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INTERGOVERNMENTAL WORKING GROUP ON PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY: CURRENT STATUS

Introduction

1. Access to essential medicines is one of the principal challenges facing public health in the Americas. The innovation-development-access cycle is inadequately meeting the needs of millions of people in our Region. Discussions surrounding the work of the Intergovernmental Working Group on Public Health, Innovation, and Intellectual Property (IGWG) have emphasized the interest of stakeholders in finding just, sustainable, and feasible solutions.

Background

2. The IGWG's origins lie in the Doha Ministerial Declaration on the TRIPS Agreement and Public Health, adopted in November 2001,¹ and in discussions on the implementation of paragraph 6 of the declaration² in tandem with consecutive World Health Assembly resolutions WHA54.11³ and WHA55.14.⁴ In May 2003, through resolution WHA56.27, the World Health Assembly created the Commission on Intellectual Property Rights, Innovation, and Public Health (CIPIH) with a mandate to:

¹ "Declaration on the TRIPS Agreement and Public Health," 14 November 2001, WT/MIN(01)/DEC/2. TRIPS is the Trade-Related Aspects of Intellectual Property Rights.

² Paragraph 6 of WT/MIN(01)/DEC/2 states: "We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002."

³ World Health Organization, 54th World Health Assembly, WHA54.11, agenda item 13.8, 21 May 2001, "WHO Medicines Strategy."

⁴ World Health Organization, 55th World Health Assembly, WHA55.14, agenda item 13.8, 18 May 2002, "Ensuring Accessibility of Essential Medicines."

- Produce an analysis of intellectual property rights, innovation, and public health, including the question of appropriate funding and incentive mechanisms for the creation of new medicines and other products against diseases that disproportionately affect developing countries.⁵
3. The CIPIH was established by the Director of the WHO in February 2004.
 4. The CIPIH report, which was the product of a series of workshops, public consultations, and sectoral studies, was presented at the end of 2005 and published in 2006. It covered the complete cycle, from innovation to development to access, pertaining to medicines and other health products and evaluated the main obstacles and challenges throughout the cycle. It contains recommendations and suggestions for action in each of the main stages identified.⁶
 5. The Governing Bodies of the Pan American Health Organization have issued various declarations on the subject of intellectual property and access to medicines, notably resolutions CD45.R7⁷ and CD45.R10⁸ of 2004. Also relevant are resolution CD46.R15 of 2005,⁹ an integral part of the fight against HIV/AIDS in the period 2006–2015, and resolution CD47.R7 of 2006¹⁰ on public health, health research, and production and access to essential medicines.

Creation of the IGWG

6. The IGWG was created following a recommendation by the CIPIH and was endorsed by the World Health Assembly through resolution WHA59.24 in April 2006. The resolution recognizes that one of the objectives of the IGWG is to draw up “a global strategy and plan of action in order to provide a medium-term framework based on the

⁵ World Health Organization, 56th World Health Assembly, WHA56.27, agenda item 14.9, 28 May 2003, “Intellectual Property Rights, Innovation, and Public Health.”

⁶ Specifically: discovery, development, distribution, and promotion of innovation in developing countries.

⁷ 45th Directing Council, 56th session of the Regional Committee, Washington, DC, 27 September–1 October 2004, Resolution CD45.R7, “Access to Medicines.”

⁸ 45th Directing Council, 56th session of the Regional Committee, Washington, DC, 27 September–1 October 2004, Resolution CD45.R10, “Scaling-up of Treatment within a Comprehensive Response to HIV/AIDS.”

⁹ 46th Directing Council, 57th Session of the Regional Committee, Washington, DC, 26–30 September 2005, Resolution CD46.R15, “Regional Strategic Plan for HIV/AIDS/STI, 2006–2015, of the Pan American Health Organization.”

¹⁰ 47th Directing Council, 58th Session of the Regional Committee, Washington, DC, 25–29 September 2006, Resolution CD47.R7, “Public Health, Health Research, Production and Access to Essential Medicines.”

recommendations of the Commission.”¹¹ Resolution WHA60.30, adopted the following year, ratified and expanded this mandate.¹² The main challenges recognized by the CIPIH and taken up by the IGWG include the need to harmonize public health objectives and the economic determinants of scientific innovation throughout the health innovation cycle, and obstacles to the dissemination of scientific advances among the most disadvantaged populations.

First Session of the IGWG, December 2006

7. The first work session of the IGWG was held from 4 to 8 December 2006. In preparing a draft plan of action, the gathering considered six strategic elements: prioritizing research and development needs; promoting research and development of new drugs; building innovative capacity; improving delivery and access; ensuring sustainable financing mechanisms; and establishing reliable monitoring and reporting systems. At the request of the Member States, technology transfer and the management of intellectual property rights were added as elements.¹³ Five countries of the Region--Argentina, Bolivia, Brazil, Colombia, and the United States of America--sent comments and suggestions to the meeting.

8. Drawing on an initial document containing the CIPIH recommendations and on the discussions of the first IGWG session, the Secretariat published a first draft of a Global Strategy and Plan of Action on 31 July 2007.¹⁴ This document was considered in a series of regional consultations.

Second Session of the IGWG, November 2007

9. Held from 5 to 10 November 2007, there was broader participation in the second work session than the first, with nearly 100 accredited state delegations in attendance and a substantial presence of civil society organizations. The meeting focused on the Draft Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property prepared by the IGWG Secretariat, incorporating the comments and suggestions for modifications received after the first session. The second session was suspended with

¹¹ World Health Organization, 59th World Health Assembly, WHA56.27, WHA59.24, “Public Health, Innovation, Essential Health Research and Intellectual Property Rights: Towards a Global Strategy and Plan of Action,” ninth plenary session, 27 May 2006, Commission A, sixth report.

¹² World Health Organization, 60th World Health Assembly, WHA60.30, agenda item 12.20, 23 May 2007, “Public Health, Innovation, and Intellectual Property.”

¹³ World Health Organization, “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.

¹⁴ World Health Organization, Intergovernmental Working Group on Public Health, Innovation, and Intellectual Property, second session, provisional agenda item 3, “Draft Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property: Report by the Secretariat,” A/PHI/IGWG/2/2.

a commitment to resume it after the Secretariat published a document based on the discussions held up to that point.¹⁵

Continuation of the Second Session

10. The IGWG resumed the second session from 17 to 19 March 2008. A working subgroup arising from Drafting Group B discussed elements 1 and 2 of the Plan of Action, focusing on progress indicators, stakeholders, and time frames. The gathering set the dates of 28 April to 3 May 2008 for completion of the Global Strategy and Plan of Action. Six countries of the Region (Brazil, Colombia, Costa Rica, Cuba, Nicaragua, and Paraguay) had previously submitted proposals for changes to the text. During the session Bolivia orally transmitted a proposed change in the Plan of Action that the Secretariat admitted as a contribution. A joint proposal by Barbados and Bolivia, submitted shortly before the beginning of the discussions on the strategy, was admitted as a working document and distributed to the participants.

11. The Region had a high profile in the renewed discussions, especially in negotiations on the Strategy, with 11 state delegations and a representative of a subregional organization participating. The contribution of the Americas to the debate was widely recognized. The discussions concluded with almost total consensus (on five of the eight elements) on the Global Strategy document.¹⁶ Several parts of the Plan of Action¹⁷ remained to be finalized by the PHI Secretariat. Notable points of agreement included the need to take advantage of TRIPS flexibilities to increase access to medicines and the need to promote innovation based on traditional healing.

The IGWG in the 61st World Health Assembly

12. The IGWG concluded the negotiations between 19 and 24 May 2008. After several days of meetings held simultaneously with the Assembly sessions, the working group reached a consensus on the 18 paragraphs that had been left unresolved in the Global Strategy. Nine delegations from the Region sent staff members for the monitoring and conclusion of the discussions.

¹⁵ World Health Organization, Intergovernmental Working Group on Public Health, Innovation, and Intellectual Property, second session, agenda item 3, “Draft Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property: Progress to Date in Drafting Groups A and B,” A/PHI/IGWG/2/Conf.Paper No. 1 Rev. 1.

¹⁶ “IGWG: Outcome Document at 14.00 hours, Saturday 3 May 2008: Draft Global Strategy on Public Health, Innovation and Intellectual Property,” white paper advance copy, http://www.who.int/phi/documents/IGWG_Outcome_document03Maypm.pdf.

¹⁷ “Draft Plan of Action: Chair’s Text,” white paper advance copy, status 3 May 2008, <http://www.who.int/phi/documents/POAWhitePaper.pdf>.

13. The Global Strategy as finally approved contains a series of specific recommendations and actions for the medium term. It calls for policies to protect and promote competition to prevent the abuse of intellectual property rights and to evaluate the public health needs of developing countries. It likewise includes recommendations to increase technology transfer and improve access to all health products.

14. A resolution was adopted to guide implementation of the Strategy, as well as subsequent work on the Plan of Action that will be analyzed by the Executive Board in January 2009. The resolution adopts the Global Strategy and those parts of the Plan of Action on which consensus was reached. It calls on the Director-General to provide support to Member States, upon request, in implementing the Global Strategy and the elements of the Plan of Action on which a consensus was reached.¹⁸

15. The Plan of Action still contains paragraphs on which a consensus has not been reached. The parts of the plan concerning time frames, indicators, and funding needs will be resolved by the Secretariat with input from countries for presentation at the 62nd World Health Assembly. The resolution also calls for a working group made up of independent experts to evaluate potential sustainable financing mechanisms for the development of new medicines.¹⁹

The IGWG in the Region

16. The regional consultation mechanism provided for in resolution WHA60.30 was especially significant for the Region of the Americas. The consultations began with an informative session for diplomatic delegations based in Washington, D.C., on 18 June 2007. At this session, held at PAHO Headquarters, several of the countries that had made contributions to the first IGWG session shared their proposals. Staff from the IGWG Secretariat and PAHO reported on the process and subsequent stages.

17. Subregional meetings were organized in 2007 by the Bolivian government in La Paz on 22-24 August 2007 and by the Brazilian government in Rio de Janeiro on 3-5 September 2007. PAHO assisted, supported, and participated actively in both gatherings, with the collaboration of the Representative Offices and regional staff. These meetings produced what is known as the Rio Document, which reflected an emerging

¹⁸ World Health Organization, 61st World Health Assembly, WHA61.21, agenda item 11.6, 24 May 2008, "Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property."

¹⁹ Resolution WHA61.21, in 4(7), requests the Director-General "to establish urgently a results-oriented and time-limited expert working group to examine current financing and coordination of research and development, as well as proposals for new and innovative sources of funding to stimulate research and development related to Type II and Type III diseases and the specific research and development needs of developing countries in relation to Type I diseases, and open to consideration of proposals from Member States, and to submit a progress report to the Sixty-second World Health Assembly and the final report to the Sixty-third World Health Assembly through the Executive Board."

subregional consensus around a set of proposals offered as an alternative to the draft prepared by the IGWG Secretariat.²⁰

18. The progress of the working group was the subject of a special information session during the 27th Pan American Sanitary Conference.²¹ As a conclusion to the consultative process in the Americas, on 22–23 October 2007 PAHO, in collaboration with Health Canada, organized and facilitated a regional consultation on the IGWG for the Americas, with a majority of the Member States present.²² Finally, the Government of Suriname, in collaboration with civil society organizations and with PAHO support, organized a meeting in Paramaribo on 19–21 February 2008 to renew the work of the IGWG in the subregion. The meeting marked the full integration of the Caribbean countries into the regional dynamic of the IGWG.

PAHO and the IGWG in the Americas

19. PAHO has provided technical support for the IGWG negotiations in the Americas, putting the Organization's resources and experts at the disposal of the countries. It has also given priority to the dissemination of detailed information on all stages and results of the process to the diplomatic delegations based in Washington, to national staff involved in the deliberations, and to the PAHO Representative Offices in the countries. At the same time, it has made efforts to get other sectors involved in the discussion, taking advantage of meetings and seminars that are related to the subject in some way.²³ It has facilitated dialogue and identified common interests in the Region to develop a regional perspective on this global problem. The IGWG process has been spearheaded by the countries. Several Member States have shown great interest in seeking solutions to the challenges posed, among other things, by the obstacles to innovation and the difficulties accessing medicines. Their involvement has strengthened the Organization's role as a facilitator and technical resource.

²⁰ "Subregional Meeting Consensus Document, Rio de Janeiro, Brazil, 3–5 September 2007," signed by Argentina, Brazil, Bolivia, Chile, Costa Rica, Cuba, Ecuador, El Salvador, Honduras, Mexico, Peru, Suriname, Uruguay, and Venezuela, http://www.who.int/phi/public_hearings/second/regional_consultations/Sub-regional_Consensus_Document.pdf. The group of signatory countries has changed since the date of the document; these are the original signers.

²¹ 59th Session of the Regional Committee.

²² See AMRO/PAHO, Regional Consultation on Public Health, Innovation and Intellectual Property, Ottawa, Canada, 22–23 October 2007, "Ottawa Americas Regional IGWG Consultation: Additions and Modifications to A/PHI/IGWG/2/, Issues considered: Context, Aims and Focus," http://www.who.int/phi/public_hearings/second/regional_consultations/RC_AMRO.pdf.

²³ These included, in particular, the Third International Course on Intellectual Property Rights and Public Health held in Buenos Aires in March 2008, and the First Latin American Conference on Research and Innovation for Health convened in Rio de Janeiro in April of the same year.

Implementation of the Global Strategy and Plan of Action

20. PAHO should continue collaborating with the process during its most critical stage, the implementation of the Global Strategy and Plan of Action. It can strengthen the activities under way to promote technological innovation, furnish advice on handling the matter of intellectual property rights from a public health standpoint, and improve public health systems in the Region. The work will now be guided by a consensus-based document, the product of two years of negotiations, with a broad range of specific actions to be carried out in a variety of areas in the medium term. This introduces new dimensions for the action of the Organization and Member States alike.

21. It is recommended that the Member States issue an explicit mandate so that PAHO, as the regional office of the World Health Organization, becomes the leading agency for implementation in the Americas of those parts of the Global Strategy and Plan of Action that recognize the Organization's steering role.

22. Together with the Member States, PAHO can contribute to the formulation of a regional perspective on the Global Strategy on Public Health, Innovation, and Intellectual Property, framed by and complementing the Global Strategy adopted by WHO. This will require dissemination of the Strategy so that the document can be endorsed by national authorities, subregional organizations, and other relevant actors as a new public health instrument.

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