STATUTES OF THE PAN AMERICAN NETWORK FOR DRUG REGULATORY HARMONIZATION—PANDRH

Background

Given the need for initiatives promoting drug regulatory harmonization in the Region of the Americas, the Ministers of Health of the Region approved the creation of the Pan American Network for Drug Regulatory Harmonization (PANDRH) during the II Pan American Conference held in Washington, D.C. in November 1999 (http://www1.paho.org/english/ad/ths/ev/conf-ii-concl.pdf?ua=1);

Since its creation, PANDRH has had two statutes: the first was approved by the II Conference in November 1999 and the second at the Meeting of the Steering Committee in June 2009 and recognized by the VI Conference held in Brasilia (Brazil) in July 2011 (http://new.paho.org/hq/dmdocuments/2010/PANDRH%20Statutes-English.pdf);

During the VII Conference in Ottawa (Canada) in September 2013, the countries approved a PANDRH Strategic Development Plan for the period 2014-2020, that includes as one of its strategic objectives the need to strengthen an efficient governance of PANDRH to support regulatory convergence processes within the context of regional integration and the need to ensure that the countries are represented in the development of health regulatory systems. On that occasion, one of the decisions of the Conference was that the PANDRH Secretariat should coordinate the preparation of a new statute, within the framework of the recommendations of the VII Conference.
(http://www.paho.org/hq/index.php?option=com_content&view=article&id=8469%3A2013-vii-conference-pan-american-network-drug-regulatory-harmonization-cpandrh&catid=1156%3Ahss-pan-american-network-drug-regulation&Itemid=513&lang=en)

Article 1. General Objectives

1.1 PANDRH's general objectives are to:

1.1.1 Strengthen the regulatory functions and systems of the countries of the Region, promoting cooperation and sharing among countries, with the Pan American Health Organization (PAHO), and with other regional and international organizations, civil society, industry associations, and academia.

1.1.2. Develop, approve and implement common proposals (projects, joint activities, technical documents, guidelines, work plans, etc.) for the regulation of health technologies, taking into account international guidelines and standards for regulatory convergence.

1.1.3 Develop core competencies aimed at supporting and strengthening good regulatory practices and regulatory science in the Member States with the goal of achieving regulatory convergence in the Region.

1.1.4 Encourage the NRAs of the Region to develop and maintain well-structured organizations to achieve effective regulatory functions as an essential part of health systems, in accordance

with national needs and PAHO/WHO established criteria that can also actively contribute to achieving the stated objectives.

Article 2. Structure of PANDRH

2.1 The components of PANDRH are: the Pan American Conference on Drug Regulatory Harmonization, the Steering Committee (SC), the Secretariat, and the technical structures needed to implement projects in the agreed strategic areas.

Article 3. Members, Participants and Observers

3.1 PANDRH will have as Members the National Regulatory Authorities of PAHO member countries. PAHO will be the Secretariat.
Representatives of Regional regulatory initiatives/frameworks in the Americas and of the Associations of producers of medicines and other health technologies in the Region will be considered Participants, in addition to the Latin American Federation of the Pharmaceutical Industry (FIFARMA) and the Latin American Association of Pharmaceutical Industries (ALIFAR) that will participate as founders of the Network.

3.2 Civil society representatives that deal with issues related to the regulation of medicines and other health technologies, as well as representatives of academia, professional societies, and scientific institutions can participate as Observers in the Network's activities whenever the issue in question is relevant to the mandates of these organizations, with prior approval from the Secretariat of the Network.

3.3 The Network may also include as Observers recognized experts, regulatory authorities from outside the Region, and representatives of international agencies and initiatives for regulatory harmonization/convergence in the area of medicines and other health technologies. Observers' participation in PANDRH will require a prior invitation from the Secretariat and the approval of the Steering Committee or the coordinating NRA in the specific strategic area, as appropriate. The participation of Observers ends with the conclusion of the specific topic.

Article 4. Participation and Declaration of Conflict of Interest

4.1 Participation in the Network's structure or activities must be preceded by a "Declaration of Interests for WHO Experts" (http://www.who.int/occupational_health/declaration_of_interest.pdf).

4.2 Regional regulatory initiatives/frameworks, industry associations, civil society organizations, representatives of academia, and professional and scientific societies must officially designate their representatives and communicate it to the Secretariat.

4.3 Observer participation in the Network's activities and meetings must be by prior invitation from the Secretariat and the approval of the Steering Committee or the coordinating NRA in the specific strategic area, as appropriate, and must be preceded by the filling and presentation of the "Declaration of Interests for WHO Experts."

Article 5. Sources of Network Financing

5.1 PANDRH's financing, including conferences, meetings of the Steering Committee, projects, and any meeting or activity held within the framework of the Network will depend on the mobilization of resources from the PAHO member countries. Additional funding sources could include:

I. Governments outside the Region;

II. Industry associations involved in the different health technologies;

III. Professional or scientific research associations;

IV. Payment for attendance at conferences and other events;

V. Nongovernmental organizations;

VI. The Network's joint fund, whose structure and management are to be established jointly with PAHO; and

VII. Other initiatives or institutions with PANDRH-related activities.

5.2 Contributions from the sources listed above will be accepted in accordance with the standards and principles that govern the planning of PAHO's activities.

5.3 PAHO's contribution will be in its role as Secretariat of the Network, with the human and financial resources involved in that activity as well as possible earmarked funds that may have been destined to PANDRH activities in the budgetary planning of PAHO.

5.4 The Network's educational activities will be self-financed, with the exception of a limited number of staff provided by the Region's health authorities and regulatory systems.

5.5. Representatives of the Member countries will use their own resources or sources approved in accordance with PAHO/WHO standards and principles for participation in the Network's activities and on-site meetings.

Article 6. The Conference

6.1 The Pan American Conference on Drug Regulatory Harmonization is an open forum for discussion of topics of common interest involving the regulation of different health technologies. It is the forum where all stakeholders in drug regulatory harmonization can participate, to provide all PANDRH structures with general directions for consideration for internal work.

6.1.1 The Conference has the following responsibilities:

6.1.1.1 Monitor and review the objectives and outcomes of the Network's strategic development plans

6.1.1.2 Support the Network's activities as well as the objectives of the strategic areas, based on reviews and approvals by the Network's Steering Committee.

6.1.1.3 Promote and maintain constructive dialogue among the Region's regulatory authorities and regulatory systems, and with other stakeholders such as industry associations, NGOs, civil society, and professional, scientific, and academic institutions.

6.1.1.4 Promote harmonization and regulatory convergence in the health systems of the Region of the Americas.

6.1.1.5 Recommend actions that contribute to national and regional implementation of the proposals presented by PANDRH structures, and follow activities developed by the Steering Committee.

6.1.1.6 Foster technical cooperation among countries and with other institutions in the area of health and product regulation, both inside and outside of the Region.

6.1.1.7 Foster dialogue with global harmonization and/or regulatory convergence initiatives, and promote study on subjects of particular interest in regulatory convergence processes, as well as the study of technical guidance documents and the possibility of implementing joint projects to solve specific regulatory problems.

6.1.1.8 Promote general effectiveness and efficiency in the Network's processes.

6.2 The Conference will normally be held every two years, on a rotating and voluntary basis, in one of the Member countries, with the approval of the Steering Committee. If more than one Member offers to hold the Conference, the Steering Committee will deliberate on this with the Secretariat.

6.3 The recommendations and conclusions of the Conference will be adopted by consensus in the plenary session. If consensus is not achieved, the different perspectives will be stated in the corresponding reports.

6.4 The Conference will be presided over by the regulatory authority of the host country, with the support of the Secretariat. The recommendations and decisions of the Steering Committee will be taken into account in the preparation of the agenda.

Article 7. The Steering Committee

7.1 The Steering Committee (SC) is the decision-making body for the strategic and operational management of the Network, providing guidance for progress on projects and activities, and making recommendations for evaluation and discussion at the Conference.

7.1.1 The SC has the following functions:

7.1.1.1 Use approved methodology to propose priority areas aimed at creating or strengthening regulatory capacities through harmonization and/or convergence.

7.1.1.2 Ensure the continuity of project implementation activities in the designated strategic areas, in coordination with the responsible regulatory authorities.

7.1.1.3 Monitor and evaluate reports on the implementation and outcomes of projects in the designated priority areas, and decide on their continuity, modification/adjustment, or suspension.

7.1.1.4 Supervise the management of the Network's financial funds;

7.1.1.5 Develop the structure and management of the Network's joint fund.

7.1.1.6 Ensure, with the support of the Secretariat and the host country, that the Conference is prepared and held so as to meet the proposed objectives.

7.1.1.7 Monitor and evaluate the implementation of the Conference's directions.

7.1.1.8 Support the Secretariat in the development and maintenance of a communications network to disseminate information on the progress of national and sub-Regional convergence and/or harmonization processes, promoting the Regional Platform on Access and Innovation for Health Technologies (PRAIS) or another similar platform as a communication tool.

7.1.1.9 Make proposals and/or decisions regarding new projects or strategic areas, and take decisions on the participation of outside experts in consultations or scientific studies, whenever this is necessary, to facilitate consensus in the Conference and to support the Network's decision-making, subject to the availability of funding.

7.1.1.10 Make proposals on topics for discussion at the Conference

7.2 The Steering Committee will be composed of the Secretariat and of Members and their corresponding Alternates, officially designated to represent each sub-Region of the Region of the Americas, as follows: North America, Central America + Cuba + the Dominican Republic, the Caribbean, the Andean Region, and the Southern Cone[1].

7.3 The Steering Committee will reserve a private space for decision-making by the representatives of the health authorities or Regional regulatory systems/frameworks appointed in accordance with point 7.2, above.

7.4 Steering Committee Members will be appointed for a four-year term, ensuring rotation among the countries in each sub Region and communicated officially to the Secretariat. Rotation will occur at the Pan American Conferences where, in order to ensure continuity of work, up to three of the five members and alternates should be changed, according to their seniority.

7.5 In its discussions and consideration of priorities and relevant subjects, the Steering Committee will invite the participation of representatives of the secretariat of national regulatory authorities of regional reference (NRAr), representatives of the Region's regulatory initiatives/frameworks and associations of producers of health technologies, as well as FIFARMA and ALIFAR in their role as founding members.

7.5.1. Representatives of non-founding associations may also be invited if they meet the criteria defined by the Steering Committee and have received an invitation.

7.6 Other representatives from the Region's NRAs or regulatory systems are free to participate as observers.

7.7 Guest observers from other NRAs, regulatory systems, or initiatives outside the Region may also participate in the Steering Committee by direct invitation from the SC or at the request of the interested parties, at least two weeks prior to the meetings, and based on case-by-case consideration and approval.

[1] **North America:** United States, Canada and Mexico
Central America + Cuba + Dominican Republic: Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, Panamá, Cuba, Dominican Republic;
Caribbean: Antigua and Barbuda, Bahamas, Barbados, Belize, Dominica, Grenada, Guyana, Haiti, Jamaica, Montserrat, St Kitts and Nevis, Saint Lucia, St Vincent and the Grenadines, Suriname, Trinidad and Tobago
Andean Region: Bolivia(Plurinational State of), Chile, Colombia, Ecuador, Peru, Venezuela(Bolivarian Republic of)
Southern Cone: Argentina, Brazil, Paraguay, Uruguay.

7.8 The Steering Committee will meet in person at least once a year and will hold virtual meetings whenever necessary. Steering Committee Members should include these activities in their institutional work plans in order to ensure their participation.

7.9 The decisions of the SC will be made by consensus and will be official whenever at least 50% of the members are present in person or remotely. If quorum is not achieved, the decisions will await future approval by the SC, either at an on-site or virtual meeting.

Article 8. The Secretariat

8.1 The Pan American Health Organization (Regional Office of the World Health Organization for the Americas PAHO/WHO) serves as Secretariat of all the Network's components (Conference, Steering Committee, and technical structures).

8.1.1 The Secretariat provides technical and administrative support to PANDRH and has the following functions:

8.1.1.1 Organize and hold the Conference jointly with the SC and the host country, and coordinate the activities resulting from the recommendations of the Conference, the decisions of the SC, and all PANDRH-related activities.

8.1.1.2 Use the PRAIS Platform as tool to support the activities of PANDRH. Accordingly, communities of practice should be created on the PRAIS Platform or other similar platforms for each sub Region of the Americas represented on the SC, in order to facilitate coordination of work and monitoring of project implementation in the strategic areas defined by the Network, and to foster and guide dialogue among members and participants.

8.1.1.3 Keep an up-to-date list of the Members of the Network, persons responsible for strategic areas, project leaders, and participants in the projects, based on information received from the Members.

8.1.1.4 Offer technical cooperation upon request from national regulatory authorities for the promotion of regulatory convergence. This could be done, either directly or with the technical assistance of experts and consultants, taking into account the requirements of the requesting NRAs or regulatory systems, the recommendations of the SC, and the needs of the Network's technical structures.

8.1.1.5 Act as liaison, spokesperson and center for dissemination of information on the Network, including the activities carried out, technical documents produced, and/or educational materials approved.

8.1.1.6 Represent the Network vis-à-vis global and interregional regulatory harmonization and convergence initiatives (ICDRA, ICH, PIC/S, APEC, WHO, etc.), in consultation and coordination with the SC and the NRAs of the Region.

8.1.1.7 Consult outside experts at the request of the SC or PANDRH technical structures, to support the study of subjects of interest, provided that financial resources are available.

8.1.1.8 Keep the PANDRH website updated and with links to websites of the NRAs of the Region, other relevant international initiatives, the PRAIS platform, and other similar sites. It should also promote wide dissemination of information on the Network; and ensure that published and archived documents are made available, as well as documents for public comments, including project reports, technical documents, situation assessments, and proposals for human resources training in the regulation of health technologies.

8.1.1.9 Support the SC in the management of the Network funds, and facilitate the preparation of the annual financial statement, with contributions from the Members responsible for projects and strategic areas.

8.1.1.10 Help the member countries to improve regulatory functions through the periodic evaluation of their capacities.

Article 9. Technical Work of PANDRH

9.1 The Network's technical work will be configured to support the directions and decisions of the Steering Committee through the implementation of projects within each of the Network's priority areas.

9.2 The execution of technical work within PANDHR will be coordinated by a NRA Member. Such work will be described in one or a group of projects as approved by the SC in order to achieve the goal of a defined strategic area.

9.3 The strategic areas will be defined using the approved prioritization methodology and will be coordinated preferably by a national regulatory authority already designated as NRAs of regional reference (NRAr) based on Resolution CD 50.R9.

9.4 The NRAs Coordinators of each strategic area will be responsible for identifying, supporting, and monitoring projects with clearly defined targets, resources, time frames, and products in order to achieve the objectives of that strategic area; and for fostering the required activity in the projects and activities in the area under their responsibility.

9.5 The projects will be led by the Members (NRAs of the countries of the Region) that volunteer to do so, based on their strengths and in close collaboration with the NRA Coordinator responsible for the corresponding strategic area. Coordinators should ensure, as much as possible fair representation among Sub-Regions on the nomination of Project Leaders within the strategic area.

9.6 Each project should include a group of subject matter experts, i.e., a person with thorough technical know-how and demonstrated experience on the subject, named by a Member (NRA) or participant, as defined in Article 3. Subject matter experts will participate in compliance with the requirements of Article 4 of these statutes. Regional regulatory systems/frameworks can nominate experts to help on the execution of projects.

9.7 Experts from other regions can participate in projects upon prior agreement with the Project Leader and the NRA Coordinator of the strategic area, provided that financial resources are available from the countries.

9.8 The number of designated representatives as Members or experts in a project will depend on the specific subject. It is advisable to have as few as possible and to rely on consultations as often as necessary. It is recommended that each project should not have more than nine (9) designated representatives (including Members and participants).

9.9 Each Coordinator of the strategic area will keep a record of the Project Leaders and participants within their area of responsibility and will inform the Secretariat of any change of designation.

9.10 The Coordinators of strategic areas, as well as Project Leaders, must submit progress reports to the Steering Committee annually or whenever requested, and every two years at the Conferences. Reports should include where applicable, a description of controversial issues for

monitoring and eventual decisions on the continuity, adjustment, or suspension of activities. NRA Coordinators and Project Leaders should therefore stay in active contact with the Secretariat and the SC on the progress of the project, alerts, exchange of information, or requests for decisions. It is advisable to use the resources available at PRAIS and other platforms as a tool to support project activities.

9.11 PANDRH will also support the existence of technical networks for the exchange of information within designated focal points on regulatory issues within the scope of PANDRH.

Article 10. Final Provisions

10.1 The Network will adopt a communications strategy that includes procedures for interactions both within and outside the Network, dissemination of documents and results, and public consultations on documents and projects. The use of virtual communications such as video conferences, teleconferences, sites of discussion of documents and dissemination of data in the Platform PRAIS or similar will be promoted.

10.2 This Statute entirely replaces the one approved by the VI Pan American Conference on Drug Regulatory Harmonization.

10.3 Situations not considered in this Statute will be dealt with by the Steering Committee with the support of the PANDRH Secretariat.

This Statute was approved in the virtual meeting of the PANDRH Steering Committee on December 16th, 2015.

ABBREVIATIONS

ALIFAR: Latin American Association of Pharmaceutical Industries

APEC: Asia-Pacific Economic Cooperation initiative

NRA: National Regulatory Authority

NRAr: National Regulatory Authority of regional reference

SC: Steering Committee

FIFARMA: Latin American Federation of the Pharmaceutical Industry

ICDRA: International Conference of Regulatory Drug Authorities

ICH: International Conference on Drug Regulatory Harmonization

NGO: Nongovernmental organizations

PAHO: Pan American Health Organization

PAHO/WHO: Pan American Health Organization/ World Health Organization

PRAIS: Regional Platform on Access and Innovation for Health Technologies

PIC/S: Pharmaceutical Inspection Cooperation Scheme