

# Access to essential medicines



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Left: AIDS activists protest outside the U.S. consulate in Cape Town, June 24, 2004. The demonstration, organised by the Treatment Action Campaign (TAC) urged US. President George W. Bush to divert funds from the war in Iraq to boost the global fight against HIV and AIDS, and called for a wider distribution of anti-retroviral drugs. REUTERS/Mike Hutchings MH/DL

## 14.1 What is access to medicines?

In the previous chapter, we learnt about the important role that medicines play in health care. Many of the new drugs developed over the last century have revolutionised medical science and the way in which we are able to prevent, treat and cure many illnesses and diseases. This has contributed significantly to increasing the quality and length of both human and animal life.

For example, for a long time, infection with HIV was seen as an “automatic death sentence”. But today, for those with access to antiretroviral medicines (ARVs), HIV infection has largely been transformed into a chronic, manageable illness. As with other incurable diseases such as diabetes, ARV treatment (ART) can extend the quality and quantity of life for people living with HIV/AIDS.

But developing and registering new medicines is not enough – they also need to be accessible. By accessibility, we mean physically available and financially affordable.

In other words, access to medicines can only be assured if a sustainable supply of affordable medicines can be guaranteed – that is, a regular, ongoing supply of affordable medicines. Even when sustainability of supply can be guaranteed, new medicines are often too expensive for poor people and governments in the developing world.

Medicines do not have to be unaffordable for the poor. This chapter aims to show that there are several ways of keeping drug prices in check. It will:

- Highlight the various regulatory mechanisms that law-makers and government officials can use to ensure that medicines are affordable.
- Explain how the legal framework in South Africa and internationally can assist government, civil society and generic drug manufacturers to increase access to essential medicines.

The chapter begins by exploring why medicines are usually so expensive and what can be done to bring drug prices down. Then we look at the ways South African law deals with the issues of affordability and availability, and how the regulatory framework can be improved to increase access to medicines.

We then consider why sustainability of supply is often under threat and what steps can be taken to guard against this.

## 14.2 Why are medicines so expensive?

### The impact of patent protection and the lack of generic competition on prices

The reason usually given to explain why medicine prices are so high is that the development of new drugs is an expensive business. People in the multinational pharmaceutical industry claim that a new drug can cost anything from US\$800 million to US\$1.5 billion. But many independent experts dispute these figures, saying that the figure is more in the range of US\$50–100 million for each newly developed drug.

The pharmaceutical industry continues to rely on the inflated figures to justify high prices for new medicines as being inevitable. Without the ability to charge these high prices, they argue, they would not be able to spend the money required to develop new medicines. But upon analysis it appears that many of the costs of what is called “research and development” (R&D) are in fact marketing costs.

For more detail on drug costs and related issues, see Angell, *The Truth About the Drug Companies: How They Deceive Us and What to Do about It*, 2004.

Central to the R&D of new medicines in any market-driven system is the creation of incentives to stimulate investment in drug development – in other words, making sure that drug companies have a financial reason to bring new medicines to the market. In the modern world, this is largely achieved through patent protection.

#### What is a patent?

- A patent is a period of legally protected market exclusivity during which no-one may make, use or import a new invention, such as a new medicine, without clear authorisation.
- By guaranteeing market exclusivity, the law makes sure that there is only a single supplier of any new medicine.
- In theory, this period of exclusivity, usually 20 years, allows the inventor to recover the costs of R&D and to invest more money into new R&D.

Patents thus create a monopoly for that product for the patent holder, meaning that the market is starved of competition, and also that sustainability of supply may be under threat.

Research shows clearly that when there is no competition and no strict price regulation, prices go up and stay high. This is especially problematic when the product concerned is an essential medicine and there is no alternative available.

When there is no connection between the need or “demand” for a medicine and its price, then we say that demand is “inelastic”. When the commodity is something essential like a medicine, prices tend to rise even more than with non-essential products. This is because demand does not decrease as prices go up, as people need access to the essential medicine to get healthy or to stay alive. Drug companies often take advantage of this to set high prices.

When demand is “elastic”, meaning there is a strong connection between price and demand, excessively high prices are less likely to be seen.

#### Example: No alternative to medicines

A washing machine with a new spin mechanism is protected by patent. If the price of the machine is too high, people will decide to purchase an older model or even wash by hand. In other words, they have alternatives to purchasing the new product. But with essential medicines, the “choice” is very often between ill health and death, and good health and life. This is not a realistic choice: people have no alternative but to buy the medicines they need to keep them healthy.

### Cost barriers in diseases of the poor

It can be argued that in some ways, the patent system has worked well, resulting in the development of medicines for diseases that affect large numbers of people in wealthy countries – like hypertension and heart diseases. But when it comes to the needs of poor people, the patent system has been fundamentally flawed. Being based on market demand rather than consumer need, it usually results in no medicines being developed for most diseases of the poor, because there is no financial incentive to develop products for low-profit or no-profit markets.

#### Key Points: Implications of patents

- Where drugs have been developed for diseases that affect wealthy and poor people, such as HIV/AIDS, patents have ensured that relatively few people are able to enjoy the benefits of expensive lifesaving medicines.
- Thus, for most people in the world who cannot access ARV medicines, HIV/AIDS remains a life-threatening condition that often leads to illness and premature death.

Drug companies and their lobbyists are often quick to point out that there are many reasons why people in poor countries have limited access to essential medicines. They are right. But there are also many examples both in South Africa and abroad that show clearly that the high price of medicines caused directly by patent protection is sometimes the only, or the most significant, barrier in the way of access.

As ARV treatment has shown, when the price barrier is removed, many of the other barriers start to fall down immediately.

## The impact of profiteering in the supply chain on prices

The supply chain refers to all the players involved in a medicine's distribution from the time from when it leaves the manufacturer's warehouse to the time it is bought in a retail pharmacy. The supply chain offers a number of opportunities for prices to be raised.

There is not a single model of supply chain. Supply chains vary between manufacturers, and between the public and private sectors. For example:

- Some companies may make use of distributors instead of wholesalers.
- The state may buy directly from drug companies, usually through formal tender processes.

We will focus on what can happen to the price of a medicine as it makes its way through the supply chain. This illustrates why it is not sufficient to target pharmaceutical manufacturers alone when taking steps to bring the prices of essential medicines down. Governments need to put in place a legal framework that addresses each of the many "supply chain opportunities".

Medicines can leave the manufacturer in one of three ways:

- Through sale to wholesalers.
- Through direct supply to health care providers, such as hospitals.
- Through direct supply to retailers, such as pharmacies.

### Wholesalers

Wholesalers have historically been the link between manufacturers, community pharmacies and other providers, such as hospital pharmacies and dispensing doctors. In the past, wholesalers bought medicines from manufacturers in bulk. As a result, they usually received substantial discounts, and they often passed these on to retailers, such as pharmacies.

### Health care providers through agents

Manufacturers also supply medicines directly to certain health care providers. In the past, manufacturers often developed very close relationships with dispensing doctors through their marketing agents (also known as “reps”), making use of all sorts of incentive schemes to ensure that their products were prescribed and dispensed. This has included directly providing medicines, often through samples and bonuses, as well as other financial enticements to promote some products over others.

More recently, direct distributors have emerged – these are companies that are either owned or controlled by manufacturers. Distributors bypass wholesalers by supplying medicines directly to retail outlets.

These direct distributors could play an important role in making sure that medicines are supplied more cheaply and efficiently, but they may also limit access to medicines by preventing certain medicines made by other manufacturers from finding their way to retailers. This happens when they are too closely controlled by certain manufacturers, who have an interest in making sure that competitors’ products are sidelined.

### Retailers: pharmacists and dispensing health practitioners

What then happens at the retail level? In South Africa in the past, the prices set by pharmacists in the dispensing of medicines were unregulated. This left pharmacies largely free to set their own dispensing fees. Dispensing fees were usually a percentage of the price of the medicine, meaning that the higher the medicine price, the higher the dispensing fee. Thus, wherever dispensers were given some freedom to determine which medicine to dispense, they had a direct financial incentive to dispense the more expensive medicine.

### The impact of taxes and duties on price

There are two more factors leading to high medicine prices, both influenced by government policy. These are:

- Value-added tax (VAT).
- Import duties.

### Value-added tax

The law makes a distinction between *essential* and *non-essential* foodstuffs, exempting essential foodstuffs from the VAT. However, all medicines are subject to 14% VAT, regardless of their therapeutic value. As a result, there is no VAT difference between cosmetic products and essential medicines. Similarly, prescription drugs of proven high therapeutic value are taxed in the same way as over-the-counter supplements of unproven efficacy.

Some people argue that, because VAT is charged only for medicines sold in the private sector, it is not a problem, as poor people access medicines in the public sector. But this overlooks the fact that many users of the public health system purchase medicines from private pharmacies. This is because many of the medicines people need are not available in state hospitals and clinics, often because of their cost or because of problems with the supply of medicines.

People often rely on community pharmacies or dispensing doctors because of the distance, time and costs involved in visiting public hospitals and clinics. For example, low wage earners cannot afford or are unable to take time off from work to wait in long queues at public health facilities.

The private health sector also includes the workplace and the not-for-profit organisation (NPO) sector. This means that employers who pay directly for medicines for their employees and NPOs that provide free health care services must also cover the costs of VAT. Again, the reason that these services are often provided is because they are not easily accessible in the public sector. Yet more money spent on VAT means less money spent on medicines. This limits access to essential medicines.

### Import duties

The second government policy that may result in higher medicine prices is the imposition of tariffs or duties on a limited number of imported active pharmaceutical ingredients (APIs) and raw materials used to manufacture APIs.

APIs are the building blocks of all medicines. Most APIs used in South Africa are imported from countries such as India. The costs of APIs make up about 70–80% of the cost of generic drugs – this can be even higher for ARV medicines.

Import duties thus have the potential to contribute directly towards increasing the cost of locally manufactured medicines. These increased costs may make it more difficult for local generic companies to compete with foreign generic companies, leading to less competition. This may lead to prices being higher than they would be in a truly competitive market.

The cost of APIs themselves is also a significant barrier to access. What is needed is more competition between API manufacturers and greater local capacity for manufacturing APIs.

## 14.3 The constitutional and policy framework for making medicines affordable in South Africa

### The National Drug Policy

In 1994, South Africa's first democratically-elected government was faced with many problems relating to the provision of health care, one of which was the high price of medicines in a largely unregulated medicines market.

The issue could not be neatly resolved as either a public or private sector problem. Many users of the public sector buy medicines in the private sector. In addition, high private sector medicine prices made access to private medicine unaffordable, contributing to the pressure on the public health system.

Recognising these challenges the new government initiated a policy review process that culminated in 1996 with the adoption of the National Drug Policy (NDP). The aim of the NDP is to promote the availability of safe and effective drugs at the lowest possible cost by:

- Monitoring and negotiating drug prices.
- Rationalising the drug pricing system.
- Promoting the use of generic medicines.

The NDP is the centrepiece of South Africa's policy framework on medicines. But today, it is important to recognise that the NDP was developed at a time when local thinking on various indirect price regulatory mechanisms (such as compulsory licensing) was still quite undeveloped. This was because the late 1990s and early 2000s were to witness important domestic and international struggles around access to essential medicines. These struggles highlighted the deficiencies of the patent system and the legal means to limit its abuses.

In other words, the NDP was adopted at a time when South Africa believed that its regulatory options were significantly narrower than they are today.

### The Constitution

According to the Constitution of the Republic of South Africa, 1996 (the Constitution), the state has a duty to take steps to put in place a legal

framework that facilitates access to health care services. According to the Constitutional Court's decision in *Minister of Health v Treatment Action Campaign (No 2)* 2002 (5) SA 721 (CC), access to health care services includes access to medicines.

The Constitution thus places an obligation on the government to take all reasonable steps to put in place and make use of a legal framework that facilitates increased access to essential medicines. This does not mean that government must just act as a provider of goods and services. It must also put in place a legal framework so that individuals are able to realise their rights through their own action. This duty refers directly to the government's role as a regulator, rather than as a provider.

Thus even if the government provides certain essential medicines free of charge in the public health sector, it is still under a constitutional duty to take steps towards reducing the prices of these drugs in the private sector and ensuring a sustainable supply of them. This point was recognised by the Constitutional Court in the 2005 judgment in the case of the *Minister of Health v New Clicks South Africa (Pty) Ltd*.

In this case the Court:

- Unanimously agreed that the Medicines Act permits the government to control prices and to make medicines “more accessible and affordable by means of a transparent pricing system”.
- Confirmed that the government has a constitutional obligation to take these types of measures.
- Stressed that when the state regulates, it must do so in a reasonable fashion, ensuring that measures intended to make medicines affordable do not – by design or accident – make them unavailable.

#### Key Point: Government's duty

The government's duty is thus to take all reasonable steps to ensure that essential medicines are accessible. At times, circumstances may demand regulatory measures such as direct price controls if these measures are the only reasonable way it may carry out its duty. Where it is possible, less invasive means can be used, such as the regulation of pricing practices rather than direct price controls.

## Policy options for state intervention

All over the world, including in developed countries like the United Kingdom and Canada, it is accepted that there is a range of measures available to government to reduce and control medicine prices. These measures form part of the legal or regulatory framework, including:

- The passing of statutes by Parliament and the provincial legislatures.
- The promulgating of regulations by relevant government ministries.

In many cases, the mere existence of a good legal framework may be enough to prevent abuses and ensure that drug manufacturers, wholesalers, distributors and dispensers play fair. Knowing that the law can be used successfully against excessive pricing may be enough of an "incentive" for a drug company to conduct business within the rules. In other cases, simply threatening to make use of a good legal framework may be enough to bring key role players to the negotiating table.

### CASE STUDY: BRAZIL

In Brazil, the federal government has often threatened to start producing generic ARV medicines if drug companies refuse to sell their patented versions at affordable prices. Rather than run the risk of losing their market exclusivity, some companies have "voluntarily" agreed to supply these drugs at significantly more affordable prices.

### CASE STUDY: SOUTH AFRICA

In 2000, the Treatment Action Campaign (TAC) spearheaded a campaign to challenge the abuse of a patent held by the drug company, Pfizer – which was charging an excessively high price for its brand of the antifungal medicine, fluconazole. Rather than risk any legal action, Pfizer developed the Diflucan Partnership Programme to donate fluconazole to developing country governments (including South Africa) for use in the public sector to prevent and treat a range of HIV/AIDS-related opportunistic infections.

### CASE STUDY: CHALLENGING ARV PRICES

In the 2004 case of *Hazel Tau and Others v GlaxoSmithKline and Boehringer Ingelheim*, the TAC and 12 others used competition law to challenge the high private sector prices of ARV medicines sold in South Africa by the two companies. This led to licences being issued to produce (or import) and sell generic ARVs.

Source: AIDS Law Project. *The Price of Life: A Report on the Excessive Pricing Complaint of SA's Competition Commission*, July 2003

For more on competition law and access to essential medicines, see pages 462 – 466.

There are two approaches to regulatory mechanisms to deal with high medicine prices:

- *Indirect price regulatory mechanisms* that try to create the conditions that result in lower medicine prices.

- *Direct price regulatory mechanisms* that aim directly to change medicine prices.

In practice, a combination of indirect and direct mechanisms is often used, and is likely to vary from country to country.

### **Indirect price regulatory mechanisms**

Indirect price regulatory mechanisms use competitive pressure to bring prices down:

- Some of these mechanisms introduce competition for the first time.

- Some aim to ensure that competitive products get to market without delay after overcoming barriers such as patent protection.

- Others try to restore lost competition.

## **INTRODUCING COMPETITION WHEN PRODUCTS ARE UNDER PATENT**

There are three key ways to “force” suppliers of patented medicines to compete with cheaper alternatives. These are compulsory licensing; revoking a patent; and parallel importation.

### *Compulsory licensing*

Compulsory licensing refers to the issuing of licences that allow generic medicines to be imported or produced locally, either by the state or by private companies. This leads to the market entry of generic competitors while a product is still under patent. These issues are regulated internationally by the World Trade Organisation (WTO) Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS).

Compulsory licences may be issued in two ways:

- the state may issue a licence to itself or to companies that import or manufacture generic medicines (also called "government-use licences"); *or*

- a court or administrative tribunal may issue a licence in response to an application made by an interested party, such as a generic manufacturer or an NPO that imports medicines.

Anyone who uses a compulsory licence to import or produce generic medicines must pay a reasonable royalty to the patent holder. This is usually somewhere between 2–10% of the selling price.

There has, predictably, been fierce opposition by multinational companies and powerful governments such as the USA to the practice of compulsory licensing. But this opposition chooses to hide the fact that many economically powerful developed countries make effective use of compulsory licensing.

Some countries have even been willing to threaten the use of compulsory licensing to ensure a sustainable supply of essential drugs. For example, after the attacks on the World Trade Centre in New York on 11 September 2001, when both the US and Canada were worried about access to the anti-anthrax drug Ciprobay, they both threatened to issue compulsory licences

### *Revoking a patent*

A patent may be revoked when an interested person applies to a court for an order removing patent protection altogether. If the order is granted, it means that anyone is able to import or manufacture the drug as long as they follow all requirements for medicine registration.

Revoking a patent does away with the need for other generic manufacturers to apply for compulsory licences – this may be costly and time-consuming. It also means that generic importers and manufacturers do not have to pay royalties, lowering the costs of production even further.

However, patent revocations are very uncommon and would be granted only in cases when there is very clear and continued abuse of a patent by its holder, as well as a public interest in stopping that abuse.

### *Parallel importation*

Parallel importation refers to the practice where patented products are imported from another country where they are sold at a cheaper price. There may be many reasons why the same product is sold in different countries at different prices.

#### Example: Lamivudine

GlaxoSmithKline's lamivudine (3TC) is sold in South Africa at a much cheaper price than in Namibia. This is because generic lamivudine is not yet available in Namibia, even though it is not patented there. Using parallel importation, importers in Namibia could import cheaper 3TC from GlaxoSmithKline in South Africa.

### Introducing competition immediately after patent expiry

It usually takes about two years between the time a patent expires and the time a generic alternative is available on the market. During this period, the previous patent holder enjoys an effective monopoly, allowing for the continuation of high prices.

The two-year delay is largely due to the drug registration process. But while strict drug regulation is essential to ensure the safety, efficacy and quality of medicines, the early entry of generic competition is also in the public interest. These possibly conflicting goals can be addressed by:

- Ensuring that the registration process runs smoothly and efficiently, with a fast-track drug regulatory process for essential medicines.
- Starting and completing the drug registration process during the life of the patent, so that generic alternatives are already registered and can therefore be sold immediately when the patent expires.

However, beginning the process during the life of the patent is sometimes considered as a violation of the patent, because the law normally prevents anyone from using a patented product without the express authorisation of the patent holder. This problem can be overcome by a simple regulatory mechanism, known as the "Bolar amendment", that allows generic manufacturers to register their medicines without infringing existing patents.

For more on the Bolar amendment, see page 460.

#### CASE STUDY: IMPACT OF COMPETITION ON PRICE

Although the patent on fluconazole expired in 2002, it was – until 2004 – sold in South Africa by only three different companies: the original patent holder (Pfizer) and two generic companies (Hexal and Ranbaxy). All three companies sold a single 150mg capsule of fluconazole for between R50 and R60 in the private sector. Before the two generic companies entered the market, Pfizer sold its version – Diflucan – at more than R120 per capsule.

With the authorisation of the Medicines Control Council (MCC), TAC imported a good quality safe and effective generic manufactured in Thailand at less than R2 a capsule.

If there had been real competitive pressure on the three companies, fluconazole would have been substantially cheaper in South Africa. This is illustrated by the fact that when, in 2004, further generics became available, both new companies introduced the 150mg version at just over R28 per capsule. This was a price reduction of around 50%.

Now that there are five competing versions of the drug on the market, it is likely that prices will drop even further. But even without further price cuts, the current price is a reduction of more than 75% of the original price charged for fluconazole when only the patented version sold by Pfizer was available.

## RESTORING LOST COMPETITION

There are a number of ways that various role players in the medicines supply chain may act to reduce competition. This is usually only possible when there is a limited number of competitors. The greater the number of competitors, the more difficult it becomes to act in anticompetitive ways.

When companies act together to restrict competition, we say they are “colluding”. Collusion can take place in a number of ways, such as by fixing prices and by dividing up markets between competitors. With market division, they may agree to carve up the market into public and private sectors, meaning that there is no competition in either. Competition law usually makes these sorts of practices unlawful.

### Direct price regulatory mechanisms

Direct price regulatory mechanisms interfere directly with the way in which medicine prices are set. They complement indirect regulatory mechanisms and are valid alternatives, particularly when it is difficult or impossible to introduce or maintain competitive pressure to keep prices down.

Direct mechanisms include mechanisms that seek accountability and transparency in setting medicine prices. There are three categories of direct regulatory mechanisms:

- State guidelines for price-setting.
- Laws prohibiting high prices.
- Direct price controls.

## STATE GUIDELINES FOR PRICE-SETTING

The state can put rules or guidelines in place that assist key role players, such as manufacturers, to set their own prices. These can determine what factors can and cannot be considered in setting prices. The value of this approach to price-setting is that it may play an important role in ensuring accountability and transparency by making it a requirement that prices are justified.

## LAWS PROHIBITING HIGH PRICES

Laws can be enacted that prohibit the setting of unjustifiably or unreasonably high prices. These provisions may also play a significant role in ensuring that pricing structures are defensible. Manufacturers are then under pressure to ensure that when they set their own prices, they take into account the fact that they may have to explain how and why prices were set at particular levels.

## DIRECT PRICE CONTROLS

The State may impose direct price controls. This may focus on drug manufacturers or extend to introducing price-capping (limits) at all levels of the medicine supply chain, such as tariff schedules for distribution and dispensing. The government usually uses direct price controls when other mechanisms are unable to deliver.

## 14.4 South Africa's legislative framework

South Africa's legal framework on access to affordable medicines has three key pieces of legislation. Only one of these, the Medicines and Related Substances Act 101 of 1965 (the Medicines Act), is a purely health statute. The other two, the Patents Act 57 of 1978 and the Competition Act 89 of 1998, fall under the authority of the Department of Trade and Industry.

A further law, the Public Finance Management Act 1 of 1999 (PFMA), deals with many aspects of state expenditure, including the procurement of goods and services, and is administered by the National Treasury.

For more on the PFMA, see Chapter 4.

Despite some shortcomings, the existing legal framework provides many opportunities for ensuring access to a sustainable supply of affordable medicines. In many ways, the Acts have already put in place much of the framework that the Constitution requires.

### The Medicines Act

The Medicines Act was originally enacted in 1965, and has been amended many times since. Those aspects of the Act that deal with ensuring the safety, efficacy and quality of medicines are explained in chapter 13. However, the most significant amendments dealing with access to essential medicines, came with the Medicines and Related Substances Control Amendment Act 90 of 1997 ("Act 90 of 1997").

Together with the first set of regulations to be issued under the updated and revised statute ("the General Regulations"), the amendments to the Act deal with a number of access issues, including:

- Measures to ensure the supply of cheaper medicines, including introducing competition through parallel importation.
- A transparent pricing system that, for the first time, requires openness and accountability in the setting of drug prices.

- Introducing a fee-for-service system at various levels in the medicine supply chain, with government setting the upper level of the “appropriate” fees.
- Promoting the use of generic medicines once branded products are no longer protected by patent, including mandatory generic substitution of off-patent medicines.
- Fast-track procedures for the registration of essential medicines.

Predictably, many in the drug industry saw the 1997 amendments as unjustifiable state interference with their rights to intellectual property. The Pharmaceutical Manufacturers’ Association (PMA) and almost all of its drug company members tried to stop the law from coming into force by applying to the Pretoria High Court in February 1998 for an order preventing President Mandela from promulgating the law.

But with the support of civil society, most notably the TAC, the government defended the Act and in 2001 the PMA unconditionally withdrew its legal challenge. After this it took another three years before the law came into full force. Some of this delay was because regulations had to be drafted. In addition, certain minor amendments to the Medicines Act were needed, resulting in the Medicines and Related Substances Amendment Act 59 of 2002.

The 1997 amendments to the Medicines Act started to come into force on 2 May 2003 and the full package of reform was brought into effect on 2 May 2004 (with certain provisions scheduled to become operative over a period of three months). This was almost 6½ years after President Mandela signed Act 90 of 1997 into law.

However, further delays were caused when, once again, litigation challenged the constitutionality of the second set of regulations. At the end of 2005, some aspects of the law were still inoperative as a result of a partially successful legal challenge to the validity of the Pricing Regulations issued under section 22G of the Act.

We will now describe the most important amendments to the Medicines Act.

### **Measures to ensure the supply of cheaper medicines**

Section 15C of the Medicines Act allows the Minister of Health to take action that results in the supply of cheaper medicines, by passing regulations that protect the health of the public.

Section 15C has an introductory provision that allows the Minister to “prescribe conditions for the supply of more affordable medicines in certain circumstances”, followed by two specific examples of the types of action that the regulations may authorise:

- Paragraph (a) appears to give the Minister very wide powers to override exclusive rights in patents.
- Paragraph (b) deals narrowly with parallel importation.

Some analysts have claimed that section 15C(a) permits compulsory licensing, and that it may even go so far as to override patents completely. Predictably, section 15C was at the heart of the PMA’s court challenge.

But by late 2005, the extent of the Minister’s powers in the paragraph remains unclear – the General Regulations do not give effect to the paragraph, meaning that it cannot be used in practice. Further, because the PMA withdrew their court challenge, the High Court did not have an opportunity to provide a proper interpretation of the provision. In addition, the government has said publicly that section 15C(a) would not be used for compulsory licensing.

### **Parallel importation**

Regulation 7 of the General Regulations provides the detail on parallel importation. It explains a number of important issues, including:

- Which medicines can be imported under section 15C(b) – only patented medicines.
- What must be included in the application for a licence to parallel import medicines.
- The powers of the Minister around the approval of licences.

The process is complex, dealing with issues of safety, quality and efficacy, as well as affordability. By late 2006, no medicines have been imported into South Africa under Regulation 7, probably as a result – in large part – of the difficult processes that must be followed.

### **Transparency and accountability**

Before the 1997 amendments to the Medicines Act, drug manufacturers were free to set their own prices, and had no legal duty to explain how these prices were calculated. In a truly competitive market, with elastic demand as a result of alternatives in the market, this should not be a problem. But where manufacturers are guaranteed market exclusivity by patents, the lack of transparency and accountability can result in excessive pricing and profiteering.

The Medicines Act aims to achieve transparency in three different ways:

- Through the operation of sections 18A and 18B it ends "perverse incentives" by prohibiting the use of financial and other incentives that particular drug companies used in the past to ensure that their products were prescribed and dispensed. It also prohibits practices such as discounts and rebates that often resulted in cheaper medicines for people in larger metropolitan areas of the country, while denying the same benefits to poor people in rural areas, small towns and under-resourced areas.
- Section 22G authorises the setting up of a Pricing Committee, whose primary task is to advise the Minister of Health on a transparent pricing system. The Pricing Committee's work is guided by the General Regulations.
- Section 22G also introduces the concept of the *single exit price* (SEP) as "the only price at which manufacturers shall sell medicines... to any person other than the state".

The Pricing Regulations, issued by the Minister on the recommendation of the Pricing Committee, gave the detail on a transparent pricing system and a single exit price. They were promulgated on 30 April 2004, with effect from 2 May 2004. However, as we explain below, their full implementation was delayed by a dispute over their constitutionality that eventually reached the Constitutional Court.

## SETTING A SINGLE EXIT PRICE

According to the Pricing Regulations, there are two ways to set the SEP:

- The *first* way, which came into effect on 2 June 2004, was based on the average price at which individual units of a particular medicine were sold in the private sector in 2003. This meant that:
  - Each tablet or capsule of a particular medicine and a particular dosage cost the same, regardless of package size.
  - The SEP included a 'logistics fee' – a fee negotiated between the manufacturer and distributor or wholesaler for their services.
  - The SEP could be adjusted upwards only once a year and according to strict state controls.
- The *second* way that had not yet come into force when the regulations became the subject of a legal dispute, was to ensure that SEPs would be in line with "international benchmarks". The law was unclear on what exactly this meant and when it would have come into force. It was

designed to ensure that medicine prices in South Africa remain in line with prices in comparable countries abroad.

In October 2006, the Department of Health published draft regulations on international benchmarking for public comment. The regulations are expected to be finalised in 2007.

Transparency is also to be achieved in another way. The Pricing Regulations gave the Director-General (DG) of Health certain powers to investigate whether medicines are reasonably priced, including a power to make certain demands on drug companies to justify their prices.

However, the DG was not given any real power to take meaningful action after determining that a medicine price was unreasonable, or any power to ensure that the companies in fact justified their prices. All the DG could do was publish the finding in the *Government Gazette*.

### **Appropriate professional fees**

Section 22G(2) of the Medicines Act allows the Minister to regulate:

- Wholesaler and distributor fees.
- Dispensing fees for pharmacists and dispensing health practitioners licensed under section 22C.
- Dispensing fees for “any other person selling Schedule 0 medicines”.

Vitamins are classified as Schedule 0 medicines.

However, the Pricing Regulations regulated dispensing fees only for pharmacists and dispensing health practitioners, drawing a clear distinction between the charges of pharmacists and those of dispensing doctors and other non-pharmacists. Fees for the sale of Schedule 0 medicines, and wholesaler and distributor fees, remained unregulated:

- This was as a result of the inclusion of a logistics fee into the SEP, instead of the setting of an appropriate wholesaler or distributor fee.
- The logistics fee was not capped by the regulations, but would instead be negotiated behind closed doors without any transparency.

The most controversial aspect of the Pricing Regulations was the level at which the dispensing fee for pharmacists was set. These provisions were the main focus of the attack on the constitutional validity of the Pricing Regulations.

## CASE STUDY: CHALLENGING THE CONSTITUTIONAL VALIDITY OF THE PRICING REGULATIONS AND AN APPROPRIATE DISPENSING FEE

In 2004, a range of organisations representing pharmacists, including the Pharmaceutical Society of South Africa (PSSA), launched a legal challenge against various aspects of the Pricing Regulations. However, the central attack was on the dispensing fee and was based on the threat it presented to the viability of pharmacies and thus on the sustainability of medicine supply.

Initially, the Cape High Court confirmed the constitutional validity of the Pricing Regulations. But on 20 November 2004, a five-judge panel of the Supreme Court of Appeal (SCA) unanimously declared the Pricing Regulations as a whole to be unconstitutional and therefore invalid, with immediate effect.

In its judgment in the PSSA case, the SCA considered the meaning of the Medicines Act's reference to an "appropriate dispensing fee" and said:

*"In determining what is appropriate one must consider the conflicting interests of all those involved and affected. On the one hand there is the public, which is entitled to access to health care including affordable medicines.*

*On the other hand there are the interests of dispensers who, in terms of the Act, are essential to the public for the supply of medicines and whose economic viability is implicitly recognised by the Act and is of national importance."* (paragraph 77)

The SCA concluded that the dispensing fee provided for in the regulations could not be considered as appropriate. It decided that:

- *"Access to medicines is seriously threatened because ... [the dispensing fee is] insufficient to cover the cost of dispensing."*
- *"This conclusion is not based on the opinion of pharmacists but on the unassailed factual material on record."* (paragraph 89)

### Promoting the use of generic medicines

Generic substitution is an important tool for reducing unnecessary expenditure on medicines. In the past, because of large financial incentives, many doctors habitually prescribed branded medicines that have no added health benefits, but which cost significantly more than generic alternatives.

In keeping with the National Drug Policy, the Medicines Act aims to promote the use of generic medicines, especially once patent protection for brand name products has expired. It does this through the provisions on generic substitution in section 22F that also apply to generic products produced under voluntary or compulsory licence.

Section 22F uses the term "interchangeable multi-source medicines" to describe generic medicines. These are defined as:

*"medicines that contain the same active substances which are identical in strength or concentration, dosage form and route of administration and meet the same or comparable standards, which comply with the requirements for therapeutic equivalence as prescribed".*

Interestingly, the Court also said that:

“it is not without significance that the Congress of SA Trade Unions, the Consumer Goods Council and the *amicus curiae* [the Treatment Action Campaign] came to the same conclusion”. (paragraph 89)

This decision was taken on appeal to the Constitutional Court, which handed down its judgment in September 2005. This is an extremely important ruling on the right of government to take measures to make medicines affordable. The Court decided that most of the regulations were valid, declaring that it:

*“unanimously accepted the validity of a single exit price being established for medicines sold in South Africa, and the validity of the regulatory structure put in place for its realisation”.*  
(paragraph 14)

However, while accepting this crucial principle, the Court itself amended several of the regulations to bring them into line with the Constitution. In addition, it also ruled that the dispensing fee was not “appropriate”. It ordered the Pricing Committee to hear new submissions on an appropriate fee and to pay “particular attention ... to the circumstances at least of rural and courier pharmacies to ensure that the right of access to health care is not prejudiced by driving such pharmacies out of the market”. (paragraph 19)

In October 2006, the Minister announced the revised dispensing fee. The new fee is based on a complicated 4-tier model that attempts to balance the amount a pharmacist can charge with the cost of keeping expensive medicines in stock. Pharmacists remain unhappy with the dispensing fee. In December 2006, a group of pharmacist associations filed an urgent application in the Pretoria High Court challenging the appropriateness of the dispensing fee, which – at the time – was scheduled to come into operation on 1 January 2007.

The law requires that generic substitution should take place when a health care provider such as a doctor or nurse prescribes a branded product that costs the same or more than a generic alternative. In such a case the person dispensing must:

- substitute the branded product with the generic alternative; *and*
- take reasonable steps to inform the prescribing health care provider that generic substitution has taken place.

However, generic substitution cannot take place, and the branded product must be dispensed:

- if the prescribing health care provider has written that the branded medicine is non-substitutable
- if the MCC has stated that the branded medicine is non-substitutable
- if the user clearly instructs the pharmacist or other health practitioner to dispense the branded product.

### Fast-tracking registration of essential medicines

The 1997 amendments to the Medicines Act introduced the concept of an *Essential Drug List* (EDL) to our law. Medicines that are placed on this list are made available at no cost in the public health sector, depending on the appropriate level of care to be provided by the particular health facility.

As promised by the National Drug Policy, in 1998 the Department of Health took a major step forward when it published Standard Treatment Guidelines and EDLs for Primary Health Care (updated in 2003), Hospital Level Care (adults) and Hospital Level Care (paediatrics).

Under section 15(2)(b) of the Medicines Act, all medicines on the EDL, as well as all other medicines that “in the opinion of the Minister ... are essential for national health”, are “subject to such procedures as may be prescribed in order to expedite the registration”.

According to the General Regulations (2 May 2003), the MCC must deal with fast-track applications in not more than nine months. Fast-track approval means that the MCC must prioritise the registration of essential medicines, at least.

While this opens up the possibility of accelerating the market entry of generic competition, it is not yet clear whether the change in the law will in fact speed up the registration process. The MCC's capacity to implement these changes remains unclear.

For further discussion of fast-tracking of essential medicines, see 13.3 on page 425.

### The Patents Act

In Chapter 5, this handbook explains how bilateral, regional and international trade agreements affect the regulatory options available to countries to protect public health. In this area of international law, there has been a big focus on the World Trade Organisation (WTO) Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS). But surprisingly little attention has been given to the fact that many developing countries already offer much more patent protection than is required under international trade agreements, including TRIPS.

South Africa's Patents Act is a good example of this. Despite all its shortcomings, it nevertheless has the potential to increase access to essential medicines in circumstances where patents are limiting access by permitting:

- State use of patented products for public purposes.
- Compulsory licensing to deal with the abuse of rights in a patent.
- The "Bolar amendment".
- State acquisition of patents.

### State use for public purposes

According to section 4 of the Patents Act, a Minister “may use an invention for public purposes on such conditions as may be agreed upon with the patentee”. In short, this means that cabinet ministers (such as health, trade and industry, and agriculture) have the power to issue compulsory licences – either to state entities or to private companies.

If there is no agreement on terms and conditions, including the royalty rate to be paid, the issue must be resolved by the Commissioner of Patents, a judge of the Pretoria High Court. The patent holder must be given a hearing before the decision can be made.

A compulsory licence can be issued even if the government does not intend to provide the cheaper generic medicines in the public health sector. This is because the term “public purpose” is sufficiently broad to include the taking of steps that result in lower drug prices in the private sector and thereby increase access to essential medicines. Even in cases where medicines are not excessively priced, a compulsory licence may also be used to ensure sustainability of supply, by introducing additional manufacturers for the product.

#### CASE STUDY: PRESSURE TO ISSUE COMPULSORY LICENCES

- On a number of occasions organisations such as the ALP and the TAC have requested the government to use section 4 to issue compulsory licences so that a sustainable supply of cheaper generic versions of ARV medicines can be made available. But this has not happened.
- However, in other countries, governments have either issued licences in this way, or at least threatened to issue licences during negotiations with drug companies for lower medicine prices or better guarantees of supply.

### Compulsory licensing

Section 56 of the Patents Act allows “any interested person” to apply to court for a compulsory licence. But section 56 may be used only when it can be shown “that the rights in a patent are being abused” – in other words, not for

any “public purpose”. This makes it more difficult to use, because patent abuse is often difficult to prove and is sometimes defined quite narrowly by courts.

### BARRIERS TO THE USE OF SECTION 56

There are two barriers that must be overcome before a licence can be issued under section 56:

- *First, the applicant must be able to show an interest.*

With medicines, this is usually satisfied by showing that you are in the business of drug manufacture or import. Thus the “interested person” test cannot be satisfied by a civil society organisation that has an interest in ensuring that licences are issued, but does not actually produce or import generic medicines.

- *Second, the applicant must show that the rights in a patent are being abused.*

Section 56(2) sets out a number of examples that are considered abusive, for example, if the patent holder is not satisfying demand on “reasonable terms” – in other words, is charging an excessive price for the patented product. It is unclear whether this is a closed list, or whether the applicant may still get a licence if it can prove that the conduct of the patent holder is abusive in some unlisted way.

Section 56 is what many people refer to as TRIPS+, meaning that it provides greater patent protection than TRIPS requires. It is also not user-friendly for people affected by lack of access to medicines. However, in South Africa there is one example where section 56 has been used to help secure voluntary licences for the importation of generic medicines.

### CASE STUDY: VOLUNTARY LICENCES

In 2003, the Generic Antiretroviral Procurement Project and the TAC Treatment Project threatened to sue Boehringer Ingelheim under section 56 in order to acquire compulsory licences to import generic nevirapine products. To avoid litigation and perhaps the grant of the first court-issued compulsory licence, Boehringer Ingelheim agreed to issue royalty-free licences to the two projects.

### Bolar amendment

The Bolar amendment gets its name partly from the US Court of Appeals for the Federal Circuit case of *Roche Products, Inc. v Bolar Pharmaceutical Co.* This case decided that testing of a medicine for the purpose of drug regulatory authority approval could not take place before the patent had expired.

As a result, in 1984 law-makers amended patent legislation to allow generic companies to complete all drug registration requirements for their products without infringing existing patents. Similar provisions are found in many other countries and have, since early 2000, been recognised by the World Trade Organisation (WTO) as justifiable “limited exceptions to the exclusive rights conferred by a patent”.

Yet it was not until January 2003 that South African law was similarly amended and section 69A of the Patents Act came into force, stating that:

*“It shall not be an act of infringement of a patent to make, use, exercise, offer to dispose of, dispose of or import the patented invention on a non-commercial scale and solely for the purposes reasonably related to the obtaining, development and submission of information required under any law that regulates the manufacture, production, distribution, use or sale of any product.”*

#### Key Points: What generic companies can do while waiting

A Bolar provision allows a generic company to take all necessary steps to register drugs with the MCC, although local production of the drugs can only begin after patent expiry. This means that:

- Even if the patent has not expired, or the generic company has not been able to secure a licence, it may nevertheless register its products with the MCC.
- However, if it sells these medicines before patent expiry or without a voluntary or compulsory licence, the patent holder may still sue for patent infringement.

By registering their medicines early, generic companies make sure that they can start selling their products as soon as patents expire or licences are issued. This prevents additional delays caused by lengthy registration.

Registration may provide an added incentive to courts or government to grant compulsory licences if they can see that doing this will result in greater access to affordable medicines.

#### State acquisition of patents

Section 78 of the Patents Act allows the Minister of Trade and Industry to acquire a patent “on behalf of the state ... on such terms and conditions as may be agreed upon”.

At first, this provision seems quite useful. If the government acquires a patent on an essential medicine, it would be free to issue royalty-free licences to generic companies for local production and importation. In this way, sufficient competition could be created to bring prices down.

The problem is that the state may acquire a patent only if the patent holder agrees, as the section 78 power is not an expropriation power. This is unlikely to happen in cases where a patent remains profitable and where the patent holder is not willing even to grant voluntary licences. This is because, in the case of licensing, the patent holder still retains its right to market the product, as well as to receive royalty payments. But once the patent has been acquired by the state, the right to market disappears and no royalty payments are due.

Section 78 would be a more effective regulatory mechanism if it allowed for a court to set the terms and conditions of the acquisition when there is a dispute. At the moment, section 78 is used when patented drugs are not profitable to manufacture. Then the patent holder may allow the state to acquire the patent to manufacture the medicine itself or find a company that is willing to do this, perhaps with state subsidies.

## The Competition Act

South Africa's Competition Act is mainly intended to regulate certain aspects of economic activity in South Africa. It aims to promote and protect competition between companies in the interests of the consumer and in order to promote economic growth. However, at least two cases have shown that competition law may also be a way to challenge the abuse of patent rights and in this way to increase access to essential medicines.

But law in this area is still relatively undeveloped. This means that we do not yet know exactly how and in what way the Act can be used. In addition, one of the most controversial aspects of competition law is its relationship with patent law. This is because patents are, by definition, anti-competitive, with the patent holder having a right to exclude competition.

Therefore most experts agree that:

- The exercise of rights in a patent does not automatically give rise to what the law recognises as "anti-competitive".
- A patent holder would have to abuse the rights in the patent before competition law has a role to play.

There are two key types of regulatory mechanisms in the Competition Act that control the exercise of rights in a patent:

- The Act prohibits the "*abuse of dominance*".
- The Act prohibits what are called "*restrictive practices*".

A third important area of competition law – *merger control* – has specific implications for the issue of access to essential medicines. This is more relevant to the regulation of the private health sector.

For information on merger control, see Chapter 6 on page 188.

### **Complaint system**

The Competition Act sets up a special forum for handling competition complaints. A complaint is filed first with the Competition Commission, an independent investigative body. The Commission must investigate the complaint and, within a year, must refer the case to the Competition Tribunal if it thinks that the law has been broken. If the Commission does not refer the case, the complainant may refer the case to the Competition Tribunal independently.

In many ways, this process resembles the way that criminal cases are prosecuted in the ordinary courts. After a survivor of crime has made a complaint (laid charges), the Director of Public Prosecutions must decide whether to prosecute. If the state decides not to prosecute, a complainant may prosecute privately. This is, however, seldom done.

Once a complaint has been referred, the Competition Tribunal, acting in many ways like a court, will decide on the merits of the case and make an appropriate order. Decisions of the Tribunal may be taken on appeal to the Competition Appeal Court. Decisions of that court may be taken on a further appeal to the Supreme Court of Appeal, or the Constitutional Court, if they raise constitutional issues. Such appeals can take place only if those courts agree to hear the matters.

In addition, decisions of the Commission, Tribunal and Competition Appeal Court may be taken to the High Court on review. Reviews focus on the fairness of the procedures adopted instead of the correctness of the decision.

### **Abuse of dominance**

Competition law recognises that companies may, for a range of reasons, dominate a particular market. In the pharmaceutical industry, market dominance is often closely related to patent protection. Nevertheless, the existence of patent protection does not automatically translate into market dominance. For example, one company may be a supplier of a patented drug for the treatment of a particular illness, but other companies may have

other patented drugs that work equally well for the same disease. When this happens, there may be competition between the different medicines, with no single product dominating the market.

When it can be shown that a company is dominant in a particular market, the provisions dealing with abuse of dominance come into effect. In general, the provisions recognise that being dominant is itself not a problem – it is a problem only when the dominance is abused by, for example, setting excessive prices. This is very similar to the concept of abuse of rights in a patent under the Patents Act.

#### Key Points: Different abuses

Sections 8 and 9 of the Competition Act recognise three broad types of abuse that are relevant to access to medicines. These are:

- Excessive pricing, or charging prices that cannot be objectively justified.
- Refusing to licence generic manufacturers.
- Engaging in prohibited price discrimination.

### CASE STUDY: EXCESSIVE PRICING OR CHARGING PRICES THAT CANNOT BE OBJECTIVELY JUSTIFIED

In 2002, a range of individuals and organisations laid a complaint against two multinational pharmaceutical companies, GlaxoSmithKline and Boehringer Ingelheim, alleging that they were abusing their market dominance by charging excessive prices for their patented ARV medicines. This case is known as the Hazel Tau case.

The complainants argued that the prices charged by GlaxoSmithKline and Boehringer for certain ARV medicines could not be justified – even when taking into account the costs of production, research and development, and an appropriate rate of profit. The Competition Commission investigated the case and found solid evidence to support the complaint. It therefore decided to refer the complaint to the Tribunal on three grounds, including prohibited excessive pricing.

In order to avoid a final legal decision on this issue, GlaxoSmithKline and Boehringer entered into an out-of-court settlement with the complainants. They agreed to license generic competitors to manufacture and/or import generic ARV medicines, and to sell those medicines that were manufactured locally throughout most of Africa. This competition has resulted in lower prices for the ARV medicines in dispute.

### REFUSING TO LICENCE GENERIC MANUFACTURERS

The Act says that one example of an abuse of dominance is “refusing access to an essential facility when it is economically feasible to do so” (section 8(b)).

In the Hazel Tau case, the Competition Commission suggested that a voluntary licence was an “essential facility” because competitors, who were in all other respects capable of making the medicines, could not do this without a licence. This reinforced the argument made by some analysts that this ground can be used in certain circumstances to force a patent holder to license certain essential medicines. In general, however, a patent holder does not abuse a dominant position simply by refusing to license competitors.

## ENGAGING IN PROHIBITED PRICE DISCRIMINATION

In practice, price discrimination generally means charging excessively low prices in one sector or market to limit or exclude competition. This form of abuse is less likely to take place when products are still under patent, because the patent itself already excludes competition.

Price discrimination may also take place when a company deliberately charges excessively low prices to drive competition out, and this is followed by sudden price hikes once the competition has been destroyed. This is also known as “predatory pricing”.

## Restrictive practices

Section 4 of the Competition Act prohibits restrictive practices. A restrictive practice refers to conduct between companies who would normally be competitors that is intended to exclude other competitors and is not in the public interest because it usually leads to high prices.

### Key Points: Prohibited restrictive practices

There are two types of restrictive practices that are prohibited. These are:

- Between companies or people in a *horizontal relationship* – a relationship between competitors.

## CASE STUDY: COMPLAINT TO COMPETITION COMMISSION

In 2003, the TAC complained to the Competition Commission that members of the National Pathology Group, a number of private companies providing essential laboratory services such as blood tests, had agreed to set particularly high prices for their services. By acting as a “cartel”, a group of service providers ensure that there is no price competition in the market, resulting in artificially high prices. TAC’s complaint was investigated but the Commission decided not to refer it to the Tribunal as aspects of it had been superseded by the resolution of other complaints regarding health providers. Despite this, the complaint contributed to greater transparency by members of the NPG in setting prices. See Chapter 6 for more detail.

■ Between parties in a *vertical relationship* – a relationship between a company and its suppliers, or between a company and customers.

So what type of conduct is prohibited? In general, these are agreements or practices between competitors that have the effect of preventing or lessening competition. Section 5 of the Act focuses on agreements and practices between parties in a vertical relationship that have a similar effect.

#### Example: A potentially restrictive merger

In 2003, the merger between Aspen Pharmacare, a generic drug manufacturer, and Fine Chemicals Corporation, a producer of active pharmaceutical ingredients, was referred to the Competition Commission for approval. This was an example of a large generic manufacturer deciding to purchase the only manufacturer of active pharmaceutical ingredients (APIs) in South Africa.

The AIDS Law Project submission on the proposed merger drew attention to the potential dangers of this type of “vertical integration” which could result in limiting access to APIs for other generic manufacturers. But it was also explained that, since most local manufacturers were not reliant on Fine Chemicals Corporation as their supplier of APIs, the proposed merger was unlikely to restrict competition.

In this instance the merger offered Aspen Pharmacare the opportunity to become more competitive internationally, meaning that it could increase its sale volumes and thus reduce its costs. This could lead to cheaper prices in South Africa.

The merger was conditionally approved.

## The Trademarks Act and Copyright Act

While patents are the main tools used by drug companies to prevent generic medicines reaching the market, two other forms of intellectual property have also been used. These are trademarks and copyright.

### Trademarks

According to the Trademarks Act 194 of 1993, a trademark is:

*“a mark used or proposed by a person in relation to goods or services for the purpose of distinguishing the goods or services in relation to which the mark is used or proposed to be used from the same kind of goods or services connected in the course of trade with any other person”.*

A trademark thus indicates the *origin of the goods or services*. Well-known examples of trademarks include:

- Nike's "swoosh" symbol.
- McDonald's golden arches in the shape of the letter "M".
- The brand names of medicines such as Combivir and Panado.

It will be interesting to see how courts in future rule on other cases dealing with the size, shape and colour of tablets. In an era of generic substitution and public sector ARV treatment programmes, it will make it easier for people to adhere to their pill regimens if all versions of a particular medicine, whether branded or generic, look the same.

#### CASE STUDY: CAN THE SHAPE OF A MEDICINE BE A TRADEMARK?

The 2003 case of *Beecham Group v Triomed* 2003 (3) SA 639 (SCA) (the Triomed case) dealt with an off-patent antibiotic marketed by SmithKline Beecham (now GlaxoSmithKline) under the trademark Augmentin.

The case focused on whether the shape of the Augmentin tablet could also be protected by trademark. Triomed markets a generic version of the drug called augmaxcil that has the same shape and colour (white) as Augmentin. The only physical difference between the tablets is that Augmentin pills have the word "Augmentin" on one side, whereas augmaxcil tablets are blank.

The Pretoria High Court granted an order correcting the Trade Marks Register by removing the shape trademark as it had been incorrectly granted. On appeal, SmithKline Beecham wanted the Supreme Court of Appeal (SCA) to confirm the registered trademark for the shape of the tablet and to decide that Triomed was infringing the trademark.

However, the SCA ruled in favour of Triomed, and said:

- "Pharmacists do not buy or dispense drugs by way of shape." (paragraph 15)
- "No pharmacist will regard the shape alone as a guarantee that the tablet comes from ... (SmithKline Beecham)." (paragraph 24)

In addition, the SCA ruled that there were very good technical reasons why the particular shape was so often chosen – "for ease of swallowing, coating and the prevention of crumbling".

## Copyright

Copyright is another form of intellectual property protection. It prevents the copying of *original* works, such as musical compositions or books, without the permission of the author.

Since the Biotech case decision (see table on next page), the new General Regulations (2003) promulgated under the Medicines Act have replaced the earlier framework that was used in the Biotech case. Today, an applicant for

registration no longer “has to submit with its application a package insert in the format stipulated”. Instead, General Regulation 9 says that “each package of a medicine shall be accompanied by a package insert”.

This means that the MCC may regulate its own process for the drafting of package inserts. The MCC now authors the package inserts on the basis of information supplied by the applicants for registration. In this way, copyright rests with the state, and there is uniformity of package inserts for all versions of the same medicine, whether brand name or generic.

#### CASE STUDY: CAN A PACKAGE INSERT BE PROTECTED BY COPYRIGHT?

In 2002, another case involved the antibiotic Augmentin, this time in a dispute about whether a generic company was infringing the copyright by copying the package insert.

This was obviously significant for access to medicines because, without a package insert, a medicine cannot be registered for use. A *package insert* deals with issues such as the scheduling status of the medicine, its dosage form, and its indications and contra-indications. If a generic company is excluded from the market in this way, it means less competition and possibly higher prices for consumers.

In *Biotech Laboratories (Pty) Ltd v Beecham Group* 2002 (4) SA 249 (SCA) (the Biotech case), the SCA confirmed the High Court’s granting of an interdict to prevent a generic company from copying SmithKline Beecham’s Augmentin package insert. The Court decided that the package insert was an original work and that it had been copied by Biotech for the purposes of registering its antibiotic Bio-Amoksoklav.

In the appeal, the MCC made it clear that the public interest is best served by standard package inserts for different versions of the same medicine. Biotech’s appeal would not have been successful if the Court had decided that the state “owned” the copyright. But the SCA ruled that, although the MCC played a key role in developing the package insert:

- The package insert had not been made by or under the direction or control of the state.
- The MCC had merely acted as editor and not as author of the package insert in question. Because of this, the copyright did not rest with the state, but rather with SmithKline Beecham.

## 14.5 Drug procurement and supply sustainability

This chapter has already explained the role that is played by patent protection in artificially keeping medicine prices high. But affordability is not the only measure of access. The availability of medicines also matters.

For example:

- A single drug manufacturer may not always be able to supply the quantities of a particular medicine that are needed.
- A sudden outbreak of a disease may use up all available stock. Producing or importing more supplies may take time, and lives may be lost as a result.
- A product recall as a result of certain manufacturing problems in a specific batch of medicines could empty all shelves of that drug. The medicine would remain registered for use, and there might still be demand for the drug, but it would not be possible to guarantee supplies.

There are a number of ways that policy or laws may threaten the sustainability of medicine supply. This might include laws that unjustifiably restrict the practice of dispensing medicines, or poor administrative systems resulting in limited supplies.

In this section, we focus on three key challenges for the government:

- Ensuring a multiplicity of suppliers.
- Ensuring the viability of all aspects of the supply chain.
- Adopting and implementing a flexible approach to state procurement.

## Ensuring a multiplicity of suppliers

The problem of sustainability of medicine supply is made substantially more challenging when dealing with a public health crisis, like HIV/AIDS or TB, that requires ongoing access to medicines for chronic treatment.

ARV treatment for HIV/AIDS requires the taking of at least three different drugs, once, twice or three times daily. Without a sustainable supply of these drugs, people on treatment might miss taking a dose (or usually more), or be forced to change their treatment regimens. Either way, this might limit their future treatment options and compromise their health.

Generally, patent systems allow for the issuing of a compulsory licence when the patent holder fails to satisfy demand. If a government can prove that demand has not been satisfied, then market exclusivity may be broken. Other legal frameworks, such as those dealing with medicine regulation and competition policy, sometimes also address this problem.

But governments should not wait for problems to occur, as this will be too late for many. Governments should be proactive in dealing with threats to the sustainability of supply. This is crucial when planning major public sector programmes that make use of chronic treatment regimens. Governments should pass and use laws allowing them to guarantee sufficient supply.

One way to ensure sustainability of supply is by striking an appropriate balance between local production and importation:

- Sole reliance on imports may be problematic when demand for the medicines in the country of production may be large, or in cases where unstable exchange rates suddenly make imports too expensive.
- In countries such as South Africa with a relatively weak local manufacturing industry, capacity for local production is limited.
- Limited capacity may also mean limited competition, resulting in unaffordable products. This is why creating capacity to manufacture medicines locally is an important part of industrial policy.

#### CASE STUDY: AVIAN INFLUENZA AND TAMIFLU

Even though there has not been a single case of the H5N1 strain of bird flu being transmitted between humans, nor conclusive proof about the efficacy of the antiviral drug oseltamivir (marketed by Roche as Tamiflu) for the treatment of the disease, developed countries have been quick to ensure that the relevant patents do not stand in the way of sustainable supplies of the medicine. Under incredible pressure, Roche has already agreed to license numerous generic suppliers to ensure that stockpiles of oseltamivir can be – and indeed are being – produced.

### Ensuring the viability of all aspects of the supply chain

In taking steps to reduce or keep medicine prices down, governments need to strike an appropriate balance between affordability and availability. Or put in another way, effective price regulation (whether direct or indirect) should not come at the expense of the viability of any essential part of the medicine supply chain.

In a market-based economy where the state does not manufacture drugs, or where state provision of medicines does not reach all who need them, the viability of the various private sector components in the supply chain must be protected. This principle was affirmed by the two highest courts in South Africa in the recent PSSA case dealing with pharmacists' dispensing fees.

For example, if manufacturers are forced to lower the price of their medicines too far, they may simply choose not to register or sell their products in South Africa. This may result in particular medicines becoming unavailable. Although this could open up the door to generic competitors, if all manufacturers are

forced to sell below cost, price controls may result in no access at all. The dangers of over-regulation are thus very clear.

## Adopting and implementing a flexible approach to state procurement

In a developing country such as South Africa, most people rely on the public sector for the provision of essential medicines. Therefore, the way that the state buys or obtains medicines may have a significant impact on their availability.

### Key Points: Competing interests

State procurement needs to be flexible in balancing three potentially competing interests:

- Industrial policy – this may include the strengthening of the domestic pharmaceutical industry and the promotion of black economic empowerment (BEE).
- The need to act speedily and often urgently.
- The need for accountability and transparency.

Very often, too much focus is placed on one or two of these interests at the expense of the others.

### CASE STUDY: PROCUREMENT UNDER SOUTH AFRICA'S OPERATIONAL PLAN

In November 2003, the Cabinet adopted South Africa's *Operational Plan for HIV and AIDS Comprehensive Care, Management and Treatment*. The Operational Plan identifies ARV treatment as one of the key interventions to be made available in the public health system to people qualifying after relevant clinical assessment.

Despite the urgent need to begin providing ARV treatment at public health facilities with sufficient capacity, initially the government decided to procure medicines solely through a formal tender process, even though the law did not require this. By its very nature, this process is not able to deliver with speed.

As a result, the TAC and the AIDS Law Project began taking steps to compel the Minister of Health to use an interim mechanism for the procurement of ARV medicines while waiting for the finalisation of the formal tender process. This speedier approach is allowed by South Africa's regulatory framework that provides flexibility when there is a need to act urgently, or it is impractical or impossible to follow a formal tender process.

Faced with the threat of legal action, the Minister agreed to allow provinces to procure interim supplies of ARV medicines pending the finalisation of the formal tender process. Consequently, a number of provinces began to provide ARV treatment in April 2004. The slowness of the formal tender process is shown by the fact that it was only in February 2005, more than 15 months after the adoption of the Operational Plan, that formal contracts for the supply of medicines were announced.

## 14.6 Where do we go from here?

This chapter has set out why drugs are usually so expensive, how sustainability of supply may be threatened and how government, civil society and generic drug manufacturers can use the current legal framework to increase access to medicines. In addition, we have considered what other regulatory mechanisms are available to law-makers and government officials to ensure that medicines are accessible.

While much can be and has been done with the existing framework, further changes to South Africa's laws are needed to ensure a sustainable supply of affordable medicines. This is not only desirable, but also a constitutional requirement. The Constitution places a duty on the government to take *all* reasonable steps to put in place and make use of a legal framework that facilitates increased access to medicines. It has to do this whether or not it decides to provide certain essential medicines free of charge in the public health sector.

Only time will tell whether the government will take the initiative, or whether it will once again be up to civil society to force the government to take its duties seriously.