



## A status update and view on: Pharmacist Initiated Management of Antiretroviral Therapy (PIMART)

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### Introduction

Effective and sustainable HIV/AIDS interventions and programmes supplying antiretroviral therapy (ART) are fundamental in reducing human immunodeficiency virus (HIV) infection rates and managing the health of those living with HIV/AIDS.<sup>1</sup> Due to the country's high prevalence of HIV/AIDS, and to address the challenge of expanding the delivery of ART programmes, the National Department of Health (NDOH), felt the public needed to have increased access to ART for the purposes of pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP). It is against this background as well as through the interest of pharmacists and pharmacy associations, that the idea of Pharmacist Initiated Management of Antiretroviral therapy (PIMART) supplementary training and certification was developed. PIMART is also in line with South Africa's public health commitment to reach the World Health Organization (WHO) and Joint United Nations programme on HIV/AIDS (UNAIDS), 95-95-95 targets, and upscaling our interventions to reduce HIV infections. According to the WHO, by 2025, 95% of all people living with HIV should have a diagnosis, 95% of whom should be taking lifesaving ARVs, and 95% of people living with HIV on treatment should achieve a suppressed viral load for the benefit of the person's health and for reducing onward HIV transmission.<sup>2</sup>

### Pharmacist Initiated Management of Antiretroviral Therapy (PIMART)

The course was designed as such that PIMART-trained pharmacists, who have completed the required supplementary training, may initiate PrEP, PEP and first-line ART, as well as the initiation of Tuberculosis Preventative Therapy (TPT).<sup>3</sup> This programme is key to increasing access to HIV prevention and treatment, especially for those patients not currently reached by traditional consultations in both the public and private healthcare sectors. It also capacitates the ability of pharmacists to provide HIV care to patients in a pharmacy setting, which is easily accessible. Treating patients in a pharmacy reduces stigma as care is offered in a less traditional clinical environment.

### Developing and legislating PIMART

The SAPC is a regulator set up by the Pharmacy Act of 1974 to regulate pharmacists, pharmacy premises, and pharmacy support personnel. It also regulates the education of pharmacists in South Africa, and accreditation of expanded scopes of practice like PIMART. Tasked with this challenge, several prominent experts from the Southern

African HIV Clinicians Society (SAHCS), assisted to develop processes and guidelines for a course in PIMART. SAHCS is a membership organisation of healthcare workers with an interest in HIV, promoting evidence-based HIV healthcare through programmes, education, and publications. The individuals involved in designing the PIMART course, were also responsible for designing other SAHCS courses like the Nurse Initiated Management of Antiretroviral Therapy (NIMART), and advanced clinical HIV management courses for doctors and nurses. Upon successful completion of the PIMART course, the Director General (DG) of Health would issue a Section 22A (15) permit, which would then be recorded with the SAPC, allowing a PIMART-trained pharmacist to practice.

In March 2021, the SAPC prepared and published the scope of practice, competency standards, and criteria for the accreditation of PIMART, for comment. PIMART was gazetted for implementation in the Government Gazette on August 13, 2021, through Board Notice 101 of 2021.

### About the course

The course, run under the auspices of SAHCS, consists of 21 modules, 24 case studies, a final exam, and a portfolio of evidence of at least 10 client consultations with doctor supervised PIMART prescriptions issued. Students must attend ongoing accredited CPD masterclasses and webinars through SAHCS to support professional development. To be allowed to practice, the intention was that students who have completed the training, must apply for a Section 22(A) 15 Permit from the NDoH and include their portfolio of evidence. This permit would then be lodged with the SAPC.<sup>4</sup>

### Defined scope of practice for PIMART-trained pharmacists

One of the underlying principles of the course is the premise that pharmacists, like doctors and nurses, are part of a healthcare team, and that referrals to physicians when needed make for safer and more efficient healthcare. An example of this type of referral would be when a discordant result is obtained during a consultation. The primary qualifying criteria for the treatment of HIV with first-line ART, is that PIMART-trained pharmacists may only treat uncomplicated non-immunocompromised HIV-positive persons. This narrow window of treatment allows for treatment within the scope of practice of a PIMART pharmacist. This defined scope and practice limitations supports the argument for the capability of PIMART-trained pharmacists to practice

as such. In addition, PIMART-trained pharmacists must also be able to take a comprehensive patient history, must be able to check, measure and report outcomes, and must be able to treat and report adverse events and anaphylactic shock. PIMART-trained pharmacists must keep correct records and support confidentiality.

### The court case for and against PIMART

However, in 2022, following the publication of the Board Notice for implementation, the Independent Practitioner Association Foundation (IPAF), a voluntary professional association of private medical practitioners, objected to the implementation of PIMART, and took the matter to court. On 14 August 2023, the North Gauteng High Court (Pretoria Division) ruled in favour of the implementation of PIMART. The High Court confirmed that PIMART is a necessary and competently designed intervention programme to support South Africa's efforts in providing access to patients diagnosed with HIV and AIDS. The SAPC argued that it is legally entitled to introduce PIMART, and that PIMART operates entirely within the scope of practice of pharmacists.

The IPAF later appealed against this decision, and on 18 September 2023, leave to appeal to the Supreme Court was granted to IPAF in the Pretoria High Court. According to the judgement, the leave to appeal was granted primarily based on the question of whether the SAPC had the authority to introduce PIMART. The issuance of Section 22A (15) permits in relation to PIMART and the recording of PIMART supplementary training with SAPC was put on hold due to the IPAF's appeal against the High Court's ruling. It is expected that the next court case, challenging this ruling, will be towards the end of 2024, with a judgement expected early in 2025.<sup>5,6</sup>

### Consequences of PIMART implementation on hold

The issuance of Section 22A (15) permits in relation to PIMART and the recording of PIMART supplementary training with SAPC is still on hold due to the IPAF's appeal against the High Court's ruling.<sup>7</sup> The interest shown by the number of pharmacists that completed the PIMART training, is also an indication that pharmacists are keen to increase access to care. Currently PIMART-trained pharmacists are unable to consult with patients if called upon and can refer the patient back to a doctor for consultation. This may lead to a missed opportunity to treat.

Outside of PIMART, pharmacists can perform an HIV telemedicine consultation, using a video consultation platform, in consultation with a doctor. This type of consultation is used to treat patients for PrEP, PEP and first line ARTs. Whilst this was not the intention of the scope of PIMART, it does however allow access to those seeking medical care, thereby preventing missed opportunities.

### Support for PIMART

PIMART is supported by the SAPC, the Pharmaceutical Society of South Africa (PSSA), the Independent Community Pharmacy Association (ICPA), and the Southern African HIV Clinicians Society (SAHCS). An article published as far back as 2021, in the SAMJ December 2021, Vol. 111, No. 12 journal, by some members from the above organisations, bears testimony to the value that PIMART can bring in reducing our HIV burden of disease, as well as highlighting the suitable qualifications pharmacists have. The authors state that "Pharmacists are trusted healthcare providers, and are critical to ensuring quality, rational use of medicines. PIMART is key to increasing access to PrEP and ART, especially for those patients not currently reached by either the public or the private healthcare sectors."<sup>8</sup>

Opposition to PIMART risks hindering progress in the fight against HIV/AIDS. Concerns by IPAF about conflicting professional roles and quality of care warrants discussion but must be weighed against the depth and quality of training extended by the PIMART course, and its public health benefits. PIMART is designed to complement existing services, and not replace services offered by other health professionals.

### Conclusion

Pharmacists are already empowered to provide HIV-related healthcare services through the legislated pharmacist-initiated therapy (PIT) protocol, and the primary care drug therapy (PCDT) qualification. Services that fall within the ambit of PCDT and PIT are PEP for healthcare workers, HIV testing, pregnancy testing and sexual health education. PIMART is a pragmatic evidence-based approach to contribute to reducing the burden of HIV disease. With the high burden of HIV/AIDS disease, and a shortage in healthcare workers, PIMART-trained pharmacists would be an added cadre of health professionals, easing the workload of doctors and nurses working in the HIV environment. Widening the scope of practice of pharmacists with supplementary training to include PrEP, PEP and first-line ART, should be considered a positive move in increasing access to care, especially considering the financially strained environment within the healthcare sector, and the burden of disease presented by HIV/AIDS.

### References

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