The Intergovernmental Working Group on Public Health, Innovation and Intellectual Property

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I. Introduction

The inaccessibility of medicines in low- and middle-income countries poses serious human rights and developmental challenges for Governments and international organizations, as well as raising grave ethical and human rights questions about the responsibilities of the research and development-based pharmaceutical industry. In response to this human rights and public-health dilemma, there has been growing attention to the relationship between intellectual property rights, innovation and public-health, leading to an intergovernmental process initiated and led by the World Health Organization (WHO) between 2006 and 2008. The Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (hereinafter "Intergovernmental Working Group") engaged WHO member States, non-governmental organizations (NGOs), intergovernmental organizations and the pharmaceutical industry in an 18-month process to produce a global strategy and plan of action. The object of the Global Strategy on Public Health, Innovation and Intellectual Property[1] (hereinafter "Global Strategy") and its Plan of Action[2] is to "provide a medium-term framework for securing an enhanced and sustainable basis for needs-driven essential health research and development relevant to diseases which disproportionately affect developing countries, proposing clear objectives and priorities for research and development, and estimating funding needs in this area".[3] The Global Strategy and Plan of Action aim to meaningfully reform the failure of global research and development to produce medicines for diseases of the developing world and to ensure more public-health-consistent applications of intellectual property rights protected under international and bilateral trade agreements.

At their best, the procedure and content of the Global Strategy and Plan of Action developed by the Intergovernmental Working Group may reflect a critical milestone in global policy on access to medicines in developing countries with the potential to significantly advance access to medicines, as well as realization of the right to development and associated human rights to health, life and the benefits of scientific progress. However, if the Global Strategy and Plan of Action are ineffective, they will simply acquiesce to a global intellectual property rights system increasingly viewed as favouring pharmaceutical industry interests at the expense of health and development in low- and middle-income countries. Whether the Global Strategy and Plan of Action successfully achieve these broader goals will only be revealed over time. This chapter focuses exclusively on whether the Intergovernmental

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[1] World Health Assembly, resolution WHA61.21, annex.

[2] Ibid., appendix.

[3] Global Strategy, para. 13.

Working Group process and resulting Global Strategy and Plan of Action are theoretically congruent with and capable of advancing the realization of the right to development in international law. Accordingly, section II explores the background leading to the Intergovernmental Working Group, section III documents the Intergovernmental Working Group process in detail and section IV analyses the Intergovernmental Working Group from a right to development perspective, assessing areas of synergy and rupture with the principles and substantive content of the right to development.[4]

II. Public health, innovation and intellectual property: the initiation of the Intergovernmental Working Group

Almost 2 billion people, virtually one third of the global population, lack regular access to essential medicines, a figure that rises to over half the population in some low-income countries in Africa and Asia.[5] Medicines are an important tool to prevent, alleviate and cure disease.[6] The inaccessibility of medicines directly impedes the realization of human rights, including the highest attainable standard of health ("the right to health") and the benefits of scientific progress.[7] It also obstructs realization of the right to development, whereby "every human person and all peoples are entitled to participate in, contribute to, and enjoy economic, social, cultural and political development, in which all human rights and fundamental freedoms can be fully realized", according to article 1 of the Declaration on the Right to Development. The Declaration is explicit that this right incorporates State duties to take all necessary measures to ensure equality of opportunity for all in their access to health services.

Access to medicines bears particularly upon individual abilities to alleviate poverty, since pharmaceuticals can consume 50-90 per cent of out-of-pocket expenditures for the poor in developing countries.[8] The accessibility and affordability of medicines similarly bears on State capacity to realize the rights to health and development, given the magnitude of pharmaceutical costs as a proportion of health-care expenditure in many developing countries (ranging between 25 and 70 per cent of total health-care expenditures). Moreover, as Amartya Sen illustrates, health has powerful instrumental effects on economic development, empowering people to make better choices and lead fuller lives, improving individual productivity, reducing poverty and income inequality and stimulating economic growth.[9] Viewed in this light, the realization of the right to health is "both a goal of the exercise of the right to development, and a means of contributing to achieving development".[10]

The relationship between medicines and development is underscored by its inclusion within Millennium Development Goal 8, which aims to develop a global partnership for development, and which explicitly includes target 8.E: "In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries."[11] The relationship between medicines and development is similarly underscored by the Noordwijk Medicines Agenda, adopted by the Organisation for Economic Co-operation and Development (OECD) in 2007, which recognizes that "access to affordable essential drugs and availability of the benefits of new technologies is a core element of development as identified in the Millennium Development Goals (goal 8), which calls for a global partnership in this area".[12] Access to medicines is therefore appropriately viewed as a core element of both the right to development and the right to health.

The human rights and development consequences of inaccessible medicines have prompted growing attention to the impact of price and intellectual property rights. While access to medicines is determined by several factors, such as rational use,[13] adequate

[4] The chapter is based on an analysis of documentation of the Intergovernmental Working Group available from the WHO website, other relevant literature (including media and scholarship on the Intergovernmental Working Group) and interviews with the secretariat of the Working Group and other WHO personnel conducted in Geneva from 18 to 20 February 2009.

[5] WHO, *WHO Medicines Strategy: Countries at the Core 2004–2007* (Geneva, 2004), p. 3.

[6] "Interim report of Task Force 5 Working Group on Access to Essential Medicines (1 February 2004), p. 9.

[7] See Alicia Ely Yamin, "Not just a tragedy: access to medications as a right under international law", *Boston University International Law Journal*, vol. 21, Issue 2 (Fall 2003).

[8] *WHO Medicines Strategy*.

[9] Amartya Sen, *Development as Freedom* (New York, Anchor Books, 2000).

[10] Daniel Tarantola and others, *Human Rights, Health and Development*, Technical Series Paper No. 08.1 (Sydney, University of New South Wales Initiative for Health and Human Rights, 2008), p. 5.

[11] See www.un.org/millenniumgoals/global.shtml. The original formulation of this commitment in the United Nations Millennium Declaration was to "encourage the pharmaceutical industry to make essential drugs more widely available and affordable by all who need them in developing countries" (General Assembly resolution 55/2, para. 20).

[12] OECD, Noordwijk Medicines Agenda, adopted on 21 June 2007 at the OECD High-Level Forum on Medicines for Neglected and Emerging Infectious Disease: Policy Coherence to Enhance Their Availability, held at Noordwijk-aan-Zee, Netherlands.

[13] Rational use of medicines denotes that they are "used in a therapeutically sound and cost-effective way by health professionals and consumers in order to maximize the potential of medicines in the provision of health care". "Progress in the rational use of medicines: report by the WHO Secretariat", document A60/24, para. 2.

infrastructure and sustainable financing,[14] pricing can have a disproportionate impact. Patents are the primary determinants of drug prices and are protected internationally under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The TRIPS Agreement requires WTO members to provide 20-year exclusive patent protection to pharmaceuticals, preventing non-consensual use.[15] The TRIPS Agreement also provides "flexibilities", which permit limits to exclusive patent protection to enable Governments to meet public-health needs. TRIPS flexibilities include measures such as compulsory licensing, where countries manufacture or import generic medicines under strict conditions, and parallel importing, where countries import lower-cost versions of patented medicines.

Countries may, however, face considerable obstacles in using these flexibilities, including corporate litigation, unilateral trade pressures and "TRIPS-plus" intellectual property rules adopted in bilateral and regional free trade agreements as well as more recently in Anti-Counterfeiting Trade Agreements.[16] In response, the Declaration on the TRIPS Agreement and Public Health, adopted in 2001 at the Doha WTO Ministerial, confirmed that TRIPS "does not and should not prevent members from taking measures to protect public-health" and that TRIPS should be interpreted and implemented in a manner supportive of a State's right to protect public-health and promote access to medicines for all.[17] The "right to use, to the full" provision was reaffirmed by the High-level Plenary Meeting of the General Assembly on the Millennium Development Goals at its sixty-fifth session in 2010.[18] At the same time, there has been growing attention to the inadequacies of the medical innovation system for producing medicines to treat diseases prevalent primarily in the developing world. As Patrice Trouiller and others illustrate in their article, only 0.1 per cent of new chemical entities produced between 1975 and 1999 were for tropical diseases and tuberculosis.[19] This neglect of innovation for medical products to treat diseases overwhelmingly incident in developing countries has seen the designation of many of these conditions as "neglected diseases".

These controversies have contributed to tensions in the relationship between the pharmaceutical industry and the broader public globally, to the extent that some suggest an unravelling of the tacit "grand bargain" between the pharmaceutical industry and society which allowed the modern global pharmaceutical industry to emerge in the second half of the twentieth century, whereby the industry's immense profits were balanced by the social enjoyment of a wide variety of life-saving and life-enhancing drugs.[20] Questions about the impact of TRIPS on access to medicines were brought into sharp focus by the explosive growth of the global AIDS pandemic in sub-Saharan Africa and the inability of millions of people infected with HIV and AIDS to access expensive antiretroviral medicines protected under TRIPS rules.[21] The contribution of pricing to inaccessibility and the dearth of new products for diseases disproportionately affecting developing countries have prompted growing attention to the relationship between intellectual property rights, innovation and public-health.[22] Thus, in February 2004, at the request of the World Health Assembly, WHO established the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) to analyse the relationship between intellectual property rights, innovation, and public-health.[23] CIPIH released its extensive final report in April 2006, considering "the various effects of intellectual property rights on upstream research, the subsequent development of medical products in both developed and developing countries and the possibility of ensuring access to them in developing countries, the impact of other funding and incentive mechanisms and fostering innovation capacity in developing countries".[24]

[14] *WHO Medicines Strategy* (see footnote 5), p. 24.

[15] TRIPS Agreement, art. 28 (1) (a) and (b).

[16] See, for instance, Richard D. Smith, Carlos Correa and Cecilia Oh, "Trade, TRIPS, and pharmaceuticals", *The Lancet,* vol. 373, Issue 9664 (2009), p. 687, and Henning Grosse Ruse-Khan, "From TRIPS to ACTA: towards a new 'gold standard' in criminal IP enforcement", Max Planck Institute for Intellectual Property, Competition and Tax Law Research Paper No.10-0 (April 2010).

[17] Declaration on the TRIPS Agreement and Public Health, para. 4 (hereinafter "Doha Declaration").

[18] General Assembly resolution 65/1, para. 78 (t).

[19] Patrice Trouiller and others, ''Drug development for neglected diseases: a deficient market and a public-health policy failure'', *The Lancet*, vol. 359, Issue 9324 (June 2002), p. 2188.

[20] Michael A. Santoro and Thomas M. Gorrie, *Ethics and the Pharmaceutical Industry: Business, Government, Professional and Advocacy Perspectives* (West Nyack, New York, Cambridge University Press, 2005).

[21] See, for example, Ellen F.M 't Hoen, "TRIPS, pharmaceutical patents, and access to essential medicines: a long way from Seattle to Doha", *Chicago Journal of International Law*, vol. 3, No. 1 (Spring 2002); Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford, Oxford University Press, 2007); Carlos Correa, "Public health and intellectual property rights", *Global Public Policy*, vol. 2, No. 3 (December 2002); Smith, Correa and Oh, "Trade, TRIPS, and pharmaceuticals"; and Zita Lazzarini, "Making access to pharmaceuticals a reality: legal options under TRIPS and the case of Brazil", *Yale Human Rights and Development Law Journal*, vol. 6 (2003).

[22] See, for example, Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy* (London, 2002); "Intellectual property rights and human rights: report of the Secretary-General (E/CN.4/Sub.2/2001/12 and Add.1); "The impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on human rights: report of the High Commissioner" (E/CN.4/Sub.2/2001/13).

[23] World Health Assembly, resolution WHA56.27, para. 2.

[24] WHO, *Public Health, Innovation and Intellectual Property Rights: Report of the Commission on Intellectual Property Rights, Innovation and Public Health* (Geneva, 2006), p. 174 (hereinafter "CIPIH report").

The report made 60 recommendations for improving current incentive and funding regimes to stimulate the creation of new medicines and facilitate access to these and existing medicines. In particular, the Commission recommended that "WHO should develop a global plan of action to secure enhanced and sustainable funding for developing countries and making accessible products to address diseases that disproportionately affect developing countries."[25] Accordingly, in May 2006 the World Health Assembly at its fifty-ninth session adopted a resolution in which it decided to establish an intergovernmental working group open to all interested member States to draw up a global strategy and plan of action in order to provide a medium-term framework based on the CIPIH recommendations. The framework would "aim, inter alia, at securing an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries, proposing clear objectives and priorities for research and development, and estimating funding needs in this area".[26]

The resolution also stipulated that the Working Group should report on its progress to the Assembly at its sixtieth session, through the Executive Board, giving particular attention to "needs-driven research and other potential areas for early implementation".[27] The resolution also requested the Director-General to invite a range of observers to the sessions of the Working Group to provide advice and expertise as necessary, including United Nations organizations, intergovernmental organizations, NGOs with which WHO had established official relations, as well as private and public entities.[28]

III. Intergovernmental Working Group on Public Health, Innovation and Intellectual Property

Between December 2006 and April 2008, the Intergovernmental Working Group met in three sessions in Geneva, bringing together WHO member States, NGOs, intergovernmental organizations and the pharmaceutical industry. In addition, regional and intercountry consultations and two public Web-based hearings were held to allow broad consultation on the draft global strategy and plan of action. The following section documents the Intergovernmental Working Group's path towards a final negotiated text as a prelude to analysing its potential lessons for realizing the right to development and achieving target 17 of Millennium Development Goal 8 (which became target 8.E in the current formulation).

A. First session: 4-8 December 2006

The first session of the Intergovernmental Working Group focused on producing a first draft of a global strategy consistent with the CIPIH report and resolution WHA59.24 and in consultation with member States, NGOs, international organizations, pharmaceutical companies and other relevant parties. To ensure broad consultation on this draft, from 1 to 14 November 2006, the secretariat of the Working Group arranged a Web-based public hearing, receiving 31 submissions from NGOs, Governments, academia, public-private partnerships and industry. These submissions introduced some of the prominent debates that were to take centre stage throughout the Intergovernmental Working Group process, including in relation to the feasibility of new incentive mechanisms like patent pools, prize funds and a medical research and development treaty in successfully generating research and development on neglected diseases.[29] Other submissions underscored the need to view access to medical care and treatment as a basic human right[30] and recommended incorporation of the four interrelated components of this right outlined in the CIPIH report, namely availability, acceptability, accessibility and quality of health-care goods, facilities and services.[31] A synopsis of these submissions was presented at the session.

A total of 103 WHO member States (over 50 per cent) attended this session.[32] In conformity with resolution WHA59.24, four additional organizations and one expert were invited to participate. Sixteen NGOs in official relations with WHO and seven

[25] Ibid., p. 187.
[26] World Health Assembly, resolution WHA59.24, para. 3 (1).
[27] Ibid., para. 3 (3).
[28] Ibid., para. 4 (2).

[29] Submissions available at www.who.int/phi/public_hearings/first/en/index.html. See, for instance, Trevor M. Jones, a previous CIPIH commissioner, and Tracey Heller, Vice-President of International Public Affairs of Novartis International Inc., arguing that incentive schemes like patent pools were unlikely to achieve their objectives, and that public-private partnerships were likelier routes to successful research and development for drugs to treat diseases in developing countries. For alternative views, see Médecins Sans Frontières, Health Action International Europe, the Consumer Project on Technology and Third World Network, saying that public-private partnerships were insufficient and that what was required was more governmental responsibility and innovative measures like patent pools, prize funds and a medical research and development treaty.
[30] Ibid. See Debra Hayes and Caroline J. Gallant, Universities Allied for Essential Medicine.
[31] Ibid. See International AIDS Vaccine Initiative.
[32] Delegation information is drawn from the official participants lists posted on the WHO website for the Intergovernmental Working Group sessions: www.who.int/phi/documents/en/.

United Nations organizations, specialized agencies and intergovernmental organizations also attended. Concerns about insufficient participation led the Working Group to recommend a process to enable NGOs which met the requirements for admission into official relations with WHO but had not yet been admitted to facilitate their participation in the Group's second session.[33] This process was approved at the 120th session of the WHO Executive Board, which authorized several additional NGOs in official relations with WHO to participate in the next intergovernmental working group session.[34] In recognition of the fact that some experts from developing countries were unable to attend, member States were also invited to submit proposals for additional experts and entities to attend the second session, in order to expand the pool available and ensure balanced regional, gender and developing-/developed-country representation.[35]

The Working Group prepared a first draft of a global strategy and plan of action which drew from the CIPIH report to propose six elements, namely prioritizing research and development needs to identify gaps in research; promoting research and development; building and improving innovative capacity; improving delivery and access; ensuring sustainable financing mechanisms for research and development; and establishing monitoring and reporting systems.[36] During negotiations, member States requested the addition of separate elements on the transfer of technology to develop new technologies and products and on management of intellectual property, as a means of emphasizing the importance of these measures.[37] Member States also added new areas of action, including ensuring that bilateral trade agreements did not seek to incorporate TRIPS-plus protection in ways that might reduce access to medicines in developing countries and encouraging trade agreements to take into account TRIPS flexibilities recognized in the Doha Declaration.[38]

In addition, at the request of the Working Group, its secretariat prepared a second draft drawing from legally binding and consensus-agreed language in the WHO Constitution, the CIPIH report, resolution WHA59.25 and other resolutions and work. This draft[39] introduced a number of overarching global principles for the strategy, including explicit reference to the rights, contained in the Universal Declaration of Human Rights, to share in scientific advancement and its benefits, and to protection of moral and material interests. The draft also recognized that research and knowledge were critical for achieving the health-related Millennium Declaration Goals.

The official report of the first session drew from both comments made by member States during the session and the public Web-based submissions to record prominent debates about the role of intellectual property rights, the mandate of WHO and the inclusion of rights language.[40] It was agreed that member States could make additional comments and suggestions on the draft global strategy before the end of February 2007 and that their input would be listed on the WHO website.[41] After soliciting comments from member States through two circular letters dispatched on 12 January and 15 February 2007,[42] 22 submissions were received with comments.[43] In July 2007, the secretariat of the Working Group released a revised version of the global strategy and a first draft plan of action[44] as the basis for negotiation at the second session and associated consultations and hearings. The draft added new areas of action within each element, notably in element 5 on the management of intellectual property, recognizing the need to explore and implement "complementary, alternative

[33] WHO, "Public health, innovation and intellectual property: progress made by the Intergovernmental Working Group: report by the secretariat", document A60/27, para. 8.

[34] The Standing Committee decided to provisionally admit NGOs to facilitate their participation in the work of the Intergovernmental Working Group if they had been in working relations with WHO for two years and otherwise met the criteria contained in section 3 of the Principles governing relations between the World Health Organization and nongovernmental organizations (available from http://www.who.int). See WHO Executive Board, "Reports of committees of the Executive Board: Standing Committee on Nongovernmental Organizations", document EB120/41, para. 21.

[35] WHO, "Intergovernmental Working Group on Public Health, Innovation and Intellectual Property: report of the first session: Geneva, 4-8 December 2006", documents A/PHI/IGWG/1/6, para. 3, and A60/27, para. 12.

[36] WHO, "Elements of a global strategy and plan of action", document A/PHI/IGWG/1/4.

[37] WHO, "Elements of a global strategy and plan of action: progress to date in the Intergovernmental Working Group", document A/PHI/IGWG/1/5, paras. 5-6.

[38] Ibid., annex 1, para. 6 (a), (f) and (h).

[39] Ibid., annex 2.

[40] For example, some member States and NGOs argued that strong intellectual property rights negatively affect access to medicines and innovation for the developing world, while others claimed that the real barriers to access to medicines were not intellectual property rights, but rather a lack of funding, infrastructure and political will. See, for example, A/PHI/IGWG/1/6, para. 14. Other countries disputed the competence of WHO to monitor intellectual property rights, arguing that the transfer of technology and management of intellectual property rights were within the jurisdiction of organizations like WTO and the World Intellectual Property Organization (WIPO), and that both WHO and the Working Group should remain focused on health. Other delegations viewed these concerns as unfounded, since neither WTO nor WIPO deal with the impact of intellectual property on access to affordable medicines and health treatment in developing countries. There was also disagreement about incorporating reference to access to medicines as a human right, although one country insisted that a global strategy would be incomplete without recognizing that "human public-health considerations have precedence over rights to intellectual property protections". See A/PHI/IGWG/1/4, annex 2, appendix.

[41] A/PHI/IGWG/1/6, para. 39.

[42] A60/27, para. 11.

[43] WHO, "Report on developments since the first session of the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property: report by the secretariat", document A/PHI/IGWG/2/3, para. 7.

[44] WHO, "Draft global strategy and plan of action on public-health, innovation and intellectual property: report by the Secretariat", document A/PHI/IGWG/2/2, annex.

and/or additional incentive schemes for research and development",[45] including prize funds and advance market commitments.

The strategy also identified global responsibility for implementing the strategy with "a range of actors, including WHO Member States, the WHO Secretariat, WIPO, WTO, national institutions, development partners, academia, pharmaceutical companies, public-private partnerships, charitable organizations and nongovernmental organizations".[46] Accordingly, the strategy attached a draft plan of action that identified lead actors and other relevant stakeholders, with Governments taking the lead for the majority of actions while WHO was designated as lead actor on approximately 30 other actions. The draft plan set medium-term time frames for implementation by 2015. It also identified 139 progress indicators, although there was consensus that these were too numerous and would be costly and difficult to apply.[47]

Regional consultations and the second Web-based public hearing

Regional and intercountry consultations were organized in August, September and October 2007 in all the WHO regions.[48] The consultations brought together member States, NGOs and experts from the regions to review the draft global strategy and plan of action. The most influential of these consultations was a subregional consultation held in Rio de Janeiro, Brazil, between Argentina, Brazil, the Plurinational State of Bolivia, Chile, Costa Rica, Cuba, Ecuador, El Salvador, Honduras, Mexico, Peru, Suriname, Uruguay and the Bolivarian Republic of Venezuela. The meeting produced a consensus document, the "Rio document", which came to have a significant influence on negotiations.[49] The Rio document emphasized the importance of considering poverty, disease burdens and growing criticism "in developed and developing countries alike, on the barriers posed by proprietary rights over the access to medicines, in particular with regard to anticompetitive practices in the field of patent rights".[50] The Rio document also proposed rights-based principles for the global strategy that became the subject of considerable debate. These principles stated that:

(a) The right to health protection is a universal and inalienable right and it is the Government's duty to ensure the means for its enforcement;

(b) The right to health takes precedence over commercial interests;

(c) The right to health implies equitable access to medicines;

(d) The promotion of technological innovation and the transfer of technology is a right of all States and should not be restricted by intellectual property rights.[51]

The influence of the Rio document was apparent at the Americas regional consultation held in Ottawa on 22 and 23 October 2007. Here, States debated the impact of intellectual property rights on access and whether WHO should act as a lead actor in the plan of action. Countries also debated the appropriateness of including the principles contained in the Rio document on the right to health. [52] The consultation introduced a new debate on whether the Intergovernmental Working Group process could appropriately deal with diseases also experienced in developed countries. This discussion relied on the specific wording of resolution WHA59.24, which, drawing on the CIPIH report, focused on type II diseases, incident in both rich and poor countries but with a substantial proportion of cases in developed countries, and type III diseases, overwhelmingly or exclusively incident in developing countries, rather than type I diseases incident in both rich and poor countries.

A second two-part Web-based public hearing was held from 15 August to 30 September 2007, dedicated to comments on the strategy and plan of action and responding to the World Health Assembly's request to the WHO Director-General to encourage the development of proposals for research and development, including incentive mechanisms.[53] Some 70 contributions were received from a wide range

[45] Ibid., para. 16.
[46] Ibid., para. 26.
[47] "Subgroup of drafting group B meeting, 17-19 March 2008: outcome document of IGWG2, subgroup discussions (November 2007 version: report of subgroup chair and plan of action elements 1 and 2)", White Paper 1, para. 4.
[48] The reports of the regional and subregional consultations and contributions from member States are available at www.who.int/phi/public_hearings/second/regional_consultations/en/index.html.
[49] Ibid.
[50] Rio document, para. 6.
[51] Ibid., paras. 12-15.
[52] For example, while Bolivia supported access to essential drugs as a fundamental part of the human right to life, Canada refused to support the principles included in the Rio document, arguing that "[t]he focus of the Global Strategy and its contents needs to be on the practical strategies and actions that should be taken to fulfill the [Working Group's] mandate … [I]f we are to have a principles section Canada would suggest that we use to the extent possible already agreed upon language".
[53] Resolution WHA60.30, para. 3 (4).

of stakeholders, including Governments and national institutions, civil society, academics, the private sector and patients' organizations.[54]

At the second hearing there was a dramatic intensification of the debates over the role of intellectual property rights and the feasibility of innovative incentive mechanisms like patent pools, a medical research and development treaty, a comprehensive advance market commitment and prize funds.[55] For example, several submissions disputed the need for new incentive mechanisms, arguing that strong intellectual property rights played a constructive role in providing incentives to medical innovation,[56] urging instead the adoption of market-based mechanisms like advance market commitments and public-private partnerships.[57] Indeed, some submissions went so far as to suggest that the Working Group sought to alter private innovation in ways akin to Soviet-style communism.[58] One submission even questioned whether the Working Group's real objectives were to strike "at the heart of the pharmaceutical industry's global franchise: chronic disease therapies … [in order to have] these therapies listed on WHO's Essential Drugs and Medicines Programme, so that developing countries can issue compulsory licenses and produce these drugs with the imprimatur of WHO and UN agencies".[59]

Other submissions debated the mandate of WHO with regard to intellectual property rights[60] and the appropriate extension of the scope of the Working Group to type I diseases.[61] Several submissions argued that the Working Group should recognize and frame itself around the right to health and medicines[62] and adopt the CIPIH report's framing of this issue as implicating the legal imperative to progressively realize the right to the highest attainable standard of health contained in the International Covenant on Economic, Social and Cultural Rights.[63]

B. Second session: 5-10 November 2007

Member State participation at the second session increased significantly, with 140 attending. In addition, 18 NGOs, 7 organizations and 11 experts as invited participants, and 16 United Nations organizations, specialized agencies and intergovernmental organizations attended. Two drafting groups were created to explore elements 5 and 6 of the global strategy respectively (on management of intellectual property and improving delivery and access), and a subgroup was created to look at the plan of action.

The draft strategy produced at the end of the second session marks a considerable shift from the prior version in several key respects. Notably, the draft strategy now framed the necessity of developing new products for diseases in developing countries and increasing access to existing products in terms of the health-related Millennium Development Goals.[64] The Rio document's influence is apparent in the strategy's incorporation of some of its key principles relating to the right to health. Interestingly, member States

[54] "Public health, innovation and intellectual property: draft global strategy and plan of action: report by the Secretariat", document EB122/12, para. 11.

[55] Contributions available at www.who.int/phi/public_hearings/second/contributions_section1/en/index.html. See also Oxfam International, "Ending the R&D crisis in public-health: promoting pro-poor medical innovation", Oxfam Briefing Paper 122 (November 2008); Frederick M. Abbott and Jerome H. Reichman, "Strategies for the protection and promotion of public-health arising out of the WTO TRIPS Agreement amendment process"; James Love, Director, Knowledge Ecology International, at http://keionline.org/; Itaru Nitta, "Green intellectual property scheme: a blueprint for the eco-/socio-friendly patent framework", Green Intellectual Property Project, *GIP Progress* (Summer 2006); Aidan Hollis, "A comprehensive advance market commitment: a useful supplement to the patent system?"

[56] Jeremiah Norris, Hudson Institute, United States of America; Harvey Bale, International Federation of Pharmaceutical Manufacturers and Associations, Switzerland; Ronald Cass, Centre for the Rule of Law, United States; Wayne Taylor, Health Leadership Institute, McMaster University, Canada; Anne Sullivan, International Association for Business and Health, United States; Jorge Quel, Hispanic-American Allergy Asthma and Immunology Association, United States; Leroy Watson, National Grange of the Order of Patrons of Husbandry, United States; Daphne Yong-d'Hervé, International Chamber of Commerce, France; Margaret De Rooy, Healthcare Evolves with Alliances and Leadership, United States; and David Hirschmann, United States Chamber of Commerce.

[57] Harvey Bale; Lawrence Kogan, Institute for Trade, Standards, and Sustainable Development, United States; Tracy Haller, Novartis, United States; Lila Feisee, Biotechnology Industry Organization, United States; Council Nedd II, Tabetha B. Ralph and Leslie O. Anderson, Alliance for Health Education and Development, United States; Brendan Barnes, European Federation of Pharmaceutical Industries and Associations, Belgium; Randall Maxey, Community Life Improvement Program and Alliance of Minority Medical Associations, United States; Herbert Perry, Health Care Advocacy Alliance, United States; and BIO Ventures for Global Health, United States.

[58] Alexander Gershman, American Russian Medical Association, United States; and Catherine Benavidez Clayton, Alliance of Health Disparities, United States.

[59] Philip Stevens, on behalf of a coalition of 24 civil society groups in the United Kingdom of Great Britain and Northern Ireland.

[60] A joint submission by Daniele Capezzone and Benedetto Della Vedova, members of the Italian Chamber of Deputies; Veaceslav Untila, Member of Parliament, Moldova; and Kelsey Zahourek, Property Rights Alliance, United States; Harald Zimmer, German Association of Research-based Pharmaceutical Manufacturers; and Ronald Cass, Centre for the Rule of Law, United States.

[61] Submissions opposing the Working Group's attention to type I diseases included Gene Copello, The AIDS Institute, United States; Lawrence Kogan; and Lila Feisee. Submissions supporting attention by the Working Group to type I diseases included Kevin Outterson, Boston University, United States; and Peter Munyi, Health Alliance International, Africa.

[62] Peter Munyi, African Civil Society Coalition on IGWG, Kenya; Christian Wagner-Ahifs, Health Action International, the Netherlands; Mohga Kamal-Yanni, Oxfam International, United Kingdom; and Spring Gombe, Knowledge Ecology International, Swtizerland.

[63] Spring Gombe.

[64] WHO, "Draft global strategy and plan of action on public-health, innovation and intellectual property: progress to date in the drafting groups A and B", document A/PHI/IGWG/2/Conf. Paper No.1 Rev.1, annex, para. 3.

came to a consensus on the principled recognition that "the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition".[65] They could not, however, agree on two other principles stating respectively that "[t]he right of everyone to the enjoyment of the highest attainable standard of physical and mental health is recognized as a fundamental human right in the international human rights instruments, in particular, in [article 12 (1) of] the International Covenant on Economic, Social and Cultural Rights" and that "[t]he objectives of public-health and the interests of trade should be appropriately balanced and coordinated" or "[t]he right to health takes precedence over commercial interests".[66] Additional rights language that remained bracketed at the conclusion of the session included recognition of the need for more efforts to implement State obligations under human rights treaties with provisions relevant to health, and to prioritize research and development in traditional medicine in accordance with international instruments referring to the rights of indigenous peoples and local communities.

Member States were similarly unable to reach agreement on the appropriate scope of the strategy with regard to type I diseases, and whether new incentive mechanisms should aim to complement the existing system of intellectual property rights or produce an alternative system. Nonetheless, the strategy does refer to some of these mechanisms, including (by consensus) the need to encourage further exploration of an essential health and biomedical research and development treaty. However, other proposed mechanisms remained bracketed, including patent pools and the consideration of alternative mechanisms such as appropriate patenting and licensing policies.

Element 5 relating to intellectual property evoked the most debate, and little agreement was achieved on it at the second session. The inability of delegations to reach consensus on this point ultimately lead the Working Group to suspend its work on 10 November 2007, agreeing to resume the second session before the sixty-first session of the World Health Assembly to be held in May 2008. The subgroup tasked with drafting the plan of action met again from 17 to 19 March 2008, in advance of the resumed second session beginning on 28 April 2008, to review proposals for stakeholders, time frames and progress indicators for all consensus sub-elements and specific actions in elements 3-8, and to discuss approaches to costing the draft strategy. The secretariat also proposed a small number of summary indicators or "reporting components", meant to provide indicators that all parties would be expected to collect as an absolute minimum within a particular period.[67] Twenty-seven member States provided written submissions for consideration at this meeting on the draft strategy and plan of action prior to the final session of the International Working Group.

C. Resumed second session: 28 April-3 May 2008

Member State participation at the resumed second session reached its highest levels, with 147 member State delegations attending. Non-State participation was also high, with 7 organizations and 11 experts invited, and 23 NGOs attending, as well as 17 United Nations organizations, specialized agencies and intergovernmental organizations. Member States engaged in intense negotiation over the draft global strategy and plan of action, with the penultimate session ending at 3 a.m. Delegates were able to reach consensus on five elements within the strategy, including element 1 on prioritizing research and development, element 2 on promoting research and development, element 3 on building and improving innovative capacity, element 7 on promoting sustainable financing mechanisms and element 8 on the establishment of monitoring and reporting systems.[68] However, delegations could not reach agreement on element 4 on transfer of technology, element 5 on management of intellectual property and element 6 on improving delivery and access. In addition, delegations could not reach consensus on the principled recognition of the right to health as a fundamental human right in the International Covenant on Economic, Social and Political Rights,[69] nor the inclusion of principles recognizing that the objectives of public-health and trade should be appropriately balanced, or that the right to health should take precedence over commercial interests.[70] Nor was there consensus on a provision that countries should avoid incorporating TRIPS-plus measures in trade agreements and national legislation that could negatively impact access to health products in developing countries, or that they

[65] Ibid., para. 16.
[66] Ibid., paras. 17-18.
[67] "Subgroup of drafting group B meeting, 17-19 March 2008 – plan of action: summary indicators/reporting components: secretariat draft text", White Paper 3, p. 1.
[68] WHO, "Draft global strategy on public-health, innovation and intellectual property, outcome document at 14.00 hours, Saturday, 3 May 2008" (hereinafter "Draft global strategy outcome document").
[69] All countries save Ecuador reached consensus on the need to delete this principle.
[70] Draft global strategy outcome document, paras. 17-18.

should take account of the impact of TRIPS-plus measures on access to health products. A range of other areas relating to counterfeit medicines and patent abuse remained bracketed, including issues relating to data exclusivity, anti-competitive practices, patentability criteria and the use of undisclosed test data.

Some bracketed provisions reflected the disagreement of a sole country. For example, all countries save the United States of America reached consensus on the need to develop new incentive mechanisms around the World Health Organization's active role in public-health, innovation and intellectual property, and the need to encourage pharmaceutical companies to adopt equitable pricing policies. Brackets also remained around many of the stakeholders identified in the draft plan of action that was concluded at the resumed second session.

D. Sixty-first session of the World Health Assembly: 24 May 2008

Most of the remaining elements of the draft global strategy and plan of action were finalized at the World Health Assembly held a few weeks later. The effort to broker a final negotiated text saw many critical debated areas either deleted or amended, including in relation to TRIPS-plus rules, new global bodies, global responsibilities and rights-based principles. For example, the provision cautioning against the adoption of TRIPS-plus protection in bilateral trade agreements was deleted, as was a reference to bilateral agreements in a provision requiring regular monitoring of agreements that may have an impact on access to health products in developing countries. In their place, countries were to take into account the public-health impact when considering adopting or implementing more extensive intellectual property protection than required by TRIPS.

Other provisions that were deleted included provisions to allow parallel imports, exploit expired or invalid patents to introduce generics, restrict the impact of data exclusivity on access, prevent anti-competitive practices and avoid restricting the use of undisclosed test data. Several institutional reforms were also removed, including recommendations to set up a global research and development fund[71] and create a coordination committee among WHO, WIPO and WTO for looking at solutions on the issue of public-health and intellectual property.[72]

Important acknowledgements of international responsibilities were deleted, including provisions that urged developed countries to increase funding for research and development focusing on the health needs of developing countries and to allocate a progressive percentage of their health research budget to the health needs of developing countries. Notably, the entire section titled "global responsibility"[73] was deleted, and instead the Plan of Action is prefaced with explanatory notes that identify stakeholders as including WHO, Governments and international intergovernmental organizations and other relevant stakeholders.

There were mixed outcomes regarding explicit recognition of the right to health. While the two bracketed principles recognizing the right to health were deleted, there was consensus about including explicit recognition of the need to implement States' obligations and commitments "arising under applicable international human rights instruments with provisions relevant to health".[74] Moreover, the Global Strategy includes, as a founding principle, recognition that the enjoyment of the right to health is a fundamental right of every human person.[75]

In many places, language was considerably altered, significantly changing the meaning and force of provisions. For example, the sentence "The high prices of medicines impede access to treatment which requires a new thinking on the mechanisms to support innovation" was altered to read "The price of medicines is one of the factors that can impede access to treatment".[76] Similarly, an earlier provision stating "The CIPIH Report provides an effective analysis of the problems" was changed to simply state "The [CIPH report] provides an analysis of the problems."[77] Moreover, the "action" language of several provisions was considerably blunted through the consensus process, with actions altered from the stronger imperative to ensure, prioritize, enable and support to the weaker recommendations to urge, encourage and promote.[78]

There are, however, several important advances in the Global Strategy. First, the debate on the scope of the Strategy regarding type of disease was resolved in favour of a broad focus. For example, the aim of the Strategy was no longer articulated as being focused on type II and III diseases and the needs of developing

[71] A/PHI/IGWG/2/Conf.Paper No.1 Rev.1, para. 42 (7.3).
[72] Ibid., para. 36 (5.1) (i).
[73] Ibid., p. 26.
[74] Global Strategy, para. 3.
[75] Ibid., para. 16.
[76] Ibid., para. 11.
[77] Ibid., para. 6.
[78] Compare, for example, paragraphs. 28 (1.2) (d), 28 (1.3) and 29 (2.2) (g).

countries in relation to type I diseases, but instead was "to promote new thinking on innovation and access to medicines".[79] Similarly, a long-contested footnote relating to the definitions of this typology of disease was retained, albeit with the specific focus on nine neglected diseases replaced by the recognition that the "prevalence of diseases and thereby their categorization in the typology can evolve over time".[80] Other previously contested sections referring to the typology were agreed to. Consensus was also reached on the need to explore new incentive mechanisms for innovations like patent pools, prizes and a medical research and development treaty, although provisions considering the use of advance market commitments were deleted. The Global Strategy also called for the establishment of a results-oriented and time-limited expert working group to examine current research and development financing and coordination, and to consider proposals for new and innovative sources of funding to stimulate research and development. However, the WHO mandate in relation to intellectual property remained unresolved and several actions remained bracketed even at the close of the Assembly.[81]

The Global Strategy as adopted is comprised of various preambular sections including context, principles and aim. Its main focus is on specifying actions and sub-actions in each of the eight elements; there are 108 actions in total. The Plan of Action appended to the Global Strategy specifies lead actors, relevant stakeholders and time frames for completion by 2015. Its specific content is discussed in more detail in the following section.

With almost all elements agreed upon, on 24 May 2008, all 193 member States attending the World Health Assembly adopted the Global Strategy and agreed parts of the Plan of Action. resolution WHA61.21 urged member States to implement them, including by providing adequate resources, and requested the Director-General to support such implementation on request, including through coordinating with intergovernmental organizations, including WIPO, WTO and the United Nations Conference on Trade and Development (UNCTAD). The resolution also requested the Director-General to urgently finalize outstanding components of the Plan of Action concerning time frames, progress indicators and estimated funding needs, and to prepare a quick start programme and begin immediate implementation of those elements falling under the responsibility of WHO.

The Director-General was further requested to urgently establish an expert working group to examine research and development financing and coordination and consider proposals for innovative funding to stimulate research and development. The Consultative Expert Working Group on Research and Development: Financing and Coordination was established under a mandate set out in resolution WHA63.28. It held its first meeting from 5 to 7 April 2011 in Geneva, attended by 19 of its 21 members. In accordance with its workplan, after Web-based public submissions, it scheduled its second meeting for July 2011, planned to conduct regional consultations, circulate a first draft of its report to members, hold its third meeting in November 2011 and then submit its progress report to the Executive Board at its 130th session, with a view to finalizing the report in early 2012 for submission to the sixty-fifth session of the World Health Assembly.[82]

Finally, resolution WHA61.21 requested the Director-General to monitor performance and progress in implementing the Global Strategy and Plan of Action and to report progress, through the Executive Board, in 2010 to the sixty-third session of the World Health Assembly and every two years thereafter, until 2015.[83]

Since the 2008 World Health Assembly, the outstanding components of the Plan of Action have been finalized, including time frames, progress indicators and estimated funding needs. The Expert Working Group on Research and Development has been established and its work is under way. The secretariat of the Intergovernmental Working Group has undertaken further work on a set of indicators to allow monitoring of overall progress in implementation. The WHO Secretariat has initiated the Quick Start Programme, which is mapping global research and development activities; identifying research gaps and setting research priorities; supporting research and development;

[79] Global Strategy, para. 13.

[80] Ibid., para. 14 (b), footnote 1.

[81] For example, there was no agreement on WHO taking a lead role in relation to education, training and capacity-building for implementing intellectual property from a public-health perspective, initiating regional programming to harmonize regulatory approval, exploring incentive schemes for research and development, encouraging the establishment of award schemes for health-related innovation and taking into account the impact on public-health of TRIPS-plus intellectual property protection.

[82] WHO Executive Board, "Consultative Expert Working Group on Research and Development: Financing and Coordination", document EB129/3, annex, appendix. Editor's note: further information on the Consultative Expert Working Group can be found at www.who.int/phi/news/cewg_2011/en/index.html. The report to the Executive Board at its 130th session on the work of the Working Group is available at http://apps.who.int/gb/ebwha/pdf_files/EB130/B130_23-en.pdf.

[83] Editor's note: the report to the World Health Assembly at its sixty-third session (2010) is contained in document A63/6 and Add.1 and 2, available from the WHO website.

promoting standard-setting for traditional medicines in developing countries; developing and strengthening regulatory capacity in developing countries; and developing a monitoring and reporting framework.[84] WHO has costed the Global Strategy at a total of $149 billion for all member States, averaging $21 billion per year.[85]

IV. Analysing the Intergovernmental Working Group and the Global Strategy and Plan of Action from a right to development perspective

Does the substance of the Global Strategy and Plan of Action serve the interests it ostensibly seeks to serve? Moreover, did the Intergovernmental Working Group process assure sufficient attention to the core human rights principles, including accountability, transparency and participation, which are at the heart of the right to development?[86] In line with these two questions, the remainder of the chapter explores (a) areas of potential congruence; and (b) rupture between the Intergovernmental Working Group process and the Global Strategy and Plan of Action and specific aspects of the right to development implicated by medicines.

A. Areas of congruence between the Intergovernmental Working Group, the Global Strategy and Plan of Action, and the right to development

Potential synergies between the Intergovernmental Working Group process, the Global Strategy and Plan of Action, and the right to development can be assessed in two separate areas: first, the extent to which the Global Strategy and Plan of Action themselves hold the potential to realize the right to development and second, the extent to which the Global Strategy and Plan of Action and Intergovernmental Working Group process were synergistic with principles central to the realization of the right to development, including participation, accountability and transparency.[87]

Synergies between the Intergovernmental Working Group, the Global Strategy and Plan of Action, and the right to development

The Declaration on the Right to Development aims to realize "economic, social, cultural and political development, in which all human rights and fundamental freedoms can be fully realized" (art. 1 (1)). As former Independent Expert on the right to development Arjun Sengupta has suggested, this articulation of the right to development can be understood as founding an entitlement to "a particular process of development in which all human rights and fundamental freedoms can be fully realized".[88] Other prominent human rights scholars argue that such a process presupposes a range of obligations, both "on individual states to ensure equal and adequate access to essential resources, and on the international community to promote fair development policies and effective international cooperation".[89]

In this light, it is apposite to ask whether the Global Strategy and Plan of Action contribute to the realization of the human rights implicated in access to, and innovation of, medicines, including in particular the rights to health and to benefit from scientific progress. Guidance in assessing the Global Strategy in this regard is provided by the interpretation of these rights by the Committee on Economic, Social and Cultural Rights, as explained in its general comments Nos. 14 (2000) and 17 (2005). In general comment No. 14 (2000) on the right to the highest attainable standard of health (art. 12 of the Covenant), the Committee indicates that this right requires as an essential element that health-care facilities, goods and services (including essential medicines) should be available, accessible, acceptable and of good quality (para. 12). State obligations in relation to medicines include a minimum core duty to provide essential drugs as defined by WHO (para. 43 (d)), as well as duties to respect (not obstruct), protect (prevent third party obstruction) and fulfil (provide) access (para. 33). States also hold international duties under this right, including the duty not to obstruct this right in other countries, to prevent corporations from violating it elsewhere, and to ensure that international agreements do not adversely impact realization of the right (para. 39).

[84] WHO Executive Board, "Public health, innovation and intellectual property—Global Strategy and Plan of Action: report by the Secretariat", document EB124/16, paras. 4-5.
[85] WHO Executive Board, "Public health, innovation and intellectual property—Global Strategy and Plan of Action: proposed time frames and estimated funding needs", document EB124/16 Add.2.
[86] See "The right to development and practical strategies for the implementation of the Millennium Development Goals, particularly goal 8: preliminary concept note" (E/CN.4/2005/WG.18/TF/2), para. 5.
[87] Ibid.
[88] Arjun Sengupta, "The human right to development," in *Development as a Human Right: Legal, Political and Economic Dimension*, Bård A. Andreassen and Stephen P. Marks, eds. (Cambridge, Massachusetts, Harvard School of Public Health, Francois-Xavier Bagnoud Centre for Health and Human Rights, 2007), p. 11.
[89] Tarantola and others, *Human Rights, Health and Development* (see footnote 10), p. 5.

The specific implications of these duties with regard to intellectual property are spelled out in general comment No. 17 (2005) 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 (art. 15, para. 1 (c), of the Covenant). Here, the Committee differentiates between human rights, which are fundamental as they are inherent to the human person, and intellectual property rights, which are first and foremost a means to incentivize invention and creativity (para. 1). Viewed in this light, the Committee suggests that intellectual property rights can be subjected to necessary and proportional limitations that do not unduly favour the private interests of authors. This means that States parties should ensure that their legal or other regimes protecting intellectual property rights do not impede their ability to comply with their core obligations under the rights to food, health and education. In particular, States parties "have a duty to prevent unreasonably high costs for access to essential medicines ... from undermining the rights of large segments of the population to health ..." (para. 35).

To what extent therefore do the Global Strategy and Plan of Action enable States to realize their domestic and international duties to respect, protect and fulfil access to affordable, accessible, acceptable and good quality medicines? Certainly, the Global Strategy's efforts to improve both access and innovation can be viewed as contributing to these goals, although improvements in access may have a more proximal impact on affordability, accessibility and safety than the more distal impacts of innovation. There is nonetheless a clear and important link between the innovation of new medical products and the ability of poor people to access the benefits of science, and both goals are equally important from the perspective of accessibility and affordability.

There is explicit recognition of the need to address these factors in the Global Strategy and Plan of Action, which adopt as a founding principle that they should promote the development of health products needed by States, especially developing countries, that are developed ethically; available in sufficient quantities; effective, safe and of good quality; affordable and accessible; and used in a rational way.[90] Similarly, the Global Strategy adopts as a principle that public policy should address the factors that contribute to the high price of health products in order to increase their affordability and accessibility, including through the promotion of competition.[91]

Several elements of the Global Strategy directly seek to ensure the affordability, accessibility and safety of medicines, particularly element 6 on improving delivery and access, which emphasizes the importance of stimulating competition and adopting appropriate pricing policies, including through the use of TRIPS flexibilities recognized by the Doha Declaration. The section on element 6 also specifies a range of actions to promote competition, including national legislation/policy to support generic production and introduction, policy to improve access to affordable health products, reducing tariffs on health products, encouraging pharmaceutical companies to consider policies conducive to promoting affordability, developing policy to monitor pricing and improve affordability and taking TRIPS-compliant measures to prevent the abuse of intellectual property rights.

Other parts of the Global Strategy address measures to ensure affordability through managing intellectual property rights, including using TRIPS flexibilities "to the full" to protect public-health[92] and providing technical support to countries to do so,[93] as well as supporting information-sharing and capacity-building.[94] Affordability is also directly impacted by measures to promote the transfer of technology, including through the production of health products in developing countries, and developing new mechanisms to promote access to key health-related technologies, including voluntary patent pools. The Global Strategy similarly seeks to assure safety and quality through improved ethical review; strengthening national regulatory capacity to monitor quality, safety and efficacy; complying with good manufacturing practices; strengthening the WHO prequalification programme; ensuring regional harmonization of regulatory approval of drugs; and promoting ethical principles for clinical trials.[95]

The Global Strategy's focus on promoting innovation of health products for diseases prevalent in developing countries has similarly important implications for affordability and accessibility. This potential impact is particularly apparent in the Global Strategy's aim of examining new incentive schemes that delink the costs of research and development from the

[90] Global Strategy, para. 24.

[91] Ibid., para. 26.
[92] Ibid., para. 35.
[93] Ibid., para. 36 (5.2).
[94] Ibid., para. 36 (5.1).
[95] Plan of Action, element (6.2) (a)-(g).

price of products, such as the awarding of prizes.[96] In this regard, the establishment at WHO of an expert working group to explore new innovative research and development funding is a promising development. Adopting innovative approaches to research and development may have significant influence on the pricing of new products developed as a result, promising important congruence with the rights to health and development.

The Global Strategy is weaker, however, in regard to emphasizing States' international obligations under the right to health. For example, while the Strategy strongly encourages the critical need to use TRIPS flexibilities to the full, this focus is undercut by the deletion from the final text of the Strategy of explicit caution against the adoption of TRIPS-plus protection in bilateral trade agreements. Instead, countries are simply encouraged to take into account the public-health impact when considering adopting or implementing more extensive intellectual property protection than required by TRIPS.[97] This provision falls far short of the recommendation in the CIPIH report that "bilateral trade agreements should not seek to incorporate TRIPS-plus protection in ways that may reduce access to medicines in developing countries".[98] This omission is problematic given a growing understanding that the adoption of TRIPS-plus standards in trade agreements can immediately prevent access to medicines.[99] This deletion therefore may significantly undercut the international duty of States to respect the realization of the right to health, including by not obstructing access. The deletion also threatens to undercut realization of the right to development since, as the high-level task force on the implementation of the right to development has recognized, "Government policies consistent with TRIPS flexibilities and conducive to access to medicines in developing countries would conform to article 2 (3) of the Declaration on the Right to Development, according to which Governments have the 'right and the duty to formulate appropriate national development policies'".[100]

International duties to fulfil the right to health are similarly undercut by the weakness of the Global Strategy and Plan of Action regarding international financing of health products. This is not to ignore the Strategy's laudable encouragement of increased investment in health-delivery infrastructure, human resource development and health-product financing,[101] given that State capacity to realize access may be constrained by resource limitations and inadequate health infrastructures. Nonetheless, this encouragement is undercut by the Plan's failure to specify the need for international financing of health products in the element of the Plan specifically devoted to promoting sustainable financing mechanisms. Instead, the Plan recommends facilitating the maximum use of existing financing to develop and deliver safe, effective and affordable health products. There are no recommendations for additional financing, and the measures specified to achieve this element are focused entirely on supporting, documenting and assessing public-private and product development partnerships.[102] The Strategy therefore fails to adequately realize international duties to fulfil the realization of the right to health in other countries, including by providing international economic assistance.[103]

Despite these weaknesses, the Global Strategy's focus on assuring the affordability, safety and quality of medicines may support the realization of the right to health and ergo the right to development. Other elements of the Strategy are directly congruent with the right to development, including the focus on building and improving innovative capacity and encouraging technology transfer. These are positive inclusions that may contribute to the realization of the right to development.

B. Synergies between the Intergovernmental Working Group process, the Global Strategy and Plan of Action, and right to development principles

Are there synergies between the Intergovernmental Working Group process and the Global Strategy and Plan of Action, and core right to development principles such as participation, accountability and transparency?[104] These principles are predominant themes within human rights more generally and implicitly mandate a focus on the poorest and most marginalized, and require effective mutual accountability and ownership and adequate mechanisms for monitoring and review.[105]

[96] Ibid., element (5.3) (a).
[97] Draft global strategy outcome document, para. 36 (5.2) (b).
[98] Recommendation 4.26.
[99] Richard D. Smith and others, "Trade, TRIPS, and pharmaceuticals," *The Lancet*, vol. 373, Issue 9664 (2009) p. 688.
[100] "Technical mission to the World Health Organization, the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property, the Special Programme on Research and Training in Tropical Diseases and the Global Fund to Fight AIDS, Tuberculosis and Malaria", report of the high-level task force on the implementation of the right to development (A/HRC/15/WG.2/TF/CRP.2), para. 8.
[101] Plan of Action, element (6.1) (a), (e) and (g).
[102] Ibid., element (7.2) (a)-(c).
[103] Committee on Economic, Social and Cultural Rights, general comment No. 14 (2000), para. 38.
[104] E/CN.4/2005/WG.18/TF/2, para. 5.
[105] See "Report of the high-level task force on the implementation of the right to development on its third session" (A/HRC/4/WG.2/TF/2).

1. Participation

The Intergovernmental Working Group process reflects a significant effort by the WHO Secretariat to ensure broad and effective participation, which, beyond holding three negotiating sessions in Geneva, also convened two public Web-based hearings and several regional and intercountry consultations. From the perspective of the right to development, these participatory efforts should be assessed in terms of whether the population groups affected directly or indirectly by a particular policy could play an effective role in the process of formulating that policy.[106] Moreover, the right to development requires that participation extend beyond "preference revelation", to include "policy choice, implementation and monitoring, assessment and accountability".[107] Genuine participation is therefore intimately connected to adherence to the other principles underlying the right to development, including non-discrimination, transparency and accountability.

Recognition of the need to ensure broad participation is evident from the very initiation of the Intergovernmental Working Group in resolution WHA59.24, which explicitly called for the participation of NGOs, experts and concerned private and public entities in the sessions (paras. 3 (2) and 4 (3)). These experts and NGOs were able to participate in the committees that negotiated the draft strategy, and this was one of the first times that non-member State participants were able to provide inputs on negotiations.[108] This certainly is an important contribution to genuine and broad participation in the Intergovernmental Working Group process. It is notable, however, that other NGOS in official relations with WHO that were invited to observe these sessions could only attend the plenary sessions and not the drafting groups; their impact on the formulation of the Strategy was therefore limited in important respects, although they could make inputs at the plenary sessions and through the public submission process.[109] It is also significant that only NGOs in "official relations" with WHO were invited as observers. WHO rules define "official relations" as applying primarily to NGOs that are international in scope and have at least two years of successful working relations with WHO.[110] These requirements both directly limit the participation of nationally oriented groups and indirectly ensure this outcome, given the resource limitations that may condition the ability of even internationally oriented groups within developing countries to establish official relations with WHO.

It is therefore unsurprising that the lists of participants in the sessions indicate that the NGOs attending were primarily international groups. While it is apparent that these NGOs played important advocacy roles within the Intergovernmental Working Group process, the absence of national groups is a significant deficit in the genuinely broad nature of participation in the sessions themselves. It is apparent that the WHO Secretariat was alive to these problems, and sought at the first session explicitly to fast-track the participation of NGOs to ensure broader participation at the second session and to expand the pool of experts and entities invited to "ensure balanced regional, gender and developing/developed country representation".[111]

Participation outside the sessions was similarly augmented through the two public Web-based hearings and regional and intercountry consultations held in each of the WHO regions. It is significant that several of the latter permitted NGO participation, albeit again primarily only of international NGOs. The public hearings provided an important participatory mechanism within the Intergovernmental Working Group process, and over 90 submissions were made through these two hearings by a range of actors, including academics, patients' groups and the private sector. The Working Group secretariat sought to ensure that the content of these submissions was considered at the sessions, and synopses of the submissions were presented at both the first and second sessions. Certainly, a number of the recommendations made in the public hearings are ultimately reflected in the final text of the Global Strategy, including regarding patent pools, a medical research and development treaty, prize funds and the inclusion of language recognizing the right to health.

The public accessibility of these hearings is certainly congruent with the principle of participation. However, it is questionable whether a Web-based hearing requiring typed submissions on a highly technical area of international policy would be genuinely accessible to the majority of people directly affected by the inaccessibility of medicines in developing countries. The implication is that if policy initiatives addressing the health needs of people in develop-

[106] "Economic, social and cultural rights—study on policies for development in a globalizing world: what can the human rights approach contribute?" (E/CN.4/Sub.2/2004/18), para. 35.
[107] Ibid., para. 36.
[108] E-mail correspondence with Dr. Elil Renganathan, Executive Secretary of the WHO Secretariat on Public Health, Innovation, Essential Health Research and Intellectual Property (25 March 2009).
[109] Ibid. (18 March 2009).
[110] WHO, Principles Governing Relations between the World Health Organization and Nongovernmental Organizations, art. 3.2-3.6.
[111] A60/27, para. 12.

ing countries are to be genuinely participatory, they should seek to ensure participation by affected communities within countries, including through measures such as national public hearings.

The unmanaged nature of Web-based hearings is similarly not without concern. For example, there was controversy around the second public hearing, given the significant increase in submissions supporting strong intellectual property rights and opposing various aspects of the Intergovernmental Working Group strategy. This increase was viewed with suspicion by civil society groups, which alleged that pharmaceutical companies had compromised the hearings through financial support of participating groups and advocacy to oppose the Working Group.[112] Irrespective of the veracity of these claims, the incident suggests the need for the management of public submissions, including through basic measures such as declarations of conflicts of interest.

The participation of WHO member States in the sessions themselves was also mixed. Just over 50 per cent of them participated in the first session, and a third of those States absent were least developed countries.[113] The Working Group secretariat recognized this deficit, and explicitly sought to broaden participation by funding the attendance of one delegate from each such country at all three sessions and engaging in additional advocacy through regional WHO offices and consultations to encourage greater developing country participation in the Working Group process. Whether because of increased funding or a growing awareness of the significance of the process, member State participation at the second session increased significantly, to 140. It reached its highest level (147) at the resumed second session.

Participation was certainly also influenced by the size of national delegations, since Working Group sessions and side meetings were sometimes held concurrently. It is notable in this respect that delegation size seemed to vary according to developmental levels; for example, many least developed countries sent only one or two delegates to the sessions, in comparison to the larger delegations of two to four delegates that most other countries could send (this was the case for 82 countries at the first session).

[112] Suwit Wibulpolprasert and others, "WHO's web-based public hearings: hijacked by pharma?", *The Lancet,* vol. 370, Issue 9601 (2007), p. 1754.

[113] See, for example, "Global strategies need truly global discussions", *The Lancet*, editorial, vol. 368, Issue 9552 (2006), p. 2034.

2. Transparency

The Intergovernmental Working Group process largely complies with the right to development criteria requiring adequate and freely available information to enable effective public scrutiny of policies, working methods and outcomes. WHO official documentation on this process is publicly accessible, with full documents from each session, public hearing and regional consultation posted on its website. The transparency of the process is, however, limited, since in line with standard WHO practice, member State negotiations were closed and remain undocumented. This lack of transparency is certainly incongruent with any human rights-based approach to policy formation, and points to a broader structural deficiency in the negotiating processes that produce important pieces of international policy such as the Intergovernmental Working Group. This lack of transparency speaks to the ultimately political nature of the document and suggests in some respects both its potential strengths and weaknesses.

3. Accountability

The Global Strategy specifies 108 actions to realize its goals of promoting innovation, building capacity, improving access and mobilizing resources. The Plan of Action identifies the lead stakeholders to take such actions, as well as additional relevant stakeholders, and explicitly establishes systems for monitoring and reporting on its progress. In accordance with the right to development, are these fair, institutionalized mechanisms of mutual accountability and review through which fulfilment is monitored and publicly reported, responsibility for action indicated and effective remedies provided?

With regard to the allocation of duties, it is apparent that the Plan of Action places responsibility for action primarily on Governments, which are identified as lead actors on most of the actions (91 of the 108 actions). There is, however, no indication of whether the Governments in question should be developed or developing countries, and this seems a prominent deficit in identifying mutual responsibilities of both developed and developing countries. It is notable that earlier versions of the Plan of Action were more explicit in specifying the responsibilities of developed countries.

It is also notable that the language of the exhortations to action in the Plan of Action is weak, with stakeholders "urged", "requested" and "invited" to

take action. This is a marked departure from a prior section that was deleted from the final text of the Global Strategy, which spoke of the "global responsibility" of a range of actors to ensure discovery and development of health products and ensure that health products are accessible and affordable for people and Governments in developing countries.

WHO is given the second most prominent role in the Global Strategy, taking the sole lead on 10 actions and sharing leadership with Governments on another 39. The organization is also designated as lead actor in monitoring performance and progress in implementation and other key areas. This prominence is an important outcome, definitively answering critiques that WHO would exceed its mandate if it were to address intellectual property issues and carving out its institutional mandate with regard to the public-health implications of intellectual property rights. The Strategy provides for regular and public monitoring of progress, requiring that progress reports be submitted to the World Health Assembly through the Executive Board every two years, with a comprehensive evaluation of the strategy to be undertaken after four years. This process is an important measure that could enable accountability as well as transparency in the realization of the Global Strategy and Plan of Action.

Since the completion of the Global Strategy, 30 progress indicators have been devised to form the basis for regular reporting to the World Health Assembly on performance and overall progress over a two-year reporting period. Each element in the Strategy has a set of indicators measuring results with respect to its key objectives.[114] A key weakness of these indicators is that all are quantitative, and none set defined targets. Thus, while they will be able to measure numerical progress in programming, policies and reports, they cannot measure the impact of such measures. Notably absent are any indicators measuring the production of new medicines or the proportion of the population with access to existing medicines. These are significant deficits in a strategy aimed at improving both innovation and access.

V. Conclusion

The Intergovernmental Working Group process is the first global cooperative initiative aimed at reforming a global system of medical research and development that to date has largely failed to meet the needs of people in developing countries.[115] The Intergovernmental Working Group and negotiated final Global Strategy and Plan of Action are seen as milestones in global policy relating to public-health and intellectual property rights, at least as important as the Doha Declaration.[116] The endorsement of the Global Strategy and Plan of Action by all 193 member States of WHO suggests its potential to advance global cooperation in relation to innovation of and access to health products for diseases prevalent in developing countries. The Global Strategy and Plan of Action may also protect developing countries seeking to use TRIPS- and Doha Declaration-compliant measures such as compulsory licensing to ensure access to affordable medicines.

The Global Strategy and Plan of Action may also serve an important normative function in global and domestic law and policy relating to access to medicines. The seriousness with which delegations treated its negotiations certainly seems to reflect a sense that its provisions could have a powerful influence as a political document.[117] Indeed, members of the Intergovernmental Working Group secretariat reported that member States treated the Working Group in the same way as treaty negotiations, with hours spent negotiating a word or comma, and the final document approved sentence by sentence, word by word. Delegations evidently realized that they were not drafting a simple WHO technical document.

The Global Strategy and Plan of Action do include potentially powerful elements capable of contributing to the realization of the right to development and health. The Global Strategy advances thinking in important respects, including confirming that the policy debate over intellectual property rights extends to diseases of the developed world and emphasizing the need for new innovative mechanisms to provide incentives for drug production. The inclusion of explicit recognition of the right to health is a similarly important element. These elements are all the more important given the endorsement of the Global Strategy and Plan of Action by all 193 WHO member States.

[114] WHO Executive Board, "Global Strategy and Plan of Action: proposed progress indicators", document EB124/16 Add.1.

[115] K. Satyanarayana and S. Srivastava, "The Inter-Governmental Working Group on Public Health, Innovation and Intellectual Property (IGWG): the way ahead", *Indian Journal of Medical Research*, vol. 128, No. 5 (November 2008), pp. 577, 579.

[116] See, for example, William New, "WHO adopts 'most important document since Doha' on IP and public-health", *IP-Watch* (29 May 2008). Available from www.ip-watch.org (quoting a leading developing country negotiator).

[117] See also Kaitlin Mara and William New, "WHO IP and health group concludes with progress; tough issues remain for Assembly", *IP-Watch* (6 May 2008). Available from www.ip-watch.org.

Yet, the failures are equally important. The utility of the Global Strategy and Plan of Action for enabling policy supportive of public-health may have important functional limitations, as its failure to caution against TRIPS-plus measures suggests. The deletion in the Strategy of acknowledgement of global responsibilities for funding is similarly problematic. Moreover, the language of many of the actions is very vague, and while the Intergovernmental Working Group may have advanced new thinking on this topic, it may have been at the expense of achieving concrete results.

Ultimately, the success of the Global Strategy and Plan of Action should be measured by the extent to which 2015 brings a marked improvement in access to existing and new medicines both between and within developing countries. Whether this goal is reached may depend in the interim on the extent to which the Global Strategy and Plan of Action contribute to remedying the material and structural inequalities that condition governmental abilities to realize the right to the highest attainable standard of health and ergo, the right to development.