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

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.

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.

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.'

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.

'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

schedule medicines in terms of their own current Nursing Act, provided they are authorised by a clinician or their medical superintendent who must take full responsibility for them.

By 1 July next year, they will need to have completed their 300 notional hours of pharmacy training and write the Pharmaceutical Council exam if they are to dispense drugs – and then function strictly according to good pharmaceutical practice.

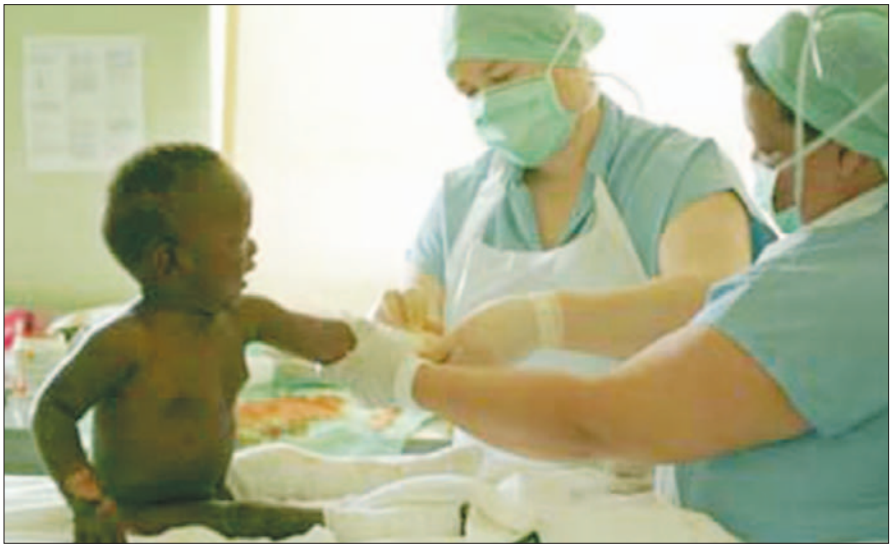
This will involve, among other requirements, storage temperature controls, record keeping, distribution of medicines, advice, proper facilities – all of which were, according to Sue Putter, a private pharmaceutical consultant and former senior manager of professional affairs at the Pharmaceutical Council, 'applied too loosely in the past'.

The new 'upgraded' Nursing Act will also prescribe the scope of practice of different categories of nurses and more strictly define which nurses may do what, what training they need and which drugs they can prescribe. 'It's motivated by quality of care – the current dispensation is much too loose,' says Putter.

Asked whether the laws would not be rendered impotent by an inability to monitor them, she said a lot would depend on the political will and the commitment of each province, adding that the capacities of individual administrations varied hugely.

'Let's face it, it can only be good for the State to comply. The first response by provinces should be to do an analysis of where they stand at the moment,' she advised.

Van Zeil said she hoped that the State would license provincial health care staff in terms of district or a group of facilities to prevent the logistical nightmare that would be created by staff shortages and nurses and clinicians having to 'plug the gaps', when staff were sick or absent from a particular site.



'Also our people do locums and outreach programmes, so this would be vital,' she said.

What was also unclear to provincial managers was whether provincial health departments would have to pay the R1 500 fee per person to apply for the dispensing licence and then the additional R800 per person for the ensuing 3 years.

Thompson said estimates were that it would cost her province and its local authorities R52.39 million to comply with the Medicines and Pharmacy Acts.

Said Putter, 'It doesn't make sense to shift money around between provinces and national, but that debate, as far as I know, hasn't even begun. There's going to have to be some negotiation between the provinces and the national department of health.'

Van Zeil said regional workshops on the implications of the new legislation were being held throughout her province.

Thompson said estimates were that it would cost her province and its local authorities R52.39 million to comply with the Medicines and Pharmacy Acts. The bulk of this (R50 million) was to upgrade existing facilities (e.g. air conditioning, refrigeration, private counselling areas), while training costs for clinicians, nurses and pharmacy assistants made up the remainder (which the province would pay).

There was no funding within the current provincial budget to offset the projected additional expenditure and her staff had done extensive costing 'to give us a tool to approach the national department for additional funds'. They were currently awaiting a response from national DOH on how licensing would be paid for.

Actual training needed to begin immediately if they were to avoid being compromised by next year's legal deadline.

Van Zeil's workshops revealed confusion among nurses and clinicians over the difference between the administration and the dispensing of medicine (the former an exact, direct dose in front of the health care practitioner and the latter more than one dose given in a labelled container to be taken away for later consumption).

'We've got people thinking they need a dispensing licence when all they are doing is administering medicine,' said Van Zeil.

From questionnaires sent out, her province had identified 1 300 health care workers who potentially need dispensing licences but this number was being 'carefully scrutinised', she added.

Both Van Zeil and Putter refuted claims made by some private sector doctors that the national health department requirements for the licensing examination would disrupt State health care delivery. Distance learning and on-the-job learning were possible and the 300 hours could be fitted in over 2 - 6 months, the pair said.

Asked about private providers contracted to the State, Van Zeil said it was a 'somewhat grey area with some uncertainty'.

'It appears that those working from a private facility will not only need a dispensing license but a permit as well,' she said.

The law would most affect State family planning clinics and non-governmental organisations working with provinces.

Thompson was awaiting legal opinion from the national health department around what was required for private practitioners, community-based organisations and private family planning clinics that rendered services on the province's behalf.

'If we can designate them as providers then it's 1 July next year, but if not then they have to comply immediately,' she said.

Asked how she saw private practitioners responding to the new dispensing laws, Putter said much would depend on the outcome of the legal challenge to what dispensers saw as economically unsustainable new maximum dispensing fees.

'If the pricing regulations stand, then I think it may well not be so attractive to dispense anymore,' she said.

Putter said the new laws meant that the English maxim of 'the King can do no wrong', that the State had applied to itself in this area of health care, would be buried forever from 1 July 2005.

Thompson said the Western Cape was 'trying to model this for other provinces – national will try and help them to replicate what is being done here'.

Chris Bateman

WINNING BACK MOTHER'S MAGICAL MILK

Within 6 years, HIV-positive South African mothers may be able to confidently and safely breastfeed their HIV-negative infants to natural weaning without transmitting the virus, thus significantly reducing the overall risks of infant mortality.

That is the goal of an ambitious and groundbreaking NIH-funded research project initiated by Professor Jerry Coovadia, Victor Diatz Professor of HIV/AIDS Research at the University of KwaZulu-Natal's Nelson Mandela Medical School.

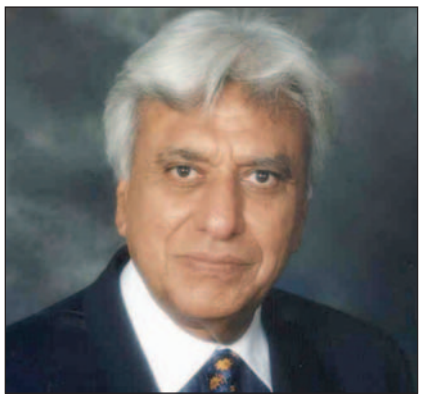
Based on the likelihood of developing a single prophylactic injection to the infant every 2 - 3 weeks, the new methodology promises to boost the already impressive drop in HIV-positive infant prevalence brought about by the current expanding roll-out of antiretroviral PMTCT drugs.

Tackling HIV breastfeeding transmission head-on instead of becoming mired in the often emotive and contentious 'Third-World-formula-feeding' debate, Coovadia and his associates at Harvard and in Austria are convinced they are on the most scientifically valid track.

'We all lived through the period when formula feeding was quite a disastrous practice and indeed, even now still is. Breastfeeding simply tops the list of interventions available for preventing some of those 11 million deaths of children under 5 globally each year,' said Coovadia.

One of the most underrated social dangers of the AIDS pandemic in developing countries is that the risk currently inherent in breastfeeding may cause it to go 'out of fashion', even among HIV-negative mothers.

One of the most underrated social dangers of the AIDS pandemic in developing countries is that the risk currently inherent in breastfeeding may cause it to go 'out of fashion', even among HIV-negative mothers. This would inevitably result in a dramatic increase in the two major infant killers, diarrhoea and pneumonia.



Professor Jerry Coovadia

Coovadia cites research showing that breastfeeding can reduce all-cause mortality of children under 5 years old by 13% in high HIV-prevalence areas and by 15% in low HIV-prevalence areas.

'Breastfeeding is still the best option – almost all the modelling exercises I've seen come to the same conclusion,' he says.