



ARV COMPLIANCE – THE NEW BATTLE TERRAIN



Dr Kgosi Letlape

Key players in the drugs war between public and private medicine are taking to the HIV/AIDS trenches as the antiretroviral drugs battlefield shifts from accessibility to compliance.

This comes after the government successfully countered, with costs, the high-stakes combined legal bid by the National Convention on Dispensing and the Affordable Medicines Trust to declare invalid the new law stripping doctors of dispensing powers.

Doctors now have to write and pass the new Pharmaceutical Council exam before dispensing drugs.

A separate challenge to the single-exit price and maximum dispensing fee regulations was in process at the time of writing while the State roll-out of ARVs is irretrievably underway in eight of nine provinces.

These developments coincide with a dramatic price drop in life-prolonging HIV/AIDS medicines.

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South African Medical Association (SAMA) Chairperson, Dr Kgosi Letlape's rebuttal was that the private sector was providing and sourcing ARV drugs long before the State. Clinicians

had gone to 'tremendous lengths' to make sure patients had ongoing supplies of difficult-to-get ARV drugs. Sweeping statements now by officials who had very little to do with the battle against HIV and AIDS were 'short-sighted and unfortunate'.

'I'm not saying there aren't problems on the ground, but this kind of talk is destructive,' he added.

Letlape said the court ruling on dispensing would have serious repercussions on the continuing private treatment of people living with AIDS and on medication for other chronic diseases.

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Many were cash-paying patients with no medical scheme cover and relied on the package deals that doctors offered. Others simply ran out of medical aid benefits, creating a compliance nightmare.

SAMA hoped to meet with the Ministry of Health 'very soon' to ensure that patients were not adversely affected.

Letlape called on doctors to record difficulties of drug access with a view to finding interim solutions.

'We hope government will take responsibility for providing access to drugs for vulnerable communities. SAMA urges the profession to help find solutions to ensure continuity of therapy.'

Another ARV compliance problem is the cross-border smuggling of cheap ARV drugs. Unchecked, this activity would aggravate what Chief Director of Pharmaceutical Services and Planning, Humphrey Zokufa, describes as a crucial phase in the effort to turn the tide of the pandemic.

He pointed to 'the lack of a critical mass' of adequately trained clinicians and nurses and the dearth of patient compliance education as even-larger existing challenges, ones which the Treatment Action Campaign (TAC) echoed loudly in a national review of the government's ARV roll-out last month.

The *Zimbabwe Standard* newspaper reported in June that unlicensed drug merchants were making a mint out of poorly educated AIDS sufferers in that country's debilitated health system. While a public sector ARV drugs roll-out began at five Zimbabwean sites in March this year, the lack of cash and fuel had by then already boosted ARV black-market prices and created a fertile environment for illegal traders.

The newspaper said ARVs were being smuggled in from South Africa, Botswana and Namibia. Thousands of Zimbabweans are seeking better lives in South Africa, bringing with them the risk of spreading drug-resistant HIV strains. At the Zimbabwean dollar price of Z\$315 000 (R356) per month for the cheapest combination therapy, profits were 'there for the taking', said the report.

Dr Des Martin, Chairman of the South African HIV Clinicians Society, said cross-border smuggling of ARVs began years ago with drugs coming into South Africa from Swaziland and Lesotho, and 'clearly that's happening in Zimbabwe now'. He said drugs that were not WHO-endorsed and came in through 'suspicious routes' would be of low quality and impact on security of supply.



The danger of magnified toxicities when body-weight restrictions were not complied with added to the potential for disaster. 'If you put inaccurate compounds in a pill and call it anything, you can make a hell of a lot of money,' Martin said. Even reputable generics could be 'offloaded with some profit'.

Dr Andrew Jamieson, medical director of SAA Netcare Travel Clinics, predicted a similar market for illegal ARVs in South Africa, 'as pressure on supply increases'. He speculated that impoverished people with no food to eat could be tempted to on-sell government-provided ARVs, but admitted that special packaging could minimise this practice.

However Martin said that for profiteers to flourish they would have to obtain drugs at a 'totally ridiculous price – and one must then assume that the product is worth very little'.

Zokufa said that if doctors prescribed responsibly, it would free the government to crack down heavily on illegal traders and thus protect its citizens. 'We may even have to go the Scorpions route. This is not an issue of fish and chips; there's a lot at stake.'

He said all government departments would have to use all their resources to protect South Africans.

'If we don't handle this right, we will have failed people – we simply cannot afford to,' he said.

Alluding to the court battles over the new drug legislation, he said it was 'untenable' for the medical profession to be in one camp and the health department in another. 'We're not fighting the prescripts of the medical profession. We want the medical profession to emerge as an important profession untainted by the commercial pressures that are there.'

Secretary General of the Zimbabwe Medical Association, Dr Paul Chimedza, said ARV drug trafficking was a common practice, but he was unable to

quantify it. As chief of the Opportunistic Infections Clinic at Harare Hospital, he said he personally advised people to source ARV drugs in South Africa where they were 'twice as cheap'.

'We don't like to use the word smuggling – fortunately it's illegal to sell or distribute drugs without a licence, and as an association and a profession we cannot condone it. 'He said the only way to eliminate the black market was to make drugs available. HIV prevalence in Zimbabwe is estimated at 24.6%.

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Chimedza said he knew of 150 people on ARVs at one site in Bulawayo and another 80 on ARVs at two sites in Harare (three of five public sector sites), while in the private sector there were no statistics currently available. People who could not afford triple therapy got it for free, and those who could do so paid half price (Z\$157 500 or R178).

A 'big step' this year had been the setting up of two companies manufacturing generic drugs that came on stream about 3 months ago. Things were 'looking up' with inflation dropping from 600% last year to an IMF prediction of 175% by the end of this year.

'At our perinatal hospital we're able to supply about 70% of the drugs required, which is a huge improvement on last year when nothing was available,' Chimedza added.

In South Africa 10 000 people in the private sector and 5 500 in the public

sector are estimated (the latter by the TAC) to be on triple therapy. At the time of going to press the TAC was bringing a court application using the Promotion of Access to Information Act to force the national Health Minister, Dr Manto Tshabalala-Msimang, to reveal time lines and targets in the government's ARV roll-out. She had until 12 July to respond.

Professor Robin Wood, head of the Desmond Tutu HIV Centre at the University of Cape Town, said he was not aware of any ARV black market locally. 'I think the big fear everyone has is that cheap drugs in the developing world will get back into the big market in the West,' he said.

Backing Zokufa's assertion that private doctors should apply their minds carefully and 'not just prescribe ARVs willy-nilly', Wood said he saw no money going into adherence counselling in the private sector.

'The State programme is putting a lot of time, money and effort into compliance. In the private sector you get a script and off you go. Ask yourself which one is more likely to cause drug resistance?' he said.



Humphrey Zokufa

Woods said there was severe prejudice towards poor people when it came to compliance. However, Cape Town research of township ARV trials showed compliance of 90% over 48 weeks, 20% better than that reported in developed countries with people on similar regimens.

'We've published some predictors as to who does and who does not take tablets, but where you live and how much money you make does not make you a better tablet-taker.'



Although he was not aware of any local black-market ARV drug smuggling, he agreed that there was potential for money to be made by unscrupulous private practitioners. Wood said the cheapest generics on the market (not licensed but on Section 21) came from India and cost the patient about R20 per month.

Zokufa said that unless compliance and monitoring were handled properly, all the efforts the government was making to get drugs on tender at very

reduced prices would be 'reduced to naught'.

'We'd then have to look at second- and third-generation ARVs at much higher prices, and we'd be back to square one, chasing our tails.'

The pharmaceutical industry needed a market for their second- and third-generation ARVs.

'We must do the first-stage roll-out very well – as it is, we've moved faster than we'd have liked to.'

While the quotation system was being used as an interim measure to purchase ARV drugs, tenders would 'definitely' be finalised by the beginning of September.

Drug planning centred on supplying 450 000 people with ARVs.

'Obviously not everyone will show up on day one – we'll probably hit that figure in 6 - 8 months' time,' Zokufa said.

Chris Bateman

DRUG LAWS – STATE TO COMPLY... BUT LATER



Her boss, Mrs Vonita Thompson, Director of Professional Support Services for the Western Cape, added, 'basically we're almost re-engineering the services, talking with every regional director and detailing and modelling every region'.

Van Zeil said the support being received from top provincial management was 'heartening'.

Contrary to the fiercely contested but ultimately accepted inception of the dispensing section of the Medicines Act by the private sector, some in the public sector are viewing the changes as an opportunity to review best practice.

Public health care workers have a year longer than their recently shaken private counterparts to comply with the tightened-up drug dispensing regulations and will be equally bound by them from 1 July next year.

In spite of the extra time, provincial human resource and pharmacy departments are scrambling to make sense of the plethora of interlocking laws aimed at improving service delivery and creating greater accessibility to health care.

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Says Margaret van Zeil, head of pharmacy practice and legislation in the Western Cape provincial administration, 'for example, if we think we may need 20 – 30 nurses licensed to dispense at a hospital, that assumes they need to dispense after hours for patients discharged on a Friday night or Saturday afternoon. So instead we question why we're dispensing medicines on a Friday night or Saturday morning and look at doing things differently.'

'There appears to be commitment and understanding of the legislation and compliance with it. It's a fantastic opportunity and a good weapon to enforce compliance and good practice,' she added.

Provincial health departments, even those with efficient spending, capable management and supportive infrastructure, simply cannot deliver without nurses prescribing and dispensing medicines. Nurses offer the bulk of care at primary and district level and can currently prescribe lower