



## **PAN AMERICAN NETWORK FOR DRUG REGULATORY HARMONIZATION (PANDRH)**

### **STATUTES**

The Pan American Network for Drug Regulatory Harmonization (PANDRH) is an initiative of the national regulatory authorities within the Region, and PAHO, that supports the processes of pharmaceutical regulatory harmonization in the Americas, within the framework of national and sub-regional health policies and recognizing pre-existing asymmetries.

The Components of PANDRH are:

The Pan American Conference on Drug Regulatory Harmonization (PANDHR), the Steering Committee (SC), the Technical Working Groups (WGs) in the areas considered as priority by the Conference, and the Secretariat.

### **I. PAN AMERICAN NETWORK**

#### **I.1. Vision**

That countries from the Region of the Americas implement pharmaceutical policies promoting access to medicines coherent with standards of quality, safety and efficacy, and pharmaceutical harmonization within the Region of the Americas through technical cooperation, contributing to the quality of life and health care of its citizens.

#### **I.2 Mission**

To promote the harmonization of pharmaceutical regulation covering aspects of quality, safety, efficacy and rational use of pharmaceutical products, the strengthening of National Regulatory Authority (NRA) capacity within the Region of the Americas based on the right of the population to access quality medicines, recognizing advances in science and technology and within the context of national and sub-regional realities.

#### **I.3. Objectives**

I.3.1 To strengthen regulatory authorities in countries of the Region promoting inter-country cooperation

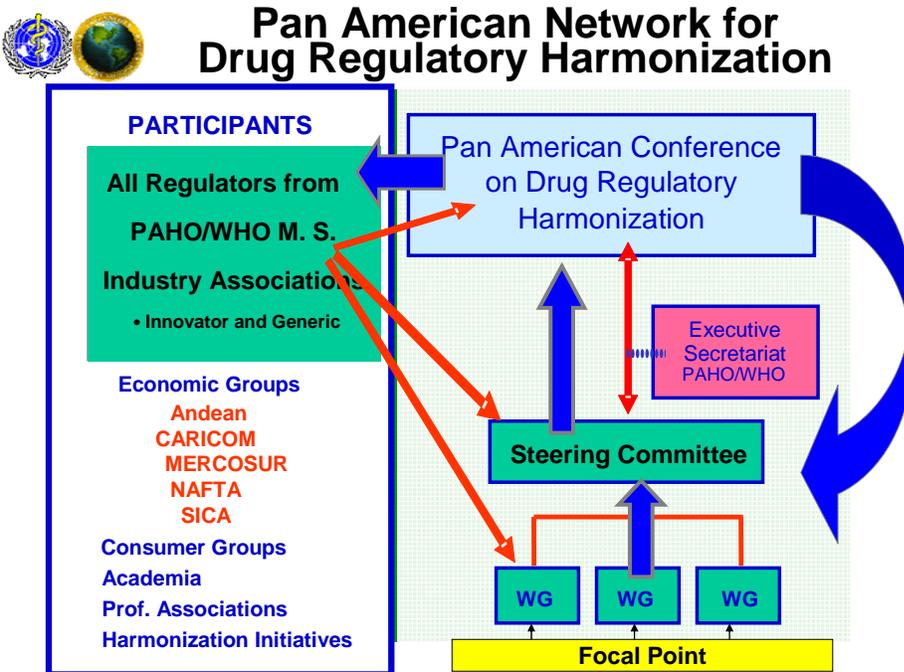
I.3.2. To develop and approve harmonized proposals (technical documents, guidelines, etc.) in medicine's regulation

I.3.3. To identify support mechanisms for the implementation, monitoring and evaluation of proposals adopted and approved by NRAs through PANDRH.

I.3.4. To promote qualification of the NRAs in the Region in accordance with criteria established by PAHO/WHO and in order to establish reference Regulatory Authorities and contribute actively to the achievement of other objectives.



## I.4. Composition of the Network



I.4.1. The PANDRH Network is composed of the Pan American Conference on Drug Regulatory Harmonization, the Steering Committee, the Secretariat, and the working groups.

## I.5. Members

I.5.1. The members of PANDRH are the NRAs of PAHO/WHO Member States, one representative from ALIFAR and one from FIFARMA.

I.5.2. PANDRH may have Observers, representatives of recognized international and/or national organizations working in the area of pharmaceutical regulation. Observers shall be approved by the PANDRH Steering Committee.

## I.6. Financing of the Network

I.6.1. The financing of PANDRH including the Conferences, the meetings of the Steering Committee and of the Working Groups, and any activity that is carried out within the framework of the Network will be requested through the Secretariat and may be derived from the following sources

- Contributions from PAHO
- Governments
- Associations of the pharmaceutical industry



- Professional associations
- Payments by attendance at the Conference and other events
- NGOs
- Other

1.6.2. The acceptance of contributions from sources cited in the previous paragraphs will be subject to the norms and principles that regulate programmed activities of PAHO.

1.6.3. The educational activities of the Network will be self-financed in such a way as to support the participation of a limited number of NRAs in such activities.

## **II. THE CONFERENCE**

### **II. 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.

### **II.2. Objectives**

II.2.1. Promote and maintain a constructive dialogue among regulatory agencies, the pharmaceutical industry, and other sectors, through periodic Conferences.

II.2.2. Encourage convergence of drug regulatory systems in the Pan American Region.

II.2.3. Adopt recommendations that contribute to the implementation, both at the national and regional level, of harmonized proposals presented by the Steering Committee and the working groups of the PANDRH Network.

II.2.4. Encourage and facilitate technical cooperation among countries.

II.2.5. Promote the analysis of priority issues of interest in processes of pharmaceutical regulatory harmonization, technical documents and guidelines addressing specific problems in regulation, and review global regulatory systems

II.2.6. Promote the overall efficiency and effectiveness of operations of Network.

### **II.3. Operational principles**

II.3.1. The Conferences will be organized every two years at a date and place determined by the Steering Committee.

II.3.2. The Conferences will be open forums for discussion for themes of interest in pharmaceutical regulation.



II.3.3. Those participating in the Pan-American Conferences for the Harmonization of Pharmaceutical Regulation are the Regulatory Authorities of the countries of the Region of the Americas, Representatives from: Regional associations of the pharmaceutical industry, Consumer groups, Academia, Professional associations, groups of economic integration and global harmonization initiatives in pharmaceutical regulation.

Note: The general public and other interested parties can participate in the Conference in accordance with conditions determined by the Steering Committee of the PANDRH.

II.3.4. The recommendations and conclusions of the conferences will be adopted by consensus in the plenary sessions. If it is not possible to reach a consensus, the different points of view will be stated in the reports.

II.3.5. Any decision taken at the Conference with regard to the recommendations, modification of the present norms and procedures of the Network and approval or adoption of the proposals presented by the Working Groups of the PANDRH is at the sole discretion of the PANDRH and is only for members of the PANDRH.

II.3.6. The NRA of participating countries will be registered at the Conference in order to be identified as the competent authority.

II.3.7. The representatives of the regional associations of the pharmaceutical industry that participate in the review and/or approval of documents presented by the WGs must be registered at the Conference, identifying themselves as members of the SC.

II.3.8. Decisions regarding proposed recommendations, guidelines, technical documents, regional studies, etc, for approval or adoption by the NRAs registered at the Conference will be taken by consensus.

II.3.9. The Conference will be chaired by the Regulatory Authority of the host country.

### **III. STEERING COMMITTEE**

#### **III.1 Mission**

The Steering Committee should facilitate advancement of the work program between Conferences by directing, coordinating, promoting, facilitating, and taking account of processes of harmonization in the Americas, according to the recommendations of the Conferences

#### **III. 2 Objectives**

III.2.1. To propose and give direction to the Conference in order to improve the functioning of the PANDRH.

III.2.2. To ensure the effectiveness of the Conference and the relevance of the topics addressed by the Conference.



III.2.3. To facilitate and analyze implementation of Conference recommendations.

III.2.4. To identify support mechanisms that will facilitate the implementation of technical documents that have been harmonized and approved by the PANDRH

III.2.5. To ensure continuity of drug harmonization activities between Conferences

### **III.3. Functions**

III.3.1. To ensure the strategic and operational management of the PANDRH.

III.3.2. To analyze and prioritize recommendations issued by the Conference.

III.3.3. To stimulate actions necessary to ensure compliance with the recommendations of the Conference.

III.3.4. To define and propose the strategies and directives to promote, coordinate, and facilitate harmonization processes in the Region.

III.3.5. To request the Secretariat to develop and maintain an information system in order to disseminate information on advances during the process of harmonization at the national and sub-regional level.

III.3.6. To identify and leverage mechanisms promoting capacity building, and scientific and technical cooperation.

III.3.7. All the members of the Steering Committee (SC) jointly and separately will promote the participation of all countries in the Conferences urging national and regional regulatory authorities, mechanisms of sub-regional integration, the pharmaceutical industry, pharmaceutical groups, academic institutions and consumer associations to attend the conferences.

III.3.8. To receive and evaluate requests for the creation of new Working Groups or extension of existing Working Groups (WG) and forward same for the consideration of the decision-making level of the PANDRH. Requests shall include a description of the problem, proposed solution, benefits and estimated costs.

Under exceptional circumstances and when justified, the SC may establish a new WG. The decision to establish such a WG will be presented in the following Conference by the SC.

III.3.9. To determine when the work program of a given WG is completed and in such circumstance request the Secretariat to inform the Members of the WG of the cessation of activities.

III.3.10 To prepare the agenda for the Conference and organize jointly with the Secretariat logistics for the Conference.



III.3.11. To request the Secretariat to organize meetings, workshops, and other related activities that the Committee considers necessary for the implementation of recommendations of the Conferences and the decisions of the PANDRH.

III.3.12. To identify experts and request additional scientific consultations to facilitate the achievement of consensus in the Conference and any decisions of PANDRH.

III.3.13. To request the Secretariat to execute studies on pertinent and relevant subjects relating to pharmaceutical regulation the results of which can be presented in the Conferences.

III.3.14. To determine the preparatory activities required for subsequent Conferences

### **III.4. Members**

III.4.1. The Steering Committee will be composed of (5) five members: national medicines regulatory authorities, or their representatives. One from each sub-regional block (The Andean Region (including Venezuela), CARICOM, Central America (including Cuba and the Dominican Republic), MERCOSUR (including Chile), and NAFTA. One representative from FIFARMA. One representative from ALIFAR

A meeting of the SC will occur when all sub-regional representatives of the SC can participate.

III.4.2. Seven (7) alternate members corresponding to five medicines regulatory authorities or their representatives who have been accredited by PANDRH from five countries; one country from each group of countries indicated in the previous numeral: One representative from FIFARMA; One representative from ALIFAR.

III.4.3. All members and alternates will retain institutional representation, and not personal.

SC members are expected to: represent the views of the NRAs of their respective sub-region; inform with the support of the Secretariat when necessary NRAs of SC activities and decisions.

### **III.5. Nomination**

III.5.1. The members of the Steering Committee will be nominated to the Conference following proposition by the countries in the respective sub-regional block.

III.5.2 . In order to maintain continuity during each Pan American Conference, up to three of the five Members and Alternates will be changed.

III.5.3 . Members will serve for a period of four years. Members with seniority in the SC will change during each Conference



### **III.6. Communication and Meetings**

III.6.1. The Steering Committee will meet at least twice every year; two meetings preferably in a place and date on which other activities related to drug regulation take place; with additional virtual meetings

III.6.2. 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.

III.6.3. The regulatory authorities of countries that are not part of the Steering Committee can also participate in the meetings of the Committee as Observers.

III.6.4. Representatives from NGOs recognized by PAHO/WHO and other stakeholders may be invited by the Steering Committee to attend meetings of the SC as observers and in order to provide input in specific issues.

### **IV. THE SECRETARIAT**

IV.1 The Secretariat of the Network in all its components: Pan American Conferences, the Steering Committee and the Working Groups will be provided by the Pan American Health Organization, Regional Office of the World Health Organization.

#### **IV.2. Functions**

IV.2.1. The Secretariat will provide technical and administrative support to the PANDRH.

IV.2.2. The Secretariat will coordinate activities arising from recommendations of the Conference, from the decisions of the Steering Committee as well as all activities related to the PANDRH.

IV.2.3. The Secretariat will organize Conferences jointly with the SC.

IV.2.4. The Secretariat will convene the Conference at the request of the SC. In addition the Secretariat will convene all meetings of the Working Groups (in liaison with the WG Coordinator) and other meetings that are developed within the framework of the Network.

IV.2.5. The Secretariat jointly with the Steering Committee will prepare the Program for the Conference and is responsible for preparing the final report of the Conference.

IV.2.6. The Secretariat will prepare the agenda of the meetings of the working groups will convene the meetings and will prepare the reports of those meetings together with the Coordinator.



IV.2.7. The Secretariat will act as center for the dissemination of information regarding the Network presenting technical documents that are processed and approved by the PANDRH.

IV.2.8. Arrange for expert advice and consultants to assist regulatory authorities in promoting drug regulatory harmonization, taking into consideration the requirements of the NRAs and the needs of the WGs.

IV.2.9. Maintain permanent communication with all members of the Steering Committee

IV.2.10. Act as liaison and representative of the Network in global and interregional harmonization organizations (ICDRA, ICH, APEC, WHO, etc) in consultation and coordination with the SC.

IV.2.11. At the request of the Steering Committee or the Coordinator of the WGs, create ad-hoc groups for the study of issues and in support of the development of proposals that advance or serve as a complementary activity to the WGs.

IV.2.12. Maintain updated WG Member Resumes and make them available to coordinators, members of the SC and other entities within PANDRH.

IV.2.13. Maintain an updated Web page for the PANDRH; promoting links between the Network Web page with that of the NRAs of the Region and with relevant international initiatives, and to promote the availability of information on the Network in different pages such as those of other related programs (AIDS, Malaria, chronic diseases, etc).

## V. WORKING GROUPS

### V.1. Composition

V.1.1. Each Working Group (WG) will be established and assigned specific tasks by the SC based on Conference recommendations.

V.1.2. The WGs will be composed of experts on the subject matter of the group, understanding “expert” to mean a person who has a thorough technical knowledge in a field and can demonstrate broad experience in the specialized subject.

V.1.3. 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.

V.1.4. A WG may have the following categories of members:

**Main Member:** represents of the NRA of a country in each sub-regional block (five members), the regional Industrial Associations ALIFAR and FIFARMA (up to two members) and those designated by the Secretariat (up to two members). The Coordinator (one of the NRAs of the Working Group) of the Working Group will retain the responsibility to identify observers and expert resources.



**Alternate or Substitute:** members designated to attend the meetings instead of the principle member.

**Observer:** from any country generally nominated by a participating NRA.

**Expert Resource:** Every group may avail of up to two experts to support a specific activity of the WG and/or to attend the meetings.

**Secretariat:** a PAHO professional will provide technical support in the development of the work program of the WG.

V.1.5. The NRAs of countries that are not represented in the WGs can designate Focal Points in the WGs of the Network. This designation is voluntary and the professionals thus designated can participate in technical discussions via e-mail on documents and guidelines that the WGs are developing. The Focal Points should be professionals in charge or responsible for the subjects of the WG within their respective regulatory. The combination of Members and Focal Points will form Networks of Technical Discussion.

Because it is not possible for each country to have a representative on every WG, country focal points will be established for each WG to promote dissemination of information and comments on WG documents. Comments from the Focal Points should be channeled to their respective Regional WG representatives.

V.1.6. Any member can, at any moment, withdraw it's participation in the working group. The changes in membership must be requested by the Coordinator of the ARN. In the case of experts or representatives of associations the Secretariat should be notified directly.

The Coordinator of the WG in consultation with the Secretariat will request designation of the new WG member from the corresponding entity.

In addition, any NRA can take the decision to change its designated WG member, informing the Secretariat of this change.

V.1.7. The Steering Committee will promote the representation of sub-regional groups in the WG. In order to promote broad participation, there will be a balance of representatives in each group and among the groups.

V.1.8. A member of a WG cannot participate in more than two Working Groups

V.1.9. The Steering Committee, will review the composition of the groups analyzing requests from new members, ratify existing members and/or reviewing renewals of designation and identifying possible replacements.

## **V.2. Coordinator**

V.2.1. Each WG will have a Coordinator and an Alternate Coordinator from different NRAs / Sub-region.



V.2.2. The coordination (incumbent and alternate) of any WG is the responsibility of a Regulatory Authority. Exceptions to this rule can be established based on scientific justification.

V.2.3. The coordinators will be selected or designated by the Working Group from NRAs with recognized competency in the technical area and that offer voluntarily to coordinate the WG. In the case where no NRA has volunteered, the SC will propose the coordinator from among the NRAs requesting their participation as coordinator.

An NRA may not coordinate more than two WGs at any given time.

V.2.4. The coordinator can voluntarily resign by submitting written notice issued by the NRA to the Secretariat

### **V.3. Functions of the Coordinator**

V.3.1. Lead the development process for technical documents in the Group

V.3.2. Follow up on the Work Plan making sure that members perform assigned tasks by the agreed deadline.

V.3.3. Chair and coordinate the meetings of the WG.

V.3.4. Report periodically to the Steering Committee on progress achieved by the Group through six-monthly written reports or when specifically requested by the Committee and approved by the Members of the Group. Issues that are contentious should be noted within the report, presenting the diverse opinions.

V.3.5. The Coordinator will seek and promote consensus among the members of the WG in decisions of the Group.

V.3.6. The WG Coordinator will liaise with the Secretariat on the organization of the WG meetings, and in accordance with the work plan of the WG.

### **V.4. Functions of the Working Groups**

V.4.1. The Working Groups are responsible for developing harmonized proposals on priority issues of interest in the area of pharmaceutical regulation

V.4.2. Develop base line and follow-up diagnostic studies, identify technical differences between countries, and formulate harmonized proposals in its area of expertise, and plans of cooperation among countries in priority topics of interest in the area of pharmaceutical regulation.

V.4.3. The WGs shall also ensure follow-up on implementation of Conference recommendations and approved proposals in its area of work at the regional and national level

V.4.4. Prepare a work plan and submit it for approval by the Steering Committee



V.4.5. To design training proposals in training and to accompany implementation during the pilot phase.

V.4.6. Develop and adapt educational material in areas or issues identified as necessary for a better comprehension and application of the proposals.

V.4.7. Assist countries in the dissemination, education, and implementation of proposals approved by the Steering Committee of the Network through technical support to countries coordinated by the Secretariat.

V.4.8. Agreements on technical documents will be reached by consensus and when this is not possible, the different points of view will be reflected in the documents.

V.4.9. Maintain country focal points not represented in the WG informed of the progress in implementation of the Work Plan and continually seek the participation of the countries of the respective sub-region in the work plan. In the situation where a country has not designated a Focal Point in the subject area of the Group, the member will ensure that the NRA is informed of progress of the Working Group.

## **V.5. Communication and Meetings**

V.5.1. In addition to regular meetings, communication means such as e-mail, videoconference and teleconference, virtual meetings / Sharepoint will be promoted.

V.5.2. All meetings of the WGs shall be convened by the Secretariat in coordination with the WG Coordinator

## **VI. Final Statement**

The present Regulations replace in their entirety the first set of Regulations governing the Conferences approved by the II Pan American Conference for the Drug Regulatory Harmonization, November 1999. It thus constitutes the Regulations of the Pan American Network for Drug Regulatory Harmonization entering into force at the time of its adoption by the VI Pan American Conference for Drug Regulatory Harmonization.

### Abbreviations

SC	Steering Committee
WG	Working Group
NRA	National Regulatory Authority
WGs	Working Groups