Pharmacist-initiated management of antiretroviral therapy (PIMART)

To the Editor: We the undersigned, a collective of pharmacy researchers, practitioners and academics, call on the Minister to consider the following points in response to the input made by the South African Medical Association (SAMA) in relation to pharmacist-initiated management of antiretroviral therapy (PIMART), dated 9 September 2021. We wish to highlight the expertise of pharmacists in all matters relating to the design, production and use of quality, safe and affordable medicines. Furthermore, we need to stress the increasing importance of and role played by pharmacists in primary care teams, which has been further reinforced during the COVID-19 pandemic and subsequent vaccination efforts.

Sub-Saharan Africa remains the region worst affected by the HIV epidemic, accounting for more than two-thirds of the global HIV burden. South Africa (SA) bears the largest HIV burden in the region, with nearly eight million individuals living with HIV; over four and a half million of these were receiving antiretroviral therapy (ART) in 2019. There have been substantial gains in recent years, with expansion of ART eligibility and adoption of the World Health Organization (WHO)-recommended universal test and treat (UTT) policy. However, many health systems across sub-Saharan Africa remain weak, under-resourced and overburdened.[1] Many countries in the region have yet to meet the Joint United Nations Programme on HIV/AIDS (UNAIDS) 90-90-90 HIV targets and are therefore at risk of missing the 95-95-95 targets by 2030. In SA, an additional three million individuals need to initiate ART to reach the target of 95% of those diagnosed receiving ART by 2030. In particular, certain key populations that have not been reached by existing health services need to be prioritised.

In a perfect world, every patient with HIV would be treated by an adult or paediatric infectious disease specialist, and prescribed an individualised regimen based on pretreatment genotyping. However, to impose that standard of care in resource-constrained settings would result in compromised access to care for many patients, and a net loss in health benefits. As a result, the WHO has advocated for a public health approach to HIV care, based on standardised regimens and with maximal reliance on task-shifting.[2] A demedicalised approach has been proposed for HIV prevention, including the provision of pre-exposure prophylaxis (PrEP).[3]

SA adopted the UTT strategy in 2016 and the ART same-day initiation (SDI) policy in 2017. While the UTT policy removes clinical barriers to ART initiation, the SDI policy aims to reduce the time from HIV diagnosis to ART start to one visit. The SDI policy makes ART initiation logistically easier for patients and can further reduce patient losses in the pre-ART phase of care. However, in SA and other low- to middle-income countries, implementation of the UTT and SDI policies was not accompanied by expanded human resources or infrastructural capacity. SA has insufficient healthcare providers to meet the needs of its population.[4] The SA system has to make maximal use of all available resources to improve access to and quality of care. SA has therefore embraced the concept of task-shifting, as advocated by the WHO. For example, SA has enabled nurse-initiated management of antiretroviral therapy (NIMART), relying on short-course training to upskill this cadre. Both NIMART and PIMART are logical extensions of the public health approach, and are also in accordance with the National Drug Policy, which states 'At primary level prescribing will be competency, not occupation, based.'[5] Key populations have also been reached by expanding access to HIV self-testing, including the provision of self-tests via community pharmacies. Pharmacies are perceived as accessible and potentially less stigmatising, particularly by men. They could therefore be an important channel to reach those key populations that currently have not accessed PrEP or ART.

Another example of maximising the efficient use of available resources is involvement of private sector pharmacies in supporting access to chronic medicines for public sector patients through the Central Chronic Medicines Dispensing and Distribution (CCMDD) programme. Pharmacists have also been key to the success of the COVID-19 national vaccination programme.

Globally, there is recognition of the need to maximise the contribution of all health professionals, by applying the concept of collaborative practice. The World Medical Association has endorsed the World Health Professions Alliance Statement on Interprofessional Collaborative Practice (ICP), which was first issued in May 2013 and updated in May 2019.[6] The document states: 'ICP requires mutual respect, competence, trust and synergy among team members. Professionals, sharing a common purpose, recognise and respect each other's body of knowledge, role and team-agreed responsibilities. When the individual contributions of all professionals are recognised, there is more likely to be appropriate and timely referral and a good matching of competencies to a person's needs. Whenever there are overlapping scopes of practice, collaborative teams ensure that the professional with the best match of expertise to the needs of the individual is engaged at the appropriate time.'

In addition, SA will not be first to consider making PrEP and post-exposure prophylaxis (PEP) readily available through pharmacies. For example, in 2019, California passed a law SB159[7] that allows community pharmacists to provide PrEP and PEP to patients without the need for a doctor's prescription. The change was evidence based and ratified as a very viable option. One such piece of evidence comes from a study by Lopez *et al.* (2019)[8] in which community pharmacists in San Francisco, USA, were allowed to provide patients with PrEP and PEP through collaborative practice agreements with the localhealth department (similar to the proposed mechanism suggested in SA with a defined medicine list and a Section 22A(15) permit). In the 20-month period during which this study was conducted, 6 patients received PEP and 53 patients completed a PrEP initiation visit, of whom 96% (n=51) filled their prescription. Approximately 47% (n=24) of clients who started PrEP self-identified as Hispanic or Latino, 10% (n=5) were black or African American, and 82% (n=42) identified as men who have sex with men. This evidence clearly demonstrates that vulnerable groups were in fact impacted by this intervention, and in essence, this is what the authors themselves concluded. Lopez *et al.*'s findings[8] emphasise the point that such an intervention would indeed increase access.

The focus is on accessible and affordable healthcare as well as alleviating the burden of disease by working together to strengthen the contribution made by doctors in the HIV/AIDS domain.

SAMA is therefore urged to give effect to this concept by supporting collaboration and effective referral practices, which lie at the very heart of the NIMART and PIMART programmes.

A Cochrane review of non-dispensing services delivered by pharmacists in ambulatory care has concluded that 'There was little or no difference between the effectiveness of interventions that were pharmacist-led compared with the same intervention being delivered by other healthcare professionals.'[9]

This group therefore urges the Minister to consider the following:

Firstly, that the scopes of practice for health professionals, as determined in regulations issued by the Minister in consultation with health professional councils, are not mutually exclusive. There are currently many areas that overlap. In particular, notice should be taken of the construct of section 22A of the Medicines and Related Substances Act (Act 101 of 1965) as amended, which enables the listing

of substances in the schedules to be prescribed by persons other than medical practitioners or dentists, provided they are deemed competent by their professional council. In addition, section 22A(15) provides for exceptional recognition of persons or organisations to 'acquire, possess, use or supply any specified Schedule 1, Schedule 2, Schedule 3, Schedule 4 or Schedule 5 substance', at the discretion of the Director-General, and after consultation with the South African Pharmacy Council (SAPC). The accusation that the SAPC has acted '*ultra vires*' is therefore patently incorrect.

Secondly, in relation to the perceived conflict of interest implicit in being able to prescribe and dispense, the fact that section 22C(1)(a) allows for medical practitioners to be licensed to dispense, after completing additional training, is evidence that the prohibition is not absolute, nor is the conflict impossible to manage by all ethical healthcare practitioners. It is the opinion of this collective that a short course can be deemed to be sufficient to enable one profession to gain sufficient knowledge to be able to safely perform tasks that are not normally part of its scope of practice.

Thirdly, pharmacists have extensive training in pathology, physiology and anatomy, pharmacology, pharmaceutics and pharmaceutical chemistry. Pharmacists have in-depth knowledge of medicines formulations and their uses. They have particular skills in pharmaceutical care planning, communication, monitoring and evaluation. During their 4-year undergraduate training, pharmacy students complete practical training in public and private sector facilities, where they learn to identify patients' medication needs and negotiate a medication management plan with the healthcare team and with the patient. Patients include those with HIV and with comorbid conditions. On completion of their degree, pharmacists undergo a year of internship and also complete another year of community service in the public sector.

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.

This letter was submitted to the Minister of Health and the Acting Director-General on 29 October 2021 by the signatories below.

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