

# **ACCESS TO ESSENTIAL MEDICINES AS A COMPONENT OF THE RIGHT TO HEALTH**

**Stephen P. Marks**

## **Introduction**

In *Human Rights Obligations of Non-State Actors*, Andrew Clapham wrote, “Perhaps the most obvious threat to human rights has come from the inability of people to achieve access to expensive medicine, particularly in the context of HIV and AIDS.”<sup>1</sup> He was referring to threats to human rights from intellectual property agreements under the World Trade Organization, which are often seen as obeying a different – and many would say utterly incompatible – logic than human rights. The right to health, in the interpretation of the Committee on Economic Social and Cultural Rights, means that “States Parties ... have a duty to prevent unreasonably high costs for access to essential medicines.”<sup>2</sup>

This chapter will explain the significance and place of the human right to essential medicines as a derivative right within the broader right to the highest attainable standard of physical and mental health. As a component of the right to health, the right to essential medicines depends not only on the production, distribution, and pricing of medicines, but also on the incentives for research and development of drugs needed to treat diseases in developing countries, functioning health systems so that drugs are part of a rational system of quality treatment and care, as well as on infrastructure,

so that they can be delivered to all areas where they are needed. Considering that these broader issues are examined in other chapters, this chapter will focus more on the impediment to the realization of the right to essential medicines caused by the protection of intellectual property. This chapter begins with an overview of some of the basic data about the health impact of the current level of access to medicines, especially in developing countries. Then the essential features of the international trade regime that affect access to medicines are discussed, including how that regime functions in constant tension with the international human rights regime. The recent trend in legislation, litigation, and advocacy to favour access to essential medicines over protection of patent-holders will then be examined before analysing the most salient formulations of the right to access to essential medicines. Finally, several of the proposals currently under consideration to overcome the economic obstacles to realizing the right to essential medicines are presented.

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#### Access to medicines in the global burden of disease

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The trend in access to medicines, particularly in poor countries, provides the evidence for policies in global health to increase access at all stages of the process from setting research priorities for the development of new drugs, to manufacturing, pricing, marketing, and distribution. ‘Essential medicines’, according to the World Health Organization (WHO), are those that “satisfy the priority health care needs of the population” and “are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price the individual and the community can afford.”<sup>3</sup> The United Nations Development Group defines ‘access’ in this context as “having medicines continuously available and affordable at public or private health facilities or medicine outlets that are within one hour’s walk from the homes of the population.”<sup>4</sup>

In 1975, half of the world’s population was without access to life-saving and other essential medicines.<sup>5</sup> While the proportion has decreased to about one-third of the world’s population, the absolute number has remained constant at approximately two billion people.<sup>6</sup> According to the WHO, expanding access to existing interventions, including medicines, for infectious diseases, maternal and child health, and noncommunicable diseases would save more than 10.5 million lives the year by 2015.<sup>7</sup>

Significantly, the MDG Gap Task Force addressed the relation between the MDG issue of access to medicines and the right to health by noting that:

“... the national constitutions define the fundamental political principles of a country and usually guarantee certain rights to their people. Health is a fundamental human right recognized in at least 135 national constitutions. Access to health care, including access to essential medicines, is a prerequisite for realizing that right. However, only five countries specifically recognize access to essential medicines and technologies as part of the fulfilment of the right to health.”<sup>8</sup>

The MDG Gap Task Force also notes “Most national constitutions do not specifically recognize access to essential medicines or technologies as part of the fulfilment of the right to health.”

The Working Group on Access to Essential Medicines of the United Nations Millennium Project approached the problem from the human rights perspective. It opened its report by stating: “The lack of access to life-saving and health-supporting medicines for an estimated 2 billion poor people stands as a direct contradiction to the fundamental principle of health as a human right.”<sup>9</sup> The Group gave priority consideration to improving access to medicines in resource-poor settings and promoting research on new medicines for diseases of poverty. It identified six barriers to access the medicines: Inadequate national commitment, inadequate human resources, failure of the international community to keep its promises to developing countries, lack of coordination of international aid, obstacles created by the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, and the current incentive structure for research and development of medicines and vaccines to address priority health needs of developing countries.<sup>10</sup> In examining the solutions to the problem, the UN Working Group underscored the “consensus that human rights should incorporate the ability of individuals to maintain and restore good health through access to at least a basic level of primary care, including essential medicines”<sup>11</sup> and listed among the general principles underpinning issues of increasing access to medicines the human right to health, as well as women’s inequality and gender disparities.<sup>12</sup>

Among the Working Group’s recommendations to improve availability of medicines is improving the rate and relevance of innovation and developing more reliable procurement and supply systems at the national and

international levels.<sup>13</sup> The Group also recommended specific steps for promoting the safety, affordability, and appropriate use of medicines.<sup>14</sup> Finally, it devoted attention to the barrier created by the system of intellectual property protection, specifically citing the conclusion of the UN Millennium Project Task Force on Trade that the TRIPS agreement, and ‘TRIPS Plus’ provisions of free-trade agreements, will over time probably have a negative impact on access to drugs in developing countries.<sup>15</sup> This trend clearly creates tension with the obligations of states to realize the right to health under the international human rights regime.

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The tension between the international trade regime and the international human rights regime

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In dissenting from the Working Group report just discussed, the representative of the pharmaceutical industry explained,

“We do not believe that the main problem in barring medicines to the poor is patent protection, nor do we accept that individual company pricing practices are fundamental to explaining why one-third of the world’s poor lack access to basic, low-cost essential medicines. An inaccurate and subjective link is forged between rights, ‘monopoly’ pricing, and global inequities in access to medicines ... We also believe that our private sector research model is worthy of preserving rather than abandoning on the risky premise that more public investment will by itself yield miracle cures against the complex scientific challenge of fighting resistant strains of infectious disease ... In short, the report fails to provide the balanced and accurate perspective necessary to stimulate fresh policy approaches that could make a real difference in the lives of the poor.”<sup>16</sup>

From the perspective of the primary legal regime governing trade in products invented and manufactured by business entities, essentially transnational corporations, the issues of access to medicines is a clear-cut matter of the patenting of a new chemical product and the process for its use, as well as the protection of the patents involved in the markets where the producers intend to sell them. The patents, which protect the inventor from anyone copying the product without license, and allow the inventor to set the price, are protected internationally under the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). TRIPS requires

WTO members to protect patents of pharmaceuticals for 20 years, thus giving drug companies exclusive rights to prevent unauthorized use, subject to domestic and international enforcement. Countries that fail to protect patents may be brought before the dispute settlement body of the WTO. As a result, in part due to the outcry over drug pricing in countries confronted by the HIV/AIDS pandemic, the least-developed countries, who were originally supposed to comply by 2006, now have until 1 January 2016 to implement TRIPS. However, all other WTO Members are bound, and even the poorest countries will be bound in less than a decade.

In addition to the delayed compliance until 2016, developing countries may avail themselves of ‘flexibilities’ to avoid patent protections through parallel importing (importing cheaper versions of drugs from countries where pharmaceuticals are not patented or where their term of protection has expired) and compulsory licensing (manufacturing generic versions of patented medicines without patent holder’s authorization under certain conditions).<sup>17</sup> Most agree that the patent system is necessary and beneficial to promote innovation in the pharmaceutical industry, but there are various barriers to developing countries taking full advantage of the flexibilities, and hundreds of free trade agreements impose greater restrictions than TRIPS (‘TRIPS-plus’ provisions).

Access to patented medicines – as the pharmaceutical dissent to the Working Group report quoted above stresses – is not the sole or even the principal obstacle to adequate provision of health products and medical devices to the poor population of developing countries. In fact, one study by Amir Attaran claims that, of the 319 products on the WHO Model List of Essential Medicines, only seventeen are patentable. Furthermore, many of those are not actually patented, bringing the patent incidence down to 1.4%.<sup>18</sup> The author not only challenges the assumptions among activists that patents cause lack of access to affordable medicines in poor countries and within the pharmaceutical industry,<sup>19</sup> that IPRs are necessary to protect to assure future research and development, but also expresses doubt that compulsory licensing can be made practicable, considering that “zero generic medicines have been manufactured this way in the past decade, treating zero patients in any country worldwide.”<sup>20</sup> In response to Attaran’s study, the Director of Medicines Policy and Standards at WHO wrote that “a statement on the percentage of patented medicines on the Model List is therefore not possible without specifying the geographical area and the specific time” and “a few patented medicines can greatly affect health

expenditure”, noting that “the economic value and public health importance of the market of ARVs and future essential medicines for neglected disease are buried in the statistics” of the quoted study.<sup>21</sup> Be that as it may, the point for the purposes of a putative human right to essential medicines is that challenging IPRs and urging use of TRIPS flexibilities do not constitute the only path toward realizing that right.

Numerous factors contribute to making essential medicines available in poor countries, including affordable prices; government commitment through a well conceived and implemented national medicines policy (NMP); adequate, sustainable and equitable public sector financing; generic substitution; transparent and widely disseminated consumer information; efficient distribution; control of taxes, duties and other markups; and careful selection and monitoring.<sup>22</sup>

As thoroughly demonstrated by Lisa Forman, corporate innovation for diseases affecting poor countries does not occur for commercial reasons but in response to “growing public pressure over corporate failures to address developing country needs”.<sup>23</sup> Drawing on the experience of the 1997 to 2001 litigation and trade pressure by the US Government and 40 pharmaceutical companies to resist South African’s law aimed at gaining access to affordable medicine, which she considers the “tipping point” of the struggle, Forman demonstrates how the Treatment Action Campaign case “brought human rights arguments drawn from international and domestic law, arguing that the right to health provided constitutional authority for the legislation itself, and was a legal interest that should be prioritized over corporate property rights.”<sup>24</sup> She concludes that this experience “can be seen to provide a strategic roadmap for advancing the completion of the process of normative diffusion, so that access to medicines as a human right starts to assume a ‘taken for granted’ quality in politics, law, and public opinion.”<sup>25</sup>

The ‘normative diffusion’ is reflected by the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG), whose Global Strategy and Plan of Action was adopted by the World Health Assembly on 24 May 2008.<sup>26</sup> This group was set up in 2006 as a follow-up to the Commission on Intellectual Property Rights, Innovation and Public Health with the aim of “securing an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries”.<sup>27</sup> The IGWG considered inputs not only from governments but also from academia, public-private partnerships, product-development partnerships and industry.<sup>28</sup> In

its Global Strategy, the IGWG both acknowledges that intellectual property rights are “an important incentive for the development of new health-care products” and quotes the provisions of the Universal Declaration of Human Rights on sharing in scientific advances and its benefits and protection of moral and material interest resulting from scientific production.<sup>29</sup>

Thus, for the IGWG, the ‘context’ of its global strategy includes intellectual property rights, human rights and the importance of flexibilities in intellectual property agreements to facilitate “increased access to pharmaceutical products by developing countries”.<sup>30</sup> Given the diversity of stakeholders involved, it is significant that the importance of all three was acknowledged. In enumerating the ‘principles’ of the strategy, the IGWG inserted the following: “The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race relation, political belief, economic or social condition.”<sup>31</sup> It is clear from this effort, which will continue through the further elaboration and implementation of the elements and plan of action, that the claim of a human right to essential medicines has been a difficult case to make. But over the past decade, the tide appears to have shifted in favour of the human right to essential medicines and perhaps even more broadly to health products and medical devices.

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#### Affirmation of the human right to essential medicines

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As mentioned above, the human right to essential medicines is much broader than a claim against the negative impact of IPRs. Nevertheless, the withdrawal of the challenge by 40 pharmaceutical companies to South Africa’s access to drugs law, the Doha Declaration, the deliberations of IGWG and similar events have used the tension with the international trade regime as a motivation for the affirmation of this right.

The TRIPS flexibilities provide a legal basis for poor countries to avoid the consequences of the patent system with regard to their capacity to make essential medicines available to their populations. The international trade regime is based on the logic of the global market and globalization. It has adjusted to the political imperative of promoting development and strategies defined by the international financial institutions in the poverty reduction programs and the UN system in the Millennium Development Goals. It has not, so far, been receptive to the claim that a human right to health, including access to essential medicines, prevails over TRIPS. With the

exception of the approach taken by the Working Group on Access to Essential Medicines of the UN Millennium Project (discussed above), these development approaches rarely articulate the human right to essential medicines. The affirmation of this right from the human rights perspective can be made, however, on the basis of core human rights instruments. These instruments have been applied to the problem of access to medicines by UN bodies including: the Office of the High Commissioner for Human Rights, the Commission on Human Rights and its Sub-Commission, the Committee on Economic, Social and Cultural Rights, and the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health as well as by a number of non-governmental and academic initiatives.

*The right to essential medicines in the core human rights instruments*

Access to essential medicines can be affirmed as a human right on the basis, not only of the right to health (Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR)) but also on two other rights set out in the ICESCR, namely, the rights “to the protection of the moral and material interests resulting from any scientific, literary or artistic production” (Article 15(1)(c)) and “to share in scientific advancement and its benefits” (Article 15(1)(b)). The former is the human rights basis for intellectual property protection, according to which creative ideas and expressions of the human mind that possess commercial value receive the legal protection of property rights called ‘intellectual property rights’ (IPRs). The major legal mechanisms for protecting IPRs are copyrights, patents, and trademarks. IPRs enable owners to select who may access and use their property, and to protect it from unauthorized use.

There is an apparent contradiction between these two rights when applied to access to medicines: Article 15(1)(c) seems to protect the ‘right’ of pharmaceutical companies to earn a profit from the drugs they develop, by setting prices that render medicines inaccessible to the destitute sick, while Article 15(1)(b) seems to protect the ‘right’ of those destitute sick to benefit from the development of new drugs. The way out of this dilemma is to distinguish intellectual property rights from human rights and consider them a temporary monopoly established for the valid social purpose of encouraging scientific invention and artistic creation. In other words, an IPR is a legally protected interest of a lower order than a human right, which implies a superior moral and legal claim. This distinction should not be interpret-

ed to imply that IPRs do not have social value for, indeed, they have a very high value, justifying limiting Article 15 rights reasonably to promote innovation and creativity.

Human rights organs have progressively addressed this dilemma, articulating in different stages the human right to essential medicines. The Commission on Human Rights adopted a resolution in 2001, in which it recognized “that access to medication in the context of pandemics such as HIV/AIDS is one fundamental element for achieving progressively the full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.”<sup>32</sup> Among a list of measures, it called on states, “to refrain from taking measures which would deny or limit equal access for all persons to preventive, curative or palliative pharmaceuticals or medical technologies used to treat pandemics such as HIV/AIDS or the most common opportunistic infections that accompany them”<sup>33</sup> and, clearly with TRIPS in mind, “to ensure that their actions as members of international organizations take due account of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health and that the application of international agreements is supportive of public health policies which promote broad access to safe, effective and affordable preventive, curative or palliative pharmaceuticals and medical technologies.”<sup>34</sup> The United States was the only government to abstain from this resolution, which was adopted on 23 April 2001 by 52 votes with no votes against.

The Office of the High Commissioner prepared a report in 2001 on the impact of the TRIPS Agreement on human rights;<sup>35</sup> and the Sub-Commission on the Promotion and Protection of Human Rights took this up in its resolution the same year on “Intellectual Property Rights and Human Rights.”<sup>36</sup> The resolution, adopted by consensus, referred to the “actual or potential conflict ... between the implementation of the TRIPS Agreement and the realization of economic, social and cultural rights.”<sup>37</sup> In the context of the upcoming Doha Ministerial meeting of the WTO, the Sub-Commission alluded to the “need to clarify the scope and meaning of several provisions of the TRIPS Agreement, in particular of Articles 7 and 8 on the objectives and principles underlying the Agreement in order to ensure that states’ obligations under the Agreement do not contradict their binding human rights obligations.”<sup>38</sup> It reminded “all governments of the primacy of human rights obligations under international law over economic

policies and agreements, and request[ed] them, in national, regional and international economic policy forums, to take international human rights obligations and principles fully into account in international economic policy formulation.”<sup>39</sup> Significantly, it urged “all governments to ensure that the implementation of the TRIPS Agreement does not negatively impact on the enjoyment of human rights as provided for in international human rights instruments by which they are bound.”<sup>40</sup>

One of the most significant events, legally and politically, for the right to essential medicines was indeed the Doha Ministerial meeting of the WTO, which adopted the Doha Declaration on the TRIPS Agreement and Public Health. In an unusually direct statement emanating from the WTO, better known for highly technical and legally complex sentences, the meeting declared: “The TRIPS agreement does not and should not prevent members from taking measures to protect public health ... in particular to promote access to medicines for all.”<sup>41</sup> To be perfectly clear, the declaration added, “In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose,” meaning parallel importing and compulsory licensing. The text acknowledges that “[e]ach member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted ... [and] the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.”<sup>42</sup> The next paragraph instructed the Council for TRIPS to find an expeditious solution to the problem of compulsory licensing for countries “with insufficient or no manufacturing capacities in the pharmaceutical sector,”<sup>43</sup> which was done in August, 2003. The Doha Declaration also extended the deadline to 1 January 2016 for the least-developed countries to apply provisions on pharmaceutical patents.

#### *Position of the Committee on Economic, Social and Cultural Rights*

The Committee threw down the gauntlet at the time of the Seattle Third Ministerial meeting of the WTO in 1999 when it “urged WTO members to ensure that their international human rights obligations are considered as a matter of priority in their negotiations which will be an important testing ground for the commitment of States to the full range of their international

obligations.”<sup>44</sup> Two years later, on 26 November 2001, the Committee held a ‘day of general discussion’ on Article 15(1)(c), following which it issued a ‘Statement on Human Rights and Intellectual Property’, in which it considered that “intellectual property rights must be balanced with the right ... to enjoy the benefits of scientific progress and its applications.”<sup>45</sup> It made explicit reference to the development of new medicines in the context of the Doha Declaration on the TRIPS Agreement and Public Health as an example of the need to strike a balance between the right to enjoy the benefits of scientific progress and its applications under Article 15(1)(b) and the right to benefit from the protection of the moral and material interests under Article 15(1)(c).<sup>46</sup> The Committee concluded by calling for “a mechanism for a human rights review of intellectual property systems.”<sup>47</sup>

The Committee clarified further the human right to essential medicines in two of its General Comments, an earlier one on the right to health, and one based on the 2001 Statement. Indeed, in 2000, the Committee, in its General Comment 14, had interpreted the obligation under Covenant Article 12(2)(d) of the Covenant (“The creation of conditions which would assure to all medical service and medical attention in the event of sickness”) to include “the provision of essential drugs.”<sup>48</sup> In clarifying the obligations of states parties, the Committee included among the facilities, goods and services which must be available in sufficient quantity within the state “essential drugs, as defined by the WHO Action Programme on Essential Drugs”.<sup>49</sup> As part of the obligation to protect, states parties have a duty “to control the marketing of medical equipment and medicines by third parties,”<sup>50</sup> which strongly suggests that the states should intervene where marketing of drugs by pharmaceutical companies is detrimental to the right to health.

But it was in General Comment 17, adopted in 2006, that the Committee challenged head-on the assumption of the international trade regime that the rights of companies holding patents over essential drugs were of the same order as the rights of those who need the drugs, by treating the former as a temporary, revocable monopoly, and the latter as human rights. Indeed, the Committee affirmed,

“In contrast with human rights, intellectual property rights are generally of a temporary nature, and can be revoked, licensed or assigned to someone else. While under most intellectual property systems, intellectual property rights, with the exception of moral rights, may be allocated, limited in time

and scope, traded, amended and even forfeited, human rights are timeless expressions of fundamental entitlements of the human person ...”<sup>51</sup>

“States Parties should,” the Committee continued,

“... ensure that their intellectual property regimes constitute no impediment of their ability to comply with their core obligations in relation to the right to health ... States thus have a duty to prevent that unreasonably high license fees or royalties for access to essential medicines ... undermine the right ... of large segments of the population to health ...”<sup>52</sup>

*Non-governmental and academic promotion of the right to access essential medicines*

Several non-governmental organizations (NGOs) have taken up the issue of access to medicines from a human rights perspective, principal among them are Médecins Sans Frontières (MSF) and Oxfam. In 1999, MSF launched the Campaign for Access to Essential Medicines and became the leader of the advocacy campaign aimed at improving access to existing medicines, diagnostics, and vaccines and at promoting the development of urgently needed better medical tools for people in poor countries.<sup>53</sup> In 2000 Oxfam also launched a major access to medicines campaign. This advocacy included focusing on a series of lawsuits from the pharmaceutical industry, including a frequently cited case against the South African government.<sup>54</sup>

Parallel to the advocacy work of NGOs are the vital private research initiatives, such as Management Sciences for Health (MSH), a private non-profit consultancy organization, which is headed by the former director of the WHO’s essential medicines department. MSH has a strong focus on technical support and capacity building, and has expertise in supply chain management and delivery of medicines. One of its key programmes, ‘Strategies for Enhancing Access to Medicines’, is funded by the Gates Foundation. The Gates Foundation is a major player in enhancing access to medicines, as is the Clinton Foundation, which has negotiated reduced prices for antiretrovirals by guaranteeing purchases and continuous demand. Other innovative financing mechanisms include UNITAID (which uses the proceeds of a solidarity tax on airline tickets to purchase drugs and diagnostics for HIV/AIDS, malaria and tuberculosis); Advance Market Commitments for vaccines (AMC) (which uses donor commitments to provide incentives to vaccine makers to produce vaccines for developing countries); The Global

Fund to Fight AIDS, Tuberculosis and Malaria; and the United States President's Emergency Plan for AIDS Relief (PEPFAR). These efforts, however, rarely make reference to access to essential medicines as a human right.

Several academic initiatives have utilized an explicit human rights approach, including international officials and academics writing in scholarly journals.<sup>55</sup> A leading scholar, Thomas Pogge, has found the patent system "morally problematic" because patents on biological organisms and pharmaceutical products "directly or indirectly, impede the global poor's access to basic foodstuffs and essential medicines".<sup>56</sup> He proposes a "full-pull plan" (as opposed to a "push" plan, which funds a particular innovator) according to which all potential innovators, such as pharmaceutical companies, would have an equal chance for a substantial reward from public funds during the life of the patent, in proportion to the extent to which the new drug or other product reduces the global burden of disease (GBD).<sup>57</sup>

The University of Montréal hosted a workshop of scholars (including Pogge), national and international officials and NGO activists from 30 September to 2 October 2005, on the 'Human Rights and Access to Essential Medicines: The Way Forward'. The meeting considered the burden of disease due to lack of access to medicines and adopted the Montréal Statement on the Human Right to Essential Medicines.<sup>58</sup>

After finding the current lack of access to medicines to be "contrary to ethical and legal duties, including human-rights obligations," the authors of the statement posit the obligation to make policies, rules, and institutions conducive to the realization of the right to essential medicines at the national and global levels.<sup>59</sup> Echoing the position taken in General Comment 14, the Montréal Statement, drawing on the WHO definition cited at the beginning of this chapter, defines essential medicines as "those that satisfy the priority health care needs of the population, in light of their public health relevance, proven quality, efficacy and safety, and comparative cost-effectiveness." The right to these medicines is part of the "core" obligations of parties to the ICESCR, requiring "immediate and effective measures and is not subject to progressive implementation."<sup>60</sup> The statement further calls on national governments in developing countries to allocate resources to making essential medicines available, and to update national lists of essential medicines, as well as to use trade flexibilities and safeguards, such as compulsory licensing and parallel importing. It calls on affluent countries to ensure fairer trade relations, alleviate crippling debt and increase assist-

ance to facilitate this right.<sup>61</sup> Finally, the statement takes issue with the present system of incentives for innovation, which is based on “return on investment rather than priority health needs and outcomes”, and advocates “alternative innovation systems that ensure that research and development are sufficient to meet priority health needs.”<sup>62</sup>

Building on the Montréal Statement, a group of institutions, from Québec and Brazil, organized a workshop at the Université de Québec on 20 November 2007, evaluating, from the right to development perspective, Target 17 of the Millennium Development Goals.<sup>63</sup> Other academic initiatives include Universities Allied for Essential Medicines (UAEM), which adopted the Philadelphia Consensus Statement at their annual conference held in Philadelphia at the beginning of October 2006, stating: “We believe that access to medical care and treatment is a basic human right.”<sup>64</sup>

#### *Draft Guidelines by the Special Rapporteur*

As part of his mandate as UN Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Paul Hunt submitted a report to the General Assembly in 2006 summarizing the responsibilities of states and of pharmaceutical companies with respect to access to medicines,<sup>65</sup> and circulated on 19 September 2007, a ‘Draft for Consultation’ of a set of ‘Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines.’<sup>66</sup>

Following consultation with states, NGOs, academics, pharmaceutical companies, UN agencies, national human rights institutions and other stakeholders, Hunt presented the Guidelines to the General Assembly in 2008, explaining that “the central objective of the Guidelines is to provide practical, constructive and specific guidance to pharmaceutical companies and other interested parties, including those who wish to monitor companies and hold them to account.”<sup>67</sup> These forty-seven Guidelines deal with general policy; the disadvantaged; transparency; management, monitoring and accountability; corruption; public policy influence, advocacy and lobbying; quality; clinical trials; neglected diseases; patents and licensing; pricing, discounting and donations; ethical promotion and marketing; public-private partnerships; and associations of pharmaceutical companies. They call upon companies to recognize the importance of human rights in their corporate mission and provide board-level responsibility and accountability for its access to medicines strategy, with a public commitment to con-

tribute to research and development for neglected diseases, and respect the right of countries to use TRIPS flexibilities. The Guidelines then address questions of management, including “an effective, transparent, accessible and independent monitoring and accountability mechanism”, both internal and external, as well as participation from a human rights perspective. Other Guidelines would have companies comply with various international standards on corruption, good manufacturing practice, human subject research, and other areas. Special provisions relate to promoting research and development on neglected diseases. Regarding patents and licensing, the Guidelines call on drug companies to “respect the right of countries to use, to the full, the provisions ... TRIPS ..., which allow flexibility for the purpose of promoting access to medicines, including the provisions relating to compulsory licensing and parallel imports” and “respect the letter and spirit of the Doha Declaration ...”

### **Conclusion**

The human right to essential medicines is a derivative right from the rights to health and to life. When the main human rights instruments were drafted, the idea that lack of access to medicines was contrary to human rights was not considered, except that access to medicines was one of a number of reasonable measures constituting healthcare. Subsequently, and particularly as a result of the AIDS pandemic, the vital need for treatment of HIV positive individuals contributed to the progressive acknowledgement that access to essential medicines, including antiretroviral treatments (ARTs), was an internationally recognized human right. This argument has been extended from HIV/AIDS to the full range of diseases that account for the disproportionate levels of mortality and morbidity in developing countries.

It may be useful to draw a parallel with the emergence of an implied derivative human right to water, formally acknowledged by the Committee on Economic, Social and Cultural Rights in 2002 in its General Comment on the Right to Water.<sup>68</sup> The analogy with the right to water is reinforced by drawing on three main arguments used by the Committee, one based on evidence, one on logic, and the third on legal construction.

First, knowledge of the problem of water, created by the failure to guarantee access to it, was uncontested and acknowledged as requiring urgent action. The Committee noted that “Over one billion persons lack access to a basic water supply, while several billion do not have access to adequate

sanitation, which is the primary cause of water contamination and diseases linked to water.”<sup>69</sup> Nearly two billion people do not have access to essential medicines and an estimated four million people could be saved annually in Africa and Southeast Asia if diagnosis and treatment with appropriate medicines were available. The criteria of magnitude and urgency of the problem are met.

The second argument is based on a logical construction, according to which water as a human right is a necessary consequence of the nature of this commodity. The Committee argues as follows: “Water is a limited natural resource and a public good fundamental for life and health. The human right to water is indispensable for leading a life in human dignity. It is a prerequisite for the realization of other human rights.”<sup>70</sup> Appropriate medicines are similarly indispensable to the health of people everywhere and the most basic drugs are a public good.<sup>71</sup>

The third basis for positing the right to water as a human right was the legal interpretation of existing human rights norms. The title of General Comment 15 mentions Articles 11 and 12 of the International Covenant on Economic, Social and Cultural Rights and the Committee explains how these two rights (adequate standard of living and health) are “inextricably related” to the right to water. The Committee relates the right to water to other human rights, including *inter alia* the right to life, the right to adequate food, the right to gain a living by work, the right to take part in cultural life. The right to essential medicines is similarly inseparable from the rights to an adequate standard of living, education, food, and housing.

Following the pattern of other general comments, the Committee then addresses the normative content of the right to water in terms of availability, quality, accessibility, and information, and devotes special attention to issues of discrimination and vulnerable groups. The Working Group on Access to Medicines organized its analysis and recommendations into three main categories: Availability, affordability, and appropriateness,<sup>72</sup> and then deals with quality<sup>73</sup> as well as crosscutting issues of human resources and gender.<sup>74</sup> In other words, the full range of essential and interrelated elements of the rights, that treaty bodies cover in their general comments, are applicable to the human right to essential medicines.

The developments described in this chapter are signs that the human right to essential medicines has advanced in terms of its normative content and its legal recognition, although it remains a daunting challenge to find accommodation with the international trade regime, bridge the gaps

in political will, find incentives for innovation and affordable pricing, and create the availability of adequate human and financial resources to ensure distribution networks. All this needs to be achieved in order for this right to be of practical value for the two billion who currently lack access to essential medicines.

- 1 Andrew Clapham, *Human Rights Obligation of Non-State Actors* (Oxford: Oxford University Press, 2006), at 175.
- 2 Committee on Economic, Social and Cultural Rights, *The right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author* (article 15, paragraph 1(c), of the Covenant), General Comment No. 17 (2005), UN doc. E/C.12/GC/1, January 12, 2006, para. 35.
- 3 World Health Organization, 'Essential Medicines: Definition', available at [http://www.who.int/medicines/services/essmedicines\\_def/en/](http://www.who.int/medicines/services/essmedicines_def/en/). See also MDG Gap Task Force, *Millennium Development Goal 8: Delivering on the Global Partnership for Achieving the Millennium Development Goals: MDG Gap Task Force Report 2008* (New York: United Nations, 2008) at 36.
- 4 MDG Gap Task Force, *supra* note 3, at 35.
- 5 UN Millennium Project, *Prescription for Healthy Development: Increasing Access to Medicines, Report of Task Force on HIV/AIDS, Malaria, TB and Access to Essential Medicines*, Working Group on Access to Essential Medicines, 2005, at 4.
- 6 World Health Organization, *WHO Medicines Strategy 2000–2003: Framework for Action in Essential Drugs and Medicines Policy 2000–2003* (Geneva: WHO, 2000), available at [www.who.int/medicines/strategy/strategy2000=2003.shtml](http://www.who.int/medicines/strategy/strategy2000=2003.shtml).
- 7 The WHO Medicines Strategy 2004–2007, (Geneva: WHO, 2004), WHO/EDM/2004.5, page v.
- 8 MDG Gap Task Force, *supra* note 3, at 42.
- 9 *Ibid.*, at 1.
- 10 *Ibid.*, at 29–31.
- 11 *Ibid.*, at 35.
- 12 *Ibid.*, at 106.
- 13 *Ibid.*, at 106–110.
- 14 *Ibid.*, at 110–118.
- 15 *Ibid.*, at 72–73.
- 16 *Ibid.*, at 136.
- 17 TRIPS Art. 31 provides for the use of a patented product without the authorization of the right holder, under the following condition: "(f) Any

- such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;" and "(h) The right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization." Thus, compulsory licensing is not available to many countries without a significant pharmaceutical sector.
- 18 Amir Attaran, 'How Do Patents And Economic Policies Affect Access To Essential Medicines In Developing Countries?' 23(3) *Health Affairs* (2004), 155–156, at 157.
  - 19 *Ibid.*, at 159.
  - 20 *Ibid.*, at 161.
  - 21 E-DRUG, 'WHO Model List of Essential Medicines and Patents', posting on [essentialdrugs.org](http://essentialdrugs.org) by Hans Hogerzeil on 23 March 2005, available at <http://www.essentialdrugs.org/edrug/archive/200503/msg00071.php>.
  - 22 The WHO essential medicines strategy has the following seven components: (1) National policies on medicines; (2) National policies on traditional medicine and complementary and alternative medicine; (3) Sustainable financing mechanisms for medicines; (4) Supplying medicines; (5) Norms and standards for pharmaceuticals; (6) Regulation and quality assurance of medicines; (7) Using medicines rationally. World Health Organization, *WHO Medicines Strategy 2004–2007: Countries at the Core*, WHO publication No. WHO/EDM/2004.5, 2004, at 25–129.
  - 23 Lisa Forman, "'Rights' and Wrongs: What Utility for the Right to Health in Reforming Trade Rules on Medicines?" 10(2) *Health and Human Rights: An International Journal* (2008).
  - 24 *Ibid.*
  - 25 *Ibid.*
  - 26 WHO Resolution 61.21 adopted by the Sixty-first World Health Assembly on 24 May 2008. It is significant for the purpose of the present examination of the tensions between international trade and human rights to note the shift in the title of the Commission to that of the IGWG with respect both to the order of the terms and the deletion of "rights" attached to "intellectual property".
  - 27 WHO Resolution 59.24 adopted by the Fifty-ninth World Health Assembly on 27 May 2006, para. 3.
  - 28 World Health Organization, *Public Health, Innovation, and Intellectual Property: Progress Made by the Intergovernmental Working Group*, Report by the Secretariat, 5 April 2007, WHO publication number A60/27, para. 4.
  - 29 World Health Organization, *Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property*, 24 May 2008, WHO publication number WHA61.21, annex, paras. 7 and 10.
  - 30 *Ibid.*, para. 12.
  - 31 This language, taken from the WHO constitution, was retained after an additional provision on human rights was deleted following a divisive debate.
  - 32 Commission on Human Rights resolution 2001/33, Access to medication in the context of pandemics such as HIV/AIDS, UN Doc. E/CN.4/RES/2001/33, 20 April 2001, para. 1.
  - 33 *Ibid.*, para. 3(a).
  - 34 *Ibid.*, para. 4(b).
  - 35 UN Doc. E/CN.4/Sub.2/2001/13, 27 June 2001.
  - 36 The Sub-Commission on the Promotion and Protection of Human Rights, Intellectual Property Rights and Human Rights, resolution 2001/21, UN Doc. E/CN.4/SUB.2/RES/2001/21, 16 August 2001.
  - 37 *Ibid.*, preamble.
  - 38 *Ibid.*
  - 39 *Ibid.*, para. 3.
  - 40 *Ibid.*, para. 5.
  - 41 World Trade Organization, Ministerial Conference, Fourth Session, Doha, 9–14 November 2001, Declaration on the TRIPS agreement and public health, adopted on 14 November 2001, Doc. WT/MIN(01)/DEC/2, 20 November 2001, para. 4, available at [http://www.wto.org/English/thewto\\_e/minist\\_e/mino1\\_e/mindecl\\_trips\\_e.htm](http://www.wto.org/English/thewto_e/minist_e/mino1_e/mindecl_trips_e.htm).
  - 42 *Ibid.*, para. 5.
  - 43 *Ibid.*, para. 6.

- 44 *Statement of the United Nations Committee on Economic, Social and Cultural Rights to the Third Ministerial Conference of the World Trade Organization* (Seattle, 30 November to 3 December 1999), UN Doc. E/C.12/1999/9, 26 November 1999, para. 8.
- 45 *Human rights and intellectual property: Statement by the Committee on Economic Social and Cultural Rights*, UN Doc. E/C.12/2001/15, 14 December 2001, para. 4.
- 46 *Ibid.*, para. 17.
- 47 *Ibid.*, para. 18.
- 48 Committee on Economic, Social and Cultural Rights (CESCR), *General Comment No. 14 on the right to the highest attainable standard of health*, 11 August 2000, UN Doc. E/C.12/2000/4, at para. 17.
- 49 *Ibid.*, para. 12 (a).
- 50 *Ibid.*, para. 35.
- 51 CESCR, *General Comment No. 17 on the right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author*, 12 January 2006, UN Doc. E/C.12/GC/17, at para. 2.
- 52 *Ibid.*, para. 35.
- 53 MSF's Campaign is described at <http://www.accessmed-msf.org/>.
- 54 At the national level, major advances in the right to essential medicines were made by such NGOs as Treatment Action Campaign (TAC) in South Africa, which sued the South African government for not providing to pregnant women a drug known to reduce mother-to-child-transmission (MTCT) of HIV and won this case on the basis of the South African constitutional guarantee of the right to health: *Treatment Action Campaign (TAC) v Minister of Health*, Constitutional Court (2002) 5 SA 721 (CC).
- 55 See for example, Phillippe Cullet, 'Human Rights and Intellectual Property Protection in the TRIPS Era' 29(2) *Human Rights Quarterly* (2007) 403–430; Carlos María Correa, 'Implications of Bilateral Free Trade Agreements on Access to Medicines' 84(5) *Bulletin of the World Health Organization* (2006) 399–404; Michael A. Santoro, 'Human Rights and Human Needs, Diverse Moral Principles Justifying Third World Access to Affordable IV/AIDS Drugs' 31(4) *North Carolina Journal of International Law and Commercial Regulation* (2006) 923–942; Hans V. Hogerzeil et al. 'Is Access to Essential Medicines as Part of the Fulfillment of the Right to Health Enforceable Through the Courts?' 368 *The Lancet* (2006) 305–311; Hans V. Hogerzeil, 'Essential Medicines and Human Rights: What Can They Learn from Each Other?' 84(5) *Bulletin of the World Health Organization* (2006) 371–375, at 371; Hans Hogerzeil, 'Access to Essential Medicines as a Human Right' 33 *Essential Drugs Monitor* (2000) 25–26; Thomas Pogge, *World Poverty and Human Rights: Cosmopolitan Responsibilities and Reforms*, Second expanded edition (UK and Malden MA: Polity Press 2008), chapter 9 entitled 'Pharmaceutical Innovation: Must We Exclude the Poor?', 222–261.
- 56 Pogge, *supra* note 55.
- 57 *Ibid.*, at 244–261. Under certain conditions, Norman Daniels considers that Pogge's incentive schemes could be "a way of moving some countries closer to satisfying a right to health, connecting the effort to human rights goals as he does.": Norman Daniels, *Just Health: Meeting Health Needs Fairly* (New York: Cambridge University Press, 2008), at 353.
- 58 The text is available in Thomas Pogge, 'Montréal Statement on the Human Right to Essential Medicines' 16(1) *Cambridge Quarterly of Healthcare Ethics* (2007), at 104–108.
- 59 *Ibid.*, para. 3.
- 60 *Ibid.*, paras. 4–5.
- 61 *Ibid.*, paras. 6–11.
- 62 *Ibid.*, paras. 14–15.
- 63 The participating institutions were l'Association pour la santé publique du Québec, Initiative luso-francophone sur l'accès au médicament et la protection du citoyen, Program on Human Rights in Development of the Harvard School of Public Health, Canadian Institutes of Health Research, le Réseau de recherche en santé des populations du Québec, and le Groupe d'étude sur

l'interdisciplinarité et les représentations sociales de l'UQAM.

- 64 See [www.essentialmedicine.org](http://www.essentialmedicine.org).
- 65 Paul Hunt, *Report of the Special Rapporteur on the right to health*, 13 September 2006, UN Doc. A/61/338.
- 66 The online version of the Guidelines was made available at [http://www2.essex.ac.uk/human\\_rights\\_centre/rth/](http://www2.essex.ac.uk/human_rights_centre/rth/).
- 67 Paul Hunt, *Report of the Special Rapporteur on the right to health*, 11 August 2008, UN Doc. A/63/263, at para. 46. Quotations from the Guidelines are from the version in the annex to that document.
- 68 CESCR, *General Comment No. 15 on the right to water*, 20 January 2003, UN Doc. E/C.12/2002/11 (2002).
- 69 The Committee cited WHO data for this claim. See, *ibid.*, para. 1, note 1.
- 70 *Ibid.*
- 71 The full implications and related strategy for treating access to essential medicines as a public good are presented by Thomas Pogge in 'Human Rights and Global Health: A Research Program' which first appeared in Christian Barry and Thomas Pogge (eds.), 'Global Institutions and Responsibilities: Achieving Global Justice', special issue of *Metaphilosophy*, 36(1-2), January 2005, and currently available as 'Chapter 9: Pharmaceutical Innovation: Must We Exclude the Poor?', Pogge, *supra* note 55.
- 72 *Supra* note 5, 58-82.
- 73 *Ibid.*, 82-85.
- 74 *Ibid.*, 21-22.