



# Fact Sheet Fact Sheet

The Medicines and Related Substances Control Amendment Act 90 of 1997

## A STEP TOWARDS ENDING APARTHEID IN HEALTH CARE

### Why do we need a new law on medicines?

In 1994 the new South African government inherited a racially divided and unequal health sector. On the one hand there was/ is a private health sector, made up of highly paid doctors and advanced medical facilities. But this sector serves only 20% of the population yet accounts for 80% of national spending on health. On the other hand **there is the public health sector, where 80% of the population seek care, but where only 20% of health expenditure takes place.**

Making health care more accessible to South Africa's poor is now a **constitutional** duty facing the government. Our Constitution says that: *"Everyone has the right to have access to health care services."* The state has a **constitutional** duty to progressively improve health care access for everyone. In many respects making health care *accessible* means making it more affordable.

Private and public health care are not independent of each other. If private care is expensive it means that more people depend on public hospitals. Similarly, if doctors and nurses get highly paid in the private sector, then health workers are sucked away from public facilities. To improve the public sector we must also address the distortions in the private sector. That is why it is our government's policy to try to make private care more affordable, so that there are less people and more resources available for the public sector. A range of policies and laws have been introduced. For example, the Medical Schemes Act, aimed to make private health care more widely available by removing unfair membership barriers and strengthening regulations governing the industry. Another area of focus has been on the affordability of medicines, where one major aim has been to increase the amount of money available for other health services by decreasing the amount spent on medicines.

The market for medicines in South Africa is very distorted and has been very profitable for multi-national drug companies. Lack of control of medicine prices, and practices in the dispensing and supply of medicines, has allowed very high prices to be set for private doctors, clinics and hospitals. This has fuelled medical inflation which in turn has remained a barrier to wider access to private care.

By contrast, **in the public sector, patented medicines have largely been unaffordable, and generic medicines have been sold at prices far above what is normal in many other countries.**

***In 1999 66% of people in a survey said "cost" was the main reason for not seeking health care when they were sick. 40% of African people said that access to medicines had got worse.***

### Background

More than three years ago, on 31 October 1997, Parliament passed the *Medicines and Related Substances Control Amendment Act, No. 90 of 1997 (Medicines Act)*. The National Council of Provinces passed the Medicines Act on 20 November 1997 and President Mandela signed the law on 25 November 1997. This law amends or changes the *Medicines and Related Substances*

*Control Act, No. 101 of 1965*. The new law contains measures that will make medicines more affordable and improve the functioning of the Medicines Control Council.

On 18 February 1998, the *Pharmaceutical Manufacturers Association* (PMA) and forty **multinational** drug companies tried to stop the Medicines Act by going to Court against the South African government. After nearly three years of

delays and counter-delays, the case will be heard in the Pretoria High Court from 5<sup>th</sup> -12<sup>th</sup> March 2001. In this period of delay, more than 400 000 people have died of AIDS-related illnesses. **Many people have died because they cannot afford expensive medicines.**



**But why are the drug companies taking the government to court?**

Across the world, drug companies made sales of more than \$315 billion in 2000. This is more than the **gross domestic product** of all the 12 countries in the Southern African Development Community (SADC). Fortune Magazine has shown that the drug companies make super-profits. The drug companies complain that the government is trying to “expropriate its property” and that it is giving the Minister of Health “too much power”. In fact, they fear competition and being exposed as organisations that profiteer from medicines.

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**TAC supports the law because it introduces a legal framework to make medicines more affordable in the public and private health care sectors. This fact sheet will explain this legal framework.**

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**How does the government intend making medicines more affordable?**

The **Medicines Act** introduces four important elements to contain health care costs to government and the private sector:

❶ **GENERIC SUBSTITUTION OF MEDICINES THAT ARE NO LONGER UNDER PATENT** is an important part of the law. This means that a pharmacist must offer a patient the generic version of a brand name medicine. A generic medicine is a drug with the same quality active ingredient that a brand name drug.

❷ Another element of the Medicines Act is the introduction of a **PRICING COMMITTEE** that will set up “transparent pricing mechanisms”. Pharmaceutical companies will have to justify the prices they charge.

❸ The third part of this law is the **PARALLEL IMPORTATION** provision - known as section 15C of the Medicines Act. This measure allows the government to import the same medicine sold by the same

**company or its licensee at a lower price in another country.**

❹ **The Medicines Act also allows INTERNATIONAL TENDERING for medicines used in the public sector.**

Governments across the world recognise that the costs of medicines are unacceptably high. **These measures are used in many countries to lower the price of medicines and they are legitimate.** Yet, the US government and the European Union supported the drug companies. Activists in HealthGap Coalition, ACT-UP, International Gay and Lesbian Human Rights Commission and South Africa forced President Clinton to stop the official pressure by issuing an Executive Order pledging not to interfere with legal measures taken by governments in Africa to reduce the cost of medicines. The European Union has also changed its position.

**Generic Substitution**

**What the Medicines Act says:**

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A pharmacist must inform everyone who buys prescribed medicines of generic alternatives and their benefits. A pharmacist is required by law to dispense the generic unless the patient expressly refuses the substitution. Generic substitution is also not allowed if the doctor writes “no substitution” on the prescription, where the product has been declared “not substitutable” by the Medicines Control Council, or, if the price of the generic medicine is higher than the brand-name medicine.

**What the Medicines Control Council said:**

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Professor Peter Folb former MCC chairperson said: *“The South African public can rest assured that the generic medicines available to us in this country are thoroughly assessed and monitored, that they are of high quality and strictly comparable with the innovator products, and that the drive towards promoting the wider use of generic medicines is not in conflict with the public health. Generic medicines are, or should be, demonstrably more affordable.”*

**What the SA Pharmacy Council said:**

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The Pharmacy Council said that research and debate showed the advantages of generic substitution but *“the implementation of generic substitution ...was, however, always opposed due to expected lobby power from those who stood the most to lose if such implementation is successful.”*

## What the Drug Companies say:

The drug companies claim that generic substitution is unfair discrimination. They also say the quality of generics will be much lower. **What is their real reason:** G. Farber, then CEO of SmithKline Beecham told Parliament that generic substitution “**will remove the ability of my company to retain the profits from its pharmaceutical operations to which it is entitled as the result of substitution by default**”.

**TAC says Mr. Farber and his drug company friends will not lose profits – they will lose the super profits that they make from health.**

## How will Generic Substitution affect you?

Many people in South Africa receive care from a private doctor who prescribes medicines for them. Wealthy households are not the only users of private doctors. In 1995, 19% of **households** with an income of less than R885.00 per month relied on the private sector for health care services. They take their prescriptions to a pharmacy where they or their medical aid pay for the medicine. Doctors often do not think of the costs of medicines or they get bonuses from drug companies for prescribing medicines.

**People who have HIV/AIDS and all households will find that generic prices are much lower for the same good quality medicines. This means that households will spend less on medicines and many more will be able to afford medicines. Medical aid costs will also be much lower.**



## What the US Government Does

**This is an extract from an official report of the United States Government**

In 1996, 43 percent of the prescription drugs sold in the United States (as measured in total countable units, such as tablets and capsules) were generic. Twelve years earlier, the figure was just 19 percent. Generic drugs cost less than their brand-name, or "innovator," counterparts. Thus, they have played an important role in holding down national spending on prescription drugs from what it would otherwise have been. Considering only sales through pharmacies, the Congressional Budget Office (CBO) estimates that by substituting generic for brand-name drugs, purchasers saved roughly \$8 billion to \$10 billion in 1994 (at retail prices).



Three factors are behind the dramatic rise in sales of generic drugs that has made those savings possible. First, the Drug Price Competition and Patent Term Restoration Act of 1984--commonly known as the Hatch-Waxman Act--made it easier and less costly for manufacturers to enter the market for generic, nonantibiotic drugs. Second, by 1980, most states had passed drug-product substitution laws that allowed pharmacists to dispense a generic drug even when the prescription called for a brand-name drug. And third, some government health programs, such as Medicaid, and many private health insurance plans have actively promoted such generic substitution.

## Price Control

### What the Medicines Act says:

The Minister of Health must appoint a pricing committee. The pricing committee can recommend that the Health Minister make regulations on “the introduction of a transparent pricing system for all medicines”. Drug companies will be allowed to set a single exit price for any medicine. Pharmacies will not be allowed to charge an amount higher than the exit price. Instead, the Pricing Committee will recommend a dispensing fee that pharmacists can charge any person.

### What the drug companies say?

They claim price controls will interfere with their constitutional right to trade. They want this provision in the Medicines Act to be declared unconstitutional. Drug companies always claim that they spend money on research and development. TAC supports the creation of a pricing committee that would be able to establish their real costs on research, development and production.

### Price Control in Other Countries:

The South African Pharmacy Council notes that in **most major markets governments have introduced some form of direct or indirect price control.**

**Direct price controls** have been introduced in Germany, Netherlands, Sweden and Denmark. They follow a reference pricing system in which a fixed price is set for a group of pharmaceuticals. This system is popular because it sets prices for medicine categories rather than every individual medicine. **Indirect price controls** are applied through tendering, negotiations, global prescribers budgets, generic buying in the public sector and by bulk buyers.

### The Canadian Example

Since 1987, Canada introduced a **Patented Medicines Review Board**. Drug companies have tried to challenge the constitutionality of this measure and lost. Even though not perfect, the Canadian price control system has managed to keep the prices of patented medicines significantly lower than the inflation rate. Canadians paid much more for patented drugs before the price controls compared to other countries. Since 1987, they have paid consistently less for patented medicines.

### Parallel imports

#### What the Medicines Act says:

The Minister of Health can prescribe conditions for the supply of more affordable medicines in certain circumstances to protect the health of the public. The law also allows the Minister of Health to import the same medicines made by the same company or someone they had licensed if it is sold at a cheaper price in another country.

### The Zantac Example

GlaxoWellcome makes the drug Zantac used for ulcers. Glaxo sells Zantac (10 x 300mg) at a very low price in India and at a very high price in the USA or Indonesia.

#### Glaxo Wellcome prices in rupees (April 1998)

India	Indonesia	Britain	USA
Rs17.39	Rs658.36	Rs603.24	Rs1200.38

#### What the Drug Companies say:

The drug companies say that parallel importation conflicts with the **World Trade Organisation's** rules on intellectual property. They are wrong. Article 6 of **TRIPS** (the agreement on intellectual property rights) says that the agreement does not cover parallel importation. **Many countries of the European Union and even the USA use parallel importing.**

### The Philippines Example

The most recent example of parallel importation has been from the Philippines government. The Philippine Department of Health and Department of Trade and Industry used a state-owned company to buy the same medicines from the same companies sold at a lower price in India. Instead of paying 5 million Philippine dollars for the medicines, the shipment only cost the government 1.5 million Philippine dollars. The Pharmaceutical and Health Care Association of the Philippines took the government to court. The drug companies asked the court to stop the

parallel importation by the government because it infringed their patents and other intellectual property rights.

The Philippines Supreme Court refused their application and argued that "the importation of the "similarly branded medicine" in accordance with the subject A.O. No. 85 will be beneficial to patients of Government hospitals by making these drugs available to them at a price lower than the prevailing price of the same drugs dispensed by the members of petitioner association.



**The Medicines Act deserves the support of all people in South Africa and internationally. It is an attempt to improve health care by lowering the price of essential medicines. In a country with over four million people living with HIV, this is especially important. If the Pharmaceutical Manufacturers Association succeed with their legal action, it will be an enormous blow, and could delay by many years the possibility of affordable medicines and quality health care for poor people in South Africa and throughout the developing world.**



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