Realising the right to health: access to HIV/AIDS-related medication

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"The role of civil society: recent developments and implications for the human right to health"

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On behalf of the Canadian HIV/AIDS Legal Network, thank you to the co-sponsors of this session for the opportunity to speak on this topic today. The Canadian HIV/AIDS Legal Network is a Canadian non-governmental organization that promotes legal and policy responses to HIV/AIDS that: respect and promote the human rights of people living with HIV/AIDS; facilitate HIV prevention; and facilitate access to care, treatment and support for people living with HIV/AIDS.

Since the 57th session of the Commission on Human Rights, there have been several likely significant developments relevant to the issue of global access to medicines that the Commission has recognized as "one fundamental element for achieving progressively the full realization of the right of everyone to the enjoyment of the highest attainable standard of health."[1] Those developments hold the potential for making a difference. Whether they translate into concrete improvements in access to medicines for real people living with HIV/AIDS – the ultimate test of their significance – remains to be seen, and remains the challenge for governments, inter-governmental organizations, and civil society.

At least three international developments are worth noting:

- the outcomes of the UN General Assembly Special Session on HIV/AIDS in June 2001;
- the establishment of a Global Fund to Fight AIDS, TB & Malaria; and
- the Declaration on the TRIPS Agreement and Public Health adopted at the recent 4th WTO Ministerial Conference (Doha, November 2001).

Comments about each of these – and the "Doha Declaration" in particular – follow below.

A fourth significant development is national in character: current litigation in South Africa to establish access to medicines to reduce mother-to-child transmission of HIV. On behalf of the Treatment Action Campaign (TAC) in South Africa, Zackie Achmat has spoken about this example which illustrates the important role of civil society in realizing the right to health, specifically the element of access to medicines.

UNGASS on HIV/AIDS

At the end of June 2001, UN Member States unanimously adopted a *Declaration of Commitment on HIV/AIDS* ("Global Crisis – Global Action")[2] in which they reiterated

[1] Resolution 2001/33, 57th Session of the Commission on Human Rights, 20 April 2001, UN Doc. No. E/CN.4/RES/2001/33.
[2] UN General Assembly, Special Session on HIV/AIDS (26th Special Session). Resolution A/RES/S-26/2 (27 June 2001).

their recognition that access to medication in the context of pandemics such as HIV/AIDS is fundamental to realizing the right to health (para. 15), and further recognized:

> • that prevention, care, support and treatment for those infected and affected by HIV/AIDS are mutually reinforcing elements of an effective response and must be integrated in a comprehensive approach to combat the epidemic (para. 17);
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> • that care, support and treatment can contribute to effective HIV prevention (para. 19);
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> • that effective prevention, care and treatment strategies will require increased availability of, and non-discriminatory access to, *inter alia* drugs (including anti-retroviral therapy), diagnostics and related technologies (para. 23);
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> • that the cost, availability and affordability of drugs and related technology are significant factors to be reviewed and addressed in all aspects and that there is a need to reduce the cost of these drugs and technologies in close collaboration with the private sector and pharmaceutical companies (para. 24); and
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> • that the lack of affordable pharmaceuticals and of feasible supply structures and health systems continues to hinder an effective response to HIV/AIDS in many countries, especially for the poorest people (para. 25).

The General Assembly further noted "that the impact of international trade agreements on access to or local manufacturing of essential drugs and on the development of new drugs needs to be evaluated further" (para. 26). The recent "Doha Declaration" from the WTO is part and parcel of that ongoing examination, and signals the beginning of a potential significant clarification of this issue.

In the light of the above, Member States declared their commitment to address the HIV/AIDS crisis by taking action, *inter alia*, as follows:

> • by 2003, ensure that national strategies, supported by regional and international strategies, are developed in close collaboration with the international community, to strengthen health-care systems and address factors affecting the provision of HIV-related drugs, including anti-retroviral drugs, *inter alia*, affordability and pricing, including differential pricing, and technical and health-care system capacity (para.55);
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> • also, in an urgent manner make every effort
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> > (1) to provide progressively and in a sustainable manner, the highest attainable standard of treatment for HIV/AIDS, including the prevention and treatment of opportunistic infections, and effective use of quality-controlled anti-retroviral therapy in a careful and monitored manner to improve adherence and effectiveness and reduce the risk of developing resistance, and
> >
> > (2) to cooperate constructively in strengthening pharmaceutical policies and practices, including those applicable to generic drugs and intellectual property

> regimes, in order further to promote innovation and the development of domestic industries consistent with international law (para. 55).

Civil society has endorsed the UN General Assembly's *Declaration of Commitment*. NGOs and community-based organizations from around the world contributed their expertise, gathered over 20 years of responding to the epidemic, to the process of producing this declaration. And, whatever its shortcomings in the face of a global crisis of such magnitude, it nonetheless represents a significant step forward – if the leadership and political commitment (including the contribution of necessary financial resources) is forthcoming.

Civil society has indicated its willingness to partner in good faith with governments in reaching the goals identified in the Declaration. Just as importantly, in the interests of transparency and accountability, civil society must be critical of governments who do not live up to their commitments. Such open dialogue is fundamental to democratic good governance and, ultimately, to the promotion and realization of human rights, including the right to the highest attainable standard of health.

Global Fund to Fight AIDS, TB & Malaria

Also in June 2001, the Global Fund to Fight AIDS, TB & Malaria was launched, representing an important step in mobilizing resources and an opportunity for States to demonstrate their commitment in following up on the *Declaration of Commitment on HIV/AIDS* emanating from the UNGASS.

But the commitment so far appears weak, and must be substantially strengthened. At least US$ 7-10 billion per year has been estimated as the amount needed to fund an effective response to the HIV/AIDS epidemic alone in low- and middle-income countries, whether via the Global Fund or through other channels. The Member States of the United Nations committed themselves to reach this target by 2005.

Yet to date, only a small sum overall has been contributed to the Fund. In 2002, the Fund will be able to disburse about US$700-800 million, about 10% or less of the total estimated amount.

Similarly, the General Assembly urged yet again in the *Declaration of Commitment on HIV/*AIDS that developed countries meet the target of 0.7% of GNP for official development assistance (ODA), a target originally agreed upon 30 years ago and repeatedly affirmed since then. Yet, since the UNGASS, there have been no dramatic increases in funding outside the context of the Global Fund that will bring most developed countries close to meeting this target within the next few years.

The Global Fund, and other avenues for "scaling up" funding for both prevention and care/treatment of infectious diseases, are crucial to mounting an effective response and to averting the worsening of an already terrible human and development toll.

In order to see the Global Fund and other resources used to realise the right to health in developing countries, civil society must (a) ensure that these resources are drastically increased, and (b) ensure that resources which are available

• are used to provide access to medicines and related diagnostics, and not solely for HIV prevention efforts (recognising that "prevention and care are mutually reinforcing elements of an effective response"[3]);

• are used as efficiently as possible, by purchasing safe, effective quality medicines and diagnostics at the best global prices, including those made available through the full use of safeguards in international and domestic laws regarding intellectual property rights; and

• are available to directly fund projects and programs operated by NGOs providing HIV/AIDS prevention, care, treatment & support.

WTO Ministerial Declaration on the TRIPS Agreement & Public Health ("Doha Declaration")[4]

As noted, the UN Member States recognized in their June 2001 *Declaration of Commitment on HIV/AIDS* that the impact of international trade agreements on access to, or local manufacturing of, essential drugs required further evaluation.

In particular, attention has focussed on the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS Agreement"), although certainly other trade agreements relating to intellectual property rights on medicines and other health goods and services are also relevant.

At the 4th WTO Ministerial Conference in Doha in November 2001, WTO member states unanimously adopted a Ministerial *Declaration on the TRIPS Agreement and Public Health*. That Declaration:

• recognized the gravity of the public health problems affected many developing and least-developed countries, especially those resulting from HIV/AIDS, TB, malaria and other epidemics;

• stressed the need for the TRIPS Agreement to be part of the wider national and international action to address these problems;

• agreed that the TRIPS Agreement "does not and should not prevent Members from taking measures to protect public health";[5]

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[3] *Declaration of Commitment on HIV7AIDS*, *supra* paragraph 17.

[4] Further analysis can be found at: *TRIPS and Rights: International Human Rights Law, Access to Medicines, and the Interpretation of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights* (prepared by R Elliott for the Canadian HIV/AIDS Legal Network & AIDS Law Project, South Africa, November 2001, via: www.aidslaw.ca).

[5] This proposition finds further support in the main Ministerial Declaration adopted in Doha, which states: "We recognized that under WTO rules no country should be prevented from taking measures for the protection of human, animal or plant life or health, or of the environment at the levels it considers appropriate, subject to the requirement that they are not applied in a manner which would constitute a means or arbitrary or unjustifiable discrimination between countries where the same conditions would prevail, or a disguised restricted on international trade, and are otherwise in accordance with the provisions of the WTO Agreements." (para. 6)

• affirmed that the TRIPS Agreement "can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all";[6]

• reaffirmed the right of WTO Members "to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose," including measures such as granting compulsory licenses and parallel importation; and

• agreed that least-developed country WTO Members will not be obliged, with respect to pharmaceutical products, to implement the provisions of the TRIPS Agreement relating to patents and the protection of undisclosed information until 2016.

In addition, the Declaration recognized that WTO Members with insufficient or no manufacturing capacities in their pharmaceutical sector "could face difficulties in making effective use of compulsory licensing" under the TRIPS Agreement, and therefore instructed the Council for TRIPS to find "an expeditious solution" to this problem and report to the General Council of the WTO before the end of 2002.

Civil society has put forward proposals for solutions that deserve serious consideration, including recognizing that production of generic medicines under compulsory licence for export to countries in need and without the domestic manufacturing capacity to meet that need is a "limited exception" to exclusive patent rights that is permissible under Article 30 of the TRIPS Agreement.

In opposition to this proposal, it has been suggested that this would run into a problem with the prohibition, under Article 27 of the TRIPS Agreement, of discrimination on the basis of field of technology. But this objection is weak. It should be noted that the WTO Ministerial Conference itself, in its Doha Declaration on the TRIPS Agreement and Public Health, has already established a precedent singling out a particular sector for differential treatment, by extending to 2016, with respect only to pharmaceutical products, the application of the TRIPS Agreement provisions on patents (Part V) and the protection of undisclosed information (Part VII), for least-developed countries.

From the perspective of realizing the human right to health, this Declaration is an important development for another reason, namely its legal effect.

There has been some debate about the legal significance of the Declaration. Therefore, from the perspective of civil society, some observations about its place and potential impact in the international legal order are warranted.

It has been suggested that the Doha Declaration is merely a "political statement," without legal effect. However, with respect, such a proposition is incorrect as a matter of law. Rather, the correct position is that the Doha Declaration does indeed have some legal effect and, therefore, represents an important instrument with respect to realizing the right to health in international law.

[6] The importance of implementing and interpreting the TRIPS Agreement in a manner supportive of public health was acknowledged again at the International Conference on Financing for Development (Monterrey, March 2002): "Monterrey Consensus": Draft outcome of the International Conference on Financing for Development, UN Doc. No. A/CONF.198/3 (para. 28).

It must be remembered that the Ministerial Conference (and the General Council of the WTO) "shall have the exclusive authority to adopt interpretations" of the WTO's multilateral trade agreements.[7]

The Doha Declaration recognizes that, in the interests of using "to the full" the flexibility in the TRIPS Agreement to protect public health (including promoting access to medicines for all), each provision of the TRIPS agreement, in accordance with the customary rules of interpretation of public international law, "shall be read in the light of the object and purpose of the Agreement" and in particular, "its objectives and principles."

With particular regard to the issue of promoting access to medicines for all, this means that the provisions on patents on health goods such as drugs, must be interpreted in the light of the provisions stating that the protection and enforcement of intellectual property rights should involve "a balance of rights and obligations" and should contribute to "the mutual advantage of producers and users" of knowledge and "in a manner conducive to social and economic welfare" (Article 7, "Objectives").

The interpretation must also take into account the principles that include States' freedom to adopt measures, consistent with the provisions of the Agreement:

> • necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, consistent with the provisions of the Agreement; and
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> • necessary to prevent the abuse of intellectual property rights by right holders and practices which unreasonably restrain trade or adversely affect the international transfer of technology. (Article 8, "Principles")

The Doha Declaration has expressly clarified that the TRIPS Agreement must be interpreted in accordance with the customary rules of interpretation of public international law.[8] Those rules are to be found in the *Vienna Convention on the Law of Treaties*.[9] And those rules clearly state that, in interpreting a treaty in good faith, at least the following must be taken into account:

> • any <u>subsequent agreement</u> between the parties regarding the interpretation of the treaty or the application of its provisions; and
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> • any <u>subsequent practice</u> in the application of the treaty which establishes the agreement of the parties regarding its interpretation; and

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[7] Agreement Establishing the World Trade Organization ("Marrakesh Agreement"), Article IX(2) (adopted 15 April 1994).

[8] This point should not have been in doubt at all, particularly since the WTO's Dispute Settlement Understanding states that the dispute settlement mechanism serves to clarify the provisions of WTO agreements "in accordance with the customary rules of interpretation of public international law" (Article 3.2), and previous jurisprudence from the WTO panels and Appellate Body had confirmed that such rules of treaty interpretation apply to the interpretation of WTO treaties.

[9] 1155 UNTS 331, 8 ILM 679 (23 May 1969, entered into force 27 January 1980), UN Doc. No. A/CONF.39 (1969).

•any relevant rules of international law applicable in the relations between the parties.

The Doha Declaration is clearly a "subsequent agreement" between the parties to the TRIPS Agreement. Most importantly, it expressly states that the Agreement "does not and should not prevent Members from taking measures to protect public health" and that "the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all."[10]

Furthermore, under the customary rules of treaty interpretation, the body of human rights law that applies to WTO Member States (either by treaty[11] or by customary international law[12]) clearly amount to "relevant rules of international law" that must be taken into account in the interpretation of the TRIPS Agreement.

This means that States obligations under the TRIPS Agreement must, as a matter of correctly applying international law, be interpreted in the light of, and in a fashion consistent with, their obligations to respect, protect and fulfil human rights – including the right to health.

This is a matter of particular importance because instruments such as the WTO Doha Declaration, the UNGASS Declaration of Commitment on HIV/AIDS, and the Commission on Human Rights' own resolution on "Access to medication in the context of pandemics such as HIV/AIDS" (Resolution 2001/33) all expressly refer to the requirement that States efforts to promote access to medication be "in accordance with applicable international law, including international agreements acceded to" by States.

As a matter of law, States' obligations under international law (including human rights treaties where applicable) include their obligation to take measures to progressively realize the right to health, and this obligation must be considered in the interpretation and implementation of the TRIPS Agreement (or other similar agreements on intellectual property rights). The Doha Declaration did not change this, for such an obligation existed before the Doha Ministerial Conference. But it did clarify such a requirement in the interpretation and implementation.

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[10] It should be noted that at the 1st WTO Ministerial Conference, the Member States "recalled" that the WTO Agreement "contains provisions conferring differential and more favourable treatment for developing countries, including special attention to the particular situation of least-developed countries": Singapore Ministerial Declaration, adopted 13 December 1996, at 1st WTO Ministerial Conference, para 13.

[11] Eg, the UN Charter binds all UN Member States and imposes a legal obligation on all states to take action to realize human rights, and to solve international health problems (Articles 55 & 56); and the International Covenant on Economic, Social & Cultural Rights imposes a legal obligation on the 152 Member States which have ratified or acceded to it to realize the right to the highest attainable standard of health, including through those steps necessary for treating epidemics (Article 12). As of June 2001, of the 141 members of the WTO, 111 had ratified or acceded to the ICESCR: "The impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on human rights", Report of the High Commissioner for Human Rights, 27 June 2001, UN Doc. No. E/CN.4/Sub.2/2001/13.

[12] Eg, the Universal Declaration of Human Rights binds all States and recognizes the rights of everyone "to a standard of living adequate for the health and well-being of himself and of his family, including… medical care" (Article 25) and the right of everyone "to share in scientific advancement and its benefits" (Article 27).

Furthermore, as a matter of law, it should be acknowledged that, in the event of any conflict between States' obligations under the TRIPS Agreement and their obligations under the international law of human rights, the latter obligation(s) shall take precedence, and such must be recognized by States and by the adjudicative mechanisms of the WTO charged with interpreting the TRIPS Agreement.

The Sub-commission on the Promotion and Protection of Human Rights, in its resolution of 17 August 2000 on *Intellectual Property Rights and Human Rights*, has recently reminded all governments of this proposition, expressly affirming "the primacy of human rights obligations over economic policies and agreements."[13]

Indeed, this proposition is rooted in the founding document of the United Nations. Article 103 of the UN Charter states that "in the event of a conflict between the obligations of the members of the UN under the present Charter and their obligations under any other international agreement, their obligations under the present Charter shall prevail." One of the fundamental purposes of the UN, as expressly recognized in the Charter, is the realization of basic human rights. The right to health is one of those basic rights, recognized in the International Covenant on Economic, Social & Cultural Rights (and several other instruments of international law[14]).

The recognition of that right is accompanied by the legal obligation upon all States to collectively ensure the fulfilment of human rights, including the right to health, throughout the world. Article 2 of the International Covenant on Economic, Social & Cultural Rights requires States "to take steps, individually and through international assistance and cooperation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized in the present Covenant by all appropriate means, including particularly the adoption of legislative measures."

Recently, this obligation has been reaffirmed by the Committee on Economic, Social & Cultural Rights in its General Comment No. 14, which notes that to comply with their international obligations in relation to the right to health,

> States parties [to the International Covenant on Economic, Social & Cultural Rights] have to respect the enjoyment of the right to health in other countries, and to prevent third parties from violating the right in other countries, if they are able to influence these third parties by way of legal or political means, in accordance with the Charter of the United Nations and applicable international law. Depending on the availability of resources, States should facilitate access to essential health facilities, goods and services in other countries, wherever possible and provide the necessary aid when required. States parties should ensure that the right to health is given due attention in international agreements and, to that end, should consider the development of further legal instruments. In relation to the conclusion of other international agreements, States parties should take steps to ensure that these instruments do not adversely impact upon the right to health.

[13] UN Doc E/CN.4/Sub.2/Res/2000/7 (17 August 2000), paras. 3-5.
[14] Eg, the Convention on the Elimination of All Forms of Racial Discrimination (1965), the Convention on the Elimination of All Forms of Discrimination Against Women (1979), and the Convention on the Rights of the Child (1989) all recognize the right to health in various formulations.

> Similarly, States parties have an obligation to ensure that their actions as members of international organizations take due account of the right to health.[15]

The language of the Doha Declaration is clear: the TRIPS Agreement "can and should" be interpreted and implemented in a manner that supports Members' right to protect public health, including promoting access to medicines for all. The Doha Declaration is an instrument of international law, with legal effect, which effect should be acknowledged and reflected elsewhere.

Conclusion

Civil society has played a key role in placing the issue of access to medicines, as a fundamental element of progressively fully realizing the right to health. Civil society has contributed to the process of mobilizing the political leadership needed for an effective response, is working to support the allocation of the necessary funds for that response, and has expertise to contribute to the development of international law as it relates to the realization of the right to health.

Thank you.

[15] General Comment No. 14 (4 July 200), UN Doc. E/C.12/2000/4, CESCR, at para. 39.