Round Table

A human rights approach to the WHO Model List of Essential Medicines

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Abstract Since the first WHO Model List of Essential Medicines was adopted in 1977, it has become a popular tool among health professionals and Member States. WHO's joint effort with the United Nations Committee on Economic, Social and Cultural Rights has resulted in the inclusion of access to essential medicines in the core content of the right to health. The Committee states that the right to health contains a series of elements, such as availability, accessibility, acceptability and quality of health goods, services and programmes, which are in line with the WHO statement that essential medicines are intended to be available within the context of health systems in adequate amounts at all times, in the appropriate dosage forms, with assured quality and information, and at a price that the individual and the community can afford. The author considers another perspective by looking at the obligations to respect, protect and fulfil the right to health undertaken by the states adhering to the International Covenant of Economic, Social and Cultural Rights (ICESCR) and explores the relationship between access to medicines, the protection of intellectual property, and human rights.

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Voir page 406 le résumé en français. En la página 406 figura un resumen en español.

يمكن الاطلاع على الملخص بالعربية في صفحة 407.

Essential medicines are those that satisfy the priority health-care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. The first WHO Model List of Essential Medicines was adopted in 1977. Since then, the number of medicines listed has increased remarkably and, because of its usefulness, the WHO Model List has become a popular tool among health professionals and Member States. An emerging perspective considers access to the essential medicines as a fundamental element when assessing compliance with the right to health. This position has been adopted by WHO, being the result of setting its work within the context of international human rights law. Currently, WHO mentions the recognition of access to essential medicines as a human right at the state level among the priorities in the framework of implementation of pharmaceutical policies in the period 2004–2007,[1] and WHO's joint effort with the United Nations Committee on Economic, Social and Cultural Rights, the body in charge of the surveillance of the International Covenant of Economic, Social and Cultural Rights (ICESCR), has resulted in the inclusion of access to essential medicines in the *core content* of the right to health.

The ICESCR is the text of reference among those international treaties recognizing the right to health. Its article 12 recognizes "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health", mandating "the creation of conditions which would assure to all medical service and medical attention in the event of sickness", among which the Committee has mentioned the supply of essential medicines. The Committee states that the right to health contains a series of interrelated and minimum elements, such as *availability, accessibility, acceptability* and *quality of health goods, services and programmes*.[2] In this framework, medicines must be available in sufficient quantity, without discrimination, overcoming physical and economical constrictions and respecting medical ethics, provided that they are scientifically and medically appropriated. These four elements are in line with the WHO statement that essential medicines are intended to be available within the context of health systems in adequate amounts at all times, in the appropriate dosage forms, with assured quality and information, and at a price that the individual and the community can afford.

Another perspective in the analysis of the relationship between the right to health and access to medicines can be adopted by looking at the obligations to respect, protect and fulfil the right to health undertaken by the states adhering to the ICESCR. The *obligation to respect* urges states not to violate the right to health with their acts. It imposes, therefore, obligations of a negative nature, which are translated, in the field of access to medicines, as not to impede the supply of drugs or introduce arbitrary discriminatory criteria in the supply of them. In pursuance of the *obligation to protect*, states must prevent infringements of the right committed by third parties — and react against them. The practical applications of this second obligation are those related to medicines' pre-qualification and pharmacovigilance activities. Lastly, the *obligation to fulfil*

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refers to the adoption of positive measures, be they legislative, budgetary or promotional, needed for the fulfilment of the right to health and, more specifically, access to essential medicines.

The Committee has remarked that states adhering to the Covenant take on obligations having immediate effect, such as the prohibition of discrimination and the obligation to ensure that the core content of the rights is complied with. Especially relevant in this regard is the Committee's identification of the supply of essential medicines as part of the core and inviolable content of the said right. Furthermore, states also assume international obligations, as section 2.1 of ICESCR provides that each Member State "undertakes to take steps, individually and through international assistance and cooperation" with a view to achieving the realization of the rights recognized in the Covenant. When dealing with the relationship between this aspect and the right to health, the Committee has pronounced that states must ensure that the right to health is given due attention in international agreements.

As far as the relationship between the protection of intellectual property and access to essential drugs is concerned, it is often said that medicines included in the WHO Model List are not protected by patent but, even if they were, various international treaties would also protect property rights. The first statement is clearly wrong, as there are patented medicines in the list. Moreover, an increase in the number of patented medicines included in the list is foreseen resulting from the gradual adoption of selection criteria based on need and not on cost, to which can be added a renewed objectivity commitment in the selection process by WHO.[3] With regard to whether property rights should prevail over the right to health, the United Nations Sub-Commission on the Promotion and Protection of Human Rights has pointed out that the right to the protection of moral and economic interests resulting from scientific research is a human right "subject to public interest limitations".[4] In this sense, within the framework of the World Trade Organization (WTO) Dispute Settlement Understanding, the *right* to access to essential medicines provides powerful arguments to states reported to be infringing intellectual property rights. In such a case, states could argue that by taking action to guarantee a minimum access to essential medicines, they are just complying with another international obligation.

Approaching access to essential medicines as a right not only opens a subjective dimension that refers to individual enforceability of the right to health, but modifies issues such as the relationship between access to medicines and intellectual property rights, strengthening the patient's position. Likewise, it allows a merely ethical valorization to be overcome in favour of the analysis of actions adopted in the framework of public health in a context of legal enforceability. Finally, the perspective emerging from the right of access to essential medicines provides simultaneously the tools to report violations and a useful framework to guide states' pharmaceutical policies in a positive direction. ■

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Résumé

Liste modèle OMS des médicaments essentiels : une approche fondée sur les droits de l'homme

Depuis l'adoption de la première liste modèle OMS des médicaments essentiels en 1977, celle-ci est devenue un outil très populaire parmi les professionnels de santé et les Etats Membres. Les efforts conjoints de l'OMS et du Comité des Droits économiques, sociaux et culturels de l'ONU ont abouti à ce que l'accès aux médicaments essentiels fasse partie intégrante du droit à la santé. Le Comité stipule que le droit à la santé recouvre une série d'éléments comme la disponibilité, l'accessibilité, l'acceptabilité et la qualité des biens, services et programmes de santé. Ces éléments sont conformes à la position de l'OMS selon laquelle des médicaments essentiels de qualité vérifiée doivent être disponibles à tout moment dans le cadre des systèmes de santé, en quantités suffisantes, sous des formes pharmaceutiques appropriées, avec une qualité garantie et accompagnés des informations nécessaires et à un prix abordable pour l'individu et pour la communauté. L'auteur aborde un autre point de vue en examinant l'obligation de respecter, de protéger et de faire appliquer le droit à la santé à laquelle ont souscrit des Etats Membres en adhérant au Pacte international relatif aux droits économiques, sociaux et culturels et étudie les relations entre l'accès aux médicaments, la protection de la propriété intellectuelle et les droits de l'homme.

Resumen

Derechos humanos y Lista Modelo OMS de Medicamentos Esenciales

Desde su adopción en 1977, la Lista Modelo OMS de Medicamentos Esenciales se ha convertido en un instrumento popular entre los profesionales de la salud y los Estados Miembros. El esfuerzo conjunto realizado por la OMS y el Comité de Derechos Económicos, Sociales y Culturales de las Naciones Unidas ha desembocado en la inclusión del acceso a los medicamentos esenciales entre los componentes centrales del derecho a la salud. El Comité señala que el derecho a la salud abarca una serie de elementos, como la disponibilidad, accesibilidad, aceptabilidad y calidad de los productos, servicios y programas de salud, que están en consonancia con la declaración de la OMS de que los medicamentos esenciales deben estar disponibles en todo momento en las cantidades adecuadas y en las formas farmacéuticas que se requieran en el ámbito de los sistemas de salud, con la calidad e información necesarias, y a un precio asequible para los individuos y la comunidad. Desde otra perspectiva, el autor considera las obligaciones de respetar, proteger y cumplir el derecho a la salud asumidas por los Estados que se han adherido al Pacto Internacional de Derechos Económicos, Sociales y Culturales (ICESCR), y analiza la relación entre el acceso a los medicamentos, la protección de la propiedad intelectual y los derechos humanos.

ملخص

الأسلوب الذي يراعي حقوق الإنسان تجاه
القائمة النموذجية للأدوية الأساسية لمنظمة الصحة العالمية

لدى اعتماد أول قائمة نموذجية للأدوية الأساسية لمنظمة الصحة العالمية في عام 1977، شاع استخدام هذه القائمة بين أرباب المهن الصحية وفي الدول الأعضاء. وقد أسفرت الجهود المشتركة بين المنظمة وبين لجنة الأمم المتحدة للحقوق الاقتصادية والاجتماعية والثقافية، عن تضمين حق الحصول على الأدوية الأساسية في صميم الحق في الصحة. وتنص اللّجنة على أن الحق في الصحة يشمل سلسلة من العناصر، مثل إتاحة السلع والخدمات والبرامج الصحية، وسهولة الحصول عليها، ومقبوليتها، وجودتها وهو ما يتفق مع بيان منظمة الصحة العالمية الذي ينص على ضرورة إتاحة الأدوية الأساسية في إطار النظم الصحية بالكميات المناسبة وفي جميع الأوقات، وبالتوليفة والجرعة المناسبة، وبالجودة المضمونة والمعلومات اللازمة، وبأسعار في متناول الأفراد والمجتمعات. ويتناول الباحث أيضاً في هذه الورقة منظوراً آخر، حيث يبحث الالتزام الذي اضطلعت به الدول الموقعة على العهد الدولي الخاص بالحقوق الاقتصادية والاجتماعية والثقافية، باحترام الحق في الصحة وحمايته وتحقيقه؛ كما يستطلع الباحث في هذه الورقة العلاقة بين الحصول على الأدوية، وحماية حقوق الملكية الفكرية، وحقوق الإنسان.

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Round Table Discussion

Drug development incentives to improve access to essential medicines

James Packard Love[a]

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 treaty[2] 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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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. ■

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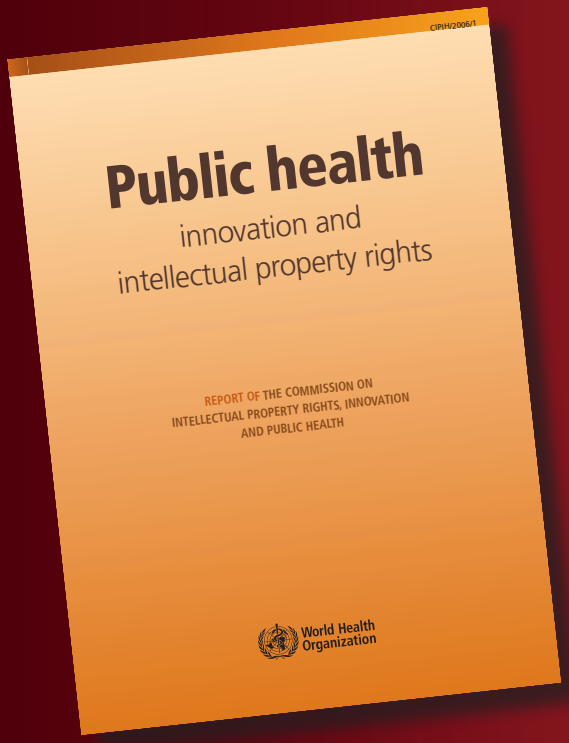
CIPIH Commission on Intellectual Property Rights, Innovation and Public Health

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



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