

Access to medicines: why it's time to change the rules



Ellen 't Hoen
MSF – Campaign for Access to Essential Medicines

Médecins Sans Frontières (MSF, or Doctors Without Borders) is an international humanitarian organisation that currently runs medical programmes in a number of Commonwealth countries: Bangladesh, Cameroon, India, Kenya, Lesotho, Malawi, Mozambique, Nigeria, Pakistan, Sierra Leone, South Africa, Sri Lanka, Uganda, and Zambia.

The focus of these programmes vary, ranging from widespread afflictions like HIV/AIDS, tuberculosis and malaria to neglected diseases like kala azar or sleeping sickness. Regardless of each individual programme's components, MSF witnesses in each and every one the problems of access to safe, affordable quality drugs, diagnostics and vaccines.

In this article, we propose to look at the research and development (R&D) environment in order to assess how its flaws contribute to this crisis and to suggest how health ministers can play a vital role in its reform.

Patents and the price crisis

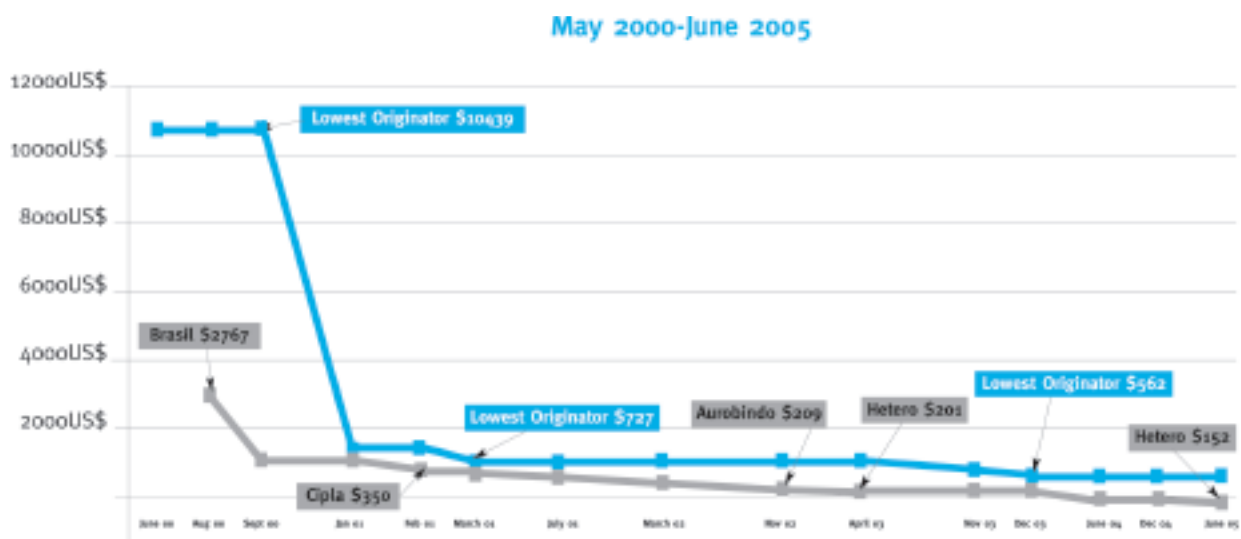
The reasons for the lack of access to essential medicines are manifold and include logistical problems of supply

and storage, substandard drug quality, weak health infrastructure and inadequate production. High drug prices, however, are a crucial barrier in preventing patients from accessing needed treatments.

Prohibitive drug prices are often the result of strong intellectual property rights (IPR). The rationale of this model is simple: patents provide limited exclusivity to inventors to exploit their product commercially, thereby encouraging innovation and benefiting society as a whole. However, the recent report by the Commission on Intellectual Property, Innovation and Public Health (CIPHI) has questioned this benefit, certainly in the case of developing countries.

But patents undoubtedly do have a major impact on the prices of products, by preventing competition.

Figure 1. Generics as a catalyst for reducing the prices of first-line antiretrovirals.



In the case of first-line triple therapy antiretrovirals (ARV), it is only with the arrival of competitor generic products on the market that originator drug companies agreed to a dramatic reduction in prices – as is well illustrated in Figure 1.

Today, first-line triple therapy is available for as little as US\$140 per patient per year. The World Health Organization (WHO) estimates that 1.3 million people are on ARVs in the developing world, and MSF currently

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treats over 60,000 patients with antiretrovirals. Although this is far from being enough, such scaling-up would not have been possible without a significant reduction in prices of ARVs due to the arrival of generics on the market, most notably from India. Eighty-four per cent of MSF's patients beginning ARV treatment are treated with generics manufactured in India.

Profits and the prioritisation of R&D

A second major inadequacy of the current R&D system is that it is steered by primarily commercial interests and fails to respond adequately to the health needs of the world. One major consequence of this is the lack of safe, appropriate and affordable diagnostics, drugs and vaccines for neglected diseases. Below are some striking illustrations of the scope of the ravages caused by neglected diseases in Commonwealth countries today and the paucity of tools to tackle them:

- Sixty million people are at risk of contracting sleeping sickness. Diagnosing this fatal disease requires a lumbar puncture, which is beyond the capacity of regular health facilities in affected countries;
- Kala-azar kills 60,000 people each year but antimony treatment developed in the 1930s has remained the mainstay of therapy despite considerable toxicity and the need for injections during the four-week treatment;
- Every day, 1,400 children die of AIDS-related complications, but existing methods to diagnose HIV in infants are too difficult and costly to perform in most poor country settings, and soluble and easy-to-take children's tablets do not exist;
- TB is responsible for nearly two million deaths each year, but treatment takes six months and is difficult to implement, due to the dependence on increasingly ineffective drugs dating from the 1950s and '60s. And the only diagnostic test simple enough to be widely implemented is sputum microscopy, which was developed in 1882 and detects the disease in only 45 to 60 per cent of cases; and

- Every year, 340 million sexually transmitted infections occur. Simple, effective treatment exists but is denied to many who are not diagnosed, because of a lack of simple, reliable tests.

Between 1975 and 2004, of the 1,556 new chemical entities marketed globally, only 20 new drugs – a mere 1.3 per cent – were for tropical diseases and tuberculosis, which account for 12 per cent of the total disease burden. Why is this? Because although these diseases kill tens of thousands of people every day, they occur overwhelmingly in the developing world; thus, they do not represent a profitable market for industry. When patients lack the purchasing power to afford their own treatment, there are no commercial incentives for companies to develop responses to these diseases and essential R&D does not take place.

Recent advances

Recent developments, such as the establishment of not-for-profit product development initiatives devoted to the development of new drugs, diagnostics, vaccines or microbicides, are important and promising. Indeed, MSF, along with the Malaysian Ministry of Health, the Kenyan Medical Research Institute and the Indian Council of Medical Research, co-founded the Drugs for Neglected Diseases initiative (DNDi) in 1999. But, as yet, these initiatives rely heavily on philanthropic funding, and sustainable sources of government financing have not been identified. Some pharmaceutical companies have also invested on a no-profit no-loss basis in R&D for neglected diseases, such as the Novartis Institute for Tropical Diseases in Singapore.

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It is important to stress that this is nowhere near meeting the huge needs for new health tools for these diseases and does not represent an adequate response. Furthermore, as recently stressed by the CIPIH, governments should not passively assume that these initiatives will solve the problem but need to do more in overcoming the shortfalls of the current R&D system.

Wealthy countries

Crucially, the prioritisation of R&D according to commercial interests – and not potential therapeutic benefit – also impacts northern patients. A survey published in April 2005 by *La Revue Prescrire*, assessing the 3,096 new products approved for the French market between 1981 and 2004, concluded that 68 per cent of them brought 'nothing new' compared to previously available preparations. In Canada, a similar study published in the *British Medical Journal* rated barely

five per cent of all newly-patented drugs approved by the Canadian Patented Medicines Prices Review Board as ‘breakthrough’. Alarming, drugs classified as ‘me-too’, or having no added therapeutic benefit, were responsible for 80 per cent of the soaring rise in prescription costs witnessed in the country; this provides a telling illustration of the waste in a system that rewards innovations that present little or no therapeutic gain.

Entrenched system

For all its inadequacies, this system is fiercely entrenched. Governments in developing countries, including many in the Commonwealth, that attempt to bring down the price of medicines have come under pressure from industrialised countries and the pharmaceutical industry. The 2001, court case opposing 39 drug companies to the South African government over its medicines act is a poignant illustration.

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The 1995, the ‘Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement’ expanded western-style IP policies to the global level, by setting minimum standards for the protection of intellectual property, including patents on pharmaceuticals. These standards are derived from rich nations and are not necessarily appropriate for developing countries, as the CIPIH points out. Indeed, the TRIPS agreement has come under fierce criticism for this ‘one-size-fits-all’ principle because of the effects of increased levels of patent protection on drug prices.

The adoption of the ‘Doha Declaration on TRIPS and Public Health in 2001’ was a response to this, in that it established the primacy of public health over trade interests. It laid out the flexibilities, such as compulsory licensing or government use, contained in the TRIPS agreement, which countries can use to overcome the barriers posed by patents. It also extends to 2016 the ‘transition period’ during which Least Developed Countries are not obliged to grant or enforce patents on pharmaceuticals products.

In recent years, however, we have seen a systematic dismantling of the ‘Doha Declaration’ through bilateral trade agreements with the United States, which include so-called ‘TRIPS plus’ provisions: these annul the achievements of Doha and confirm the lack of political support for the use of TRIPS flexibilities to encourage generic competition. Developing countries that conclude trade agreements with the United States see themselves confronted with demands to tighten the levels of IP protection beyond what they are required to do under WTO rules.

Price crisis returns

The importation by countries all over the world of Indian generics was possible because pharmaceutical products were not patentable there. Following the full implementation of the TRIPS agreement in India as of January 2005, Indian generics may no longer be able to

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provide the competition that drives prices down. Access to affordable new drugs is threatened once more.

This is all the more significant as resistance to first-line ARVs is now emerging. Patients needing to switch to second-line treatment will face unaffordable treatment costs. Figure 2 shows how patents are making second-line drugs far more expensive than first-line medications. In Kenya, for example, MSF pays US\$1,400 per patient per year for a second-line regimen, compared to only US\$200 for first-line drugs – that’s a seven-fold price difference. In middle-income developing countries, that price difference can be even more dramatic: second-line medications can cost up to 28 times more than the first-line treatment.

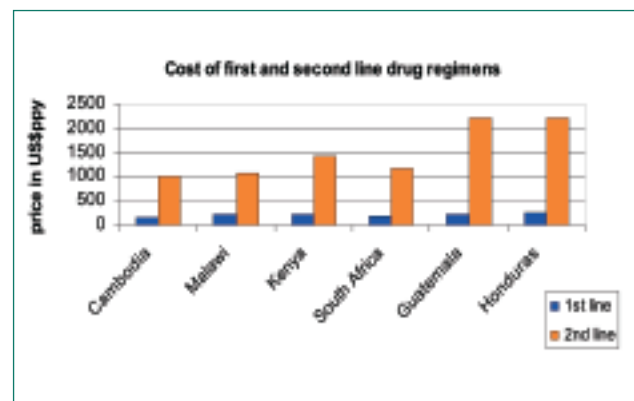


Figure 2. The second-line price crisis.

The major consequence of TRIPS implementation is that new medicines that are developed will continue to have high prices and remain inaccessible for the majority of the population in developing and least-developed countries. Patent laws may also hamper the development of new drugs or formulations. Indeed, generic producers will also be blocked from developing fixed-dose combinations until the relevant patents on the individual components of the combinations expire. All of this means that access to essential medicines could become dramatically more difficult in the coming years if no action is taken. From 2005 onwards, all new drugs may be subject to at least 20 years of patent protection in all but the least-developed countries and non-WTO members.

Box 1. Prominent scientists call for changes to the R&D system.

In a letter to the members of the WHO Executive Board, over 280 scientists from 50 countries, including five Nobel Prize winners, affirmed their support for the Kenyan proposal:

“At a time of huge progress in basic research science, and more money being spent on biomedical R&D than ever, we are deeply concerned about the ability of existing mechanisms to translate this into a global improvement in public health. We have all felt the impact and promise of the free availability of genome sequence data, notably from the human genome project. At the same time we see research activities increasingly complicated by legal restrictions, such as intellectual property rights, which can interfere with free data exchange and can limit biomedical research progress. We do not see a good balance between medical need and resource allocation in the existing system to support R&D. For example, there is less focus on neglected diseases, vaccines or replacement antibiotics than their potential impact on global health outcomes would justify.”

Tackling the time bomb

This health time bomb needs to be tackled urgently. The challenge to increase access will be much greater for the drugs being developed today.

Faced with these new challenges, the public health safeguards affirmed in the ‘Doha Declaration’ have become even more important. It is imperative that producing countries such as Brazil, Thailand and India are restrictive in the granting of patents and that they routinely make use of compulsory licences or government-use provisions, including allowing the export of these medicines to enable generic competition to drive prices down. Strong political resolve will be needed to do this. Essential medicines are not a luxury whose availability can be left to market forces, but are a crucial component of the fulfilment of the right to health.

Promise for change

Many of these considerations are at the root of a proposed resolution by Kenya and Brazil to be debated at the 59th World Health Assembly held on 22 to 26 May, 2006.

The joint Kenyan-Brazilian resolution seeks the establishment of a Global Framework for essential health R&D, based on the principle of equitable sharing of the costs. It asks WHO to facilitate in creating a ‘working group’ of interested member states to examine incentives to encourage greater, more sustainable investment in useful research and development that responds and is prioritised according to patients’ needs. Such a working group would submit a progress report to the World

Health Assembly in May 2008 and a final report with concrete proposals to the Executive Board in January 2009.

Moral imperative

This resolution is a call to member states to make global health and medicines a strategic sector and to ensure that priorities for health R&D are set according to health needs of patients, especially in resource-poor settings. This resolution will help ensure that progress in basic science and biomedicine is translated into improved and safer drugs and that the essential medicines of the future are developed.

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As the leading global agency on health needs, WHO and its member states must play a crucial role in the setting of priorities and the development of policy recommendations on how priority research can and should be carried out. This resolution is a unique opportunity for this to happen and to start looking at ways to mend the huge gaps in the current system. The recently published CIPIH report reminds us of the urgent moral imperative to act, and to act now.

Médecins Sans Frontières (MSF) is an international humanitarian aid organisation that provides emergency medical assistance to populations in danger in more than 80 countries. Since 1999, MSF has been campaigning internationally to find long-term, sustainable solutions to this crisis of access to essential medicines. The campaign is pushing to lower the prices of existing medicines, to bring abandoned drugs back into production, to stimulate research and development for diseases that primarily affect the poor and to overcome other barriers to access.

Ellen 't Hoen, LL.M. has been Director of Policy and Advocacy of Médecins Sans Frontières's Campaign for Access to Essential Medicines since 1999. She previously headed the consumer network Health Action International's policy and campaigns unit, and was the international coordinator of the medicines journal La Revue Prescrire.

Médecins Sans Frontières Campaign for Access to Essential Medicines

8, rue Saint-Sabin, 75544 Paris Cedex 11

Tel: + 33 (0) 14 021 2825

Fax: + 33 (0) 14 806 6868

E-mail: ellen.t.hoen@paris.msf.org

Website: www.accessmed-msf.org