

Round Table Discussion

Drug development incentives to improve access to essential medicines

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It is hardly a matter of controversy that, as a general principle, access to essential medicines is an issue of human rights. The Universal Declaration on Human Rights makes reference to the right to medical care (Article 25) and the right to share in the benefits of scientific advancements (Article 27). Countless declarations — such as those relating to access to treatment for acquired immunodeficiency syndrome (AIDS), the WHO revised drug strategy and the WTO Doha Declaration on TRIPS and Public Health — have focused on the need for governments to promote access to medicines for all. The interesting question is not whether access to medicine is a human right but, rather, how governments intend to give practical effect to these lofty aspirations.

We live in a world of vast disparities of incomes and opportunities, which translate into vast disparities of access to decent housing, medical services, education and many other elements relevant to human rights. Often, too, there are vast disparities in terms of access to medicines, but this need not be inevitable.

Medicines are knowledge goods, sharing an important characteristic with many other knowledge goods. It may be expensive to develop a medicine, but it is often not expensive to copy one. An AIDS drug such as stavudine that sells for US\$ 3800 for a year of treatment in the United States is copied as a generic product for about US\$ 21 for a year of treatment.

While it is nearly impossible to avoid having to make tough choices for scarce physical goods and services, knowledge goods are different. Scarcity is a deliberate choice, enforced through social mechanisms such as patents, which create monopolies and predictably drive prices far above the costs of making copies. Do we need to make knowledge goods expensive, and then deal with the inevitable disparities of access associated with high prices? Or can we imagine different

incentives for drug development that would coexist with pricing at marginal cost?

In 2005, Representative Sanders introduced HR 417 in the US Congress. This legislation is a working model for a new paradigm for drug development — the Medical Innovation Prize Fund — that would provide huge rewards for the development of new drugs without introducing artificial scarcity for new inventions. It would go much further towards choosing abundance over scarcity, by creating a rational, evidence-based system for rewarding inventions to provide better health outcomes. It also provides incentives to develop products that would address global public health problems, including new treatments for neglected diseases such as malaria or emerging health problems such as severe acute respiratory syndrome (SARS) or avian flu.

The Medical Innovation Prize Fund would eliminate market monopolies for medicines in the United States, driving prices close to marginal costs. It is not an attack on intellectual property but a new system of intellectual property: one that separates the market for innovation from the market for the physical copies of the knowledge good.

The Prize Fund approach would require a new global trade framework to deal with the issue of sharing the global burden of the costs of research and development. In a separate but related effort, a new global trade framework has been proposed that would obligate governments to support R&D, but would give them much flexibility in the mechanisms they adopt to do so. It would also create a system for identifying and stimulating R&D in the areas of the greatest need and priority, including new medicines for poor populations.^{1,2}

Taken together, the Medical Innovation Prize Fund and the medical R&D treaty² trace a serious and important road map towards fulfilling the lofty aspirations of human rights to essential medicines, in a manner that is consistent with sustainable financial support for R&D on new medicines. ■

Competing interests: none declared.

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2. *Call for global R&D health treaty resonates loudly*. European Commission Research Headlines, 25 March 2005. Available from: http://europa.eu.int/comm/research/headlines/news/article_05_03_25_en.html

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Rights and practical access to medicines

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The argument that access to essential medicines should be considered as a fundamental element when assessing compliance with the right to health is reasonable and well considered. As public health and biomedical interventions have increasingly come to rely on medicines as a central component to securing good health, it makes sense to incorporate such interventions into our concepts of basic rights.

A couple of caveats should nevertheless be considered. First, in emphasizing the value of medicines it is important to avoid an overreliance or overemphasis on pharmaceuticals as the answer to the world's major health problems. Broader social, political and economic programmes concerning the equitable and efficient management of an array of public goods should not be eclipsed by an excessive reliance on medicines as a means of bringing health to populations. Certainly, the considerations raised by such issues as access to medicines to treat AIDS demand attention, but when addressing broader health issues it is important to keep in mind that dealing with individual maladies at the molecular level should not distract us from focusing on social conditions that may be largely responsible for causing the maladies in the first place.

Second, as regards the intellectual property issues involved in guaranteeing access to essential medicines, protection of intellectual property rights is indeed generally "subject to

public interest limitations". Such limitations, however, are often difficult to define and even more difficult to invoke. It is worth noting that, in the United States at least, many of the patents underlying medicines are based on research that was conducted with state funding. The fruits of such research have been patentable only since 1984 when the US Government passed the Bayh–Dole Act. I would argue that modifying this Act to recognize a right of access to essential medicines could be a constructive model for incorporating this element into the right to health. Specifically, the Act could be amended to stipulate that, if products were developed with federal funding, the federal government would retain the power to issue a compulsory licence on behalf of the patent holder to relevant generic manufacturers to produce the drug on reasonable terms in such a manner as to make it available and accessible in places where it would not otherwise be so. Alternatively, the amendment might delegate power to WHO or an equivalent organization to issue the compulsory licence.

This approach would provide notice to patent holders that their products might be subject to a rights-based compulsory licence. It also would allow for health activists to focus their attentions on lobbying a democratically responsive political institution rather than trying to bargain with individual private pharmaceutical corporations whose primary responsibility is to their shareholders. ■

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Human rights: a potentially powerful force for essential medicines

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Health policy-makers need ways to increase access peoples' access to essential medicines. The human rights framework provides new tools for analysis, action, accountability, alignment of policies, and advocacy.

To support the *analysis* of how well access to essential medicines is being realized in countries, the UN human rights treaty bodies work with WHO to identify appropriate indicators for the right to the enjoyment of the highest attainable standard of health (the right to health).

These indicators will incorporate measures to increase access to essential medicines and form an integral component of the regular State Party reports. National benchmarks will be set against these indicators in order to monitor progress.

One article in this issue of the *Bulletin* argues for benchmarks to monitor implementation of various World Health Assembly resolutions on access to medicines and amendments to the Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS).¹ The UN Special Rapporteur on the Right to Health, Paul Hunt, also works with WHO to set appropriate actions and indicators on essential medicines before the UN Human Rights Council.

Human rights norms and principles offer a useful framework for *action* at the national level by providing guidance both on the content of the health programmes and on the process by which programmes are developed. Guiding human rights principles include freedom from discrimination, attention to vulnerable populations (including their right to participate at all stages of the programming cycle), and the rights to information and to education.

The human rights-based approach also includes capacity-building to enable duty bearers to meet their human rights obligations and to enable rights-holders to enjoy and claim their rights.²

Systems of *accountability* are also part of a human rights-based approach.

International accountability comes through country reports by the UN treaty bodies; international scrutiny of failure to meet human rights obligations can spur governments to make corrections.

National accountability and redress can be provided through the courts. Judicial decisions in several low- and middle-income countries have already been rendered in support of access to essential medicines. National and international accountability requirements can therefore help the Ministry of Health to put access to medicines higher on the national political agenda, as part of the government's overall human rights performance.

Recognizing that access to essential medicines is part of government-wide human rights obligations also encourages *alignment of policies* with the obligation to move towards the highest attainable standard of health. Ministries of finance, trade and planning are equally responsible for safeguarding the right to health; they need to work with the ministry of health to

ensure intersectoral cooperation and policy coherence. Intersectoral efforts to make best use of TRIPS' flexibilities are a good example of such cooperation.

Finally, the debates about how different intellectual property regimes could stimulate innovation and also increase access to essential medicines highlight the powerful *advocacy* role that human rights can play in achieving health objectives. One of the articles in this issue describes medicines as knowledge goods and the author argues that we should separate incentives to innovate, from market forces to sell.³ Everyone has the right to enjoy the benefits of scientific progress and its applications.⁴ This right could be used to more effect in ensuring equitable access to such benefits.

The UN Committee on Economic, Social and Cultural Rights recently issued a General Comment distinguishing intellectual property rights from human rights.⁵ While intellectual property rights can be allocated, traded, amended, forfeited and are basically limited in time and scope, human rights are timeless expressions of fundamental entitlements of the human person.

Overall, this Round Table argues that the public interest limitations to the protection of intellectual property should incorporate a human rights perspective.⁶ Another article asserts that approaching access to essential medicines as a right strengthens the patient's position.⁷

At the World Summit in 2005, UN Member States unanimously resolved to integrate the promotion and protection of human rights into national policies and to support the further mainstreaming of human rights throughout the United Nations system.⁸

The Health and Human Rights Team in WHO supports technical programmes in integrating human rights, complementing traditional public health approaches. An example is provided elsewhere in this issue — how human rights support WHO's work in the area of essential medicines.⁹

The human rights framework is not a panacea. Yet it can provide a fresh perspective on issues of pressing concern such as access to essential medicines, and catalyse overall efforts to ensure greater access to essential medicines. ■

Competing interests: none declared.

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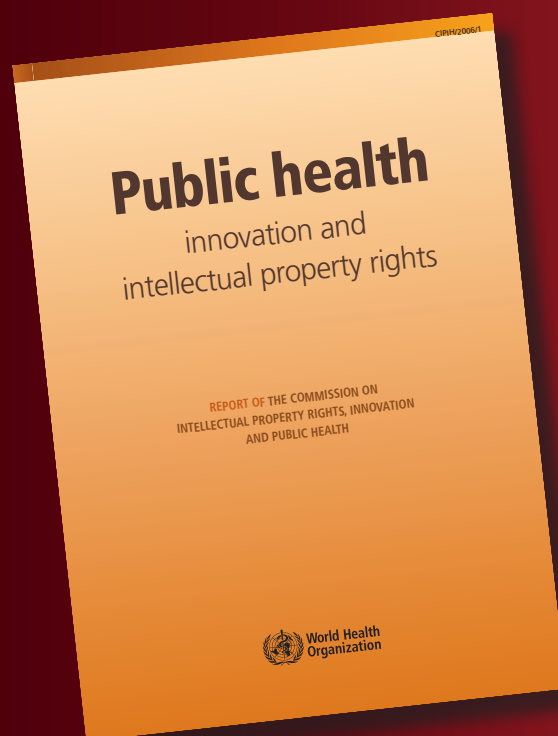
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The Commission on Intellectual Property Rights, Innovation and Public Health has completed its report:



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