

REPUBLIC OF SOUTH AFRICA



IN THE HIGH COURT OF SOUTH AFRICA

GAUTENG DIVISION, PRETORIA

CASE NO: 7452/2022

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

Date: 14 August 2023

E van der Schyff

In the matter between:

THE IPA FOUNDATION (NPC)

APPLICANT

and

SOUTH AFRICAN PHARMACY COUNCIL

FIRST RESPONDENT

MINISTER OF HEALTH

SECOND RESPONDENT

DIRECTOR-GENERAL: NATIONAL DEPARTMENT
OF HEALTH

THIRD RESPONDENT

JUDGMENT

Van der Schyff J

Introduction

- [1] This is a review application launched by the applicant (IPA) in terms of ss 3 and 6(2) of the Promotion of Administrative Justice Act 3 of 2000 (PAJA), and 'in addition, or in the alternative', on grounds of legality. The South African Pharmacy Council (the SAPC or the Council) is the first respondent. IPA challenges the SAPC's decision to implement,¹ and the subsequent implementation of Pharmacist-Initiated Management of Antiretroviral Treatment (PIMART).² The question as to what PIMART entails is dealt with herein below.
- [2] IPA claims that the SAPC failed to provide interested parties with adequate opportunity to give comments or make representations before PIMART was implemented. IPA further contends that by adopting PIMART, the SAPC unjustifiably and irrationally extended the scope of practice of a pharmacist to encroach on the domain of medical practitioners, that the extension is irreconcilable and in conflict with existing legislation, and not authorised by the empowering legislative framework. IPA also believes that the SAPC misled the third respondent when it informed it that there was extensive consultation with stakeholders in developing PIMART. This, IPA holds, led the third respondent to approve issuing s 22A(15)-permits for PIMART services to be rendered.
- [3] The SAPC, in turn, seeks that the application be dismissed. The SAPC submits that the decision to introduce PIMART to pharmacists' scope of practice is rational and reasonable, particularly if regard is had to the narrow scope thereof. Pharmacy-provided primary healthcare is a well-known and functional concept in South Africa and manifests in pharmacist-initiated therapy (PIT), and primary care drug therapy (PCDT). PIT and PCDT are catered for in the existing legislative framework. The accreditation and standard of the professional training that pharmacists require to enable them to provide PIT and PCDT, respectively, are regulated by the Pharmacy Act 53 of 1974 (the Pharmacy Act). To provide PCDT, pharmacists must be authorised to prescribe schedule 4 medication, and the provisions of s 22A(15) of the Medicines and Related Substances Control Act 101 of 1965 (the Medicines Act)

¹ Communicated in terms of Board Notice 17 of 2021.

² In terms of Board Notice 101 of 2021.

are utilised for obtaining s 22A(15)-permits. These s 22A(15)-permits authorise, suitably qualified pharmacists to prescribe specific medication for prescribed conditions, something they would not otherwise have been able to do.

- [4] Pharmacists qualified to provide PCDT can, amongst others, provide 'Occupational Post Exposure HIV Prophylaxis for Health Care Workers'. PIT services already provided by pharmacists include HIV testing, emergency post-coital contraception, pregnancy testing, urine test analysis, and patient wellness regarding sexual health. PIT and PCDT already empower pharmacists to consult, diagnose and manage patients.

- [5] The SAPC contends that IPA is wrong in perceiving PIMART to constitute an encroachment on the domain of medical practitioners, and states that it is a measure within the ambit and control of the SAPC that falls under its mandate. The SAPC's case is that the introduction of PIMART is not an extension of the scope of pharmacists' practice by introducing a novel facet to it, but the widening thereof by the incorporation of a specific category of PIT and PCDT in a system that already provides for PIT and PCDT services for prescribed conditions. I understand PIMART to constitute a specialised category of PIT and PCDT that requires additional training.

- [6] IPA seeks no relief against the second and third respondents, who were only cited insofar as they might have or claim to have a direct or substantial interest in the matter. Despite being properly served with the application, these respondents did not enter the fray.

PAJA or legality review

- [7] IPA states in its founding affidavit that the impugned decisions and actions it regards as reviewable under PAJA 'are also reviewable on the basis of legality and the rule of law' and the application similarly constitutes, 'in addition and/or alternative to a PAJA review, a legality review.' Despite this cautionary approach followed by IPA, I do not perceive the grounds of review IPA relies on to extend to review grounds

outside of the PAJA-parameter.³ IPA's reference to the SAPC's decisions and actions being *ultra vires* is nothing more than expressing the view that the SAPC was not authorised by the 'empowering provision' to take the decisions and actions it took and that the introduction of PIMART is not rationally connected to the purpose of the empowering provision. IPA, in essence, contends that the SAPC misconstrued the power conferred on it by the empowering legislation (the Pharmacy Act) as enabling it to extend the scope of pharmacists' practice unilaterally. Thus, It is unnecessary to engage in an in-depth discussion as to whether a party can simultaneously rely on PAJA and the principle of legality.⁴ It suffices to state that it was authoritatively held in *Bato Star Fishing (Pty) v Minister of Environmental Affairs and Tourism*⁵ that whenever administrative action as defined in PAJA is taken on review, as it is *in casu*, PAJA applies.

- [8] To determine whether the prescripts of s 3 of PAJA are met, or whether there is merit in the grounds of review listed, it is necessary to have regard to the background and context within which the PIMART initiative was developed, to grasp what PIMART entails and to understand the legislative landscape.

Background and context

- [9] The World Health Organisation (WHO), in its 'Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection; Recommendations for a Public Health Approach',⁶ recommends that all people living with HIV must be provided with antiretroviral treatment (ART) to bring the globe one step closer to achieving universal access to HIV treatment and care, in striving to end AIDS as a public health threat. According to UNAIDS, twenty years of evidence demonstrates

³ IPA was at pains to indicate each impugned action and the corresponding PAJA review ground in its heads of argument.

⁴ In this regard, Professor JR de Ville holds the view that the common law grounds of review that are not explicitly mentioned in s6(2) of PAJA can furthermore easily be accommodated within s 6(2)(i) which provides for review if 'the action is otherwise unconstitutional or unlawful'.

⁵ 2004 (4) SA 490 (CC) at par [25].

⁶ <https://www.who.int/publications/i/item/9789241549684>. Accessed on 14 July 2023.

that HIV treatment is highly effective in reducing the transmission of HIV.⁷ UNAIDS informs that people living with HIV on antiretroviral therapy who have an undetectable level of HIV in their blood have no risk of transmitting HIV sexually.

- [10] To address the challenge of delivering large-scale, sustainable, and effective ART programs in a resource-restrained context amidst the rising HIV infection rate, the Department of Health requested the SAPC to consider and implement an intervention that would ensure that patients have increased access to antiretroviral medicines for the purposes of providing Pre-Exposure Prophylaxis⁸ ('PrEP') and Post-Exposure Prophylaxis⁹ ('PEP').
- [11] This shift from physician-initiated and managed ART commenced with the introduction of 'Nurse Initiated Management of Antiretroviral Therapy', NIMART. It is apposite to state that NIMART, in its fullest sense, involves nurse-initiation of patients onto ART, re-prescription for patients stable on ART, and appropriate referral to physicians as needed.¹⁰ This development accords with global recommendations and guidelines on task-shifting as a method of strengthening and expanding the health workforce to rapidly increase access to, amongst others, HIV health services promoted by the WHO.¹¹ The WHO identified the potential for task-

⁷ https://www.unaids.org/sites/default/files/media_asset/undetectable-untransmittable_en.pdf. Accessed on 14 July 2023.

⁸ PrEP is the use of antiretroviral drugs by HIV-uninfected individuals to prevent HIV infection. – Kennedy, C. Yeh, P.T. *et al* 'PrEP distribution in pharmacies: a systematic review' (2022) *BMJ Open* 12(2) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8860049/>. Accessed on 13 July 2023. It is usually provided to HIV-negative persons who may be deemed to be at a high risk of contracting HIV due to various factors, e.g., persons with partners engaging in sexually risky behavior and sex workers. PrEP is the acronym for pre-exposure prophylaxis.

⁹ PEP is medication provided to persons who may have had a recent exposure to HIV to prevent infection with HIV. – 'Accessibility of PrEP and PEP across the world' - <https://sexualhealthalliance.com/nymphomedia-blog/accessibility-of-prep-and-pep-across-the-world>. Accessed on 13 July 2023.

¹⁰ Georgeo, D. Colvin, C.J *et al.* (2012) 'Implementing nurse-initiated and managed antiretroviral treatment (NIMART) in South Africa: a qualitative process evaluation of the STRETCH trial. *Implementation Sci* 7-66; Jones, M. and Cameron, D. (2017) 'Evaluating 5 years' NIMART mentoring in South Africa's HIV treatment programme: Success, challenges and future needs' *S Afr Med J* 107(10) 839-842.

¹¹ 'Task Shifting – Global Recommendations and Guidelines' (2008).

shifting that involves 'other cadres that do not traditionally have a clinical function, for example, pharmacists ...'. The issue of pharmacists prescribing PrEP and PEP is a burning issue internationally, with pharmacists being authorised to independently prescribe PrEP and PEP to prevent HIV in, at least, Colorado, Oregon and California,¹² and Brazil, with a collaborative approach followed in many other jurisdictions.¹³

- [12] The SAPC, after investigating different options, requested the Director-General on 15 August 2018 to consider issuing s 22A(15)-permits to pharmacists who have completed a supplementary training qualification for PrEP and PEP. The PIMART qualification was subsequently developed in collaboration with the Southern African HIV Clinicians Society and the School of Pharmacy of the North-West University. The SAPC recommended that permits be issued only to pharmacists who successfully completed the PIMART course accredited by it.
- [13] It is relevant to note that s 22A(15) of the Medicines Act (hereafter only referred to as s 22A(15)) is being used to issue permits to enable primary care drug therapy (PCDT). Permits issued in terms of s 22A(15) in the PCDT context are accompanied by a list of medicines and conditions in line with the Standard Treatment Guidelines and the Essential Medicines List published by the Department of Health.
- [14] On 22 March 2021, the SAPC published Board Notice 17 of 2021 for public comment and stakeholder engagement regarding the adoption of PIMART. The schedule attached to the notice sets out – (i) the scope of practice of a pharmacist who provides PIMART services; (ii) competency standards for a pharmacist who provides

https://apps.who.int/iris/bitstream/handle/10665/43821/9789241596312_eng.pdf. Accessed on 13 July 2023.

¹² Zhao, A. Dangerfield II, D.T. *et al.* Pharmacy-Based Interventions to Increase Use of HIV Pre-exposure Prophylaxis in the United States: A Scoping Review (2022) *AIDS Behav* 26 (5), 1377-1392 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8527816/>. Accessed on 13 July 2023. Several states have, however proposed legislation that will allow pharmacists to initiate PrEP and PEP – NASTAD Pharmacist-Initiated PrEP and PEP <https://nastad.org/sites/default/files/2021-11/PDF-Pharmacist-Initiated-PrEP-PEP.pdf>. Accessed on 13 July 2023.

¹³ Urano, K *et al.* 'Impact of physician-pharmacist collaborative protocol-based pharmacotherapy management for HIV outpatients: a retrospective cohort study' <https://jphcs.biomedcentral.com/articles/10.1186/s40780-020-00165-9>. Accessed on 28 July 2023.

PIMART services; and (iii) criteria for accreditation/approval by the SAPC of a curriculum leading to the awarding of a PIMART course. Interested parties and stakeholders were invited to submit, within 60 days of publication of the notice, substantiated comments on or representation regarding PIMART. The prescribed notice period ended on 21 May 2021. The SAPC conducted meetings during June 2021 and considered the comments received.

- [15] A meeting was subsequently held with the Director-General: Health on 30 June 2021. The minutes reflect that the Director-General was, *inter alia*, informed that the 'SAPC has approved for implementation, the scope of practice, competency standards and criteria for accreditation of providers who wish to train pharmacists to offer Pharmacists Initiated Management of Antiretroviral Therapy (PIMART) services after extensive consultation with the stakeholders'.

- [16] On 12 August 2021, the Director-General approved issuing s 22A(15)-permits to pharmacists who are duly qualified to provide PIMART services. On 13 August 2021, Board Notice 101 of 2021 was published for implementation of the said scope of practice of pharmacists who provided PIMART services, competency standards, and accreditation criteria.

- [17] On 8 September 2021, after the publication of Board Notice 101 of 2021, through which PIMART was implemented, IPA submitted its comments and objections regarding PIMART to the SAPC. IPA concedes that the comments were submitted far outside the prescribed 60-day notice period provided in Board Notice 17 of 2021 and after the publication of the board notice through which PIMART was implemented. IPA claims that Board Notice 17 of 2021, which invited comments and presentations, was published when its members were addressing and struggling to overcome another wave of the Covid-19 pandemic.

- [18] On 27 September 2021, the Forum of Statutory Health Professional Councils ('the Forum') held a meeting to discuss, amongst others, the implication of Board Notice 101 of 2021. At this meeting, comments were made, and concerns were raised by the Health Professions Council of South Africa, the South African Nursing Council,

and the Allied Health Professions Council of South Africa. The SAPC made a presentation, responded to the comments, and endeavoured to address the concerns. The concerned stakeholders agreed that there would be further engagement on Board Notice 101 of 2021 through a subcommittee of the Forum. No subsequent resolutions have been taken by the Forum in this regard.

What does PIMART entail?

[19] In considering this review application, it is necessary to understand what the published scope of practice of a pharmacist who provides PIMART, entails.

[20] In addition to the acts and services which form part of the scope of practice of the pharmacist as prescribed in terms of regulations 3 and 4 of the 'Regulations relating to the practice of pharmacy', the SAPC determined that a pharmacist who has completed the PIMART supplementary training, and was issued a s 22A(15)-permit:

'must be allowed to perform consultations with patients at a pharmacy or in an approved primary health care setting, which includes:

- (a) history taking, performing of screening and confirmatory tests, ordering, conducting and interpretation of diagnostic and laboratory tests in line with NDoH 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 Pre-Exposure Prophylaxis (PrEP) and Post-Exposure Prophylaxis (PEP), who are not pregnant or under 15 years of age;
- (c) decision on safe and appropriate therapy;
- (d) initiate antiretroviral treatment limited to PrEP, PEP and 1st line Antiretroviral Therapy (ART) plus initiation of TB-Preventative Therapy (TPT) in line with NDoH 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.'

[21] The services provided in terms of the PIMART initiative can be separated into two broad categories. The first is preventative measures, and this encompasses providing PrEp and PEP.¹⁴ The second constitutes a treatment regime that exceeds preventative measures, namely initiating ART and TPT, in line with the National Department of Health guidelines. Although the SAPC claims, and counsel for the SAPC emphasised, that PIMART provides for first-line treatment only in respect of 'uncomplicated non-immunocompromised-HIV-positive persons', this limitation is not included in the gazetted scope of practice of a pharmacist providing PIMART services. The scope of practice does, however, provide for referral to other health care providers, amongst others, when discordant results are obtained.

The legislative landscape

[22] Pharmacists and medical doctors operate in distinct and separate professional domains. The respective professions' scopes of practice are determined by regulations promulgated in terms of the Health Professions Act 56 of 1974 (the Health Professions Act) and the Pharmacy Act, respectively.

[23] The boundaries of the respective domains are closely guarded, and some tension exists between the groups. The tension between pharmacists and doctors in South Africa has been the theme of a study with the results published in 1998.¹⁵ Gilbert's study reveals a 'deep ongoing sense of competition'. The issue is not new and is

¹⁴ See notes [8] and [9] above for an explanation of the acronyms.

¹⁵ Gilbert, L. (1998) 'Dispensing Doctors and Prescribing Pharmacists: A South African Perspective' *Soc. Sci. Med.* Volume 46, No. 1, 83-95.

also not only limited to South Africa. Gilbert refers to Pascall and Robinson,¹⁶ who argue that 'boundary disputes between occupations and competition over work roles are an inevitable component of a complex health care system with an elaborate division of labour and changing social and technological environment.' Gilbert also refers to Eaton and Webb,¹⁷ who referred to the extended role of community pharmacy as 'boundary encroachment', claiming that it is an attempt to extend the boundaries of pharmacy practice into the territory of the medical profession, the boundary, in this case, being between prescribing and dispensing.

- [24] IPA contends that the implementation of PIMART and the concomitant extension (widening) of the scope of practice of pharmacists that it brings about is not supported by the existing legislative framework, and claims that it is beyond a pharmacist's scope of practice to diagnose and treat diseases. The SAPC, in turn, claims that the decision to implement PIMART and its implementation fall within its statutory mandate.
- [25] The different healthcare cadres jealously guard the boundaries of their respective scopes of practice. This, it must be pointed out, despite the WHO's call for a collaborative approach to primary health care issues, and the embracing of task-shifting.¹⁸ That IPA's objection to PIMART seems to be rooted, partially at least, in this professional tension, is evinced by its fear that the decision to develop and implement PIMART might 'open the floodgates' and is a 'negative precedent setting occurrence relevant to the provision of medicine' that may 'inevitably pave the way for pharmacists to ultimately treat and prescribe other schedule 4 drugs over the counter in respect of acute illnesses.' However, IPA's exposition of the existing legislative landscape is one-dimensional and incomplete. It does not refer to the exceptions provided in the respective statutes and regulations. The SAPC, on the other hand, although referring to the SAPHRA Guidelines, refrains from dealing with the policy requirement to 'closely liaise' with the HPCSA as it features in the

¹⁶ Pascall, G and Robinson, K. (1993) 'Health work: division in health care labour.' In *Dilemmas in Health Care*, eds B. Davey and J. Popay, 83-103. Open University Press.

¹⁷ Eaton, G and Webb, B. (1979) Boundary encroachment: pharmacists in the clinical setting. *Sociology of Health and Illness* 1, 69-89.

¹⁸ See note [11] above.

SAPHRA Guidelines- an aspect more fully discussed below. It is, therefore, appropriate to commence this discussion by emphasising that the respective scopes of practice of healthcare professions in South Africa, are not, as IPA claims, entirely exclusive to the identified professions.

- [26] The applicable legal framework comprises the National Drug Policy, The Medicines Act, the Health Professions Act and Regulations, the Pharmacy Act and Regulations, The National Health Act, and the SAPHRA Guidelines relating to the scheduling of substances.
- [27] The National Drug Policy envisages development consistent with the World Health Organisation's promotion of task-shifting to advance access to medicine and improve efficiency in health systems.¹⁹ Although the policy document does not signal the broad-based authorisation of prescribing rights for pharmacists, it indicates a preference for adopting competency-based measures as criteria for access to expanded prescribing privileges by holding – 'At primary level prescribing will be competency, not occupation, based.'²⁰ Section 22A(15) of the Medicines Act is the legal avenue through which pharmacists can obtain permits to prescribe schedule 3-5 substances.
- [28] The Medicines and Related Substances Act of 1965 prescribes that pharmacists may only sell schedule 1 and 2 substances without a prescription, schedule 3 substances in certain prescribed circumstances, and schedule 4, 5, and 7 substances only on prescription by a medical practitioner. Section 22A of the Act, however, allows for the fluidity of scopes of practice between the healthcare professions in that s 22A(14)(b)²¹ allows healthcare professionals, other than

¹⁹ SAPHRA Guideline. https://www.sahpra.org.za/wp-content/uploads/2022/05/SAHPGL-CEM-NS-04_v3-Scheduling-of-Substances-for-Prescribing-by-Authorised-Prescribers-other-than-Medical-Practitioners-or-Dentists.pdf. Accessed on 14 July 2023.

²⁰ SAPHRA Guideline, *supra*, at par [2.2].

²¹ 'Notwithstanding anything to the contrary contained in this section ... (b) no nurse or a person registered under the Health Professions Act, 1974, other than a medical practitioner or dentist may prescribe a medicine or Scheduled substance unless he or she has been authorized to do so by his or her professional counsel concerned.'

medical practitioners, to be identified and approved as authorised prescribers. Section 22A(15) recognises that certain healthcare professionals may need to prescribe and dispense certain medicines that may not be contained in ss 22A(2) to 22A(5). Section 22C(1)(a) allows for healthcare professionals other than pharmacists to dispense by issuing a licence to compound and dispense medicines on prescribed conditions. The relevance of s 22A(15) and its use within PIT, and subsequently PIMART, is dealt with below. IPA failed to consider, or refer to, the relevance of s 22A(15) when it bluntly stated that pharmacists may only sell schedule 1 and 2 substances without a prescription.

- [29] Cognisance should also be taken of the SAHPRA Guideline' Scheduling of Substances for Prescribing by Authorised Prescribers other than Medical Practitioners or Dentists',²² (the SAPHRA Guideline / the guideline). SAPHRA is the South African Health Products Regulatory Authority. Both parties referred to the policy in passing, but neither dealt with its content in detail. The purpose of the guideline, as stated in the guideline reads as follows:

'This document provides guidance on the process for amending the Schedules to the Medicines and Related Substances Act, 1965 (Act 101 of 1965) to allow prescription rights to authorised health professionals, other than medical practitioners or dentists, in accordance with the provisions of section 22A of the Act. It also covers the process for [providing] input to the Director-General of Health in relation to applications for exceptional access by means of section 22A(15) permits.'

- [30] Point 3.1 of the SAPHRA Guidelines prescribes that applications for amending the Schedules in order to designate specific substances to be prescribed by selected health professionals in accordance with s 22A must provide at least the following information:

²² https://www.sahpra.org.za/wp-content/uploads/2022/05/SAHPGL-CEM-NS-04_v3-Scheduling-of-Substances-for-Prescribing-by-Authorised-Prescribers-other-than-Medical-Practitioners-or-Dentists.pdf. Accessed on 14 July 2023.

- i. Clear identification of the category of holders of registration. The category may be defined as having gained registration, e.g., after having completed a designated supplementary course or post-graduate qualification. The course or qualification must be accredited for this purpose by the statutory council concerned, as enabled in the applicable legislation. The provider of such a course or qualification must also be accredited by the statutory council concerned as provided for in the applicable legislation;
- ii. A clear explanation of the competencies held by such holders of registration, indicating the clinical conditions which would be appropriate to be diagnosed and managed by such persons;
- iii. A clear explanation, with justification, of the means of ensuring the competence of such holders of registration to manage the clinical conditions listed. This would entail a detailed description of the curriculum, the nature of the practical clinical training provided, as well as the approach to assessment of clinical competence;
- iv. A clear and justified listing of the substances to be included in Schedules 1 to 6 (as appropriate), linked to the list of conditions to be managed by such holders of registration. While the most current PHC STG/EML may be used as a reference in determining this list, consideration may need to be given to the inclusion of additional examples of pharmacological classes that are of comparable efficacy and safety, where the STG/EML lists only one example from that class.

[31] Paragraph 3.2 of the SAPHRA Guideline requires:

'In addition to the information listed above, the applicant should provide evidence of close liaison with the Health Professions Council of South Africa regarding the design of any training programme which deals with diagnosis and prescribing. Where the applicant is a particular Professional Board of the Health Professions Council of South Africa, input should be sought from the Professional Board most appropriate to the area of clinical practice as well as the Council itself.'

- [32] The requirement listed in points 3.1 and 3.2 of the SAPHRA Guideline applies *mutatis mutandis* to any application submitted to the Director-General in terms of s 22A(15) on which the input of the South African Health Products Regulatory Authority is requested.
- [33] These guidelines are relevant because it is indicative of the fact that persons, other than medical practitioners and dentists may be authorised to prescribe scheduled substances. I am alive to the fact that it is stated in the guideline that while the Director-General 'can look to the South African Health Products Regulatory Authority' for advice' when an application to issue a s 22A(15)-permit is considered, '[s]uch input should not in any way restrict the ability of the Director-General to make individual determinations for specific circumstances.' The SAPHRA guideline that the input of the HPCSA needs to be obtained when training courses are developed is thus not a legislative obligation when s 22A(15)-permits are applied for.
- [34] Section 52 of the Health Professions Act 56 of 1974 (the Health Professions Act) provides for medical practitioners, dentists, or other persons registered in terms of the Act, to compound or dispense medicine on the authority and subject to the conditions of a licence granted by the Director-General. This section withered the boundaries of the scopes of practice of medical practitioners and pharmacists and allowed licensed medical practitioners and dentists to conduct actions previously reserved for pharmacists.
- [35] Regulation 2 of the 'Health Profession Council of South Africa: Regulations defining the scope of the profession of medicine'²³,²⁴ lists the acts which are deemed to be acts pertaining to the medical profession. These include, amongst others, the physical and/or clinical examination of any person, diagnosing a person's physical health status, and advising such person on his or her physical health status. Regulation 3, however, provides that:

²³ Medicine means the profession of a person registered as a medical practitioner or an intern in medicine.

²⁴ GNR. 237 of 6 March 2009 published in GG No. 31958.

'The provisions of regulation 2 shall not be construed as prohibiting –

- (a) any person registered under any legislation regulating health care providers from performing any act specified in that regulation in accordance with the provisions of such legislation.'

- [36] Regulation 4 prescribes that any person who wishes to perform any of the acts prescribed in regulation 2 shall apply in the prescribed manner to the board for registration as a medical practitioner. Seeing that regulation 3, however, provides for persons registered under any legislation regulating health care, to perform the acts listed in regulation 2, such persons need not register as medical practitioners, as is suggested by IPA. The SAPC points out that nurses providing NIMART were not required to register when NIMART was implemented.
- [37] The Pharmacy Act was promulgated to provide for the establishment of the SAPC and for its objects and general powers, to extend the control of the SAPC to the public sector, and to provide for pharmacy education and training, requirements for registration, the practice of pharmacy, the ownership of pharmacies, the investigative and disciplinary powers of the SAPC and matters connected therewith. The SAPC is pertinently empowered to prescribe the scope of practice *of the various categories of persons* registered in terms of the Pharmacy Act.²⁵ (My emphasis).
- [38] Section 35A of the Pharmacy Act determines that the control of pharmacy practice; the scope of practice of persons registered in terms of the Act; the services or acts which shall for purposes of this Act be deemed to be services or acts specially pertaining to pharmacists; and the conditions under which those services may be performed, shall be prescribed. The Act authorises the Minister to make regulations, in consultation with the SAPC, pertaining to, amongst others, the practice of pharmacy. The Minister determines the scope of practice of pharmacy, whilst the SAPC is empowered to prescribe the scope of practice *of the various categories of persons* registered in terms of the Act. There is a nuanced differentiation between the powers of the Minister and the powers of the SAPC. The scope of practice of the

²⁵ S 4(zJ) of the Pharmacy Act.

various categories of persons registered in terms of the Pharmacy Act, cannot, as far as pharmacists are concerned, extend the scope of practice of pharmacy, or add to the 'acts specifically pertaining to the profession of a pharmacist', as determined by the Minister.

- [39] The Minister of Health, in consultation with the SAPC, promulgated, several sets of regulations. The most pertinent for current purposes is the 'Regulation relating to the practice of pharmacy'.²⁶ Regulation 3 lists the acts that are regarded as acts specially pertaining to the profession of a pharmacist. The first of these is 'the provision of pharmaceutical care by taking responsibility for the patient's medicine related needs and being accountable for meeting these needs, which shall include but not be limited to the following functions: ... (e) the provision of pharmacist initiated therapy...'

- [40] 'Pharmacist initiated therapy' is defined in the regulations to mean:

'diagnosing a health need, prescribing and supplying of medicine to meet the health need of a patient or group of patients or, where necessary, the referral to another health care provider by a pharmacists who has received the necessary authorisation from council'.

- [41] In terms of regulation 18, pharmacist initiated therapy (PIT) may be provided in a community or institutional pharmacy. Regulation 18(8) further provides that 'primary drug care therapy' (PDCT) may be provided at community and institutional pharmacies with prior authorisation from the SAPC. PCDT is defined in the regulations to mean:

'diagnosing a health need, prescribing and supplying of medicine to meet the health needs of a patient or group of patients or, where necessary, the referral to another health care provider by a pharmacist who has received the necessary authorisation from council.'

²⁶ GNR. 1158 Of 20 November 2000.

The regulation also provides that HIV screening tests be provided in these pharmacies to promote public health in accordance with guidelines and standards determined by a competent authority.

- [42] Section 50 of the National Health Act establishes a forum known as the Forum of Statutory Health Professional Councils (the Forum). All statutory health professional councils must be represented on the Forum. The HPCSA and SAPC are, amongst others, defined to be statutory health professional councils. This Forum must, amongst others, ensure communication and liaison between the statutory health professional councils upon matters affecting more than one of the registered professions, promote good practice in health services and sharing of information between the statutory health professional councils, and advise the Minister and the individual statutory health professional councils concerning, *inter alia*, the scopes of practice of the registered professions.

Procedural fairness

- [43] The question of whether the implementation of PIMART materially and adversely affects any person's rights or legitimate expectations is a vexing question. IPA essentially contends that by allowing pharmacists to provide services currently only provided by medical practitioners and nurses registered to provide NIMART services, PIMART allows for an additional competitor to enter the field. This, IPA contends, materially and adversely affects the rights of its members.
- [44] The SAPC's counsel submitted that if regard is had to the narrow scope of PIMART as primarily developed to initiate antiretroviral treatment limited to PrEP, PEP, and first-line Antiretroviral Therapy (ART) plus initiation of TB-Preventative Therapy (TPT) therapy in line with National Department of Health guidelines, it is difficult to see how PIMART adversely affect any rights or legitimate expectations of medical practitioners. Although the implementation of PIMART can ostensibly give rise to some competition between licensed pharmacists and family practitioners, the rights

of family practitioners to provide such services cannot be said to be curtailed or limited through the implementation of the initiative.

- [45] PIMART is an initiative presenting members of the public with a choice of whether they want to approach a pharmacist or general practitioner for the limited services provided by a pharmacist who has been issued a s 22A(15)-permit to provide PIMART services. Competition, *per se*, does not limit or curtail the rights of medical practitioners to continue providing the services they currently provide. Even if the assumed competition is regarded to affect family practitioner's rights adversely, the alleged adverse effect it holds for medical practitioners has to be considered against the need to expand primary health care services aimed at preventing and treating HIV, and the abovementioned development foreseen in the National Drug Policy to advancing access to medicine and improving efficiency in health systems.
- [46] IPA identifies the general public as a second party affected by the implementation of PIMART and asserts *locus standi* in the public interest in terms of s 38(d) of the Constitution. IPA is correct in its view. PIMART was explicitly developed to benefit the general public by broadening access to PrEP, PEP, and first-line ART. If PIMART does not sufficiently safeguard the interests of the public to safe and efficient health care, its implementation would adversely affect the rights of the general public to safe health care. It is thus necessary to consider whether the administrative action was procedurally fair.
- [47] The parties agree that 'one of the enduring characteristics of procedural fairness is its flexibility' and that '[t]he application of procedural fairness must be considered with regard to the facts and circumstances of each case.'²⁷ Hoexter explained that:²⁸

'... procedural fairness is a principle of good administration that requires sensitive rather than heavy-handed application. Context is all-important:

²⁷ *Janse van Rensburg NO v Minister of Trade and Industry NO* 2001 (1) SA 29 (CC) at par [24].

²⁸ Hoexter, C. *Administrative Law in South Africa*, 2nd ed, JUTA at 362.

the content of fairness is not static but must be tailored to the particular circumstances of each case.'

- [48] IPA's first challenge to the validity of the SAPC's decision to implement, and the subsequent implementation of PIMART, is based on the ground of procedural fairness. This attack is launched on two fronts. IPA contends that the publication of Board Notice 17 of 2021, through which interested parties were invited to submit comments or representation on (i) the scope of PIMART services; (ii) competency standards for a pharmacist who provides PIMART; and (iii) criteria for accreditation/ approval by the SAPC of a curriculum leading to the awarding of a PIMART course, was:
- i. published at an inopportune time in that IPA members were preoccupied with dealing with the COVID-19 pandemic, and
 - ii. only published in the Government Gazette, a publication that is not generally read.
- [49] The SAPC published Board Notice 17 of 2021 wherein comments and recommendations on PIMART were invited, in the *Government Gazette* of 22 March 2021. It also published the notice on its website – as it ordinarily does with all its board notices.
- [50] In answer to the IPA's challenge based on procedural fairness, the SAPC contends that publication in the Government Gazette was sufficient. The SAPC emphasises that sight should not be lost of the fact that the rules which the SAPC creates, and by necessary implication, the scope of practice of pharmacists, are mainly limited to the pharmacy profession it regulates. It can, therefore, not be compared to public institutions that regularly facilitate public participation to disseminate information to a broader audience. Public knowledge of its intention to allow pharmacists to provide PIMART services in a circumscribed context was enhanced through publication on its website. Through its collaboration with the Southern African HIV Clinicians Society, whose members include numerous medical doctors, the development of PIMART was given great exposure.

- [51] The SAPC denies that the board notice was strategically published at an inopportune time. Comments were received from five groups to wit – Clicks Retailers (Pty) Ltd, the Department of Health of the Western Cape, the Independent Community Pharmacy Association, the Pharmaceutical Society of South Africa National Office, and S Buys [Pharmacy] Academy (Pty) Ltd.
- [52] It is common cause that by publishing Board Notice 17 of 2021, the SAPC followed the statutory prescript of s 49(4) of the Pharmacy Act. The section prescribes that:
- '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 this regard.'
- [53] Section 49(4) is intrinsically linked to s 35A of the Pharmacy Act. The SAPC is empowered through s 35A(b) to make rules relating to: a code of conduct for pharmacists and other persons registered in terms of the Act, what constitutes good pharmacy practice, and, the services for which a pharmacist may levy a fee and guidelines for levying such a fee or fees. PIMART, in my view, does not fall into this category since it does not fall in the category of 'rules' referred to in s 35A(b). Publication according to the prescript of s 49 to foster transparency and invite comments and recommendations can, however, not be faulted.
- [54] To comment on or make representations regarding the PIMART initiative requires specified profession-related knowledge that members of the public do not readily possess. It would serve no purpose to require publication in general newspapers in this instance. I do not agree with IPA that the nature and extent of the public interest in the implementation of PIMART required public participation to the extent required when rights in minerals are applied for in terms of the Mineral and Petroleum Resources Development Act 28 of 2002. Prospecting or mining activities

inadvertently impact e.g., landowners due to the nature thereof, the same cannot be said of PIMART.

- [55] Members of the health professions' fraternity, on the other hand, should expect notices to be published in the *Government Gazette* because that is the required manner in which notices of import and legal effect are published, a fact evinced by The National Health Act 61 of 2003 prescribing publication of a diverse range of notices in the *Gazette*.²⁹
- [56] As for the IPA's challenge to the timing of the publication, the SAPC points out that the IPA is a professional organisation and a distinct legal entity from its members. Whilst individual members might have been preoccupied with the Covid pandemic, no mention is made of the functionaries of the organisation and why they did not alert the members to the publication. IPA contends that 'it was published at a time when interested parties simply could ill-afford moving or at very least dividing its attention away from the Covid-19 pandemic to that of providing substantiated comments or representation pertaining to the notice.' IPA does not identify in its founding affidavit any party that is an interested party who did not know about the publication, nor does it explain why it did not send a communication to the SAPC explaining that it wants to comment and make representations but needs more time to do so due to the impact of the Covid-pandemic and the complex nature of the subject matter. IPA does not explain how the subsequent publication of Board Notice 101 of 2021 came to its attention.
- [57] I find nothing sinister in the timing of the publication of Board Notice 17 of 2021, as IPA seems to suggest. SAHC's participation in the development, its endorsement of the initiative, the communications sent to its members, and the fact that pilot projects were already conducted necessarily mean that this initiative could not, even if the SAPC wanted to, have been introduced in a clandestine way. It is not something that was hidden in secrecy. Against this background, I find it improbable, and it is not

²⁹ See, e.g., ss 30(1)(c); 54(1), 68(3); 72(2).

alleged, that none of IPA's members had timeous knowledge of the publication of Board Notice 17 of 2021.

- [58] On a reading of Board Notice 17 of 2021, it is evident that the nature and extent of PIMART are adequately explained.
- [59] In light of the above, I am satisfied that the SAPC gave adequate notice of its intention to adopt PIMART, that the nature and purpose of PIMART were adequately explained, and that the IPA and other interested and affected parties were provided with a reasonable opportunity to comment or make representations. The administrative action in question was procedurally fair.

Substantive grounds of review: Section 6(2) of PAJA

- [60] It is trite that a competent authority taking administrative action must be authorised to do so. An action will be invalid if there is no authorisation for the action. In addition, the taking of a decision must be within the limits as provided for in the empowering statute. The SAPC has only those powers conferred on it through applicable statutes. There must be a rational connection between the information that was before the SAPC and the decision taken. The decision must also be rationally connected to the purpose for which it was taken, the purpose of the empowering provision, and the reasons given for it. Section 6(2) of PAJA, further, amongst others, prescribes that the decision must not have been materially influenced by an error of law, taken for an ulterior purpose, in bad faith, arbitrarily or capriciously, or because irrelevant considerations were taken into account and relevant considerations were not considered. The decision must also not be otherwise unconstitutional or unlawful.
- [61] As stated above, the legal framework applicable to the matter at hand determines the scope of the SAPC's powers. IPA's contention that the Medicines Act and the Health Professions Act disallow pharmacists from prescribing schedule 3, 4, and 5 medication does not consider the exceptions provided for in the statutes, or in particular, the option of obtaining a s 22A(15)-permit.

- [62] The SAPC is empowered to prescribe the scope of practice of the various categories of persons registered in terms of the Pharmacy Act. This power is only limited by the boundaries of the 'practice of pharmacy', or the 'scope of practice of a pharmacist' as prescribed by the Minister. The provision of pharmacist-initiated therapy, which comprises the supply of medicine to meet the health needs of a patient without a prescription of a person authorised to prescribe medicine, and PCDT, which in addition comprises diagnosing a health need, prescribing and supplying medicine by pharmacists who have received the necessary authorisation from the SAPC, and the promotion of public health are, amongst others, services or acts already regarded to be services or acts pertaining to the scope of practice of pharmacists. The development and implementation of PIMART, does not expand the existing scope of practice of pharmacists that generically provides for PIT and PCDT. It introduced a specialised category of PIT and PCDT focused on preventing and treating HIV.
- [63] The decision to implement PIMART fell within the ambit of the SAPC's power, and there was no statutory obligation to consult with the HPCSA, or the Forum prior to its implementation. Consultation with the HPCSA and the Forum may arguably have resulted in an outcome supported by IPA, or an outcome that IPA would have regarded as a 'better outcome', but that is not the test on review. The reviewing court's view on what the best decision would have been is irrelevant. The only question is whether the decision was regular or irregular. Where no statutorily imposed obligation to consult with the HPSCA or the Forum exists, the failure to consult cannot be considered irregular.
- [64] The SAPC, as guardian of the standard and quality of services provided by pharmacists is the guardian of the quality of training and supplementary training of pharmacists. The Minister, in consultation with the SAPC, promulgated regulations relating to the training and supplementary training of pharmacists. By developing the PIMART course, and the criteria for its accreditation, the SAPC acted within its mandate. In any event, the evidence indicates that the PIMART course was developed by suitably qualified experts in the field, which experts include medical

practitioners. IPA's concern that the initiative was developed without the input of medical professionals is without merit. The contention that the decision to implement PIMART was materially influenced by an error of law,³⁰ insofar as this contention relates to the SAPC's perceived power to implement PIMART, is thus without merit.

- [65] Having been properly mandated to implement PIMART, an initiative that was developed and implemented in an effort to promote public health, and widen access to public health care as far as the prevention and treatment of HIV are concerned, can not be said to have resulted from a decision where the decisionmaker took irrelevant considerations into account or failed to consider relevant considerations. The evidence before this court indicates that the SAPC considered the risks associated with pharmacists initiating first-line ART and TPT, and providing PrEP and PEP, and had regard to those risks when considering to approve the PIMART training course. The evidence of Professor Van Wyk and Ms. Jankelowitz supports a finding that the PIMART training course was developed to ensure that pharmacists who successfully completed the training would be 'suitably qualified to safely and effectively assist in providing ART'. Ms. Jankelowitz informs the court that:

"Since its inception in 1998, SAHCS has been at the forefront of the battle against this epidemic by driving and coordinating continuous medical education to all levels of healthcare workers, with the support of local and international HIV experts committed to improving HIV/TB care in Southern Africa.'

She explains that the individuals involved in designing the guidelines and training course for PIMART are all specialists, clinicians and/or academics regarded as being at the top of their field.³¹ The same individuals compiled the SAHCS's Advanced HIV Management Course for Doctors, NIMART, Advanced HIV Management courses for nurses, and Advanced HIV Disease courses for doctors.

³⁰ S 6(2)(d).

³¹ The team includes the Head of Division of Infectious Diseases, Helen Josphe Hospital at the University of the Witwatersrand, a Professor of Medicine, Ezintsha, University of the Witwatersrand, the Chief Specialist and Head of the Department of Infectious Diseases at the University of KwaZulu-Natal, a medical doctor and a former Infectious Diseases physician.

- [66] There is no basis for finding that the SAPC's decision was taken for an ulterior purpose or that the SAPC acted with an ulterior motive.³² The extensive record with numerous minutes of meetings of the SAPC and its respective committees is indicative thereof that the SAPC applied its mind considering the development and implementation of PIMART.
- [67] In considering whether the decision to implement PIMART is irrational, arbitrary, or capricious,³³ one has to consider the context within which the decision was taken. Arbitrariness has been held to 'connote caprice, or the exercise of the will instead of reason or principle; without a consideration of the merits.'³⁴ The word has also been said to denote 'the absence of reason or, at the very least, the absence of a justifiable reason'.³⁵ It can also be said to be a decision lacking in logic.³⁶
- [68] Although the SAPC did not provide IPA with the reasons for its decision to implement PIMART when reasons were requested in October 2021, the reasons provided by the SAPC, and the additional information provided by Ms. Jankelowitz, dispel any suspicion that the decision to implement PIMART was taken arbitrarily or capriciously. The existing pilot projects emphasise the value of the initiative. The untapped value of pharmacists in fighting HIV was emphasised by the efficient role pharmacies played in meeting health care needs, and providing health care services during the Covid-19 pandemic. The idea to implement the PIMART initiative is not a mere whim, it is consistent with the WHO's vision and a worldwide movement to promote widely accessible primary health care.
- [69] The SAPC's contention that neither PrEP nor PEP requires a diagnosis before it can be administered stands uncontested. PrEP, explains the SAPC, requires a standardised protocol, which includes eligibility requirements, treatment protocols,

³² S 6(2)(e)(ii).

³³ S 6(2)(e)(vi).

³⁴ *Johannesburg Liquor Licensing Board v Kuhn* 1963 (4) SA 666 (A) 671.

³⁵ *Woolworths (Pty) Ltd v Whitehead* 2000 (3) SA 529 (LAC) par [128].

³⁶ De Ville, J.R., 'Judicial Review of Administrative Action in South Africa' 2005 LexisNexis, fn33 at p 198.

and contra-indications, all of which pharmacists have been trained to understand and implement.

- [70] External conditions that are objectively determinable and do not require any diagnosis underpin providing PEP to patients. As explained above, PEP is medication provided to persons who may have had a recent exposure to HIV to prevent infection with HIV, which must be provided as soon as possible and within 72 hours of the probable exposure. Pharmacists registered to provide PCDT services and issued with s 22A(15)-permits are already authorised to provide 'Occupational Post Exposure HIV Prophylaxis for Health Care Workers'. I see no reason why pharmacists who have successfully completed the existing accredited PIMART training course, cannot prescribe PrEP and PEP to members of the public. It does not make logical sense on any level that a female can receive emergency contraception from a pharmacy within 72 hours after having intercourse, consensually or otherwise, but not simultaneously be provided with potentially lifesaving PEP, while a health worker who was exposed to HIV during the course of his or her employment, can be provided with PEP at a pharmacy.
- [71] As far as the initiation of first-line ART and TPT is concerned, IPA's overarching concern seems to be rooted in its view that the treatment of HIV is oversimplified and that it does not cater to the inherent complexities associated with HIV treatment. If regard is had, however, to the existing supplementary PCDT training, the accreditation criteria for the PIMART training course, the extent of the training course as it was developed by specialists in the field, and the proviso for referral to another health care provider where for example, discordant results are obtained, I am of the view that the SAPC extensively considered the development and implementation of PIMART. The need to widen access to first-line ART and TPT on community level is not a figment of SAPC's imagination, but a dire need that is also evinced in other countries. The decision to utilise PIT as a vehicle for PIMART and to enable adequately trained pharmacists to provide PIMART services is a decision that is rationally connected to the purpose for which it was taken, the information before the SAPC and the reasons provided for it by the SAPC. It is also a decision that is

rationality connected to the SAPC's objective to assist in the promotion of the health of the population of the Republic.

Miscellaneous issues

Condonation

- [72] In the notice of motion, IPA seeks that the period of 180-days referred to in s 7(1) of PAJA, to the extent that it is deemed necessary, be extended in terms of s 9(1)(b) to the date of service of the application on the respondents.
- [73] IPA explains that consequent to the publication of Board Notice 101 of 2021 on 13 August 2023, and after numerous consultations with its legal representatives, it requested the SAPC to provide reasons for its decision to implement, and the implementation of PIMART. The request, however, went unanswered, and by the time the application was issued, no reasons were provided. Upon the expiry of the 90-day period for such reasons to have been provided, IPA instructed their attorneys to proceed with the review application.
- [74] The SAPC did not explicitly take issue with IPA's condonation application in its answering affidavit, save for stating in general that it opposes all of the relief sought in the application by IPA. The SAPC, in turn, requested condonation for the late filing of its answering affidavit.
- [75] Section 7(1)(b) provides that any proceedings for judicial review must be instituted without unreasonable delay and not later than 180 days after the date on which the person concerned became aware of the action and the reasons for it. *In casu*, reasons for the decision were requested on 11 October 2021. IPA ostensibly became aware of the SAPC's decision to implement and the implementation of the PIMART initiative on publication of Board Notice 101 of 2021 in the *Government Gazette* of 13 August 2021. Reasons for the decision were requested on 11 October 2021, within the stipulated 90-day period. The application was instituted in February 2022, well within the 180-day period provided for in s 7(1), and the papers do not indicate that it was not instituted without unreasonable delay.

[76] The late filing of the SAPC's answering affidavit is condoned.

Striking out application

[77] A litigant must make out its case in its founding papers. IPA sought to make an impermissible case in reply by attaching supporting affidavits of several associations supporting the review application. It contends in its heads of argument that a *'multitude of associations operating within the professional medical ambit stand opposed to the implementation of PIMART as provided for in Notice 101 of 2021 and the amendment to inter alia the scope of practice of pharmacists'*. Nine professional associations are mentioned and listed for the first time in the replying affidavit. These professional associations are not parties to the litigation, and the affidavit-annexures attached to the replying affidavit in support of the review application were not placed before the Council and do not form part of the record. The application to strike the new matter contained in the replying affidavit and the annexures to the replying affidavit is granted.

[78] The existence of the affidavits attached to IPA's replying affidavit is indicative of the fact that the associations mentioned are aware of the review proceedings. No applications for joinder were instituted. In considering whether this court should *mero motu* order the joinder of the parties mentioned in the replying affidavit, both parties' counsel submitted that it is in the interest of justice for the review application to proceed. It was submitted that these associations were aware of the proceedings and would have frequented to join if they deemed it in their best interest. The application proceeded.

Costs

[79] There is no reason to deviate from the principle that costs follow success.

ORDER

In the result, the following order is granted:

1. The application is dismissed with costs.



E van der Schyff

Judge of the High Court

Delivered: This judgment is handed down electronically by uploading it to the electronic file of this matter on CaseLines. As a courtesy gesture, it will be sent to the parties/their legal representatives by email.

For the applicant:	Adv. J.C. Uys SC
Instructed by:	BRAND POTGIETER INCORPORATED
For the first respondent:	Adv. B. Leech SC
With:	Adv. S.L. Mohapi
Instructed by:	WERKMANS ATTORNEYS
Date of the hearing:	23 May 2023
Date of judgment:	14 August 2023