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STRATEGY ON HEALTH-RELATED LAW

Introduction

1. Although the Directing Council and the Pan American Sanitary Conference have established some technical guidelines and general principles on the formulation and reform of domestic laws relating to health issues, these are scattered across various documents; it is therefore important to set out more specific lines of action in a single technical document and a resolution of the Governing Bodies of the Pan American Health Organization (PAHO). This consolidation will enable PAHO Member States to better identify the objectives and activities required to strengthen domestic laws as unifying frameworks in the area of health. The aim of these legal frameworks is to ensure: access to health care without discrimination; implementation of the principles established by public policies; support for the organization of health services; strengthening of collaboration between the health sector (including personnel responsible for the formulation of regulations) and other branches of the State that are not always involved, such as legislatures and courts of law, among others; access to quality health goods, technologies, and services; and protection of the right to health and other related human rights, especially those of the most vulnerable groups.

2. The objectives of this technical document are: *a)* to compile the mandates adopted by the Governing Bodies of PAHO on health-related law, which are currently scattered across various documents; *b)* to review basic concepts having to do with health-related law and clarify the links between public health, law, and health-related regulations; *c)* to analyze the trends and challenges that the Secretariat has noted in its technical collaboration activities (between 2004 and 2013); and *d)* to propose the principles, values, vision, purpose, objectives, and strategic lines of a strategy on health-related law (2014–2023) for approval by Member States during the 53rd Directing Council.

Background

3. In 1946, the Member States of the World Health Organization (WHO) agreed on a fundamental international principle, namely 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....”ⁱ, which is generally recognized as the right to health.

4. Since then, the Member States of the United Nations and the Organization of American States have adopted various legal instruments (treaties, pacts, protocols, conventions, declarations, standards, and technical guidelines) that protect the right to health and form part of public international law.ⁱⁱ

5. In 1970, the XVIII Pan American Sanitary Conference presented a study of the principal health-related domestic laws (between 1948 and 1968) in a technical document entitled “Health Legislation” and adopted resolution CSP18.40, urging Member States to: promote the revision and modernization of their health laws and regulations, and to encourage universities to give due attention to the teaching of health legislation in law schools, medical schools, and schools of public health. Furthermore, the Conference requested the Director to provide technical assistance to the countries that requested it in revising and modernizing their health legislation; to sponsor meetings of interdisciplinary study groups to discuss legal matters and the unification of the basic principles of health legislation, including a guide for countries on the essential aspects of such legislation; and to continue to carry out studies on modernization of the Pan American Sanitary Code (1, 2).

6. In 2007, in the Health Agenda for the Americas (2008–2017), the PAHO Member States renewed their commitment to the international principle set down in the Constitution of WHO—the principle mentioned above—and recognized that in order to achieve improvements in the health situation “...the National Health Authority should have legal frameworks that support, and allow for auditing of, its management...”ⁱⁱⁱ (3).

7. In 2010, the Directing Council of PAHO, through resolution CD50.R8, called on the Member States of PAHO to “... support PAHO’s technical cooperation in the formulation, review and, if necessary, reform of national health plans and legislation, incorporating the applicable international human rights instruments...”(4).

8. In addition, the PAHO Directing Council has affirmed in other technical documents and resolutions that international human right instruments establish important legal standards and recommendations that should be incorporated into health-related laws, policies, and plans in order to give effect to the right to health and other related human rights.

9. In 2014, the 52nd Directing Council of PAHO approved the Strategic Plan 2014-2019 (Official Document 345, hereinafter “Strategic Plan”) and the Program and Budget of PAHO 2014–2015, which establish categories (categories 2, 3, 4, and 5), program areas, outputs and outcomes, and indicators for the formulation, implementation, review, and/or reform of health-related laws, regulatory frameworks, and regulations in the context of: *a*) health determinants; *b*) the life course, gender, ethnicity, equity, and human rights; *c*) health governance and financing for the achievement of universal health coverage (UHC); *d*) prevention and the control of tobacco use; and *e*) core alert and

response capacities of PAHO Member States for the implementation of the provisions of the International Health Regulations (IHR),^{iv} among others^v (5).

10. In addition to the aforementioned institutional mandates concerning health-related legislation, between 2004 and 2013 the Governing Bodies of PAHO identified other priority areas and called on Member States to formulate, implement review, and/or reform laws and regulations relating to various public health problems. However, the Governing Bodies of PAHO have not indicated specifically how Member States should be supported in these areas or what technical guidelines and strategic lines of action are needed to implement mandates concerning health-related legislation in the following areas:

- a) Communicable diseases
 - i. HIV infection/AIDS and sexually transmitted infections (6);
 - ii. malaria and other vector-borne diseases (7);
 - iii. vaccine-preventable diseases (8).

- b) Noncommunicable diseases and risk factors
 - i. noncommunicable disease prevention and control (9);
 - ii. harmful alcohol consumption (10);
 - iii. road safety (11);
 - iv. tobacco consumption (12);
 - v. prevention and control of diabetes and obesity (13);
 - vi. chronic kidney disease in agricultural communities (14);
 - vii. mental health (15);
 - viii. disorders caused by use of psychoactive substances (16);
 - ix. disability and rehabilitation (17).

- c) Health determinants, health promotion, and healthy life course
 - i. reduction of maternal mortality and morbidity (18);
 - ii. neonatal, newborn, and child health (19);
 - iii. child health (20);
 - iv. adolescent and young adult health (21);
 - v. active and healthy aging (22);
 - vi. gender equality and equity (23);
 - vii. disparities in access to health services for lesbian, gay, bisexual, and trans persons (24);
 - viii. health of indigenous populations (25).

- d) Health systems
 - i. social protection in health (26);
 - ii. access to essential medicines and other technologies (27);
 - iii. human organ donation and transplantation (28).

Basic concepts and links between health-related laws and public policies

11. The concept of health-related law is broad and encompasses not only laws having to do with health systems and services, but also many other areas where fundamental intersections exist between health and law. Although this document does not propose an exhaustive classification of all possible categories of health-related law, it does put forward four essential categories that may be useful for the implementation of the PAHO Governing Bodies' mandates mentioned above (29):

- a) national Constitutions which recognize the right to health;
- b) domestic health-related laws and regulations aimed at preventing risks of disease, injury, and disability, with a special focus on populations in situations of greatest vulnerability;
- c) domestic health-related laws, including executive and legislative standards, regulatory decrees, regulations, and judicial orders aimed at ensuring access to quality health care; and
- d) domestic and international health-related laws, standards and regulations concerning intellectual property, trade, national security, human rights, the environment, and obligations of the private sector and nongovernmental actors. As noted above, such laws include treaties, pacts, protocols, conventions, framework agreements, declarations, and standards of international law.

12. Health-related law is essential to strengthen and complement the implementation of health-related policies, plans, and programs. Law establishes a framework of minimum legal obligations and duties of States for upholding the population's right to health (and identifying, preventing, and minimizing risks). Moreover, it makes it possible to establish accountability, responsibilities, and limits on States and other stakeholders in the use of their governmental powers and functions (29).

13. The six principal links between public policies and health-related laws are:

- a) health-related laws are instruments for protecting the right to health and other related human rights;
- b) such laws codify, organize, and harmonize the principles and technical guidelines established by public policies, which might otherwise be scattered across various instruments;
- c) they establish a framework of legal obligations for meeting targets and objectives;

- d) they organize and strengthen the implementation of health services, including community services and primary health care centers;
- e) they establish a legal framework for linking public health with other sectors of the State, particularly in the context of the social and economic determinants of health. These sectors include labor, housing, education, legislative, judicial, correctional, transportation, social protection and security; and
- f) they facilitate the implementation of basic actions needed to uphold the right to health, such as access to quality health care without discrimination (including patient protection in health services, access to essential treatments and medicines, accreditation of health services, and development of human resources.)^{vi} (30).

Situation Analysis

14. This section presents trends and challenges that have been identified by the Governing Bodies of PAHO and observed by the Pan American Sanitary Bureau (the Bureau) between 2004 and 2013.

Trends (2004–2013)^{vii}

- a) The Bureau has experienced growing demand for technical cooperation from legislatures, courts of law, and human rights offices (ombudspersons) in Member States for the formulation or reform of laws relating to health and human rights.^{viii}
- b) Increasingly, ministries of health also are requesting technical cooperation from the Bureau in formulating and reforming health-related decrees, rules, and regulations in order to bring them into line with best practices and public international law instruments.^{ix}
- c) Some national Constitutions have been reformed to ensure human rights in social protection systems, while others have provided for the right to “the good way of living” (*el buen vivir*); cultural and ethnic/racial diversity, access to traditional medicine, safe drinking water, sanitation, and an adequate diet, among others.^x
- d) Some national laws have been reformed to ensure universal access to health services and care for specific populations. These laws seek to protect maternal and neonatal health; reproductive rights; people living with HIV infection, disability, or mental disorders; and children, adolescents, and older persons, amongst others.^{xi}
- e) Some PAHO Member States have enacted laws to guarantee universal access to health insurance and other medical benefits, including the right to health goods such as vaccines and essential medicines.^{xii}
- f) Other Member States have enacted laws and regulations reforming the national social security system in areas such as governance and stewardship, for example by creating national health councils.^{xiii}

- g) A large number of Member States have enacted laws that control and regulate tobacco use or create smoke-free spaces, in accordance with the WHO Framework Convention on Tobacco Control and applicable international human rights instruments.^{xiv}

Most significant challenges^{xv}

- a) Limited knowledge in some ministries of health, and the legislative and judicial branches, of technical standards and guidelines relating to public health—useful for the formulation of health-related legislation—and of existing obligations under applicable international human rights instruments.^{xvi}
- b) Limited coordination between the legislative branch (particularly health commissions) and the health authority (particularly the sector concerned with governance and stewardship) in the adoption and implementation of executive orders, laws, regulatory decrees, and regulations relating to health.^{xvii}
- c) Absence of a legal and regulatory framework ensuring the right to health, in accordance with obligations that may be applicable under national constitutions, and the human rights instruments of the United Nations and inter-American systems.^{xviii}
- d) The need to formulate specific legal and regulatory frameworks to regulate the tax-related powers that States may employ to protect the health of the population.^{xix}
- e) The need to reform national laws (especially civil and criminal codes) that influence the protection of health during the life course.^{xx}
- f) The need to formulate domestic legislation and regulations that specifically govern and regulate priority areas that influence health, such as noncommunicable diseases, risk factors, and environmental health, with special emphasis on climate change.^{xxi}
- g) The need to revise Member States' laws and regulations in order to bring them into conformity with the provisions of the IHRs and other international legal instruments.^{xxii}

Proposed Strategy on Health-related Law

15. The strategy on health-related law proposed in the present document requires the Bureau to play a broader advisory and coordination role with Member States (including the three branches of government and human rights offices) and other relevant actors.

Vision of the strategy

16. The vision is to ensure that all countries have the capacity to enact legal and regulatory frameworks to facilitate the promotion of, respect for, and protection and fulfillment of the right to health, and other related human rights, as appropriate.

Purpose of the strategy

17. To strengthen the integrated response of national health, legislative, judicial, and other related sectors (education, labor, housing, human rights offices, and others) to formulate, implement, review and/or reform constitutional mandates, laws, regulations, regulatory decrees, and judicial orders aimed at promoting and protecting the right to health and other related human rights.

Objectives of the strategy

18. To promote, as appropriate:
- a) greater coordination between the legislative branch and the health authority in the formulation, implementation, review and/or reform of health-related laws, executive orders, regulatory decrees, and regulations;
 - b) the adoption of legislative measures that will more effectively protect health and reduce risk factors; and
 - c) the implementation of specific legislative and regulatory measures related to all areas that affect the population's exercise of the right to health (for example, noncommunicable diseases, risk factors, environmental health, and universal health coverage).
19. To harmonize, unify, and implement, in a more strategic manner the mandates issued by PAHO's Governing Bodies dispersed in different documents throughout the years related to the formulation and revision of health-related laws and regulations.

Principles and values of the strategy

20. Emphasis will be placed on the following principles and values, which health-related legal and regulatory frameworks should facilitate:
- a) Promotion of, respect for, and protection and fulfillment of the **right to health and other related human rights**, in accordance with international law instruments, as appropriate, in order to: reduce the burden of communicable and noncommunicable diseases and their risk factors, protect health throughout the life course, achieve universal health coverage, and strengthen Member States' response to all types of threats to the right to health and human security.
 - b) **Nondiscrimination** to protect the right to health, especially for the most marginalized, excluded, and vulnerable groups, subject to the fundamental principle of equal protection under the law.
 - c) **Equity** in access to quality health facilities, goods, and services.
 - d) Promotion and protection of the **economic, social, and cultural determinants** of health as fundamental elements without which the enjoyment of the right to health is not possible.

- e) Integration of other cross-cutting issues (**gender and ethnic/racial equality**) into health-related laws and regulations.

Strategic lines of action

21. The strategic interventions that countries may implement through their laws and regulations to promote and protect the right to health include (29):

- a) the capacity to create, reduce, or increase taxes on certain products in order to encourage the population to adopt healthier lifestyles or cease (or not initiate) certain risk behaviors;
- b) the capacity to positively influence the health information that the population receives;
- c) the authority to positively influence the socioeconomic environment and reform it (for example, through subsidies);
- d) the authority to positively influence the physical environment and reform it (for example, through notices placed in buildings, dwellings, and public transportation);
- e) the adoption of health laws and regulations that directly or indirectly affect people, professionals, and commercial activities related to public health; and
- f) deregulation as a measure for reforming laws—such as criminal laws—that represent a barrier to public health.

22. Described below are the strategic lines, which will have a duration of 10 years (2014–2023), and their specific objectives, that will contribute to the implementation of technical collaboration in the area of health-related law.

Strategic line 1: Interventions for the promotion of healthy lifestyles and the reduction of risk factors

Objectives

- 1.1 To provide technical cooperation to Member States to ensure that health-related laws, decrees, rules, and regulations engage a life-course approach, with special attention to maternal and neonatal health, the right to sexual and reproductive health, and the health of children, adolescents, and older persons, based on the norms and standards set out in applicable international human rights instruments.
- 1.2 To provide technical cooperation to Member States in the formulation, implementation, review and/or reform of laws and regulations that reduce the use of products that are harmful to health, such as tobacco and alcohol, among others, in accordance with applicable instruments of international law.
- 1.3 To provide technical cooperation to Member States to increase the capacity of the health authority and the legislative branch to develop and implement, as

necessary, legislative measures for establishing a system of prices, taxes, incentives, disincentives, fiscal measures, or other regulatory measures applicable to products that are harmful to health.

- 1.4 To provide technical cooperation to Member States in the formulation, implementation, review and/or reform of laws and regulations aimed at promoting a healthy diet and well-being. These may include measures aimed at reducing consumption of saturated fats and salt /sodium, eliminating partially hydrogenated vegetable oils in foods, and reducing the negative impact on children of the promotion of foods and beverages with high saturated fat and sugar content, among others.
- 1.5 To strengthen the technical capacity of the health authority to collaborate with national legislatures and regional parliamentary bodies, in coordination with other sectors (such as agriculture, human rights offices, trade, education, labor, development, environment, and transportation, as appropriate), in order to integrate the technical norms, standards, and guidelines approved by PAHO and WHO and other applicable health related international law instruments, into domestic laws and regulations.
- 1.6 To provide technical cooperation to Member States to increase the capacity of the health authority, in collaboration with the other sectors, as necessary, to identify practices and laws that are hindering the enjoyment of the right to health, the right to live in the community and other related human rights, in accordance with applicable instruments of international law.
- 1.7 To provide technical cooperation to Member States in the formulation, implementation, review and/or reform of laws and regulations that protect people's health by regulating, as appropriate, individual behaviors which reduce mortality and disability, such as road safety measures, among others.

Strategic line 2: Interventions for the dissemination of strategic information on health with the support of various sectors

Objectives

- 2.1 To provide technical cooperation to Member States in the promotion and exchange of best practices and successful experiences with regard to health-related legislative reforms and regulatory frameworks and support in the development and revision of documents—such as manuals, tools, and model legislation—in accordance with the technical guidelines of PAHO and WHO and applicable international law instruments. In addition, to develop a database on health law and international law that countries can use and adapt to their own national realities.

- 2.2 To provide technical cooperation to Member States, in coordination with the health authority, the legislative branch, and other relevant sectors—including civil society and consumer organizations—in the formulation and adoption of laws and regulations against the promotion of false or ambiguous information in packaging, labeling, and advertising of products—such as food, beverages, and other items—that may be misleading with respect to their effects on the consumer’s health, and for the inclusion of health warnings on packaging.
- 2.3 To provide technical cooperation to Member States to strengthen the capacity of the health authority in its role of stewardship and governance, in order to formulate health-related regulations and regulatory decrees, in accordance with applicable technical guidelines and international law instruments.
- 2.4 To provide technical cooperation to Member States using an all of society approach at different levels—local, national, subregional, and regional—on the recommendations, resolutions, strategies, technical guidelines, learning tools, and legal instruments approved by PAHO and WHO—such as the IHRs and the Framework Convention on Tobacco Control—and on applicable health-related human rights instruments, which may be useful for the formulation of specific health-related laws, decrees, rules, and regulations.
- 2.5 To strengthen and expand PAHO’s technical collaboration with international and regional partners, such as the World Bank, the Inter-American Development Bank, the Organization of American States, the Specialized Agencies of the United Nations, and the committees, organs, and special rapporteurs of the United Nations and inter-American systems. This collaboration should seek to disseminate and implement legal instruments relating to public health—such as the IHRs and the Framework Convention on Tobacco Control—and promote health-related legislative reform based on PAHO and WHO resolutions, strategies, and technical guidelines on public health, as well as on other international human rights instruments that may be applicable.

Strategic line 3: Interventions to favorably influence socioeconomic and cultural environments

Objectives

- 3.1 To provide technical cooperation to Member States to formulate, implement, review and/or reform laws and regulations that establish joint responsibilities between the health authority and other relevant public sectors involved in the promotion and protection of the social and economic determinants of health.
- 3.2 To provide technical cooperation to Member States in the formulation, implementation, review and/or reform of health-related domestic laws and regulations in order to address social and economic determinants of health, such as: access to clean drinking water; adequate sanitary conditions; wholesome food;

- adequate nutrition and housing; healthy working conditions; protection of the environment; climate change, and access to health education and information, in accordance with applicable international human rights instruments and the post-2015 development agenda of the United Nations.
- 3.3 To provide technical cooperation to Member States and support subregional and regional consultations with the health authority, the legislative branch, and organizations of indigenous and Afro-descendant populations (among others) to, formulate, implement, revise and/or reform legislative and regulatory frameworks to: incorporate ethnic/racial variables into health information systems; incorporate indigenous practitioners and traditional medicine and practices into health systems, where appropriate; and train health human resources in traditional medicine and ethnic/racial and intercultural approaches to health, in accordance with the United Nations Declaration on the Rights of Indigenous People, the Indigenous and Tribal Peoples Convention (No. 169) of the International Labor Organization, the United Nations International Convention on the Elimination of All Forms of Racial Discrimination, and other applicable international human rights instruments.

Strategic line 4: Interventions to enhance access to quality health facilities, goods, and services^{xiii}

Objectives

- 4.1 To provide technical cooperation to Member States in the formulation, implementation, review and/or reform of laws, executive decrees, rules, and regulations aimed at achieving universal health coverage and that define measures related to social protection in health, in accordance with their respective national Constitutions and, as appropriate, international instruments that protect the right to health and other related human rights.
- 4.2 To provide technical cooperation to Member States to promote and strengthen the technical capacity of health workers in collaboration with other government entities—such as human rights offices and the legislative and judicial branches—to better monitor and evaluate the implementation of laws and regulations applicable in health services, particularly in rural areas and where services are provided to vulnerable populations, including older adults, persons with mental disorders or disabilities, women, adolescents, and children.
- 4.3 To provide technical cooperation to Member States in the formulation, implementation, revision and/or reform of laws and regulations that promote access to high-quality essential medicines and technologies for the prevention, control, and elimination of diseases.
- 4.4 To provide technical cooperation to Member States in the formulation, implementation, review and/or reform of laws and regulations that protect and

ensure health services—including mental health services—for persons with disabilities and users of psychoactive substances, in the community and at the primary care level, in conformity with the Convention on the Rights of Persons with Disability and other applicable international human rights instruments, as appropriate.

Strategic line 5: Interventions to facilitate coordination between the legislative branch and the health authority^{xxiv}

Objectives

- 5.1 To provide technical cooperation to Member States in order to promote and strengthen coordination between the legislative branch (especially parliamentary/congressional commissions on health) and the health authority (especially, the stewardship and governance sector) in the formulation, adoption, and implementation of health-related executive orders, regulatory decrees, and regulations and ensure their complementarity with laws already formulated and enacted;
- 5.2 To provide technical cooperation to Member States in the formulation, implementation, review and/or reform of laws and regulations in accordance with the IHRs and other international law instruments, as appropriate, particularly in reference to preparedness, surveillance, response, and early recovery in respect of diseases with the potential to cause outbreaks, epidemics, pandemics, or other events, and emergencies that may endanger human health and safety.

Strategic line 6: Interventions for the elimination of health-related legislative barriers

Objectives

- 6.1 To provide technical cooperation to Member States in the review and/or reform of domestic laws (especially civil and criminal codes) that negatively influence physical and mental health during the life course, especially in regard to the exercise of reproductive rights by women and adolescents; the exercise of legal capacity by adolescents and persons with disabilities; and legislative and judicial barriers to access to health services, care, and information, with respect to autonomy, privacy, identity, and gender expression, sexual orientation, or ethnicity.
- 6.2 To provide technical cooperation to Member States in the formulation, implementation, review and or reform of domestic laws and regulations on the use of psychoactive substances that complement national policies on drugs and which are consistent with the conventions on drug control and the applicable human rights instruments of the inter-American and United Nations systems, as appropriate.

- 6.3 To provide technical cooperation to Member States in the implementation of integrated and coordinated actions between the health authority, the legislative and judicial branches, and the correctional system, to determine the impact of the application of criminal laws on health protection for certain population groups (criminalization), and to review—and, if necessary, reform—criminal codes and laws that hinder the access of certain population groups to health services, in accordance with international human rights instruments and the technical guidelines of PAHO and WHO on public health.

Action by the Executive Committee

23. The Executive Committee is invited to examine and analyze this document and to make comments and suggestions concerning health-related law as an essential tool for promoting health equity, fighting disease, improving the quality and prolonging the length of the lives of the peoples of the Americas, and protecting the right of everyone to the enjoyment of the highest attainable standard of health. The Committee is also invited to consider the adoption of the proposed resolution contained in Annex A.

Annexes

Notes

- i The WHO Constitution was adopted by the International Health Conference, held in New York from 19 June to 22 July 1946; it was signed on 22 July 1946 by the representatives of 61 States and subsequently ratified by 194 States.
- ii The United Nations International Covenant on Economic, Social and Cultural Rights protects “the right of everyone to the enjoyment of the highest attainable standard of...health” (Article 12) and the Protocol of San Salvador of the Organization of American States protects “the right to health” (Article 10). Similarly, the Universal Declaration of Human Rights establishes that “...everyone has the right to a standard of living adequate for the health and well-being of himself and of his family...” The American Declaration on the Rights and Duties of Man protects the “right to the preservation of health and to well-being.” In addition, the protection of health as a human right is enshrined in 19 of the 35 Constitutions of the Member States of PAHO (Bolivia, Brazil, Cuba, Chile, Dominican Republic, Ecuador, El Salvador, Guatemala, Guyana, Haiti, Honduras, Mexico, Nicaragua, Panama, Paraguay, Peru, Suriname, and Uruguay).
- iii The Health Agenda for the Americas (2008–2017), adopted in Panama on 3 June 2007, is a high-level policy instrument on health-related issues which is intended to guide the preparation of future national health plans and the strategic plans of all the organizations engaged in health cooperation with the countries of the Americas. The document is available at:
http://www.paho.org/English/DD/PIN/Health_Agenda.pdf.
- iv The IHRs are an international legal instrument adopted by the WHO World Health Assembly in 1969 (and subsequently revised in 1973, 1981, and 2005). They establish the procedures for early reporting to PAHO/WHO of diseases and events that pose a threat to global health. The IHRs require that the human rights of travelers and other people be protected, in accordance with binding instruments and standards of international law. Category 5 of the PAHO Strategic Plan calls for the reform of national legal norms and procedures to facilitate compliance with the IHRs. The PAHO Strategic Plan 2014–2019 is available at:
http://www.paho.org/hq/index.php?option=com_docman&task=doc_download&gid=22850&Itemid=270&lang=en
 See also the report to the Directing Council of PAHO (2009) on the progress achieved with regard to the IHRs, available at:
http://www.paho.org/hq/index.php?option=com_docman&task=doc_download&gid=2764&Itemid=
- v For example, the PAHO Program and Budget 2014–2015 establishes outputs for the formulation or reform of policies, plans and laws in accordance with human rights norms and standards (category 3); the formulation and implementation of legislation for ethnic/racial groups (category 3); the implementation of laws in line with the WHO Framework Convention on Tobacco Control (category 2); and the development and implementation of legislative and regulatory frameworks to support universal health coverage (category 4). The PAHO Program and Budget 2014–2015 is available at:
http://www.paho.org/hq/index.php?option=com_docman&task=doc_download&gid=22756&Itemid=270&lang=en
- vi The Secretariats of WHO and PAHO have undertaken an in-depth analysis of the most important links that exist between health-related legislation and policies in the context of mental health systems and services. See the WHO publication *Quality improvement for mental health* (Mental Health Policy and Service Guidance Package), published in 2003, available at:
http://www.who.int/entity/mental_health/policy/services/8_quality%20improvement_WEB_07.pdf, pp. 19–20.
- vii This section incorporates trends and challenges identified by the Governing Bodies of PAHO between 2004 and 2013, which are compiled in the reports of the Director of the Pan American Sanitary Bureau; in Scientific and Technical Publication No. 622, *Health in the Americas*; and in tools published by the PAHO Secretariat. It also includes trends and challenges identified by the PAHO Office of Legal Counsel during a regional technical meeting (held at PAHO Headquarters in Washington DC) and three

subregional technical meetings on health-related legislative initiatives, which were held in 2013 and 2014 in El Salvador (Central America and Spanish-speaking Caribbean), Peru (South America), and Barbados (English-speaking Caribbean), with the support of the PAHO/WHO Representative Offices and national health authorities. At these meetings, which were supported financially by the Spanish Agency for International Development Cooperation, Norway, and the Nordic Trust Fund of the World Bank, input was collected from a total of 160 participants representing ministries of health, legislative and judicial branches, human rights defenders, academia, international and regional organizations, and civil society organizations, among others. For more information on the regional and subregional meetings, see:

http://www.paho.org/hq/index.php?option=com_content&view=article&id=9238%3Alegislative-experts-define-strategies-to-use-legislation-to-promote-the-right-to-health-in-the-americas&catid=1443%3Anews-front-page-items&Itemid=1&lang=en (regional technical meeting, Washington DC.); http://www.paho.org/nutricio_nydesarrollo/?p=4312 (technical meeting for South America), http://www.paho.org/els/index.php?option=com_content&view=article&id=890:expert-you-determine-strategies-in-order-to-use-the-legislation-as-tool-for-promoting-the-right-to-the-health-and-others-rights-humans-related-in-centroamerica-and-the-Caribbean-hispano&catid=671:els-news-of-the-salvador&Itemid=291 (technical meeting for Central America and the Spanish-speaking Caribbean), http://www.paho.org/ecc/index.php?option=com_content&view=article&id=278:expert-propose-strategies-to-utilize-legislative-tools-to-promote-the-right-to-health-and-other-related-human-rights-in-the-caribbean-sub-region&catid=297:events (technical meeting for the English-speaking Caribbean subregion).

- viii In technical document CD50/12, “Health and Human Rights,” approved in 2010, the Secretariat identified this as a trend experienced between 2004 and 2010. Document CD50/12 is available at: http://www.paho.org/hq/index.php?option=com_docman&task=doc_download&gid=7979&Itemid=.
- ix Idem. See also *Health in the Americas* 2007, volume I, which analyzes the technical collaboration provided by PAHO between 2004 and 2007 to ministries of health and other actors with regard to the formulation or reform of laws, decrees, rules, and regulations (pp. 325–326).
- x See the Annual Report of the Director of Pan American Sanitary Bureau, Document CD49/3, Rev. 1, “Advancing toward “Health for All”: Progress in Primary Health Care in the Americas”, September 2009, available at: <http://www2.paho.org/hq/dmdocuments/2009/CD49-03-e.pdf>.
- xi Technical document CD50/12, “Health and Human Rights,” presented in 2010 by the Secretariat of PASB to the Directing Council, noted the legislative reforms relating to vulnerable groups that PAHO had facilitated at the request of Member States between 2004 and 2010. This document is available at: http://www.paho.org/hq/index.php?option=com_docman&task=doc_download&gid=7979&Itemid=. See also the trends with respect to legislative reforms on HIV infection, mental health, maternal health, disability, and adolescent and child health, analyzed by the PAHO Secretariat between 2001 and 2013 in the PAHO publications *Supporting the Implementation of Mental Health Policies in the Americas: a Human Rights Law-Based Approach. Findings, Trends, and Targets for Public Health Action* (http://www.paho.org/hq/index.php?option=com_docman&task=doc_download&gid=10586&Itemid=) and *The Right of Young People to Health and Gender Identities* (http://www.paho.org/hq/index.php?option=com_docman&task=doc_download&gid=16022&Itemid=).
- xii See note 16.
- xiii Idem. Also see note 17.
- xiv Tobacco Control Report for the Region of the Americas, Pan American Health Organization, 2013. Available at: http://www.paho.org/hq/index.php?option=com_docman&task=doc_download&gid=24768&Itemid=270&lang=en
- xv See note 13.
- xvi Technical document CD50/12 presented by the PASB Secretariat to the Directing Council of PAHO, “Health and Human Rights,” and published in 2010, identified this as a challenge during the period 2004–2010. This document is available at: http://www.paho.org/hq/index.php?option=com_docman&task=doc_download&gid=7979&Itemid=. See also the risks listed under category 3 of the PAHO Strategic Plan 2014–2019, Official Document 345, pp. 85–86.

- xvii See note 14. The Pan American Sanitary Conference in 2007 noted the insufficient interaction among the various actors engaged in formulating health-related laws and regulations. See the issues and challenges under Strategic Objective 11 of the Strategic Plan 2008–2012, p. 89. Available at: <http://www1.paho.org/english/gov/csp/od328-full-e.pdf>.
- xviii See Category 4 of the PAHO Strategic Plan 2014–2019, Official Document 345, pp. 80–99.
- xix Several experts in global health-related law—such as Lawrence Gostin of the Georgetown University Law School and academic institutions such as the O’Neill Institute—have noted the challenges of incorporating into laws and regulations the taxing powers and capacities, obligations, and limitations of States with respect to health protection. For more information on the O’Neill Institute and its publications on global law, see <https://www.law.georgetown.edu/oneillinstitute/about/index.cfm>.
- xx See Category 3 of the PAHO Strategic Plan 2014–2019, Official Document 345, pp. 74–88.
- xxi See Directing Council Document CD52/7, Rev. 1, “Plan of Action for the Prevention and Control of Noncommunicable Diseases,” published in 2013, available at: http://www.paho.org/hq/index.php?option=com_docman&task=doc_download&gid=22741&Itemid=270&lang=en.
- xxii See note 6.
- xxiii The United Nations Committee on Economic, Social and Cultural Rights has interpreted the right of every person to the enjoyment of the highest attainable standard of health to encompass, as essential elements, access to health facilities, goods, and services, including: availability, non-discrimination, physical accessibility, economic accessibility (affordability), information accessibility, acceptability, and quality. General Comment 14, which interprets Article 12 of the International Covenant on Economic, Social and Cultural Rights, is available at: <http://docstore.ohchr.org/SelfServices/FilesHandler.ashx?enc=4slQ6QSmIBEDzFEovLCuW1AVC1NkPsgUedPIF1vfPMJ2c7ey6PAz2qaojTzDJmC0y%2b9t%2bsAtGDNzdEqA6SuP2todLyou9M8h2mYFfkSg51c%2b4KWdLsPDZxuMYXyUj0d8>.
- xxiv See paragraph (b) under “Most Significant Challenges (2004-2013)” in the “Situation Analysis” section of this document.

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154th SESSION OF THE EXECUTIVE COMMITTEE

Washington, D.C., USA, 16-20 June 2014

CE154/20
Annex A
Original: Spanish

PROPOSED RESOLUTION

STRATEGY ON HEALTH-RELATED LAW

THE 154th SESSION OF THE EXECUTIVE COMMITTEE,

Having considered the document *Strategy on Health-related Law* (Document CE154/20),

RESOLVES:

To recommend that the Directing Council adopt a resolution along the following lines:

STRATEGY ON HEALTH-RELATED LAW

THE 53rd DIRECTING COUNCIL

Having considered the document on health-related law (Document CD53/___);

Taking into account that the Constitution of the World Health Organization (WHO) establishes a fundamental international principle, namely 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...;"

Aware that the PAHO Strategic Plan 2014–2019 establishes various categories, program areas, outputs and outcomes, and indicators relating to the formulation, implementation, review, and/or reform of health-related laws, regulatory frameworks, and regulations in the context of social and economic determinants of health; the life course; gender equity and equality; ethnic equality; human rights; equity, governance, financing and other measures necessary for the achievement of universal health coverage; prevention and the control of tobacco use; and core alert and response capacities of PAHO Member States for the implementation of the International Health Regulations, among others;

Recognizing that the Directing Council of PAHO in its Resolution CD50.R8 (“Health and Human Rights”) called on the PAHO Member States to “support PAHO’s technical cooperation in the formulation, review and, if necessary, reform of [...] health [...] legislation, incorporating the applicable international human rights instruments”;

Noting that the Pan American Sanitary Conference and the Directing Council have recommended that Member States formulate, strengthen, reform, and adopt laws and regulations on access to care for people living with HIV (Resolution CD45.R10); prevention and control of noncommunicable diseases (Resolution CD52.R9); harmful use of alcohol (Resolution CD51.R14); road safety (Resolution CD51.R6); prevention and management of diabetes and obesity (Resolution CD48.R9); mental health (Resolution CD49.R17); psychoactive substance use disorders (Resolution CD51.R7); disability and rehabilitation (Resolution CD47.R1); reduction in maternal mortality and morbidity (Resolution CD51.R12); child health (Resolution CSP28.R20); adolescent and youth health (CD48.R5); active and healthy aging (CD49.R15); disparities in health service access for lesbian, gay, bisexual, and trans (LGBT) persons (Resolution CD52.R6); social protection (Resolution CD52.R11); and health of indigenous peoples (Resolution CD47.R18); among others;

Aware that health-related laws and regulations are essential in order to strengthen and complement the implementation of health-related policies, plans, and programs; establish a framework of legal obligations and duties of States for promoting and protecting the right of everyone to the enjoyment of the highest attainable standard of health; and make it possible to clarify accountability, responsibilities, and limits on States and other actors in the use of their powers and functions;

Recognizing that in some PAHO Member States health-related matters may fall under different jurisdictions,

RESOLVES:

1. To adopt the strategy on health-related law (Document CD53/...) in order to respond effectively and efficiently to current and emerging public health needs in the Region with appropriate legislative frameworks, including solid regulations.
2. To urge Member States, taking into account their national context, financial and budgetary resources, and laws currently in force, to:
 - a) promote and strengthen collaboration between the health authority and the legislative branch in the formulation, implementation, review and/or reform of health-related laws and regulations, incorporating all the elements necessary to achieve and protect the right to health;
 - b) promote the formulation, implementation, review and/or reform of health-related laws and regulations aimed at reducing the use of harmful products, creating healthy spaces, promoting a healthy diet, and protecting the well-being of the population, in accordance with international law instruments, as appropriate;

- c) strengthen the technical capacity of the health authority, the tax authority, and the legislative branch to formulate, implement, review, and/or reform laws and regulations establishing a system of prices and/or fiscal measures that create incentives or disincentives—such as taxes, and subsidies—or other measures to reduce the use of products that are harmful to health and promote healthy habits, reducing the risk factors associated with noncommunicable diseases, among others;
 - d) strengthen the technical capacity of the health authority to collaborate with national legislatures and regional parliamentary bodies, in coordination with other sectors, in order to integrate the technical norms, standards, and guidelines approved by PAHO and WHO and other applicable health-related international law instruments, into domestic laws and regulations;
 - e) promote and support collaboration between the health authority, the legislative branch, and other relevant sectors—including civil society and consumer organizations—in the formulation, implementation, review and/or reform of laws and regulations against the promotion of false, ambiguous, or deceptive information in packaging, labeling, and advertising of products that may be misleading with respect to their effects on the health of consumers;
 - f) promote and support the formulation, implementation, review and/or reform of laws and regulations that establish joint responsibilities between the health authority and other public sectors directly concerned with the promotion and protection of the social and economic determinants of health, in accordance with applicable international human rights instruments, as appropriate, and the post-2015 development agenda of the United Nations;
 - g) promote and support the review—and, if necessary, the reform—of laws (especially civil and criminal codes) that negatively influence physical, mental, sexual, and reproductive health during the life course, especially those laws that represent barriers to access to health services, care, and information;
 - h) promote and strengthen the technical capacity of health workers in collaboration with other government entities—such as human rights offices and the legislative and judicial branches—to better evaluate and monitor the implementation of laws and regulations in the health services;
 - i) promote the formulation, implementation, review and/or reform of laws and regulations aimed at achieving universal health coverage and that define measures related to social protection in health;
 - j) strengthen the technical capacity of the health authority to formulate, implement, review and/or reform laws and regulations in accordance with the International Health Regulations, the Framework Convention on Tobacco Control, and other health-related instruments of international law, as appropriate.
3. To request the Director, within the financial possibilities of the Organization, to promote the implementation of the Strategy on Health-related Law.



Report on the Financial and Administrative Implications of the Proposed Resolution for PASB

1. Agenda item: 4.12 - Regional Strategy on Health-related Law

2. Linkage to Program and Budget 2014-2015:

a) Categories:

Category 2 (Noncommunicable Diseases); Category 3 (Determinants of Health and Promoting Health throughout the Life Course); Category 4 (Health Systems); Category 5 (Preparedness, Surveillance, and Response)

b) Program areas and outcomes:

Noncommunicable Diseases and Risk Factors (Outcome: 2.1. Increased access to interventions to prevent and manage noncommunicable diseases and their risk factors);

Mental Health and Psychoactive Substance Use Disorders (Outcome 2.2. Increased service coverage for mental health and psychoactive substance use disorders);

Disabilities and Rehabilitation (Outcome 2.4. Increased access to social and health services for people with disabilities, including prevention);

Women, Maternal, Newborn, Child, Adolescent, and Adult Health, and Sexual and Reproductive Health (Outcome 3.1. Increased access to interventions to improve the health of women, newborns, children, adolescents, and adults);

Aging and Health (Outcome 3.2. Increased access to interventions for older adults to maintain an independent life);

Gender, Equity, Human Rights, and Ethnicity (Outcome 3.3. Increased country capacity to integrate gender, equity, human rights, and ethnicity in health);

Health Governance and Financing; National Health Policies, Strategies, and Plans (Outcome 4.1. Increased national capacity for achieving universal health coverage); and

Alert and Response Capacities (for IHR) (Outcome 5.1. All countries have the minimum core capacities required by the International Health Regulations (2005))

for all-hazard alert and response.

3. Financial implications:

a) Total estimated cost for implementation over the lifecycle of the resolution (estimated to the nearest US\$ 10,000, including staff and activities):

The planned lifecycle of the Strategy is 10 years (2014–2023). Its annual estimated implementation cost is USD \$850,000. These costs are already included in those estimated for the implementation of the 2014-2019 PAHO Strategic Plan.

b) Estimated cost for the 2014–2015 biennium (estimated to the nearest US\$ 10,000, including staff and activities):

The 2014-2015 budget for the Office of the Legal Counsel (LEG) is USD \$4,725,800, including all sources of funding. This amount includes, in addition to other program activities under the responsibility of LEG, the annual estimated cost of USD \$850,000 (stated above) for the implementation of the Strategy on Health-related Law. Funding gaps are expected to be covered through resource mobilization actions which are currently in progress.

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

The technical cooperation activities for the implementation of the Strategy will be integrated into the already programmed activities of LEG, prioritizing the activities and maximizing efficiencies.

4. Administrative implications

a) Indicate the levels of the Organization at which the work will be undertaken:

Regional, subregional, and country.

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

Not applicable.

c) Time frames (indicate broad time frames for the implementation and evaluation):

2014-2023.

ANALYTICAL FORM TO LINK AGENDA ITEM WITH ORGANIZATIONAL MANDATES

1. Agenda item: 4.12 - Strategy on Health-related Law

2. Responsible unit: Office of the Legal Counsel (LEG)

3. Preparing officer: Dr. Heidi V. Jiménez, Legal Counsel (LEG)

4. List of collaborating centers and national institutions linked to this agenda item:

- Organization of American States (OAS)
- O'Neill Institute for National and Global Health Law, Georgetown University Law Center (Washington D.C.)
- Andean Parliament
- Central American Parliament (PARLACEN)
- Parliamentary Confederation of the Americas (COPA)
- Inter-Parliamentary Union (IPU)
- Hemispheric Network of Legislators and Former Legislators for Early Childhood
- Inter-American Commission on Human Rights (IACHR)
- Swedish International Development Cooperation Agency (SIDA)
- Spanish Agency for International Development Cooperation (AECID)
- Tobacco Free Kids Initiative
- World Bank Nordic Trust Fund
- University of Southern California, Program on Global Health and Human Rights
- Washington College of Law, American University (Washington D.C.)
- International Development Law Organization (IDLO)
- World Bank Institute
- International Monetary Fund

- Ibero-American Network on Health Law
- Center for Studies and Research on Health Law (CEPEDISA), University of São Paulo
- Center for Study and Research on Health Law and Biolaw (CEDSABIO)
- International Health Central American Institute
- The NCD Alliance
- European Commission
- United Nations Office of the High Commissioner for Human Rights
- United Nations Committee on Economic, Social and Cultural Rights (CESCR)
- United Nations Committee on the Rights of Persons with Disabilities (CRPD)
- Committee for the Elimination of All Forms of Discrimination against Women (CEDAW)
- Inter-American Institute of Human Rights
- United Nations Economic Commission for Latin America and the Caribbean (ECLAC)
- Latin American and Caribbean Demographic Centre (CELADE)
- PAHO/WHO Collaborating Centre for Addiction and Mental Health at the University of Toronto
- Center for Reproductive Rights (CRR)
- HelpAge International
- United Nations Educational, Scientific and Cultural Organization (UNESCO)
- United Nations Environment Programme (UNEP)
- Disability Rights International (MDRI)
- United Nations Population Fund (UNFPA)
- United Nations Children’s Fund (UNICEF)
- United Nations Development Programme (UNDP)
- Joint United Nations Programme on HIV/AIDS (UNAIDS)
- The New York Academy of Medicine
- International Planned Parenthood Federation (IPPF)
- Global Action on Aging, Centre for Human Rights, University of Essex
- School of Law of the University of Texas
- San Carlos University (Guatemala)
- University of the West Indies
- University of Pune (India)

5. Link between agenda item and Health Agenda for the Americas 2008-2017

- Declaration of the Ministers and Secretaries of Health
- Statement of Intent: paragraphs 2 and 3
- Principles and Values: paragraphs 9, 11 and 12

6. Link between agenda item and the PAHO Strategic Plan 2014-2019:

a) Categories:

Category 2 (Noncommunicable Diseases); Category 3 (Determinants of Health and Promoting Health throughout the Life Course); Category 4 (Health Systems); Category 5 (Preparedness, Surveillance, and Response)

b) Program areas and outcomes:

Noncommunicable Diseases and Risk Factors (Outcome: 2.1. Increased access to interventions to prevent and manage noncommunicable diseases and their risk factors);

Mental Health and Psychoactive Substance Use Disorders (Outcome 2.2. Increased service coverage for mental health and psychoactive substance use disorders);

Disabilities and Rehabilitation (Outcome 2.4. Increased access to social and health services for people with disabilities, including prevention);

Women, Maternal, Newborn, Child, Adolescent, and Adult Health, and Sexual and Reproductive Health (Outcome 3.1. Increased access to interventions to improve the health of women, newborns, children, adolescents, and adults);

Ageing and Health (Outcome 3.2. Increased access to interventions for older adults to maintain an independent life);

Gender, Equity, Human Rights, and Ethnicity (Outcome 3.3. Increased country capacity to integrate gender, equity, human rights, and ethnicity in health);

Health Governance and Financing; National Health Policies, Strategies, and Plans (Outcome 4.1. Increased national capacity for achieving universal health coverage); and

Alert and Response Capacities (for IHR) (Outcome 5.1. All countries have the minimum core capacities required by the International Health Regulations (2005) for all-hazard alert and response.

7. Best practices in this area and examples from countries within the Region of the Americas:

In 2013 and 2014, the PAHO Office of the Legal Counsel (LEG) organized a regional technical meeting (held at PAHO Headquarters in Washington D.C.) and three subregional technical meetings on health-related legislative initiatives, with the support of the PAHO/WHO Representative Offices and national health authorities of Central America (El Salvador), South America (Peru), and the Caribbean subregion (Barbados). At these meetings, which were supported financially by the Spanish Agency for International Development Cooperation, Norway, Canada, and the Nordic Trust Fund of the World Bank, input was collected from a total of 150 participants representing ministries of health, legislative and judicial branches, human rights defenders, academia, international and regional organizations, and civil society organizations, among others.

For more information on the regional and subregional meetings, please see:

- Regional Technical Meeting, Washington D.C.
http://www.paho.org/hq/index.php?option=com_content&view=article&id=9238%3Alegal-experts-define-strategies-to-use-legislation-to-promote-the-right-to-health-in-the-americas&catid=1443%3Anews-front-page-items&Itemid=1&lang=en
- Technical Meeting for South America, Peru
<http://www.paho.org/nutricionydesarrollo/?p=4312>
- Technical Meeting for Central America and the Spanish-speaking Caribbean, El Salvador
http://www.paho.org/els/index.php?option=com_content&view=article&id=890:expertos-definen-estrategias-para-utilizar-la-legislacion-como-herramienta-para-promover-el-derecho-a-la-salud-y-otros-derechos-humanos-relacionados-en-centroamerica-y-el-caribe-hispano&catid=671:els.-noticias-de-el-salvador&Itemid=291
- Technical Meeting for the Caribbean subregion, Barbados
http://www.paho.org/ecc/index.php?option=com_content&view=article&id=278:experts-propose-strategies-to-utilize-legislative-tools-to-promote-the-right-to-health-and-other-related-human-rights-in-the-caribbean-sub-region&catid=297:events

In addition, LEG, in close collaboration with FGL, CHA, NMH, and HSS, has carried out the following technical collaboration activities between 2010 and 2014, which have led to the formulation and/or reform of health-related legislation in 23 countries of the Region:

- Dissemination of international human right instruments in 23 countries in the context of health of persons with mental disorders, older persons, persons with disabilities, women, and adolescents (sexual/reproductive health), persons living with HIV and indigenous peoples. This dissemination of instruments has been carried out through training workshops and technical consultations that have included ministries of health, ministries of education, ministries of labor, courts of law, human rights defenders, lawmakers, police, correctional systems, universities, and civil society organizations and the Inter-American Commission on Human Rights (including organizations of health service users and their family members);
- In coordination with FGL, trainings have been offered for lawmakers in the legislatures of Brazil, the Dominican Republic, El Salvador, and Paraguay;
- Collaboration with Member States to incorporate international human rights norms and standards into draft legislation on mental health (Argentina, Barbados, Belize, El Salvador, Grenada, Paraguay, Saint Kitts and Nevis, Saint Lucia, Trinidad and Tobago, and Venezuela); disability (Chile and Guyana); health of older persons (Belize); HIV (Guatemala); and reproductive health (Honduras and Peru);
- Technical collaboration with the Inter-American Commission on Human Rights (IACHR) of the OAS and with Member States of PAHO in the implementation of interim or emergency relief measures to protect the health and other related human rights of 450 people interned in mental health facilities (Paraguay) and on the repair of the hyperbaric chambers and rehabilitation services for the Miskito indigenous population (Nicaragua and Honduras), which have facilitated the reform of mental health law in Paraguay.

- Currently, LEG in collaboration with the aforementioned technical units is working with some Member States on the reform of legislation on mental health, disability, HIV, foods, maternal health, adolescent health, sexual/reproductive health, tobacco control, human resources for health, health systems and services, and health information.

8. Financial implications of this agenda item:

No financial impact for the Bureau has been identified for this agenda item..

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