



PAN AMERICAN HEALTH ORGANIZATION  
WORLD HEALTH ORGANIZATION



## **48th DIRECTING COUNCIL**

### **60th SESSION OF THE REGIONAL COMMITTEE**

*Washington, D.C., USA, 29 September-3 October 2008*

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*Provisional Agenda Item 4.14*

CD48/18 (Eng.)  
26 August 2008  
ORIGINAL: SPANISH

### **PUBLIC HEALTH, INNOVATION, AND INTELLECTUAL PROPERTY: A REGIONAL PERSPECTIVE**

#### **Introduction**

1. Drugs and pharmaceutical products are among the most important tools that public health systems have at their disposal to meet the challenges of the health situation. Ensuring timely access to these products with quality assurance for the population that needs them is one of the main challenges for any pharmaceutical policy. The obstacles that must be faced, however, cannot be understood in all their dimensions without considering the full cycle from discovery and development on up to consumption by the population, bearing in mind the many factors involved.

#### **Origins of the Intergovernmental Working Group**

2. Measures to protect intellectual property in the area of drugs and pharmaceutical products are an additional factor in a context marked by the persistence of diseases that disproportionately affect vulnerable populations in developing countries without an effective pharmacological response at accessible prices and under acceptable conditions.

3. Both the World Health Organization (WHO) and other international organizations have repeatedly underscored the pertinence of analyzing public health needs beyond the context of trade agreements and treaties, which can sometimes be interpreted in a way that limits production of particular drugs or access to them.<sup>1</sup> The [Doha Declaration](#)

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<sup>1</sup> See 52nd World Health Assembly Resolution WHA52.19 and its follow-up in the Report by the Secretariat [A53/10](#) "Revised Drug Strategy" of 13 March 2000 at: [http://ftp.who.int/gb/archive/pdf\\_files/WHA53/ea10.pdf](http://ftp.who.int/gb/archive/pdf_files/WHA53/ea10.pdf) and 59th World Health Assembly Resolution [WHA59.26](#) "International Trade and Health" at: [http://www.who.int/gb/ebwha/pdf\\_files/WHA59/A59\\_R26-en.pdf](http://www.who.int/gb/ebwha/pdf_files/WHA59/A59_R26-en.pdf)

(November 2001) contains flexibilities in the application of the Agreement on Trade-Related Aspects of Intellectual Property Rights ([TRIPS](#)) to protect public health.<sup>2</sup>

4. The particular situation of countries that lack pharmaceutical production capacity of their own was the object of intense discussions that culminated in a decision by the World Health Assembly to convene a group of experts to study the principal factors and conflicting positions and suggest possible solutions.<sup>3</sup>

5. The results of the group's deliberations and analysis were expressed in a series of recommendations that include the creation of an Intergovernmental Working Group (IGWG) to discuss a medium-term Global Strategy on Public Health, Innovation, and Intellectual Property.<sup>4</sup>

6. From December 2006 to May 2008, the IGWG represented the greatest global effort to date to find the solution and response to the limits and barriers of the discovery-development-innovation cycle for drugs, pharmaceuticals, and health products, an effort that involved a considerable number of governments and members of organized civil society, industry, academia, and other relevant stakeholders. After an extensive dialogue and negotiations, the process culminated in the approval, by consensus, of the Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property, contained in Resolution [WHA61.21](#) (May 2008).<sup>5</sup>

7. The Region of the Americas was the origin and scene of a substantive part of the discussions,<sup>6</sup> which benefited from the presence and technical assistance of PAHO and the pronouncements of its Governing Bodies.<sup>7</sup>

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<sup>2</sup> See 4th WTO Ministerial Conference, Doha, Qatar, 20 November 2001 [WT/MIN\(01\)/DEC/2 Declaration on the TRIPS Agreement and Public Health](#) at: [http://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.htm](http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm).

<sup>3</sup> See 56th World Health Assembly, 28 May 2003. Resolution [WHA56.27 Intellectual Property Rights, Innovation, and Public Health](#) [http://www.who.int/gb/ebwha/pdf\\_files/WHA56/ea56r27.pdf](http://www.who.int/gb/ebwha/pdf_files/WHA56/ea56r27.pdf)

<sup>4</sup> See [Public Health, Innovation and Intellectual Property Rights. Report of the Commission on Intellectual Property Rights, Innovation and Public Health](#) WHO, 2006 at <http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf>, 59th World Health Assembly, 25 May 2003 Resolution [WHA59.24 Public Health, Innovation, Essential Health Research, and Intellectual Property Rights: Towards a Global Strategy and Plan of Action](#) at: [http://www.who.int/gb/ebwha/pdf\\_files/WHA59/A59\\_R24-en.pdf](http://www.who.int/gb/ebwha/pdf_files/WHA59/A59_R24-en.pdf)

<sup>5</sup> 61st World Health Assembly Resolution [WHA61.21 Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property](#).

<sup>6</sup> See 142nd Session of the Executive Committee [CE142/INF/4 Intergovernmental Working Group on Public Health, Innovation and Intellectual Property: Current Status](#), paragraphs 7-14 *At the subregional level, it is important to point out the meetings held by the Government of Bolivia in La Paz from 22 to 24 August 2007 and by the Brazilian authorities in Rio de Janeiro from 3 to 5 September 2007. PAHO was present, actively supporting and assisting the two gatherings through the presence of the Representative Offices and regional officials. The fruit of these meetings was the Rio Document, which reflected a*

## Regional Context

8. The inequalities and inequities affecting the Region in the field of health, both among and within countries, are characteristic of a Hemisphere that, after a decade of stagnation, has seen significant improvements in some of its social and health indices, but where nevertheless, some population groups continue to suffer from exclusion and marginalization that limit their ability to access health goods and services.<sup>8</sup> Inequity remains a tremendous challenge to social cohesion and the economic viability of the Hemisphere:

*In 2004, 222 million people were listed as living in poverty; by 2006, that figure had fallen to 205 million. While in 2004, 96 million people were identified as living in extreme poverty or indigence, by 2006 the figure had dropped to 81 million. Nevertheless, inequity within the countries remains the Region's greatest challenge. Prospective studies using the Gini coefficient forecast that in 2015, the Americas will still be the world's most inequitable region.<sup>9</sup>*

9. The existence of diverse experiences in subregional customs integration, the presence of countries with certified, well-developed pharmaceutical production alongside countries with little productive capacity, the signing and implementation of several bilateral and multilateral free trade agreements, and the consolidation of efforts to harmonize health policies and coordinate pharmaceutical regulations demonstrate the importance to the Region of factors linked to the discovery, development, and access to drugs.<sup>10</sup>

10. The Region is also facing an epidemiological transition marked by the growing prevalence of noncommunicable diseases such as heart disease, diabetes, and cancer, added to the challenge of neglected diseases such as Chagas' disease and leishmaniasis,

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*subregional consensus on a set of alternative proposals to the draft prepared by the IGWG Secretariat.*  
See: <http://www.paho.org/english/gov/ce/ce142-INF4-e.pdf>

<sup>7</sup> In particular, see 47th Directing Council, 58th Session of the Regional Committee, 25-29 September 2006 [CD47/20 Report of the Commission on Intellectual Property Rights, Innovation and Public Health](http://www.paho.org/english/gov/cd/CD47-20-e.pdf) at <http://www.paho.org/english/gov/cd/CD47-20-e.pdf>, 47th Directing Council, 58th Session of the Regional Committee 25-29 September 2006. Resolution [CD47.R7 Public Health, Health Research, Production and Access to Essential Medicines](http://www.paho.org/english/gov/cd/CD47.r7-e.pdf) at <http://www.paho.org/english/gov/cd/CD47.r7-e.pdf>. The IGWG process in the Americas was also discussed in an informative session at the 27th Pan American Sanitary Conference, 59th Session of the Regional Committee, held from 1 to 5 October 2007.

<sup>8</sup> See PAHO report [Health in the Americas 2007](http://whocc.who.ch/bookorders/anglais/detart1.jsp?sesslan=1&codlan=1&codcol=61&codcch=622) Volume I PAHO Scientific Publication No. 622. pp. 32-37 at <http://whocc.who.ch/bookorders/anglais/detart1.jsp?sesslan=1&codlan=1&codcol=61&codcch=622>.

<sup>9</sup> 27th Pan American Sanitary Conference, 59th Session of the Regional Committee [CSP27/14 "Faces, Voices, and Places: A Community-based Response to the Millennium Development Goals. A Strategy from the Local to the Regional"](http://www.paho.org/english/gov/csp/csp27-14-e.pdf) at <http://www.paho.org/english/gov/csp/csp27-14-e.pdf>.

<sup>10</sup> [Health in the Americas 2007](http://whocc.who.ch/bookorders/anglais/detart1.jsp?sesslan=1&codlan=1&codcol=61&codcch=622). Op. Cit. at: <http://whocc.who.ch/bookorders/anglais/detart1.jsp?sesslan=1&codlan=1&codcol=61&codcch=622>.

along with other communicable diseases such as HIV/AIDS, malaria, and tuberculosis. The ability to have safe, accessible, effective drugs is a critical determinant of the authorities' potential response to the needs of their peoples.

11. The IGWG negotiations and discussions have therefore been especially intense in the Americas in terms of the level of participation and contributions and the involvement of relevant stakeholders. This intensity has translated into a fluid intraregional dialogue and the drafting of proposals that reflect concern and interest aroused in the connection between innovation and intellectual property<sup>11</sup> from a public health perspective.

### **Regional Adaptation of the Global Strategy**

12. Implementation of the various elements of the Strategy in the Region should take place within the mandates and policies stipulated in the [Regional Strategic Plan 2008-2012](#)<sup>12</sup> and the [Health Agenda for the Americas 2008-2017](#),<sup>13</sup> complemented with the relevant resolutions and mandates<sup>14</sup> already adopted by the Governing Bodies.

13. Resolution [WHA61.21](#) itself confirms and ratifies earlier mandates of the World Health Assembly on access to drugs, intellectual property, and the promotion of technological innovation.<sup>15</sup> The Directing Council and the Pan American Sanitary Conference have likewise focused attention on these issues in the regional context.<sup>16</sup> PAHO's commitment to achieving the Millennium Development Goals should be also

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<sup>11</sup> See [CE142/INF/4](#) op. cit. paragraphs 16-19, the *Rio Document*, at: <http://www.paho.org/english/gov/ce/ce142-INF4-e.pdf>

<sup>12</sup> See [CE142/DIV/3](#). Updated Strategic Plan. Official Document 328 at: [http://intranet.paho.org/DPM/PPS/Strategic\\_Plan0812\\_INTRANET-eng.doc](http://intranet.paho.org/DPM/PPS/Strategic_Plan0812_INTRANET-eng.doc)

<sup>13</sup> [Health Agenda for the Americas 2008-2017](#) Panama, 3 June 2007 at: [http://www.paho.org/English/DD/PIN/Health\\_Agenda.pdf](http://www.paho.org/English/DD/PIN/Health_Agenda.pdf)

<sup>14</sup> Especially CD45.R7 (2004) [Access to Medicines](#), CD45.R10 (2004) [Scaling-up of Treatment within a Comprehensive Response to HIV/AIDS](#), CD46.R15 (2005) [Regional Strategic Plan for HIV/AIDS/STI 2006-2015](#), CD.47.R7 (2006) [Public Health, Health Research, Production, and Access to Essential Medicines](#).

<sup>15</sup> 61st World Health Assembly [WHA61.21](#). [Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property Recalling Resolutions WHA49.14 and WHA52.19 on the Revised Drug Strategy, WHA53.14, WHA54.10 and WHA57.14 on HIV/AIDS, WHA56.27 on Intellectual Property Rights, Innovation, and Public Health, WHA58.34 on the Ministerial Summit on Health Research, WHA59.26 on International Trade and Health, and WHA60.30 on Public Health, Innovation and Intellectual Property](#) at [http://www.who.int/gb/ebwha/pdf\\_files/A61/A61\\_R21-en.pdf](http://www.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf).

<sup>16</sup> 46th Directing Council, 57th Session of the Regional Committee 26-30 September 2005 Resolution [CD46.R15](#) [Regional Strategic Plan for HIV/AIDS/STI, 2006-2015, of the Pan American Health Organization](#) at <http://www.paho.org/english/gov/cd/CD46.r15-e.pdf>, and 47th Directing Council, 58th Session of the Regional Committee, 25-29 September 2006 [CD47.R7](#) [Public Health, Health Research, Production, and Access to Essential Medicines](#) <http://www.paho.org/english/gov/cd/CD47.r7-e.pdf>.

mentioned and considered in the complementary and coherent development of a regional perspective aligned with global proposals.<sup>17</sup>

14. The strategic role of PAHO is acknowledged in Resolution WHA61.21, paragraph 15 under “The Principles:”

*Accordingly, the WHO shall play a strategic and central role in the relationship between public health and innovation and intellectual property within its mandates (including those contained in relevant WHA resolutions), capacities and constitutional objectives, bearing in mind those of other relevant intergovernmental organizations. In this context, the WHO, including the regional and, when appropriate, country offices, need to strengthen its institutional competencies and relevant programs in order to play its role in implementing this global strategy with its plan of action.<sup>18</sup>*

15. Crafting a regional perspective requires the reorganization and linkage of earlier developments, decisions, and mandates, in addition to a careful reading of the Global Strategy to identify all areas where activities are already under way and reinforce areas of action where additional interventions or more robust participation is necessary.

16. The objectives of the [Strategic Plan 2008-2012 for the Pan American Sanitary Bureau](#) include several whose anticipated activities and expected results are consistent with the proposals in the Global Strategy:<sup>19</sup>

<i>Strategic Objective 1</i>	To reduce the health, social, and economic burden of communicable diseases.
<i>Strategic Objective 2</i>	To combat HIV/AIDS, tuberculosis, and malaria
<i>Strategic Objective 10</i>	To improve the organization, management, and delivery of health services
<i>Strategic Objective 11</i>	To strengthen leadership, governance, and the evidence base of health systems
<i>Strategic Objective 12</i>	To ensure improved access, quality, and use of medical products and technologies
<i>Strategic Objective 15</i>	To provide leadership, strengthen governance, and foster partnerships and collaboration with Member States, the United Nations system, and other stakeholders to fulfill the mandate of PAHO/WHO in advancing the Global Health Agenda, as set forth in WHO’s Eleventh General Programme of Work and the Health Agenda for the Americas

<sup>17</sup> See [CSP27/14](#) and CD45.R7, CD45/8.

<sup>18</sup> Paragraph 15 Resolution [WHA61.21](#). [http://www.who.int/gb/ebwha/pdf\\_files/A61/A61\\_R21-en.pdf](http://www.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf)

<sup>19</sup> The objectives are coherently aligned with the objectives set forth in WHO’s 11th Programme of Work and endorsed in the Global Health Agenda.

17. The Health Agenda for the Americas 2008-2017, approved by all the PAHO Member States contains several areas of action that are closely linked to the Global Strategy for the Region.<sup>20</sup>

- a) Strengthening the national health authority
- c) Increasing social protection and access to quality health services
- d) Diminishing health inequalities among countries and inequities within them
- f) Strengthening the management and development of health workers
- g) Harnessing knowledge, science, and technology

18. Combining and implementing the two strategic documents will lead to regional adoption of the Global Strategy, integrating the indicators and expected results contained in the Strategic Plan and adhering to the Health Agenda's principles of inclusion, participation, and transparency.

19. Implementing the Strategy will demand an exhaustive effort to identify regional actors and capabilities in order to spell out responsibilities and expectations. The process should include the health authorities and the responsible officials from industry, trade, foreign affairs, science and technology, and the treasury or finance, as well as dependent institutions.

20. Parliaments and the legislative apparatus are the most appropriate mechanisms for assisting with the regulatory, legal, bureaucratic, and administrative changes necessary for translating political will into deeds. The judiciary and its various branches, especially the branch devoted to the awarding of patents, should be involved, and its personnel should receive training for a complete understanding of the Strategy.

21. Academia, the pharmaceutical industry (both innovative and generic), and organized civil society groups have a role to play in developing a regional perspective for the Global Strategy. Indigenous organizations, communities, and leaders and their representatives should be included in the process, so that their traditional knowledge, concerns, and demands become part of the regional perspective.

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<sup>20</sup> Paragraphs 32 (Investment in science and technology), 48. (Taking advantage of flexibilities in trade agreements), 61 (Challenges with respect to health workers) 64 (Facilities. Research coordination mechanisms) 65 (Use of evidence in decision-making) 68 (Bioethics) and 69 (Access to health education and information) of the Health Agenda for the Americas [http://www.paho.org/English/DD/PIN/Health\\_Agenda.pdf](http://www.paho.org/English/DD/PIN/Health_Agenda.pdf).

22. Moreover, PAHO's presence in each country and its close ties with the public authorities guarantee greater involvement in the dialogues and exchanges necessary for ensuring systematic participatory implementation, allowing it to serve as a facilitator for the different national, subregional, and regional stakeholders and initiatives.

### **Implementation**

23. The definition and construction of a regional perspective will serve as a guide and reference for gradual implementation, with a clear medium-term objective (2012) of the initial consolidation of dynamics and processes.<sup>21</sup> Implementation will be based largely on co-responsibility with the actors and stakeholders.

### ***Advocacy and the Dissemination of Information***

24. The construction of a regional perspective is largely based on empowering the national authorities, increasing their knowledge, use, and understanding of the [Global Strategy](#) and its Plan of Action. Thus, the dissemination of these instruments is essential.

25. Virtual tools for dialogue and meetings, as well as the Organization's new web-based communication strategy, will facilitate the sharing of information and the transmission of knowledge about the Strategy.

26. The objective is not only regional adaptation of the Strategy but development of the associated national and subregional capacity. Periodic meetings and distance education will create groups of multipliers who receive ongoing assistance and monitoring from the Organization.

27. Advantage will be taken of existing mechanisms and devices for information processing and the dissemination of best practices, as well as the current networks for knowledge transfer in the Region and worldwide, including the Collaborating Centers. The emphasis will be on communities of practice and use of the expertise locator as a way of boosting the efficiency and effectiveness of the activities.

### ***Facilitation of Regional and International Cooperation***

28. Cooperation among countries will be one of the key elements for implementation of the Strategy and the eventual construction of the regional perspective. The objective is to promote subregional leadership as a precursor and the driving force behind the exchange with other subregions and regions, if appropriate.

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<sup>21</sup> We understand "dynamics" as institutional reforms, legal amendments, budget allotments, and the design of policies, activities, and programs. We understand "processes" as information exchange, systematic exercises in cooperation and the dissemination of information and knowledge, and the standardized, regulated operations of information networks.

29. PAHO will support and monitor cooperation activities with a view to identifying best practices and replicating experiences whenever possible, both regionally and globally.

30. Maximum interagency collaboration with United Nations agencies (UNDP, UNAIDS, etc.), agencies of the Inter-American System (Inter-American Development Bank, OAS, LAIA, LAES), and the international financial institutions (World Bank, Global Fund, GAVI) is essential for developing an Inter-American vision of the Strategy and its effective implementation.

### ***Regional Implementation Mechanisms***

31. For this purpose, the suitability of regional implementation and coordination mechanisms as permanent platforms or forums will be evaluated.

32. Support will be provided for the creation of a regional platform comprised of a broad-based, geographically balanced group of representatives from the health sector, academia, civil society, industry, and other stakeholders. Its composition and operations will reflect the need to set regional and subregional priorities in the area of innovation, access, and intellectual property. Stakeholders and entities that are important for the implementation of the Strategy will also be identified, facilitating interinstitutional interaction and consensus. Implementation of the Strategy in the Region will also be monitored and followed up to ensure its coherence and continuity and thereby optimize resources and programs.

33. PAHO will serve as the technical coordinator of this platform, advised by expert committees and professionals who will meet on a regular basis, in order to contribute to the drafting of an agenda of priorities in innovation, develop information handling and management strategies, and coordinate interaction with the various regional and supraregional networks, dealing with relevant aspects of the regional perspective for the Global Strategy.

34. Implementation of the Strategy and the consolidation of a regional perspective should contribute to the design and adoption of evidence-based policies, actions, and programs grounded in ethical principles that consider not only the estimated impact but the anticipated costs as well.

### ***Financing***

35. Political support for the regional perspective should be coupled with the mobilization of resources and complemented with impact assessment indicators for the measures, actions, and programs. PAHO can coordinate specific agreements between financing agencies and the receiving countries, following the guidelines of the Paris



Convention and the Monterey Conference on Financing for Development, and consider the priorities set by the Member States in the Strategic Plan.

36. PAHO will maintain an open consultative process among the stakeholders to facilitate additional priority setting, based on the resources mobilized for developing the regional perspective.

**Action by the Directing Council**

37. Once it has examined the document, the Directing Council is requested to consider the recommendations contained in the proposed resolution (see Annex B).

Annexes



**PAN AMERICAN HEALTH ORGANIZATION**  
*Pan American Sanitary Bureau, Regional Office of the*  
**WORLD HEALTH ORGANIZATION**

CD48/18 (Eng.)  
Annex A

**ANALYTICAL FORM TO LINK AGENDA ITEM WITH ORGANIZATIONAL AREAS**

**1. Agenda Item:** 4.14

**2. Agenda Title:** Public Health, Innovation, and Intellectual Property: A Regional Perspective

**3. Responsible Unit:** Essential Drugs and Biologicals.  
Technology, Health Care, and Research Area

**4. Preparing Officer:** Jaume Vidal

**5. List of collaborating centers and national institutions linked to this Agenda item:**

Ministries of health of all the Member States (and observers)  
 Institutes and Schools of Public Health;  
 Country Intellectual Property Offices;  
 Departments of Science and Technology;  
Health Sciences Information (BIREME), São Paulo, Brazil  
 Oswaldo Cruz Foundation (FIOCRUZ), Rio de Janeiro, Brazil  
 University of Toronto, Toronto, Canada  
 Interdisciplinary Center for Bioethics Studies, University of Chile (CIEB), Santiago, Chile, Chile  
 University of Buenos Aires (UBA), Buenos Aires, Argentina  
 Carlos III Health Institute, Madrid, Spain  
 National Institutes of Health, Office of Technology Transfer, Rockville, United States

**6. Link between Agenda item and Health Agenda for the Americas:**

- a) Strengthening the National Health Authority
- c) Increasing Social Protection and Access to Quality Health Services
- d) Diminishing Health Inequalities among the Countries and Inequities within Them
- f) Strengthening the Management and Development of Health Workers
- g) Harnessing Knowledge, Science, and Technology

**7. Link between Agenda item and Strategic Plan 2008-2012:**

Strategic Objective 1. To reduce the health, social, and economic burden of communicable diseases.  
Strategic Objective 2. To combat HIV/AIDS, tuberculosis, and malaria  
Strategic Objective 10. To improve the organization, management, and delivery of health services  
Strategic Objective 11 To strengthen leadership, governance, and the evidence base of health systems  
Strategic Objective 12 To ensure improved access, quality, and use of medical products and technologies  
Strategic Objective 15 To provide leadership, strengthen governance, and foster partnerships and collaboration with Member States, the United Nations system, and other stakeholders to fulfill the mandate of PAHO/WHO in advancing the global health agenda, as set out in WHO's Eleventh General Programme of Work, and the Health Agenda for the Americas

**8. Best practices in this area and examples from other countries within AMRO:**

Regional Program. Millennium Development Goals. Framework Convention on Tobacco Control.  
 Examples from other the countries: Brazilian Health and Industry Complex, coordination of lists of essential drugs for joint procurement Central America, technological cooperation from CECMED (Cuba),

project for awarding patent licenses (NIH, United States), gradual licensing program (Health Canada, Canada).

**9. Financial implications of Agenda item:**

Strengthening of existing programs. Supplementary funds, US\$ 2.0 - 2.5 million



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CD48/18 (Eng.)  
Annex B

*Item 4.14 (Eng.)*  
25 August 2008  
ORIGINAL: SPANISH

### ***PROPOSED RESOLUTION***

#### **PUBLIC HEALTH, INNOVATION, AND INTELLECTUAL PROPERTY: A REGIONAL PERSPECTIVE**

##### ***THE 48th DIRECTING COUNCIL,***

Having considered the report *Public Health, Innovation, and Intellectual Property: A Regional Perspective* (Document CD48/18);

Taking account of the participation and important contribution of the Region to the discussions leading to the approval of the Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property (Resolution WHA61.21 (2008));

Recalling Directing Council resolutions CD45.R7 (2004) on access to medicines; CD45.R10 (2004), on the scaling-up of treatment within a comprehensive response to HIV/AIDS; CD46.R15 (2005), on the Regional Strategic Plan for HIV/AIDS/STI 2006-2015 of the Pan American Health Organization, and CD47.R7 (2006), on public health, health research, production and access to essential medicines, as well as World Health Assembly Resolutions WHA59.24, Public Health, Innovation, Essential Health Research and Intellectual Property Rights: Towards a Global Strategy and Plan of Action, and WHA60.30, Public Health, Innovation and Intellectual Property;

Recalling likewise the Strategic Plan 2008-2012 for PASB, the Health Agenda for the Americas 2009-2017, and other regional and subregional declarations and agreements; and

Committing itself to a meaningful and systematic implementation of the Global Strategy consistent with the needs of the Region,

***RESOLVES:***

1. To urge Member States to:
  - (a) promote research and technological innovation as a strategic aspect of public health policy in the pharmaceutical, scientific, and industrial sphere to ensure coordination between national health and national innovation systems;
  - (b) strengthen relations and collaboration among the key stakeholders who, from different spheres (public, private, academic, industrial, and scientific), can assist, adapt, finance, or implement the Global Strategy and agreed parts of the plan of action;
  - (c) translate the political will expressed during the discussions of the Global Strategy into budgetary allotments consistent with the health priorities identified during implementation of the Strategy;
  - (d) make cooperation among countries and within subregional integration blocs a reality in order to expand, intensify, and adequately channel technology transfer and promote research and technological innovation among countries.
2. Request the Director to:
  - (a) ensure maximum dissemination of the text of the Global Strategy and its implementation, contributing to the ownership of the text by all relevant stakeholders: States, organized civil society, academia, industry, and the respective social sectors;
  - (b) collaborate constructively with other international organizations working in the Region with responsibility for regional, subregional, and national implementation of the Strategy;
  - (c) promote and coordinate a regional platform as a mechanism for setting innovation priorities, facilitating implementation of the Strategy, sharing relevant information, and monitoring the process;
  - (d) evaluate periodically the progress in implementing the Strategy in the Region.



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CD48/18 (Eng.)  
Annex C

### **Report on the Financial and Administrative Implications for the Secretariat of the Resolutions Proposed for Adoption by the Directing Council**

#### **1. Resolution: Public Health, Innovation, and Intellectual Property: A Regional Perspective**

#### **2. Linkage to program budget:**

<b>Area of work</b>	<b>Expected results</b>
Technology, Health Care and Research (THR)	<ul style="list-style-type: none"><li>• Desarrollo y construcción de una perspectiva regional de la Estrategia Global, incluyendo mapeo e identificación de prioridades en investigación sanitaria, necesidades no satisfechas por el actual ciclo de innovación y capacidades sub-regionales para cooperación a nivel regional.</li><li>• Configuración de un mecanismo regional de implementación de la Estrategia que permita el desarrollo de un dialogo participativo e inclusivo entre los actores relevantes.</li><li>• Difusión de los principales elementos de la Estrategia y desarrollo de su aplicación regional, sub-regional y nacional.</li><li>• Fortalecimiento de espacios de cooperación inter-institucional entre Innovación, Acceso y Propiedad Intelectual.</li></ul>

#### **3. Financial implications**

- a) Total estimated cost for implementation over the “life-cycle” of the resolution (estimated to the nearest US\$ 10,000; including staff and activities):**

US\$2,500,000 (2008-2012): WDC/Representative Offices/Collaborating Centers/Civil Society

<b><u>Headquarters WDC/Representative Offices</u></b>	US\$1,850,000
<b><u>Collaborating Centers</u></b>	US\$ 200,000
<b><u>Civil Society</u></b>	US\$ 150,000
<b><u>Other</u></b>	US\$ 300,000

**Technological Innovation** US\$ 600,000

**Dissemination.** Development of important elements of the strategy in a regional framework: studies and analysis. Publication of sectoral studies. Identification of subregional and regional initiatives and capacities/needs/opportunities. US\$100,000

**Technical cooperation.** Workshops, training (complemented virtual monitoring through Elluminate) US\$250,000

Multisectoral national workshops; Support for country-country cooperation;

**Regional and subregional meetings.** Priority setting, monitoring, and dissemination of information about the progress made. Exchanges, discussions, and dialogues (complemented with virtual monitoring through Elluminate) US\$250,000

**Intellectual Property** US\$600,000

**Dissemination.** Publications, studies, and analysis. Reproduction/translation of pertinent material in the Region (ICSTD, South Center, WHO) US\$100,000

**Technical cooperation.** Support for the replication of successful experiences and cooperation with government institutions: legislative bodies, judicial sectors. Assistance with legal and institutional reform processes. Workshops, training (complemented with virtual monitoring through Elluminate) US\$200,000

**Regional and subregional meetings.** Exchanges, discussions, and dialogues (complemented virtual monitoring through Elluminate) US\$300,000

**Access** US\$650,000

**Dissemination.** Access to information and the results of scientific activity as strategic elements of health policy. Support for evidence-based decision-making. Publications, studies, and analysis. US\$100,000

**Technical cooperation.** Replication of open-access experiences and collective management of database. Strengthening of existing activities. Workshops, training (complemented with virtual monitoring through Elluminate) US\$300,000

**Regional and subregional meetings.** Support for a broad understanding of access (drugs but also pharmaceutical information) at sector meetings and workshops (PARF Network and subregional harmonization forums) Exchanges, discussions, and dialogues US\$250,000

**Collaborating Centers** US\$200,000

Support for the preparation of thematic studies and participation in partnerships and joint activities with other institutions. Organization of national and subregional courses and training activities.

Call for a fellowships program similar to the Leaders in International Public Health Program as part of the Strategy, in cooperation with governments and other national institutions.

**Civil Society** US\$150,000

Support for the presence of organized civil society representatives at meetings on the Strategy and regional perspective, as well as other related topics. Also, support to train national NGOs for monitoring and follow-up work.

**Miscellaneous** US\$300,000

Creation of a Fund to finance the travel of health professionals to WDC for 6-8 weeks of training, with their integration into the work teams and the discipline of the Organization.

**b) Estimated cost for the biennium 2008-2009 (estimated to the nearest US\$ 10,000; including staff and activities):**

US\$1,000,000 Start of planning, mapping of stakeholders and counterparts, and identification of goals and objectives.

**c) Of the estimated cost noted in (b,) what can be subsumed under existing programmed activities?**

Approximately 40%

**4. Administrative implications**

**a) Implementation locales (indicate the levels of the Organization at which the work will be undertaken and identify the specific regions, where relevant):**

Creation of a functional coordinating group at Headquarters, under THR, with the participation other programs. Designation of focal points in the Representative Offices with a counterpart in the national authorities. Caribbean, Central America as priorities. Andean area and Southern Cone as subregional leaders (depending on the topic).

**Additional staffing requirements (indicate additional required staff full-time equivalents, noting necessary skills profile):**

One professional post (P-4) for the design, formulation, and coordination of technical activities and one additional administrative post (G). Information and communication management: SharePoint, Elluminate, virtual meetings. Coordination with the Leaders in International Public Health Program and other internship systems. Distance and face-to-face education for professionals from the Region (6-month periods with applicable expected result on return).