

## 5 Increasing access to medicines

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As has been demonstrated in the previous chapter, access to medicines in many less developed countries is extremely low. According to the WHO, an estimated 30 per cent of the world population lacks regular access to existing drugs, with this figure rising to over 50 per cent in the poorest parts of Africa and Asia (WHO, 2003). As chapter 4 has also shown, there is some concern that certain diseases unique to less developed countries do not represent a viable commercial prospect for would-be innovators of new medicines, resulting in a shortage of appropriate treatments. Citing this alleged ‘market-failure’ as justification, some have proposed alternative mechanisms to the commercial R&D paradigm in order to stimulate research into these areas.

This chapter examines some of the factors that prevent existing medicines from being distributed in the most effective manner, as well as those elements of governance which actively undermine the supply of new medicines.

We begin with a description of the major barriers to access, which include weak healthcare systems, taxes on imported medicines, and poorly functioning insurance markets. We then examine several related issues, including the impact of poor government policy on the supply of medicine and the impact of pre-market regulations and price controls.

## **Weak healthcare systems**

Healthcare systems and associated infrastructure are vital for the effective distribution of medicines. If healthcare systems are starved of resources, it is unlikely that they will be able either to procure necessary drugs or be able to employ sufficient numbers of doctors and other trained personnel necessary to prescribe and administer medicines.

The majority of low-income countries lack the basic infrastructure required to distribute medicine successfully. Road networks are often unreliable or non-existent, making it difficult to ensure a constant supply of medicines to remote areas (Saleh & Ibrahim, 2005). Electricity is often unavailable, especially in rural areas; where it is available, it is often supplied in an erratic fashion. This increases the cost and difficulty of running refrigeration systems in clinics and hospitals. As a result, vaccines are often not maintained at sufficiently low temperatures to ensure product stability. Protease inhibitors (used in second-line ARV treatments) are one example of a drug that needs to be refrigerated (Kumarasamy, 2004), yet due to erratic power supplies and other issues, it is impossible to ensure constant refrigeration in the world's poorest countries.

In this situation, it is extremely difficult to ensure the distribution of the safe and effective medicines that have already been developed to tackle the diseases of poverty. For example, a relatively effective treatment for tuberculosis is Directly Observed Therapy Short Course (DOTS), which requires between 6 to 8 months with close patient monitoring to ensure compliance. ARV treatment for AIDS sufferers also requires close supervision over the lifetime of the patient. Even in the relatively efficient health care systems of high-income countries, maintaining adherence to HAART (Highly Active Anti-Retroviral Therapy) treatment during clinical trials is fraught with complexity (Kumarasamy, 2004). Achieving such adherence in poor countries with weak health care systems is practically impossible.

Intervention by global public health authorities and the provision of public funds is not a guarantee that existing medicines will

be effectively distributed. Consider the example of malaria, discussed in the next chapter: despite the establishment of the Roll Back Malaria initiative and the injection of specific funds, the most modern and potent anti-malarial drugs were still not being correctly used six years after the initiative began (Attaran, 2004).

Weak healthcare systems do not simply result in a failure to distribute existing treatments. They also have a knock-on effect for the demand for new drugs, and can act as a serious disincentive to would-be innovators of new medicines. If a product is unlikely to reach its intended market, what is the point of developing it in the first place? Well-equipped and properly staffed modern medical facilities are adept at disseminating the latest medical tools and drugs (Dussault & Dubois, 2003). Conversely, inefficient distribution and communications channels have an adverse effect on the speed with which new medicines reach patients, if they reach them at all (Gambardella et al., 2000).

Frequently, public spending and foreign aid injections into national health systems do not translate into the delivery of services and medicines to the poor. A multi-country study by Filmer and Pritchett (1999) showed that public spending on health in lower-income countries has only a minute impact on mortality. The authors showed that a significant proportion of deaths of children below five years could be averted for as little as US \$10 each, yet even in the poorest countries, the average amount spent by governments per child death averted is a staggering US \$50,000–\$100,000.

There are many reasons for this low level of performance. First, public health agencies tend to be woefully inefficient and corrupt, especially in lower-income countries. As a result, the proportion of a donor's contribution that actually results in delivery of healthcare services (whether they are vaccines or nurses' salaries) is often very low. Health officials may sell aid-financed drugs on the black market. Studies in Guinea, Cameroon, Uganda, and Tanzania estimated that 30 to 70 per cent of government drugs disappeared before reaching the intended patients (Filmer, Hammer & Pritchett, 2000).

Second, social programs nominally targeted at low-income groups are frequently captured by the articulate and influential rich (Deolalikar, 1995; Castro-Leal et al., 1999; Barat et al., 2003).

Third, public funding and provision can crowd out private funding and provision of healthcare. If a government starts to provide a good or service for 'free', this is a clear signal to private providers to exit the market. The net amount of healthcare provided may remain constant – but where there was once diversity of provision, there is now an effective monopoly, which has its own efficiency problems. As a result, public funding and provision typically has little to no impact on actual health outcomes (Filmer, Hammer & Pritchett, 2000).

### **Case study: How the South African health system hinders access to medicines**

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The experience of the South African public health system offers some insights as to why 20 per cent of the country's population is unable to access essential medicines (UN, 1999).

At the outset it should be made clear that there are two distinct and separate health sectors in South Africa. The dichotomy is largely a hangover from past policies formulated under the apartheid regime. On the one hand the private health sector provides a world-class health service, with excellent facilities, advanced technology, well-remunerated staff and good access to all medicines. On the other hand the public sector is plagued with inefficiency and for the most part South Africa's public health care system struggles to meet the needs of the patients it is supposed to be serving. The result is that patients seldom receive the level of care that they deserve.

The South African government receives medicines at substantially reduced costs from large multinational pharmaceutical companies. However, historic and ongoing lack of infrastructure, personnel and poor logistics means that frequently the medicines do not reach those for whom they

were intended. Furthermore, those that do have access to public sector health facilities usually end up queuing for hours, and are often turned away, trying to get even the most basic medicines. Not surprisingly, in 2000 the World Health Organisation (WHO) ranked South Africa's health-care system 175th out of the 191 member countries.

There is also a great deal of theft in public hospitals. For instance, in Mpumalanga province, 46 medical professionals ended up behind bars in the first two months of 2003, charged with the theft and resale of government medicines meant for the rural poor in Mpumalanga. Those arrested included a manager of a rural hospital, doctors, pharmacists and medical technicians as well as a syndicate of 'bag men' who delivered stolen drugs, including birth control pills, pain killers and antibiotics, to private doctors.

The medicine shortages caused by the syndicate's medicine thefts reportedly prevented routine operations from being performed, and complicated the day-to-day treatment of patients at the Rob Ferreira and Themba hospitals in Nelspruit, the capital of Mpumalanga.<sup>14</sup> The extent and nature of theft and corruption in the public health system reinforces the severe shortcomings in hospital management, administration and control systems.

The South African drug regulator, the Medicines Control Council (MCC), is notoriously inefficient and tardy with its approval process. On average, drugs that have already been registered for use in the US, EU and Japan can wait for 39 months to be approved by the South African system. A further barrier to access in South Africa is Value Added Tax (VAT). The SA government continues to charge VAT on pharmaceuticals despite the fact that the tax is highly regressive since it disproportionately affects the poorest members of society.

If the South African government is serious about increasing access to medicines to the poorest of the poor, then they will

waive VAT on all medicines. VAT is counter-intuitive in the sense that if one of government's primary objectives is to have a healthy and productive workforce, surely it does not want to tax the sick and vulnerable. The VAT received by government on pharmaceuticals is relatively insignificant. However sick people could use the money that would have been spent on VAT for a number of beneficial alternatives, including food.

According to the latest estimates by the official government statistical agency, Statistics South Africa (SSA), approximately 26 per cent of the South African labour force is unemployed. If discouraged work seekers are also included, this figure jumps to approximately 41 per cent. The consequence of mass unemployment is that there are large numbers of individuals that currently live in extreme poverty. Indeed, it is estimated that there approximately 5 million people in South Africa live on less than a dollar a day. Therefore, it is not unreasonable to assume that many of them simply cannot afford to buy even basic pharmaceutical drugs. While the government claims to take responsibility for the health care of the indigent, it is obviously not capable of meeting unlimited demands.

How do we remedy this situation? In the long run, the only way to increase access to medicines is through increasing the wealth of the citizens of a country and this is only possible through economic growth. In the short term, the government can substantially improve its distribution of drugs by privatising the distribution process and reduce waiting times by simply approving drugs that have already been approved for use in developed countries. Finally, the South African government's preferred policy of price controls will not increase access. On the contrary, it will simply reduce supply by eroding the incentives of potential suppliers.

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## Taxes and tariffs

Many governments of lower-income countries compound the problem of weak healthcare systems by imposing a range of taxes on medicines, including port charges, central, regional and local taxation, as well as import tariffs and VAT. Other government-imposed measures or regulations may include pre-shipment and inspection costs, and pharmacy board fees. Taken together, these add significantly to a drug's retail price, with negative consequences for access to medicines, especially for the poorest.

In a survey of nine countries, Levison and Laing found that that costs resulting from government policy or regulation added an average of 68.6 per cent to the cost of imported pharmaceuticals (Levison & Laing, 2003).

### Why Do Governments Tax Medicines?

Given the massive negative impact of local price inflators on the cost of medicines for the poor, it must be asked why governments choose to implement such policies. There are two main reasons: to protect local industry and to raise revenue.

*Protection of local industry.* In some cases, policies are designed to protect domestic industry, without little if any regard for how this may affect citizens. Both Levison (2003) and the European Commission (2003) observe that Nigeria, Pakistan, India and China all have significant local industries and are included in the group of countries with the highest import duties. Opponents of tariff removal support this policy, suggesting that reducing or abolishing tariffs could undermine the domestic industry which relies on high import barriers to survive. This argument is somewhat tenuous, as very few low-income countries – other than those listed above – have indigenous pharmaceutical industries of any significance. At any rate, industry

protection via tariffs often leads to entrenched inefficiencies and results in expensive, poor quality products.

*Income Generation.* Taxes and tariffs generate revenue for the government. In some very poor countries, import tariffs in general represent an important source of income for governments where collection of other sorts of taxes is difficult. However, tariffs on medicines are rarely a significant source of revenue.

### **Taxes and tariffs under the microscope**

Tariffs are often a particularly important factor in determining the end-user price of pharmaceuticals in low-income countries (Bate et al., 2005). A 57-country study conducted on behalf of the European Commission in 2003 examined taxes and tariffs on pharmaceutical products used in the treatment of communicable diseases.<sup>15</sup> The study found that the countries that apply the highest tariff rates include Nigeria, Pakistan, India and China (European Commission, 2003). As a result, large sections of the populations of these countries are being priced out of treatment by their own governments.<sup>16</sup>

Another disturbing government levy on pharmaceuticals is value added tax (VAT). VAT is a revenue-raising instrument that can exist at several levels of the political system, and may be applied to different classes of products, or certain sectors (Levison & Laing, 2003). The European Commission (2003) found that VAT was imposed on pharmaceuticals at average rates of over 12 per cent.

Table 2 shows the combined impact of taxes and tariffs (customs duty + VAT + other duties) on the retail price of medicines in selected poor countries. The global average is 18 per cent, with Malaysia having the lowest rate (0.01 per cent) and India the highest (55 per cent).<sup>20</sup>

By driving up the cost of medicines, these taxes and tariffs price the poorest people out of the market for life-saving treatments.



Table 2 **Duties and taxes on retail medicines***Country Combined total duties and taxes*

India	55%
Sierra Leone	40%
Nigeria	34%
Pakistan	33%
Bolivia	32%
Bangladesh	29%
China	28%
Jamaica	27%
Morocco	25%
Georgia	25%
Mexico	24%

Table adapted from European Commission, 2003.

They are regressive because they adversely affect the poor and the sick. Such government policies effectively impose a wedge between the demand for drugs and their supply. In markets where profit margins are already low, drug companies have fewer incentives to supply their existing products, much less to innovate new products specifically aimed at these markets. As Levison (2003) observes: “Economically...tariffs impede the action of a competitive market where the best drug will achieve the best price and [they] protect inefficient [local] producers who charge high drug prices.” (Appendix Figure 2 shows how taxes restrict the demand for medicines.)

### **Non-tariff barriers**

Beyond visible barriers such as tariffs, manufacturers wishing to export to overseas markets often face significant hurdles and complexity in registering their products. These tend to emanate from local drug approval agencies, and often appear to be designed to protect local industry rather than achieving better outcomes for patients.

Some examples of such non-tariff barriers are the following:

- ◆ *Harmonisation.* Certain countries are guilty of requiring importers to attain standards higher than those required by relevant trade bodies, often without any scientific justification.
- ◆ *Transparency:* Many countries fail to provide adequate information regarding the regulations and procedural norms concerning methods of sampling, inspection and testing of drugs. New regulations are often introduced without giving the producers in exporting countries an opportunity to understand and/or comply those regulations. Often the standards are available only in the language of the importing country or are presented in a very complicated manner. As a result, exporters lack clear guidance about the specific requirements, which can lead to rejection at the point of import.
- ◆ *Conformity assessment issues:* Importing countries may require testing to occur at a single location which may be at an inconvenient location, adding an additional burden of cost and time. Certificates may have limited validity, requiring frequent re-testing, while on occasion importing countries may not recognise the certificates of international bodies.
- ◆ *Marketing restrictions:* Often, importing countries require their own standard of labeling on products, which can be cumbersome to exporters from lower-income countries who are trying to export to a range of different countries, all with different criteria.
- ◆ *Restrictions on port of entry:* Several countries allow imports only through designated ports, which increases transit times and transaction costs.

One example is South Africa's Medicines Control Council (MCC), which requires that all new medicines must attain its own regulatory approval before they can be marketed in the country – even if they have already been approved by reputable foreign regulatory

bodies such as the US FDA. However, the extreme inefficiency of the MCC means that drugs which have already been registered for use in the US, EU and Japan wait an average 39 months for approval in the South African system.

Another example comes from Namibia, which announced in 2002 that all medicines registered in the country prior to independence (1990) should be re-registered (Bate et al., 2005).

The low purchasing power of the majority of citizens in poor countries means they do not constitute significant markets for foreign manufacturers. In the face of such non-tariff barriers, companies will often forego the regulatory complexity and expense of registering their products in that country (and will instead invest their resources elsewhere). The result is that fewer medicines are approved – even when they are desperately needed – and there is a lower level of local competition in the marketplace which would otherwise drive prices down and increase access.

To make matters worse, many governments now adopt the WHO's list of 'essential medicines' as the basic formulary, denying their citizens access to medicines not on the list (see Box).

### **WHO Essential medicines list**

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If poor people in the U.S. and the EU had access only to the limited range of options on the World Health Organization's Model List of Essential Medicines (EML), most doctors would denounce that situation as unacceptable. So, too, would most healthcare workers in other developed countries around the world. Why then has no one questioned the rationale behind the WHO's List of Essential Medicines – frequently the authority that dictates the drug selection process for many health Ministries in poorer countries?

The WHO EML represents the most comprehensive

international compilation of essential medicines for public health. The list was compiled beginning in 1975, in the wake of World Health Assembly's decision to focus on high quality, reasonably priced essential medicines. Since it was first published in 1977, the WHO EML has ostensibly aimed to provide for the majority of people worldwide affordable, safe and effective medicines for most of their health needs.

The first model list identified 208 individual drugs and since then multiple deletions and insertions have been made. Drugs can be removed from the list if their safety is found to be questionable following the appearance of new data.

Despite this, the concept of the EML is ill-fitted to the myriad health needs of people in lower-income countries. Diseases such as diabetes, hypertension, cancer, cardiovascular disorders, gastrointestinal disorders, dermatological disorders and arthritis are just as common in Africa as in developed countries. Yet the WHO Essential List of Medicines does not provide medical practitioners in Africa with sufficient choice for dealing with these diseases.

Medical practitioners are well aware that each individual responds to medicine in a unique way. An anti-anginal medicine such as Verapamil produces a range of different results in any given population. It may not work in one individual who suffers from anginal disorder yet it may produce good results in another individual who has very similar symptoms. So why recommend only a few products as 'essential' if we know that different people respond differently to the very same drug product?

Unfortunately, in Africa, if your disease cannot be treated with any of the drugs on the WHO List of Essential Medicines, you are simply out of luck. You need to go outside the essential list to get relief, but that may not be possible. Most African health ministries have adopted the

WHO guideline as their approach to healthcare, making it all but impossible to obtain the most appropriate drugs. This approach is irrational, and is not good for public health.

The African healthcare crisis extends beyond the highly publicised problems of HIV/AIDS and malaria. Although the international community has paid little attention, hypertension and diabetes are also widespread in Africa, and the combined number of deaths from those two diseases nearly equals the toll from HIV/AIDS.

When it comes to treating those diseases, however, Africans have limited options. Even those who can afford drugs that are not on the EML do not have the opportunity to do so. That is because most African governments allow the importation of only those drugs that are on the list. When it comes to drugs for hypertension, for example, there are only six drugs on the WHO list. If one of those six listed drugs cannot control an African's hypertension, he or she will die because no other hypertension drugs are registered for sale in that country.

The disease burden in lower-income countries is coming increasingly to resemble that of higher income countries, especially in terms of cardiovascular diseases and cancers. Plenty of new drugs are coming on stream to combat these diseases, but the rationale behind the EML denies patients in poorer countries access to these new drugs. This is because the EML deliberately favours listing generic medicines over patented ones. In this way, the treatments available to patients in poorer countries do not match the contours of the disease burden. This also discourages innovation, as the EML sends confusing and inaccurate signals with regard to which diseases are most prevalent at the local level.

Tensions are mounting. In Kenya, a dispute has broken out between those who import essential medicines and

those who want to import brand name drugs, of which generic copies are sold in Kenya. Importers of 'essential' medicines on the WHO list do not want brand name drugs to be imported because importers are afraid of competition. They know there is a vibrant market for these drugs, which poses a threat to their commercial interests.

A more fundamental question must also be considered: Why even define some drugs as essential and not others? All drug products are essential to those people who need them. Each disease requires personalized treatment. Our goal should be to provide doctors with enough options to use exactly the right drug to fit the needs of each patient. Instead, the drug list seems to be designed to suit the needs of various vested-interests and pressure groups. As a result, the EML does not correspond with the actual demand for drugs on the ground.

### **Inadequate health insurance**

Health insurance enables individuals to pool their financial resources and thereby protect themselves against the risk of unexpected and expensive illness. In return for monetary payment, an insurer agrees to compensate the individual in a specified way should defined, uncertain events actually happen.

When health insurance systems function well, demand for healthcare increases because larger numbers of people are covered against the costs of ill health. Several studies have shown the link between greater uptake of therapeutic medicines among poor and vulnerable populations, and the availability of health insurance in the United States (Department of Health and Human Services, 2002; Poisal & Chulis, 2000). However, many low-income countries do not have properly functioning health insurance schemes. In 1998 not one low-income country with a gross national product (GNP) per capita below US \$761 had a social health insurance scheme (Carrin,

2002). Those individuals not covered by insurance pay for health-care out of their own resources (or are nominally provided such services by the state). Since these people are already poor, their ability to purchase medicines – especially expensive medicines – is likely to be very low indeed. So the lack of availability of insurance acts as a significant barrier to access to medicines and constraint on demand.

One reason for the low level of insurance coverage in poor countries is the lack of adequate court systems and generally an absence of the rule of law, which makes the enforcement of legal agreements difficult, long-winded and expensive. Health insurance takes the form of a contract in which payment is made in advance of pay-out by the insuring company. In an environment where contracts are difficult to enforce, it is not surprising that many people are unwilling to risk paying into an insurance scheme. This specifically relates to a failure on the part of government to create an adequate rule of law and supporting institutions.

Another reason for low levels of insurance coverage in poor countries relates to the level of regulation placed upon private health insurers. For example, insurance companies may be required to offer certain kinds of insurance, regardless of whether or not consumers want the coverage. This is the case in South Africa, where the government has banned insurers from excluding high risk applicants, and compelled them to include cover that is not necessarily appropriate. The South African government is also working towards establishing a system that will require well-run funds to transfer their surpluses to badly-run funds. This latter intervention will limit the ability of actuaries to balance contributions against risk. Such regulations increase the costs associated with offering insurance, which increases the price at which it is offered. As a result, relatively fewer people are able to afford insurance. Paradoxically, regulations intended to protect consumers ultimately harm them (Soderlund & Hansl, 2000).

Governments also stifle the development of properly functioning insurance markets in less obvious ways. Weak governance

structures, including poorly defined property rights, excessively bureaucratic rules for business, and an absence of the rule of law in many middle and low income countries mean that large sections of the population are forced to seek employment in the informal economy. The informal economy tends to be disjointed, which implies that it would be difficult for potential insurance companies to take advantage of economies of scale. At the same time, the diversity and transience of such workers and their dependents means that enrolment is difficult and costly, if not altogether impossible.

The International Labour Organisation estimates, for example, that between 1990 and 2000, 85 per cent of all new jobs in Latin America were created in the informal sector. In Zambia, only 10 per cent of the workforce is employed in the formal sector. Accordingly, in sub-Saharan Africa only around 25 per cent of the work force is enrolled in health insurance schemes and most of those have been civil servants or employees of large multinational companies (Shaw & Ainsworth, 1995).

The size of the informal economy in many lower-income countries is directly attributable to weak governance. As Peruvian economist Hernando de Soto has convincingly argued, a lack of enforceable property rights and contracts, coupled with excessive regulation and bureaucracy, stifles the creation of legitimate employment opportunities (de Soto, 2000). A recent World Bank study found that, on average, it takes a business in a rich nation six procedures, 8 per cent of income per capita, and 27 days to become legally recognized. In poor or lower-middle-income economies, by contrast, it takes an average of 11 procedures, 122 per cent of income per capita, and 59 days. These relatively high costs mean that to a large extent, economic activity in such countries is informal. The same study found that weak property rights and heavy business regulation have an especially adverse effect on the ability of women and the poor to join the formal sector, despite the fact that such regulation is often designed to protect them (Wofford & Shanahan, 2004).

By presiding over such destructive governance, governments not only diminish the ability of their citizens to create wealth, but also



hinder the ability of functioning health insurance markets to develop. Without functional insurance markets, it seems unlikely that medicines will ever be available universally.

The lack of insurance has a knock-on effect on the potential market for drugs, acting as a disincentive to pharmaceutical innovation. Properly insured populations provide a stable and predictable market for medicines, reducing the investment risks of innovators. For those concerned about both access to existing medicines and the incentives to innovate new medicines, it is essential to ensure that effective insurance schemes are allowed to flourish. For this to happen, the regulatory environment needs to be as accommodating as possible. This should be a priority for policy makers who share these concerns. (Appendix Figure 3 shows what would happen to the market for medicines in poor countries if these demand-side barriers were lifted).

### **Barriers to innovation of new medicines**

The absence of a functioning market economy not only keeps people poor and undermines access to and demand for medicines and other goods; it also directly affects the supply of medicines. Governments that fail to foster the rule of law discourage companies from supplying medicines in several ways. Slow, expensive and corrupt court systems make it difficult to enforce contracts, which in turn discourage potential suppliers from entering into supply contracts. Also, the risk that trucks carrying medicines will be stopped and the cargo stolen or impounded, or a bribe levied by corrupt law enforcement officers reduces the incentives of companies to supply medicines. In addition, difficulties enforcing trademarks mean that a company which attempts to market its products may find that it faces competition from cheaper – but typically less effective, ineffective, or even harmful – counterfeit products. The evidence suggests that judicial dysfunction impedes economic growth, and restricts the ability of inventors and creators to commercialise their inventions (Sherwood, 2000).

As such, these general institutional failures greatly reduce the incentives to develop new medicines, especially for diseases that primarily affect the poor. In addition, there are several specific issues in the institutions of many poorer countries that negatively affect incentives to develop new medicines.

### Weak intellectual property legislation in low and middle-income countries

Some have claimed that patents create a barrier to access to medicines by increasing prices. While this is theoretically plausible, this scenario still does not explain the low rate of access to medicines that are already off patent and thus open to competitive, generic-based production.

It is true that when a state grants a patent, it provides the inventor with temporary exclusivity over the patent product or process. This can incur real costs, including the possibility to keep prices artificially high when, in absence of legal protection, market forces would drive prices down to their marginal cost – the lowest price at which a good can be sold without the producer making a loss. However, as Amir Attaran has shown, more than 98 per cent of drugs on the WHO's 'Essential Medicines' list are not patented in any poor country. As we have also illustrated, there are many factors that conspire against access, but patents on these specific medicines are not one of them (Attaran, 2004). In any case, these criticisms of patent protection must also be weighed against their benefits.

When it comes to creating incentives to encourage the development of new medicines for the diseases of poverty, protection of intellectual property (IP) can play a crucially important role. The high cost of developing a new pharmaceutical product (estimated at upwards of \$500 million in the US) (DiMasi et al., 2003), combined with the relatively low cost of copying the same product (typically a few millions of dollars), means that developers must be assured that they 'own' the product before they will commit such substantial sums.

Patents stimulate competition in several important ways that

contribute to an environment in which new, better, more effective and efficient medicines replace older, less effective and efficient ones. Importantly, this environment is also one where access to such innovations can be encouraged through mechanisms of markets.

One such mechanism is the provision of information about new medicines, through advertising and other marketing tools. By increasing demand for the medicine, such marketing sends a signal to other pharmaceutical companies that it may be worth investing in a competing product.

More generally, IP protection in countries with incipient or extant knowledge-based industries is likely to spur economic growth, with positive consequences for the demand for medicines.<sup>21</sup> Weak IP laws enable the emergence of copy industries at the expense of innovator industries – with negative consequences for economic growth because the added value of the copy industries is typically lower than that of innovator industries.<sup>22</sup> In addition, innovator companies based in countries with strong IP protection will be less likely to engage in joint knowledge-oriented projects with firms in countries with weak intellectual property protection (Maskus, 2000).

It is perhaps not surprising, then, that between 1997 and 2001, 180 of the 184 new molecular entities were developed in the US, the EU and Japan,<sup>23</sup> where intellectual property protection is the strongest.

In addition to providing incentives to local companies to invest in the development of innovative products, IP protection in poor countries may spur innovation by foreign companies to serve local needs (e.g. developing drugs and vaccines to treat and prevent tropical diseases) (Lanjouw, 1998). By contrast, countries that exploit their weak intellectual property regimes by threatening to issue compulsory licenses for drugs reduce the incentives to invest in such research and development (Rozek, 2000).

The contrasting cases of India and Singapore shed some light on the link between strong intellectual property legislation and innovation.

In India, Indira Gandhi's government passed laws in 1972 that made it impossible to patent pharmaceutical products, with the result that the past 33 years have seen practically no new drugs created within that country to tackle its most pressing diseases. Instead, a large generics industry developed. Yet for all the copies of medicines being produced by India's then 20,000 or more pharmaceutical companies (many of them small-scale 'mom and pop' operations), access to medicines in India remained deplorably low, standing at less than 40 per cent in 1999 (Lanjouw, 1999). In addition, despite being a global centre for the manufacture of generic AIDS drugs, only 12,000 of India's 5 million HIV positive citizens were receiving antiretroviral drugs by the end of 2005 (UNAIDS, 2006).

India's implementation of a TRIPS-compliant patent law has probably in part reduced the number of companies producing copies of drugs but it has had no discernable impact on rates of access to medicines, which almost certainly remain extremely low. Again, the fact is that there are far more serious problems at play which affect access to medicines besides intellectual property rights, such as an entirely inadequate medical infrastructure.

Nevertheless, the recent changes in India's intellectual property law already have stimulated Indian firms to develop drugs for diseases that predominantly affect the local population. For instance, Nicholas Piramal has recently opened a US \$20 million research and development centre in Bombay to carry out basic research in a wide range of health problems, ranging from cancer to malaria. Ranbaxy (India's largest pharmaceutical company) and Dr. Reddy's are also pursuing similar R&D projects. India currently has the largest number of FDA approved pharmaceutical manufacturing companies outside the US, and has increased spending on R&D from 4 per cent, five years ago, to 8 per cent today.<sup>24</sup>

The change in patent law is also attracting significant foreign investment. Multi-national pharmaceutical companies such as Merck and Bristol-Meyers Squibb now see India as a prime location for establishing research facilities. India is attractive not only

because of its lower basic costs, but also because of the many well-educated researchers that can reliably conduct capital-intensive clinical trials and more complicated forms of later stage drug development. The management consultants McKinsey estimate that by 2010, US and European pharmaceutical companies will spend US \$1.5 billion annually in India on clinical trials alone (Padma, 2005).

Many Western firms are also seeking to partner with local expertise. One recent example is collaboration between Danish-based Novo Nordisk and Dr. Reddy's to create a new treatment for diabetes. Japanese firms have also expressed interest in investing substantial sums into Indian R&D projects. Instead of imposing prohibitive barriers, as it once did, the Indian government actively has courted these foreign investments by providing incentives, such as a 10-year tax break to pharmaceutical companies that are involved in research and development.

Such developments mean that an Indian firm may well develop a vaccine for malaria or improve current tuberculosis therapies, resistance to which contributes to the deaths of over 1,000 people each day in India alone. Investments are even going into R&D for a vaccine for HIV/AIDS. Human trials are underway for the second preventative HIV vaccine candidate produced in India.<sup>25</sup>

In a relatively short time, India's new patent law is also hastening collaboration between the information technology sector and the pharmaceutical and biotechnology industries. Until recently, the fledgling research-based biotech and pharmaceutical sectors relied on patenting in the U.S and Europe.

Instead of exporting raw materials and basic active ingredients that are used to manufacture generics, firms in India now have the ability to compete globally, producing high value-added, life-saving medicines. This will also contribute to the country's continuing economic growth and its concomitant increase in life expectancy (which has already risen from 36 years in 1951 to its current estimated level of 61 years).

Singapore likewise illustrates the benefits of improved patent

protection. In 2001 it implemented a new patent law which brought the country into compliance with international standards. As a result, US \$5 billion in FDI has helped to sustain that country's position as one of Asia's strongest economies. Singapore's burgeoning biomedical science sector has played a central role: output in 2004 was US \$9.7 billion, a 33.2 per cent increase on the previous year.<sup>26</sup> This is not limited to investment on the part of established western pharmaceutical companies, as a host of younger indigenous R&D companies are also scaling up their operations.<sup>27</sup> Singapore's emergence as a significant location for value-added R&D has also contributed to the search for new medicines for diseases endemic to poor countries. A high profile investment in Singapore is the Novartis Institute for Tropical Diseases, which opened in July 2004. It will focus initially on researching treatments for dengue fever and drug resistant tuberculosis.

### **Hypothetical: Creating a market for malaria treatment**

To evaluate the impact of improved IP protection on incentives to develop and market a new drug for one of the diseases of poverty, consider the potential market for a new malaria treatment.

While the costs of researching and developing a new drug in the US and other wealthy countries are estimated to be US \$800 million, the costs of developing a drug in a less developed country would be far lower. Because of comparative advantages of producing in those countries, we assume that the cost would be around US \$100 million (taking into account failure rates, etc.).

Currently, approximately 300 million people suffer from malaria each year. If 10 per cent of those pay for a new treatment, that amounts to 30 million treatments per year. Although patents are valid for 20 years after filing, the effective life of a patent for a new drug is on average cut to

about 10 years because of the time it takes to develop, test and comply with regulatory requirements (IFPMA, 2004). That means a total of 300 million courses of treatment while the drug is under patent.

Assuming a discount rate of 15 per cent, each course of therapy needs to yield a margin of only 62 cents in order for the developer to break even on sales. The average cost of production for a course of Artemisinin Combination Therapy treatment is currently estimated at US \$2.40.<sup>28</sup> Assuming that a new drug would cost a similar amount, the total cost of one course of treatment need be only around US \$3.50 for the developer of the drug to cover the cost of development, production and marketing – and even make a profit (albeit a relatively small amount). At such a price, a new, patented malaria therapy would be competitive in the market and might plausibly sell the necessary 30 million courses per year.

If it were possible effectively to patent a new malaria drug in relevant markets, it seems plausible that there would exist a private sector company which could produce a cost-effective and efficacious new malaria treatment.

Sadly, however, the barriers to innovation and access described in this chapter mean that the discovery and development of drugs for the diseases of poverty is currently not financially viable for private sector firms, except as part of their philanthropic efforts.

### **Inappropriate levels of intellectual property protection in developed countries**

From the above, it is clear that intellectual property protection in most lower-income countries is almost certainly too weak, with the result that the level of for-profit development of medicines for the diseases endemic to those countries is too low.

However, concerns have been raised that in certain respects, intellectual property protection in some wealthier countries may be too strong. In particular, we are concerned that in some cases patents are granted for what appear to be mere discoveries rather than genuine innovations. For example, in some cases a genetic sequence has been patented even though the use of that sequence has not been identified. This might have the perverse effect of creating too broad a patent, blocking downstream innovations. On the other hand, it is possible that without such patents, investments in biotech research would be far lower, and the discoveries that form the basis of downstream pharmaceutical products would never come into being.

Likewise, there has been much criticism of patents granted for research tools. These, it is argued, raise the cost of research without providing any substantive benefits. On the other hand, it is again possible that without the possibility of patents, there would be insufficient incentives to invest in the development of the research tool in the first place.

After the fact, it is often easy to argue that an invention was 'obvious.' To engineers who develop laser-guidance systems, the light bulb no doubt seems 'obvious.' To the developers of modern hybrid cars, perhaps the internal combustion engine seems 'obvious'. But the reason the innovations seem obvious after the fact is that they are already there and in some sense have been factored into all downstream innovations. What is not clear is whether they – and the downstream innovations upon which they depend – would in fact have been developed had there been no means by which the inventors could have captured the rewards of their investments.

Nevertheless, the question remains as to how best to ensure that patents that are granted are not too broad. This may be addressed in various ways. Some, for example, argue that greater pre-grant scrutiny of patents would reduce the number of egregious patents that are granted. In our opinion this is not a good solution. In a TRIPS-compliant system where patents are granted



for 20 years after filing, it would likely further delay the granting of patents. This would both delay investments in R&D related to the patented innovation and reduce the effective life of the patent once granted. In the context of medicines, this would mean fewer new drugs and longer delays in their appearance on the market.

Others argue that the rules applied by patent examiners should be changed. For example, it has been suggested that patent applications should be evaluated not only on the basis of the three standard criteria (novelty, non-obviousness, and utility)<sup>29</sup> but also on the basis of their effectiveness. This, however, presupposes that effectiveness can be measured prior to the development and testing of a product, which usually it cannot – especially in the case of new molecular entities. In such circumstances, the requirement of ‘effectiveness’ will lead to arbitrary decisions by patent examiners and judges, and patents will not be granted to many potentially effective products.

We believe that there are better solutions, including:

- ◆ **Simplified procedures for granting patents.** At present, many countries have highly bureaucratized patent agencies, which are extremely slow in making decisions on the granting of patents; streamlining procedures along the lines of international best-practice could improve the situation.
- ◆ **The introduction of regional patent granting agencies.** Where resource constraints are a problem for patent offices, such agencies could reduce costs and increase throughput, thereby increasing the competitiveness of the whole region.
- ◆ **Improved incentives for patent agents to make decisions.** For example, introducing a performance related pay system (appropriately constrained by quality requirements) might increase throughput of patent applications; contracting out the service to the private sector could have a similar effect.
- ◆ **Simplified procedures for challenging patents in courts.** This would enable more rapid and less costly resolution of disputes.
- ◆ **The introduction of petty patents or ‘utility models.’** This would be useful for certain classes of product where a full

patent might not be justified – these might apply, for example, to research tools and certain genetic sequences.

- ◆ **Competition between patenting authorities.** While it may be desirable to have common minimum standards for patents, such as those to which members of the WTO have agreed under TRIPS, it is important also to retain a degree of competition between authorities in order to ensure that the appropriate breadth of patents may be discovered.<sup>30</sup>

### **Pre-market regulations**

Companies are required to comply with an increasing number of regulations before they can launch a pharmaceutical product onto the market. This drives up the costs of supply, making the end product more expensive and thus less affordable for customers in lower-income countries. According to a survey of 20 leading pharmaceutical companies conducted by the CMR Institute for *Regulatory Science* in 2003, 65 per cent of companies felt that the change in the regulatory environment over the preceding three years had increased the cost and time of bringing new medicines to market. Furthermore, 23 per cent of those surveyed felt that the increasing regulatory burden was directly responsible for the decline in NME submissions (CMR, 2004). In South Africa, the situation is exacerbated by the Department of Health's stipulation that it approve all new drugs, even if they have been approved already in the EU, US or Japan. This can add delays of two or more years before new medicines are available in South Africa.

Because regulatory bodies are beholden to national governments, their tendency is to ensure that the potential side effects of new drugs are minimised as far as possible. This is because the publicity surrounding the discovery of an unsafe drug in the market leads to a public outcry, resulting in high political costs for national regulatory authorities. The missed gains from new medicines that are delayed or refused approval are less obvious (or even intangible) to the general public, so regulators have an incentive to err on the

side of caution. However, if the regulator only considers potentially harmful side effects, this will have the unintended consequence of raising the cost, and delaying or preventing the approval of new drugs.

One consequence of an excessively precautionary approach is that regulatory authorities allow new medicines or vaccines to be sold to the public only after extensive pre-clinical and clinical trials have been performed. These trials examine the safety, quality and efficacy of the new drug in treating or curing diseases. Estimates of the average time it takes to for a new drug to go through these trials range from 8.5 to 13.5 years, a process which adds considerable costs to the drug development process (DiMasi, 1995; Adams & Brantner, 2003; Dranover & Meltzer, 1994).

Estimates of the cost of bringing a new drug to market vary; some researchers suggest that the total cost is over US \$800 million (DiMasi et al., 2003). As such, manufacturers have strong incentives to concentrate their resources on developing 'blockbuster' drugs that will provide a return on that significant investment. Meanwhile, there is less incentive to invest in drugs for rarer conditions in the richer world (such as psychiatric disorders) and even for relatively common diseases in lower-income countries.

Professor Sir Michael Rawlins, Chairman of the UK's National Institute for Health and Clinical Excellence, has argued that many of the preclinical and clinical studies required by various regulatory agencies add little to the safety of the final product, but instead contribute unnecessarily to the estimated US \$300–450 million cost of clinical development (Rawlins, 2004). Clearly removing excessively precautionary regulatory barriers would speed up drug development and reduce costs, creating stronger incentives to invest in the development of new drugs for diseases that may otherwise be relatively unprofitable.

To some extent, the length of time it takes for new drugs to enter the market, and the consequent cost to society of delays, is an issue recognised by regulatory agencies. The FDA has adopted 'fast-track approval' and 'accelerated approval' for certain classes of drugs,

while the European Medicines Agency has instituted stiff targets for the marketing approval of orphan drugs. These represent a step in the right direction, but governments are often tempted to impose further regulations on drugs manufacturers when they come under political pressure. A recent example comes from the United Kingdom, where the health minister Lord Warner revealed that he is considering a fourth stage of clinical trials to alleviate safety fears surrounding new drugs. Legislators should resist the temptation to assuage public fears through such excessive regulation, because it would increase the time and expense of getting a drug to market. This would be most harmful for the development of drugs for regions or diseases where returns are the lowest – most typically, diseases endemic to lower-income countries.

One solution that would ensure new drugs reach markets as quickly as possible – in part by reducing the ability of local drug regulatory agencies to impose arbitrary and overly stringent requirements on new registrations – would be to enable competition between existing national drug regulators, as well as between private certification boards (Sauer, 2005).

Such accountable, competitive regulators would set the standards of regulation at levels demanded by those making choices about drug regimens. For many drugs, this would mean swifter approvals and a reduction in development costs, leading to an increase in the number of drugs developed for most diseases – especially those which affect the poorest and those which affect relatively smaller populations – while also reducing the price of medicines to all.

Public health would be safeguarded by the desire of these agencies to defend their own reputations. The importance of reputation in maintaining clients and attracting new ones, the existence of a free press engaging in investigative journalism, and expected penalties through the legal system for corrupt and dangerous decisions by these regulators, should lead to a well-functioning market in drug approval. A drug approval agency that bends to pressure from pharmaceutical companies, for example,

would be quickly exposed, and the marketability of their future products would suffer.

### **Data exclusivity**

Another aspect of pre-market regulation is the treatment of the data submitted to regulatory authorities. These data are submitted on the basis of 'data exclusivity,' an agreement that the authorities will not release them for a specified period and that during this period other firms may not rely upon the data as the basis for their applications for licenses.

This period of data exclusivity varies from 5 to 11 years.<sup>31</sup> Once it expires, competing companies are free to access and rely upon the data and thereby avoid having to conduct duplicative research (and associated costs).<sup>32</sup>

It has been alleged that these periods of data exclusivity hinder generic competition, thereby keeping the price of medicines unnecessarily high. But while the introduction of competition typically leads to price reductions on medicines, the net effect will depend on the impact it has on the incentives to invest in research and development. Companies invest heavily in the development of the data they supply to regulators during the approval process. If these data are then shared with other companies, the value to the originator is reduced. This erosion of value has negative consequences for the ability to raise the funds required to conduct future tests, and is likely to act as a disincentive to companies which might otherwise bring new, therapeutically beneficial medicines to the marketplace.<sup>33</sup>

Unclear rules governing the submission of data to regulatory authorities will only increase legal disputes between research-based companies and their generic counterparts. These disputes are already common and their frivolous costs must now be factored into the rapidly rising total cost of delivering a drug to the marketplace. While great effort is being expended towards containing these costs, the failure properly to address data exclusivity arrangements

threatens not only to increase costs, but also to reduce the incentives to innovate as well.

### **Price differentiation**

The ability to sell a product at different prices to different consumers enables companies with a degree of market exclusivity to ensure that their products reach as many consumers as possible while still maximising revenue. If a company is able to segment markets precisely according to each individual's willingness to pay, then every consumer willing to pay at least the marginal cost of production for the product should be able to purchase that product. This would both maximise the number of people who benefit from the product and would also maximise revenue to the company, which in principle would enable more to be spent on R&D.

Perfect market segmentation means that the number of consumers served and the price paid by the poorest consumer are the same as that which would exist in a perfectly competitive market (Appendix Figure 5).

In practice, market segmentation is costly to enact – primarily because of the need to prevent low-price purchasers reselling to higher-price purchasers – and the larger the number of market segments, the greater the cost. So, firms weigh up the benefits of adding a segment with the cost of enforcing the additional segmentation. Typically, firms segment markets first by overall market (which is usually a country or trading bloc) and then by sub-categories, such as: individuals (which may be further segmented by age and income), businesses, charities, and governmental bodies. So, for example, drug prices in South Africa are far lower than in Europe and the US (Reekie, 1997). This means that market segmentation can be particularly beneficial for patients in poorer countries.

Where the overall market for a product is very large and where that market is readily segmented (i.e. the cost of enforcing the segmentation is low compared to the benefits), companies may set the

lowest price close to the marginal cost of production. In the context of a disease such as HIV/AIDS, where the total market for medicines is massive and the humanitarian case for widespread distribution is great, companies may even choose to sell below marginal costs in some markets, provided that sufficient profit is recuperated in others (Danzon & Furukawa, 2003).

Market segmentation is underpinned by intellectual property – especially patents and trademarks – and contracts. If the intellectual property rights and contracts are respected,<sup>34</sup> firms can operate freely within the marketplace without running the risk of having separate national or international markets compromised by the resale of the lowest priced medicines into markets where prices are relatively higher.<sup>35</sup> However, infringements upon intellectual property rights mean that firms cannot control their own pricing schemes, with serious consequences. Not only does this act as a disincentive for firms to sell their products in poor countries, it may also inhibit future innovation.

In short, price differentiation allows companies to cater for people who otherwise could not afford to purchase their products. It allows countries that are not able to shoulder the costs of R&D themselves to afford expensive medicines. It also means output is higher than the level that would occur if no differentiation were possible. Moreover, the innovator is able to generate more revenue, providing a greater pool of resources for investing in new drug development.

### **Price controls**

Unfortunately, governments often restrict the ability of companies to implement differential pricing strategies. For example, they frequently impose price controls on drugs, capping the price of drugs and making any other sales price illegal. Nearly all economically advanced countries – with the notable exception of the United States – impose price controls on medicines in one form or another (Danzon & Furukawa, 2003). Because the controlled price is effectively the *only*

price, this prevents competition that would drive the price lower; in other words, the price 'ceiling' becoming a price floor (U.S. Dept of Commerce, 2004).

Drug price controls discourage companies from registering products in certain markets, leading to shortages in supplies and illegal trade in medicines. This in turn provides a route for counterfeit medicines to enter the market. A 2003 study illustrated that one of the risks of parallel importation from countries which have regulations that ensure low drug prices is that medicine manufacturers prefer to delay or cancel the launch of a particular product in the price-controlling countries (Danzon et al., 2003). The study showed that between 1994 and 1998, there were 85 New Chemical Entities launched in the US and UK. However, out of a maximum possible 2,125 registrations of these NCEs in 25 countries, only 55 per cent (1,167) were actually registered. The research also showed that those countries with lower expected prices or a smaller expected market size – most typically lower-income countries – experience longer delays in drug registration.

Delays in registration of new medicines are particularly harmful to sufferers of HIV/AIDS. Research shows that one new anti-retroviral (ARV) HIV/AIDS drug prevents around 6,000 deaths in the US the following year and ultimately prevents around 34,000 deaths (Lichtenberg, 2003). Although new ARVs cost more than older, off-patent ones, they can substantially reduce the number of lost productive work days, so in many cases pay for themselves in a purely financial sense (one study estimated that 21.3 per cent fewer days were lost with the introduction of each new ARV) (Lichtenberg, 2003). Newer drugs also reduce the amount of time patients spend in hospital, negating any financial benefit from using older, off-patent drugs.

Price controls also have a number of other adverse impacts:

### Reduced supply

Regulations on drug prices drive pharmacies into bankruptcy as their margins are squeezed, and make the distribution of drugs to remote and rural regions financially unviable. For example, the price



caps forced on certain drugs in South Africa have been implicated in the closure of 103 pharmacies.<sup>36</sup> Price controls will likely reduce profit margins on controlled-price pharmaceuticals. As a result, wholesalers and pharmacies are likely to carry a smaller range of drugs. If the price controls are widespread or targeted at the most popular drugs, they may have such a negative impact on profits that it is not worth a wholesaler distributing them to far-flung pharmacies – and so pharmacies in rural areas will be more likely to close. The lack of profitability in the sale and distribution of medicines will also reduce the incentives for pharmacists to invest in training, which will make them less effective purveyors of healthcare advice. This would be particularly damaging to the rural poor, whose contact with professional healthcare is very often limited to local pharmacists.

### Reduced innovation

In many countries (especially Canada, and countries in Europe and Australasia), government control over healthcare systems has led directly to price controls of one kind or another. Ageing populations, combined with more effective but more costly treatments for many diseases puts upwards pressure on healthcare costs. Politicians may be wary to increase spending on health, especially where the spending affects the incomes of taxpayers and can be seen as the result of their actions – because of the potential it could have on their chances to be re-elected.

The relatively short electoral cycle creates incentives on the part of politicians to achieve short-term savings, even when these will lead to longer-term costs or longer-term harm to health. The result has been strong pressures to restrict access to more costly new pharmaceuticals which are relatively more expensive, even though in many cases these new drugs would reduce the subsequent need for more expensive procedures and hospital treatment.

A striking example comes from Canada, whose Patented Medicines Review Board sets strict guidelines on the price of medicines. This board also has the power to compel a supplier to reduce prices

if they exceed pre-determined levels (Menon, 2001). Likewise, Germany's government sets levels at which it will reimburse purchases of specific classes of drugs, with consumers paying any difference. This has the result that the consumer's perception of the cost of buying newer drugs is much greater than the real price differential. As a result, consumers have an incentive to buy older drugs that are less effective.

Price controls reduce the ability of producers to implement effective price differentiation strategies. In essence, fewer drugs are supplied at a price higher than would be paid by the poorest consumer but lower than would be paid by the wealthiest consumer. As a result, wholesalers and retailers are likely to carry a smaller range of drugs. If the price controls are widespread and targeted at the most profitable drugs, they are likely to have a substantial impact on profits throughout the value chain. That means not only fewer wholesalers and pharmacies, but also less investment in new drugs by pharmaceutical companies. (The economic consequences can be seen in Appendix Figure 6.)

Economic theory is backed up by increasing amounts of empirical evidence. Price controls have had a direct negative impact on the numbers of new drugs that are submitted for regulatory approval. A recent US Department of Commerce study found that the price controls used by a range of OECD countries have resulted in a significant decrease in spending on both old and new drugs (U.S. Department of Commerce, 2004). It found that these controls have decreased the price, pushing it closer to marginal production costs, which in turn leaves less revenue for future investment in R&D. The study estimated that, after extrapolating to a broader set of OECD countries, the diminished returns as a result of price controls are in the range of US \$18 billion to \$27 billion annually. If this lost revenue could be recouped through deregulated pricing strategies, the study calculates that an additional three or four new molecular entities (NMEs) could be developed every year. To put this into context, only 30 NMEs were approved by the FDA between 2000 and 2003.

Price controls in some European countries have also hindered

Europe's ability to develop new medicines. In 1992, six out of ten best selling medicines were developed in Europe; by 2002 only 2 out of 10 were of European origin. If the US were to introduce price controls, it is estimated that this would result in a reduction pharmaceutical R&D by some 30 per cent. This would translate into 330 to 365 fewer new drugs within a twenty-year period (Giacotto, 2004).

### **Compulsory licenses**

Compulsory licenses – or the threat of issuing a compulsory license – can have a similar effect on innovation as price controls. In the interest of improving public health, compulsory licenses can be a way for extremely poor countries to procure relatively inexpensive medicines (when all attempts to secure such products voluntarily have been exhausted). The issuance of such licenses in a medical state of emergency has always been permitted under the original TRIPs Agreement for countries with manufacturing capacity. The 2001 WTO Doha TRIPs agreement extends this safeguard to countries without manufacturing capacity – enabling them to procure from companies with manufacturing capacity but where otherwise production would be restricted to patent holders – thereby protecting the interests of the poorest nations.

In practise, however, middle-income countries such as Brazil have often used the threat of compulsory licensing as a negotiating tool to secure lower prices.<sup>37</sup> While this can prove to be a politically popular move in the short term, it undermines the ability of innovator companies effectively to price differentiate. It also places increased strain on pricing strategies aimed at offering the cheapest medicines to patients in extremely poor countries, and acts as a further disincentive for firms to develop new and improved medicines for the diseases of poverty (Kremer et al., 2004). (Appendix Figure 4 shows what would happen if both demand and supply-side constraints were lifted.)

## Discussion

Clearly, many urgent health concerns in the poorest parts of the world could be addressed if existing drugs and interventions were to be distributed properly. However, a variety of factors conspire to prevent people from receiving the medicines they need. As we have seen, poor road and electricity networks hinder the distribution of drugs, as does the shortage of medical facilities such as clinics, hospitals and pharmacies. Health insurance systems, which would enhance access to medical care, are currently inadequate because the governments of lower-income countries frequently fail to foster the kind of institutional environments in which they can thrive.

But people are also denied medicines in more insidious ways. Governments in lower-income countries impose burdensome taxes and tariffs on imported medicines, pricing many people out of treatment. Governments also impose often unjustifiable non-tariff barriers, such as arbitrary licensing restrictions. At the same time, governments nominally offer healthcare services to everyone, but in practice they do so in ways that primarily benefit a small number of citizens (mostly the elite) at a very high cost. As a result, government-financed healthcare systems in such countries are often poorly resourced and poorly managed. Meanwhile, the private sector often is over-regulated. These glaring failures of governance help to ensure that universal access to essential medicines remains a long way off for many regions of the world.

The manifold failures in drug distribution also have ramifications that reach beyond the immediate health needs. Because these failures diminish demand for medicines, they make it less likely that new medicines will be created. In richer countries this is less of a problem because effective demand is higher.

Producers respond to the perceived demands of consumers, whether those consumers are individuals, health agencies, insurance companies or governments. (This is illustrated in Appendix Figure 1.) This has led to the creation of a wide variety of drugs to combat the range of disorders suffered by consumers in rich country markets. However, in lower income countries the absolute size of

the market is constrained by the weakness of distribution mechanisms, leading to a concomitant decrease in supply. If a medicine stands little chance of actually reaching its intended consumer, there is little point in risking large amounts of capital in developing a drug specifically designed for a poorer market. As a result, certain diseases endemic to these regions, such as the cluster of so-called 'neglected diseases',<sup>38</sup> have failed to attract sufficient research from commercial drugs companies. More problematic is the fact that these same constraints also limit the distribution of all kinds of pre-existing medicines. Access to these medicines would improve if the many barriers to access identified in this chapter were addressed as a matter of priority.

## Appendix

Figure 1 Market equilibrium

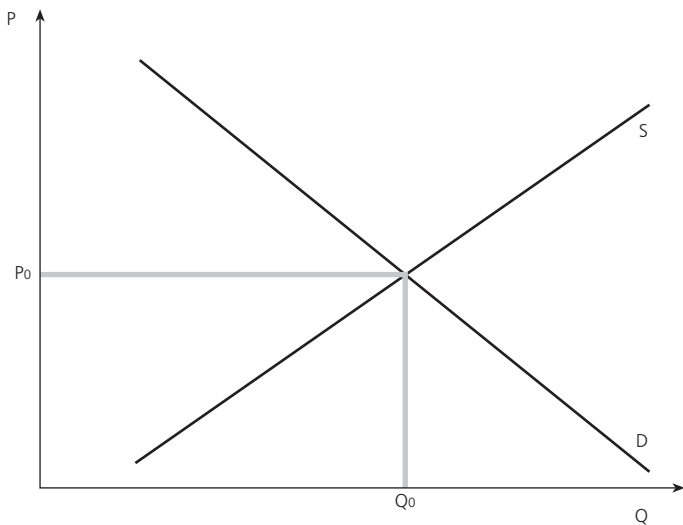
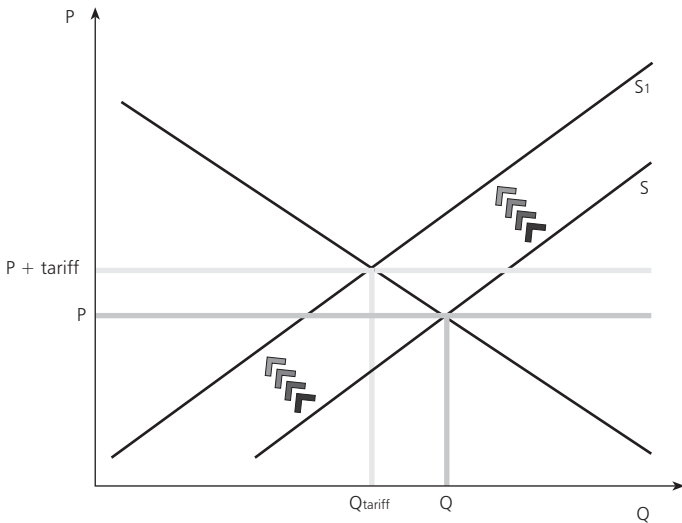


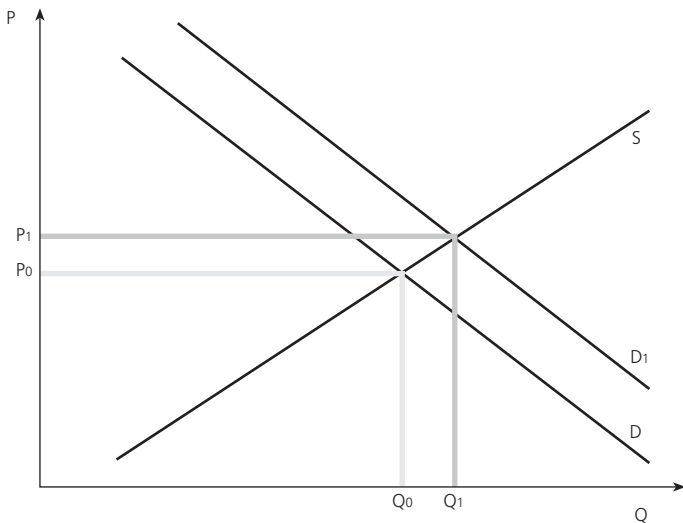
Figure 1 shows consumer willingness to pay, represented by the 'demand' curve,  $D$ , and industry willingness to supply, represented by the 'supply' curve,  $S$ . The intersection of these two curves shows the total quantity that will be supplied,  $Q_0$  and the minimum price charged,  $P_0$ .

Figure 2 Effect of taxes and tariffs on demand for medicines



If a government imposes a tax on a medicine, this raises the minimum price artificially. Figure 2 shows the effect of adding such a tax; the supply curve is effectively shifted inwards because suppliers must now add the tax to the amount that they charge. As a result, the amount supplied falls from  $Q_0$  to  $Q_{\text{tariff}}$ .

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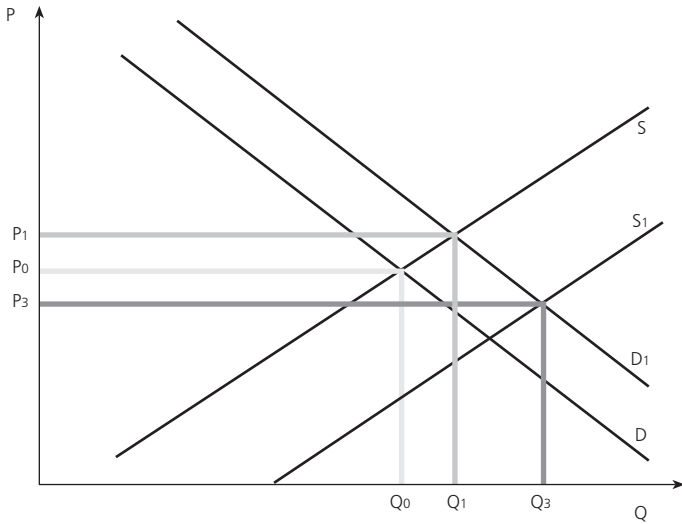
**Figure 3 The impact of a rightward shift in the demand curve**

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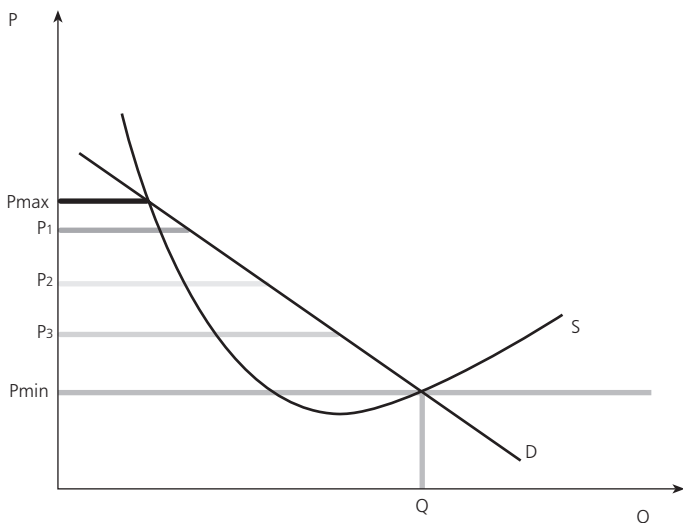
Figure 3 shows that when consumer willingness to pay increases (for example as a result of a rise in income), the demand curve shifts to the right. This leads to an increase in the amount supplied (from  $Q_0$  to  $Q_1$ ) and also to an increase in the minimum price (from  $P_0$  to  $P_1$ ). This is because the supply has been met by moving along the original supply curve, for which the cost of producing an incremental unit is assumed to rise as output rises — because more expensive production methods have to be brought on-stream.



Figure 4 The impact of a rightward shift in the supply curve

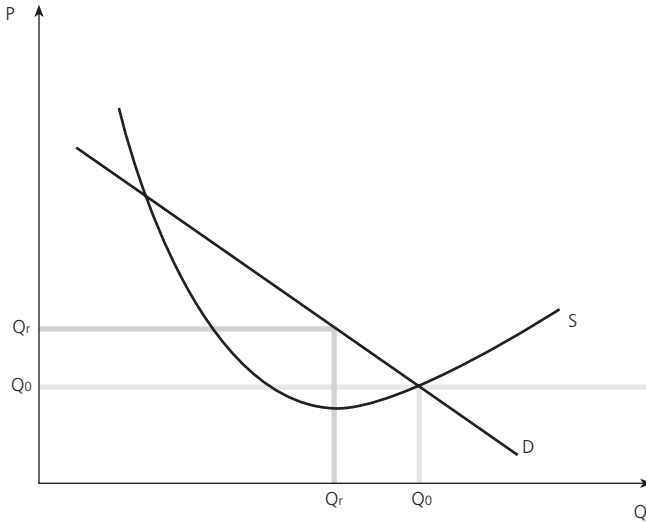


However, the rise in price (as a result of the expansion in the demand curve in Figure 3) is likely to be seen by entrepreneurs as an opportunity to make money by supplying the market using new technologies (these might be, for example, new production technologies, or they might be new drugs in the same class). As those entrepreneurs enter the market, supply increases to Q<sub>3</sub>, and the price falls to P<sub>3</sub>. This can be represented as a rightward shift in the supply curve (Figure 4).

**Figure 5 Perfect market segmentation**

If a supplier has an element of market power (for example as a result of the temporary market exclusivity conferred by a patent), then in principle he is able to set prices and will do so in such a way as to maximise profits. The textbook economics analysis of such situations assumes that the supplier will choose only one price, which will be higher than the marginal cost of production. However, if the supplier is able to segment the market perfectly, then he will sell at a wide range of different prices to different consumers and will maximise profits by setting the minimum price ( $P_{\min}$ ) at which he sells just above the marginal cost of production and the maximum price at  $P_{\max}$ . He will then sell total quantity  $Q$ , which is the same as the perfectly competitive quantity. This is shown in Figure 5.

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**Figure 6 Regulated market**

The quantity sold under a regulated market,  $Q_r$ , is lower than the quantity sold under a segmented market,  $Q_0$ , where the firm is able to price its product based on the willingness to pay of different groups of consumers. The price paid by the poorest consumer in the regulated market,  $P_r$ , is higher than the lowest price charged in a segmented market,  $P_0$ .