

# Patents, pills and public health

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Can TRIPS deliver?

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**Note on terminology**

The terms 'North' and 'South' have been used to refer to countries of the developed and the developing worlds respectively.

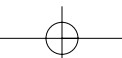
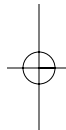
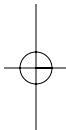
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# Executive Summary

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This report aims to provide the media, policy-makers, non-governmental organisations and other concerned groups with an introduction to the issues surrounding the international agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and public health.

In the South, cost is one of the key factors inhibiting access to new drugs, in particular for HIV/AIDS and associated diseases. In many countries, the patent – intellectual property right – granted to the manufacturers of a new drug means a monopoly. This prevents other companies from marketing an alternative, cheaper ‘generic’ version. In other countries, where patent recognition is more restricted, such generic versions may be produced or marketed, and the cost of drugs is substantially reduced. For example, thanks to generics, the annual cost of treating HIV/AIDS has fallen from \$10,000 to \$200 in some parts of the South.

To comply with TRIPS, however, patent legislation is being introduced in many countries where previously it did not exist. While the pharmaceutical industry argues that such a policy is necessary to promote innovation, others believe that the impact will be to reduce competition, push up prices and limit still further access to drugs in the world’s poorest countries.

There are alternative means of increasing access to medicines. These include compulsory licensing, where a patent is overridden in return for payment of a royalty, and differential pricing, where poorer countries pay considerably less for a product than wealthier ones. However, such measures continue to be subject to dispute.

While TRIPS remains the focus of intense international debate, within many countries there has been relatively little discussion of the potential impact of the agreement. Increasingly, however, legislators, health providers, the media and others are becoming aware that a debate on TRIPS is an essential part of the process of ensuring equitable access to health for all the world’s citizens. For this to happen, Southern governments need to prioritise the development of healthcare systems capable of delivering essential drugs to all – including the poorest sectors of society. The challenge for the international community – and the pharmaceutical industry – is to support them in doing so.

*A longer version of this report, including more detailed country studies and resources, may be found on [www.panos.org.uk](http://www.panos.org.uk)*

*A national checklist of issues for journalists and policy-makers may be found on the inside back cover.*

## **Statistics**

- A third of the world's population have no access to essential drugs, a figure that rises to half the population in the poorest countries of Africa and Asia
- In 2000, the US spent \$3,724 on healthcare per person. Somalia spent \$11
- 74 per cent of health expenditure in sub-Saharan Africa, 25 per cent in Latin America and the Caribbean, and 7.4 per cent in developed countries goes on medicines
- In rich countries, under 40 per cent of medicines are purchased privately, whereas the figure is 67 per cent for sub-Saharan Africa and as high as 81 per cent in Asia and the Pacific
- The cost of the same treatment for tuberculosis represents income from 500 working hours in Tanzania, 100 in Zimbabwe, 20 in Thailand and 1.4 in Switzerland. The comparable costs for gonorrhoea are 120 hours in Tanzania, 20 in Zimbabwe, 6 in Thailand and 0.4 in Switzerland
- Over 300 medicines are on the World Health Organisation's Essential Drug List. Fewer than 20 are patented
- The World Health Organisation calculates that in developed countries, the manufacturer's price of a medicine typically represents 50 to 60 per cent of the final consumer price, while in some developing countries up to 80 per cent of the consumer price consists of import duties, taxes, distribution costs and dispensing fees
- The World Bank estimates that IP protection will lead to increased foreign investment in middle-income countries, but full implementation of TRIPS would mean a loss to developing countries of \$20 billion in patent payments (for all sectors, including health)
- WHO suggests that implementing patent protection where it did not already exist would result in the average price of drugs rising, with projected increases varying from 12 to 200 per cent
- In 1999, the price of Glaxo Wellcome's Zidovudine (AZT) around the globe varied from \$124.95 to \$53.50 per 250mg/40 capsule pack
- 144 countries are members of the World Trade Organisation; 31 countries have applied to join

## Glossary

bioequivalence	(of drugs) having the same effect on the body as another drug
Bolar Provision	a rule in patent law which allows generic manufacturers to develop drugs while they are still under patent so that they can be stockpiled and then marketed immediately the patent expires
compulsory licensing	a licence issued by a court or government to produce a generic version of a patented product, while the patent holder is compensated through royalties from sales
evergreening	extending a monopoly by taking out a new patent on a minor aspect of a product once the main patent is due to expire
generic	a version of a patented drug that meets bioequivalence tests and has the same pharmaceutical presentation and dosage as the original drug
intellectual property (IP)	a creation of the mind, such as inventions, artistic works and trademarks
invention	a product or process which is new, useful and capable of manufacture
parallel trade	the import of branded patented goods without the approval of the patent holder
patent	the intellectual property right for an invention
TRIPS	international agreement on Trade-Related Aspects of Intellectual Property Rights
TRIPS-Plus	legislation and policy ensuring stronger protection for patents than required by TRIPS
voluntary licensing	the granting by the patent holder to a third party of the right to manufacture a product for a specific market

# 1 The global healthcare gap

Poverty and poor health go hand in hand. In the world's least-developed countries, life expectancy is a third less than in the richest ones. Many people in the South die from diseases that in the North have been mostly eradicated or are easily treated.

## Unequal situations: spending on health in selected countries

	Annual health expenditure per capita (\$)	Health expenditure as % GNP	Life expectancy at birth Males/ Females	Doctors per 100,000 people
US	3,724	13.7	73.8/79.7	279.0
Japan	1,759	7.1	77.6/84.3	193.2
UK	1,193	5.8	74.7/79.7	164.0
Chile	581	6.1	73.4/79.9	110.3
Brazil	428	6.5	63.7/71.7	127.2
Cuba	109	6.3	73.5/77.4	530.4
Afghanistan	89	3.2	45.3/47.2	11.0
India	84	5.2	59.6/61.2	48.0
Sri Lanka	77	3.0	65.8/73.4	36.5
Uganda	44	4.1	41.9/42.4	n/a
Sierra Leone	31	4.9	33.2/35.4	7.3
Somalia	11	1.5	44.0/44.7	4.0

Source: *The World Health Report 2000, WHO*

When a government has few resources to spend on healthcare, its people suffer, particularly those who are poor themselves. Poverty is not the only cause of poor health, but it undermines the foundations of good health by depriving people of clean water and sanitation, a good diet, education and comprehensive vaccination programmes. And it restricts access to healthcare by weakening infrastructures, limiting the numbers of medical personnel, reducing access to drugs and encouraging corruption. Against such a background, it is not surprising that preventable infections such as HIV/AIDS, tuberculosis and malaria tend to be most prevalent in countries where there is least money to spend on health.

Not only does poverty lead to ill health, but ill health often leads to poverty. Where public health services and insurance are inadequate, if a family member falls sick, healthcare and medicines can easily push households further into debt.

## Who pays?

Healthcare is either paid for in advance, through government taxes and national or private insurance, or paid at point of use. Pre-payment through government, which spreads the burden of healthcare costs through the whole community, is the commonest means of finance in most wealthy countries. In poor countries, however, most people pay for healthcare when they use it, which means the burden falls heaviest on those least able to bear it.

In Germany in 2000, for example, healthcare absorbed 10.6 per cent of the country's gross domestic product (GDP = national wealth); three quarters of that figure came from public funds and only one quarter from private sources. In the same year healthcare in India absorbed 4.9 per cent of GDP; less than 18 per cent of that sum came from public funds and 82 per cent from individuals. In other words, not only did India spend much less of its national wealth on health than Germany, but Indians spent four times more on health than did the state.<sup>1</sup>

Drugs are a critical factor in the cost of healthcare and in poorer countries they form a higher proportion of the total healthcare bill. Seventy-four per cent of health expenditure in sub-Saharan Africa, 25 per cent in Latin America and the Caribbean, but only 7.4 per cent in developed countries, goes on medicines. Here too, individuals in poorer countries bear a larger proportion of the cost. In rich countries, under 40 per cent of medicines are purchased privately, whereas the figure is 67 per cent for sub-Saharan Africa and as high as 81 per cent in Asia and the Pacific.

It is those who can least afford it who spend the highest proportion of their income on medicinal drugs. In practical terms this means, for example, that the cost of the same treatment for tuberculosis represents income from 500 working hours in Tanzania, 100 in Zimbabwe, 20 in Thailand and 1.4 in Switzerland. The comparable costs for gonorrhoea are 120 hours in Tanzania, 20 in Zimbabwe, 6 in Thailand and 0.4 in Switzerland.<sup>2</sup>

And where incomes are low – below a dollar a day – even the cheapest medicines are out of reach. A third of the world's population has no access to essential drugs, a figure that rises to half the population in the poorest countries of Africa and Asia.<sup>3</sup> And it is these countries that are most affected by disease.

Lack of basic healthcare, including essential drugs, is not only a tragedy for individuals, but also a significant burden for the society in which they live. Those who are ill or who die from treatable diseases represent lost productivity and wealth for their families, communities and nations.

## 2 Patents and the pharmaceutical industry

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Globalisation of trade in the last 20 years has been accompanied by the development of international standards for intellectual property rights. These have been codified in the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, discussed in the next chapter.

- **Intellectual property** refers to creations of the mind such as inventions and artistic works
- An **invention** can be defined as a product or a process which is new, useful and capable of manufacture
- A **patent** is the intellectual property right for an invention – the monopoly right to benefit financially from the invention for a limited period. Patents were originally designed for industrial technical inventions

A patent is applied for and functions in each country separately. Most countries have laws to protect intellectual property and a national patent office to assess and approve patent applications. Different countries may have different views about whether something fulfils the requirements for a patent – that it is really something new, for example. Some countries have formed regional patent offices, such as the European Patent Office and the African Regional Industrial Property Organisation, to examine patent applications. The World Intellectual Property Organisation (WIPO) accepts a single international application that is valid in many countries, but patents are still granted on a national basis.

**The World Intellectual Property Organisation (WIPO)** is the principal international institution responsible for organising the negotiation and administration of intellectual property (IP) treaties. WIPO's mission is to promote IP protection globally and to harmonise national legislation. It is not required to consider the benefits or costs of increased protection for intellectual property rights.

Patents have often been a source of dispute between nations. Richer countries tend to insist on patents to protect manufacturers,

while poorer ones tend to ignore them in order to create wealth. In the nineteenth century, the US built up its industrial base by copying many British inventions; today it is one of the strongest defenders of the patent system.

The first patent statute was passed in Venice, Italy in 1484, but many countries have not had a patenting system until recently. Even in the North, pharmaceutical patents were not fully applied in many countries until the 1970s. During the same decade India and Brazil loosened patents on pharmaceuticals, partly for the benefit of public health and partly to stimulate national economic development.

The argument underlying wide recognition of patents is that they provide financial incentives for research and development (R&D). Innovations often require substantial investment of time and money and if an invention is made public without patent protection, the inventor may not be able to recoup or benefit from that investment. Without patents, or if patents are ignored, there would be less incentive to innovate and, in the pharmaceutical industry, fewer new drugs to tackle such diseases as HIV/AIDS, tuberculosis and cancer.

Those who favour weak patent protection argue that the monopoly granted to patents allows the patent holder to charge high prices, depriving the poor of an essential product or technology. Without the ability to copy patented products, particularly in countries where the patent holder has little commercial interest, nations will not be able to use and develop new technologies.

“Applying stringent patent protection in developing countries will not generate more revenue for companies, but it will significantly limit poor people’s access to vital medicines,” says the British non-governmental organisation Oxfam.<sup>4</sup>

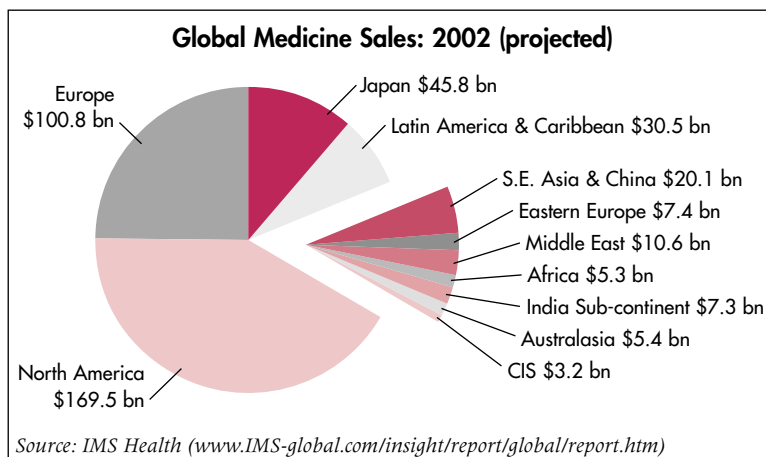
## The pharmaceutical industry

Generally speaking, medicinal drugs are made by two kinds of companies.

- **Pharmaceutical companies** which primarily undertake R&D and hold patents in their new discoveries (also known as originators or the research-based industry). Most pharmaceuticals are based in the North. Patented products from the pharmaceutical companies are often referred to as “brands”; Retrovir, Viagra and Zantac are examples of branded goods.
- **Generics manufacturers** which primarily produce medicines based on formulae in the public domain or patented by other companies. They may do some additional research to produce their own versions. Generics are based both in the North and the developing world.

The primary goal of both pharmaceutical and generic companies is to make a profit. For pharmaceuticals, profit mostly comes from the sales of patented drugs, which only they have the right to manufacture and sell. For generics, profit generally comes from selling unpatented – no longer patented or patented elsewhere – drugs at prices lower than those of their competitors.

The pharmaceutical sector is overwhelmingly Northern-based and dominated by a few large multinational companies. Most of its profits are also made in the North. Although developing countries comprise over 80 per cent of the world's population, they only represent 21 per cent of global medicine sales.<sup>5</sup>



## Research, development and marketing

New drugs only reach the market after a lengthy process of R&D. This includes identifying, synthesising, developing, testing (in laboratories and on people) and securing approval for the new product. Many drug candidates fail; according to industry estimates, not more than one in 5,000 compounds synthesised in the early stages of research reaches the market.<sup>6</sup>

While the importance of R&D is not denied, there is considerable disagreement as to how costly it is. Recent estimates of \$802 million<sup>7</sup> per drug that reaches the market – a figure that includes the cost of failed candidates – have been challenged by critics, who claim that this figure ignores several factors that significantly reduce costs. These include: the contributions of publicly funded research and tax deductions to R&D; the fact that significant funding may be invested in trials to bolster marketing claims rather than develop new products; the development of new technologies that reduce the length of time and procedures needed to develop new drugs.<sup>8</sup>

Public Citizen, a US consumer organisation, claims that once tax deductions and other accounting practices are included, the figure is under \$150 million per new drug.<sup>9</sup> The Global Alliance for TB Drug Development calculates that a new drug for tuberculosis could be developed for \$115–\$240 million.<sup>10</sup>

Costs in general could be reduced by moving R&D to a developing country. B K Raizada, Senior Vice-President of Indian medicine manufacturer Ranbaxy Laboratories, estimates that R&D costs in his country are about 30 per cent of those in the US.<sup>11</sup> The Global Alliance estimates the trial component for a new TB drug in the South would be around \$10 million, compared to \$27 million in the industrialised world.<sup>12</sup>

Public institutions also play a major role in research, often discovering new molecules which are then developed and marketed by the pharmaceutical industry. Seventy per cent of therapeutically important drugs introduced in the US between 1981 and 1991 were produced with government involvement; some, such as AZT, DDI and D4t,<sup>13</sup> which are all used in HIV/AIDS treatment, have made considerable profit for their manufacturers.

Both the academic and small biotechnology sectors are proving to be greater pharmaceutical innovators than the large, research-based pharmaceutical companies.<sup>14</sup>

From one perspective, the public contribution to R&D is increasing. Eighty per cent of new drugs were generated entirely within companies in the 1960s, a ratio which fell to about 50 per cent in the 1990s. Observers estimate that 60 per cent of drugs would not have been discovered or would have had their discoveries delayed without public sector research.<sup>15</sup> However, some analysts are concerned that the role of the public sector is shrinking, as private funding of research in universities increases and public research is increasingly viewed as an investment that needs to create economic value.

The industry spends more on advertising and marketing new drugs than on R&D and until very recently, pharmaceutical companies were consistently among the world's most profitable commercial enterprises. In most cases, profits exceed spending on R&D.<sup>16</sup> The industry has been the most profitable in the US for each of the past 10 years – in 2001 it was five and a half times more profitable than the average for Fortune 500 companies.<sup>17</sup> The compensation (salary, shares, bonuses etc) paid to the industry's highest officers reflects this: in 2001 the five highest-paid drug company executives received over \$183 million, considerably more than the entire health budget of many impoverished nations.<sup>18</sup>

Most advertising and marketing is carried out in the US, where, until recently, the cost of drugs was relatively uncontroversial. Marketing, to both the public and the medical profession, is essential when there is little therapeutic advantage between drugs.

### Relative spending by pharmaceutical companies

Company	Per cent of revenues spent on marketing/ advertising/administration	Per cent of revenues spent on R&D (2001)
Merck	13	5
Pfizer	35	15
Bristol Myers Squibb	27	12
Abbott Laboratories	23	10
Wyeth	37	13
Pharmacia	44	16
Eli Lilly	30	19
Schering-Plough	36	13
Allergan	42	15

Source: *Families USA* ([www.familiesusa.org/new2001data.htm](http://www.familiesusa.org/new2001data.htm))

### The price of drugs

The above costs, plus the costs of ingredients and production, are factored into a manufacturer's price of a patented product. (Generic – unpatented – drugs have relatively few R&D costs.) However, once these costs are taken into consideration, the actual price charged by manufacturers is primarily determined by what the market will bear – how great a demand there is for the product and, where demand is high, whether there is competition.

The manufacturer's price represents only part of the price paid by consumers, who may be individuals, governments or other healthcare providers. The consumer price must also cover government taxes, if any, and distributors' and retailers' margins. The World Health Organisation (WHO) calculates that in developed countries, the manufacturer's price typically represents 50 to 60 per cent of the final consumer price, while in some developing countries up to 80 per cent of the consumer price consists of import duties, taxes, distribution costs and dispensing fees.<sup>19</sup>

### **The World Health Organisation's Essential Drugs List**

comprises medicines that “satisfy the priority healthcare needs of the population... selected with due regard to public health relevance, evidence on efficacy and safety and comparative cost-effectiveness... They are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford”.<sup>20</sup> Over 300 medicines are on the list, fewer than 20 of which are patented. Member states are encouraged to develop their own essential medicines list, and by early 2002, over 150 nations had done so.

### **Competition**

Do patents lead to higher prices? The industry responds that the link between patents and high prices is weak or non-existent and price is not the only factor in access to drugs. Apart from HIV/AIDS and drug-resistant infectious diseases, almost all the leading causes of death and illness in developing countries can be treated or prevented by old, inexpensive drugs and vaccines that have long been off patent. Yet few people in the developing world with those diseases are treated – under 15 per cent of people with tuberculosis in India and Brazil receive life-saving generic medicines.

Harvey Bale, Director-General of the International Federation of Pharmaceutical Manufacturers' Associations, believes the real barriers to access to drugs are: “a combination of poverty, lack of access to sufficient international financial assistance, the absence of trained medical personnel in many regions of all developing countries, lack of diagnostic equipment, lack of effective political leadership to address health as a priority”.<sup>21</sup> A 1993 World Bank study estimates that in many African countries, inefficiency may have led to only 12 per cent of tax money allocated to the purchase of drugs being effectively utilised.<sup>22</sup>

The industry argues that patents are not a monopoly. Patented medicines often compete with off-patent products, and with each other. However, while that is true for some illnesses and therapies, such as high blood pressure, there are many cases in which patented drugs do have a monopoly. There are many patented antiretroviral (ARV) drugs, for example, but the nature of HIV/AIDS treatment is such that the patented drugs are not alternatives that compete with each other but must be used in combination. Without generic versions there would be no competition.

The industry points out that patented drugs form a small percentage of drugs consumed. Only five per cent of the top-selling 200 drugs in the US in 1994 were patented, as are fewer than 20 of the products on the WHO Essential Drug List. However, although patented drugs are a smaller proportion by volume, they form a higher proportion of healthcare by cost.

The industry says that patents do not prevent the sale of other drugs, for example, a 2001 study in 53 African countries concluded that patents on ARV drugs for HIV had only been applied for in 172 of 795 possible cases. This had allowed importation of the generic versions in the remaining 623 cases.<sup>23</sup> Critics of the study point out that South Africa, the region's richest country and with the highest number of people living with HIV, had most patents in force, and that patents on particular drugs in other countries often blocked use of the combination therapy that is key to HIV treatment.<sup>24</sup> In other words, patents are applied for, and restrict choice, where there is a potential market, as in South Africa.

The industry notes that competition from generics does not always bring prices down: in 1999 Argentina had annual dosage costs for two of the main AIDS triple therapy drugs of over \$10,000 per person per year, even though the country had several generic manufacturers, while in Brazil, with only one seller, the cost was \$5,019.<sup>25</sup>

However, Argentina appears to be the exception rather than the rule. Prices of ARVs have fallen substantially in most countries where generic versions are available – from \$10,000 a year to as little as \$209 a year – while remaining high elsewhere. In Uganda in October 2000, “there was an 80 to 90 per cent price cut when [the leading clinic] brought in generics”.<sup>26</sup> And a 1995 study found that the prices of new drugs were on average about five times higher than for older drugs in Pakistan, and as much as 25 times higher in Sri Lanka.

## Extending patents

Tension persists over whether and how the period of patents can be extended. While the TRIPS agreement (see next chapter) mandates 20 years' protection from the time a patent is first applied for, manufacturers argue that safety regulation procedures can take eight or nine years, thus reducing effective patent life to no more than eleven years.<sup>27</sup> The pharmaceutical industry is therefore keen to extend patents whenever possible, while generic manufacturers and others seek to limit patent life.

This means that towards the end of a product's patent, two conflicting processes come into play. On the one hand, the Bolar

Provision, recognised in many, but not all, countries, allows generic companies to develop drugs (and research if necessary) while they are still under patent so that they can stockpile them for sale immediately the patent expires. On the other hand, to protect a drug's monopoly, manufacturers may claim additional patents on drugs that are about to go off patent – a process known as “evergreening”. The industry is often accused of disguising minimal developments with little or no additional therapeutic value as innovations, claiming patents for them under legal loopholes. “[Pharmaceutical] companies today have found that the return on investment for legal tactics is a lot higher than the return on investment for R&D,” says Sharon Levine, associate executive director of a US healthcare provider.<sup>28</sup> A patent can also be extended informally, if a pharmaceutical company pays a generic manufacturer to delay market entry of the generic version.

### **“Neglected” diseases**

Pharmaceutical companies tend to restrict R&D to commercially attractive products. Much research is dedicated to conditions considered priorities in wealthier countries; many, such as baldness and erectile dysfunction, are not life-threatening, while others, such as persistent obesity, are only life-threatening in the long term.

But very little R&D goes into diseases that occur mainly in developing countries – life-threatening conditions that only, or primarily, affect the world's poor – because the potential economic return is too small to justify investment. Of 11 leading pharmaceutical companies surveyed in 2001, only five were undertaking research into sleeping sickness, leishmaniasis and Chagas disease and only two reported research into malaria. And of 1,393 new drugs approved between 1975 and 1999, only 13 were for tropical diseases.<sup>29</sup>

Critics claim that Northern governments have failed to influence drug development through direct funding of appropriate research or through policies such as tax incentives that might influence the private sector. In comparison, the UN system has been more proactive. In 1975 the Special Programme for Research and Training in Tropical Diseases was established with the objective of conducting research into new medicines to help control a defined group of tropical diseases. It also trains scientists and strengthens institutions from disease-endemic countries to encourage them to play a larger role in the research process.

## Nigeria: A question of political will

*Nigeria once hosted one of Africa's best pharmaceutical industries. Now, counterfeit drugs, a poor distribution system and corruption mean that it is difficult for people to get the drugs they need.*

Georgina Ahamefule was at the end of her tether. In October 2000, she developed a painful cough. Her doctor diagnosed tuberculosis (TB).

Because it is government policy to give free drugs for the treatment of TB, Georgina, 43 and HIV-positive since 1995, thought that she would get the necessary medicines. Yet because they were often not available in government clinics, she had to purchase them from the private market at a very high cost. "My doctor had told me that if I disrupted the treatment schedule or was unable to complete the dosage, I ran the risk of developing multi-drug resistant TB," she said.

Up to 30,000 Nigerians die of tuberculosis every year. Most of these lives could be saved if Directly Observed Treatment, Short-course (DOTS), involving a series of non-patented drugs, was more widely available. At market prices, DOTS costs \$130 for a course of treatment, a fortune in a country where the minimum wage is \$53 a month and most middle-income workers earn around \$150.

Apart from TB and malaria, government health services are no longer free. To qualify for treatment, patients must buy a registration card and then pay for prescriptions and laboratory tests at prevailing market prices.

Nigeria has one of the poorest doctor-to-patient ratios in Africa, with one doctor per 3,500 people. In 1998 only 2.5 per cent of the government's budget was spent on health. Lack of modern or functioning facilities and medical personnel means long waits and inefficient services.

And yet Nigeria once hosted one of Africa's best pharmaceutical industries. "The local pharmaceutical industry is at its worst ebb," says Mrs Stella Okoli, chair of the pharmaceutical group of the Manufacturers' Association of Nigeria. "In 1990, up to 137 indigenous and foreign-owned pharmaceutical firms were operating; now, only 77 are."

In the early 1960s and 1970s, a substantial share of commonly prescribed drugs such as paracetamol were produced by state-owned manufacturers, which, due to alleged mismanagement and poor funding, are now out of production.

Counterfeit or adulterated drugs are another problem. According to Dr Niyi Ogundiran of the WHO, up to 40 per cent of all drugs in Nigeria are either smuggled in illegally or are counterfeits. The

National Agency for Food and Drugs Administration and Control (NAFDAC) claims that between April 2001 and April 2002, it seized and destroyed over \$15.7 million-worth of imported fake drugs. Local pharmaceutical companies have announced a yearly loss of \$78 million to the adulterated drugs market.

There are other problems too. The distribution systems are poorly regulated. Some are controlled by cartels, sometimes likened to mafias. The system of registering pharmacies is often ignored. A 2000 study by a team of pharmacologists from the College of Medicine, University of Lagos, found that of the 117 stores visited, 54 were unregistered. Over six per cent of drugs sold in the pharmacies were past their expiry dates.

Another obstacle is corruption. Sharp practices by unscrupulous medical personnel at state-owned pharmacies are common. Malaria or TB drugs clearly labelled “not to be sold; for free distribution only” appear at private pharmacies located next to public hospitals. Patients who are supposed to receive these drugs free at hospitals are told they are out of stock and referred to the pharmacies outside, or told they could be helped if some money is paid.

“There are clearly a lot of leakages in the system,” says Dr Dan Onwujekwe, a clinician who has done extensive research on tuberculosis treatment in Nigeria. “Pilfering goes on. Drugs are not well accounted for.”

Experts believe many of these problems can be overcome. NAFDAC has taken steps to reorganise the drug distribution system and stem the spate of counterfeiting. It has embarked on strong promotional campaigns and taken measures to stop the cartels.

In addition, local manufacture by state-owned companies of commonly prescribed off-patent drugs such as chloroquine, paracetamol and tuberculosis drugs could significantly reduce prices and discourage counterfeiting. “The one thing that we need is political will,” says Onwujekwe.

Current efforts by government need to be strengthened; equally important is activism by civil society to ensure that the reforms are sustained and institutionalised.

**Omololu Falobi** *is project director of Journalists Against AIDS (JAAIDS) Nigeria, a media-based non-governmental organisation that he helped to establish in 1997.*

## Russia: The challenge of access to medicines

*On paper, Russia's healthcare statistics are impressive. In reality, as the country amends its legislation to join the World Trade Organisation, the system is crumbling and the domestic drugs market is struggling to survive.*

Access to drugs is "one of the greatest challenges of Russia's public health sector" according to Natalia Podgorbunskih, head of the pharmaceutical division of the Ministry of Health.

On paper, the healthcare statistics are impressive, with 42 doctors and 96 nurses per 1,000 people and 1.4 million beds for a population of 144.8 million. In practice, however, only three per cent of the country's gross domestic product goes on health. Most facilities lack modern equipment and are short of drugs and medical supplies. "Patients are often asked to bring everything from bedsheets to syringes with them when going into hospital," says Tatyana Siburina from the Ministry of Health.

Doctors earn less than the national average of 4,300 rubles (\$130) a month. Not surprisingly, many enter the pharmaceutical industry or private clinics, where salaries are higher. They commonly accept money and gifts from patients for officially free services, while many public hospitals officially charge patients for "extra" examinations and treatment.

Theoretically, the state pays for medicines on the national Essential Drugs List, while patients pick up the bill for more expensive treatments. In reality it is estimated that 70 per cent of drugs are bought by patients. Russians are entitled to receive drugs free if they suffer from serious diseases such as HIV/AIDS and tuberculosis. But, according to Oleg Yurin, Deputy Head of the Federal AIDS Prevention Center in Moscow, "although on paper antiretroviral treatment is covered by the Federal AIDS programme, in reality it is available to very few."

The cost of a drug is not the only factor influencing prescriptions. Doctors frequently act as distributors for pharmaceutical companies, sometimes prescribing not the most appropriate or cheapest drug, but the drug sold by the company they represent.

The only region to significantly improve access to drugs is the Komi Republic, where a state-controlled Pharmaceutical Chamber purchases drugs for hospitals and state pharmacies directly from producers. Prices have fallen as a result of competition and a reduction in the number of middlemen.

Opinions differ as to whether regulation helps reduce prices or forces them up. Alexander Afanasiev of the Pharmaceutical Sub-Committee in the Duma (the Russian Parliament) says, "prices are

often lower in regions where they are not dictated by local authorities". He argues that where regions set a lower margin for cheaper drugs and a higher one for more expensive ones, manufacturers focus on expensive drugs and cheaper ones are ousted from the market.

In Russia's drug market "cheap" usually means "domestically produced", while "expensive" means "imported". According to the national Pharmexpert Market Research Center, imported drugs comprise 68 per cent of market value, but only 38 per cent of volume.

Russia has about 300 drug manufacturers, the top 10 of which produce about half the country's drugs. Ninety per cent of domestically produced drugs cost no more than \$0.15 in manufacturers' prices. "Medicines dating back to the Soviet times have a certain consumer market – people buy them out of habit and because they don't have the money to purchase more expensive drugs," explains Svetlana Grudachyova of Pharmexpert.

But in some experts' eyes, the quality of domestic drugs is uncertain. The Association of International Pharmaceutical Manufacturers claims that counterfeit drugs occupy at least 12 per cent of the market.

Meanwhile, domestic manufacturers complain that the government is not making their lives easier. In 2002, a 24 per cent company profit tax was reintroduced on essential drugs, in addition to a 10 per cent value added tax.

Russia has applied to join the World Trade Organisation (WTO) and has begun to amend its legislation. To continue production, domestic manufacturers will have to comply with international standards. The switch could cost up to three billion dollars, according to one industry executive. "The day all Russian manufacturers have to comply... most of them will simply have to close," says Alexander Tyulaev of Akrihin, Russia's number two manufacturer.

Membership of the WTO will open the door to the export market. But this might be a one-way passage. "What use is it to us if they lift export restrictions, when no-one is interested in importing Russian drugs," asks Tyulaev.

Afanasiev says Russia is not ready for the WTO. "When Russia enters the WTO it will become even more open to imported drugs, but we will not get an opportunity to sell our medicines abroad in exchange, because they aren't competitive enough. Domestic manufacturers should be given some time to get back on their feet before we rush to join."

**Lina Rozovskaya** is a freelance reporter specialising in health issues

## 3 TRIPS: a global intellectual property regime

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The World Trade Organisation (WTO), to which two thirds of the world's nations belong, regulates international trade. The WTO argues that a stable and transparent global intellectual property regime is an essential prerequisite for expanded international trade and investment. The basis for this regime is the international agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) signed in 1993.<sup>30</sup>

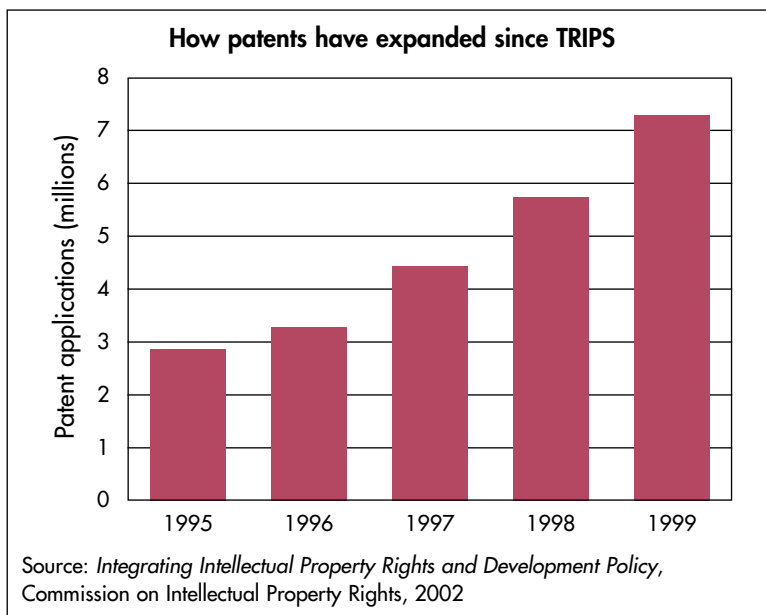
Under TRIPS, patents are granted for products and processes, with protection set at 20 years from the date of application. Under TRIPS, all members of the WTO, including those countries which had no patent protection, or very little, must now introduce a new and standardised level of protection. Developed countries had until 1996 to do so, most developing countries had until 2000, with some allowed to extend until 2005, while there are 30 least-developed countries that have until 2016 to pass legislation requiring patent protection for pharmaceuticals and agricultural chemicals.

TRIPS has not been universally welcomed, particularly in countries where patent protection has been weak. But in order to achieve WTO membership, patent legislation had to be accepted as part of a package of benefits for developing countries, such as lowered tariffs for the agricultural products they wanted to export.

Whether or not the overall package benefits the South is a matter for debate. The arguments in favour of patent law are that it encourages multinationals to invest, and supports innovation by producers within the country. People who argue against it say that it will raise prices and discourage innovation.

Poor countries are generally at a disadvantage in international negotiations, partly because their positions are often compromised by economic dependence on wealthy countries – which support TRIPS – and partly because their personnel often have little training in the field in which they are negotiating. The US in particular is frequently criticised for using its power to achieve its goals at the expense of others, either during negotiation or as a unilateral action under Provision S301 of the US Trade and Tariff Act.

Dr Supachai Panitchpakdi, the Director-General of the WTO, said: “There are many things in the TRIPS requirements that we need to reconsider, so that the requirements would not place an unnecessary burden on the poor countries. It would also enable the poor countries to pursue their developmental goals, for example educational development and healthcare development.”



## Human rights and development

Critics are concerned that TRIPS will not only reduce competition and raise prices, but by doing so, will threaten both human rights and the development process. UN human rights bodies have alerted governments to the “apparent conflicts between the intellectual property rights regime embodied in the TRIPS agreement on the one hand, and international human rights law on the other” and reminded “all governments of the primacy of human rights obligations over economic policies and agreements”.<sup>31</sup> They have called on member states to refrain from taking measures which would limit equal access to medicines “used to treat HIV/AIDS or the most common opportunistic infections that accompany them”.<sup>32</sup> It is now accepted that there is a right to access to treatment.

The independent UK Commission on Intellectual Property Rights which comprised a wide range of international experts and

finalised its report in September 2002, concludes that TRIPS may harm development and it is inappropriate to apply the same standards to all nations regardless of national wealth or technological capability. “Standards of IP protection that may be suitable for developed countries may produce more costs than benefits when applied in developing countries, which rely in large part on knowledge generated elsewhere to satisfy their basic needs and foster development.”<sup>33</sup>

And while the World Bank estimates that IP protection will lead to increased foreign investment in middle-income countries, it estimates that full implementation of TRIPS would mean a loss to developing countries of \$20 billion in patent payments (for all sectors, including health).<sup>34</sup>

Growing concern in the South about the implications of TRIPS led to the Doha Declaration, signed by WTO ministers in November 2001. The Declaration affirmed that the agreement “should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all”.

Nevertheless, as several country studies in this report confirm, developing countries are often placed under considerable pressure to adopt legislation ensuring stronger protection for patents than under TRIPS. This approach, known as TRIPS-Plus, includes broad, rather than narrow, definitions of patents, and severe restrictions on techniques such as compulsory licensing and parallel trade (discussed in the next chapter) that would increase access to drugs. It also includes pressure on countries to implement legislation in advance of the 2005 or 2016 deadline, with the result – as the Uganda report following Chapter 5 demonstrates – that draft or enacted laws may be deeply flawed.

## **The Free Trade Area of the Americas: Protecting people’s health?**

*The US is heavily influencing the negotiation of the new Americas agreement on trade. A groundswell of opinion throughout the area is rising in protest.*

The North American Free Trade Agreement (NAFTA) was established in 1994 by Canada, Mexico and the US to establish a free trade zone across the three countries. NAFTA had a mixed reception, with supporters, including governments and major industries, arguing that it opens access to markets and creates employment opportunities, while opponents, often small businesses

and non-governmental organisations, believe that it has caused many workers to lose jobs and has adversely affected people's incomes.

Whatever its successes or failures, NAFTA will soon be superseded. Negotiations to establish a Free Trade Area of the Americas (FTAA), which covers the whole continent, are expected to be complete by 2005. However, lack of transparency in the negotiations worries many organisations, which suspect that under the new regime, intellectual property rights will be over-protected at the expense of the health of hundreds of millions of the region's inhabitants.

Two stances over patent protection have emerged. The US wants the FTAA to strengthen intellectual property protection. Almost every other country in the Americas wants the principles of the Doha Declaration to be included in the FTAA. This would enable the agreement to support public health and promote access to existing medicines while giving some respect to the rights of patent holders.

The current, US-influenced draft of the FTAA extends the rights of patent holders beyond those granted by TRIPS and those recognised in national legislations. It includes clauses that would extend patent protection beyond the 20-year limit. A World Trade Organisation (WTO) panel has stated that such patent extensions do not constitute a "legitimate interest" of patent owners.

Currently a patent can be revoked under certain conditions, including non-operation within a certain time and anti-competitive practices. The FTAA draft proposes that a patent can only be revoked when reasons exist that would have justified the refusal to grant it in the first place. This would deny countries the freedom to revoke a patent should circumstances change within the 20-year period. The patent could not be revoked if a country considers that a company's practices are anti-competitive.

Under the draft FTAA, countries which have licences to manufacture drugs would not be allowed to export them to smaller countries which don't have any manufacturing capacity, leaving them to buy more expensive patented drugs. There are a number of private and public drug manufacturers in the region that would be affected by the new agreement. They mainly produce generic medicines, covering the population's basic needs with high-quality, low-cost products. In Argentina, the drugs industry represents around 11 per cent of the industrial gross product and local companies hold 52 per cent of the internal drugs market. The Dominican Republic has developed a high-quality and competitive pharmaceutical industry, saving an estimated \$200 million a year in

drug imports.<sup>35</sup> Brazil has also developed a successful manufacturing programme, particularly in HIV/AIDS drugs, and it is one of the few countries in the region providing ARV therapy to all who need it.

Negotiations in the FTAA are conducted through a committee of deputy trade ministers from each country. Although a ministerial declaration in April 2001 reaffirmed commitment to a transparent negotiation process through increasing and sustained communication with civil society, many governments have not invited input from civil society.

Across Latin America, activists are demanding a process of official consultation with civil society and human-rights groups which is “transparent and participative, that assures the immediate access to documents under negotiation, and an evaluation process before the adoption of the agreement(s)”.

The exclusion of civil society, lack of transparency and the power of the US lead many to believe that the FTAA will impose a more restrictive patent regime than under TRIPS, benefiting commercial enterprises rather than people’s health.

**Guillermo Murillo** works for the *Agua Buena Human Rights Association* in Costa Rica

## China: The challenges of joining the WTO

*Some business analysts predict that China will become the world’s largest pharmaceutical market by 2020. But the country is still assessing the impact of joining the WTO on its domestic market.*

China’s pharmaceutical industry has grown by an average of 17.5 per cent per year since 1978, when economic reforms were followed by a series of policy changes, including the introduction of a national Essential Drugs List.

In 2000, the production of pharmaceutical raw materials reached 240,000 tons, the second highest in the world after the US. The industry’s total output was \$28 billion, accounting for 5.7 per cent of world market share. \$3.8 billion worth of pharmaceuticals were exported.

In addition to other drugs, China produces many Traditional Chinese Medicines (TCM) – 8,000 different types in 1998. These come under the same intellectual property laws as other medicines.

Patents for pharmaceutical and chemical products have been applied in China since 1993, with other laws to protect intellectual property in place since 1982. China’s most recent drug law came

into effect in December 2001, the same month that the country joined the WTO. It stipulates that medicine sales should follow international conventions – and also meet China’s needs.

It is too early to measure the impact of WTO membership on the country’s pharmaceutical industry. Furthermore, the pressures placed on the industry by membership will be matched by internal change, including the reform of social security and the medical and health systems.

There are 16,000 pharmaceutical wholesalers in China, although fewer than 1,000 are large-scale and only 70 have annual sales exceeding \$30 million. In recent years, however, severe competition has caused enterprises to reduce profits to a minimum. At the same time, structural problems in the industry have become apparent. Only two innovative drugs produced in China have been approved internationally and more than 97 per cent of drugs produced are generics.

In addition, China’s production standards are low, with only 87 companies being awarded the internationally accepted Good Manufacturing Practice certification. Faced with severe penalties of \$400 million to \$1 billion in penalty fees, generic manufacturers will be forced to cease production of illegal copies and reduce export volume. While some companies could gain technologically as a result of association with multinationals, the majority must either invest in research or obtain production licences (each licence could cost at least five million dollars) from the multinationals. In both cases, the costs are likely to be out of reach for the majority of companies.

By 2005, customs duty on imported pharmaceutical products will be reduced from 10 to 4.2 per cent. For non-patented drugs, this will reduce the competitive edge that domestic products have over imported ones. However, it is unclear whether patented drugs will also take advantage of this reduction in tax or whether lack of competition will keep prices high.

Traditional Chinese Medicine may be less affected than the conventional pharmaceutical industry by WTO membership. Competition from other countries will place pressure on domestic producers, but this is expected to have a beneficial effect in forcing the restructuring of the TCM industry. This will include establishing a scientific basis for the efficacy of herbal medicines, which is imperative if China is to develop medicines that conform to international standards and to produce more for export.

Publicly listed companies in the pharmaceutical industry will also be affected by WTO membership. The negative impact is expected

to be relatively minor on those which mainly manufacture penicillin and Vitamin C, as most of their products are made for export and WTO membership will facilitate their overseas market expansion. However, publicly listed companies mainly oriented towards the domestic market will face competition from imports and reduced opportunities to manufacture generic drugs under the new regime.

Under WTO membership, multinational pharmaceutical companies will be able to acquire a large share of the Chinese pharmaceutical market. They may be able to gain control over distribution networks and not have to rely on the existing complex and costly system. An open market will give them a better chance of having their products included on China's provincial and municipal lists of drugs that are subject to state reimbursement.

China has also agreed that current trading rights and distribution restrictions are to be phased out over a three-year period, allowing foreign companies to import most products, including pharmaceuticals, into any part of China. Western imports are expected to top \$60 billion by 2010 and some business analysts predict that China will become the world's largest pharmaceutical market by 2020. On the other hand, it is considered unlikely that foreign pharmaceutical enterprises will enter the Chinese market at the basic level of unpatented drugs, where they will face stiff competition from domestic Chinese enterprises.

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## **India: The pharmaceutical industry post-TRIPS**

*The debate over the patenting of pharmaceuticals rages in a country with a large domestic industry and considerable international clout.*

Until the early 1970s, Indian patent law was relatively strict. Drug prices were amongst the highest in the world and only 30 per cent of sales were manufactured domestically. In 1972, however, the 1970 Indian Patents Act came into force, loosening patent protection. Pharmaceutical processes but not products could be patented and only for seven years.

In the next 20 years the industry flourished. By 2000, 500,000 people were employed in a sector comprising 20,000 private enterprises, and domestically produced drugs accounted for over 70 per cent of the market. India is the world's fourteenth-largest

market for pharmaceutical products in value terms and the fourth-largest market in unit terms. Exports of finished formulations rose from \$9.6 million in 1980–81 to \$1.3 billion in 1999–2000.

Nearly 65 per cent of the Indian export market is to the developed world. The larger companies both copied drugs patented elsewhere and fostered R&D. However, although the money spent on R&D reached \$66 million in 1999–2000, as a percentage of overall sales it remained very low, averaging two per cent of turnover.

During this period, prices fell significantly. By the 1990s, the cost of both patented and non-patented drugs in India was much lower than in the developed world and significantly less than in neighbouring Pakistan, where health and income conditions were similar but patent protection had not been abolished.

To comply with TRIPS, the 1970 Act was first amended in 1999, though not agreed by Parliament until May 2002. This changed the law in several key areas. Perhaps the most important is that product patents will be recognised – although applications will not be processed until December 2004 (the “mailbox” system). Exclusive marketing rights will be granted before then if a patent for the product has been granted in another WTO member country – and the application has not previously been rejected in India.

Those who support a weak intellectual property regime consider that the new legislation goes too far in some aspects – for example, new dosage forms or new formulations have been included as “inventions” that are eligible for patents – but recognise that some important provisions of the 1970 Act have been retained. These include the use of the patented product or process for the “purpose merely of experiment or research including the imparting of instructions to pupils”.

Some prominent sections of the industry are very much in favour of the new laws. But they recognise that investment in R&D will have to be stepped up. Most Indian pharmaceutical companies spend less than 0.25 per cent of turnover on R&D. Overall, this needs to be increased to nine per cent to keep abreast of global competition.

The Organisation of Pharmaceutical Producers in India mostly represents companies with a R&D base. According to spokesperson P S Khanna, the organisation does not believe that the amended Act goes far enough in protecting payments and is not TRIPS compliant. Khanna says that strong patent laws are needed as only a healthy industry can bear the costs of R&D and strong patent laws are required for investment.

Amar Lulla, joint managing director of Cipla, a leading Indian pharmaceutical company that exports generic versions of ARV drugs, feels that while companies may stand to gain from product patenting, the consumer will suffer. "Unlike other consumables, medicines are not a matter of choice but necessity. Patents mean a monopoly and the right to charge any price." Nevertheless, Lulla believes, the Indian industry will survive because of the generic market.

Gajanan Wakankar, executive director of the Indian Drug Manufacturers' Association, also believes the future is in generics, as each year some 20 to 40 medicines go off patent. Even then, he cautions, developed countries often harass companies exporting off-patent drugs.

**T K Rajalakshmi** works for *Frontline* magazine



Heldur Nelsson / Panos Pictures

*Research student in Chennai, India. Indians as individuals spend four times more on health than the state.*

## 4 Increasing access

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As the Doha Declaration confirms, TRIPS includes mechanisms intended to safeguard public health while respecting intellectual property rights. But while the principle of the need to increase access to medicines in poor countries is widely recognised, the means of doing so is disputed.

### Compulsory licensing

In January 2001, South African HIV/AIDS treatment activist Zackie Ahmat went to Thailand to buy 5,000 pills of the generic version of an anti-fungal drug patented by the US pharmaceutical giant Pfizer. He paid \$0.21 a pill. The price of the patented version in South Africa was \$13 a pill.<sup>36</sup> While the difference in price between generic and patented drugs is not always so dramatic, it is a powerful argument in favour of extending generic production wherever possible.

Compulsory licensing is a mechanism allowed under TRIPS which increases access to generic drugs. A government or, if authorised to do so, a court, issues a licence to a manufacturer to produce a generic version of a patented product, while the patent holder is compensated through royalties – which usually average four per cent – from sales.

Many developed countries, including the US, have a compulsory licensing provision and have used it extensively for a variety of purposes, including computers, biotechnology and other modern technologies.<sup>37</sup> Under TRIPS, compulsory licences may be issued for reasons of “national emergency” and “extreme urgency”. The Doha Declaration confirmed that nations have “freedom to determine the grounds upon which such licences are granted” and “to determine what constitutes a national emergency or other circumstances of extreme urgency”. Failure to exploit a patent, or anti-competitive practices by the patent holder, are also grounds to issue a licence, successfully used by Brazil, as described below.

Proponents of a strong IP regime argue that compulsory licensing should be used very seldom. Pharmaceutical companies argue against it on several grounds. These include not only the argument that widespread use of licences would inhibit innovation, but the risk that the product manufactured by the licensee would not be as efficacious as the original. They also say that if only one manufacturer is granted a licence for a product, there is little

incentive to retail it at the lowest possible price. Compulsory licensing “imposes costs on the national governments faced with having to approve and monitor the products produced by the licensees” and “encourage[s] copying by local firms who may grow accustomed to free riding on the innovative activities of the research-based pharmaceutical firms. In the long run, these local firms are actually denied opportunities to develop technology transfer into their home countries and to expand beyond national boundaries,”<sup>38</sup> says an independent research organisation.

Others see regular use of compulsory licensing as an important means for governments in developing countries to safeguard public health at affordable prices, build local manufacturing capacity through enforced transfer of technology, and prevent anti-competitive practices. Compulsory licensing explicitly recognises patents and rewards patent holders through royalty payments. Questions of efficacy can be resolved by state regulatory authorities while widespread application of licences would encourage the development of a competitive pharmaceutical market.

Compulsory licensing is practised by a very few developing countries to address health needs. In September 2002 Malaysia announced that it would issue licences for drugs to combat diseases such as AIDS. The Brazilian government has used the threat of compulsory licences to persuade pharmaceutical companies to provide ARV drugs at greatly reduced prices. But most countries seem reluctant to grant licences, fearing litigation by patent holders, being challenged for violating WTO rules, or reprisals by the US.

A particularly contentious aspect of compulsory licensing is licensing for export. TRIPS stipulates that drugs manufactured under licence must be “predominantly” for the domestic market. A narrow interpretation of this rule would mean that small and poor countries with little or no manufacturing base would be unable to issue licences to manufacturers in other countries, since those manufacturers would be unable to export their products. On the other hand, the WHO argues that licensing for export is justifiable. “The basic public health principle is clear: the people of a country which does not have the capacity for domestic production of a needed product should be no less protected by compulsory licensing provisions (or indeed other TRIPS safeguards), nor should they face any greater procedural hurdles, compared to people who happen to live in countries capable of producing the product.”<sup>39</sup>

In India, the impact of compulsory licensing on the industry is still uncertain. For example, Rifampicin, a patented drug used for treating tuberculosis, is manufactured by 20 companies in India.

“The patented drug is simply unaffordable,” says Gajanan Wakankar, executive director of the Indian Drug Manufacturers’ Association. Least-developed countries with no manufacturing facilities should have the right to issue compulsory licenses to companies in developing countries. “If Nepal has a life-threatening emergency, it should be given the right to issue licenses to Indian manufacturers,” says Wakankar.

The advantage of compulsory licensing is that it has the potential to check prices and induce competition, but this is only possible where there are manufacturing facilities and technical expertise.

Most experts consider that drugs “required to address emergencies” will always constitute a small fraction of the total number of drugs manufactured.

A meeting of the TRIPS Council in September 2002 resulted in little progress on this issue. While countries agreed that it was essential to increase poor countries’ access to medicines, none of the methods proposed by different countries, including amending TRIPS and allowing governments to act without the consent of patent holders to address public health needs, won broad approval.

### **Voluntary licensing**

The pharmaceutical industry argues that voluntary licences, also known as patent waivers, are a fairer and equally or more efficient means of increasing access. Several multinational companies have allowed South African generic companies to manufacture versions of their patented drugs, although under conditions (including higher prices than the generic versions and restricted sales) that have been criticised by activists.<sup>40</sup>

However, companies appear reluctant to grant such waivers on a regular basis. Some refrain from pursuing patent claims in least-developed countries, but critics, such as Ken Bluestone of Voluntary Service Overseas (VSO), a British non-governmental organisation, claim that this does not go far enough. “Countries have to know that they are able to legally import cheaper medicines.”

### **Parallel trade**

Governments and private consumers continue to try to access drugs as cheaply as possible. This includes two primary mechanisms: parallel trade and differential pricing.

Parallel trade is the import of branded or patented goods without the approval of the patent holder. It occurs when there are profitable differences in prices between two countries; a product is bought cheaply in one and sold at a higher price in another.

Parallel trade is widely practised in the European Union. In the UK it represents 13 per cent of total pharmaceutical sales.<sup>41</sup> In 1999, the price of Glaxo Wellcome's Zidovudine (AZT) around the globe varied from \$124.95 to \$53.50 per 250mg/40 capsule pack, allowing significant opportunities for parallel trade.<sup>42</sup>

TRIPS does not determine whether parallel trade should be permitted and the legality varies according to national legislation. Under the principle of **Domestic Exhaustion**, the patent holder retains the right of control of the patent even after the goods have been sold, which means that imports from another country by anyone other than the patent holder are not allowed. Under the principle of **Regional Exhaustion**, goods cannot be imported into any other country in the region. Under the principle of **International Exhaustion**, however, once the patent holder has sold the goods in one country, anyone may buy and export them to another country.

The pharmaceutical industry argues that parallel trade harms those countries where cheap drugs are exported rather than bought by local consumers and that the primary beneficiaries are the traders who buy and sell the drugs rather than the consumer. Manufacturers also lose profits from unsold drugs at the higher price. The industry therefore prefers Domestic Exhaustion, which allows them to keep a strong position in separated markets, while campaigners for softer IP laws argue that parallel importing encourages competition and brings prices down.

Activists have long argued that a database comparing the prices of essential drugs in different countries would allow consumers to buy at the cheapest rates. Pharmaceutical manufacturers argue that such a database would be misleading since it obscures factors such as government taxes and distributors' and retailers' margins. Nevertheless, in 2002 the governing body of the WHO mandated the organisation to begin this process. Results may be found on [www.who.int/medicines/organization/par/ipc/drugpriceinfo.shtml](http://www.who.int/medicines/organization/par/ipc/drugpriceinfo.shtml)

### Differential Pricing

Differential pricing occurs when the patent holder sets different prices for its products according to the purchaser's ability to pay. Differential pricing (also known as preferential, tiered or equity pricing) benefits both the consumer – if prices are reduced to an affordable level – and the patent holder, who maintains or increases market share.

Companies which lower their prices in the developing world do not lose money; high prices in poor countries generate very little of

the industry's income while lower prices increase the volume of sales. Because the costs of administration and R&D are met by sales in the industrialised world, only the costs of ingredients, production and shipping need to be covered by sales to developing countries. However, there is little transparency from the pharmaceutical companies as to these costs.

Differential pricing is practised in many aspects of healthcare, and reductions of up to 99 per cent in the US price of contraceptives and vaccines have been achieved.<sup>43</sup> Some governments negotiate reductions separately; others, particularly smaller countries, come together in purchasing groups. For instance, in 2002, the 15 countries of the Caribbean Community (CARICOM) negotiated 70–90 per cent reductions in the price of ARV drugs from pharmaceutical companies.<sup>44</sup>

Differential pricing is welcomed with caution by the pharmaceutical industry, despite the fact that it risks increasing the demands for lower prices in wealthier countries, thereby threatening the pharmaceuticals' primary source of profit. It also risks the drugs being resold and exported as parallel imports elsewhere. In October 2002, ARV drugs from GlaxoSmithKline (GSK) sold to West African countries at reduced prices, were reportedly offered for sale in the Netherlands. Mechanisms to prevent such incidents include different packaging on different-priced products and stronger anti-corruption measures in the destination countries.

Some non-governmental organisations (NGOs) give a cautious welcome to differential pricing, but argue that processing fees, limited distribution and a range of restrictions imposed by the pharmaceutical companies limit the numbers who can benefit. GlaxoSmithKline's September 2002 announcement that it had concluded preferential pricing agreements on its ARV and anti-malarial medicines was criticised by the NGO Médecins Sans Frontières (MSF) on the basis that eligible countries represented only 11 per cent of the world's population. In addition, while the price of drugs that had generic competitors was reduced by up to 33 per cent, the price of another drug that had no competition was reduced by only two per cent. "That the price discounts offered by GSK are steepest when there are other producers serves to underscore the importance of generic competition," said an MSF representative.<sup>45</sup>

Critics also point out that differential pricing offers depend on the manufacturers' decision rather than patient need. In July 2002 MSF noted that Bristol Myers Squibb's discounts were offered to sub-Saharan Africa but not to Central America, and alleged that

the company “places arbitrary restrictions and burdens on potential recipients”.<sup>46</sup>

Two international attempts to increase access to drugs have been widely publicised, but have as yet failed to make much impact. The first of these, the **Accelerating Access Initiative**, launched in May 2000 by the Joint UN Programme on HIV/AIDS (UNAIDS) and five pharmaceutical companies, mostly depends on differential pricing. By July 2002, however, only 20,000 out of the estimated five million people in the developing world requiring ARV drugs were receiving them through the Programme.<sup>47</sup>

In October 2002, 18 months after its 2001 launch, the **Global Fund for HIV/AIDS, Tuberculosis and Malaria**, announced that generic drugs could be purchased with its grants.<sup>48</sup> However, in its first 18 months of operation, the Fund has been offered only \$2.1 billion, while receiving \$8 billion worth of requests. Many of its grants are for prevention purposes and the numbers of people who are eligible for drugs under the Fund have not been calculated.

## Donated drugs

Some companies donate medicines to public healthcare providers in poor countries. The combined donations of five major companies rose from \$415 million in 1997 to \$611 million in 1999.<sup>49</sup>

But for several reasons, drug donations are not a viable long-term solution to widespread and chronic diseases. They are dependent on the donor’s good will, are necessarily restricted in volume because donors must sell drugs in order to survive. They can be a burden on public health systems, drawing staff from existing healthcare structures to manage separate disbursement systems to keep drugs from being diverted. The number of patients or geographical regions covered may be restricted and irrespective of need. Donations may also discourage rational drug use and hamper development of an indigenous generic capacity.

According to MSF, tax deductions mean that drug donations actually cost the public sector of a donor country (such as the US) more than four times as much as other mechanisms that achieve the same results, such as purchase of generics or differential pricing. “The data also show that the donor company does not have an incentive to lower its prices to a level affordable to the developing world, although its real manufacturing costs may allow

it. The current system of incentives encourages drug donations over better policy options that would be more sustainable and less costly to the public.<sup>50</sup>

However, drug donations are recommended and welcomed in specific circumstances, particularly where a disease is restricted to a particular region and treatment or cure can be effected in short, easy doses. One example is Merck's donation of mectizan to treat river blindness in 1998; an estimated 25 million people in 32 countries were treated.<sup>51</sup> Ethical guidelines on donations have been approved by a consortium of non-governmental and international organisations, including MSF and the WHO,<sup>52</sup> and a perspective from the pharmaceutical industry is also available.<sup>53</sup>

## Kenya: Problems with cut-price drugs

*Cut-price drugs seemed like an ideal solution to Kenya's growing healthcare problems. But they proved to be more problematic than people had expected.*

Kenya's health system is in crisis. A weak national currency, a growing population, rising prices of drugs and medical supplies and the impact of HIV/AIDS have all contributed to a decline in the country's health expenditure over the last 20 years. In 1997, annual per capita health expenditure was seven dollars. Only 50 per cent of this came from the government; payments by individuals and insurance companies contributed 44 per cent and donors and non-governmental organisations financed the remaining six per cent.

The system is inefficient. Administration costs are high, with 70 per cent of spending allocated to salaries and only 30 per cent to services. There is only one doctor for every 10,000 people.

Two million Kenyans are living with HIV/AIDS and an average of 700 people die from the disease every day. Patients with HIV occupy about 50 per cent of the country's hospital beds. To address this problem, several major pharmaceutical companies have offered drugs free or at 10 per cent or less of their price in the industrialised world. However, there has not been a quick uptake and, according to Dr Kenneth Chebet, head of the National STD/AIDS Control Programme, by mid-2002 only 2,000 Kenyans were benefiting from these initiatives.

One problem is lack of guaranteed lifelong access. In April 2002 the non-governmental Coalition for Access to Essential Medicines accused the pharmaceutical company Bristol Myers Squibb of failing to provide a constant supply of its cut-price Videx and Zerit

tablets, forcing patients to switch to alternative medicines or interrupt treatment. Both options can be harmful to health, and the former can be expensive. Epivir can substitute for Zerit but costs 4,000 shillings [\$51.20] a month instead of 400 [\$5.10], forcing many to simply cease taking the drug until it is available again. Dr John Wasonga of Nairobi's Mbagathi hospital complained that at times they are "obliged to hand out 100 mg pills and supply patients with razor blades so that they can cut the pills and get some approximation of the correct dose".

In such a case the ideal solution would be for local distributors to keep enough stocks of ARVs to cover potential glitches in distribution, but Bristol Myers Squibb and other companies only extend credit on normally priced drugs.

Other initiatives to increase access to drugs include 10 per cent of a \$50 million loan from the World Bank to establish regional treatment centres to prescribe free ARV drugs. The National AIDS Control Council has disbursed \$90,000 to train clinical personnel on the management and use of ARVs.

Perhaps more important for its long-term impact on the country's health is the legislation that has been adopted to comply with the membership of the World Trade Organisation. The 2001 Industrial Property Act allows the import of any drug. But in June 2002, only a month after the Act came into effect, an amendment made it mandatory for those ordering the importation of patented drugs, including generics, to seek the approval of the patent holder. "This negates the whole purpose of the Act – to enable Kenyans to import generic antiretrovirals directly at low cost," said Dr Newton Kulundu, chairman of the Parliamentary Health Committee.

Christopher Ouma of Action Aid said there was "most likely a conspiracy between the Attorney-General's office and the pharmaceutical industry". However, after pressure from non-governmental organisations and other stakeholders, the amendment was reversed two months later. A combination of generic anti-AIDS drugs costing \$300 a year can now be legally imported, compared to \$850 for the cheapest branded therapy, although even the lower price is still far beyond the reach of ordinary Kenyans.

Problems remain, particularly with bureaucracy. Most generic medicines are still awaiting registration by the national Pharmacy and Poisons Board, even though manufacturers applied for such registration as far back as 1999. According to Ouma, "only three generic ARVs have been approved so far, but these three cannot be combined into one triple-therapy".

Sophie-Marie Scouflaire, Regional Pharmacist for Médecins Sans Frontières, believes that the Pharmacy and Poisons Board is ineffective and should be restructured along the lines of the Uganda National Drugs Authority, a technical body and quasi-independent of the government. Kenya's Public Health Minister, Professor Sam Onger, however, says haste would be dangerous. "ARVs are not chewing-gums to be given to Kenyans at a whim."

**John Kamau** is the editor of *Rights Features Press Service*

## **Brazil: A successful model for HIV control**

*Brazil's success in controlling the epidemic holds lessons for other countries.*

In 1992 the World Bank estimated that 1.2 million people would be infected by HIV in Brazil by the year 2000. Eight years later, the actual figure was less than half that number. The country's success in controlling the epidemic can be attributed to two factors – an outspoken prevention campaign and determination to provide basic care to all who need it at reasonable cost.

Brazil's declared intention in the late 1990s to integrate prevention and treatment was initially criticised by those in the international community who argued that developing countries could not afford the costs of ARV drugs. However, the policy of providing free ARV therapy to all those who need it has been justified not only by humanitarian considerations, but also by the fact that it has proved cost-effective. Between 1996 and 2001 around 358,000 AIDS hospitalisations were prevented, representing savings of approximately \$1.1 billion.

To sustain this policy consistently, it was essential that drug prices be reduced. This was achieved through a twofold strategy: increase in the local production of generic drugs and negotiating discounts on patented drugs.

The national drug policy approved by the Ministry of Health in 1998 comprised four sub-programmes: basic care; drugs for endemic diseases, including HIV/AIDS; high-cost drugs for diseases requiring long term treatment; and drugs to treat mental illnesses. Consequently, anti-HIV drugs are only the most visible part of a broader programme. While the sub-programmes have different arrangements in terms of buying and distributing drugs, their primary goal is rationalisation of distribution systems and price reduction.

A generic drug, as defined by a 1999 law, must have the same pharmaceutical presentation and dosage as the original drug. The law also establishes that, should the prices of the generic and

patented drug be the same, the generic version should have preference in public purchases. The intention of the law is to foster competition and bring down prices. Increasing generics' share in the total pharmaceutical market is an efficient means of keeping drug prices under control.

Until the end of the 1980s most medicines sold in Brazil were locally produced. When the import policy was liberalised in the 1990s, domestic subsidiaries of foreign pharmaceutical companies boosted imports, causing a huge deficit in the Brazilian balance of trade in medicines.

Today, multinational companies have a strong position in the Brazilian pharmaceutical market, generating approximately 80 per cent of total pharmaceutical sales. The government is trying to encourage more local production and many foreign producers of generic drugs are establishing local plants, replacing imports with locally manufactured products (which several companies hope to export from Brazil). It is therefore likely that the pro-generics policy will continue to boost the country's balance of trade in pharmaceuticals in the near future.

Another significant component of the policy has been investment by the Ministry of Health in publicly owned manufacturers of pharmaceutical products. In 1999 public producers accounted for no more than 18 per cent of the total amount of ARV drugs bought by the Federal Government. In the following year, one publicly owned company alone provided approximately 30 per cent of the ARV drugs used in Brazil. Even more significant is the investment in technological capabilities, including research.

As part of the national drugs policy, in October 1999 the government regulated some aspects of the patent law, allowing the authorities to issue compulsory licenses if, after three years, the owner of the patent did not begin to manufacture the drug locally. The aim of the legislation was clear: the government was seeking to increase its bargaining power in negotiations with the suppliers of patented drugs. This clause triggered a strong response from the US government. After several months of unfruitful negotiations, in January 2001 the US decided to challenge the Brazilian legislation on patents at the WTO for violating the TRIPS agreement. But in June 2001, following a firm response from the Brazilian government and the mobilisation of public opinion, the US withdrew its complaint.

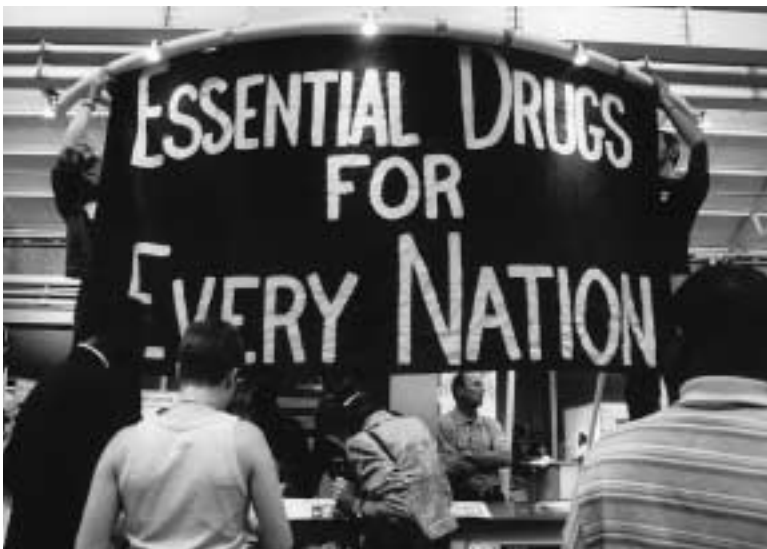
The Brazilian strategy has led to ARV drugs becoming more and more affordable, falling from a peak of \$4,860 per patient per year in 1997 to an estimated \$2,530 in 2001.

All this has strengthened government bargaining power vis-à-vis the pharmaceutical companies. As one example, from 1998 to 2001 the ministry of health obtained a 34 per cent discount on the price of ARV Nelfinavir from Roche, the patent holder. In 2001, the new rebates offered by the Swiss company were considered insufficient by the minister and the government announced its intention to issue a compulsory licence. Roche then decided to resume negotiations and within a week the government announced that the company had conceded a further 40 per cent discount.

In addition, the country has offered its expertise in AIDS drug manufacturing to other developing countries. Some are interested in obtaining the technology transfer, others in direct drug purchases. Cooperation agreements have been signed with four African countries and seven others have shown an interest in such exchanges.

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Gisele Wulfsohn / Panos Pictures



AIDS activists protest the high prices of ARV drugs in Durban, South Africa at the 12th International AIDS Conference, July 2000.

## 5 Country perspectives

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Developing country governments vary in their response to the real or apparent conflict between patents and public health. While some resist significant pressure to implement strong intellectual property (IP) regimes, others, intentionally or by default, draft policies and legislation that strengthen the hand of patent holders.

The UK Commission on Intellectual Property Rights argues that “policies required in countries with relatively advanced technological capability where most poor people happen to live, for instance India or China, may well differ from those in other countries with a weak capability, such as many countries in sub-Saharan Africa. The impact of IP policies on poor people will also vary according to socio-economic circumstances. What works in India, will not necessarily work in Brazil or Botswana.”<sup>54</sup>

Although Southern countries have until 2005 or 2016 to implement TRIPS-compliant legislation, in many the process is already complete or near completion. As the articles from Pakistan and Uganda indicate, drafted or enacted legislation frequently prioritises patent rights over public health.

Ken Bluestone of the British charity VSO argues that “many countries will have to redraft their national legislation if they are to take advantage of the new political climate post-Doha. The debate must be rekindled in these countries. It is far more challenging to change existing legislation in some cases than develop something from scratch.”<sup>55</sup>

### Patent Offices

Effective implementation of patent legislation depends to a large part on the efficiency of the national or regional patent office, which accepts and rules on national patent applications. As a far greater number of patent applications than was the norm before TRIPS floods into patent offices, in many countries the patent office does not have sufficient capacity to deal efficiently with the larger number of applications. While the US Patent and Trademark Office has an annual budget of \$1 billion and a staff of more than 3,000 scientists, engineers and legal experts,<sup>56</sup> the equivalent office in Pakistan, with half the population of the US, has an annual budget of \$80,000 and seven technical staff. One study suggests that on average it would cost a country \$1.5 to \$2 million to build a basic infrastructure to implement TRIPS<sup>57</sup> – money that is often

unavailable. Pakistan is not untypical, and the result in many countries, observers fear, is that patents will be granted that should otherwise be refused, while the overworked system will also deter third parties from protesting unreasonable patents.

Yet even in the US the system is not perfect, and 46 per cent of patents when challenged found to be invalid. In countries with overburdened patent offices and few specialised lawyers, it is likely that a considerable number of patents are invalid but not challenged in the courts. During the transition period for medium developing countries – until 2005 – applications are generally dealt with under the “mailbox” system, where the application is not examined until the end of the transition period but exclusive market rights (EMR), which are tantamount to a temporary patent, are allowed. Least-developed countries, which do not have to amend their legislation until 2016, are allowed to waive EMR.

### Drug regulation and supply

Patented drugs are only a minority of drugs consumed, but they represent a considerable percentage of healthcare. In 2000, three per cent of the Brazilian healthcare budget was spent on ARV drugs,<sup>58</sup> although HIV/AIDS affects less than 0.3 per cent of the population.

To ensure adequate supply and distribution, an efficient state body is essential for the regulation of all drugs. Yet according to the WHO, fewer than one in six countries has effective drug regulation with an independent agency ensuring comprehensive and up-to-date laws for all drug products, and developing appropriate standards for the production, dissemination and consumption of all drugs.<sup>59</sup>

The WHO says four factors are critical for securing access to essential drugs:

- 1 **Rational selection and use.**
- 2 **Adequate financing** – government funding ensures the best access to essential drugs and countries which allocate adequate funding to high-impact public health problems such as tuberculosis, malaria, HIV/AIDS and childhood illness experience greater economic development.
- 3 **Affordable prices** – which can be partly achieved by reducing or eliminating import duties and taxes.
- 4 A reliable mix of **public and private supply systems.** Many countries have unregulated private supply networks for profitable urban areas and inefficient public supply systems for the rest of the country, and lack of regulation frequently leads to corruption – in particular the diversion of products from their intended market for sale elsewhere.

## Pakistan: Legislation and bureaucracy

*The Patent Office in Pakistan is understaffed and underequipped – leading to a potential backlog of applications in 2005.*

Prices of drugs in Pakistan are higher than in other countries of the region.<sup>60</sup> During the last decade 156 drugs have registered an increase in price of between 200 and 700 per cent.

Any further rise in the price of drugs to consumers would have serious implications in a country where the average annual per capita income is \$460 and 38 per cent of the 140 million population earn less than a dollar a day. Government-provided healthcare reaches only 20 per cent of the population, with most of the remaining 80 per cent uninsured. It is estimated that almost half the population has no access to primary healthcare.

The price of drugs has been a sensitive issue for many years. In 1993, prices were deregulated as part of the free market agenda adopted under pressure from international finance institutions. However, following significant price rises they were frozen again in 1994. Then in March 2002, as part of an agreement with the International Monetary Fund, the government raised general sales tax on non-life-saving drugs from 0 to 15 per cent. That decision was rescinded five months later after widespread protest. That, in turn, led to severe shortages on the market as the government had not announced a mechanism for refunding tax on existing stocks.

As a member of the WTO, Pakistan is moving to introduce TRIPs-compliant domestic patent laws. Until 2000, patents were governed by the Patent and Design Act 1911, a law introduced in colonial times. The Patent Ordinance 2000 is criticised for being made in haste and without public consultation. “There wasn’t enough debate. The process wasn’t given enough time,” says Aziz ur Rehman, a specialist in intellectual property rights who teaches at the Islamabad-based Islamic University.

Zafar Mirza of TheNetwork for Consumer Protection, a leading non-governmental organisation, claims that the new law does not fully exploit all the public health provisions in TRIPs. “The government genuinely thinks it has framed a good law. It doesn’t want to accept that the law is flawed. It could have been a robust piece of legislation,” he says. He adds: “The debate is how to have a provision which could be invoked when drugs are available in the market but are out of the reach of the people.”

Implementation of the law depends largely on the capacity of the Patent Office and the judiciary. The Patent Office was established in 1948. Headed by controller Yasmeen Abbasi, a law graduate with

training in patent-related issues, the Patent Office falls under the jurisdiction of the Ministry of Commerce and Industry. Sitting in a poorly furnished hall are two assistant controllers, and four patent examiners, who comprise the only technical staff to handle all patent applications, including pharmaceutical.

Last year the Patent Office received 1,200 applications for patent and design registration – an average of 300 per examiner or more than one every working day. All paperwork, filing and documentation is done manually. Computers have been provided by the World Intellectual Property Organisation, but the appropriate software had not been developed by mid-2002.

Because patents are under transition and product patents will not be granted before 2005, applications are being received under the “mailbox” system. Currently, 90 per cent of pharmaceutical applications are from multinational corporations, and 95 per cent of those are related to chemicals, both product and process. Exclusive marketing rights are granted to all patent applicants, preventing generic versions being sold before resolution of the patent in 2005.

Abbasi points out that since TRIPs the workload on her office has increased many times. However, the real challenge will come when the mailbox is “opened” and thousands of applications will have to be processed within the stipulated period of 20 months. That will be impossible under the current set-up. Abbasi has requested a better working environment, computerisation, online research facilities, staff incentives and specific examiners for specific fields. She has proposed that a proportion of application fees be allocated to the Patent Office rather than going to the national exchequer.

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## **Thailand: The impact of pressure from the US**

*The US has imposed all kinds of pressure, including sanctions, to force Thailand to buy products from American companies.*

Being able to buy essential drugs at an affordable price is an important element in every public health system. Thailand is no exception. Under intense pressure from the US, however, changes in legislation have meant that Thailand’s capacity to produce drugs for its own people has been increasingly limited in the last decade.

Since 1975 the Pharmaceutical Research and Manufacturers of America (PhRMA), representing all major pharmaceutical companies in the US, has claimed that because Thai patent law referred only to pharmaceutical processes and not products, they

were losing \$30 million a year in sales. In consequence, the US imposed \$165 millions' worth of sanctions on eight Thai products exported to the US, which had a severe impact on the Thai economy.

In August 1989 the Thai Food and Drug Administration (TFDA) introduced an "interim measure" allowing a minimum of two years' market exclusivity for all new drugs under a Safety Monitoring Program (SMP). During this period, no generic product was allowed to register. The conditionally approved drugs were only available in public or private hospitals or clinics where physicians can monitor adverse reactions and submit periodical reports to the TFDA. In practice, however, pharmaceutical companies used the SMP to maintain market exclusivity and usually requested two one-year extension periods, allowing them to extend the market monopoly to four years.

In 1992 the Thai Patent Act was amended to include protection for pharmaceutical products and the period of protection was extended from 15 to 20 years from filing date. However, because the Act did not cover drugs invented prior to 1991, the US continued to apply pressure on the Thai government. In 1994 the TFDA revised the SMP regulation to provide protection for products patented abroad between 1986 and 1991. The agency also imposed processes that meant a branded drug had five to six years before the generic equivalent could be marketed.

Even though the Patent Act was implemented before TRIPS, due to pressure from the US, its provisions and regulations were sometimes even more restrictive than the international agreement.

The Safety Monitoring Program has significantly delayed development of generic equivalents for such HIV drugs as fluconazole, ganciclovir, stavudine, lamivudine and nevirapine, even though none of these are patented in Thailand. However, some generic drugs have completed the SMP, with the result that in 1998 the price of fluconazole fell from \$6.10 to \$0.60 per 200 mg capsule; two years later the cost of stavudine decreased from \$2.20 to \$0.34 per 40 mg capsule.

In January 2001 the SMP was revised. Market exclusivity was abolished for drugs benefiting from the 1992 patent law and maintained for those drugs that the US government sought to protect (drugs patented abroad between 1986 and 1991), but even these modest changes were challenged by the US embassy.

In 2002 the Thai pharmaceutical industry consisted of 171 small or medium-sized private companies, 17 large foreign joint-venture enterprises and the publicly owned Government Pharmaceutical Organisation (GPO). As the law changed, the proportion of

imported drugs went up from 34 to 45 per cent and that of locally manufactured drugs went down from 65 to 55 per cent.

In 1995 the Intellectual Property Information Center (IPIC) was established by the Department of Intellectual Property (DIP) to improve the DIP's examination capability and make industrial property information more accessible to the general public. However, academics and generic product producers face many problems in searching the IPIC database, because of deficiencies in the software. Fewer bioequivalence studies are being conducted for generics, partly because of the long time needed to research the database and the inability of government agencies to confirm patent status. There are many reports of patent infringement by original drug owners to stop the generic producers in the pre-marketing process of drug registration.

DIP faces considerable constraints in granting product patents. In 2000, of 5,049 patent applications filed (about 1,000 of which referred to drugs), only 416 were granted. There are few officers in the Patent Office responsible for granting pharmaceutical product patents and none is a pharmaceutical scientist.

In May 2001, the AIDS Access Foundation and two people with HIV living in Thailand filed a suit against the pharmaceutical company Bristol Myers Squibb (BMS) and the DIP. They claimed that both had illegally issued a patent for the ARV didanosine without specifying the range of ingredients per dosage, and thus giving BMS unlimited exclusive rights. In October 2002, the plaintiffs won their case, as a result of which, other companies may produce didanosine using the same formulation but with different quantities from that specified in the patent.

The GPO will start making a tablet form of didanosine in three months' time, said its director Dr Thongchai Thavichachart. It currently makes a powdered form of didanosine. Dr Thongchai said they would initially make 5,000 tablets but would hold off marketing the product until they were sure Bristol Myers Squibb would not appeal.

Meanwhile, deputy health minister Pracha Phromnok has said that the Thai and Zambian ministers of Public Health are discussing a joint venture to make the anti-AIDS drug.

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## Uganda: Lessons for reform

*Appointing US consultants to review its existing patent law proved to be more problematic than the government expected.*

In the 1990s Uganda began reforming its commercial laws. The ministry of justice hired American consultants to study existing laws, including patent law, and make proposals for reform. Two Ugandan law firms were co-opted to co-execute the task.

The consultants' final report was issued in 1998 and the national Law Reform Commission received funding from USAID to carry forward the reform process. This included funding for another consultant to provide technical expertise to help the Commission put together the first drafts of various laws.

The reform of commercial laws was based on two considerations: developments in international law and the theory that existing laws were an impediment to foreign direct investment and technology transfer. In the case of intellectual property law, the immediate consideration was that, as a member of the World Trade Organisation, Uganda was obliged to comply with TRIPS. Although the country had several years to implement new legislation, the government was persuaded to reform patent law quickly, by the argument from USAID that there was no need to exhaust the transitional period because the country was losing out on foreign investment and technology transfer.

The consultation included representatives of the Law Reform Commission and other ministries, in particular the Finance and Justice. Other major stakeholders, such as the National Drug Authority and the Ministry of Health did not participate. International organisations, which have the mandate to provide technical assistance, were never involved. The involvement of civil society was also minimal.

The USAID-funded consultant focused on compliance with international standards as the main objective of the reform process, seeing the need for change to facilitate business rather than to meet social and economic needs. The government did not commission any independent study with local consultants to generate alternative policy considerations.

The draft industrial property law was developed as one of a cluster of commercial laws drawn up by a task force which met several times in late 2001. Criticisms lodged against the bill-drafting process included: too little time allocated for the volume of work; only one task force established to consider a wide range of laws; irregular and often poor attendance, lack of training for the task

force, and lack of expertise in the area of intellectual property rights. And finally, failure to invite known experts from within Uganda and neighbouring Kenya, which had recently passed similar legislation, to participate.

The bill itself was also strongly criticised by the Coalition for Health Promotion and Social Development (HEPS). HEPS' primary concern was that the bill was not sensitive to public health.

To bring this question to public awareness, HEPS held briefings for journalists on issues regarding patent law reform and its relevance to public health. Consequently articles appeared in local and international media pointing out the need for caution in reforming patent law. Some degree of public interest was stimulated and public health concerns raised. As a result, the commission is reconsidering its draft to include most of the proposals above, although the revised draft had not been made public by mid-2002.

It is likely that the US will try to push its interests. But HEPS continues to try to interest the public in the debate and is working to involve other national and international bodies.

The most important lesson for any developing country that seeks to reform its laws is that failure to do an independent study and to identify policy objectives exposes the country to foreign interests. Consultants may be useful but one can never tell where their interests fall. This uncertainty is even worse where donors hire consultants as part of the project package.

The other lesson is that stakeholders should be involved early enough to enable them to get to proper grips with issues under debate.

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Sean Sprague / Panos Pictures



*Woman visiting AIDS patient in Uganda.*

## 6 The way forward

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Patents and profits are closely linked. In wealthier countries, where the burden of healthcare on both individuals and governments is relatively low (although in the US in recent years pharmaceutical companies have increasingly come under attack for the rising price of drugs), the patent system ensures continuing development of new drugs. In poorer countries, where the burden of healthcare is high, the system has failed to provide an adequate response to neglected diseases and has restricted access to cheaper drugs.

Furthermore, the profit motive fails both the pharmaceutical industry and the consumer in the South as long as high prices are maintained in markets where millions of potential customers cannot afford much-needed products.

While patents play an important role in encouraging innovation, that role is largely confined to the industrialised world, which can absorb the higher prices that ensue from R&D. Applying strict patent laws in poor countries is unlikely to generate more revenue for pharmaceutical companies, but by reducing competition and keeping prices high, it will significantly limit people's access to essential medicines and hamper long-term development. In other words, legislation that is valid for wealthy economies may be highly inappropriate when applied to the world's poor.

The UN Development Programme (UNDP) points out that "Current practices are preventing the fair implementation of TRIPS... A single set of minimum rules may seem to create a level playing field, since one set of rules applies to all. But as currently practised, the game is not fair because the players are of such unequal strength, economically and institutionally."<sup>61</sup> Sir Hugh Laddie, a UK High Court patents judge, adds that "higher IP standards should not be pressed on developing countries without a serious and objective assessment of their development impact".<sup>62</sup>

Many developing countries need to undertake an urgent review of TRIPS-compliant legislation to ensure that it takes full advantage of the mechanisms in the agreement to increase access to essential drugs and support public health.

Two mechanisms proposed to increase access to drugs – differential pricing and compulsory licensing – appear to offer the greatest hope of meeting public health needs in the developing world, although they require clear boundary mechanisms, such as

legislation and packaging, to ensure that patent holders' rights are respected. Voluntary licensing is an option that few patent holders seem willing to consider except on an exceptional basis. Parallel trade may be a temporary solution and essential in drawing attention to inequities in the system, but in the long-term it threatens the viability of differential pricing and compulsory licensing.

There are a number of measures being taken by international organisations. The current Director-General of the World Health Organisation, Gro Harlem Brundtland, has said that "When trade agreements affect health, WHO must be involved from the beginning. We need to analyse and monitor how new international agreements can support public health."<sup>63</sup> Since 1996, the WHO has had a mandate to assist countries to incorporate provisions in national patent laws to ensure and increase access to drugs. Dr Supachai Panitchpakdi, the Director-General of the WTO, has said that countries need to examine TRIPS "and its consequences on developing countries... particularly at its impact on the supply of pharmaceutical products. This is one thing that needs to be brought into the bigger picture."

WHO has set up a steering committee to monitor the impact of globalisation and TRIPS on access to drugs in specific regions. A new body, the Management of Intellectual Property In Health R&D is scheduled to be set up in 2002, with support from the Rockefeller Foundation, to help researchers in developing countries find their way around the complexities of intellectual property laws. By giving training and free legal advice to governments and researchers in poorer countries, the new organisation will address the fact that the complexities of intellectual property law, and the cost of the professional advice needed to address them, tend to bias the international patent system towards the interests of the rich nations.

## Recommendations

While the pharmaceutical industry and some Northern governments are content with the status quo, many agencies, from UN bodies to non-governmental organisations and the independent Commission on Intellectual Property Rights, believe that the potential negative impact of TRIPS on the developing world must be minimised. Their recommendations include:

### **At international level:**

- Alternative methods of worldwide sharing of R&D costs should be developed.
- Unilateral pressure on countries to adopt trade, patent or health legislation that is not in the public interest and is not legally required should be ended.
- Reliable cost data on the development of new drugs should be made public.
- Commitment of funding by the international community, and many different partnerships between governments, multilaterals, non-governmental organisations, research institutions and private companies.
- Public involvement to ensure development of new drugs for certain priority health problems.
- WIPO should integrate development objectives into its approach to intellectual property protection.<sup>64</sup>

### **From a national perspective:**

- Ministries of health must work closely with other ministries (trade, justice etc) to formulate and/or revise national patent legislation to ensure that public health needs are fully taken into account.
- National legislation should narrow to an absolute minimum the type and scope of pharmaceutical patents.
- Developing countries should ensure that their legislation allows for compulsory licensing.
- Proposed national legislation should be subject to extensive scrutiny by policy-makers, the media, non-governmental organisations and others representing patients' needs and rights.
- Least-developed countries should delay granting of pharmaceutical patents as long as possible.
- Development objectives should be integrated into the promotion of intellectual property rights in developing countries.
- There should be policies and commitment by governments to establish funding priorities and national healthcare capacity.

## Resources

The website associated with this document, ([www.panos.org.uk](http://www.panos.org.uk)) gives more information and direct links. Other resources can be gleaned from the footnotes.

### International Health

#### **World Health Organisation** (headquarters)

CH-1211 Geneva 27, Switzerland

Tel: +41 22 791 21 11 Fax: +41 22 791 3111 [www.who.int](http://www.who.int)  
library@who.int (publications) info@who.int (general enquiries)

### Trade and TRIPS

#### **World Trade Organisation**

Rue de Lausanne 154, CH-1211 Geneva 21, Switzerland

Tel: +41 22 739 51 11 Fax: +41 22 731 4206  
[www.wto.org](http://www.wto.org) enquiries@wto.org

#### **World Intellectual Property Organisation**

Chemin des Colombettes 34, Geneva, Switzerland

Tel: +41 22 338 91 11 Fax: +41 22 733 5428  
[www.wipo.int](http://www.wipo.int) wipo.mail@wipo.int

### Pharmaceutical Industry

#### **Pharmaceutical Research and Manufacturers of America (PhRMA)**

1100 Fifteenth Street NW, Washington, DC 20005, US

Tel: +1 202 835 3400 Fax: +1 202 835 3414 [www.phrma.org](http://www.phrma.org)

#### **International Federation of Pharmaceutical Manufacturers Associations (IFPMA)**

30 rue de St-Jean, P.O. Box 758, 1211 Geneva 13, Switzerland

Tel: +41 22 338 32 00 Fax: + 41 22 338 3299  
[www.ifpma.org](http://www.ifpma.org) admin@ifpma.org

### Non-governmental organisations

*The organisations listed here generally support a weak intellectual property regime.*

#### **Consumer Project on Technology**

P.O. Box 19367, Washington, DC 20036, US

Tel: +1 202 387 8030 Fax: +1 202 234 5176  
[www.cptech.org](http://www.cptech.org) mpalmedo@cptech.org

**Health Action International**

c/o HAI Europe, Jacob van Lennepkade 334-T, 1053 NJ  
 Amsterdam, Netherlands  
 Tel: +31 20 683 3684 Fax: +31 20 685 5002  
 www.haiweb.org info@haiweb.org

**Médecins Sans Frontières (MSF) / Access to Essential Medicines Campaign**

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*Mainly US-oriented, but carry information relevant to the debate as a whole.*

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**National**

For national information, consult such organisations as Ministries of Health, Trade/Commerce, Justice; national Statistics Office, national Patent Office, national WHO office, national offices of non-governmental organisations.

## Notes

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