

Essential Drugs in Southern Africa Need Protection from Public Health Safeguards under TRIPs

By René Loewenson

'The question that arises is what intervention can the developing countries make to ensure that a process which, by its nature, will favour the rich, addresses also what are clearly the more urgent needs of our people, millions of whom lack the most basic things that a human being needs.'

South African President Thabo Mbeki, speaking on globalisation (opening address of the Non Aligned Movement Summit, Durban, August 31, 1998)

This article investigates the consequences of the WTO TRIPs Agreement on drug access for Southern African Development Community (SADC) countries.¹ It outlines the key content of the essential drug policies needed to manage the public health problems in the region, and explores the impact of the TRIPs Agreement on these policies. It highlights the options that SADC governments have to address these impacts and the current policy measures which SADC governments and other institutions are pursuing to sustain essential drug access and meet public health obligations.

The Health Challenges

The health context for these policy measures is important. Human poverty affects more than a quarter of the population in all SADC countries, and most poor people depend on public sector provision for health care. The burden of disease is equally high. Nearly a third of children are underweight, one in ten infants dies in their first year of life and one in 200 women dies due to pregnancy or childbirth complications. Southern Africa is the worst affected region in the world for HIV/AIDS, drastically reducing life expectancy to amongst the lowest in the world. The region also has a high prevalence of tuberculosis, pneumonia, malaria, other communicable diseases and malnutrition.

What Role for Essential Drugs?

The Essential Drug Concept, developed by WHO in 1977, aims to prioritise a limited list of vital and essential drugs that are effective, safe, good quality and affordable for treating the priority health problems of the majority of the population.² The concept has been embraced by all SADC member states. WHO regularly updates its Model Essential Drug List, but countries have to make their own Essential Drug Lists for the various levels (primary care, hospital care) based on their own morbidity patterns, treatment guidelines and available human and financial resources.³

Affordability is one of the criteria for becoming an Essential Drug. Some new, life-saving but expensive (mostly patented) drugs are therefore excluded from the current Essential Drug Lists. Consequently, these drugs do not benefit from tax exemption and fast-track registration procedures, and are not seen as priorities in many countries. A new category of 'life-saving, not-yet-affordable' essential drugs needs to be considered, on which efforts to reduce prices can be concentrated.

The WHO estimates that 33 percent of the world's population does not yet have regular access to essential drugs. Barriers to access include poor health care infrastructure, inadequate financing, irrational drug use and non-affordability of new drugs. Poor drug availability increases the ill health burden and reduces confidence in and use of public health services, the major source of care for the poor.

In relation to essential drugs, SADC Health Ministers have:

- made a commitment to ensure that all SADC citizens have access to them;
- initiated a review of bulk purchasing of TB drugs and harmonisation of drug registration;
- begun negotiating with the pharmaceutical industry to drastically lower their prices for essential drugs that are currently not affordable, e.g., drugs for HIV/AIDS, resistant TB, malaria and sexually transmitted diseases;
- begun investigating the use of public health safeguards under TRIPs, such as compulsory licensing, parallel importing and an 'early working' for generics or 'Bolar' clause.

How Will TRIPs Affect Peoples' Access to Essential Drugs?

The TRIPs Agreement has relevance to drug policies in those articles that protect public health and patentable subject matter.⁴ These articles protect intellectual property rights through patent arrangements that exclude third party use, offering for sale, selling or importing of such products for a minimum of 20 years from the date the patent application is filed. Civil claims around breach of patents put the burden of proof on the defendant.

Pre-TRIPs, many developing countries did not recognise patents for pharmaceuticals, or only for processes (and not for products). This allowed copies of new drugs to be made through reverse engineering and patenting another pathway. TRIPs obliges all WTO member states to implement product patent protection for all drugs patented after 1995. This will make it impossible to produce generic copies for at least 20 years, and will thus raise prices.

Currently, most essential drugs are not patented. In South Africa, less than five percent of the 693 essential drugs are patent-protected. TRIPs is thus less of an issue for the vast share of *existing* essential drugs than it is for *new and future* essential drugs, patented after 1995. The increased costs of patented drugs will put a significant burden on public health budgets. These include new drugs for HIV/AIDS, resistant tuberculosis, malaria and reserve antibiotics. SADC will thus face a challenge in accessing these new essential drugs at affordable prices. The price differences can be substantial, as exemplified in the table below:

Best price found for drugs from reliable manufacturers⁵

Medicine (price in USD)	South Africa (patented)	India (generic)	Brazil (generic)
Zidovudine 100mg	0.4	0.2	0.2
Lamivudine 150mg	1.1	0.5	0.8
Didanosine 100mg	0.7		0.5
Stavudine 40mg	2.5	0.6	0.3
Nevirapine 200mg	3.0	2.1	2.5
Fluconazole 200mg	4.1	0.6	0.2
Ceftriaxone 1g	10.9	1.8	

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Least-developed countries must make their patent laws TRIPs compliant by 2006. They can continue to import or produce generic copies of drugs patented before 1995 if they had no patent protection, but from 2006 they will have to honour drug patents filed in their country after 1995.⁶ SADC countries that do not qualify for LDC status (e.g., Botswana, South Africa, Zimbabwe, Mauritius) had to be TRIPs compliant on 1st January 2000.

South Africa voluntarily became TRIPs compliant in 1997. Its experience is instructive for other SADC countries. The 1996 South African National Drug Policy led to legislation in 1997 to enable parallel import and compulsory licenses. Although these remedies are permitted in TRIPs under certain circumstances, the Act was legally challenged by the South African Pharmaceutical Manufacturers Association on grounds of conflict with TRIPs and alleged failure to protect registration information from unfair commercial use. The US Government threatened trade sanctions over the same Act, and put South Africa on its 301 'watch list'. Pressure also came from the European Union (see page 14, *ed.*).⁷

The case signalled the response that SADC countries would need to deal with, should they attempt to invoke provisions that, in principle, exist within TRIPs. At the same time these disputes strain relations between governments and their pharmaceutical industries, and make drug policies more difficult to implement. With the public health burden and resource limits of most SADC countries, a more sustainable solution is required to ensure drug access, including new drugs needed for priority public health actions.

Options for SADC Countries

Signatories to TRIPs have flexibility in how they implement the Agreement, as TRIPs only defines the *minimum* requirements. SADC countries are now studying how to formulate or adapt their legislation to widen their options to access essential drugs. This means using the provisions in TRIPs Article 30 to provide for limited exceptions to the exclusive rights conferred by a patent, provided that they are limited, justified, and do not unreasonably affect the patent owner. The exceptions enable countries to parallel import the drugs or to compulsorily license them, provided their national laws provide for this.

The strongest grounds for such exceptions are in the interests of public health, given that TRIPs enables members to give the highest possible priority to protecting the public interest.⁸ SADC countries are thus challenged to define an acceptable and evidence-based definition of public health interests that can justify the exceptions they seek to impose on patent owners.

In SADC countries that currently do not have patent laws, or in cases where drug companies have not sought patent protection, generic copies of drugs can be imported.

TRIPs allows certain public health 'safeguards' for patented drugs:

- When a patented product is marketed at a lower cost in another

country, countries may revert to 'parallel import' of that drug from the country where the same manufacturer sells it at a lower price, but only if they have enabled the principle of 'exhaustion' in their national patent act.⁹

- Countries may insert 'compulsory license' clauses in their national legislation. Such licences would allow a government, under certain circumstances, to import or produce a more affordable generic copy of the patented product, and pay a royalty to the patent holder. These exceptions are, however, time-limited, and conditional.
- In order to benefit from lower priced generic drugs immediately after patent expiry, governments could insert 'Bolar' or 'early working' clauses in the patent act. These would allow generic companies to develop and test (but not stockpile for sale) generic drugs in the last years of a patented drug.

SADC countries need to fulfil all of the above conditions. This means they must have the expertise and institutions necessary for the appropriate laws, patent registration and health registration data provisions, as well as the capacity to defend themselves in legal battles in case of disputes within WTO around their actions.

Countries can also seek remedies not regulated under TRIPs, such as:

- voluntary price reductions / donations from industry
- price controls
- voluntary license from patent holders for local production / transfer of technology, emergency use.

Some of these remedies have been more widely raised in recent months. Five multinational drug companies offered on 12 May 2000 to make AIDS-related drugs cheaper by 60-85 percent for developing countries, in collaboration with UNAIDS. Boehringer Ingelheim offered its nevirapine free for five years to mother-to-child transmission prevention programmes in developing countries.

Pfizer offered fluconazole free until end 2002 to South African public sector patients with cryptococcus meningitis.

In August 2000, SADC health ministers developed a joint strategy on how to deal with these offers. They insisted that donations be equitable (i.e. available to all citizens in all SADC countries), as well as affordable, accessible, appropriate, acceptable and sustainable (at least five years).¹⁰

It would appear that legal remedies that use the leeway offered within TRIPs on public health grounds offer a more sustainable approach within the control of SADC health authorities than current price measures. This is exemplified for example in the table above, which compares price reductions or donations with compulsory licensing.

These considerations are probably one reason why SADC ministers of health have rejected offers through media for price reductions in the search for more sustainable longer-term measures. It is also doubtful whether even an 85-90 percent price reduction is enough for the huge cost burden implied in making these drugs equitably accessible in HIV/AIDS therapy, given the scale of the epidemic.

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Price reductions/donations and compulsory licensing

Compulsory Licenses	Reduced Price Offers
Patents Act decides	Voluntary offers
National controls	Patent holders in control
Non-exclusive	Exclusive
Allow generics	Brandname only
Clear procedure	Terms not (yet) clear
Prices probably cheaper	Prices lower, but not as low as with compulsory licenses
Conditions listed in TRIPs, royalties	Conditions unclear

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The South African experience cited above signals further the investments and areas of potential dispute that will need to be addressed if SADC countries are to ensure access to new essential drugs, even within the TRIPs framework.

- SADC member states will need to implement legal and institutional measures to take up the 'public health safeguards' permitted under the TRIPs Agreement. SADC offers an important framework for organising and channelling such support to member states. The World Health Organisation (WHO) also has a mandate to provide such support.¹¹
- The pharmaceutical industry will need to balance considerations of property rights and cost returns against public health interests, and the potentially wide market for new drug products if prices are put at more affordable levels. At a deeper level, the deep disconnect between current drug price structures and the needs of the majority of people within regions such as SADC should be a stimulus to the industry to review its policies and to participate in a wider public review of drug access policies. The current proposals for price subsidies and tiered pricing arrangements themselves signal that the present situation is not tenable.
- Clients, particularly low income communities, and the civic organisations that represent them, face pressure to become more informed and involved in the negotiations around health service and drug access. Organisations such as Doctors without Borders (MSF) and Health Action International have taken a proactive role in raising awareness on complex WTO issues at community level, and in taking up issues of drug access and cost at global level. So too have local civic networks such as the Treatment Action Campaign in South Africa and the Community Working Group on Health in Zimbabwe. Such civil input is important for strengthening state actions in public health interest. It is also important that clients know their options in terms of generic drugs, and become more informed consumers of health products. This implies greater and more proactive public information dissemination on drugs and drug use.

The challenge of ensuring equitable and affordable access to new essential drugs under TRIPs in SADC countries once again highlights the agility that states must develop in the uneven WTO playing field, particularly if they are to make trade integrate public health and equity considerations. This is not simply an issue for SADC – it goes back to how the WTO takes account of such issues in framing trade agreements. This pressure for a more proactive integration of such issues within WTO was found for example in the 1999 World Health Assembly, when countries raised a wider global concern that trade agreements be more sensitive to public health considerations.

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ENDNOTES

¹ The Southern African Development Community (SADC) comprises Angola, Botswana, DRC, Lesotho, Malawi, Mauritius, Mozambique, Namibia, Seychelles, South Africa, Swaziland, Tanzania, Zambia and Zimbabwe. It is an economic, political and social community of nations, covering 193 million people. SADC's Health Sector Desk is co-ordinated by South Africa, as well the SADC Trade and Investment Sector Desk.

² WHO's strategy to achieve access to Essential Drugs is based on four pillars: rational selection; affordable prices; sustainable financing, and reliable health and supply systems. See <http://www.who.int/medicines>

³ For example, Zimbabwe just published its 4th Essential Drugs List and Standard Treatment Guidelines. Info: ndtpac@healthnet.zw South Africa's Treatment Guidelines for PHC and Hospitals (December 1998) are available at <http://www.sadap.org.za/edl>

⁴ TRIPs Articles 1, 27.1, 27.2, 27.3, 28, 28.1(b), 33, 34, 65 and 70

⁵ MSF. 2000. HIV/AIDS medicines pricing report. Available at: <http://msf.org/advocacy/accessmed/reports/2000/07/aidspricing/>

⁶ Patent protection for drugs before 1995 was available in South Africa and Zimbabwe.

⁷ Patrick Bond. *Globalization, Pharmaceutical Pricing and South African Health Policy: Managing Confrontation with US Firms and Politicians*. International Journal of Health Services Vol. 29, No.4, 1999.

⁸ TRIPs Articles 7 and 8.

⁹ Although TRIPs seems to prevent parallel import in Article 28.1, this is subject to the exhaustion Article 6, where it is stated that countries cannot be taken to dispute settlement if their patent legislation allows exhaustion.

¹⁰ SADC Principles to guide negotiations with pharmaceutical companies on provision of drugs for the treatment of HIV/AIDS related conditions in SADC countries. August 2000.

¹¹ WHO Assembly resolution WHA52/19. May 1999.

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