied with s 49(4), it fulfilled its statutory obligation, and there was no further legal requirement. I therefore conclude that the SAPC adhered to procedural fairness requirement.

Rationality

[44] The IPA did not rely on this ground of review in its founding papers. It introduced it in its notice of appeal and elaborated on it, in its heads of argument. As a result, the SAPC did not have an opportunity to respond to this ground in its papers in the high court. Despite this, the SAPC has not suffered any prejudice. There is sufficient factual background in its founding affidavit regarding the development of PIMART, upon which procedural rationality can be assessed.

[45] Where an administrative ‘decision is challenged on the grounds of rationality, courts must examine the means chosen to determine whether they are rationally connected to the objective sought to be achieved’.¹⁹ In *Albutt v Centre for the Study of Violence and Reconciliation (Albutt)*,²⁰ the Constitutional Court emphasised that ‘the purpose of the enquiry is to determine [not] whether the means selected are rationally related to the objective sought to be achieved’,²¹ rather than whether other means could have been used.

[46] In *Democratic Alliance v President of South Africa*,²² after reviewing some of its earlier decisions on rationality, including *Albutt*, the Constitutional Court stressed that rationality review is concerned with the evaluation of a relationship between means and ends: the relationship, connection or link between the means employed to achieve a particular purpose on the one hand and the purpose or end itself. It further explained:

‘The aim of the evaluation of the relationship is not to determine whether some means will achieve the purpose better than others but only whether the means employed are rationally related to the purpose for which the power was conferred. Once there is a rational relationship, an executive decision of the kind with which we are here concerned is constitutional.’

¹⁹ *Albutt v Centre for the Study of Violence and Reconciliation and Others* [2010] ZACC 4; 2010 (3) SA 293 (CC); 2010 (2) SACR 101 (CC); 2010 (5) BCLR 391 (CC) para 51.

²⁰ *Ibid.*

²¹ *Ibid.*

²² *Democratic Alliance v President of South Africa and Others* [2012] ZACC 24; 2013 (1) SA 248 (CC); 2012 (12) BCLR 1297 (CC).

[47] The IPA's argument on procedural rationality should be assessed in light of the factual background preceding the introduction of PIMART by the SAPC, which I have outlined in some detail. In summary, the SAPC justified the rationale for implementing PIMART as follows. Despite previous efforts to reduce new HIV infections, such as NIMART and PIT, new infection rates remained high. As a result, the department decided to involve pharmacists, among other medical professionals, because their accessibility allows them to deliver first-line HIV treatment, particularly in rural areas. This accessibility is particularly important, as the unchallenged evidence before the Court is that millions of people in the rural areas of South Africa remain undiagnosed and untreated for HIV.

[48] PIMART was thus a crucial intervention in the public interest, devised by a group of medical experts. These included the HIV Clinicians Society, a team of healthcare professionals heavily involved in caring for and treating people living with HIV/AIDS. What is more, its development involved designing specialised training programmes for pharmacists to enable them to provide PIMART services.

[49] Thus, through PIMART, the SAPC aimed to improve access to healthcare for HIV first-line treatment, given the inadequacy of previous initiatives. PIMART was rationally connected to that objective, as it promotes the right to access healthcare and supports the fight against HIV. Therefore, contrary to the IPA's contentions, PIMART is an essential intervention in the fight against HIV/AIDS. Its introduction constitutes a rational legislative and practical measure within the competence of the SAPC as an organ of the State in enhancing access to healthcare for HIV treatment, in fulfilment of the State's obligation

under s 27(2) of the Constitution.²³ These are legitimate and compelling public interests. Viewed in this light, PIMART is eminently rational. It follows that there is no merit in IPA's submissions on procedural rationality.

Rationality under s 6(2) of the PAJA

[50] Although in its papers the IPA raised several issues under this rubric, in this Court, it focused mainly on two, with which I deal in turn. First, it emphasised the distinct professional domains of pharmacists and medical doctors as regulated by the Pharmacy Act and the Health Professions Act 56 of 1974 (the Health Professions Act), respectively. Based on that distinction, the IPA argued that the decision to implement PIMART was not authorised by the empowering provisions of these Acts, thereby breaching s 6(2)(e)(i). The IPA contended that these statutes do not permit the SAPC to expand the scope of a pharmacist's treatment to include PIMART, as this would encroach upon the professional domain of medical practitioners (the encroachment issue).

[51] Second, the IPA contended that the implementation of PIMART conflicted with existing legislation, namely, the Medicines Act and the Health Professions Act, in violation of s 6(2)(f)(i). According to the IPA, the effect of these statutes is that pharmacists are not authorised to diagnose or treat diseases, as that 'is expressly beyond a pharmacist's scope of practice...'. The IPA further argued that a pharmacist lacks the clinical training and experience to initiate and manage a patient on HIV/AIDS therapy, nor the clinical expertise to monitor the patient's outcomes (legislation contravention issue).

²³ Section 27(1)(a) and (2) mandates that 'the [S]tate must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation' of the right to, *inter alia*, 'health care services'.

The encroachment issue

[52] The IPA's concerns are based on the notion that PIMART serves as a blanket licence for pharmacists to treat HIV patients. It does not. As mentioned, PIMART's scope is limited and applies only to accredited pharmacists. It is restricted to prevention, first-line antiretroviral therapy, and the initiation of TPT for uncomplicated, non-immunocompromised HIV-positive individuals, in accordance with the department's guidelines.

[53] The PIMART scope of practice includes three main categories. Part (a) covers screening and confirmatory tests. Parts (b) to (f) mainly involve dispensing PrEP and PEP, limited to patients who are at least 15 years old and not pregnant. The treatment involves prescribing preventive medication, specifically initiating and managing first-line antiretroviral therapy, following clearly defined and evidence-based protocols. Parts (g) and (h) allow for referral to another healthcare provider when needed, along with maintaining confidential records.

[54] Thus, the introduction of PIMART will not alter the scope of practice of medical practitioners involved in treating HIV/AIDS. The fact is that medical practitioners do not have exclusive rights to care for people living with HIV/AIDS. As evidenced by the background facts, this is a collaborative effort involving various health professionals.

Legislation contravention issue

[55] As mentioned, the IPA asserted that pharmacists are not authorised to prescribe medicines under schedules 3, 4 and 5, based on s 22A of the Medicines Act. The section provides for control of medicines, scheduled substances, medical devices and *in vitro* diagnostics. In terms of s 22A(4), pharmacists may only offer schedule 1 and 2 medicines without a prescription. They can offer Schedule 3

medicines in certain specified circumstances. For Schedule 4, 5, and 7 medicines, pharmacists can only do so on prescription by a medical practitioner.²⁴

[56] Section 22A(15) carves out an exception to the above provision, by authorising the Director-General to issue permits to health practitioners other than medical practitioners, authorising them to provide any of the scheduled medicines. It provides:

‘Notwithstanding anything to the contrary contained in this section, the Director-General may, after consultation with the Pharmacy Council of South Africa . . . issue a permit to any person or organisation performing a health service, authorising such person or organisation to acquire, possess, use or supply any specified Schedule 1, Schedule 2, Schedule 3, Schedule 4 or Schedule 5 substance, and such permit shall be subject to such conditions as the Director-General may determine.’

[57] This is the provision that the Director-General used to allow PIMART-accredited pharmacists to apply for permits to prescribe substances classified as Schedule 3-5. The IPA disregards this provision in its argument that expanding a

²⁴ Section 22A(4) of the Medicines Act reads:

‘Any Schedule 1 substance shall not be sold-

(a) by any person other than-

(i) a pharmacist, or a pharmacist intern or pharmacist’s assistant acting under the personal supervision of a pharmacist;

(ii) a manufacturer of or wholesale dealer in pharmaceutical products for sale to any person who may lawfully possess such substance;

(iii) a medical practitioner or dentist, who may-

(aa) prescribe such substance;

(bb) compound and dispense such substance only if he or she is the holder of a licence as contemplated in section 22C (1) (a);

(iv) a veterinarian who may prescribe, compound or dispense such substance;

(v) a practitioner, nurse or a person registered under the Health Professions Act, 1974, other than a medical practitioner or dentist, who may-

(aa) prescribe only the Scheduled substances identified in the Schedule for that purpose;

(bb) compound and dispense the Scheduled substances referred to in item (aa) only if he or she is the holder of a licence contemplated in section 22C (1) (a);

(b) to any person apparently under the age of 12 years except upon a prescription issued by an authorised prescriber and dispensed by a pharmacist, pharmacist intern or pharmacist’s assistant or by a veterinarian or a person who is the holder of a licence as contemplated in section 22C (1) (a), or on a written order disclosing the purpose for which such substance is to be used and bears a signature known to the seller as the signature of a person known to such seller and who is apparently over the age of 12 years;

(c) unless the seller, other than a manufacturer or wholesale dealer in pharmaceutical products, enters in a prescription book required to be kept in the prescribed manner, the prescribed particulars of such sale.’

pharmacist's scope conflicts with the Medicines Act. The Director-General acted within the powers granted by this provision, the validity of which the IPA has not challenged. Therefore, in the absence of a challenge to this empowering provision, the IPA's arguments about the unsuitability of pharmacists prescribing Schedule 3, 4, and 5 substances are futile.

The IPA's residual arguments

[58] The IPA argued that in adopting and implementing PIMART, the SAPC: (a) considered irrelevant factors in breach of s 6(2)(e)(ii); (b) acted arbitrarily or capriciously in contravention of s 6(2)(e)(vi); (c) had no rational connection to: (i) the purpose for which it was taken; (ii) the purpose of the empowering provision; (iii) the information before the SAPC; and (d) failed to provide reasons when requested to do so.

[59] As mentioned, PIMART was an initiative created in response to a persistent rise in new HIV infection rates, despite previous efforts. The SAPC, at the department's request, deemed PIMART suitable for addressing this issue. As the high court correctly found, the SAPC evaluated the risks associated with pharmacists initiating first-line ART and TPT, as well as providing PrEP and PEP, and considered these risks when deciding to approve the PIMART training course. The uncontested evidence presented by the SAPC demonstrates that the approved accreditation process for PIMART was rigorous and thorough.

[60] Considering all these factors, it cannot reasonably be argued that the SAPC disregarded relevant considerations or failed to consider important ones. Furthermore, there is no basis to claim that the SAPC acted arbitrarily or capriciously. There clearly was a rational connection between PIMART and its purpose, which was to expand access to first-hand HIV therapy, authorised by the Pharmacy Act. The information available to the SAPC indicated that HIV

infection rates were rising. It also identified pharmacists as being well-positioned to provide the first line of HIV therapy. Therefore, the implementation of PIMART was grounded in the information before the SAPC.

[61] I turn to the IPA's complaint that the SAPC failed to furnish it with reasons for its decisions when requested to do so. Section 5(3) of the PAJA provides:

'If an administrator fails to furnish adequate reasons for an administrative action it must, subject to subsection (4) and in the absence of proof to the contrary, be presumed in any proceedings for judicial review that the administrative action was taken without good reason.'

[62] This provision establishes a rebuttable presumption that if an administrator does not provide reasons for its decision, it was made without good cause. The burden is on the administrator in subsequent review proceedings to rebut this presumption. In the present case, the SAPC has clearly discharged that burden, and the IPA's counsel, correctly, did not assert otherwise.

[63] The IPA also complained about the high court's finding that publishing the adoption of PIMART in the *Gazette* was not a statutory requirement. The high court referenced s 35A(b) of the Pharmacy Act, which authorises the SAPC to make rules related to pharmacists. The court stated that since PIMART does not fall under the category of 'rules' specified in s 35A(b), there was no obligation to publish its implementation. Nothing turns on this finding, as, despite it, the high court concluded that the publication met the procedural fairness requirement. Besides, it is settled that an appeal does not lie against the reasons for judgment but against the substantive order of the lower court.²⁵ It is immaterial whether we agree with the high court's reasoning on this issue, since the result of the appeal remains the same.²⁶

²⁵ *ABSA Bank Ltd v Mkhize, Absa Bank Ltd v Chetty; Absa Bank Ltd v Mliphha* [2013] ZASCA 139; [2014] 1 All SA 1 (SCA); 2014 (5) SA 16 (SCA) para 64.

²⁶ *Western Johannesburg Rent Board v Ursula Mansions (Pty) Ltd* 1948 (3) SA 353 (A) at 354.

[64] In all the circumstances, the appeal must fail. Costs should follow the result. The following order is made:

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

T MAKGOKA
JUDGE OF APPEAL

Appearances:

For appellant: J C Uys SC (with him TB Mirtle)

Instructed by: Brand Potgieter Inc., Johannesburg
Lovius Block Inc., Bloemfontein

For respondent: B E Leech SC (with him S L Mohapi)

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