

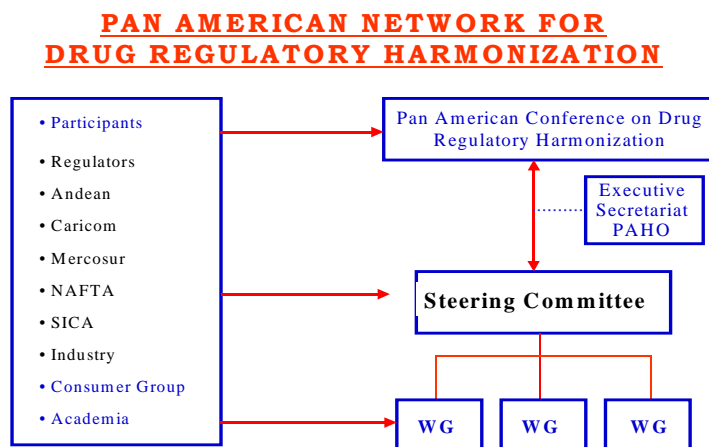
**PAN AMERICAN NETWORK FOR DRUG
REGULATORY HARMONIZATION
(Norms and Regulations)**

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PAN AMERICAN NETWORK FOR DRUG REGULATORY HARMONIZATION

The Pan American Network for Drug Regulatory Harmonization (PANDRHA) is an initiative to support the processes of drug regulatory harmonization throughout the Americas.

The Pan American Conference on Drug Regulatory Harmonization, the Steering Committee and the Working Groups on as many themes defined as priorities by the Conference, are the main components of PANDRHA.



1. THE CONFERENCE

1.1 *Mission*

The Conference should promote drug regulatory harmonization for all aspects of quality, safety, and efficacy of pharmaceutical products as a contribution to the quality of life and health care of the citizens of the Member Countries of the Americas.

1.2 *Objectives*

- To promote and maintain a constructive dialogue among regulatory agencies, the pharmaceutical industry, and other sectors, through periodic Conferences.
- To encourage convergence of drug regulatory systems in the Pan American Region
- To adopt recommendations for implementation at national and regional levels.
- To encourage and facilitate technical cooperation among countries.

- To promote harmonization of medicinal drug regulation requirements, and guidelines for specific regulatory issues.

1.3 Goals

- To examine global regulatory systems.
- To develop and adopt proposals for technical/regulatory harmonization.
- To review existing medicinal drug regulation requirements and guidelines for specific issues.
- To identify and discuss medicinal drug regulation implementation issues.

1.4 Functions

- To promote the participation of all interested parties in the Americas and those invited by the Steering Committee. National and regional medicinal drug regulatory authorities, subregional integration agencies, pharmaceutical industry, pharmaceutical bodies, academia, and consumer associations should be encouraged to attend.
- Conferences shall be held every two years on the dates and place determined by the Steering Committee
- To adopt all Conference recommendations and conclusions through consensus in plenary sessions. If consensus cannot be reached, the different points of view will be recorded.

1.5 Participants

- Regulatory Authorities from each Member States
- Representatives from:
 - Regional and national pharmaceutical industry associations (research-based, generic, OTC, other)
 - Consumer groups
 - Academia
 - Professional pharmaceutical associations
 - Regional economic integration groups
 - Global drug harmonization initiatives
 - Other interested groups

2. THE STEERING COMMITTEE

2.1 *Mission*

The Steering Committee should facilitate advancement between Conferences by coordinating, promoting, facilitating and monitoring harmonization processes in the Americas.

2.2 *Objectives*

- To ensure the effectiveness of the Conference and the relevance of the topics addressed by the Conference.
- To facilitate and monitor implementation of Conference recommendations.
- To ensure continuity of drug harmonization activities between Conferences.
- To facilitate consensus-building and resolutions of issues between and at the Conferences.

2.3 *Goals*

- To identify experts and request broader scientific consultation to facilitate consensus at the Conferences.
- To develop and maintain an information system to disseminate information on the progress of harmonization processes at national and subregional levels.
- To identify mechanisms for fostering capacity building and technical and scientific cooperation.
- To provide current, accurate information on regulatory systems on a timely manner.

2.4 *Functions*

- To organize meetings, workshops, and other related activities to carry out the recommendations of the Conference.
- To establish study groups on regulatory topics identified by the Conference as relevant.
- To determine the preparatory activities required for subsequent Conferences.
- To determine the best methods to resolve issues to reach consensus.
- To convene meetings at which a quorum of two thirds of the membership are present.

2.5 Members

- Five Members compose the Steering Committee: Regulators from five (5) countries, or their representative. One from each Sub-Regional Group (Andean Area, CARICOM, Central America [including Cuba and the Dominican Republic], MERCOSUR [including Chile], and NAFTA).
- One representative from FIFARMA.
- One representative from ALIFAR.
- Five (5) Alternate Members. Regulators from five (5) countries, or their representatives. One from each Sub-Regional Group.
- Two (2) Substitute Members: One from FIFARMA and one from ALIFAR.

2.6 Nomination

- The Pan American Conference will nominate the members of the Steering Committee.
- With the exception of the representatives from ALIFAR and FIFARMA, all other Members and Alternates should be regulatory authorities from Member States of PAHO.
- In order to maintain continuity during each Pan American Conference, up to three of the five Members and Alternates will be changed.
- Members will serve for a period of four years. Members with more seniority in the SC will change during each Conference.
- Nomination of members will take into account representation from the different geographical groups, including all countries in the American Region.

2.7 Communication and Meetings

- The Steering Committee will meet at least once every year preferably in a place and date on which other activities related to drug regulation take place.
- Video, telephone, and virtual conferences will be promoted as a means to discuss and exchange information among members of the SC. E-mail should also be used by the Secretariat to keep SC members abreast of new developments.
- Regulators from countries not represented in the SC may participate at meetings of the SC.
- Representatives from NGOs recognized by PAHO/WHO and other stakeholders invited by the Steering Committee may attend meetings of the SC as observers.

3. FINANCING

- Financing for the Conferences, the meetings of the Steering Committee and those of the working groups, including preparatory activities, will be sought from the following sources:
 - Pharmaceutical industry associations
 - Professional associations
 - Governments
 - Conference registration fees
 - PAHO contributions
 - NGOs
 - Other

4. SECRETARIAT

- The Pan American Health Organization will serve as the Secretariat of the Network, the Conference, and the Steering Committee.
- The Secretariat shall:
 - Provide administrative and technical support to the Network;
 - Coordinate actions deriving from recommendations made by the Conference;
 - Act as a clearinghouse for information;
 - Arrange for expert advice and consultants to assist regulatory authorities in promoting medicinal drug regulatory harmonization;
 - Act as liaison, whenever appropriate, with similar programs such as ICDRA (organized by WHO), ICH, and other national or regional trade agencies, and others as necessary;
 - Maintain permanent communication with all members of the Steering Committee; and
 - Seek financing sources for the operations of the Network.

5. WORKING GROUPS

- Each Working Group (WG) will be established and assigned specific tasks by the SC based on Conference recommendations.

5.1 *Thematic Leader and Members*

- Each WG will have a Thematic Leader and/or a Coordinator and an Alternate Coordinator.

- Thematic Leaders, Coordinators, and Members of the WG will be appointed/selected by the SC and all shall be representative of national regulatory authorities. The SC can make exceptions to this rule.
- The minister of health of participants' countries shall confirm the member of the Working Group representing governmental institutions.
- Members of the Working Group should be experts in the specific area of the WG. Experts are defined as persons with deep theoretical knowledge and verifiable practical experience in the field.
- The Secretariat shall keep a file with the curricula vitae of all WG members.
- The number of members in each WG will depend on the subject. It is advisable to keep it as small as possible to encourage consultation outside the group as needed. A total of up to 9 members is recommended.
- It is unlikely that a country will have a representative in all WG.
- A member of a WG cannot participate as such in more than two Working Groups.
- Any member may, at any time, through written notice to the Secretariat, resign his/her membership from the WG.
- Each WG shall develop diagnostic studies, identify technical gaps among countries, formulate harmonized proposals in its area of expertise, and a cooperation plan among countries.
- WGs shall also follow-up the implementation of Conference recommendations and approved proposals in its area of work at the national and subregional levels.
- Members who cannot attend two consecutive meetings will forfeit their representation.
- Whenever an expert attends two consecutive meetings in representation of another member, that expert will replace the member indefinitely.
- Representation in the WG will be flexible, and vary from WG to WG depending on the subject area. Representation should include stakeholders and technical experts from the public or private sectors. The Steering Committee will encourage representation from subregional groups.
- To assure the effectiveness of a WG, continuity of its representatives should be encouraged to the extent possible.
- To encourage maximum participation, WG representation will be balanced within the WG and among WGs.
- Proposals for new Working Groups shall be approved and adopted by the Conference.

5.2 Work Plan

- A well-defined, written work plan should be developed by each WG.
- All work plans will be authorized/approved by the SC.

5.3 Communication and meetings

- The use of means of communications such as e-mail, videoconference and teleconference should be encouraged.
- Fifty-one percent (51%) of the members shall constitute a quorum for any meeting of the WGs.
- All meetings of the WGs shall be convened by the Secretariat.

5.4 Reporting Mechanisms

- The Thematic Leader or Coordinator shall make periodic updates of WG progress to the SC at designated times.
- The Thematic Leader or Coordinator from each WG will submit a written report to the SC at designated times.