

Distr.  
LIMITED

A/HRC/12/WG.2/TF/CRP.5  
27 March 2009

ENGLISH ONLY

HUMAN RIGHTS COUNCIL  
Twelfth session  
Working Group on the Right to Development  
High Level Task Force on  
the implementation of the right to development  
Fifth session  
Geneva, 1- 9 April 2009  
Item 4 of the provisional agenda

**DESK REVIEW OF THE INTERGOVERNMENTAL WORKING GROUP ON PUBLIC  
HEALTH, INNOVATION AND INTELLECTUAL PROPERTY FROM A RIGHT TO  
DEVELOPMENT PERSPECTIVE<sup>1</sup>**

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<sup>1</sup> Note by the Secretariat: The opinions, findings, interpretations or conclusions expressed in this paper are those of the expert, do not necessarily represent the views of the United Nations and do not commit the United Nations. The designations employed and the presentation of the material in this paper are those of the expert and do not imply the expression of any opinion whatsoever on the part of the United Nations concerning the legal status of any country, territory, city or area of its authorities, or concerning the delimitation of its frontiers or boundaries.

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## INTRODUCTION

1. This desk review has been commissioned by the High-Level Task Force on the implementation of the Right to Development, in pursuance of its mandate to use the right to development to strengthen global partnerships for development as defined in Millennium Development Goal (MDG) 8. In accordance with this mandate, the Task Force has elaborated criteria for periodic evaluation of global development partnerships to be applied, on a pilot-basis, to selected partnerships.<sup>3</sup>

2. At its Fourth Session in January 2008, the Task Force decided to take up consideration of Target 17 of MDG8E, which aims to “in cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries”.<sup>4</sup> The Task Force recognized that Target 17 bears on the realization of the right to development, since the inaccessibility of medicines “stands as a direct contradiction to the fundamental principle of health as a human right”.<sup>5</sup> At its 2008 Session, the Working Group on the Right to Development recommended a work plan for the Task Force which gave priority to the issue of access to essential medicines in developing countries including through a desk review of the work of the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG). The Human Rights Council endorsed this work plan at its 9<sup>th</sup> session in September 2008.<sup>6</sup>

3. The IGWG process engaged WHO Member States, nongovernmental organizations, intergovernmental organizations and the pharmaceutical industry in an eighteen month process to produce a Global Strategy and Plan of Action 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 R&D, and estimating funding needs in this area”.<sup>7</sup>

4. The IGWG Global Strategy and Plan of Action (GSPA) aims therefore to meaningfully reform both the failure of global R&D to produce medicines for diseases of the developing world, as well as the intellectual property rights protected under international and bilateral trade agreements that have often constrained developing country realization of access to affordable medicines. The GSPA may therefore offer a critical milestone in global policy on medicines access in developing countries, with the potential to significantly advance the realization of MDG8E, the right to development and associated human rights to health, life and the benefits of scientific progress.

5. Accordingly, this desk review was commissioned to assess IGWG and the GSPA from a right to development perspective, documenting the IGWG process leading to the adoption of the

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<sup>3</sup> United Nations Commission on Human Rights, Report of the Working Group on the Right to Development on its seventh session (Geneva, 9-13 January 2006), UN. Doc. E/CN.4/2006/26, para. 67.

<sup>4</sup> Millennium Development Goal 8, Target 17.

<sup>5</sup> United Nations Human Rights Council, Report of the High-Level Task Force on the Implementation of the Right to Development on its Fourth Session, UN Doc. A/HRC/8/WG.2/TF/2, 31 January 2008, para. 74.

<sup>6</sup> United Nations Human Rights Council, The Right to Development, resolution 9/3, para. 2.b.

<sup>7</sup> Sixty First World Health Assembly, Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property- Annex: Global Strategy on Public Health, Innovation and Intellectual Property, Resolution WHA 61.21, 24 May 2008, para. 13.

GSPA, and mapping the Task Force's right to development criteria against the GSPA. In particular, the review was asked to (1) explore areas of potential synergy between the IGWG process and GSPA and the right to development, (2) suggest right to development criteria for inclusion in the GSPA, and (3) identify lessons learned from the IGWG process that can aid efforts to refine and develop right to development criteria in relation to MDG8E.

6. The review is structured as follows: the first part explores the background leading to IGWG, the second part documents IGWG, and the third part analyzes IGWG from a right to development perspective. Attached as annexes 1, 2 and 3, are a matrix mapping the elements of the GSPA against the right to development criteria, and revised IGWG and right to development criteria.

7. The review is based on an analysis of IGWG documentation available from the WHO website, other relevant literature (including media and scholarship on IGWG), and interviews with the IGWG secretariat and other WHO personnel, conducted in Geneva from 18-20 February 2009. A list of interviewees is attached as annex 4.

## I. BACKGROUND LEADING TO THE INITIATION OF THE IGWG

8. Almost two billion people (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.<sup>8</sup> Medicines are "by far the most significant tool that society possesses to prevent, alleviate and cure disease".<sup>9</sup> The inaccessibility of medicines therefore directly impedes the realization of human rights including the highest attainable standard of health ('the right to health') and the benefits of scientific progress.<sup>10</sup> 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".<sup>11</sup>

9. Access to medicines bears particularly upon individual abilities to alleviate poverty, since pharmaceuticals can consume fifty to ninety percent of out of pocket expenditures for the poor in developing countries.<sup>12</sup> 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 twenty five to seventy percent of total health care expenditures).<sup>13</sup> 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.<sup>14</sup> The realization of the right to

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<sup>8</sup> WHO, WHO Medicines Strategy: Countries at the Core 2004–2007 (Geneva, 2004), p. 3.

<sup>9</sup> United Nations Millennium Project, Interim Report of Task Force 5 Working Group on Access to Essential Medicines, February 2004, p. 9.

<sup>10</sup> See Alicia Ely Yamin, Not Just a Tragedy: Access to Medications as a Right under International Law, (2003) 21 Boston U. Int'l L. J. 325.

<sup>11</sup> United Nations Declaration on the Right to Development, adopted by General Assembly resolution 41/128 of 4 December 1986, article 1.

<sup>12</sup> WHO, WHO Medicines Strategy: Countries at the Core 2004–2007, WHO/EDM/2004.5.

<sup>13</sup> Ibid.

<sup>14</sup> See Amartya Sen, "Development as Freedom", (New York: Anchor Books, 2000).

health is therefore “both a goal of the exercise of the right to development, and a means of contributing to achieving development”.<sup>15</sup>

10. The relationship between medicines and development is underscored by its inclusion within MDG8 on global partnerships for development. This relationship is explicitly emphasised by the ‘Noordwijk Medicines Agenda,’ adopted by the 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”.<sup>16</sup> Access to medicines is therefore appropriately viewed as a core element of both the right to development and the right to health.

11. The human rights and development consequences of inaccessible medicines have prompted growing attention to the impact of price and intellectual property rights on access. While access to medicines is determined by several factors, such as rational use, adequate infrastructure, and sustainable financing,<sup>17</sup> pricing can have a disproportionate impact on access. Patents are primary determinants of drug prices, and are protected internationally under the World Trade Organization’s (WTO) *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS). The TRIPS agreement requires WTO members to provide twenty-year exclusive patent protection to pharmaceuticals preventing non-consensual use.<sup>18</sup> The TRIPS agreement also provides ‘flexibilities,’ which permit limits to exclusive patent protection to enable governments to meet public-health needs, such as compulsory licensing where countries manufacture or import generic medicines under strict conditions.<sup>19</sup>

12. However countries may face obstacles in using these flexibilities, including through corporate litigation, unilateral trade pressures, and ‘TRIPS-plus’ intellectual property rules adopted in bilateral and regional free trade agreements (FTA).<sup>20</sup> In response, the Doha Ministerial Declaration on the TRIPS Agreement and Public Health adopted in 2001 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.<sup>21</sup>

13. At the same time, there has been growing attention to the inadequacies of the medical innovation system for producing medicines to treat diseases primarily prevalent in the developing world. As Trouiller et al. famously illustrate, only 0.1 percent of new chemical entities produced between 1975 and 1999 were for tropical diseases and tuberculosis.<sup>22</sup> Indeed,

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<sup>15</sup> Daniel Tarantola et al., “Human Rights, Health and Development”, Technical Series Paper 08.1 (Sydney: The UNSW Initiative for Health and Human Rights, The University of New South Wales).

<sup>16</sup> OECD, Noordwijk Medicines Agenda, Noordwijk-aan-Zee, Netherlands, 21 June 2007.

<sup>17</sup> WHO Medicines Strategy (2004), p. 24.

<sup>18</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights, Annexure 1C to the Marrakesh Agreement Establishing the World Trade Organization, signed in Marrakesh, Morocco on 15 April 1994, [TRIPS], articles 28.1.a and b.

<sup>19</sup> TRIPS, article 31.

<sup>20</sup> See for instance, Richard D. Smith, Carlos Correa and Cecilia Oh, “Trade, TRIPS and Pharmaceuticals”, (2009) *The Lancet* 373, p. 687.

<sup>21</sup> WTO Ministerial Conference, Declaration on the TRIPS Agreement and Public Health, (Doha, 9-14 November 2001), para. 4.

<sup>22</sup> P. Trouiller, et al., “Drug Development for Neglected Diseases: A Deficient Market and a Public Health Policy Failure”, *The Lancet* 359 (2002): p. 2188.

the 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”.

14. 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. Thus, in February 2004, at the request of the World Health Assembly, the WHO established the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH), to analyze the relationship between intellectual property rights, innovation, and public health.<sup>23</sup> The CIPIH released its extensive final report in April 2006, considering the impact 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, [and] the impact of other funding and incentive mechanisms and fostering innovation capacity in developing countries.<sup>24</sup>

15. The report made sixty 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 “WHO should develop a global plan of action to secure enhanced and sustainable funding for developing and making accessible products to address diseases that disproportionately affect developing countries”.<sup>25</sup>

16. Accordingly, in May 2006 the 59<sup>th</sup> World Health Assembly passed resolution 59.24, calling for the establishment of an intergovernmental working group open to all interested Member States to draw up a global strategy and plan of action to provide a medium-term framework based on the CIPIH recommendations, which 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.”<sup>26</sup>

17. The Resolution authorized the Working Group to report on its progress to the 60<sup>th</sup> World Health Assembly through the Executive Board, giving particular attention to “needs-driven research and other potential areas for early implementation”.<sup>27</sup> The Resolution also requested the Director-General to invite a range of observers to the sessions, including UN organizations, intergovernmental organizations, and nongovernmental organizations with which WHO had established official relations.<sup>28</sup> In addition, the Director-General was requested to invite experts and concerned private and public entities to attend and provide advice and expertise as necessary.<sup>29</sup>

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<sup>23</sup> World Health Assembly, “Intellectual Property Rights, Innovation and Public Health”, WHA Resolution 56.27, 28 May 2003, para. 2.

<sup>24</sup> WHO, *Public Health Innovation and Intellectual Property Rights: Report of the Commission on Intellectual Property Rights, Innovation and Public Health*. (Geneva, 2006), p174 [CIPIH Report (2006)].

<sup>25</sup> CIPIH Report (2006), p. 187.

<sup>26</sup> World Health Assembly, “Public Health, Innovation, Essential Health Research and Intellectual Property Rights: Towards a Global Strategy and Plan of Action”, Resolution WHA59.24, 27 May 2006, para.3.1.

<sup>27</sup> WHA resolution 59.24, 27 May 2006, para. 3.2.

<sup>28</sup> *Ibid.*, para. 3.2. and 4. 2.

<sup>29</sup> *Ibid.*, para. 3.2. and 4. 3.

## II. THE INTERGOVERNMENTAL WORKING GROUP ON PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY

18. Between December 2006 and April 2008, an Intergovernmental Working Group met through three sessions in Geneva, which brought together WHO Member States, nongovernmental organizations, intergovernmental organizations and the pharmaceutical industry. In addition, regional and inter-country consultations and two public web-based hearings were held to allow broad consultation on the 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 analyzing its potential lessons for realizing the right to development and achieving target 17 of MD8E.

### A. First Session: 4-8 December 2006

19. The first session of the Intergovernmental Working Group focused on producing a first draft of a global strategy consistent with the CIPIH Report and WHA Resolution 59.24 and in consultation with Member States, nongovernmental organizations, international organizations, pharmaceutical companies and other relevant parties. To ensure broad consultation on this draft, from 1 to 14 November 2006, the IGWG secretariat arranged a web-based public hearing, receiving thirty-one 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 IGWG process, including in relation to the feasibility of new incentive mechanisms like patent pools, prize funds and a medical R&D treaty in successfully generating R&D on neglected diseases.<sup>30</sup> Other submissions underscored the need to view access to medical care and treatment as a basic human right,<sup>31</sup> 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.<sup>32</sup> A synopsis of these submissions was presented at the session.

20. One hundred and three Member States (approximately fifty percent of all WHO Member States) attended this session.<sup>33</sup> In conformity with WHA resolution 59.24, four additional organizations and one expert were invited to participate. Another sixteen NGOs in official relations with WHO, seven UN organizations, specialized agencies and intergovernmental organizations also attended. Concerns about insufficient participation lead the Working Group to recommend a process to fast-track NGOs in official relations with WHO to enable their participation in the Group's second session.<sup>34</sup> This process was approved by the WHO Executive

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<sup>30</sup> See for instance, Trevor M. Jones, a previous CIPIH Commissioner and Tracey Heller- 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 R & D for drugs to treat diseases in developing countries). For alternative views, see Médecins sans Frontières, Health Action International, Cptech, Third World Network (public-private partnerships were insufficient, what was required was more governmental responsibility and innovative measures like patent pools, prize funds and a medical R&D treaty). See

[http://www.who.int/phi/public\\_hearings/first/en/index.html](http://www.who.int/phi/public_hearings/first/en/index.html)

<sup>31</sup> See Debra Hayes and Caroline J. Gallant, Universities Allied for Essential Medicine.

<sup>32</sup> See International AIDS Vaccine Initiative.

<sup>33</sup> Delegation information is drawn from the official participants lists posted on the WHO's website for the IGWG sessions. See <http://www.who.int/phi/documents/en/>

<sup>34</sup> World Health Organization, "Public Health, Innovation and Intellectual Property: Progress Made by the Intergovernmental Working Group: Report by the Secretariat", A60/27, 5 April 2007, para. 8.

Board at its 120<sup>th</sup> Session, which authorized several additional NGOs in official relations with WHO to participate in the next intergovernmental working group session.<sup>35</sup> 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.<sup>36</sup>

21. The Working Group prepared a first draft of the GSPA, 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 R&D, and establishing monitoring and reporting systems.<sup>37</sup> During negotiations, Member States requested the addition of separate elements on the transfer of technology to develop new technologies and products, and management of intellectual property, as a means of emphasizing the importance of these measures.<sup>38</sup> 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.<sup>39</sup>

22. In addition, on the request of the Working Group, the IGWG Secretariat prepared a second draft drawing from legally binding and consensus agreed language in the WHO Constitution, CIPIH Report, resolution WHA 59.25 and other resolutions and work. This draft (Annex 2) introduced a number of overarching global principles for the strategy, including explicit reference to the UDHR rights to share in scientific advancement and its benefits, and to protection of moral and material interests.<sup>40</sup> The draft also recognized that research and knowledge were critical for achieving the health-related Millennium Declaration Goals.

23. The official report of the first session drew from both Member State comments during the Session and the public web-based submissions to record prominent debates about the role of intellectual property rights, WHO's mandate and the inclusion of rights language. 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,

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<sup>35</sup> The Standing Committee decided to provisionally admit NGOs to facilitate their participation in IGWG's work if they had been in working relations with WHO for two years, and otherwise met the criteria in section 3 of the WHO Principles Governing Relations with Nongovernmental organizations. See WHO Executive Board, "Reports of Committees of the Executive Board: Standing Committee on Nongovernmental Organizations", EB 120/41, 27 January 2007, para. 21, and WHO, "Principles Governing Relations with Nongovernmental Organizations", article 3, on <http://www.who.int>

<sup>36</sup> WHO, "Report of the First Session Geneva, 4-8 December 2006", A/PHI/IGWG/1/6, 25 January 2007, para. 3, and WHO, "Public Health, Innovation and Intellectual Property: Progress Made by the Intergovernmental Working Group: Report by the Secretariat," A60/27, 5 April 2007, para. 12.

<sup>37</sup> WHO, "Elements of a Global Strategy and Plan of Action", A/PHI/IGWG/1/4, 2 November 2006.

<sup>38</sup> WHO, "Elements of a Global Strategy and Plan of Action: Progress to date in the Intergovernmental Working Group", A/PHI/IGWG/1/5, 8 December 2006, paras. 5 and 6. [WHO, Progress to date, 8 December 2006].

<sup>39</sup> WHO, Progress to date, 8 December 2006, para. 6.a, f and h.

<sup>40</sup> Ibid., Annex 2, para. 2.

infrastructure and political will<sup>41</sup>. Other countries disputed WHO's competence 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 WIPO, and that both WHO and the Working Group should remain focused on health.<sup>42</sup> 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.<sup>43</sup>

24. There was also disagreement about incorporating reference to access to medicines as a human right,<sup>44</sup> albeit that one country insisted that the Global Strategy was incomplete without recognition that "human public health considerations have precedence over rights to intellectual property protections".<sup>45</sup>

25. 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 WHO's website.<sup>46</sup> After soliciting comments from Member States through two circular letters dispatched on 12 January and 15 February,<sup>47</sup> twenty-two submissions were received with comments.<sup>48</sup> In July 2007, the IGWG Secretariat released a revised version of the global strategy and a first draft plan of action 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 and/or additional incentive schemes for research and development", including prize funds and advance-market commitments.<sup>49</sup>

26. 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".<sup>50</sup> 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 thirty other actions. The Plan set medium-term time-frames for implementation by 2015. It also identified one hundred and thirty nine progress indicators, albeit

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<sup>41</sup> WHO, Intergovernmental Working Group on Public Health, Innovation and Intellectual Property, Report of the First Session Geneva, 4-8 December 2006, A/PHI/IGWG/1/6, 25 January 2007, para. 14 [WHO, Report of First Session, 25 January 2007].

<sup>42</sup> WHO, Report of First Session, 25 January 2007, paras. 20, 21 and 31.

<sup>43</sup> *Ibid.*, para. 31.

<sup>44</sup> *Ibid.*, para. 37.

<sup>45</sup> WHO, Elements of a Global Strategy and Plan of Action: Progress to date in the Intergovernmental Working Group, A/PHI/IGWG/1/5, 8 December 2006, Annex 2, appendix.

<sup>46</sup> WHO, Report of First Session, 25 January 2007, para. 39.

<sup>47</sup> WHO, "Progress Made by the Intergovernmental Working Group: Report by the Secretariat", A60/27, 5 April 2007, para. 11.

<sup>48</sup> WHO, "Draft Global Strategy and Plan of Action: Report by the Secretariat", 31 July 2007, EB122/12, para. 6 [WHO, Report by the Secretariat, 31 July 2007].

<sup>49</sup> WHO, Report by the Secretariat, 31 July 2007, para. 17.5.3.a-d.

<sup>50</sup> *Ibid.*, para. 26.

that there was consensus that these were too numerous and would be costly and difficult to apply.<sup>51</sup>

## **B. Regional Consultations and the Second Web-Based Public Hearing**

27. Regional and inter-country consultations were organized in August, September and October 2007 in all the WHO regions, including AFRO in the Congo, AMRO/PAHO in Canada, EMRO in Egypt, EURO in Serbia, SEARO in the Maldives and WPRO in the Philippines. 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 took place in Rio de Janeiro, between Argentina, Brazil, Chile, Costa Rica, Cuba, Ecuador, El Salvador, Honduras, Mexico, Peru, Suriname, Uruguay and Venezuela. This meeting produced the ‘Rio document,’ which came to have a significant influence on negotiations.<sup>52</sup> 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”.<sup>53</sup> 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, and;
- (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.<sup>54</sup>

28. The influence of the Rio document was apparent at the AMRO/PAHO consultation held in Ottawa, Canada from 22-23 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 debate the appropriateness of including Rio’s principles on the right to health.<sup>55</sup> The consultation also introduced a new debate over whether the IGWG process could appropriately deal with diseases experienced primarily in developed countries. This discussion relied on the specific wording of WHA resolution 59.24 which drawing on the CIPIH report, focused on Type II diseases incident in both rich and poor countries but with a substantial

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<sup>51</sup> Sub-group of Drafting Group B Meeting, 17-19 March 2008, White Paper 1, 3 March 2008, Outcome Document of IGWG2 Sub-Group Discussions (November 2007 version- Report of Subgroup Chair and Plan of Action Elements 1 and 2), para. 4.

<sup>52</sup> “Rio Document”, Sub-regional Meeting Consensus Document, Rio de Janeiro, Brazil, A/PHI/IGWG/2/2, 3-5 September 2007 [Rio document, 3-5 September 2007].

<sup>53</sup> Rio Document, 3-5 September 2007, para. 6.

<sup>54</sup> *Ibid.*, paras. 12-15.

<sup>55</sup> 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 IGWG’s mandate ... if we are to have a principles section [we suggest that we use to the extent possible already agreed upon language]”.

proportion of cases in developed countries, Type III diseases overwhelmingly or exclusively incident in developing countries diseases, rather than Type I diseases incident in both rich and poor countries.<sup>56</sup>

29. 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 60<sup>th</sup> World Health Assembly's request to the Director-General to encourage the development of proposals for R&D, including incentive mechanisms.<sup>57</sup> Approximately sixty-five contributions were received from a wide range of stakeholders, including governments and national institutions, civil society, academics, the private sector and patient's organizations.<sup>58</sup> The second hearing saw a dramatic intensification of debates over the role of intellectual property rights, and the feasibility of innovative incentive mechanisms.<sup>59</sup>

30. A number of submissions analyzed and proposed new incentive mechanisms like patent pools, a medical R&D treaty, a comprehensive advance market commitment and prize funds.<sup>60</sup> Many submissions however disputed the need for new incentive mechanisms, arguing that strong intellectual property rights played a constructive role in providing incentives to medical innovation.<sup>61</sup> Opponents of new incentives emphasized the need to instead adopt market-based mechanisms, including advance market commitments and public-private partnerships.<sup>62</sup> Some submissions went so far as to suggest that IGWG sought to alter private innovation in ways akin to Soviet-style communism.<sup>63</sup> One submission even questioned whether IGWG'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".<sup>64</sup>

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<sup>56</sup> AMRO/PAHO- Regional Consultation on Public Health, Innovation and Intellectual Property, Ottawa, Canada, 22-23 October 2007.

<sup>57</sup> World Health Assembly, "Public Health, Innovation and Intellectual Property", WHA Resolution 60.30, 24 May 2007, para. 3.4.

<sup>58</sup> WHO, Report by the Secretariat, 31 July 2007, para. 11.

<sup>59</sup> See Oxfam International, "Ending the R&D Crisis in Public Health: Promoting Pro-Poor Medical Innovation", Oxfam Briefing Paper 122, November 2008.

<sup>60</sup> 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", Florida State University and Duke University; James Love, Knowledge Ecology International; Itaru Nitta, Green Intellectual Property Scheme System to impose a levy on patent applicants to establish a trust fund to facilitate eco-Aidan Hollis, A Comprehensive Advanced Market Commitment; Thomas Pogge, Track2.

<sup>61</sup> Jeremiah Norris, Hudson Institute, USA; Harvey Bale, IFPMA; Ronald Cass, Centre for the Rule of Law; Wayne Taylor, Health Leadership Institute, McMaster University; Anne Sullivan, International Association for Business and Health; Hispanic-American Allergy Asthma and Immunology Association; the National Grange of the Order of Patrons of Husbandry; International Chamber of Commerce; Healthcare Evolves with Alliance and Leadership; and US Chamber of Commerce.

<sup>62</sup> Harvey Bale, IFPMA; Lawrence Kogan, Institute for Trade, Standards and Sustainable Development; Tracy Haller, Novartis; Lila Feisee, Biotechnology Industry Organization; Council Nedd, Tabetha B. Ralph and Leslie O. Anderson, Alliance for Health Education and Development, USA; Lawrence Kogan, Institute for Trade, Standards and Sustainable Development; Brendan Barnes, European Federation of Pharmaceutical Industries and Associations; Community Life Improvement Program and Alliance of Minority Medical Associations; Health Care Advocacy Alliance; and Bioventures for Global Health.

<sup>63</sup> Alexander Gershman, American Russian Medical Association; and Catherine Benavidex Clayton, Alliance of Health Disparities.

<sup>64</sup> Philip Stevens, for 24 Civil Society Groups.

31. Other submissions debated WHO's appropriate mandate with regard to intellectual property rights,<sup>65</sup> and the appropriate extension of the scope of IGWG to Type I diseases.<sup>66</sup> Several submissions argued that IGWG should recognize and frame itself around the right to health and medicines,<sup>67</sup> 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 ICESCR.<sup>68</sup>

### C. Second Session: 5-10 November 2007

32. Member state participation at the second session increased significantly, with one hundred and forty Member States attending. In addition, eighteen NGOs, seven organizations and eleven experts as invited participants, and sixteen UN organizations, specialized agencies and intergovernmental organizations attended. Two drafting groups were created to explore elements five and six of the Global Strategy respectively (on management of intellectual property and improving delivery and access), and a sub-group was created to look at the plan of action.

33. 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.<sup>69</sup> 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 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".<sup>70</sup> They could not however agree on two other principles, stating respectively, that "The 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 the International Covenant on Economic, Social and Cultural Rights Article 12.1" and "The objectives of public health and the interests of trade should be appropriately balanced and coordinated/or the right to health takes precedence over commercial interests."<sup>71</sup>

34. Additional rights language that remained bracketed at the conclusion of the session included recognition of the need for more efforts to implement obligations under human rights

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<sup>65</sup> Daniele Capezzone, Benedetto Della Vedova, Veaceslav Untila and Kelsey Zahourek, Government Institution, European Parliamentarians and the Property Rights Alliance, Italy; Harold Zimmer, German Association of Research-based pharmaceutical manufacturers; and Ronald Cass, Centre for the Rule of Law.

<sup>66</sup> Submissions opposing IGWG's attention to type I disease include Gene Copello, The AIDS Institute; Lawrence Kogan, Institute for Trade, Standards and Sustainable Development; and Lila Feisee, Biotechnology Industry Organization. Submissions supporting IGWG's attention to type I disease include Kevin Outtersson, Boston University; and Peter Munyi, HAI, Africa.

<sup>67</sup> African Civil Society Coalition; Christian Wagner, Health Action International, Europe; Mogha Kamal-Yanni, OXFAM; Spring Gombe, Knowledge Ecology International.

<sup>68</sup> Spring Gombe, Knowledge Ecology International.

<sup>69</sup> 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", A/PHI/IGWG/2/Conf.Paper No.1 Rev.1, 14 December 2007, para. 3 [Progress to Date in Drafting Groups A and B, 14 December 2007].

<sup>70</sup> Progress to Date in Drafting Groups A and B, 14 December 2007, para. 16.

<sup>71</sup> Ibid. para. 17 and 18.

treaties with provisions relevant to health, and to prioritize R&D in traditional medicine in accordance with international instruments referring to the rights of indigenous peoples and local communities.<sup>72</sup>

35. Member states were unable to reach agreement on the appropriate scope of the strategy with regard to Type I disease, with related text bracketed.<sup>73</sup> The question of new incentive mechanisms remained similarly contested, and Member States could not agree whether the aim of exploring incentive schemes should be to complement the existing system or produce an alternative system.<sup>74</sup> 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 R&D treaty.<sup>75</sup> However other proposed mechanisms remained bracketed, including patent pools, and the consideration of alternative mechanisms such as appropriate patenting and licensing policies.<sup>76</sup>

36. Element 5 relating to intellectual property evoked the most debate, and little consensus was ultimately achieved on it at this session. The inability of delegations to reach consensus on this point ultimately led the group to suspend its work on 10 November 2007, agreeing to resume the second session before the 61<sup>st</sup> Health Assembly in May 2008.

37. The subgroup tasked with drafting the plan of action met again from 17-19 March 2008, in advance of the resumption of the Intergovernmental Working Group session 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 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.<sup>77</sup> Twenty-seven member states provided written submissions for consideration at this meeting on the Draft Strategy and Plan of Action prior to the final IGWG session.

#### **D. Resumed Second Session: 28 April to 3 May 2008**

38. Member state participation at the resumed second session reached its highest levels, with one hundred and forty seven Member State delegations attending. Seven organizations and eleven experts were invited, and twenty-three NGOs attended, as did seventeen UN organizations, specialized agencies and intergovernmental organizations.

39. Member States engaged in intense negotiation over the Global Strategy and Plan of Action, with the penultimate session ending at 3am.<sup>78</sup> Delegates were able to reach consensus on five elements within the strategy, including element 1 on prioritizing R&D, element 2 on promoting R&D, element 3 on building and improving innovative capacity, element 7 on

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<sup>72</sup> Progress to Date in Drafting Groups A and B, 14 December 2007, paras. 3 and 28.1.3.

<sup>73</sup> Ibid., paras. 13, footnote to 14.b, 28.1.1.a.

<sup>74</sup> Ibid., para. 14.e.

<sup>75</sup> Ibid., para. 30.2.3.c.

<sup>76</sup> Ibid., para. 34.4.3.a and b.

<sup>77</sup> Sub-group of Drafting Group B Meeting, 17-19 March 2008, Plan of Action: Summary Indicators/Reporting Components- Secretariat Draft Text, White Paper 3, March 2008, p. 1.

<sup>78</sup> Interview with Elil Renganathan, Geneva, 18 February 2009.

promoting sustainable financing mechanisms, and element 8 on the establishment of monitoring and reporting systems.<sup>79</sup> 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.

40. In addition, delegations could not reach consensus on the principled recognition of the right to health as a fundamental human right in ICESCR,<sup>80</sup> 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.<sup>81</sup>

41. 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 should take account of the impact of TRIPS-plus measures on access to health products.<sup>82</sup> A range of other areas relating to generic entry and patent abuse remained bracketed, including relating to data-exclusivity, anti-competitive practices, patentability criteria and the use of undisclosed test data.<sup>83</sup>

42. Some bracketed provisions reflected the disagreement of a sole country—for example, all countries save for the USA reached consensus on the need to develop new incentive mechanisms, around WHO's active role in public health, innovation and intellectual property,<sup>84</sup> and the need to encourage pharmaceutical companies to adopt equitable pricing policies.<sup>85</sup>

43. Brackets also remained on many of the stakeholders identified in the Plan of Action that was concluded at the resumed second session.

#### **E. 61<sup>st</sup> World Health Assembly: 24 May 2008**

44. Most of the remaining elements of the 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.

45. 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.<sup>86</sup> 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.<sup>87</sup>

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<sup>79</sup> WHO, "Draft Global Strategy on Public Health, Innovation and Intellectual Property", Outcome document at 14.00 hours, Saturday 3 May 2008 [Draft Global Strategy Outcome document, 3 May 2008].

<sup>80</sup> All countries save for Ecuador reached consensus on the need to delete this principle.

<sup>81</sup> Draft Global Strategy Outcome document, 3 May 2008, paras. 17 and 18.

<sup>82</sup> *Ibid.*, para. 36.5.2.b.

<sup>83</sup> *Ibid.*, para. 36.5.3.b-e.

<sup>84</sup> *Ibid.*, para. 4 and 15.

<sup>85</sup> *Ibid.*, para. 39.6.3.d and e.

<sup>86</sup> *Ibid.*, para. 38.

<sup>87</sup> *Ibid.*, para. 36.5.2.b

46. 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 R&D fund, and create a coordination committee among WHO, WIPO and WTO for looking at solutions on the issue of public health and intellectual property.<sup>88</sup>

47. Important acknowledgements of international responsibilities were deleted, including provisions that urged developed countries to increase funding for R&D 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 on global responsibility 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.

48. The outcomes with regard to the explicit recognition of the right to health were mixed. While the three 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".<sup>89</sup> Moreover, the Strategy includes as a founding principle, recognition that the enjoyment of the right to health is a fundamental right of every human person<sup>90</sup>.

49. In many places, language was considerably altered, significantly changing the meaning and force of provisions. For example, a sentence stating that "the high price of medicines impedes 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".<sup>91</sup> 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".<sup>92</sup> 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.<sup>93</sup>

50. There are however several important advances in the Strategy. The debate on the scope of the Strategy regarding type of disease was resolved in favor of a broad focus. For example, the aim of the strategy was no longer articulated as being focused on type II, III disease, and the needs of developing countries in relation to type I disease, but instead was said to be "to promote new thinking on innovation and access to medicines."<sup>94</sup> Similarly, a long contested footnote relating to the definitions of this typology of disease was retained, albeit with the specific focus

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<sup>88</sup> Draft Global Strategy Outcome document, 3 May 2008, para. 35.5.1.i.

<sup>89</sup> Global Strategy and Plan of Action (24 May 2008), para. 3.

<sup>90</sup> *Ibid.*, para. 16.

<sup>91</sup> *Ibid.*, para. 11.

<sup>92</sup> *Ibid.*, para. 6.

<sup>93</sup> Compare for example paras. 28.1.2.d, 28.1.3, 29.2.2.g in WHO, Draft Global Strategy Outcome document (3 May 2008) and Global Strategy and Plan of Action (24 May 2008).

<sup>94</sup> Global Strategy and Plan of Action (24 May 2008), para. 13.

on nine neglected diseases replaced with the recognition that the “prevalence of disease and thereby their categorization in the typology can evolve over time”.<sup>95</sup> Other previously contested sections referring to the typology were agreed to.<sup>96</sup>

51. Consensus was also reached on the need to explore new incentive mechanisms for innovations like patent pools and prizes, although provisions considering the use of advance market commitments were deleted.<sup>97</sup> The Strategy also called for the establishment of a results-oriented and time-limited expert working group to examine current R&D financing and coordination, and consider proposals for new and innovative sources of funding to stimulate R&D.<sup>98</sup>

52. However WHO’s mandate in relation to intellectual property remained unresolved, and several actions remained bracketed even at the close of the Assembly. 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 R&D, 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.<sup>99</sup>

53. 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. WHA resolution 61.21 urged member states to implement the strategy and plan of action, including through providing adequate resources,<sup>100</sup> and called on the Director-General to support such implementation on request, including through coordinating with intergovernmental organizations, including WIPO, WTO and UNCTAD.<sup>101</sup> The resolution also requested the Director-General to urgently finalize outstanding components of the plan of action concerning timeframes, progress indicators and estimated funding needs, and to prepare a quick start program and begin immediate implementation of those elements falling under WHO’s responsibility.<sup>102</sup>

54. The Director-General was further requested to urgently establish the expert working group to examine R&D financing and coordination and consider proposals for innovative funding to stimulate R&D.<sup>103</sup> The group would be open to Member State proposals, and would submit a progress report to the Sixty-second World Health Assembly in May 2009, and a final report to the Sixty-third World Health Assembly in May 2010. Finally, the resolution requested the Director-General to monitor performance and progress in implementing the GSPA, and to report progress through the Executive Board in 2010 to the Sixty-third World Health Assembly, and subsequently every two years, until 2015, to the Health Assembly.<sup>104</sup>

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<sup>95</sup> Global Strategy and Plan of Action (24 May 2008), para. 14.b, footnote 1.

<sup>96</sup> *Ibid.*, paras. 27; 28.1.1.a; 29.2.1.d. 34.4.3.b.

<sup>97</sup> *Ibid.*, paras.34.4.3.a, and 36.5.3.a.

<sup>98</sup> *Ibid.*, para. 42.7.1.a

<sup>99</sup> *Ibid.*, paras. 5.1.a-c.,7.1.f, 5.3.a, 3.5 and 6.1.a.

<sup>100</sup> *Ibid.*, paras. 2.1 and 2.

<sup>101</sup> *Ibid.*, paras. 4.1, 4.2 and 4.3.

<sup>102</sup> *Ibid.*, para. 4.6.

<sup>103</sup> *Ibid.*, para. 4.7.

<sup>104</sup> *Ibid.*, para. 4.10.

55. Since the 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 R&D has been established, and its work is underway. The IGWG Secretariat has undertaken further work on a set of indicators to allow monitoring of overall progress in implementation. The Secretariat has initiated the Quick Start Program, which is mapping global R&D activities, identifying research gaps and research priority setting, supporting R&D and promoting standard setting for traditional medicines in developing countries, developing and strengthening regulatory capacity in developing countries, and developing a monitoring and reporting framework.<sup>105</sup> WHO has costed the Strategy at a total of US \$149 billion for all Member States, averaging \$21 billion per year.<sup>106</sup>

### III. ANALYZING IGWG FROM A RIGHT TO DEVELOPMENT PERSPECTIVE

56. The remainder of the paper looks at three guiding questions for a right to development analysis of the IGWG process and outcomes: (a) what are the areas of potential congruence and synergy between the IGWG process and outcomes and the right to development? (b) what lessons can be learned from the IGWG process to aid efforts to refine and develop right to development criteria in relation to Target 8E of MDG8, and (c) how could the right to development criteria be better reflected in the plan of action attached to the IGWG Global Strategy? The completed matrix mapping the elements of the Global Strategy and Plan of Action against the right to development criteria is attached, as are recommendations for both revised IGWG and right to development criteria.

#### A. Areas of Congruence between IGWG and the Right to Development

57. Potential synergies between IGWG and the right to development can be assessed in two separate areas: (1) the extent to which the IGWG Global Strategy and Plan of Action holds the potential to realize the right to development, and (2) the extent to which the IGWG process itself is synergistic with principles central to the realization of the right to development, including participation, accountability and transparency.<sup>107</sup>

#### *Synergies between IGWG and the right to development*

58. 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”.<sup>108</sup> As Sengupta has suggested, in this articulation the right to development can be understood as founding an entitlement to “a particular process of development in which all

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<sup>105</sup> WHO Executive Board, “Global Strategy and Plan of Action – Report by the Secretariat”, EB 124/16, 20 November 2008, paras. 4-5.

<sup>106</sup> WHO Executive Board, “Global Strategy and Plan of Action – Proposed Time Frames and Estimated Funding Needs”, EB124/16 Add.2, 21 January 2009.

<sup>107</sup> United Nations Commission on Human Rights, “The Right to Development and Practical Strategies for the Implementation of the Millennium Development Goals, particularly Goal 8: Preliminary Concept Note”, UN Doc. E/CN.4/2005/WG.18/TF/2, para. 5.

<sup>108</sup> Declaration on the Right to Development, article 1.

human rights and fundamental freedoms can be fully realized”.<sup>109</sup> 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”.<sup>110</sup>

59. In this light, it is apposite to ask whether the GSPA contributes to the realization by Member States and the international community of the human rights implicated in access to and innovation of medicines, including in particular rights to health and to benefit from scientific progress. Guidance in assessing the Strategy in this regard is provided by the United Nations Committee on Economic, Social and Cultural Rights’ (CESCR) interpretation of these rights in General Comments 14 and 17.

60. In General Comment 14 on the right to health, 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.<sup>111</sup> State obligations in relation to medicines include a minimum core duty to provide essential drugs as defined by the WHO, as well as duties to respect (not obstruct), protect (prevent third party obstruction) and fulfill (provide) access.<sup>112</sup> States also hold international duties under this right, including not to obstruct this right in other countries, to prevent corporations violating it elsewhere, and to ensure that international agreements do not adversely impact on the right.<sup>113</sup>

61. The specific implications of these duties with regard to intellectual property is spelled out in General Comment 17 on the author’s right to protection of their moral interests. Here, the Committee differentiates between human rights, which are fundamental as they are inherent to the human person as such, and intellectual property rights that are first and foremost means by which States seek to provide incentives for inventiveness and creativity.<sup>114</sup> Viewed in this light, the committee suggests that intellectual property rights can be subjected to necessary and proportional limitations that do not unduly favor the private interests of authors. This means that state 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 rights to food, health, and education. In particular, state parties “have a duty to prevent unreasonably high costs for access to essential medicines.”<sup>115</sup>

62. To what extent therefore does the GSPA enable states to realize their domestic and international duties to respect, protect and fulfill access to affordable, accessible, acceptable and

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<sup>109</sup> Arjun Sengupta, “The Human Right to Development,” in Bard A. Andreassen and Stephen P. Marks, “Development as a Human Right: Legal, Political and Economic Dimensions”, (Harvard School of Public Health and Francois-Xavier Bagnoud Centre for Health and Human Rights), p. 11.

<sup>110</sup> Daniel Tarantola et al, “Human Rights, Health and Development,” Technical Series Paper 08.1 (Sydney: The UNSW Initiative for Health and Human Rights, The University of New South Wales), p. 5.

<sup>111</sup> United Nations Committee on Economic, Social, and Cultural Rights, General Comment No. 14: The Right to the Highest Attainable Standard of Health, UN Doc E/C.12/2000/4, (11 August 2000), para. 12 [CESCR, General Comment 14].

<sup>112</sup> CESCR, General Comment 14, paras. 34-43.

<sup>113</sup> Ibid., para. 39.

<sup>114</sup> UN CESCR, “General Comment 17 (2005): 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),” 12 January 2006, UN Doc. E/C.12/GC/17, para. 1.

<sup>115</sup> CESCR, General Comment 17, para. 55.

good quality medicines? Certainly, the Strategy's efforts to improve both access and innovation can both 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.

63. There is explicit recognition of the need to address these factors in the GSPA, which adopts as a founding principle, that it should promote the development of health products needed by Member 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.<sup>116</sup> The Strategy similarly adopts as a principle, that public policy should address factors that contribute to the price of health products to increase their affordability and accessibility, including through competition.<sup>117</sup>

64. Several elements of the Global Strategy directly seek to ensure the affordability, accessibility and safety of medicines, particularly element six 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.<sup>118</sup> The section 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.<sup>119</sup>

65. Other parts of the Strategy address measures to ensure affordability through managing intellectual property rights, including using "to the full" TRIPS flexibilities to protect public health, and providing technical support to countries to do so, as well as supporting information sharing and capacity building.<sup>120</sup> 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.<sup>121</sup>

66. The 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 program, ensuring regional harmonization of regulatory approval of drugs, and promoting ethical principles for clinical trials.<sup>122</sup>

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<sup>116</sup> Global Strategy and Plan of Action (24 May 2008), para. 24.

<sup>117</sup> Ibid., para. 26.

<sup>118</sup> Ibid., paras. 37 and 38.

<sup>119</sup> Ibid., elements 6.3.a-f.

<sup>120</sup> Ibid., para. 35, and elements 5.1 and 5.2.

<sup>121</sup> Ibid., element 4.1, 4.3.a.

<sup>122</sup> WHA Resolution 61.21, 24 May 2008, elements 6.2.a-g.

67. The 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 Strategy's aim of examining new incentive schemes that delink the costs of R&D from the price of products, such as the awarding of prizes.<sup>123</sup> The establishment at WHO of an expert working group to explore new innovative R&D funding is a promising initiative in this regard. These innovative approaches to R&D may have significant influence on the pricing of new products developed as a result, and promise important congruence with the rights to health and development.

68. The Strategy is weaker however in two respects regarding Member States realization of their 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 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.<sup>124</sup> This provision falls far short of the CIPIH recommendation that "bilateral trade agreements should not seek to incorporate TRIPS-plus protection in ways that may reduce access to medicines in developing countries".<sup>125</sup> This omission is problematic given a growing understanding that the adoption of TRIPS-plus standards in trade agreements can immediately prevent access to medicines.<sup>126</sup> This deletion therefore may significantly undercut the international duty of Member States to respect the realization of the right to health, including through not obstructing access.

69. International duties to fulfil the right to health are similarly undercut by the plan's weakness regarding international financing of health products. This is not to ignore the Strategy's laudable encouragement of increased investment in health-delivery infrastructure and health product financing,<sup>127</sup> 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.<sup>128</sup> The Strategy therefore fails to adequately realize international duties to fulfil the realization of the right to health in other countries.

70. Despite these weaknesses, the 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<sup>129</sup> and

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<sup>123</sup> Global Strategy and Plan of Action (24 May 2008), element 5.3.a.

<sup>124</sup> WHO, Draft Global Strategy Outcome document, 3 May 2008, para. 36.5.2.b.

<sup>125</sup> CIPIH Report 2006, recommendation 4.26, p. 182.

<sup>126</sup> Richard D. Smith et al., "Trade, TRIPS and Pharmaceuticals," (2009) *The Lancet* 373, p. 688.

<sup>127</sup> WHA Resolution 61.21 (24 May 2008) elements 6.1.a, e and g.

<sup>128</sup> Global Strategy and Plan of Action (24 May 2008), element 7.2.a-c.

<sup>129</sup> *Ibid.*

encouraging technology transfer.<sup>130</sup> These are positive inclusions that may contribute to the realization of the right to development.

### *Synergies between IGWG and right to development principles*

71. The following section explores synergies between the IGWG process and core right to development principles such as participation, accountability and transparency.<sup>131</sup> These principles are predominant themes that undergird the structure, process and outcome criteria formulated by the Task Force, which implicitly mandate a focus on the poorest and most marginalized, and require effective mutual accountability and ownership and adequate mechanisms for monitoring and review.<sup>132</sup>

### **Participation**

72. The IGWG process reflects a significant effort 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 inter-country 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.<sup>133</sup> Moreover, the right to development requires that participation extend beyond preference revelation, to include “policy choice, implementation and monitoring, assessment and accountability”.<sup>134</sup> Genuine participation is therefore intimately connected to adherence with the other principles underlying the right to development, including non-discrimination, transparency and accountability.

73. Recognition of the need to ensure broad participation is evident from the very initiation of the intergovernmental working group in WHA resolution 59.24, which explicitly called for the participation of nongovernmental organizations, experts and concerned private and public entities in the sessions.<sup>135</sup> These experts and NGOs were able to participate in the committees that negotiated the strategy, and this was one of the first times that non-member state participants were able to provide inputs on negotiations.<sup>136</sup> This certainly is an important and positive contribution to genuine and broad participation in the IGWG 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, albeit that they could make inputs at the

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<sup>130</sup> Global Strategy and Plan of Action (24 May 2008), elements 3.1.a, 3.3, 3.2.c, 3.2.d and 4.1.a and 4.2.a respectively.

<sup>131</sup> United Nations Commission on Human Rights, “The Right to Development and Practical Strategies for the Implementation of the Millennium Development Goals, particularly Goal 8: Preliminary Concept Note”, UN Doc. E/CN.4/2005/WG.18/TF/2, para. 5.

<sup>132</sup> United Nations Human Rights Council, Report of the High-Level Task Force on the Implementation of the Right to Development on its Third Session, UN Doc. A/HRC/4/WG.2/TF/2, 13 February 2007, paras. 70 and 67.

<sup>133</sup> United Nations Commission on Human Rights, “Economic, Social and Cultural Rights: Study on Policies for Development in a Globalizing World: What Can the Human Rights Approach Contribute? Note by the Secretariat”, (Paper prepared by S.R. Osmani), UN Doc. E/CN.4/Sub.2/2004/18, 7 June 2004, para. 35 [Osmani, 2004].

<sup>134</sup> Osmani, 2004, para. 36.

<sup>135</sup> WHA Resolution 59.24, para. 3.2 and 4.3.

<sup>136</sup> Email correspondence with Elil Renganathan, 25 March 2009.

plenary sessions and through the public submission process.<sup>137</sup> It is also significant that only NGOs in ‘official relations’ with the WHO were invited as observers. WHO rules define ‘official relations’ as applying primarily to NGOs that are international in scope, and with at least two years of successful working relations with WHO.<sup>138</sup> 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 the WHO.

74. It is unsurprising therefore that the participant lists to the sessions indicate that NGOs attending were primarily international groups. While it is apparent that these NGOs played important advocacy roles within the IGWG 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 Secretariat was alive to these problems, and sought explicitly at the first session 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”.<sup>139</sup>

75. Participation outside of the sessions was similarly augmented through the two public web-based hearings and regional and inter-country 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 IGWG process, and over ninety submissions were made through these two hearings by a range of actors, including academics, patients’ groups and the private sector. The IGWG 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 Strategy, including regarding patent pools, a medical R&D treaty, prize funds and the inclusion of language recognizing the right to health.

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

77. 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 IGWG strategy. This increase was viewed suspiciously by civil society groups, that alleged that pharmaceutical companies had compromised the hearings through financial support of

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<sup>137</sup> Email correspondence with Elil Renganathan, 18 March 2009.

<sup>138</sup> WHO, “Principles Governing Relations with Nongovernmental Organizations”, article 3.2-3.6, on <http://www.who.int>

<sup>139</sup> WHO, “Progress Made by the Intergovernmental Working Group: Report by the Secretariat”, 5 April 2007, A60/27, para. 12.

participating groups and advocacy to oppose IGWG.<sup>140</sup> 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.

78. The participation of Member States in the sessions themselves was also mixed. There was just over fifty percent participation in the first session by all WHO member states, and a third of those states absent were least developed countries.<sup>141</sup> The IGWG Secretariat recognized this deficit, and explicitly sought to broaden participation by funding the attendance of one delegate from such countries during all three sessions, and engaging in additional advocacy through regional WHO offices and consultations to encourage greater developing country participation in the IGWG 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 one hundred and forty Member States. It reached its highest level at the resumed second session, with one hundred and forty seven Member State delegations attending.

79. Participation certainly was 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 eighty two countries at the first session).

### **Transparency**

80. The IGWG 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's 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. Certainly this lack of transparency is 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 like IGWG. This lack of transparency speaks to the ultimately political nature of the document, and suggests in some respects both its potential strengths and weaknesses.

### **Accountability**

81. The Strategy specifies one hundred and eight 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

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<sup>140</sup> Suwit Wibulpolprasert et al., "WHO's web-based public hearings: Hijacked by pharma?", (2007) *The Lancet* 370:24, p. 1754.

<sup>141</sup> See for example, "Global strategies need truly global discussions", (2006) *The Lancet* 368:9, p. 2034.

accountability and review through which fulfillment is monitored and publicly reported, responsibility for action indicated, and effective remedies provided?

82. With regard to the allocation of duties, it is apparent that the Plan of Action primarily places responsibility for action on governments, who are identified as lead actors on most of the actions (91/108 actions). There is however no identification 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.

83. The strategy also allocates little responsibility to the pharmaceutical industry. They are specifically identified as lead actors (together with governments) in only three actions – including promoting transfer of technology through investment and capacity building and identification of best practices, and as the subjects of encouragement to consider policies conducive to access, including differential pricing.<sup>142</sup> It is notable too that they are not specifically identified as relevant stakeholders in the Plan of Action, which refers instead to ‘relevant health-related industries including both public and private.’<sup>143</sup>

84. 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.<sup>144</sup> This is a marked departure from a prior section that was deleted from the final 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.

85. WHO is given the second most prominent role in the Strategy, taking the sole lead on ten actions, and sharing leadership with governments on another thirty-nine. The organization is also designated as lead actor in monitoring performance and progress in implementation, and other key areas.<sup>145</sup> 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.

86. 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.<sup>146</sup> This process is an important measure that could enable accountability, as well as transparency in the realization of the GSPA.

87. Since the completion of the strategy, thirty progress indicators have been devised to form the basis for regular reporting to the Health Assembly on performance and overall progress over a two-year reporting period. Each element in the strategy has a set of indicators measuring

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<sup>142</sup> Global Strategy and Plan of Action (24 May 2008), elements 4.1.b, 4.1.c and 6.3.d.

<sup>143</sup> Ibid., Appendix: Plan of Action Explanatory Notes, p. 22.

<sup>144</sup> Ibid., Appendix: Plan of Action Explanatory Notes, p. 22.

<sup>145</sup> Ibid., para. 44.

<sup>146</sup> Ibid., para. 43.

results with respect to its key objectives.<sup>147</sup> 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.

## **B. Reflecting the Right to Development Criteria in the IGWG Plan of Action**

88. The right to development criteria could augment existing IGWG actions, as well as form the basis for actions currently not included. Despite acknowledging the importance of meeting the health-related Millennium Development Goals, there is no explicit recognition of the right to development in either the Global Strategy or Plan of Action.<sup>148</sup> The Strategy includes several explicit references to other human rights, including as a founding principle, 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”.<sup>149</sup> The Strategy also explicitly recognizes the rights in the UDHR to share in scientific advancement and its benefits, and the author’s right to protection of moral and material interests.<sup>150</sup>

89. Certainly the Global Strategy and Plan of Action’s ambitions of ensuring innovation and access to medicines to treat diseases in developing countries could implicitly realize these rights. However there is no explicit recognition of these rights in the Plan of Action’s elements and actions. This omission contradicts structural criteria (b), which specifies that partnerships should draw on all relevant international human rights instruments in elaborating development strategies and monitoring and evaluation tools. The Plan of Action’s implicit recognition of the substantive content of the right to health and to share in scientific benefits is not an adequate substitute for the explicit inclusion of rights-based criteria.<sup>151</sup> Explicit rights-oriented language, actions and indicators should therefore be added to the Plan of Action.

90. For example, countries should be required to “take into account, where appropriate, the impact on public health and *the realization of the right to the highest attainable standard of health* when considering adopting or implementing more extensive intellectual property protection than is required by [TRIPS]”.<sup>152</sup> In accordance with criteria (m), countries should also be required to carry out systematic assessments of the impact on public health and realization of the right to health of TRIPS-plus intellectual property rights protection, by collecting data that should be disaggregated sufficiently to monitor the impacts on vulnerable population groups including the poor.

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<sup>147</sup> WHO Executive Board, “Global Strategy and Plan of Action – Proposed Progress Indicators,” EB 124/16 Add.1, 18 December 2008.

<sup>148</sup> Global Strategy and Plan of Action, (24 May 2008), para. 3.

<sup>149</sup> Ibid., para. 16.

<sup>150</sup> Ibid., para. 10.

<sup>151</sup> See Tarantola et al., p. 13.

<sup>152</sup> Global Strategy and Plan of Action, (24 May 2008), elements 5.2.b.

91. Similarly, the element on monitoring should be amended to require WHO to continue to monitor, from both a public health and right to health perspective, the impact of intellectual property rights on development and access to health care products.<sup>153</sup>

92. The Plan of Action should also include an explicit indicator aimed at realizing access to essential medicines in fulfillment of the right to health. A suitable indicator based on recommendations made by the WHO and recent scholarship would assess whether access to essential medicines or technologies as part of the fulfillment of the right to health, is recognized in the constitution or national legislation,<sup>154</sup> paying particular attention to the needs of poor and disadvantaged individuals, communities and populations, and to gender-related issues.<sup>155</sup> This indicator should similarly form part of the right to development criteria for realizing MDG8E.

93. A similar indicator should be used to assess whether access to essential medicines or technologies as part of the fulfillment of the right to health, is recognized in a state's international development policies related to public health, innovation and intellectual property rights, paying particular attention to the needs of poor and disadvantaged individuals, communities and populations, and to gender-related issues.

94. In accordance with right to development criteria (j), the Plan of Action should seek to involve groups and communities in developing countries in elaborating, implementing and evaluating progress with IGWG by domestic governments. Thus, "concerned communities" should be engaged by WHO as relevant stakeholders in establishing systems to monitor performance and progress of the implementation of each element of the Strategy and Plan of Action.<sup>156</sup> Concerned communities should also be included as relevant stakeholders in monitoring the impact of intellectual property rights on the development and access to health care products.<sup>157</sup>

95. The work of the former UN Special Rapporteur on the Right to Health in formulating human rights guidelines for pharmaceutical companies should be utilized in this respect, with pharmaceutical companies required to "integrate human rights, including the right to the highest attainable standard of health, into their strategies, policies, programs, projects and activities".<sup>158</sup>

96. A list setting out these revised criteria is attached as annex 2.

### **C. Lessons from IGWG for Refining Right to Development Criteria for MDG8E**

97. The IGWG Global Strategy specifies several actions that could be used to refine right to development criteria measuring compliance with MDG8E's goal to "in cooperation with

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<sup>153</sup> Global Strategy and Plan of Action, (24 May 2008), element 8.1.c.

<sup>154</sup> WHO, "Medium-Term Strategic Plan 2008-2013". This indicator is also recommended in Gunilla Backman et al., "Health Systems and the Right to Health: An Assessment of 194 Countries", (2008) *The Lancet* 372: 2047-85, 2057.

<sup>155</sup> This formulation is taken from United Nations General Assembly, *The Right to Health - Note by the Secretary-General: Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Annex: Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines*, UN. Doc. A/63/263, 11 August 2008, guideline 5.

<sup>156</sup> Global Strategy and Plan of Action, (24 May 2008), element 8.1.a.

<sup>157</sup> *Ibid.*, element 8.1.c.

<sup>158</sup> *Human Rights Guidelines for Pharmaceutical Companies* (11 August 2008), guideline 2.

pharmaceutical companies, provide access to affordable essential drugs in developing countries".<sup>159</sup> The original indicator for this target required consideration of the "proportion of the population with access to affordable essential drugs on a sustainable basis".<sup>160</sup> The Millennium Gap Task Force has recommended an additional ten indicators at the national and global level to achieve this goal, many of which are reflected in the IGWG Strategy's recommended actions.<sup>161</sup> Areas of overlap include eliminating taxes and duties on essential medicines, ensuring adequate availability of essential medicines in public health care facilities, monitoring medicine prices and availability, reducing trade and distribution markups on essential drug prices, encouraging differential pricing practices, promoting generic production and uptake, and increasing R&D funding for developing country diseases.

98. The IGWG Global Strategy provides additional criteria that could be used to refine the MDG8E indicators aimed at assuring affordability and innovation including:

- (a) adapting national legislation to use TRIPS flexibilities to the full, including those recognized by the Doha Declaration and WTO decision of 30 August 2003;
- (b) exporting pharmaceutical products to countries with insufficient or no manufacturing capacity in the pharmaceutical sector;
- (c) increasing overall R&D on diseases prevalent in developing countries, leading to the development of good quality, affordable and available products;
- (d) promoting the generation, transfer, acquisition and voluntary sharing of new knowledge and technologies to develop new health products and medical devices to tackle the health problems of developing countries.<sup>162</sup>

99. Given the vagueness of the IGWG indicator on TRIPS-plus agreements, the earlier CIPIH recommendation should instead be used, namely: countries concluding bilateral trade agreements should not seek to incorporate TRIPS-plus protection in ways that may reduce access to medicines in developing countries.

100. A list of IGWG criteria revised in accordance with the right to health and development is attached as annex 3.

#### IV CONCLUSION

101. The IGWG process is the first global cooperative initiative aimed at reforming a global system of medical research and development that has largely failed to meet the needs of people in developing countries.<sup>163</sup> The intergovernmental working group and negotiated final GSPA are seen as milestones in global policy relating to public health and intellectual property rights, at

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<sup>159</sup> Millennium Development Goal 8, Target 17.

<sup>160</sup> *Ibid.*, Indicator 48.

<sup>161</sup> Millennium Development Goal Task Force, "Delivering on the Global Partnership for Achieving the Millennium Development Goals", MDG Gap Task Force Report 2008, (New York, United Nations, 2008), p. 33-34.

<sup>162</sup> Global Strategy and Plan of Action (24 May 2008), elements 5.2.a, 5.2.d, 1.2.e. and 2.2.g.

<sup>163</sup> K. Satyanarayana and S. Srivastava, "The Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG) – The Way Ahead", (2008) 128 *Indian J. of Med. Res.* 577, 579.

least as important as the Doha Declaration.<sup>164</sup> The endorsement of the GSPA by all 193 Member States of the WHO suggests its potential to advance global cooperation in relation to innovation of and access to health products for disease prevalent in developing countries. The GSPA may also protect developing countries seeking to use TRIPS and Doha compliant measures such as compulsory licensing to ensure access to affordable medicines.

102. The GSPA may also serve an important normative function in global and domestic law and policy relating to medicines access. Certainly the seriousness with which delegations treated its negotiations seems to reflect a sense that its provisions could have a powerful influence as a political document.<sup>165</sup> Indeed members of the IGWG Secretariat reported that Member States treated IGWG 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.<sup>166</sup> Delegations evidently realized that they were not drafting a simple technical WHO document.<sup>167</sup>

103. The GSPA does include potentially powerful elements capable of contributing to the realization of the right to development and health. The 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 GSPA by all 193 Member States of the WHO.

104. Yet, the Strategy's failures are equally important. The GSPA's utility for enabling policy supportive of public health may have important functional limitations, as its failure to caution against TRIPS-plus measures suggests. The Strategy's deletion of acknowledgement of global responsibilities for funding is similarly problematic. Moreover the language of many of the actions is very vague, and as one interviewee who participated in the negotiations suggests, while IGWG may have advanced new thinking on this topic, it may have been at the expense of achieving concrete results.<sup>168</sup>

105. Ultimately, the Strategy and Plan of Action's success 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 GSPA contributes 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.

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<sup>164</sup> See for example, William New, "WHO Adopts 'Most Important Document Since Doha' on IP and Public Health," IP-Watch, 29 May 2008: <http://www.ip-watch.org/weblog> (quoting a leading developing country negotiator).

<sup>165</sup> See also Kaitlin Mara and William New, "WHO IP and Health Group Concludes with Progress; Tough Issues Remain for Assembly", 6 May 2008, [www.ip-watch.org](http://www.ip-watch.org)

<sup>166</sup> Interview with German Velasquez, 20 February 2009.

<sup>167</sup> Ibid.

<sup>168</sup> Interview with Joanne Hamilton, 19 February 2009.

## LIST OF ACRONYMS

CIPIH	Commission on Intellectual Property Rights, Innovation and Public Health
FTA	Free Trade Agreements
GSPA	Global Strategy and Plan of Action
ICESCR	International Covenant on Economic, Social and Cultural Rights
IGWG	Intergovernmental Working Group on Public Health, Innovation and Intellectual Property
MDG	Millennium Development Goals
NGO	nongovernmental organization
OECD	Organization for Economic Cooperation and Development
R&D	research and development
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UDHR	Universal Declaration of Human Rights
UNCTAD	United Nations Conference on Trade and Development
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organizations

**Annex I: Application of Right to Development Criteria to the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property Global Strategy and Plan of Action**

**Key: Elements of the Global Strategy and Plan of Action**

- Element 1 - Prioritizing Research and Development Needs
- Element 2 - Promoting Research and Development
- Element 3 - Building and Improving Innovative Capacity
- Element 4 - Transfer of Technology
- Element 5 - Application and Management of Intellectual Property Rights to Contribute to Innovation and Promote Public Health
- Element 6 - Improving Delivery and Access
- Element 7 - Promoting Sustainable Financing Mechanisms
- Element 8 - Establishing Monitoring and Reporting Systems

*Structural criteria/ obligations*

<b>Current formulation of process criteria (A/HRC/8/WG.2/TF/2, 31 January 2008, Annex II): “The extent to which a partnership...”</b>	<b>Elements of the Global Strategy and Plan of Action relevant to this criterion</b>
a) Contributes to creating an enabling environment for sustainable development and the realization of all human rights	Elements 1-8
(b) Draws on all relevant international human rights instruments, including those relating to the RTD, in elaborating the content of development strategies and tools for monitoring and evaluating their implementation	Global Strategy, paras. 3; 10; 16
(c) Promotes good governance, democracy and the rule of law and effective anti-corruption measures at the national and international levels	Not applicable
(d) Follows a human rights-based approach to development, and integrates the principles of equality, non-discrimination, participation, transparency, and accountability in its development strategies	Accountability- Element 8 See discussion infra section three
(e) Establishes priorities that are	Elements 1-8 but no disaggregation

responsive to the needs of the most vulnerable and marginalized segments of the population, with positive measures to realize their human rights	within countries
(f) Recognizes mutual and reciprocal responsibilities among the partners, taking into account their respective capacities and resources and the special vulnerability of Least Developed Countries	Element 8 – Monitoring and Reporting Element 6.1.b – develop mechanisms in LDC to improve access to medicines
(g) Ensures that human rights obligations are respected in all aspects of the relationship between the partners, through harmonization of policies	Element 5.1.g-promote health representative participation in intellectual property related negotiations Element 5.2.b-take into account public health impact when adopting TRIPS-plus intellectual property protection

*Process criteria/obligations*

<b>Current formulation of process criteria (A/HRC/8/WG.2/TF/2, 31 January 2008, Annex II): “The extent to which a partnership...”</b>	<b>Elements of the Global Strategy and Plan of Action relevant to this criterion</b>
(h) Ensures that adequate information is freely available to enable effective public scrutiny of its policies, working methods and outcomes	Element 8 – Monitoring and Reporting IGWG documentation publicly accessible on <a href="http://www.who.int">http://www.who.int</a>
(i) Promotes gender equality and the rights of women	No explicit gender-related provisions
(j) Provides for the meaningful consultation and participation of all stakeholders, including affected populations and their representatives, as well as relevant civil society groups and experts, in processes of elaborating, implementing and evaluating development policies, programmes and projects	Element 8 – Monitoring and Reporting
(k) Respects the right of each state to determine its own development policies in accordance with international law, and	Element 2 – Promoting Research and Development Element 3-Building and Improving

the role of national parliaments to review and approve such policies	Innovative Capacity Element 4 – Transfer of Technology Element 5 – Application and Management of Intellectual Property
(l) Includes fair institutionalized mechanisms of mutual accountability and review, through which the fulfillment by all partners of their agreed commitments is monitored and publicly reported, responsibility for action is indicated, and effective remedies are provided	Element 8 - Monitoring and Reporting
(m) Monitors and evaluates progress in achieving development strategies by carrying out systematic assessments of the human rights impact of its policies and projects based on appropriate indicators and contributes to strengthening the capacity to collect and disseminate timely data, which should be disaggregated sufficiently to monitor the impacts on vulnerable population groups and the poor	Element 5.2.b-take public health impact into account when adopting TRIPS-plus intellectual property Element 8.1.c-monitor the impact of intellectual property rights from a public health perspective

*Outcome criteria/ obligations*

<b>Current formulation of outcome criteria (A/HRC/8/WG.2/TF/2, January 31, 2008, Annex II): “The extent to which a partnership...”</b>	<b>Elements of the Global Strategy and Plan of Action relevant to this criterion</b>
(n) Ensures that developing countries, through their own efforts and through international assistance and cooperation, have the human and financial resources to implement successfully development strategies based on these criteria;	Elements 2 – 7
(o) Establishes, as needed, safety nets, to provide for the needs of vulnerable populations in time of natural, financial or other crisis	Not applicable
(p) Achieves the constant improvement of the well-being of populations and all	Elements 1-8

<p>individuals, on the basis of their active, free, and meaningful participation in development and in the fair distribution of the benefits, in accordance with article 2, paragraph 3, of the Declaration on the Right to Development</p>	
<p>(q) Contributes to development that is sustainable and equitable, with a view to ensuring continually increasing opportunities for all and a fair distribution of resources</p>	<p>Elements 1-8</p>

## **ANNEX II: Revising the Plan of Action According to Right to Development Criteria**

### *Element 5 – Application and Management of Intellectual Property*

1. *Revised element 5.2.b* - Countries should take into account, where appropriate, the impact on public health and the realization of the right to the highest attainable standard of health when considering adopting or implementing more extensive intellectual property protection than is required by [TRIPS].
2. *New element 5.2.b.bis* - Countries should carry out systematic assessments of the impact on public health and realization of the right to health of TRIPS-plus intellectual property rights protection, by collecting data that should be disaggregated sufficiently to monitor the impacts on vulnerable population groups and the poor.

### *Element 6 – Delivery and Access*

3. *New element* - Ensure that access to essential medicines or technologies as part of the fulfillment of the right to health, is recognized in the constitution or national legislation, paying particular attention to the needs of poor and disadvantaged individuals, communities and populations, and to gender-related issues.
4. *New element* - Ensure that access to essential medicines or technologies as part of the fulfillment of the right to health, is recognized in a state's international development policies related to public health, innovation and intellectual property rights, paying particular attention to the needs of poor and disadvantaged individuals, communities and populations, and to gender-related issues.

### *Element 8- Monitoring and Reporting*

5. *Revised 8.1.c* - WHO should continue to monitor, from a public health *and right to health* perspective, the impact of intellectual property rights on development and access to health care products.
6. *Revised 8.1.a* – add “concerned communities” as relevant stakeholders in establishing systems to monitor performance and progress in implementation of the Strategy and Plan of Action.
7. *Revised 8.1.c* - add “concerned communities” as relevant stakeholders in monitoring the impact of intellectual property rights on the development and access to health care products.

### *New Element*

8. Require pharmaceutical companies to integrate human rights, including the right to the highest attainable standard of health, into their strategies, policies, programs, projects and activities.

**ANNEX III: Right to Development Sub-Criteria for Measuring MDG8E**

1. The extent to which countries adapt national legislation to use TRIPS flexibilities to the full, including those recognized by the Doha Declaration and WTO decision of 30 August 2003.
2. The extent to which countries promote generic production and uptake (including generic substitution policies on essential medicines).
3. The extent to which countries update national policy on medicines.
4. The extent to which countries update the national list of medicines.
5. The extent to which countries seek to reduce trade and distribution markups on essential drug prices.
6. The extent to which countries regularly monitor medicine prices and availability.
7. The extent to which countries seek to eliminate taxes and duties on essential medicines.
8. The extent to which countries promote the generation, transfer, acquisition and voluntary sharing of new knowledge and technologies to develop new health products and medical devices to tackle the health problems of developing countries.
9. The extent to which countries ensure adequate availability of essential medicines in public health care facilities.
10. The extent to which countries encourage pharmaceutical companies to apply differential pricing practices.
11. The extent to which countries increase R&D funding for developing country diseases.
12. The extent to which countries increase overall R&D on developing country disease leading to the development of good quality, affordable and available products.
13. The extent to which countries export pharmaceutical products to countries with insufficient or no manufacturing capacity in the pharmaceutical sector.
14. The extent to which countries concluding bilateral trade agreements do not incorporate TRIPS-plus protection in ways that may reduce access to medicines in developing countries.
15. The extent to which countries ensure that access to essential medicines or technologies as part of the fulfillment of the right to health, is recognized in the constitution or national legislation, paying particular attention to the needs of poor and disadvantaged individuals, communities and populations, and to gender-related issues.
16. The extent to which countries ensure that access to essential medicines or technologies as part of the fulfillment of the right to health, is recognized in their international development

policies related to public health, innovation and intellectual property rights, paying particular attention to the needs of poor and disadvantaged individuals, communities and populations, and to gender-related issues.

**ANNEX IV: List of Interviewees, Geneva, 18-20 February 2009**

1. Elil Renganathan - Executive Secretary, WHO Secretariat on Public Health, Innovation and Intellectual Property, (three meetings).
2. Precious Matsoso - Director, Public Health Innovation and Intellectual Property (two meetings).
3. Hans Hogerzeil - WHO Department of Essential Medicines and Pharmaceutical Policies .
4. Helen Nygren Krug - WHO Department of Ethics, Trade, Health and Human Rights Law.
5. Joanne Hamilton - WHO Department of Ethics, Trade, Health and Human Rights Law.
6. Benedikte Dal - WHO Department of Ethics, Trade, Health and Human Rights Law.
7. Dennis Daumere - WHO Department of Neglected Tropical Disease.
8. German Velasquez - Director, WHO Secretariat on Public Health, Innovation and Intellectual Property.