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Access to medicines: why high prices of new medicines are detrimental for poor people and public health in developing countries

Abstract

Der Zugang zu leistbaren Medikamenten wird Menschen in Entwicklungsländern besonders erschwert. Die wenigsten sind versichert, daher stürzen die hohen Kosten Bedürftige in immer größere Armut. Entwicklungsländer sind durch Infektionskrankheiten und nicht übertragbare Krankheiten (NCD) doppelt belastet.

NCDs betreffen nicht nur die Ärmsten der Armen, sondern aus Gründen der Urbanisierung und Globalisierung auch Menschen der Mittelklasse. Faktoren wie Luftverschmutzung führen zu Asthma, erhöhter Tabakverbrauch, Alkoholmissbrauch und Fettleibigkeit zu verschiedenen Erscheinungsformen von Krebs.

Entwicklungsländer sind auf Generika angewiesen um die benötigten Medikamente zur Verfügung stellen zu können. Da jedoch 1995 viele Entwicklungsländer der WTO beigetreten sind, sind sie nun verpflichtet das Übereinkommen über handelsbezogene Aspekte der Rechte am geistigen Eigentum (TRIPS) zu erfüllen. Dieses Übereinkommen gewährt Medikamenten-Patente für einen Zeitraum von mindestens 20 Jahren. In diesem Zeitraum hat der Erzeugerkonzern ein Monopol auf seine Produkte und kann somit den Preis bestimmen.
Konzerne behaupten, der Schutz des Immaterialgüterrechts sei notwendig um Verluste der Firmen wettzumachen und weiterhin genügend Mittel für die Forschung zu haben.

Das Thema ist kontrovers und erfordert den Einsatz der Regierungen und Pharmakonzerne, wie auch der Zivilbevölkerung.

Oxfam

Ill health reinforces poverty in developing countries. Women have the least access to health services when they are ill, whilst also providing care for sick members of the family. Most poor people lack insurance, paying for treatments out of the family budget. Medical costs often drive people into poverty, and the high cost of medicines is particularly responsible. This is the harsh reality that provides the background to this paper, which deals with one aspect of accessible health care: namely that

stronger intellectual property rights increase the price of medicines needed to treat the range of diseases dominating public health.

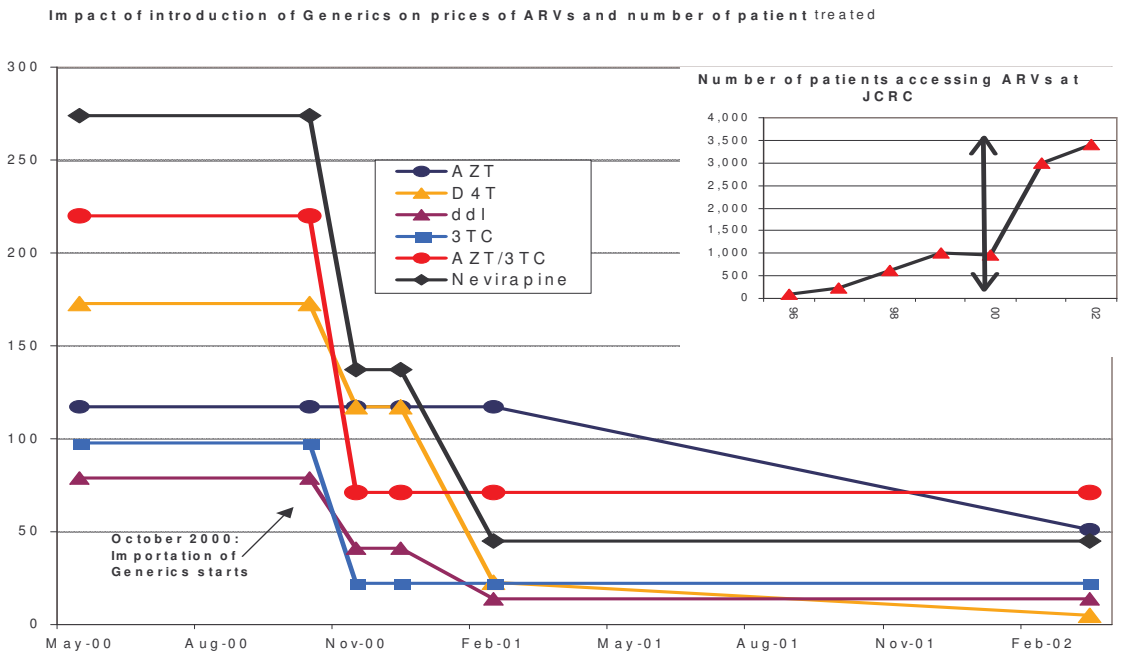
Developing countries carry a double burden of both infectious and non-communicable diseases (NCDs), many of which require treatment for life.

- Malaria claims the lives of a million people a year, most of whom are children and pregnant women. Of these, 90% are African[i]. Inexpensive anti-malarial medicines are now ineffective, and new products are expensive.
- 2 million people die annually from TB, and half a million people were infected with Multi drug resistant (MDR) TB in 2004. [ii]Extensively drug resistant TB (XTB) accounts for more than half of all MDR-TB cases worldwide[iii]. The cost of treating resistant strains is prohibitive.
- Gonorrhoea affects more women than men. Poverty and the high prices of effective medicines are major causes of drug resistance that develops in 60% of infections annually[iv].

NCDs are still wrongly considered to be diseases of affluent societies, and little funding is allocated to prevent or treat them. But NCDs affect poor as well as middle class people in developing countries. As a result of urbanisation and the impact of globalisation NCDs are on the increase. Factors such as air pollution are escalating the incidence of asthma in urban slums, while exposure to pesticides increases the risk of cancer in rural populations. The rise of tobacco consumption – particularly affecting the young - is preparing the way for greatly increased incidence of many cancers and cardiovascular diseases. Traditional healthy diets are being abandoned, while at the same time physical activity is declining and environmental pollution is worsening. Smoking, alcohol abuse, and obesity are affecting adolescents in particular. A group of doctors interviewed recently in Uganda ranked hypertension and diabetes, together with malaria and other infections as the cases they see most frequently[v]. More than 35% of Nigerian women are overweight.[vi]

- NCDs account for at least 40 % of all deaths in developing countries[vii].
- 194 million people have diabetes worldwide- 120 million in developing countries[viii]. More than ½ the world's new diabetic cases are in India and China[ix].
- In 2001, cancer was the second leading cause of death in developing countries- after cardiovascular diseases[x]
- In 2005, over 90% of cervical cancer cases were in developing countries. The rate of cervical cancer among African and Asian women is far higher than in the UK or US.[xi]
- Peru, Brazil, Paraguay, and Uruguay are in the top quartile of countries with the highest prevalence rate of childhood asthma[xii]
- There are 20 million people living with hypertension in Africa. The mortality rate is 10 times higher in Tanzania than in the UK[xiii]

Developing countries rely on generics to provide access to medicines. Evidence shows that generic competition is one of the most effective market mechanisms for reducing prices. An Oxfam study in Uganda provides data that shows that as more companies entered the market for antiretrovirals, prices went down[xiv]. Since the research, competition and availability of funding resulted in the current low level of prices. In the case of Uganda (as shown in the diagram), as prices dropped, the number of patients accessing medicines went up.



However this source of medicines is drying up because India and other developing countries have begun to implement the Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS). In 1995 most countries became members of the World Trade Organisation, and have had to abide by the TRIPS agreement rules or face trade sanctions. TRIPS raised intellectual property protection to a level similar to that of the US and other rich nations despite the differences in economic and social development, health profile and health sector capacity that exists. TRIPS includes patents on product and process for a minimum period of 20 years during which the originator company has a monopoly on the medicine and can therefore set the price. This is illustrated by the fact that the price of 2nd line antiretrovirals to treat HIV and AIDS – that are unaffected by generic competition - are around 10 times higher than 1st line ARVS, where competition is active[xv]

Hepatitis C affects 170 million people worldwide: Egypt has the highest prevalence of the disease. The price of pegylated interferon supplied by Schering and Roche is unaffordable to all but a tiny minority of Egyptians. A 24-week treatment costs around US$ 6,800, or one and a half times the salary of the minister of health for the same period. Fortunately, pegylated interferon was in the Egyptian market before the implementation of TRIPS. Thus an Egyptian generic company was able to manufacture and sell the drug at a quarter of the price charged by the originator company[xvi].

The rising tide of NCDs and infections such as HIV and Hepatitis C and B requires access to inexpensive medicines that will be affected by the new patent rules. Despite the safeguards available under TRIPS, pharmaceutical companies have already begun to assert their newly acquired intellectual property rights by challenging a number of governments' decisions to use the flexibilities built into the Agreement: Abbott has challenged Thailand; Pfizer the Philippines; and Novartis India[xvii].

Earlier this year the Thai government issued compulsory licenses on three key drugs for the treatment of HIV and prevention of heart attacks. Compulsory licensing is a legal safeguard that enables governments to override patents in order to protect public health. Although Merck and Abbott offered to decrease the price of their HIV drugs to middle-income countries - including Thailand - the price was still too high for the government to afford free medicines for patients in its successful HIV treatment programme. Merck is still trying to reach a settlement with the government on the price of the medicines it sells in Thailand. Abbott retaliated by withdrawing its drugs, included a new heat stable antiretroviral, from the Thai market. In addition, pressure was exerted through the office of the US Trade Representative (USTR) that put Thailand on the Priority Watch List of the 301 Report, implying the threat of trade sanctions at a later date. So far the Thai government has resisted the mounting pressure to reverse its decision.

India is often called the pharmacy of the developing world. Indian generic companies produce affordable medicines for domestic consumption and also for export to many developing countries. Indian generics provide 70% of HIV treatment in 87 developing countries, purchased by UNICEF, IDA, the Global Fund and the Clinton Foundation since July 2005. Buying from Indian generic companies is producing a cost-savings of up to 90% to the PEPFAR, the US President's AIDS initiative. [xviii] These are inexpensive copies of originator medicines produced legally under India's national patent law. In amending its Intellectual Property law to comply with TRIPS, the Indian government defined patentability in a way that was intended to block all frivolous patents. This safeguard has been used by an Indian court to reject the patent on imatinib mesylate (Glivec), a blood cancer drug manufactured by Novartis. Five Indian generic companies make a generic version of this medicine at a tenth of the price charged by Novartis. Not surprisingly, Novartis is challenging the decision of the court. Yet Novartis has gone further, challenging the law itself as non-TRIPS compliant. Indian patient groups and other NGOs are currently campaigning for Novartis to withdraw the court case. If Novartis wins, patients in India and other developing countries will be deprived of affordable generic medicines: patents could also be issued on any modified molecules - thus allowing originator companies to maintain lengthy monopolies on the medicines and control prices. Prices of much needed new medicines will inevitably rise, with unacceptable implications for individual and public health.

In a further escalation of controls, pharmaceutical companies have exerted pressure through bilateral and regional Free Trade Agreements that operate outside the WTO. Until recently, the US FTAs included requirements on governments to restrict the use of compulsory licensing, parallel trade and other TRIPS flexibilities. US FTAs have also imposed new rules that go beyond TRIPS, such as further extending the patent term, linking drug registration with the patent status, and providing at least five years of exclusivity on clinical data. The implementation of the five-year rule will force generic companies to repeat clinical trials in order to be able to register their drugs during that period of exclusivity. In addition to wasting money, leading to higher costs and prices, such a practice is unethical since it subjects patients to clinical trials on drugs that are already approved for effectiveness and safety. Normally generic companies have only to submit data on the bio-equivalence of their medicines. In recent months, a new US trade agenda has eliminated some of these onerous provisions for completed free trade agreements that are awaiting ratification by Congress. For example, these FTAs will no longer require patent extension or drug

registration-patent linkage, and will reiterate the Parties' commitment to the Doha Declaration[1] by explicitly stating that the IP provisions "do not and should not prevent a Party from taking measures to protect public health by promoting access to medicines for all." [xix]. However, the US FTAs continue to impose five years of data exclusivity upon developing countries, which will have serious consequences for public health.

Companies argue that protection of Intellectual Property is necessary if they are to recoup their investment in R&D and to maintain healthy pipelines of new drugs. However, evidence shows no connection between IP and R&D for diseases prevalent in developing countries. Treatment for such diseases does not offer highly profitable opportunities for pharmaceutical companies and hence there has been hardly any investment for diseases such as malaria, which kills one million people every year. In the past few years public outcry has led to an increase in governmental and philanthropic funding for increased investment in R&D for neglected diseases such as malaria. Companies recover their costs through sales in rich countries, and in so doing maintain the profitability of the pharmaceutical industry – regularly ranked one of the most profitable global industries.

Looking to the future, access to affordable medicines will increasingly feature as a controversial issue that must be resolved. This is not only because health is increasingly being recognised as a human right, but also because the epidemiology of public health is changing, with new diseases coming to the fore at the same time that existing infections continue in highly resistant forms. Finding a way forward will require a high order of leadership and commitment by governments, pharmaceutical companies and civil society. The alternative will be a world destabilised by continuing poverty that is driven by health inequalities. Developing country governments will be increasingly frustrated, unable to effectively provide for the health needs of their populations. And in addition global pandemics will become unmanageable. The clock is already ticking!

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