sur
international journal
on human rights
8

Year 5 • Number 8
June 2008
English Edition

HUMAN RIGHTS UNIVERSITY NETWORK SUR
A project of Conectas Human Rights

ISSN 1806-6445

SUR - INTERNATIONAL JOURNAL ON HUMAN RIGHTS is a biannual journal published in English, Portuguese and Spanish by Sur - Human Rights University Network.
It is available on the Internet at <http://www.surjournal.org>

SUR - International Journal on Human Rights is listed in the *International Bibliography of the Social Sciences* (IBSS).

PRINTING
Prol Editora Gráfica Ltda.

SUBSCRIPTION AND CONTACT
Sur – Human Rights University Network
Rua Pamplona, 1197 - Casa 4 São Paulo/SP - Brasil -
CEP: 01405-030 Tel.: (5511) 3884-7440 - Fax (5511) 3884-1122
E-mail: <surjournal@surjournal.org>
Internet: <http://www.surjournal.org>

The financial assistance of the Ford Foundation, the United Nations Democracy Fund and the United Nations are gratefully acknowledged.

SUR - HUMAN RIGHTS UNIVERSITY NETWORK is a network of academics working together with the mission to strengthen the voice of universities in the South on human rights and social justice, and to create stronger cooperation between them, civil society organizations and the United Nations. Conectas Human Rights, a not-for-profit organization founded in Brazil, is home to Sur. (See website <www.conectas.org> and portal <www.conectasur.org>. To access the online version of the journal, please go to: <www.surjournal.org>.)

CONTENTS

PRESENTATION

■ ■ ■

With the aim of seeking out different perspectives and dealing with subjects of a specialized nature, Conectas Human Rights has been creating partnerships with non-governmental human rights organizations in diverse parts of the world. In this issue of Sur – International Human Rights Journal, which is principally focused on access to medicines, a new cooperative partnership was formed with the Brazilian Interdisciplinary AIDS Association – ABIA.

Founded in 1987, it is the mission of ABIA to promote access to treatment and assistance to persons living with HIV and AIDS. Along these lines, ABIA has been monitoring public policies and developing projects regarding education, prevention, and access to information about HIV/AIDS. ABIA has also been coordinating the Working Group on Intellectual Property of the Brazilian Network for the Integration of Peoples – GTPI – REBRIP, in order to enrich and enlarge the debate over the harmful impacts of the rigid rules regarding intellectual property in the area of access to essential medicines, in addition to contributing to the construction of alternatives to the present model.

This eighth issue of the Sur Journal is divided into two parts: the first specifically examines access to medicines, while the second deals with questions that evaluate the present state of human rights in general.

Beginning with the discussion over access to medicines, the main problems related to the often conflicting interaction between human rights and international trade are debated. Those questions deal with the conflict between the human right to health and the protection of pharmaceutical innovations; efforts at making businesses responsible and breaking away from the protective framework initially confined to the sphere of the State; and the developing of the public debate over the political use of judicial power.

In the article by Chaves, Vieira and Reis the system for the protection of intellectual property is discussed, taking as a starting point the situation in Brazil. The relevance of the Brazilian case is based on Brazil's adoption of a policy of universal access to medicines for the treatment of AIDS as well as its recent adoption of a compulsory license for the supply of antiretroviral medicines. The model of universal access and the adoption of a compulsory license represent important benchmarks for the recognition of the preference of human rights over economic interests. The article also presents the main action strategies adopted by a Brazilian group of activists that has had a profound effect on the area. The description of these strategies is important because it enhances the possibility of exchanging experiences with other activist groups in the South.

In the article by Pogge, the author discusses the argument that patents stimulate pharmaceutical innovation. For the author, this system strengthens monopolies and the

concentration of research on the symptoms, and not the causes, of chronic illnesses. At the same time the treatment of specific illnesses of poorer populations is relegated to a secondary position because it is less profitable, thus increasing the rate of avoidable deaths. The author goes beyond simply spelling out the problem. He presents a proposal that would complement the patent system: a Health Impact Fund, financed by governments. This Fund would stimulate the development of new medicines with the promise of re-compensating successful innovators in proportion to the impact of the medicine on the global burden of illness.

The article by Hunt and Khosla deals with the responsibility of pharmaceutical businesses, along with the presentation of normative guidelines for health rights. In this sense, the article written by the Rapporteur of the United Nations on the right to health could be interpreted almost as "soft law", assisting in the structuring of this right in regard to the access to medicines.

In the last article of this first part of the Journal, which was authored by Contesse and Lovera, the question of access to medicines is analyzed beginning with individual cases that depict the perspective of those that lack access to medicines in Chile. The authors show how the litigation process can be used politically to create a public debate to sensitize the executive and legislative branches of the government to enact new public policies.

In the second part of this issue of the Sur Journal, the following issues are discussed: the justiciability of economic, social, and cultural rights (Cavallaro and Brewer); the growing consolidation of sexual rights as autonomous rights (Mattar); the participatory preparation and adoption of a new international treaty on rights of persons with disabilities (Dhanda); and the challenges that have to be overcome by non-governmental human rights organizations (Abregu).

We would like to thank the following professors and partners for their contribution in the selection of articles for this issue: Alejandro Garro, Bernardo Sorj, Carlos Correa, Denise Hirao, Frans Viljoen, J. Paul Martin, Jeremy Julian Sarkin, Juan Amaya, Julieta Rossi, Mustapha Al-Sayyed, Richard Pierre Claude, Roberto Garretón, Roger Raupp Rios, and Vinodh Jaichand.

Finally, we would like to announce that the next edition of Sur Journal will be a special issue in commemoration of the sixtieth anniversary of the Universal Declaration of Human Rights. The next issue will be published in partnership with the *International Service for Human Rights*.

The Editors

PAUL HUNT

Paul Hunt, Professor of Law, United Nations Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.
In 1998, Paul Hunt - a national of New Zealand - was elected by the UN to serve as an independent expert on the UN Committee on Economic, Social and Cultural Rights (1999-2002). In 2002, he was appointed UN Special Rapporteur on the right to health — the first appointment to this new human rights mechanism. As Special Rapporteur, he endeavours to help States, and other actors, better promote and protect the right to health. An independent expert, he undertakes country missions and reports to the UN General Assembly and UN Commission on Human Rights (now the UN Human Rights Council). He is a Professor in law, and member of the Human Rights Centre, at the University of Essex (England) and Adjunct Professor at the University of Waikato (New Zealand).

Email: paulhunt28@yahoo.co.uk

RAJAT KHOSLA

Rajat Khosla, Senior Research Officer, Human Rights centre, University of Essex, UK
Rajat is a Senior Research Officer in the Right to Health Unit, Human Rights Centre. He is a human rights lawyer researching and writing on issues related to economic, social and cultural rights. Rajat is also the coordinator of a postgraduate course on Human Rights and Development, part of the LLM in International Human Rights Law at the University of Essex. He has previously worked as a consultant researcher for the Centre for the Study of Developing Societies (CSDS) in India. He has also worked as an advocate in the Supreme Court of India on several public interest cases involving socio-economic rights.

Address: Human Rights Centre University of Essex Wivenhoe Park Colchester CO4 3SQ United Kingdom
Email: rkhosl@essex.ac.uk

ABSTRACT

This article considers the component of the right to the highest standard of health that relates to medicines, including essential medicines. Using the right-to-health analytical framework that has been developed in recent years, the first section focuses on the responsibilities of States. The second section provides a brief introduction to the responsibilities of pharmaceutical companies.

Original in English.

KEYWORDS

Medicines – Right to health – Human rights – TRIPS – WHO

THE HUMAN RIGHT TO MEDICINES

Paul Hunt and Rajat Khosla

A. Introduction

Almost 2 billion people lack access to essential medicines.[1] This deprivation causes immense and avoidable suffering: ill health, pain, fear, loss of dignity and life.[2] Improving access to existing medicines could save 10 million lives each year, 4 million of them in Africa and South-East Asia.[3] Besides deprivation, gross inequity in access to medicines remains the overriding feature of the world pharmaceutical situation.[4] Average per capita spending on medicines in high income countries is 100 times higher than in low-income countries: about US$ 400 compared with US$ 4. WHO estimates that 15 per cent of the world's population consumes over 90 per cent of the world's production of pharmaceuticals.[5]

Existing national and international policies, rules and institutions give rise to these massive deprivations and inequalities. National supply systems for medicines often do not reach those living in poverty. If they do, the medicines are often unaffordable. Historically, research and development have not addressed the priority health needs of those living in poverty. Alternative arrangements are feasible and reforms are urgently required. Indeed, they are demanded by legal and ethical duties, including those arising from international human rights law.

Millennium Development Goals, such as reducing child mortality, improving maternal health, and combating HIV/AIDS, malaria and other diseases, depend upon improving access to medicines. Indeed, one of the Millennium Development Goal targets is to provide, "in cooperation with pharmaceutical companies, access to affordable essential drugs in developing countries".[6] Crucially, implementation

Notes to this text start on page 112.

of the right to the highest attainable standard of health can help to achieve the health related Goals.

Medical care in the event of sickness, as well as the prevention, treatment and control of diseases, are central features of the right to the highest attainable standard of health (the terms the "right to the highest attainable standard of health" and "right to health" are used as a convenient abbreviation for the more accurate formulation of the "right of everyone to the enjoyment of the highest attainable standard of physical and mental health").[7] These features depend upon access to medicines. Thus, access to medicines forms an indispensable part of the right to the highest attainable standard of health. Numerous court cases, as well as resolutions of the UN Commission on Human Rights, confirm that access to essential medicines is a fundamental element of the right to health.[8] Some of the cases also confirm that access to essential medicines issues are closely connected to other human rights, such as the right to life.

This article briefly examines the medicines component of the right to health. While the article focuses upon the responsibilities of States, it also provides a brief introduction to the responsibilities of pharmaceutical companies. The article is offered as a preliminary contribution to far-reaching human rights issues of the first importance.

The right-to-health analytical framework

In recent years, the UN Committee on Economic, Social and Cultural Rights, WHO, the UN Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, civil society organizations, academics and many others, have developed a way of "unpacking" or analysing the right to health with a view to making it easier to understand and apply to health-related policies, programmes and projects in practice. The analytical framework that has been developed is made up of ten key elements and has general application to all aspects of the right to health, including the underlying determinants of health: this has been demonstrated by the Special Rapporteur in his use of the framework throughout his work.

While the analytical framework is set out in more detail elsewhere,[9] its key elements may be very briefly summarized as follows:

(a) Identification of the relevant national and international human rights laws, norms and standards;

(b) Recognition that the right to health is subject to resource constraints and progressive realization, requiring the identification of indicators and benchmarks to measure progress (or the lack of it) over time;

(c) Nonetheless, recognition that some obligations arising from the right to health are subject to neither resource constraints nor progressive realization, but are of immediate effect, for example, the obligation to avoid de jure and de facto discrimination;

(d) Recognition that the right to health includes freedoms (e.g. freedom from non-consensual treatment and non-consensual participation in clinical trials) and entitlements (e.g. to a system of health care and protection). For the most part, freedoms do not have budgetary implications, while entitlements do;

(e) All health services, goods and facilities shall be available, accessible, acceptable and of good quality;

(f) States have duties to respect, protect and fulfil the right to the highest attainable standard of health;

(g) Because of their crucial importance, the analytical framework demands that special attention is given to issues of non-discrimination, equality and vulnerability;

(h) The right to health requires that there is an opportunity for the active and informed participation of individuals and communities in decision making that bears upon their health;

(i) Developing countries have a responsibility to seek international assistance and cooperation, while developed States have some responsibilities towards the realization of the right to health in developing countries; and

(j) The right to health requires that there are effective, transparent and accessible monitoring and accountability mechanisms available at the national and international levels.

By way of illustration, this article briefly applies elements of this analytical framework to access to medicines.

B. The responsibilities of States

Ensuring medicines are available, accessible, culturally acceptable and of good quality[10]

States have to do all they reasonably can to make sure that existing medicines are available in sufficient quantities in their jurisdictions. For example, they

might have to make use of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities by passing and using compulsory licence legislation, thereby ensuring that medicines reach their jurisdictions in adequate quantities. Historically, research and development have not addressed the priority health needs of low-income and middle-income countries. Thus, within a framework of international assistance and cooperation, States are required to take effective measures to promote the development and availability of new drugs, vaccines and diagnostic tools for those diseases causing a heavy burden in developing countries.[11] States therefore are required to resort to a variety of economic, financial and commercial incentives in order to influence research and development into specific health needs.

In short, States not only have a duty to ensure that existing medicines are available within their borders, they also have a responsibility to take reasonable measures to ensure that much-needed new medicines are developed and thereby become available.

In addition to being available, medicines must also be accessible. Accessibility has four dimensions. First, medicines must be accessible in all parts of the country (for example, in remote rural areas as well as in urban centres). This has major implications for the design of medicine supply systems, including outreach programmes. Second, medicines must be economically accessible (i.e. affordable) to all, including those living in poverty. This has major implications for medicine funding and pricing arrangements. It may also mean that a State has to revisit import duties and other taxes on medicines if they are helping to take medicines beyond the reach of the poor. Third, medicines must be accessible without discrimination on any of the prohibited grounds, such as sex, race, ethnicity and socio-economic status. As discussed in the next section, the principle of non-discrimination may require a State to take measures to ensure equality of access for all individuals and groups, such as disadvantaged minorities. Fourth, reliable information about medicines must be accessible to patients and health professionals so they can take well-informed decisions and use medicines safely.

As well as being available and accessible, medicines and associated issues must be culturally acceptable and respectful of medical ethics. For example, national measures should support the proper use of traditional medicine and its integration into health-care systems, while clinical trials must ensure the informed consent of research subjects.

Medicines must also be of good quality. If rejected in the North because they are beyond their expiry date and unsafe, medicines must not be recycled to the South. Because medicines may be counterfeit or tampered with, States must establish a regulatory system to check medicine safety and quality.

Combating discrimination, inequality and vulnerability

The right to health requires a national medicines policy to be designed to ensure access for disadvantaged individuals and groups, including women and girls, ethnic minority and indigenous populations, people living in poverty, people living with HIV/AIDS, internally displaced people, the elderly, people with disabilities, prisoners and others.

This preoccupation with vulnerability and disadvantage arises from two of the most fundamental principles of international human rights law: non-discrimination and equality. Importantly, these twin principles do not always demand equal treatment; on the contrary, they sometimes require a State to take measures in favour of disadvantaged individuals and communities. Although closely linked to the ethical concept of equity, the principles of non-discrimination and equality have the advantage of being reinforced by law and accountability mechanisms.

In relation to access to medicines, non-discrimination and equality have numerous implications. For example, a State is obliged to establish a national medicine supply system that includes programmes specifically tailored to reach the vulnerable and disadvantaged. It is also required to tackle the cultural, social and political factors that inhibit vulnerable groups' access to health care generally and to medicines in particular. So far as possible, data must be disaggregated to identify vulnerable groups and monitor their progress towards equal access.[12]

In relation to medicines, how is progressive realization to be measured and monitored? What are the obligations of immediate effect?

The right to the highest attainable standard of health — and thus access to medicines — is subject to progressive realization and resource availability, in accordance with article 2 (1), of the International Covenant on Economic, Social and Cultural Rights. Put simply, progressive realization means that a State is required to be doing better in two years time than it is doing today, while resource availability means that what is required of a developed State is of a higher standard than what is required of a developing State.

This has a number of important implications. For example, States need appropriate indicators and benchmarks so they know whether or not they are progressively realizing the right to health.[13] But it also has an important qualification: the right to health includes some core obligations of immediate effect, without which the right would be largely deprived of its *raison d'être*.[14]

For example, States have an immediate obligation to avoid discrimination and also to make certain pharmaceuticals — known as "essential medicines" — available and accessible throughout their jurisdictions.[15] These core obligations of immediate effect are not subject to progressive realization.

Guided by the WHO Model List of Essential Medicines, a State is required to prepare a national essential medicines list, by way of a participatory inclusive process. If a State declines to prepare its own national essential medicines list, the WHO model list will apply, subject to any obvious contextual revisions. A State has a core obligation of immediate effect — not subject to progressive realization — to make available and accessible throughout its jurisdiction the essential medicines on its national list.[16]

In summary, the right to health encompasses access to non-essential and essential medicines. While a State is required to progressively realise access to non essential medicines, it has a core obligation of immediate effect to make essential medicines available and accessible throughout its jurisdiction. This article encompasses non-essential and essential medicines.

Duties to respect, protect and fulfil

States have duties to respect, protect and fulfil the right to the highest attainable standard of health.[17] For example, the *duty to respect* obliges a State to ensure that its medicines policy does not discriminate against women, ethnic minorities, or other disadvantaged groups. The *duty to protect* requires a State to ensure that third parties do not obstruct enjoyment of the right to health, for example, a State is required to ensure that privatization in the health sector advances, and does not hinder, the realization of the right to health. The *duty to fulfil* requires a State to provide those living in poverty with essential medicines if they would otherwise be unable to access them.

In other words, while a State may contract the delivery of health services to a private company, it does not contract out of its right-to-health obligations. A State always retains residual responsibility for the proper regulation of its health and medicines systems, as well as for the well-being of the most disadvantaged in its jurisdiction.

Participation in health policymaking

The active and informed participation of individuals and communities in health policymaking that affects them is an important feature of the right to the highest attainable standard of health. In most cases, a local community will have a keen sense of its health priorities; it is entitled to participate in the identification

of priorities and targets that guide the technical deliberations underlying the policy formulation that will affect its members.

When formulating its national medicine policy and programmes, a State is required to take steps to ensure the active and informed participation of all those affected, not only professional associations and universities, but also rural communities, non-governmental organizations, patients and consumer associations, and representatives of disadvantaged groups.

International assistance and cooperation in health

The primary obligation for implementing the right to health falls upon the national authorities in the State in question. However, States have the obligation to take steps individually and through international assistance and cooperation towards the full realization of various rights, including the right to health.[18]

In the context of medicines, this responsibility means that no rich State should encourage a developing country to accept intellectual property standards that do not take into account the safeguards and flexibilities included under the TRIPS Agreement.[19] In other words, developed States should not encourage a developing country to accept "TRIPS-plus" standards in any bilateral or multilateral trade agreement.[20] They should help developing countries establish effective, integrated, inclusive health systems that include reliable medicine supply systems delivering quality affordable medicines for all, and support research and development into the priority health needs of developing countries.

Monitoring and accountability

The right to health brings with it the crucial requirement of establishing accessible, transparent and effective mechanisms of monitoring and accountability. Those with right-to-health responsibilities must be held to account in relation to the discharge of their duties, with a view to identifying successes and difficulties; so far as necessary, policy and other adjustments can then be made. There are many different forms of monitoring and accountability mechanisms. While a State will decide which are most appropriate in its particular case, all mechanisms must be effective, accessible and transparent.

A national medicines policy should therefore be subjected to appropriate monitoring and accountability. This requires that the policy set out: the Government's right-to health obligations in relation to medicines; an implementation plan that identifies objectives, timelines, duty holders and their responsibilities, indicators, benchmarks, and reporting procedures. From time to time, a suitable national body (e.g. a health ombudsman) will have to consider the degree to which those responsible for the implementation of the national

medicines policy have fulfilled their duties — not with a view to sanction and punishment, but with a view to establishing which policies and institutions are working and which are not, with the aim of improving the realization of the right to medicines for all.

A selection of specific, practical issues regarding access to medicines

Ensuring access to medicines for all gives rise to a wide range of specific, practical and important issues. By way of illustration, this section briefly introduces four of these issues, keeping in mind the analytical framework signalled in the preceding paragraphs.

A reliable system for the supply of good quality affordable medicines

Whether it chooses a supply system that is public, private or mixed, a State has a legal obligation to ensure that there is a reliable, efficient, transparent system for the supply of quality affordable medicines throughout its jurisdiction. The supply system must be attuned to current needs, obtain good value for money, minimize waste and avoid corruption. Crucially, it must be designed to serve those living in poverty and isolated communities, as well as wealthy urban elites.

Of course, this obligation is subject to the resources available in a particular country: Canada is obliged to ensure better access to a wider range of medicines than Chad. However, the obligation of both developed and developing States is subject to progressive realization: all States are required to ensure better access to a wider range of medicines in two years' time than exists today.

To measure this progressive realization (or lack of it), States must develop disaggregated indicators and benchmarks for a reliable, efficient medicine supply system.[21] These indicators have to reflect human rights features, for example, the degree to which the system ensures equal access for disadvantaged groups (hence the need for disaggregated indicators), and provides effective monitoring and accountability mechanisms.

Quality of medicines

International human rights standards are clear: a State has a legal obligation to ensure that medicines of good quality are available throughout its jurisdiction. Thus, effective medicine regulation is required to ensure the safety, efficacy, and quality of medicines available in both public and private sectors, as well as

the accuracy and appropriateness of medicine information available to health professionals and the public.

While the safety and quality of medicines is a problem in many developed and developing States, the magnitude of the problem is much greater in developing countries, where poor quality medicines may be the only ones to reach the poor. In recent assessments carried out by WHO, 50-90 per cent of anti-malarial drug samples failed quality control tests, while more than half of antiretrovirals did not meet international standards.[22] The sale of counterfeit and substandard medicines remains a global concern.

One third of States have either no medicine regulatory authority or inadequate capacity to regulate the medicines market.[23] The absence of such an authority is clearly inconsistent with the right to the highest attainable standard of health. In line with their human rights responsibility of international assistance and cooperation, developed States should actively help developing countries establish appropriate medicine regulatory authorities.

Financing of medicines

Whether a medicine is affordable depends upon many factors, including financing (i.e. how they are paid for) and pricing. There are different ways of financing medicines, including by way of public or private health insurance, patients' fees, donations, loans, and so on. These are complex issues and here the Special Rapporteur confines himself to one point. Whatever the chosen financing arrangement, a State has a human rights obligation to ensure that medicines are economically accessible (i.e. affordable) to all.

In many high-income countries, over 70 per cent of medicines are publicly funded whereas in low- and middle-income countries public expenditure does not cover the basic medicine needs of the majority of the population. In these countries, patients themselves pay for 50 to 90 per cent of medicines. Where the cost of medicines is borne by households, it can further impoverish already disadvantaged populations, and inhibit equitable access to medicines.

In developed countries, a course of antibiotics for pneumonia may be bought for the equivalent of two or three hours' wages; in developing countries, a course may cost one month's wages.[24] In developed countries, one year's HIV treatment may consume the equivalent of four to six months' salary and, in most cases, will be covered by health insurance; in many developing countries, one year's HIV paediatric treatment may consume the equivalent of an adult's income for 10 years. Such striking inequalities are deeply repugnant and underscore the importance of developed States' responsibility for international assistance and cooperation.

For present purposes, however, the crucial point is that in developed

countries most medicines are paid from public funding, whereas in developing countries the majority of households buy their medicines with money from their own pockets. In developing countries, inadequate public funding in the health sector makes medicines less affordable, especially for those living in poverty.

Corruption

In some medicine supply systems, corruption is endemic. Products are diverted; unofficial "fees" are required for customs clearance; counterfeit medicines are permitted to circulate and so on. Corruption can be deadly. As Dora Akunyili, head of Nigeria's Food and Drug Authority, put it: "drug counterfeiting, facilitated by corruption, kills *en masse* and anybody can be a victim".[25]

Those living in poverty are disproportionately affected by corruption in the health sector because they are less able to afford small bribes for services that are meant to be free, or to pay for private alternatives where corruption has depleted public health services.

The right to health includes participation, access to information, transparency, monitoring and accountability. Each of these features helps to establish an environment in which corruption cannot survive. In short, a right-to-health policy is also an anti-corruption policy. Thus, the application of the right to health can help to reduce corruption in health systems in general, as well as medicine supply systems in particular.

Conclusion

It is crucial for all States to have an up-to-date national medicines policy and detailed implementation plan. The policy should include a national list of essential medicines. At the turn of the century, almost 100 States did not have a national medicines policy.[26] Two thirds of those with a policy did not have an implementation plan.[27] Under these circumstances it is difficult to argue how any State can be in conformity with its right-to-health obligations if it does not have an up-to-date and appropriate national medicines policy, implementation plan and essential medicines list, prepared by way of a participatory inclusive process.[28]

C. The responsibilities of pharmaceutical companies

The previous section emphasized the primary responsibility of States to increase access to medicines. But, of course, this is a shared responsibility. If there is to be an increase in access to medicines, numerous national and

international actors have an indispensable role to play. The Millennium Development Goals recognize that pharmaceutical companies are among those who share this responsibility. Goal 8, a global partnership for development, has a number of targets, not least: "*in cooperation with pharmaceutical companies,* provide access to affordable, essential drugs in developing countries" (emphasis added).

A few years back, a British Government policy paper on access to medicines elaborated on this point: "responsibility for increasing access to essential medicines rests with the whole international community. Progress depends on everyone working in partnership to build health systems in developing countries, increase financing, make medicines more affordable, and increase the amount of new medicines developed for diseases affecting developing countries".[29] Significantly, the paper continued: "in this context there is a particular role for pharmaceutical companies. As the producers of existing, and developers of new, medicines they can — and do — make a difference within their sphere of influence".

The pharmaceutical sector has a profound impact on the implementation of the right to the highest attainable standard of health. States and others have criticized the pharmaceutical sector for setting prices too high, erratic drug donations, imbalanced research and development, lobbying for TRIPS plus standards, inappropriate drug promotion, problematic clinical trials, and other practices that are seen to obstruct a State's ability to discharge its right to health responsibilities.[30] However, States and others have also commended some significant progress in recent years, such as the more widespread use of differential pricing, predictable and sustainable drug donations, and a renewed commitment to research and development into neglected diseases.[31]

There is congruity between corporate responsibility, good practices and the right to health. While the right-to-health analytical framework (as outlined before) is primarily designed for States, its application can help to identify policy interventions that a pharmaceutical company can — and should — take to improve access to medicines. The right to health can be promoted and protected without recourse to the courts, by shaping good policies. While it is commendable that some of the companies have joined corporate responsibility self-reporting initiatives, they fall short of the independent accountability mechanisms anticipated by human rights. (Some independent accountability mechanisms are non-judicial, for example a Health Ombudsman.)

Although a number of pharmaceutical companies report on their corporate citizenship or corporate responsibility activities, few make specific references in their corporate mission statements to human rights in general, or the right to health in particular. Even fewer appear to have carefully examined their policies through the lens of the right to the highest attainable

standard of health. This is a missed opportunity because all pharmaceutical companies, whether large or small, research based or generic, and whether or not their reach is global, would find it beneficial to adopt a rights-sensitive approach to their businesses, as outlined in the excellent joint publication of the Global Compact, Business Leaders Initiative on Human Rights and OHCHR.[32]

In recent years, the general understanding of economic, social and cultural rights has deepened. If this momentum is to be maintained, it is necessary to move from general discussions about economic, social and cultural rights to consideration of specific rights, in relation to specific sectors, actors and issues. This is the point that has now been reached in relation to pharmaceutical companies and the right to health. Today, general statements about pharmaceutical companies and economic, social and cultural rights provide the indispensable foundation for a more detailed examination of specific right-to-health issues arising in the pharmaceutical sector. In short, it is time to explore further the right-to-health responsibilities of pharmaceutical companies that were acknowledged in general terms by the UN Committee on Economic, Social and Cultural Rights in its general comment 14, paragraph 42.

For this reason the UN Special Rapporteur has embarked on a process of preparing draft Guidelines for States and pharmaceutical companies on access to medicines.[33] The draft Guidelines for pharmaceutical companies consider specific issues, such as differential pricing, donations, research and development for neglected diseases, public-private partnerships, drug promotion, clinical trials, and corruption.[34] As observed by the UN Special Representative of the Secretary-General on the issue of human rights and transnational corporations and other business enterprises: "it is essential to achieve greater conceptual clarity with regard to the respective responsibilities of States and corporations […] In doing so we should bear in mind that companies are constrained not only by legal standards but also by social norms and moral considerations."[35]

Conclusion

A consensus is emerging that business enterprises, like all actors in society, have some legal and ethical human rights responsibilities. According to its Preamble, the Universal Declaration of Human Rights gives rise to some human rights responsibilities for "every organ of society", which must include business enterprises.[36] The United Nations Global Compact, with more than 2,300 participating companies, affirms that businesses should support and respect the protection of international human rights.[37] The Organization for

Economic Cooperation and Development's Guidelines for Multinational Enterprises require businesses to "respect the human rights of those affected by their activities consistent with the host Government's obligations and commitments".[38] While holding that the draft Norms on the Responsibilities of Transnational Corporations and Other Business Enterprises with Regard to Human Rights of the Sub-Commission on the Promotion and Protection of Human Rights had no legal standing, the Commission on Human Rights found that the Norms contained "useful elements and ideas".[39] Some national courts have recognized the impact of pharmaceutical company pricing policies on the human rights of patients.[40] Significantly, some companies have prepared their own guidelines and other statements explicitly affirming their human rights responsibilities.[41]

Today, the key issues include, *first*, clarifying the scope and content of these human rights responsibilities and, *second*, identifying which are legal and which are ethical. The draft Guidelines are a modest endeavour focusing on the first of these issues in the specific context of pharmaceutical companies. As for the second, it is inconceivable that some human rights do not place legal responsibilities on business enterprises.[42]

D. Conclusions

Today, the content of the right to the highest attainable standard of health is becoming clearer. In 2000, the UN Committee on Economic, Social and Cultural Rights developed a general framework that unpacked the right to health in terms of freedoms and entitlements; health care and underlying determinants of health; non-discrimination; participation; monitoring and accountability, and so on.[43] This article endeavours to apply the framework to medicines, a health issue encompassed by the Millennium Development Goals.

The right to health makes a number of important contributions to the struggle to improve access to medicines. It sharpens analysis of the causes, as well as the responsibilities of various stakeholders. Policies informed by the right to health are likely to be more equitable, sustainable and effective. This contribution is already recognized in the context of some health policies and programmes.[44] In relation to policy making about medicines, there is also a growing appreciation of the positive contribution that can be made by taking into account the right to the highest attainable standard of health.

Additionally, experience confirms that traditional human rights techniques, including "naming and shaming" and taking court cases, continue to have an indispensable role to play in the realization of various elements of the right to health, not least access to medicines.

NOTES

1. WORLD HEALTH ORGANIZATION (WHO). *Medicines strategy: countries at the core, 2004-2007.*, Geneva, WHO, 2004. Fewer than one quarter of all AIDS patients in Africa, and less than one tenth of children with AIDS, receive the life-saving antiretroviral medicines they need, according to WHO statistics presented at the XVI International AIDS Conference, Toronto, 2006.

2. Some of this chapter draws upon the Montreal Statement on the Human Right to Essential Medicines (2005), see MARKS, S. (ed.). *Health and human rights: basic international documents*, Harvard: HUP, 2006.

3. UNITED KINGDOM, Department for International Development (DFID). *Increasing access to essential medicines in the developing world*. London, DFID, 2004.

4. WORLD HEALTH ORGANIZATION (WHO). *Medicines strategy 2004-2007*, op.cit.

5. Ibid.

6. UNITED NATIONS ORGANIZATION. *Millennium Development Goals*. New York, 2000, Target 17 of Goal 8. Available at: <http://www.undp.org/mdg/>. Accessed on: 8 Nov. 2007.

7. INTERNATIONAL COVENANT ON ECONOMIC, SOCIAL AND CULTURAL RIGHTS (ICESCR), 1976, article 12 (2) (c) and (d). Available at: <http://www.unhchr.ch/html/menu3/b/a_cescr.htm>. Accessed on: 8 Nov. 2007.

8. For an excellent summary of relevant national jurisprudence, see HOGERZEIL, H. et al. Is access to essential medicines as part of the fulfilment of the right to health enforceable through the courts?, *Lancet*, London, 2006. See also UNITED NATIONS ORGANIZATION. *Commission on Human Rights resolutions,* 2005/23, 2004/26 and 2003/29. Available at: <http://www.ohchr.org/english/>. Accessed on: 8 Nov. 2007.

9. For instance, see UN SPECIAL RAPPORTUER ON THE RIGHT TO HEALTH. *Report on mental disability*, E/CN.4/2005/51, 10 Feb. 2005 and also on *Mission to Uganda*, E/CN.4/2006/48/Add.2, 19 Jan. 2006. Available at: <http://www2.essex.ac.uk/human_rights_centre/rth/reports.shtm>. Accessed on: 8 Nov. 2007.

10. See UN COMMITTEE ON THE ECONOMIC, SOCIAL AND CULTURAL RIGHTS (CESCR). *General Comment 14*, para. 12. Available at: <http://www.ohchr.org/english/>. Accessed on: 12 Nov. 2007.

11. For this right-to-health problem in the context of Uganda's neglected diseases, see the UN SPECIAL RAPPORTEUR. *Report on mission to Uganda*, op. cit., especially from para. 62.

12. See UN SPECIAL RAPPORTEUR ON THE RIGHT TO HEALTH. *Report on a human rights-based approach to health indicators*, E/CN.4/2006/48, from para. 62. Available at: <http://www2.essex.ac.uk/human_rights_centre/rth/reports.shtm>. Accessed on: 15 Nov. 2007.

13. See human rights-based approach to health indicators set out in E/CN.4/2006/48; see also HUNT, P. and MACNAUGHTON, G. A human rights-based approach to health Indicators. In BADERIN, M. and MCCORQUODALE, R.(ed.). *Economic, social and cultural rights in action*. London: OUP, 2007.

14. UNITED NATIONS COMMITTEE ON ECONOMIC, SOCIAL AND CULTURAL RIGHTS (CESCR). *General comment 3*, para. 10.

15. Id. *General Comment 14*, paras. 43-44.

16. Ibid, paras. 12 (1) and 43 (4).

17. Ibid, paras. 34-37.

18. See UN SPECIAL RAPPORTEUR ON THE RIGHT TO HEALTH. *Report on health professional skills drain*, A/60/348. Available at: <http://www2.essex.ac.uk/human_rights_centre/rth/reports.shtm>. Accessed on: 15 Nov. 2007.

19 For example, see the UN SPECIAL RAPPORTEUR, *Reports on the World Trade Organization,* E/CN.4/2004/49/Add.1, from para. 66; and ___. *Peru*, E/CN.4/2005/51/Add.3, from para. 47. Available at: <http://www2.essex.ac.uk/human_rights_centre/rth/reports.shtm>. Accessed on: 15 Nov. 2007.

20 TRIPS-plus obligations are those which go beyond those imposed by the World Trade Organisation (WTO)'s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

21 WORLD HEALTH ORGANIZATION. *Medicines Strategy, 2004-2007*, chapter 4, op. cit.

22 Ibid.

23 Ibid.

24 WORLD HEALTH ORGANIZATION. *World Health Assembly gives a resounding support to WHO technical programmes*. WHO, Press Release 1999. Available at: <http://www.who.int/inf-pr-1999/en/pr99-wha18.html>. Accessed on: 16 Nov. 2007.

25. *Global Corruption Report*. Transparency International, 2006.

26. HOGERZEIL, H. Essential medicines and human rights. *WHO Bulletin*, 2006.

27. *The world medicines situation*. WHO, 2004.

28. In this context, States should give close attention to WHO's commendable work on access to medicines, including its *Medicines Strategy 2004-2007*, op. cit.

29. UNITED KINGDOM, Department for International Development (DFID). *Increasing people's access to essential medicines in developing countries*. London: DFID, 2005.

30. Some of this information has been provided while on mission and confirmed in, for example, REPORT OF TASK FORCE 5 WORKING GROUP ON ACCESS TO ESSENTIAL MEDICINES. *Prescription for healthy development: increasing access to medicines*. Millennium Project, 2005; CULLET, P. Patents and medicines: the relationship between TRIPS and the human right to health. *International Affairs, v. 79, p. 139-160*, 2003 and ODO, Godwin C., *The human rights responsibilities of pharmaceutical corporations in relation to the right to health*. Unpublished LL.M Dissertation: University of Essex, 2004.

31. On the latter, see MORAN, M. and others, The new landscape of neglected disease drug

Development. *The Welcome Trust*, London, 2005.

32. See Business Leaders Initiative on Human Rights. *A guide for integrating human rights into business management*. Available at:

<http://www.corporatecitizenship.novartis.com/downloads/people-communities/A_guide_for_integrating_human_rights_into_business_management.pdf >. Accessed on: 12 Nov. 2007.

33. The draft Guidelines are available at: <http://www2.essex.ac.uk/human_rights_centre/rth/>. Accessed on 15 Nov. 2007.

34. E.g. WHO. *Public Health, Innovation and Intellectual Property Rights*. Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH), 2006; DFID. *Increasing people's access to essential medicines in developing countries.* London, 2005; LEISINGER, K. On corporate responsibility and human rights. Basel, April2006. Available at: http://www.reports-and-materials.org/Leisinger-On-Corporate-Responsibility-for-Human-Rights-Apr-2006.pdf. Accessed on 13 March 2008; Consumers International. *Branding the cure: a consumer perspective on corporate social responsibility, drug promotion and the pharmaceutical industry,* 2006. Available at: <http://www.consumersinternational.org/Shared_ASP_Files/UploadedFiles/ECD91B6F-FE37-45C0-AE34-898BFB39C700_BrandingtheCure-fullreport.pdf>. Accessed on 13 March 2008.

35. OHCHR. *Interim report of the Special Representative*, E/CN.4/2006/97, para. 70. Available at: <http://www.ohchr.org/english>. Accessed on 12 Nov. 2007.

36. ROBINSON, M. The business case for human rights. In: Visions of Ethical Business, *Financial Times Management*, London, Financial Times Professional, 1998; DE MELLO, S.V. Human rights: what role for business?. *New Academy Review,* v. 2, n. 1, Liverpool, 2003.

37. For more information on the Global Compact, see <http://www.unglobalcompact.org/>. Accessed on: 12 Nov. 2007.

38. *The OECD Guidelines for Multinational Enterprises*, 2000.

39. Norms on the responsibilities of transnational corporations and other business enterprises with regard to human rights (E/CN.4/Sub.2/2003/12/Rev.2) (2003). Available at: <http://www.ohchr.org/english/>. Accessed on: 12 Nov. 2007.

40. The Central Intellectual Property and International Trade Court, *AIDS Access Foundation and others v. Bristol-Myers Squibb and others*, 2002 (10) BC Tor Por 34/2544.

41. NORVATIS FOUNDATION. "Novartis Corporate Citizenship Guideline 4 (Human Rights)". Available at: <www.novartisfoundation.com>. Accessed on: 10 Nov. 2007.

42. A view consistent with the interim report of the UN Special Representative of the Secretary-General on the issue of human rights and transnational corporations, see, for example, E/CN.4/2006/97, para. 61, last sentence. Generally, see CLAPHAM, A. *Human rights obligations of non-State actors*. London: OUP, 2006.

43. CESCR, General Comment 14, op. cit.

44. See for examples HUNT, P. et. Al. *Neglected diseases: a human rights analysis*. WHO, TDR, Special Topics No.6, 2007.

RESUMO

O presente artigo analisa o acesso a medicamentos, em especial aqueles considerados essenciais, como parte do direito a desfrutar do mais elevado nível possível de saúde. A partir da estrutura analítica do direito à saúde elaborada nos últimos anos, a primeira parte deste artigo concentra-se nos deveres atribuídos aos Estados. A segunda parte procura nos introduzir à responsabilidade das empresas farmacêuticas.

PALAVRAS-CHAVE
Medicamentos – Direito à saúde – Direitos humanos – TRIPS – OMS

RESUMEN

Este artículo analiza el componente del derecho al disfrute del más alto nivel posible de salud que se relaciona con el acceso a los medicamentos, incluyendo los medicamentos esenciales. Utilizando el marco analítico del derecho a la salud que ha sido desarrollado en los años recientes, la primera sección se concentra en las responsabilidades de los Estados. La segunda sección provee una breve introducción a las responsabilidades de las compañías farmacéuticas.

PALABRAS CLAVES
Medicamentos – Derecho a la salud – Derechos humanos – TRIPS – OMS

PREVIOUS NUMBERS

Previous numbers are available at <www.surjournal.org>.

SUR 1

EMILIO GARCÍA MÉNDEZ
Origin, Concept and Future of Human Rights: Reflections for a New Agenda

FLAVIA PIOVESAN
Social, Economic and Cultural Rights and Civil and Political Rights

OSCAR VILHENA VIEIRA and A. SCOTT DUPREE
Reflections on Civil Society and Human Rights

JEREMY SARKIN
The Coming of Age of Claims for Reparations for Human Rights Abuses Committed in the South

VINODH JAICHAND
Public Interest Litigation Strategies for Advancing Human Rights in Domestic Systems of Law

PAUL CHEVIGNY
Repression in the United States after the September 11 Attack

SERGIO VIEIRA DE MELLO
Only Member States Can Make the UN WorkFive Questions for the Human Rights Field

SUR 2

SALIL SHETTY
Millennium Declaration and Development Goals: Opportunities for Human Rights

FATEH AZZAM
Reflections on Human Rights Approaches to Implementing the Millennium Development Goals

RICHARD PIERRE CLAUDE
The Right to Education and Human Rights Education

JOSÉ REINALDO DE LIMA LOPES
The Right to Recognition for Gays and Lesbians

E.S. NWAUCHE AND J.C. NWOBIKE
Implementing the Right to Development

STEVEN FREELAND
Human Rights, the Environment and Conflict: Addressing Crimes against the Environment

FIONA MACAULAY
Civil Society-State Partnerships for the Promotion of Citizen Security in Brazil

EDWIN REKOSH
Who Defines the Public Interest?

VÍCTOR E. ABRAMOVICH
Courses of Action in Economic, Social and Cultural Rights: Instruments and Allies

SUR 3

CAROLINE DOMMEN
Trade and Human Rights: Towards Coherence

CARLOS M. CORREA
TRIPS Agreement and Access to Drugs in Developing Countries

BERNARDO SORJ
Security, Human Security and Latin America

ALBERTO BOVINO
Evidential Issues before the Inter-American Court of Human Rights

NICO HORN
Eddie Mabo and Namibia: Land Reform and Pre-Colonial Land Rights

NLERUM S. OKOGBULE
Access to Justice and Human Rights Protection in Nigeria: Problems and Prospects

MARÍA JOSÉ GUEMBE
Reopening of Trials for Crimes Committed by the Argentine Military Dictatorship

JOSÉ RICARDO CUNHA
Human Rights and Justiciability: A Survey Conducted in Rio de Janeiro

LOUISE ARBOUR
Plan of Action Submitted by the United Nations High Commissioner for Human Rights

SUR 4

FERNANDE RAINE
The measurement challenge in human rights

MARIO MELO
Recent advances in the justiciability of indigenous rights in the Inter American System of Human Rights

ISABELA FIGUEROA
Indigenous peoples versus oil companies: Constitutional control within resistance

ROBERT ARCHER
The strengths of different traditions: What can be gained and what might be lost by combining rights and development?

J. PAUL MARTIN
Development and rights revisited: Lessons from Africa