

Operations Report

Technical Working Groups of the Pan American Network for Drug Regulatory Harmonization (PANDRH)



Pan American
Health
Organization



World Health
Organization
REGIONAL OFFICE FOR THE Americas

Operations Report

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I. Introduction

The Technical Working Groups of the Pan American Network for Drug Regulatory Harmonization (PANDRH) were created for the purpose of:

- Developing harmonization proposals on priority topics in the area of pharmaceutical regulation;
- Developing diagnostic studies;
- Identifying technical differences among the countries and formulating harmonization proposals and plans for cooperation among the countries on priority topics in each of the Working Groups' areas;
- Following up on recommendations proposed and approved at CPANDRH events, as they apply to each Working Group at both the regional and national levels;
- Preparing a work plan for approval by PANDRH's Steering Committee;
- Designing training proposals and monitoring the implementation of the corresponding pilot projects;
- Developing educational materials identified as necessary to enable better understanding and implementation of proposals;
- Providing direct advisory services coordinated by the Secretariat in order to assist countries in disseminating, training for, and implementing proposals approved by PANDRH's Steering Committee;
- Keeping the national focal points (not represented in the Working Groups) informed of progress made in the work plan and continually urging the countries in each subregion to participate in the network.

This report is meant to serve as input for PANDRH's Steering Committee decision on the Working Groups' continued operations and on restructuring the governance model to guarantee network flexibility and efficiency.

Context: Regional Background

In light of common interests shared by the countries of the Region, over the years various initiatives have been organized at the subregional level (i.e., the Andean Community, the Caribbean Community (CARICOM), the Southern Cone Common Market (MERCOSUR), the Central American Integration System (SICA), and the North American Free Trade Agreement (NAFTA). Their common purpose has been to promote economic integration and cooperation, thus ensuring equality, wellbeing, and foreign policy integration among member states.¹ The issues discussed by such initiatives include drug policy formulation, implementation, and monitoring. Other initiatives and forums—such as the Latin American Integration Association (ALADI), the International Conference of Drug Regulatory Authorities (ICDRA), and the International Conference on Harmonisation (ICH), among others—have served in a more regional context, although their work has not solely targeted the countries of the Americas.

The Region's need for initiatives to promote drug regulatory harmonization led to the establishment of PANDRH

¹ More information on these subregional initiatives can be found on their websites: CARICOM <http://www.caricom.org/>; Andean Community <http://www.comunidadandina.org/>; MERCOSUR <http://www.mercosur.int/msweb/portal%20intermediario/>; NAFTA: <http://www.ustr.gov/trade-agreements/free-trade-agreements/north-american-free-trade-agreement-nafta>; SICA: <http://www.sica.int/>

in 1999. As stated in its statutes, PANDRH is a joint initiative of the Region's national regulatory agencies (NRAs) in collaboration with the Pan American Health Organization (PAHO). PANDRH's aim is to support drug regulatory harmonization in the Americas within the framework of national and subregional circumstances and health policies while recognizing preexisting asymmetries in regulatory capacities. PANDRH's mission is to promote drug regulatory harmonization, covering aspects related to the quality, safety, efficacy, and rational use of pharmaceutical products, and build NRA capacities in the Region within the context of the population's right to access to quality medicines that reflect the latest scientific and technological advances.

PANDRH is made up of four parts: the Pan American Conferences on Drug Regulatory Harmonization (CPANDRH), the Steering Committee, the Technical Working Groups, and the Secretariat (consisting of PAHO staff members). In principle, each of these four components facilitates the network's effective operations. To date, PANDRH has held seven conferences with the following objectives:

- Promoting constructive dialogue among regulatory bodies, industry, and other sectors;
- Promoting convergence in drug regulatory systems;
- Adopting recommendations of the Working Groups;
- Promoting and facilitating technical cooperation among countries;
- Promoting the analysis of technical handbooks, guidelines, and other documents devoted to priority topics for harmonization processes;
- Promoting the efficacy and effectiveness of network processes.

In September 2013, the VII PANDRH Conference (VII CPANDRH) was held in Ottawa, Canada. Its discussions focused on the proposal for a *Strategic Development Plan* for the 2014–2020 period. The plan was adopted during the conference with lines of action based on four strategic objectives:

1. Strengthening network governance to support regulatory convergence processes (within the context of regional integration) and ensuring representativeness of the countries as they develop their health regulatory systems;
2. Defining priorities, mechanisms, and strategies to prepare technical standards based on country needs and regulatory system development;
3. Strengthening regional capacities in regulatory science and good regulatory practices, thus supporting sustainable professional development;
4. Facilitating the exchange of information and experiences among network NRAs and NRAs outside the Region in order to contribute to developing regulatory convergence at the global level.

Future implementation of this plan and its strategic objectives will be supported by recommendations and activities resulting from active dialogue at the conference. Those recommendations include asking each Working Group for a report detailing: its level of activity, participating members, work plan, results achieved, products developed and, if applicable, a proposal for the group's continued operations, explained in the current context of the Region and accompanied by a proposed work plan.

This report brings together the individual reports prepared by PANDRH's 13 Working Groups. It highlights the results of the study carried out by the Secretariat on the adoption and implementation of technical guidelines, as well as the survey on the regulatory challenges faced in the Region. Discussions at VII CPANDRH shed light on the inability of PANDRH's current governance model to facilitate linkages among the Region's numerous integration and convergence initiatives, given the complexity of drug regulatory integration, convergence, and harmonization processes in the Americas. Nor is the governance model able to guarantee adequate country representativeness in network discussions and decisions. The information presented later in this report is geared toward the following:

1. Providing guidance for Steering Committee discussions on the Working Groups' continued operations;
2. Supporting the process of preparing a new governance model aimed at guaranteeing flexibility and improving network operations in keeping with the current regional context.

II. Technical Working Groups of the Pan American Network for Drug Regulatory Harmonization

STRUCTURE OF THE WORKING GROUPS

To date, PANDRH has formed 13 Working Groups for the various tasks outlined in the Introduction of this report and included in the network's statutes (see page 1) . The Working Groups consist of experts in each group's subject area. Their membership includes full members, alternate members (or substitutes), observers, experts/resources, and members of the Secretariat; the latter provides technical support in preparing the group's work plan. Although it is recommended that each group not exceed nine members, the number also depends on the issue being addressed.²

Regional Impact of PANDRH's Technical Working Groups

In 2013, the PANDRH Secretariat conducted a study to measure the adoption and implementation of eight technical guidelines prepared by the network. This section proposes measuring the Working Groups' impact on drug regulatory policies in the countries of the Region in terms of development of the technical guidelines and their adoption and implementation. The following criteria provided a basis for selecting the eight technical guidelines.

Inclusion Criteria	Exclusion Criteria
<ul style="list-style-type: none"> Guidelines providing relevant information on critical issues related to regulatory operations aimed at guaranteeing the quality, safety, and efficacy of pharmaceutical products. Guidelines prepared by PANDRH's Working Groups. Guidelines related to PANDRH Working Groups' mission and objectives. Guidelines adopted during PANDRH conferences. 	<ul style="list-style-type: none"> Guidelines prepared by Working Groups that have not been published on PANDRH's website. Guidelines prepared by Working Groups that have not been finalized. Guidelines prepared by Working Groups that were not adopted at PANDRH conferences.

In the table below, the eight policy guidelines evaluated in the study (each prepared by a different Working Group) are listed, along with the degree to which each guideline has been adopted (totally, partially, or not at all). Please note that although this table shows the level of impact of the eight Working Groups' work, the reports prepared by each Working Group (contained in Annexes 1–13) show the level of their activity.

² More information on the Working Groups and on network statutes can be found at the following website: [http://www2.paho.org/hq/dmdocuments/2010/PANDRH_Statutes_Final_1109%20\(2\).pdf](http://www2.paho.org/hq/dmdocuments/2010/PANDRH_Statutes_Final_1109%20(2).pdf)

Technical Working Group	Technical Guideline Developed	Total Adoption	Partial Adoption	Non-Adoption
		(percentage of countries that adopted the guideline)		
Good Manufacturing Practices	Guideline for Good Manufacturing Practices Inspections (data based on responses from 18 countries)	61.1	5.6	33.3
Bioequivalence	Framework for Implementation of Equivalence Requirements for Pharmaceutical Products (data based on responses from 19 countries)	21.1	15.8	63.2
Good Laboratory Practices	Document on Self-Evaluation of Good Laboratory Practices (data based on responses from 15 countries)	86.7	0.0	13.3
Counterfeit Medicines	Guidelines for Consideration by Health Authorities in Cases of Suspected Counterfeiting of Medical Products (in Spanish only; data based on responses from 18 countries)	22.2	27.8	50.0
Good Clinical Practices	Good Clinical Practice: Document of the Americas (data based on responses from 15 countries)	46.7	26.7	26.7
Pharmacovigilance	Good Pharmacovigilance for the Americas (in Spanish only; data based on responses from 19 countries)	15.7	63.2	21.1
Vaccines	Harmonized Requirements for the Licensing of Vaccines in the Americas and Guidelines for Preparation of Application (data based on responses from 19 countries)	21.1	36.8	42.1
Biotechnological Products	Recommendations for the Evaluation of Similar Biotherapeutic Products (data based on responses from 18 countries)	11.1	33.3	55.6

Results of the study on adoption and implementation of the PANDRH guidelines indicate the following:

Good Laboratory Practices

The guideline on *Self-Evaluation of Good Laboratory Practices* (GLP) showed the greatest degree of adoption. Unlike the other documents, this one involves a self-evaluation exercise carried out by Official Medicines Control Laboratories (OMCL) for preliminary classification by the World Health Organization (WHO). The document was accompanied by a training course on its use, which could account for its high level of adoption.

In light of the objectives met by the group and circumstances in the Region, the Working Group included in its report a proposal for continuing its operations; the aim is to obtain long-term support for GLP implementation in the OMCL and to strengthen establishment of the OMCL network (see Annex 1).

Biotechnological Products

The technical guideline prepared by the Working Group on Biotechnological Products, *Recommendations for the Evaluation of Similar Biotherapeutic Products*, resulted in a lesser degree of adoption. The results of the study showed: out of the 56% of the countries that have not adopted the document, to date 80% of them do not have any type of regulation. The remaining 20% either based their regulations on other initiatives or had some previous type of regulation.

In its report, the Working Group on Biotechnological Products stated that four of the activities proposed in its current work plan have not achieved any progress; but the group was unable to identify any possible challenges or limitations associated with the nonperformance of these activities. In the study on regulatory challenges carried out by PANDRH's Secretariat, the countries of the Region identified biotechnological products as the second-highest priority area for future investment of resources.³ The Working Group proposes continuing its operations, based on these study results and its proposed work plan, which details concrete activities grounded in priorities and needs identified by the countries. The Working Group's mission will be to promote the development of regulations on biotechnological products in the countries of the Region, thus generating more effective and harmonized mechanisms to regulate this type of medicines (see Annex 2).

Counterfeit Medicines

The document *Guidelines for Consideration by Health Authorities in Cases of Suspected Counterfeiting of Medical Products* was adopted in its entirety by 22% of the countries. This low percentage of total adoption may be due to the following: of the 50% of countries that did not adopt the document, 78% of them have specific regulations based on other initiatives. The study also shows that although 89% of the countries surveyed have some type of structure in place to inspect the medicines supply chain, only 61% have inspectors trained to identify counterfeit medicines.

Given that the counterfeit medicines Working Group proposes continued operations, it is critically important that the group take into account the results of this study when formulating its work plan, since they point out some areas of weakness in the countries. The preparation of a work plan backed by study data will more efficiently uphold the group's mission to promote, facilitate, and encourage the implementation of proactive strategies aimed at preventing and combatting counterfeit medicines (see Annex 3).

Good Clinical Practice

The guideline prepared by the Working Group on Good Clinical Practice (GCP), entitled *Guidelines for Good Clinical Practice: Document of the Americas*, was adopted in its entirety by 47% of the countries surveyed. Of the 27% that did not adopt the document, 50% of the NRAs relied on other harmonization initiatives; the remaining 50% did not have any type of regulation at that time.

The proposal submitted by the Working Group for continuing its operations focuses on disseminating and using existing guidelines—including those of other regions or countries—and avoiding production of new documents. Such an approach could actually promote adoption of the group's technical guideline in countries that do not have any kind of regulation. This would result in the group's work achieving greater impact in the countries of the Region. The Working Group on GCPs proposes a new structure for itself, which could serve as input when establishing new groups and structuring PANDRH's new governance model (see Annex 4).

³ For more information on the results of the study carried out by the network's Secretariat, see the following online presentation from the VII PANDRH Conference, entitled *Overview of Regulatory Capacity and NRA Priorities Based on PRAIS Data and NRA Survey* (by Murilo Freitas), under the heading of "Defining priorities, strategies, and mechanisms for regulatory convergence and harmonization."

Pharmacovigilance

The guideline prepared by the Working Group on Pharmacovigilance, entitled *Good Pharmacovigilance for the Americas*, was adopted in its entirety by 16% of the countries surveyed. However, the document also gained the highest degree of partial adoption (63%). Although the results show a 27% rate of non-adoption, the study nonetheless highlighted the guide's high impact: some 79% of the countries surveyed used the guideline to establish the terms "event," "adverse," "adverse reaction," "serious adverse event," and other terms used in event reporting.

The Working Group's report includes a proposal to continue its operations, with a view to:

- Identifying existing gaps;
- Supporting the coordination of performance evaluation in medicines surveillance programs;
- Continuing to update and harmonize regulations;
- Developing active medicines surveillance systems in the countries;
- Preparing strategies to monitor the implementation of the technical guidelines produced;
- Promoting the strengthening of capacities through different strategies;
- Harmonizing databases;
- Continuing and optimizing communications, coordinated activities, and information exchange through the Regional Platform on Access and Innovation for Health Technologies (PRAIS) (see Annex 5).

Vaccines

The guideline prepared by the Working Group on Vaccines, entitled *Harmonized Requirements for the Licensing of Vaccines in the Americas and Guidelines for Preparation of Application*, was adopted in its entirety by 21% of the countries surveyed.

The two objectives stated in the group's proposal for its continued operations were as follows:

- 1) Implementation of the technical guidelines evaluated in the study conducted by the Secretariat, as stated in the current work plan;
- 2) Implementation of the recommendations made at VII CPANDRH.

If the Working Group's continued operations are approved, a higher level of implementation of its technical guidelines could be expected. This could very well happen, given that of the 42% of countries that did not adopt the document, 75% do not have any specific requirements for registering vaccines (see Annex 6).

Good Manufacturing Practices

The *Guideline for Good Manufacturing Practices Inspection* was prepared by its Working Group in response to the group's original work plan, which was approved in 2002 at III CPANDRH. The purpose of this guideline was to support both regulatory authorities, as they conduct inspections and the pharmaceutical industry, as it validates and applies internationally recognized manufacturing standards. As the results of the Secretariat's study pointed out, 61% of the countries surveyed adopted this guideline in its entirety. All of the 33% of NRAs that reported not adopting this document as a guideline nonetheless included all of the aspects it covers in their standards, although they did so on the basis of other regulatory guidelines.

The report prepared by the Working Group on GMPs lists the activities held to meet each of the objectives proposed in its work plan. Based on its report, the group did not seem to indicate it had held any activity after 2012, which means it did not include a proposal for its continued operations (see Annex 7).

Bioequivalence

Similarly, the Working Group on Bioequivalence does not propose continuity, because the group ceased to meet after V CPANDRH in 2008, having presented its technical guideline, entitled *Framework for Implementation of Equivalence Requirements for Pharmaceutical Products*. One recommendation made at V CPANDRH suggested gradually implementing equivalence demonstration requirements, granting priority to *in vivo* studies based on any health risks posed by such products. The results of the Secretariat's study indicated that 21% of the countries surveyed adopted this guideline in its entirety, while 16% partially adopted it. Only 37% of the NRAs adopted the document either totally or partially, considered a rather low level of adoption, given both the magnitude and impact on decision-making of granting health registration to high-quality, safe, and effective generic products (see Annex 8).

Five PANDRH Technical Working Groups were not included in the Secretariat's study:

1. Pharmacopoeia (see Annex 9)
2. Medicines Registration (see Annex 10)
3. Medicinal Plants (see Annex 11)
4. Medicines Classification (see Annex 12)
5. Medicines Promotion (see Annex 13)

It should be noted that to date, the Working Group on Medicinal Plants has not prepared any policy documents of a technical nature. None of the operational reports from any of the five above-mentioned Working Groups contains a proposal for continued operations.

Pharmacopoeia

The Working Group on Pharmacopoeia was formed in the year 2000. Its mission was to create a forum for discussion and information exchange that would facilitate the adoption of harmonized procedures, culminating in a Pharmacopoeia for the Americas. The group stopped meeting after 14 May 2007, having been unable to achieve its objective of a harmonized pharmacopoeia.

Medicines Registration

The Working Group on Medicines Registration was formed following a request included in one of the recommendations made at III CPANDRH in 2002. Its mission was to promote and facilitate the harmonization of regionally recognized and appropriate technical criteria for medicines registration, thus helping guarantee their quality, safety, efficacy, and availability in the Americas. Given the scant participation of the group's members, this Working Group suspended its activities in September 2012.

Medicinal Plants

The Working Group on Medicinal Plants was formed in 2002. Its mission was to promote a common understanding of medicinal plants in the Region of the Americas and to make recommendations on fostering harmonization when regulating these products, given their traditional and sustained use. It is noteworthy that although one of the group's

activities proposed “permanently updating the documents available on medicinal plants on the PAHO website,” to date the group has not held any meetings. Nor has it included in its report any proposal for its continued operations.

Medicines Classification

The Working Group on Medicines Classification was formed at II CPANDRH in November 1999. Its mission was to harmonize classification criteria applicable to over-the-counter, non-prescription medicines sold in countries of the Americas. On the basis of recommendations made at IV CPANDRH in 2005, the group issued new mandates for carrying out its work. However, at that same meeting, PANDRH set up a Working Group on Medicines Promotion to monitor the work of the medicines classification group.

Medicines Promotion

As stated above, the Working Group on Medicines Promotion was formed in 2005 at IV CPANDRH. Its mission was to promote and harmonize criteria for promoting medicines, thus contributing to their rational use within the scope of health policy in the Region. Although the group has not submitted a proposal for its continued operations, its report points out the need to support: dissemination and discussion of ethical criteria; training on critical evaluation of promotional schemes; information exchanges; and preparation of a sanctions framework. The report also notes that the Working Group could play a supportive role in these tasks. As a result, this Working Group proposes that if the Steering Committee decides in favor of the group’s continued operation, the Steering Committee should also be in charge of evaluating the justification, advisability, and restructuring of the group.

III. Points for the Steering Committee to Consider

GENERAL CONSIDERATIONS

Based on the operations reports submitted by PANDRH's technical working groups and on the process followed in formulating this report, the network has asked the Steering Committee to consider these points when deciding whether to continue Working Group operations.

- Some Working Groups have not been able to achieve the active participation of the regulatory authorities in public discussions of technical guidelines or regulations. Similarly, more than one Working Group has found it impossible to sustain active participation of group members.
- Some Working Groups have mentioned that the non-utilization of distance technologies is a challenge to effective group communication and operations. Based on this observation, and in order to facilitate and support the tasks proposed in the Working Groups' work plans, PANDRH recommends promoting the use of PRAIS and of communities of practice.
- In the study carried out by the PANDRH Secretariat on regulatory challenges facing the Region, 80% of the countries identified the issue of medical devices as a priority for future investments. Since no Working Group has so far been exclusively designated to deal with this issue, a request has been submitted to the Steering Committee to decide how to respond to the demand for medical devices in the countries.
- Of the 13 operations reports submitted by the Working Groups,
 - Three were prepared on the basis of active discussion among members of those groups, taking into account support provided by the Secretariat.
 - Four were written by the Secretariat with support from Working Group coordinators and, in some instances, from group members.
 - The remaining six were compiled by the PANDRH Secretariat, since these groups are no longer active.

When deciding whether to continue Working Groups' operations, it will be important to reevaluate the groups' structures in order to more efficiently support PANDRH tasks and promote greater participation and commitment from each group's members.

- For the purposes of this report, Working Groups are considered active only if they have submitted proposals for continued operations. If the Steering Committee decides to keep the Working Groups as one of PANDRH's components, the next step should be to make a request to specify which ones should continue in operation.
- The results of the study on the adoption and implementation of PANDRH's guidelines show the crucial need to strengthen human resources and establish mechanisms for continuing education. The results of the diagnostic study on the challenges facing drug regulatory harmonization going forward (also carried out by the Secretariat) showed that 62% of the countries of the Region do not have any training program on the core functions of a regulator and that 39% do not have any training course for new staff members hired by the NRAs. On the basis of information from both studies, PANDRH considers it important to include and strengthen activities geared to training NRA staff. This would give the Working Groups' efforts to strengthen drug regulatory harmonization processes greater impact in the countries of the Region.

IV. Recommendations of the PANDRH Steering Committee and Next Steps

During the PANDRH Steering Committee meeting hosted by PAHO in Washington D.C., 8 – 9 March 2014, members of the Committee received this report in order to generate recommendations on a case-by-case basis; the aim is to recommend whether current Technical Working Groups should continue supporting PANDRH prior to adoption of a new (updated) PANDRH status.

In this regard, members of the PANDRH Steering Committee who attended that meeting recommend that active Technical Working Groups should continue with their proposed work plans until a new PANDRH governance model is adopted.

In addition, PANDRH Steering Committee members mentioned that active technical working groups should follow the VII PANDRH Conference recommendations, which include the following:

- Be evaluated periodically based on results;
- Have a flexible structure to incorporate diverse members (including experts from other global harmonization/convergence initiatives);
- Work beyond development of guidelines and technical documents to enable communication, information exchange and practical implementation of PANDRH recommendations.

For more information on the proposed work plans for continuity, please refer to Annexes 1 to 13 of this report.

Annexes

to the Operations Report: Technical Working Groups of the Pan American Network for Drug Regulatory Harmonization (PANDRH)

The following 13 Annexes contain an Operations Report from each of PANDRH's 13 Technical Working Groups. This comes in response to the conclusion drawn at VII CPANDRH in 2013 that each of the network's Working Groups should present a report to the Steering Committee detailing the following: its level of activity, members, work plan, results obtained, and products generated, as well as a proposal for its continued operations if applicable, justified, and accompanied by a work plan. The reports submitted are presented here.

Each of the 13 reports is divided into four sections as follows:

I. *Original Mission and Objectives*

This section provides each group's mission and objectives to date. Some groups also provide information on the date, place, and purpose of the group's creation.

II. *Group Members*

This section lists members and the countries they represent. Most also indicate institutional affiliations. Usually the members are divided into Titular Members, Alternate Members, and the Secretariat.

III. *Work Plan to date*

This section provides objectives, activities, and results obtained to date; it points to factors that limit achieving any original objective as yet unmet. The work plan is generally structured in a uniform tabular format, followed by interpretive comments, summaries, or supplementary information provided by the group on their activities and results.

IV. *Continuity Proposal*

This final section refers to PANDRH's decision to evaluate group performance and continue the group if there is adequate justification for doing so based on regional circumstances and priorities. If the group is active and sees a need to continue its operations, it will include a proposed work plan for 2014–2015 with proposed objectives, activities, and expected results, along with a timeline for their fulfillment. This is followed by comments on the involvement of external experts (if any) and by the justification for continuity of the group's operations. If the group is inactive, that will be noted and no continuity proposal will be provided.

Annex 1: Operations Report, Working Group on Good Laboratory Practice (WG GLP)

I. Original Mission and Objectives

Mission

To strengthen the performance of Official Medicines Control Laboratories (OMCL) in the countries of the Region of the Americas through implementation of Good Laboratory Practice (GLP) in order to guarantee the quality of laboratory test results and facilitate mutual recognition of these results.

Objectives

1. Support the implementation of GLPs in OMCL
2. Promote the establishment of an OMCL Network

II. Current Members

The GLP Working Group was created in June 2005, with representatives from the subregions, the pharmaceutical industry, and the United States Pharmacopeial Convention (USP), at the request of the External Quality Control Program (EQPC).

Titular Members

Southern Cone Common Market (MERCOSUR): Sigrid Mathison, Uruguay

Andean Community: Ofelia Villalba, Peru

Central American Integration System (SICA): Nilka Guerrero, Panama

Caribbean Community (CARICOM): Lucette Cargill, Jamaica

USP: Damian Cairatti, United States of America

Latin American Federation of the Pharmaceutical Industry (FIFARMA): Thomas Schultz, United States

Coordinating Member: María Gloria Olate, Chile

Alternate Members

MERCOSUR: Olga Gruc, Argentina

Andean Community: Cecilia Garnica, Bolivia

SICA: Ana Lara Sterling, Cuba

CARICOM: Mrs. C. Álvarez, Trinidad and Tobago

Secretariat (PAHO/WHO)

José M. Parisi, Washington, D.C.

III. Work Plan to date

The table below shows results obtained to date; for any original objective as yet unmet, the table specifies any limiting factors.

Objective	Limiting factors (if applicable)	Activity carried out	Result obtained	Date
Support the implementation of GLPs in OMCL.	N/A	Holding courses and workshops on GLPs.	Twenty GLP courses provided and over 30 GLP workshops held.	2005–2013
		Development of PANDRH's technical documents on GLPs.	Seven PANDRH technical documents on GLPs finalized.	2008–2013
		Implementing guidelines contained in PANDRH's technical documents.	Guidelines contained in the seven technical documents on GLPs implemented.	2008–2013
		Preparing OMCLs for prequalification by WHO.	Five laboratories prequalified by WHO.	2010–2013
Promote establishment of an OMCL network.	N/A	Strengthening the OMCL network.	Twenty-five laboratories actively integrated into the network.	2005–2013
		Setting up the External Quality Control Program (EQCP).	Ten stages completed.	2002–2013
		Holding OMCL meetings.	Four on-site meetings held;	2005–2012
			Six virtual meetings held.	2012–2013
		Participating in PAHO's Regional Platform on Access and Innovation for Health Technologies (PRAIS).	Community of practice created on the PRAIS platform.	2013

IV. Continuity Proposal

(The Working Group has provided the following information with a view to its continued operations.)

1. Proposed work plan for 2014–2015, with expected results and timeline.
2. Need to incorporate other experts (inside and outside the Region) for achieving those results.
3. Justification for the group's continuity based on the realities and priorities of the Region.

Proposed Work Plan, 2014–2015

Objective	Limiting factors (if applicable)	Proposed activity	Expected result	Date
Support implementation of GLPs in the OMCL.	N/A	Holding GLP courses and workshops.	Three courses and four workshops on GLPs held.	2014–2015
	N/A	Preparing PANDRH technical Documents on GLPs.	Preparation of at least one PANDRH Technical Document prepared on GLPs.	2014–2015
	N/A	Implementing PANDRH's technical documents.	Twenty laboratories self-evaluated.	2014–2015
	N/A	Preparing OMCL for prequalification by WHO.	Requests for prequalification made to WHO by four laboratories.	2014–2015
Strengthen establishment of the OMCL network.	N/A	Strengthening the OMCL network.	Four external audits conducted on Quality Management System (QMS.)	2014–2015
	N/A	Setting up the External Quality Control Program.	Two stages completed.	2014–2015
	N/A	Holding OMCL meetings.	Four virtual meetings of the entire OMCL network held.	2014–2015
	N/A	Participating interactively in the PRAIS platform.	Usefulness of participation in the virtual forum demonstrated.	2014–2015

Justification for the group's continuity

The GLP Working Group obtained fundamental results in terms of promoting harmonization and medicines quality in the Region, thus strengthening the capacities of the OMCL. Based on the results obtained, the GLP Working Group has met its proposed objectives. Its continuity is justified based on the circumstances and priorities of the Region.

Annex 2: Operations Report, Working Group on Biotechnological Products (WG BIO)

Note: The preparation of this report involved contributions from Brazil, Chile, Cuba, Panama, and Peru, as well as the Latin American Association of Pharmaceutical Industries (ALIFAR) and the Secretariat.

I. Original Mission and Objectives

Date of Creation

The Working Group on Biotechnological Products was created in 2010, following presentation of proposals for its formation by the pharmaceutical industry and the Secretariat and after having taken into consideration the regional situation analysis on the regulation of biotechnological products.

The context of this group's creation highlights the following:

- The *Fourth Pan American Conference on Drug Regulatory Harmonization (IV CPANDRH)*, held in the Dominican Republic in 2005, recognized the importance of forming a working group on biologicals to encompass all aspects of their regulation.
- V CPANDRH, held in Argentina in 2008, highlighted the interest of some Latin American and Caribbean countries in having harmonized guidelines available for regulating this type of products.
- 2010 was a groundbreaking year for the Working Group, which marked:
 - Submission of proposals to PANDRH's Steering Committee for creating a working group on biologicals, which the committee consensually approved;
 - Formulation of objectives and selection of coordinating and alternate countries as members of the group;
 - The group's first meeting, held in the Dominican Republic.

Mission

To promote development in regulation of biotechnological products in the countries of the Americas, generating more effective and harmonized mechanisms for regulation of this category of medicines.

Objectives

1. Compile a list of all regulations related to biotechnological products currently in place at the country level and make them available at the regional level.
2. Compile a glossary of terms to help understand the situation in Member States and facilitate further development of related documents.
3. Promote information exchange among national regulatory authorities (NRAs) in the Region.
4. Identify regional documents and guidelines for short- and medium-term development and develop them as appropriate.

5. Identify other issues related to regulating biotechnological products that may require special treatment and establish work plans to address them.
6. Develop tools and training programs to strengthen capacity-building among the NRAs of Members States to aid in regulatory oversight of biotechnological products and related issues.

II. Current Members

Titular Members

MERCOSUR: Patricia Aprea, Argentina (Alternate Coordinator)

Andean Community: Hans Vásquez, Peru

SICA: Gioconda Castillero, Panama

CARICOM: Junia Walcott, Trinidad and Tobago

North American Free Trade Agreement (NAFTA): Jian Wang, Canada

FIFARMA: José Manuel Cousiño, Argentina

ALIFAR: Valentina Carricarte, Argentina

PAHO/WHO: Olga L. Jacobo, Cuba / María T. Ibarz, Venezuela

Alternate Members

MERCOSUR: Marcelo Moreira, Brazil (Coordinator)

Andean Community: Fabiola Muñoz, Chile

SICA: Ana Beatriz Cordero, Guatemala

CARICOM: Maryam Hinds, Barbados

NAFTA: Agnes V. Klein, Canada

ALIFAR: Henrique Uchio Tada, Brazil

Secretariat (PAHO/WHO)

María L. Pombo, Washington, D.C.

III. Work Plan to date

The table below shows results obtained to date; for any original objective as yet unmet, the table specifies any limiting factors.

Objective	Limiting factors (if applicable)	Activity carried out	Result obtained	Date
Compile a list of all regulations related to biotechnological products in place at the country level and make them available at the regional level.		Compiling regulations on biotechnological products from each NRA participating in the biotechnological products Working Group and from any WHO recommendations, including those related to similar biologicals as they become available.	Regulations on biotechnological products compiled from the Working Group's member countries.	Dec 2010
		Compiling regulations on biotechnological products from other NRAs, including those related to similar biologicals as they become available.	Regulations from other countries (not members of the Working Group) compiled.	Dec 2010
		Disseminating information compiled at the regional level through the mechanism established for this purpose (PAHO website or another mechanism).	Information disseminated via a restricted-access information exchange site (SharePoint) to persons identified as focal points for that topic; the main use of this information is to generate a mechanism to enable precise identification of NRA needs in the area of biotechnological product regulation.	Activity concluded in 2010

continues

Objective	Limiting factors (if applicable)	Activity carried out	Result obtained	Date
Establish a glossary of terms to help understand the situation in Member States and facilitate further development of related documents.	Factors unidentified.	Identifying terms related to biotechnological products (from the regulations compiled in Objective 1) for inclusion in the glossary.	No progress made.	N/A
		Producing a document containing terms related to biotechnological product regulation, based on:		
		Definitions established in the regulations compiled in Objective 1 as well as in the WHO Drug Glossary and its Spanish version, <i>Glosario de medicamentos: Desarrollo, Evaluación y Uso</i> , translated and published by PAHO/WHO		
		Disseminating the draft glossary of terms produced by the biotechnological products Working Group and holding consultative reviews.		
Promote information exchange among NRAs in the Americas.	See footnote below ¹	Generating a proposal to promote the exchange of information related to biotechnological product regulation among the Region's NRAs.	Information exchange mainly generated via e-mail among various Working Group members; on certain occasions, "coordinated" by the Secretariat, exchange made possible via Elluminate sessions.	Continuous activity
		Creating a system for information exchange on biotechnological product regulation.	Community of practice on surveillance of biologicals made available by the Secretariat on the PRAIS platform to members of the Working Group and other regulatory authorities, with training provided on its use and access. Elluminate link made available for use by the Working Group for both moderator and participants when convening virtual meetings.	Continuous activity

continues

¹ Certain biotechnological products Working Group members mention having used PRAIS as a mechanism for information exchange. However, this has not been confirmed by administrators at the Secretariat. Active participation on the part of regulatory authorities has not been achieved. Nor has their active participation been promoted in the current public debate on PANDRH's technical guidelines or related regulations. There has been a steady exchange of e-mails among some, but not all, Working Group members

Objective	Limiting factors (if applicable)	Activity carried out	Result obtained	Date
Identify regional documents and guidelines for short- and medium-term development and develop them as appropriate.		[Linked to other objectives]	–	N/A
		Translating into Spanish and Portuguese the WHO document, Guidelines on Evaluation of Similar Biotherapeutic Products (SBPs) (6), and obtaining copyright permission for its later publication.	Translation completed.	Jan 2011
		Carrying out technical review of Spanish and Portuguese translations of the WHO document, Guidelines on Evaluation of Similar Biotherapeutic Products (SBPs).	Review carried out by the Working Group's Spanish- and Portuguese-speaking members. Guidelines edited by the Secretariat.	Feb 2011
Identify other issues related to the regulation of biotechnological products that may require special treatment and establish work plans to address them.		Publishing the <i>Spanish and Portuguese</i> versions of the WHO document, <i>Guidelines on Evaluation of Similar Biotherapeutic Products (SBPs)</i> , so as to contribute to PANDRH's work.	Edited document published (by the Secretariat).	Jun 2011
		Proposing information to be contained on PANDRH's biotechnological products Working Group website.	Subjects to be included identified by the Secretariat, which is responsible for updating the website.	Continuous activity
Develop tools and training programs to strengthen capacity-building among the NRAs of Member States to aid in regulatory oversight of biotechnological products and related matters.			Virtual and face-to-face (on-site) technical cooperation meetings held to build NRA capacity in biotechnological product regulation, development of appropriate national regulations, and implementation of PANDRH's recommendations.	
		Disseminating related reference materials.	Working Group members involved as participants in these activities, spreading the word on regional harmonization initiatives in various related fora; in the particular case of Central America, its Executive Secretariat of Ministers of Health (SE-COMISCA) published in its journal an article on the quality and regulation of biotechnological products in Central America.	Continuous activity

IV. Continuity Proposal

The group is providing the following information with a view to its continued operations.

1. Proposed work plan for 2014–2015, with expected results and timeline.
2. Need to incorporate other experts (inside and outside the Region) for achieving those results.
3. Justification for the group's continuity (based on the realities and priorities of the Region).

Proposed Work Plan, 2014–2015

Objective	Limiting factors (if applicable)	Proposed activity	Expected result	Date
Determine a strategy for the NRAs to implement the guidelines contained in PANDRH's Technical Document No. 7.	Lack of commitment from all countries to continue work involving the review and adaptation of national regulations and subsequent establishment of the recommended international guidelines on the evaluation of similar biotherapeutic products.	Raising high-level awareness of the importance of implementing such guidelines.	Commitment obtained.	Jun 2014
		Sending the plan to all member countries.	Work plan for implementation disseminated.	Aug 2014
		Monitoring the implementation process (to be carried out by the coordinator and Secretariat).	Implementation of guidelines contained in PANDRH Technical Document No. 7.	2014–2016
		Adopting a communications strategy to disseminate the level of implementation of the guidelines contained in PANDRH's Technical Document No. 7, as well as in other technical documents published by PANDRH.	Knowledge obtained of the degree of implementation of the guidelines contained in PANDRH's Technical Document No. 7.	Continuous activity
		Countries' setting up a plan to implement the guidelines contained in the document within a maximum time frame of three years.	Guidelines contained in PANDRH's Technical Document No. 7 implemented.	Dec 2014

continues

Objective	Limiting factors (if applicable)	Proposed activity	Expected result	Date
Identify documents and/or guidelines needed by the Region for short- and medium-term development.	Lack of resource time exclusively devoted to performing the tasks outlined in the Work Plan:	Identifying documents and/or guides needed by the Region.	Regional needs identified.	Continuous activity
	Working Group members, and especially its coordinator, have indicated that full-time dedication to the activities proposed in the work plan is needed to optimize participation and enable corresponding follow-up.	Participating in the preparation of documents and/or guidelines in accordance with regional needs.	Documents and/or guidelines elaborated.	Continuous activity
	They also suggest that full-time dedication be carried out through PAHO internships and not simultaneously with the NRAs' routine work.	Promoting the dissemination of documents and/or guidelines.	Information disseminated.	Continuous activity
	They are also asking PANDRH's Steering Committee to determine timing and members' resource time, based on priority areas and topics, and to study the feasibility of funding such internships through NRA support.			
Promote training activities related to biotechnological products.	An unequal playing field regarding the degree of progress made in regulation and regulators' expertise on biotechnological products.	Identifying topics where there is a need for training and institutional development in the NRAs.	Topics identified.	Continuous activity
	Subsequent need to prioritize training.	Promoting training on identified topics, setting goals and deadlines that improve training procedures.	Training promoted.	Continuous activity
Promote information exchange among NRAs in the Region, thus guaranteeing transparency.	Need to generate greater NRA participation in information exchange activities.	Elaborating a proposal for minimal information to be published by all NRAs.	NRA web links (URLs) sent to Secretariat.	Dec 2014
	Need to distribute and delegate responsibilities when developing these activities.	Establishing PRAIS as the sole communication tool for information-sharing on regulating biologicals.	Unique, more effective mechanism established for sharing information and regulatory experiences.	Continuous activity

continues

Objective	Limiting factors (if applicable)	Proposed activity	Expected result	Date
Continue with training activities for registration and control of biotechnological medicines, especially through implementation of guidelines contained in WHO and PAHO technical documents.	Need to identify real needs for staff training within each NRA and develop a regional training network.	Conducting refresher courses for NRAs in view of the new technical guidelines/ documents published by WHO.	NRA refresher courses held and training provided.	Continuous activity

Need to incorporate other experts

The Working Group has been operating pursuant to PANDRH statutes, with permanent and alternate members designated by the various subregions. However, the group no longer considers this to be the most appropriate way to proceed.

To bring about a more flexible structure, the group suggests incorporating other experts, including leaders in regulatory science and more specific subject areas, in order to enrich its discussions and to ensure more informed decision-making on the part of the authorities. These experts should always be invited to participate as long as the topics of discussion are in line with their expertise.

Anecdotally, the Working Group emphasized, when meeting with PANDRH's Steering Committee, an event that took place during its first meeting in 2010. In this particular case, the representative nominated to represent Central America devoted almost all resource time to providing advisory services to the pharmaceutical industry, despite having been nominated by Steering Committee members to represent the Central American regulatory authorities. Details on this event are documented in the group's meeting report and in the minutes taken during PANDRH's Steering Committee meeting.

The group suggests the Coordinator's term of office cover at least four years and be eligible for renewal for another four years to allow for measuring concrete results. These periods also coincide with PANDRH's conferences. Furthermore, to promote a more rapid and participatory response, the group's Coordinator and all of its members should be assigned to developing a single product. In this way, the person responsible for the product will have time to assume the tasks outlined in the work plan, which otherwise might be difficult, given daily routines and other tasks and responsibilities during work hours. To further accomplish this, the group suggests that the person responsible for the product have a period of time at PAHO Headquarters to enable full-time devotion to carrying out concrete product-development tasks and achieve results quickly. The Steering Committee should determine the time frame and resource hours contributed by the Coordinator and by each group member, based on the priority assigned to each topic. Additionally, the group reiterated the need for the Secretariat to carry out mediation and monitoring functions in activities involving group members; the aim is to enable meeting the objectives set, given that it is difficult for the Coordinator to carry out such tasks and even more difficult to achieve consensus among members.

Justification for the group's continuity

The formation of the Working Group on Biotechnological Products constituted an effort to provide a tool with potential to promote strengthening of regulatory authorities in the Americas. Its continuity is justified by analyzing the priorities set by PANDRH's member countries at VII CPANDRH.

PANDRH's biotechnological products Working Group obtained concrete results within a short period of time by holding three face-to-face (on-site) meetings and several virtual meetings, which were essential for building and strengthening relationships among the group's member countries.

The group's objectives and work plan aim to facilitate access to regional-level regulations on available biotechnological products. On this basis, the group formulated the guidelines contained in PANDRH's Technical Document No. 7, a PAHO translation into Spanish and Portuguese of the WHO document entitled Guidelines on Evaluation of Similar Biotherapeutic Products (SBPs). This document, *Recomendaciones para la Evaluación de Productos Bioterapéuticos Similares (PBS) / Diretrizes para a Avaliação de Produtos Bioterapeuticos Similares (PBSs)*, was approved during VI CPANDRH.

Above and beyond the preparation of a single technical handbook, the Working Group has promoted information exchange among member countries and conducted joint activities aimed at strengthening technical cooperation, succeeding in building NRA capacities in Ecuador and El Salvador in areas related to regulating biotechnological products.

The group has elaborated a proposed work plan for the next two years that identifies concrete activities based on the priorities and needs identified by the countries of the Region.

The Working Group believes that with the adoption of a more flexible structure and an evaluation of the NRAs' current situation, the group will have the opportunity to identify and support regulatory authorities in successfully carrying out their basic functions.

The work plan proposes that authorities carry out a critical functional assessment and identify existing gaps, as well as their capacities/strengths for regulating biotechnological products, including their capacity to conduct training workshops (either virtually or face to face). This work plan will play an important role in identifying common, real needs for staff training and in proposing the development of a regional trainers' network supported by both group members and experts.

In order to put PANDRH's recommendations into practice, current capacities within the NRAs and the body of external experts/leaders in regulatory science need to be utilized. Establishing the following will help optimize this process.

- a. Priority-setting by the group.
- b. Recognition from those authorities capable of promoting technical assistance.
- c. Support from PANDRH's Steering Committee.

The group will look for efforts being made by NRAs in member countries to train their human resources through a training scheme based on institutional development plans aimed at bridging gaps the NRAs identified.

This entire effort and verification of results obtained should be periodically evaluated, based on an analysis of responses to surveys currently under development by the Secretariat.

Accordingly, the Working Group suggests maintaining and strengthening its efforts, taking into account what is described above, in order to fulfill its mission: to promote the development of the regulation of biotechnological products in the countries of the Americas, and generate more effective and harmonized mechanisms for regulation of this category of medicines.

Annex 3: Operations Report, Working Group on Counterfeit Medicines (WG CFM)

I. Original Mission and Objectives

Date of Creation: December 2001

Mission

To promote, facilitate, and encourage implementation of proactive strategies for preventing and fighting counterfeit medicines and thus contribute to the improvement of health care in countries in the Americas.

Objectives

- Formulate proposals to develop policies and strategies for consideration and implementation by the countries.
- Develop and promote training programs to optimize inspection/research processes.
- Promote information exchange.

II. Current Members

Titular Members

MERCOSUR: Tiago Lanius Rauber, Brazil

Andean Community: Marisa Papen, Peru

SICA: Eric Conte, Panama

CARICOM: Princess Osbourne; Alternate: David Crawford

NAFTA: Michelle Limoli, Pharm. D., United States

ALIFAR: Miguel A. Maito, Argentina

FIFARMA: Néstor Garrido Aranda, Peru

PAHO/WHO: María José Sánchez, Argentina

Alternate Members

MERCOSUR: María José Sánchez, Argentina

Andean Community: Delia Villarroel, Bolivia

SICA: Reynaldo Hevia Pumariega, Cuba

CARICOM: Princess Osbourne; Alternate: David Crawford

ALIFAR: Carmen E. Pérez

Secretariat (PAHO/WHO)

José Luis Castro, Washington, D.C.

III. Work Plan to date

The table below shows results obtained to date; for any original objective as yet unmet, the table specifies any limiting factors in that regard.

Objective	Limiting factors (if applicable)	Activity carried out	Result obtained	Date
Formulate proposals to develop policies and strategies for consideration and implementation by the countries.	Limited member participation.	Formulating a critical path proposal for implementing national programs.	Countries provided with a reference document.	
Prepare criteria and standards for adoption in national legislation and optimize inspection/ research processes.	Limited member participation.	Formulating guidelines to be considered in light of suspected counterfeiting of medical products.	Countries provided with a reference document.	
		Formulating a proposal for indicators.	Countries provided with a reference document.	
		Conducting a situation analysis.	Countries provided with a reference document.	
		Holding tool generation seminars devoted to generating tools and proposals to prevent and fight medicines counterfeiting.	National task forces created.	
Promote information exchange.	Limited member participation.	Developing a model for a regional network of focal points.	Information exchange initiated.	

IV. Continuity Proposal

The group is providing the following information with a view to its continued operations:

1. Proposed work plan for 2014–2015, with expected results and timeline.
2. Need to incorporate other experts (inside and outside the Region) for achieving those results.
3. Justification for the group's continuity (based on the realities and priorities of the Region).

Proposed Work Plan, 2014–2015

Objective	Limiting factors (if applicable)	Proposed activity	Expected result	Date
Promote the exchange of information and experiences.		Holding tool generation seminars.	National workforces developed.	
		Providing a community of practice on the PRAIS platform.	Information and documents exchanged.	
		Providing support to countries instrumental in the tool generation seminars.	Sustainability of activities ensured.	
		Holding a virtual workshop and virtual sessions on analyzing and evaluating the implementation of the global reporting mechanism.	Participation in the mechanism ensured.	
Prepare proposals on criteria and standards.		Conducting a traceability analysis.	Decisions made on the ensuing document.	
		Holding workshops to disseminate the group's documents/guidelines.	Documents/guidelines disseminated and adapted.	

Justification for the group's continuity

The problem of counterfeit medicines is real. For the Region of the Americas, coordination through the mechanism of WHO Member States has become necessary, as is continued support for sharing experiences and information.

Annex 4: Operations Report, Working Group on Good Clinical Practice (WG GCP)

I. Original Mission and Objectives

Date and Purpose of Creation

In Buenos Aires in May 1999, a regional Working Group on Good Clinical Practice (GCP) was formed for the purpose of promoting the development of standardized guidelines on GCPs needed in the Region. As a result of the technical report prepared and presented at II CPANDRH in November 1999, the Working Group on Good Clinical Practice was formally established as one of the network's priority areas.

Mission

Original

To promote harmonization of GCPs in the Americas.

Current

To promote improvement in both the quality of clinical trials conducted in the Region, through the harmonization of GCPs in the Americas, and in the quality of other technical documents (regulations and guidelines) in order to generate more effective mechanisms for carrying out clinical trials.

Objectives

Original

- Promote the implementation of GCPs in the Americas by elaborating a document with guidelines to be adopted and implemented by the governments.
- Disseminate the document *Guidelines for Good Clinical Practice: Document of the Americas* with recommendations for adopting these guidelines in national regulations.
- Develop and implement educational programs on GCPs, gearing them especially for staff in the regulatory agencies.

Added and incorporated in 2010

- Promote information exchange among NRAs in the Region of the Americas.
- Identify regional documents and guidelines for short- and medium-term development.
- Develop tools and training activities geared towards strengthening NRAs in the Region.

II. Current Members

Titular Members

MERCOSUR: Alejandra Croci, Uruguay

Andean Community: María Vargas Huillcanina, Peru

SICA: María Amparo Pascual, Cuba (Coordinator)

CARICOM: Junia Forde Walcott, Trinidad and Tobago

NAFTA: David Lepay, United States of America

ALIFAR: João Carlos Fernandes, Brazil

FIFARMA: Pablo Viard, Argentina

Alternate Members

MERCOSUR: Agustina Bissio, Argentina

Andean Community: Eduardo Johnson, Chile

SICA: Ileana Herrera Gallegos, Costa Rica

CARICOM: Pamela Payne-Wilson, Barbados

ALIFAR: Enrique Uchio Tada, Brazil

FIFARMA: Ronoldy Valencia, United States

Secretariat (PAHO/WHO)

José D. Peña, Chile

III. Work Plan to date

The table below shows results obtained to date; for any original objective as yet unmet, the table specifies any limiting factors.

Objective	Limiting factors (if applicable)	Activity carried out	Result obtained	Date
Promote implementation of GCPs in the Americas by developing a document with guidelines to be adopted and implemented by governments.		Carrying out a situation analysis on GCPs in the countries of the Americas.	Evidence of need to harmonize regulations in a group of countries and then introduce them into others.	2000
			Evidence of weakness in the areas of: research ethics committees, informed consent procedures, and protecting vulnerable populations.	
		Preparing guidelines and procedures for research ethics committees and informed consent procedures.	Guidelines prepared and approved at III CPANDRH.	2002
		Preparing <i>Guidelines for Good Clinical Practice: Document of the Americas</i> .	Two aforementioned documents incorporated.	2003-2004
			Document approved at IV CPANDRH.	2005
		Preparing guidelines for pediatric studies.	Guidelines prepared.	2006–2007
			Preliminary version approved at V CPANDRH.	2008
			Modifications made on the basis of recommendations made at V CPANDRH.	2011
		Preparing guidelines on use of placebos.	Final version approved at VI CPANDRH.	2011
			Guidelines prepared.	2011
		Preparation of the researchers' handbook.	Guidelines approved at VI CPANDRH.	2011
			Handbook prepared.	2011
		Handbook approved at VI CPANDRH.	2011	

continues

Objective	Limiting factors (if applicable)	Activity carried out	Result obtained	Date
Disseminate Guidelines for Good Clinical Practice: Document of the Americas, with recommendations for their adoption in national regulations.	This objective not met satisfactorily due to:	Setting up a dissemination program with interested countries.	National workshop held in Chile.	2006
	• Lack of a printed document for distribution to NRAs through PAHO/WHO Representative Offices.		National workshop held in Peru.	2007
	• Interruption of the group's activities, due to the Secretariat coordinator's illness (2008—2010), until designation of new coordinator.		Cooperation on GCPs initiated between Cuba and Ecuador.	2008—2009
	• Interruption of the cooperation project due to change of authorities in Ecuador.	Assessing implementation status (carried out at the request of the Secretariat to Dr. Saidón (resource person).	Document adopted by only seven out of 15 countries for various reasons.	2013
	• Interruption of dissemination workshop activities in the countries due to lack of resources.			
	• All the above causes coupled with a lack of systematic work in the Working Group.			
Develop and implement educational programs on GCP especially geared toward regulatory staff.	Non-utilization of distance technologies when faced with a lack of resources to conduct regular face-to-face (on-site) courses in the other countries.	Establishing a regional education program and holding seminars in several countries.	Courses offered in Guatemala in 2001, Peru in 2002, Chile in 2006, and Peru in 2007.	2001—2007

Summary of limiting factors and critical points that limited implementation

(based on the survey conducted by Dr. Patricia Saidón)

Lack of:

- Human resources;
- Specific training for technical staff in the NRAs;
- Updating with respect to new guidelines for clinical research;
- Harmonization of NRA regulations with *Guidelines for Good Clinical Practice: Document of the Americas*, and with other international guidelines;
- Training research ethics committees on the guidelines;
- Infrastructure common to a large number of institutions providing health services.

IV. Continuity Proposal

The group is providing the following information with a view to its continued operations:

1. Proposed work plan for 2014–2015, with expected results and timeline;
2. Need to incorporate other experts (inside and outside the Region) for achieving those results;
3. Justification for the group’s continuity (based on the realities and priorities of the Region).

Proposed Work Plan 2014–2015

Note: When selecting the 2014–2015 objectives, the group took into account the agreements and recommendations made at VII CPANDRH, as well as criteria related to members’ level of activity (with a view to who has been the most active) over the most recent period.

Objective	Limiting factors (if applicable)	Proposed activity	Expected result	Date
Implementation of harmonization documents approved in the period 2005–2011 and measurement through indicators.				
Implementation of <i>Guidelines for Good Clinical Practice: Document of the Americas</i> in at least those countries that do not have regulations.		Restructuring the group to have fewer members, keeping those who have been active, and incorporating new members, including outside experts.	Working group consolidated with new methods to deal with the objectives where resources are lacking.	1st quarter 2014
	Need to update <i>Guidelines for Good Clinical Practice: Document of the Americas</i> (approved over eight years ago).	Distributing the document’s chapters among group members for updating.		
		Searching for regulations and other related documents from other regions for review.	Guidelines for <i>Good Clinical Practice: Document of the Americas</i> updated and presented to the Secretariat for approval.	3rd quarter 2014
		Preparing a timetable assigning work and responsibilities.		
		Holding monthly virtual sessions to check on progress until end of updating process.		
	Lack of an NRA contact in countries selected for implementation.	Selecting those countries that do not have regulation but have the political will to implement the updated GCP guidelines.	Selections of countries with the political will to implement the guidelines, with staff designated for training and implementation.	3rd quarter 2014
Low priority placed on this topic and the need to mobilize resources outside PAHO.	Seeking alternative funding to print and disseminate the document, either through the countries or through subregional organizations.	Funds raised from external sources.	4th quarter 2014	
	Preparing distance seminars using technology for virtual courses.	Distance seminars prepared and accredited.	4th quarter 2014	
	Holding distance seminars for those designated as “replicators.”	Designated NRA staff trained.	All quarters 2015	

continues

Objective	Limiting factors (if applicable)	Proposed activity	Expected result	Date
Implementation of guidelines for pediatric studies and use of placebos, as well as researchers' handbook, in the countries that already have regulations.		Updating the pediatric studies guide in accordance with those issued over the past year.	Guidelines updated according to the latest guides from FDA, European Medicines Agency (EMA), and the International Conference on Harmonization (ICH).	2nd quarter 2014
		Submitting guidelines for approval.	Up-to-date pediatrics guidelines approved.	3rd quarter 2014
		Looking for funding alternatives for printing and disseminating the document.	Funds raised.	4th quarter 2014
		Implementing activities by multiplying and training "replicators" via distance seminars in selected countries.	Staff trained.	1st quarter 2015
		Disseminating guidelines on the use of placebos and the researchers' handbook in selected countries via staff designated by the NRAs.	Documents widely disseminated.	1st quarter 2015
		Conducting a survey to measure implementation of the guidelines.	Indicators applied and results obtained.	3rd quarter 2015
Incorporate guidelines from other regions or countries on topics related to adverse events and inspections.	Need to place priority on performance of NRA functions (as recognized at VI CPANDRH and addressed at VII CPANDRH).	Reviewing documents from other regions and countries.	Documents reviewed.	3rd quarter 2015
		Disseminating the documents virtually.	Documents widely disseminated.	4th quarter 2015
Perfect the process of ethical review in research.	Need to use experiences from countries that are already working on the topic and obtain support from the PAHO Research Program.	Conducting a survey on the status of research ethics committees in the Region.	Survey conducted by countries and results obtained.	3rd quarter 2014
		Setting up a joint project with the PAHO Research Program to register and improve research ethics committees.	Project concluded.	4th quarter 2014
		Creating registries in countries and incorporating research ethics committees into the PAHO research platform.	Registries created in at least seven countries of the Region and placed on the platform.	3rd quarter 2015

continues

Objective	Limiting factors (if applicable)	Proposed activity	Expected result	Date
Promote public records on clinical trials through a regional platform of national registries, thus ensuring greater transparency in this activity.		Promoting and broadening the experiences of countries that have a primary registry in place for public registration of clinical trials.	Experiences shared from the primary registries of the two countries in the Region that have one.	2nd quarter 2014
		Having a clinical trial registry up and running in the countries of the Region that have a primary registry.	Clinical trial registries implemented in the countries of the Region that did not have one in their primary registries.	3rd quarter 2014
		Contributing to the creation of the proposed PAHO regional platform for clinical trial registries.	Regional platform created for public records of clinical trials.	1st quarter 2015
Restructure the Working Group and establish new work, monitoring, and evaluation procedures based on indicators.	Need to restructure the Working Group to make it more concentrated and dynamic, have it apply more systematic methods, and have it use more advanced technologies.	Restructuring the group to contain fewer members, keeping those who have been active and incorporating new members, including outside experts.	Working group consolidated, applying new methods to tackle objectives where there are no resources.	1st quarter 2014
Implement harmonization documents approved from 2005–2011 and measure implementation by applying indicators.	Lack of resources due to the level of priority assigned (Level 7).	Review of the activity proposal by objective and timetable.	Plan developed, with activities and timetable.	1st quarter 2014
		Prepare indicators and measurement criteria to assess whether objectives have been met.	Indicators and measurement criteria prepared for each objective.	2nd quarter 2014
		Elect or confirm the group's coordinator for the next two years.	Coordinator elected for two years (2014–2015).	2nd quarter 2014
Restructure the Working Group and establish new work, monitoring, and evaluation procedures based on indicators.	Need to restructure the Working Group to make it more concentrated and dynamic, have it apply more systematic methods, and have it use more advanced technologies.	Restructuring the group to contain fewer members, keeping those who have been active and incorporating new members, including outside experts.	Working group consolidated, applying new methods to tackle objectives where there are no resources.	1st quarter 2014
Implement harmonization documents approved from 2005–2011 and measure implementation by applying indicators.	Lack of resources due to the level of priority assigned (Level 7).	Review of the activity proposal by objective and timetable.	Plan developed, with activities and timetable.	1st quarter 2014
		Prepare indicators and measurement criteria to assess whether objectives have been met.	Indicators and measurement criteria prepared for each objective.	2nd quarter 2014
		Elect or confirm the group's coordinator for the next two years.	Coordinator elected for two years (2014–2015).	2nd quarter 2014

continues

Objective	Limiting factors (if applicable)	Proposed activity	Expected result	Date	
Identify and implement <i>Guidelines for Good Clinical Practice: Document of the Americas</i> in the countries that do not have regulations for clinical trials.	Need to update the <i>Guidelines for Good Clinical Practice: Document of the Americas</i> (approved over eight years ago) within the framework of new requirements.	Distributing the document's chapters among group members for updating.			
		Searching for regulations and related documents from other regions for review.	<i>Guidelines for Good Clinical Practice: Document of the Americas</i> updated and presented to the Secretariat for approval	3rd quarter 2014	
		Preparing a timetable for group work and designating those responsible.			
	No contact person in the NRAs of the countries selected for implementation.	Holding a monthly virtual session to check on status of updating efforts.			
		Selecting countries that do not have regulations but have the political will to implement the updated GCP guidelines and that have designated a contact person in their NRA for this purpose.	Selection of countries that have the political will to implement the guidelines and NRA staff designated for training and implementation.	4th quarter 2014	
		Assessing and monitoring compliance with the work plan and with applying the indicators.	Objective and group's performance evaluated.	4th quarter 2014	
		Seeking funding alternatives for printing and disseminating the document, possibly from countries or subregional organizations.	Funds rose from external sources.	1st quarter 2015	
	Need to adjust level of priority assigned (Level 7).	Preparing distance seminars using virtual course technology.	Distance seminars prepared and accredited.	2nd quarter 2015	
		Providing training to those designated as "replicators" through distance seminars.	Designated NRA staff trained.	3rd quarter 2015	
		Assessing and monitoring compliance with the work plan and with applying the indicators.	Objective and group's performance evaluated.	4th quarter 2015	

continues

Objective	Limiting factors (if applicable)	Proposed activity	Expected result	Date
Identify and implement <i>Guidelines for Good Clinical Practice: Document of the Americas</i> in the countries that do not have regulations for research ethics committees.	Failure to update the Document of the Americas (approved over eight years ago) within the framework of new requirements.	Distributing the document's chapters among group members for updating.	Document of the Americas updated and presented to the Secretariat for approval.	3rd quarter 2014
		Searching for the regulations and other related documents from other regions for review.		
		Preparing a timetable for group work and designating those responsible.		
		Holding a monthly virtual session to monitor status of updating efforts.		
	Need for a contact person in the NRAs of the countries selected for implementation.	Selecting those countries that do not have regulations but have the political will to implement the updated GCP guidelines and that have designated a contact person in their NRA for this purpose.	Countries selected that have the political will to implement the guidelines and NRA staff designated for training and implementation.	4th quarter 2014
		Assessing and monitoring compliance with the work plan and with applying the indicators.	Objective and group's performance evaluated.	4th quarter 2014
	Need to adjust level of priority assigned (Level 7).	Seeking funding alternatives for printing and disseminating the document, possibly from countries or subregional organizations.	Funds rose from external sources.	1st quarter 2015
		Preparing distance seminars using virtual course technology.	Distance seminars prepared and accredited.	2nd quarter 2015
		Providing training to those designated as "replicators" through distance seminars.	Designated NRA staff trained.	3rd quarter 2015
		Assessing and monitoring compliance with the work plan and with applying the indicators.	Objective and group's performance evaluated.	4th quarter 2015

continues

Objective	Limiting factors (if applicable)	Proposed activity	Expected result	Date
Implement the guidelines for pediatric studies and the use of placebos, as well as the researchers' manual.		Updating the pediatric study guide in line with guidelines issued over the past year.	Guide updated in line with the latest guides from FDA, EMA, and ICH.	3rd quarter 2014
		Submitting updated pediatric guidelines for approval.	Updated pediatric guidelines approved.	4th quarter 2014
		Seeking alternative funding for printing and disseminating the document.	Funds raised.	4th quarter 2014
		Assessing and monitoring compliance with the activity plan and with applying the indicators.	Objective and group's performance evaluated.	4th quarter 2014
		Carrying out implementation activities by means of the multiplication and training of "replicators" via distance seminars in the selected countries.	NRA staff trained.	1st quarter 2015
		Disseminating the guidelines on the use of placebos and the researchers' manual in the selected countries through staff designated by the NRAs.	Documents widely disseminated.	2nd quarter 2015
		Conducting a survey to measure implementation of the guidelines.	Indicators applied and results obtained.	4th quarter 2015
Incorporate guides from other regions or countries in the areas of safety, reporting adverse events, and annual safety reports as per the Development Safety Update Reports (DSURs).	Need to assign priority to the performance of NRA functions (as recognized in VI CPANDRH and indicated in VII CPANDRH).	Reviewing documents from other regions and countries.	Documents reviewed.	3rd quarter 2015
		Disseminating the documents virtually.	Documents widely disseminated.	4th quarter 2015
Incorporate inspection guides into clinical trials.	Need to assign priority to the performance of NRA functions (as recognized in the VI CPANDRH and indicated in the VII CPANDRH).	Reviewing documents from other regions and countries.	Documents reviewed.	3rd quarter 2015
		Disseminating the documents virtually.	Documents widely disseminated.	4th quarter 2015

continues

Objective	Limiting factors (if applicable)	Proposed activity	Expected result	Date
Prepare guidelines and support documents for the process of ethical evaluation of clinical trials.	Ethical evaluation in the countries of the Region is very heterogeneous and greatly limits GCP application. To deal with this, countries that are already working in this area could share their experiences, and the PAHO Research Program could provide support.	Conducting a survey on research ethics committees in the Region.	Survey conducted by the countries and results obtained.	3rd quarter 2014
		Conducting a joint project with the PAHO Research Program on research ethics committees' registration and improvement.	Project concluded.	4th quarter 2014
		Assessing and monitoring compliance with the activity plan and with applying the indicators.	Objective and group's performance evaluated.	4th quarter 2014
		Setting up a program to improve research ethics committees by offering distance learning courses.	Research ethics committees' staff trained.	1st and 2nd quarter 2015
		Creating research ethics committees registries in the countries and incorporating the committees into the PAHO research platform.	Registries created in at least seven countries of the Region and placed on the platform.	3rd and 4th quarters 2015
		Assessing and monitoring compliance with the activity plan and with applying the indicators.	Objective and group's performance evaluated.	4th quarter 2015
Promote public records on clinical trials through a regional platform of national registries to ensure greater transparency in this activity.	Insufficient level of priority assigned.	Promoting and sharing the experiences of those countries that have a primary public registry in place for public registration of clinical trials.	Experiences shared from two countries in the Region that have primary registries in place.	3rd quarter 2014
		Setting up a clinical trial registry in countries in the Region that do not have a primary registry.	Increase in the number of countries in the Region with primary registries containing a registry for clinical trial records.	4th quarter 2014
		Assessing and monitoring compliance with the activity plan and with applying the indicators.	Objective and group's performance evaluated.	4th quarter 2014
		Contributing to creation of the proposed PAHO regional platform for clinical trial registries.	Regional platform created containing public records of clinical trials.	1st and 2nd quarter 2015
		Assessing and monitoring compliance with the activity plan and with applying the indicators.	Objective and group's performance evaluated.	4th quarter 2015

continues

Need to incorporate other experts (from both inside and outside the Region) for achieving expected results

The group deems it advisable to incorporate Dr. Agnes V. Klein, Director, Centre for Evaluation of Radiopharmaceuticals and Biotherapeutics at the Ministry of Health of Canada (Health Canada), as an expert associated with the group through her previous collaboration and her solid achievement in preparing the GCP guidelines for review and implementation. She is fluent in both languages (English and Spanish) and could contribute to training and refresher courses for NRA staff via virtual modalities.

Justification for the group's continuity (based on the circumstances and priorities of the Region)

The rapid growth of clinical trials in the Region of the Americas has had an impact on the situation of countries that in some cases do not have a regulatory agency strong enough to face the scientific and ethical challenges required in the process of research on human subjects. To not be given more time to deal with this would be to waste the time and effort already invested by the GCP Working Groups over the past 10 years. To implement what has already been approved would require a minimum of material resources and the application of different but more dynamic and flexible procedures.

The average age of regulations governing clinical trials in the countries of the Region is eight years. There are still countries in the Americas that do not have regulations governing clinical trials and still have not adopted GCPs.

No mechanisms have been established for information exchange on the safety and efficacy of the products being investigated.

Since 2009, there has been a need to develop clinical trials for pediatric patients in order to acquire information on safety and efficacy in this group of patients. This accounts for the rise in requests for this type of clinical trials in the Americas.

On the other hand, two topics have remained indispensable for the countries of the Region: adverse events and inspections, which, without creating new guidelines/documents, call for work on disseminating and using already-existing guidelines from other regions or countries. This would contribute to one of the first recommendations made at VII CPANDRH: Focus on subjects that represent basic NRA functions.

The basic strategy would be based on training, consciousness-raising, and promoting complete adoption of the guidelines by all parties involved (research ethics committees, researchers, and sponsors) in the clinical research process.

The new topics included have been reiterated on several occasions and in several scenarios in order to ensure transparency and safety of the population, which, in the group's opinion, should be a priority. To this end, the group is proposing topics that promote ethical review in research through development of research ethics committees and with participation of the Regional Program on Bioethics and the PAHO Research Program. Another subject that has been proposed is promotion of public records of clinical trials, based on the experience of the two countries in the Region that have a primary registry approved by WHO. PAHO has shown interest in creating a public records platform to which this group would contribute. Neither case calls for a huge investment of resources but could produce a multitude of benefits.

With regard to specific mandates and defined timelines, the proposal would involve a two-year mandate for the coordinator to evaluate results and monitor compliance every year, at the end of the biennium, and upon the election of a new coordinator.

Regarding the members, the group suggests having fewer members and having each one take on a specific topic, rather than having all members deal with all topics. Implementing already-existing guidelines would involve their distribution to selected countries by group members according to subregion. Formation of the group and membership should not require strict representation from every subregion, unless this contributes to resource-mobilization through organizations from a given subregion. A collective evaluation of group members should take place every two years to decide whether each member will remain in or leave the group. New temporary members can be incorporated, and, in accordance with their performance, become regular members at the end of the biennium. Industry should be regularly represented and academia (universities), incorporated.

A virtual communication forum will be created among group members to allow for ongoing exchange and sharing of information resources in order to better contribute to the implementation of PANDRH's recommendations.

Annex 5: Operations Report, Working Group on Pharmacovigilance (WG PV)

I. Original Mission and Objectives

Date of Creation

The Working Group on Pharmacovigilance was created at IV CPANDRH in 2005 and held its first meeting in Salvador, Brazil, in 2006.

Mission

To develop and strengthen pharmacovigilance through regulatory harmonization activities and proposals promoting the safety and rational use of medicines as a necessary component of public health policies in the Americas.

Objectives

1. Promote the generation and dissemination of knowledge, criteria, and methodologies used in medicines surveillance for integration into educational and training activities aimed at all actors involved in medicines.
2. Analyze and promote the development of standardized tools to support medicines surveillance in the Region.
3. Develop and promote a network that allows for information-sharing, communication, and decision-making support for medicines surveillance.
4. Promote integrated medicines surveillance as a building block of medical programs and public health policies.
5. Promote and disseminate research on medicines surveillance and assess its impact on public health, with emphasis on patient safety.

II. Current Members

Titular Members

MERCOSUR: Salomé Fernández, Uruguay

Andean Community: Chief Coordinator to be designated, Colombia

SICA: Indira Credidío, Panama

CARICOM: Maryam Hinds, Barbados

NAFTA: Carmen Becerril, Mexico

ALIFAR: Juan Arriola Colmenares, Peru

FIFARMA: Ronoldy Valencia, United States

PAHO/WHO: Julián Pérez Peña, Cuba

Alternate Members

MERCOSUR: Marcia Gonçalves, Brazil

Andean Community : Silvia Alvarez, Peru

SICA: Helbert Saénz, Guatemala

NAFTA: Heather Sutcliffe

ALIFAR: Juan Arriola Colmenares, Peru

FIFARMA: Daniel Ciriano, Argentina

Other experts: Mariano Madurga (AEMPS), Albert Figueras(ICF, collaborating Center of WHO)

Secretariat (PAHO/WHO)

José L. Castro, Washington, D.C.

III. Work Plan to date

The table below shows results obtained to date; for any original objective as yet unmet, the table specifies any limiting factors.

Objective	Limiting factors (if applicable)	Activity carried out	Result obtained	Date
Promote the generation and dissemination of knowledge, criteria and methodologies used in medicines surveillance for integration into educational and training activities aimed at all actors involved in medicines.	Lack of participation among group members.	Holding training through PAHO's Virtual Public Health Campus (VPHC).	Pharmacovigilance course held, training more than 100 staff from medicines surveillance programs from 12 countries.	2010, 2011, 2013
			12 projects developed.	2012–2013
	Limited funding.	Holding workshops in the countries.	Course held on monitoring new vaccines, training 45 staff from pharmacovigilance, epidemiology, and registry programs from eight countries.	2013
			Medicines surveillance capacities built and national pharmacovigilance plans developed.	2009–2013
Analyze and promote the development of standardized tools to support medicines surveillance in the Region.		Carrying out a situation analysis.	Information obtained on the development of medicines surveillance activities in the countries of the Region.	2006
		Developing documents on relevant topics in the area of drug surveillance.	Guidelines on Good Pharmacovigilance Practices in the Americas published (also in Spanish and Portuguese) (PANDRH Technical Document No. 5).	2011
			Manual produced on how to set up and run a focal points network.	2012
			Notes and summaries published on the PRAIS platform.	2013
		Developing a project on active vaccine monitoring.	Project developed and pilot proposed.	2013

continues

Objective	Limiting factors (if applicable)	Activity carried out	Result obtained	Date
Develop and promote a network for information-sharing, communication, and decision-making support in the area of medicines surveillance.	Lack of participation among group members.	Structuring the Regional Network of Pharmacovigilance Focal Points and the community of practice on the PRAIS platform.	Network and community of practice up and running.	2013
Promote the integration of drug surveillance as a fundamental building block of medical programs and public health policies.		Drafting coordination procedures with the Expanded Program on Immunization (EPI).	Procedures drafted by consensus.	2013
		Document experiences in coordinating medicines surveillance and other public health programs.	Document containing successful experiences drafted.	2013

IV. Continuity Proposal

The group is providing the following information with a view to its continued operations:

1. Proposed work plan for 2014–2015, with expected results and timeline;
2. Need to incorporate other experts (inside and outside the Region) for achieving those results;
3. Justification for the group's continuity (based on the realities and priorities of the Region).

Proposed Work Plan 2014–2015

Objective	Limiting factors (if applicable)	Proposed activity	Expected result	Date
Identify gaps/opportunities.		Conducting a survey.	Gaps/opportunities identified.	2014
Provide support in the form of coordinating performance evaluations for national medicines surveillance programs.		Reaching a consensus on indicators and evaluation mechanisms for pharmacovigilance programs and centers.	Evaluations piloted.	2014–2015
Continue to update and harmonize regulations.		Elaborating documents on signal generation, periodic safety update reports, risk management, successful experiences, and inspections.	Documents finalized and published.	2014
Develop active medicines surveillance schemes in the countries.		Implementation of the pilot project on active vaccine pharmacovigilance.	Results obtained from the pilot project.	2014–2015
Develop strategies to monitor implementation of the technical guidelines generated.		Generating a strategy.	Strategy developed and monitoring commenced.	2014–2016
Strengthen capacities by means of different strategies.		Training trainers.	Pharmacovigilance trainers trained.	2014–2016
		Expanding virtual training sessions.	Human resources in pharmacovigilance strengthened.	
Harmonize databases.		Providing technical support for harmonizing the databases of the EPI and NRAs.	Coordinated pilot project in progress in one country.	2014–2016
Maintain and optimize shared communication, coordination, and information exchange.		Continuing with communication and exchange within the community of practice on the PRAIS platform and within the Regional Network of Focal Points.		2014–2016
		Implementing improvements in systematization.		

Justification for the group's continuity

The group's continuity proposal is based on the following needs, as expressed by representatives from the countries of the Region:

- Harmonizing criteria and standards;
- Strengthening management in pharmacovigilance centers and national drug surveillance programs;
- Updating knowledge;
- Exchanging information for decision-making;
- Providing technical support and encouraging technical collaboration among countries;
- Designating contact persons from other regions and liaising with them;
- Assessing the impact of the activities carried out;
- Evaluating their impact on public health;
- Providing support for integration with other public health programs (e.g., Immunization);
- Providing support for active medicines surveillance plans.

Annex 6: Operations Report, Working Group on Vaccines (WG V)

I. Original Mission and Objectives

Date of creation

PANDRH's Working Group on Vaccines was created in 2005; its main objective was to develop a harmonized document for registration of vaccines in the Region of the Americas.

Mission

To promote the regulatory harmonization for vaccines with the aim of ensuring the quality, safety and efficacy of these products and to develop mechanisms that will improve vaccine availability in countries of the Americas.

Objectives

1. To harmonize requirements for authorization of vaccine clinical trials and follow up with activities to monitor this harmonization process.
2. To harmonize technical requirements for the registration (marketing authorization) of vaccines and monitor their implementation.
3. To promote the exchange of information and the convergence and recognition of the vaccine regulation systems among the NRAs of the Region.
4. To set up tools and organize training activities for technical staff of NRAs in the Region.
5. To harmonize GMP requirements, specifically for vaccines and follow up with activities to monitor this harmonization process.
6. To promote the establishment of systems for the vigilance of adverse events following immunization (AEFI) in the region.
7. To identify other important issues on vaccines regulation that may deserve special attention and establish an appropriate working plan to address them.

II. Current Members

Main Members

MERCOSUR: Marina Rossi, Argentina (Alternate Coordinator)

Andean Community : María T. Ibarz, Venezuela

SICA: Olga L. Jacobo, Cuba (Coordinator)

CARICOM: Princess Osbourne, Jamaica

NAFTA: Maria Baca Estrada, Canada

FIFARMA: Aldo A. Topasio, Chile

ALIFAR: Hector Ostrowski, Argentina

Alternate Members

MERCOSUR: Maria Fernanda Reis e Thees, Brazil

Andean Community : Leonor Suarez Cozarelli, Ecuador

SICA: Martha Escobar, Panama

CARICOM: Stella Harrigin, Trinidad and Tobago

FIFARMA: Tarsila Rey, Mexico

Secretariat (PAHO/WHO)

María Luz Pombo, Washington D.C.

III. Work Plan to date

The table below shows results obtained to date; for any original objective as yet unmet, the table specifies any limiting factors.

Objective	Limitations (if applicable)	Actions (undertaken or proposed)	Results (achieved or proposed)	Date
Develop the document "Harmonized Requirements for the Registration of Vaccines in the Americas."	N/A	Generation of survey on requirements for the granting of health registration of vaccines.	Survey generated and sent to all the countries of the Region.	Oct 2005
		Distribution and collection of information from the countries of the region.	Survey response from 15 countries.	Nov 2005
		Analysis and proposed draft survey of the harmonized requirements for the registration of vaccines. (Second meeting of the Working Group, Caracas, Venezuela.)	Analysis and discussion of the information collected on the meeting of the working group.	7–9 Dec 2005
		Generation of harmonized technical document for the registration of vaccines. (Draft)	Drafting of the first draft of the document.	May 2006
		Outreach and consultation on drafts of the document.	Document sent to the countries and industry for comments.	Jun 2006
		Analysis of the comments received. Meeting of the Working Group (Canada)	Analysis completed.	27–29 Jun 2006
		Changes to the document format according to the common technical document (CTD) format of the ICH.	Generated the final version.	Sep 2006
		Public consultation for comments.	Comments from industry received.	2007
		Final editing of the document.	Completion of the final version.	2007
		Proposal sent to the Steering Committee.		Sep 2008
		Presentation of the proposal during V CPANDRH in Buenos Aires, Argentina.	Approval by the Board of Directors.	Nov 2008
		Perform translation into three languages.	Made available in English, French, and Spanish.	2009
		Publication.		Mar 2010
Implementation of the document.	N/A	Survey sent to countries to determine the level of implementation.	Data collection and analysis.	May 2012
		Workshop considerations relating to the implementation of the technical document (Canada).	Analysis of implementation of the document completed and plan of actions identified.	22–23 Sep 2012
		Poster on the work performed developed by the Vaccines Working Group.	Presentation at VII CPANDRH.	Sep 2013

IV. Continuity Proposal

The group is providing the following information with a view to its continued operations:

1. Proposed work plan for 2014–2015, with expected results and timeline;
2. Need to incorporate other experts (inside and outside the Region) for achieving those results;
3. Justification for the group's continuity (based on the realities and priorities of the Region).

Proposed Work Plan 2014–2015

Objective	Limitations (if applicable)	Proposed Action	Results obtained	Date
Implementation of the document "Harmonized Requirements for the Registration of Vaccines in the Americas."		Revision of the format (numbering) of the document to match the CTD format of the ICH.	Document (with the format in compliance with the CTD format of the ICH) in electronic version for implementation in specific countries.	Jan 2014
		Communication with the countries of the region to determine their commitment to implementation.	Obtain a formal commitment from each country regarding the implementation of the document.	Mar 2014
		Request that countries provide implementation plans.	Determination of the time required and the potential limitations.	Mar 2014
		Analysis of the plans and commitments by the countries.	Identification of the current situation in each country and identification of potential limitations.	Jun 2014
		Develop an action plan to support the countries that require it.	Identification of the action needed in order to achieve implementation in the countries.	Sept 2014
		Develop a review template document to support the evaluation of submissions for marketing authorization.	Draft available for review and comments.	Jun 2014
		Gather comments and prepare the final version of the review template.	Evaluation format available for all countries.	Oct 2014
		Monitoring of the implementation plan by the Coordinator and Secretariat.	Achieving implementation in most countries.	2015
Implementation of WHO Recommendations for Vaccines.		Organize a workshop to support the adoption of WHO recommendations for batch release and post registration changes.	Determine the level of implementation of WHO guidelines in the region. Identify the limitations for their implementation and analyze the situation in order to provide training opportunities for the NRAs.	1st term 2015
		Develop a plan of action based on the outcomes of the workshop.	Identify new activities.	2nd term 2015

Need to incorporate other experts (from both inside and outside the Region) for achieving expected results

The group has been working in accordance with the statutes of PANDRH, with permanent members and alternates appointed by subregions, which appears not to be the best approach; there may be other, more suitable experts whose participation is limited because they are not appointed as members. Therefore, it is suggested that the Technical Working Groups be comprised of relevant experts from different NRAs and from the pharmaceutical industry.

The communication between the Coordinator and members has been accomplished through email and virtual meetings of Elluminate, but in both cases, problems have been encountered due to poor response and low participation in the virtual meetings. The role of the Coordinator requires active participation, which is difficult due to the limited time available to meet the commitments of the group. In addition, all members of the group have responsibilities in their respective institutions and find it difficult to actively participate in the PANDRH Working Groups. This means that the Board of Directors of the PANDRH network should review the work of the Coordinator and the group and propose achievement of specific tasks in the short term. One suggestion is that the Coordinator be given a work assignment within PAHO headquarters and that the Board of Directors determines specific areas of work and priorities. In addition, it is suggested that other members of the Working Group have specific tasks assigned. This group suggests that the Coordinator should stay in the position for three years in order to measure concrete results of the work achieved.

Justification for the group's continuity (based on the realities and priorities of the Region)

In a short period of time, the Vaccines Working Group achieved concrete results (PANDRH Common Technical Document No 1). In addition, the group has developed a work plan identifying specific activities according to the needs and priorities of the Region. The group has received support from the PAHO Secretariat at all times. The proposed work plan is based on the recommendations of VII CPANDRH; it addresses not only development of guidelines but also improvement of communication mechanisms, flexibility of structure, focus on relevant, core activities, such as batch release, and implementation of WHO recommendations.

Annex 7: Operations Report, Working Group on Good Manufacturing Practice (GMP)

I. Original Mission and Objectives

Date of creation

- The Working Group on Good Manufacturing Practices was created in 1999 at II CPANDRH against the following backdrop.
- *The First Pan American Conference on Drug Regulatory Harmonization* (I CPANDRH), held in 1997, included a situation analysis of GMPs in the Region; the analysis highlighted the dissimilar requirements for applying GMPs, coupled with scant, weak, and imprecise legislation. Representatives from NRAs indicated the need to apply harmonized standards for GMPs, as recommended by WHO, which called for training inspectors and conducting joint, mutually recognized inspections.
- At II CPANDRH, held in 1999, regulatory advances were presented and a request was made for continued harmonization efforts, application of recognized standards, and respect for the existence of different circumstances among the countries of the Region in terms of health policies and legislation. The Working Group on GMPs was thus formed, establishing as its cornerstones the goals of guaranteeing the quality of pharmaceutical products and training professionals from government and industrial sectors. The group's priority strategies were to be aimed at providing training programs in GMPs.

Mission

To promote knowledge and implementation of GMPs as a strategy for improving the quality of medicines in the countries of the Americas.

Objectives

1. Promote democratization of knowledge of GMPs through coordinated activities for dissemination, training, and specialization aimed at health authorities, the industrial sector, academia, and other sectors identified as core in the process of GMP implementation.
2. Develop harmonized guidelines or questionnaires for inspections aimed at verifying compliance with GMPs in the countries of the Americas, based on WHO Report 32.
3. Provide support to regulatory authorities for monitoring GMP implementation.
4. Raise the level of awareness and provide support to regulatory authorities as they assume leadership in each country to implement and monitor GMPs.

II. Group Members until 2005

United States: Justina Molzon (group coordinator), Associate Director for International Programs, Center for Drug Evaluation and Research, FDA

Argentina: Rodolfo Mochetto, National Institute of Drugs, ANMAT

Brazil: Marcelo Vogler Morães, Inspection and Drug Control, ANVISA

Canada: France Dansereau, Chief of the Inspection Unit, National Coordination Centre, Health Products and Food Branch Inspectorate, Health Canada

Mexico: Sonia Zamudio Alonso, Executive Directorate of Risk Management, Federal Commission for the Protection against Sanitary Risk (COFEPRIS)

Guatemala: Norma de Pinto, Ministry of Health

Venezuela: Elsa Castejón, Advisor, Drugs and Cosmetic Directorate, Ministry of Health

FIFARMA: Anthony Ventura

Venezuela: Marisela Benaim, ALIFAR

Chile: Magdalena Reyes, Inspection Division, Institute of Public Health

Other experts providing support

Rebeca Rodríguez, District Director, Office of Regulatory Affairs, FDA (SJ-DO/ORAFDA)

Millie Barber, SJ-DO/ORAFDA

Arlene Badillo, FDA

Secretariat (PAHO/WHO)

Rosario D'Alessio, Washington D.C.

Juana M. de Rodríguez, Guatemala

III. Work Plan to date

The table below shows results obtained to date; for any original objective as yet unmet, the table specifies any limiting factors.

Objective	Limiting factors (if applicable)	Activity carried out	Result obtained	Date
Promote democratization of knowledge of GMPs through coordinated activities for dissemination, training, and specialization aimed at health authorities, the industrial sector, academia, and other sectors identified as core actors in the process of implementing GMPs.		Holding a course in Puerto Rico on GMPs using WHO modules.	<p>Two regional courses jointly organized by the GMP coordinator at the FDA and the University of Puerto Rico (UPR), using educational material from the FDA (June 2001).</p> <p>Based on WHO modules, 22 national courses on GMPs jointly organized in 22 countries of the Region and taught by professors from schools of pharmacy at Latin American universities.</p> <p>Courses attended by over 700 professionals from government, industrial, and educational sectors in the pharmaceutical arena; professionals recommended offering further courses on specific aspects of GMPs (water, air, validation, etc.).</p> <p>Three additional modules subsequently prepared by WHO on validation, water for pharmaceutical use, and air management systems to supplement core modules.</p> <p>Material prepared by WHO then used as a basis for courses offered by PANDRH's GMP Working Group on special aspects of GMPs.</p>	2001–2005
		Holding courses on implementation of the <i>Guideline for Good Manufacturing Practices Inspection</i> (also in Spanish).	<p>Course held: training provided to eight professionals from the Ministry of Health working in the NRA, two professors of pharmaceutical technology from the National University, and 30 participants from the manufacturing sector.</p> <p>Commitment obtained from the NRA and the training institute to offer the same kinds of courses in the future.</p>	For countries of Central America: Guatemala, 9–13 January 2006
Develop harmonized guidelines or questionnaires for inspections aimed at verifying compliance with GMPs in the countries of the Americas, based on WHO Report 32.		Preparing the Guideline for Good Manufacturing Practices Inspection for the pharmaceutical industry, in support of NRAs and industry as they verify and apply GMP standards.	Guide adopted at IV CPANDRH.	

continues

Objective	Limiting factors (if applicable)	Activity carried out	Result obtained	Date
Provide support to regulatory authorities for monitoring GMP implementation.		Conducting plant visits to manufacturing sites during the courses to enable better understanding of both the guide and the methodology for its use.	Regulations modified by the majority of countries in the Region. WHO Report 92 on GMPs and its updates implemented.	2005–2012
Raise the level of awareness and provide support to regulatory authorities as they assume leadership in implementing and monitoring GMPs in each country.		Conducting plant visits to manufacturing sites during the courses to enable better understanding of both the guide and the methodology for its use.	Regulations modified by the majority of countries in the Region. WHO Report 92 on GMPs and its updates implemented.	2005–2012

Work Plan Highlights

- The GMP Working Group, in response to its work plan approved at the CPANDRH, developed the *Guideline for Good Manufacturing Practices Inspection* for the pharmaceutical industry. The guideline's purpose was to provide support to both NRAs during their inspections and the pharmaceutical industry during the process of verifying and applying internationally-recognized pharmaceutical manufacturing standards.
- Training programs on GMPs were developed using WHO modules. The training program on applying the *Guideline for Good Manufacturing Practices Inspection* was designed and implemented.
- Monitoring mechanisms were devised for GMP implementation. GMP standards under development in other fora (WHO and ICH) were identified.

Summary of Results Obtained

- The Working Group fostered training processes in GMPs by offering courses using WHO modules. Subsequently, the group offered courses on implementing the *Guideline for Good Manufacturing Practices Inspection*. These courses were aimed at inspectors from national regulatory authorities, training institutes, and industry. The courses were organized by groups of countries based on subregion: Central America, the Andean Community, and MERCOSUR.
- The Working Group prepared the *Guideline for Good Manufacturing Practices Inspection* for the pharmaceutical industry in support of both NRAs and industry in their efforts to verify and apply GMP standards. This guide was adopted at IV CPANDRH in 2005.
- At V CPANDRH in 2008, the Working Group presented and adopted the documents *Decision Tree for the Implementation of the Guideline for Good Manufacturing Practices Inspection*, *Good Manufacturing Practices for Pharmaceutical Ingredients* (ICH Guide Q7), and *Code of Ethics* for inspectors of GMPs. A request was made to promote harmonization of procedures and exchange of information among the countries of the Americas.

IV. Continuity Proposal

No continuity proposal is attached. The Secretariat should use the information contained in Section III on past activities and results obtained when deciding on the group's continuity, based on current needs in the Region.

Annex 8: Operations Report, Working Group on Bioequivalence (WG BE)

I. Original Mission and Objectives

Date of creation

The Working Group on Bioequivalence was formally established at II CPANDRH in November 1999; its formation was based on recommendations made at I CPANDRH (1997) to begin work on BE as a priority for regulatory harmonization, thus recognizing BE as a priority area in harmonization processes.

Mission

To contribute to harmonized bioequivalence criteria and promote the interchangeability of pharmaceutical products in the Americas.

Objectives

1. Promote bioequivalence of pharmaceutical products in the countries of the Region.
2. Formulate recommendations and guidelines for interpretation, evaluation, and application of the scientific principles of BE.
3. Promote and develop education and training activities in the countries of the Americas aimed at applying principles of BE.
4. Develop scientific criteria for products requiring *in vitro* and/or *in vivo* BE studies, as well as for those that do not need BE studies.
5. Develop a list of priority pharmaceuticals (core and recommended) that require *in vivo* BE studies.
6. Develop a list of pharmaceutical products that do not require *in vivo* BE studies.
7. Develop a list of comparators for BE studies for use in the Region of the Americas.
8. Develop a set of indicators for use in evaluating BE studies carried out in the Americas.
9. Adapt training program to include sharing regulatory experiences with carrying out BE studies in the Americas.

II. Original Members (non-current)

ALIFAR: Silvia Giarcovich

ANMAT: Ricardo Bolaños, Argentina

Brazil: Silvia Storpirtis

Brazil: Tatiana Lowande

Canada: Conrad Pereira

Chile: Alexis Aceituno

Chile: Pezoa Reyes

Costa Rica: Graciela Salazar

FDA: Aída Sánchez, United States

FDA: Justina Molzon, United States

FIFARMA: Loreta Márquez

Jamaica: Eugene Brown

University of Texas: Salomon Stavchansky

USP: Vinod Shaw

Venezuela: Irene Gonçalvez

Venezuela: Maggi Kabbad

Secretariat (PAHO/WHO)

Rosario D'Alessio and Nelly Marín, former PAHO/WHO staff members, Washington DC.

III. Work Plan to date

The table below shows results obtained to date; for any original objective as yet unmet, the table specifies any limiting factors.

Objective	Limiting factors (if applicable)	Activity carried out	Result obtained	Date
Promote bioequivalence of pharmaceutical products in the countries of the Region.				
Formulate recommendations and guidelines for interpretation, evaluation, and application of the scientific principles of BE.				
Promote and develop education and training activities in the countries of the Americas aimed at applying principles of BE.			PANDRH Technical Report N° 8, Framework for Implementation of Equivalence Requirements for Pharmaceutical Products published.	
Develop scientific criteria for products requiring <i>in vitro</i> or <i>in vivo</i> BE studies, as well as for those that do not need them.		Developing a document with recommendations and guidelines for the interpretation, evaluation, and application of the scientific principles of BE.		
Develop a list of priority pharmaceuticals (core and recommended) that require <i>in vivo</i> BE studies.	N/A		Four training activities held.	Nov 2008
Develop a list of pharmaceutical products that do not require <i>in vivo</i> BE studies.			Venezuela, 2001	
Develop a list of comparators for BE studies for use in the Region of the Americas.			Costa Rica, 2002	
Develop a set of indicators for use in evaluating BE studies carried out in the Americas.			Costa Rica, 2005	
Adapt training program to include sharing regulatory experiences with carrying out BE studies in the Americas.			Uruguay, 2006	

IV. Continuity Proposal

Group continuity is not an issue, because the Working Group on Bioequivalence stopped meeting following the approval of Technical Document No. 8 at V CPANDRH in November 2008. At that time, the group recommended the gradual implementation of requirements for demonstrating BE, placing priority on *in vivo* studies where the products involved a health risk. These criteria for gradual implementation and prioritization of health risks are complemented by biowaivers based on the Biopharmaceutical Classification System presented in the WHO document. The latter is important in that it provides support for criteria and decision-making within NRAs.

Annex 9: Operations Report, Working Group on Pharmacopeia (WG P or PWG)

I. Original Mission and Objectives

Date of creation

The Working Group on Pharmacopeia was created in the year 2000 with representatives of the four pharmacopeias of the Region of the Americas: Argentina, Brazil, Mexico (Pharmacopeia of the United Mexican States / FEUM), and the United States (USP).

Mission

To create a forum for discussion and information exchange to facilitate the adoption of harmonized procedures and achievement of a Pharmacopeia for the Americas.

Objective

Establish a harmonized Pharmacopeia for the Americas.

II. Original Members (non-current)

Representatives from the four above-mentioned pharmacopeias

Pharmacopeia Argentina: Carlos Chiale

Brazilian Pharmacopeia: Celso Betancourt

FEUM: Carmen Becerril

USP: Horacio Pappa (Coordinator)

Secretariat (PAHO/WHO)

Rosario D'Alessio (Washington, D.C.)

III. Work Plan to date

The table below shows results obtained to date; for any original objective as yet unmet, the table specifies any limiting factors.

Objective	Limiting factors (if applicable)	Activity carried out	Result obtained	Date
Build and strengthen ties among the four pharmacopeias.	Lack of political will on the part of the four pharmacopeias to participate and interact.	Establishing fluid relations.		
		Sharing information.	Ten meetings held.	
Develop a harmonized Pharmacopeia for the Americas.		Exchanging publications and data.	Six teleconferences held.	14 Apr 2000–
		Providing training.	Eight general chapters harmonized.	14 May 2007
		Holding public meetings.	Three monographs harmonized.	
		Developing harmonization protocols.		

IV. Continuity Proposal

Continuing the group's activities is not applicable, since the group stopped meeting after 14 May 2007. It was unable to meet its objective of developing a harmonized Pharmacopeia for the Americas.

Annex 10: Operations Report, Working Group on Medicines Registration (WG MR)

I. Original Mission and Objectives

Date of creation

III CPANDRH, held in Washington, D.C. (24–26 April, 2002), recommended the formation of the Working Group on Medicines Registration.

Mission

To promote and facilitate harmonization of regionally recognized and appropriate technical criteria for registering medicines, thus contributing to medicines quality, safety, efficiency, and availability in the Americas.

Objectives

- Establish a database on pharmaceutical legislation in the Americas and make it available on the PANDRH website.
- Assist countries in adopting the harmonized proposal adopted by PANDRH and contained in *PANDRH Technical Report No 10, Requirements for Medicines Registration in the Americas*; formulate recommendations to optimize the process of medicines registration at the national level in coordination with the PANDRH Secretariat.
- Monitor implementation of actions recommended by PANDRH to advance drug regulatory harmonization, using selected indicators and preparing updated reports.
- Develop diagnostic studies as needed to aid in the harmonization process, including those aimed at measuring the impact of having common requirements for medicines registration.
- Develop educational tools, documents, and guidelines to be used in the process of registering pharmaceutical products.
- Promote the assessment of drug regulatory agencies/bureaus to improve their efficiency.
- Organize and participate in educational activities aimed at training regulatory staff.
- Promote the establishment of a regional network of drug regulatory authorities.

II. Current Members

Titular Members

MERCOSUR: Silvia Boni, Argentina (Coordinator)

Andean Community: Marcela Pezzani, Chile

SICA: Rodrigo Pérez Massipe, Cuba

CARICOM: Gloria Creary, Jamaica

NAFTA: Justina Molzon, United States

ALIFAR: Veronica Grimoldi, Argentina

FIFARMA: Alessandra Nicoli, Brazil

Alternate Members

MERCOSUR: Meiruze Sousa Freitas and Rejane Gomes Silva, Brazil

Andean Community: María Teresa Ibarz, Venezuela

SICA: Josip De Lora, Panama

CARICOM: Stella Harrigin, Trinidad and Tobago

ALIFAR: Ana María Fallas Quesada, Costa Rica

Secretariat (PAHO/WHO)

Adriana Ivama, Barbados

III. Work Plan to date

The section below shows results obtained to date; for any original objective as yet unmet, the table specifies any limiting factors.

The group held 24 virtual meetings using the collaborative platform *Elluminate* between September 2010 and September 2012. Among the difficulties encountered in carrying out its work, the group noted irregular participation on the part of some of its members. Nonetheless, those who did participate were able to draw up a draft document in the form of guidelines for medicines registration in the Region. Four of the sections in the draft—Summary of Product Characteristics/SPC), Quality Information (from Investigación Farmacéutica/IFA, a pharmaceutical research company), Nonclinical Reports, and Clinical Reports—were adopted at VI CPANDRH. Subsequently, in accordance with PAHO/WHO publishing rules and to maintain uniformity with the draft document, the title of the document was finalized as *Requirements for the Registration of Drugs in the Americas* and published as PANDRH Technical Document No. 10 in June 2013. It contains four modules and two annexes.

Having produced this document, the group then discussed models for changes in medicines registries and for registry certification among the member countries, based on WHO recommendations. The group also discussed a model offering feasible alternatives for human resource development *vis-à-vis* the implementation of the proposed requirements. However, again due to low levels of member participation, the group suspended its activities in September 2012.

Main Achievement

The overriding achievement of the working group was its development of the above-mentioned PANDRH Technical Document No. 10, *Requirements for the Registration of Drugs in the Americas*. This publication should facilitate the dissemination of its content, as well as the adoption of the guidelines therein by PANDRH's member countries.

Technical Document No. 10 has been published in both English and Spanish and can be accessed via the following links:

English: http://www.paho.org/hq/index.php?option=com_docman&task=doc_view&gid=22110&Itemid

Spanish: http://www.paho.org/hq/index.php?option=com_docman&task=doc_view&gid=22113&Itemid

IV. Continuity Proposal

Continuity of the group's activities is not applicable, because, as the previous section mentioned, the group suspended its activities in September 2012.

Annex 11: Operations Report, Working Group on Medicinal Plants (WG MP)

I. Original Mission and Objectives

Date of creation

In accordance with the recommendation made at the Regional Meeting on Regulatory Aspects of Herbal Products held in Jamaica in November 2000, in April 2002 III CPANDRH established the Working Group on Medicinal Plants for the Region. Its goal was to analyze the regulatory aspects of medicinal plants and devise harmonized proposals for their regulation in the Americas.

Mission

To promote a common understanding of medicinal plants/herbal medicines in the Region of the Americas and make recommendations to foster harmonization in the regulation of these products, considering their traditional and sustained use.

Objectives

1. Promote and improve the exchange of information on medicinal plants.
2. Promote the quality assurance, safety, and efficacy of medicinal plants in the Americas, including developing a program for their surveillance and control.
3. Develop harmonized proposals on the subject of medicinal plants and provide support to countries as they implement these proposals, once PANDRH adopts them.
4. Promote training programs and activities for health care providers, consumers, and the general public.

II. Group Members to March 2006

Members

Bolivia: Vanesa Mejía Loza

Brazil: Edmundo Machado Netto

Canada: Michael Smith

Jamaica: Princess Osbourne

Mexico: Rosalía Reyes Pérez

Panama: Pablo Solís

ALIFAR: Carlos Silva

Secretariat (PAHO/WHO)

Victoria de Urioste, Bolivia

III. Work Plan to date

The table below shows results obtained to date; for any original objective as yet unmet, the table specifies any limiting factors.

Work Plan, 2006–2007 (updated in 2006)

Objective	Activity carried out	Result obtained	Date
Objective 1: Promote and strengthen information exchange on medicinal plants.			
Updating all terms referring to medicinal plants in the Spanish version of the Drug Glossary.	Compiling existing terms in WHO's English version.	List of WHO terms from the last 4–5 years compiled.	Jul 2006
	Including new terms from the WHO glossary.	List of new terms compiled.	
	Reviewing and updating existing terms in the glossary.	Up-to-date glossary with terms referring to medicinal plants finalized.	Aug-Oct 2006 (e-mail)
Make national legislation on medicinal plants available.	Sending documents and/or indicating their specific URLs to the PANDRH Secretariat.	Production of consolidated document containing all national legislation on medicinal plants available on the Working Group's website.	15 May 2006
Continually update documents on medicinal plants available on the PAHO website.	Looking for the new documents on the website and/or emailing documents to the PANDRH Secretariat.	Up-to-date reference document section available on the Working Group's website.	Ongoing
Objective 2: Promote the quality, safety, and efficacy of medicinal plants in the Americas, developing a program for their surveillance and control.			
Prepare a proposal for classification or categorization of medicinal plants	Obtaining information on the current status of classification or categorization of medicinal plants in all countries.	Representative from each regional bloc (Mexico, Brazil, Bolivia, Panama and Jamaica) designated.	15 May 2006
	Preparing the preliminary version of the proposal.	Preliminary document produced.	30 Jun 2006
	Discussing and analyzing the proposal.	Discussion paper produced.	Jul–Aug 2006
	Development of the draft.	Draft proposal elaborated.	Sep 2006
	Publishing the draft on the website.	Draft document published.	Oct 2006
	Analyzing the observations made on the draft, received via the website.	Discussion paper produced.	Feb-Mar 2007
	Preparing the final version for presentation at CPANDRH.	Document on classification and categorization of medicinal plants finalized.	Jul 2007

Objective	Activity carried out	Result obtained	Date
Prepare a uniform, harmonized format for monographs on medicinal plants	Preparing the preliminary version of the proposal.	Uniform format developed.	15 May 2006
	Discussing and analyzing the proposal.	Discussion paper produced.	Jul–Aug 2006
	Development of the draft.	Draft document developed.	Sep 2006
	Publishing the draft on the website.	Draft document published.	Oct 2006
	Analyzing the observations on the draft, received via the website.	Discussion paper produced.	Feb–Mar 2007
	Preparing the final version for presentation at CPANDRH.	Document finalized with a uniform, harmonized format for monographs on medicinal plants.	Jul 2007

Objective 3: Develop harmonized proposals on medicinal plants and support countries in implementing them once PANDRH adopts them.

Prepare a harmonized proposal on marketing requirements based on the proposal for classification or categorization of medicinal plants (Objective 2.1).	Analyzing and updating the proposal on registration requirements (defined in Jamaica in 2000).	Up-to-date, current version finalized.	15 May 2006
	Analyzing and updating the contents of information provided on the packaging and labeling of medicinal plants (using as a basis the proposals from the Working Groups on Medicines Registration [requirements document] and Medicines Classification).	Harmonized proposal finalized with the Medicines Registration and Medicines Classification Working Groups on information contained in packaging, labeling, and leaflets (“Drug Facts”).	15 May 2006
	Preparing the preliminary version of the proposal.	Information received, document consolidated.	30 Jun 2006
	Discussing and analyzing the proposal.	Agreement reached among members for final version.	Jul–Aug 2006
	Preparing the draft.	Draft finalized and mailing list compiled for sharing with the general public.	Sep 2006
	Publishing the draft on the website.	Document published on the website.	Oct 2006
	Analyzing the observations made on the draft, received via the website.	Observations consolidated in a single document.	Feb.–Mar 2007
	Preparing the final version for presentation at CPANDRH.	Harmonized document on common requirements finalized.	Jul 2007

Summary of Objectives, Activities, and Expected Results

The work plan shown in the table above was developed by the Working Group on Medicinal Plants in 2006. It consists of three general activities, strategic activities, and expected results, itemized as follows.

1. Update terms referring to medicinal plants in the *Glosario de medicamentos* to include those published in WHO’s Drug Glossary, which will result in including and translating terms that WHO has included over the past 4–5 years. (*Glosario de medicamentos* is PAHO’s Spanish version of WHO’s Drug Glossary.) This update should include new terms published by WHO, as well as a review of existing terms in the glossary, and, thus, generate an up-to-date glossary with terms referring to medicinal plants.
2. Disseminate national legislation on medicinal plants. This will call for having the documents made available on specific websites, which will enable preparation of a consolidated document containing all national legislation on medicinal plants, available on the Working Group’s website.

3. Continuously update all available documents on medicinal plants on the PAHO and PANDRH websites, and provide an up-to-date section with reference documents on medicinal plants on the Working Group's website.

Summary of Results Obtained

Defining the activities that the medicinal plants Working Group needs to develop was a great step forward, as was made evident in its Work Plan. However, the Working Group has not produced any technical documents.

IV. Continuity Proposal

No continuity proposal is submitted, given the group's current inactivity. However, the group perceives an overriding need to revisit leadership issues in harmonizing regulations on herbal products. These include mechanisms of articulation, with structures established in the countries to deal with advances made in the areas of traditional medicine and interculturalism. Such issues also involve activities undertaken at the global level for the purpose of carrying out interventions that are more cost-effective and will ensure the appropriate, rational use of effective, safe, high-quality herbal products (with a view to instituting training programs).

Based on the above, the decision on whether to revive the group will be up to the Secretariat.

Annex 12: Operations Report, Working Group on Medicines Classification (WG MC)

I. Original Mission and Objectives

Date of creation

The Working Group on Medicines Classification was established at II CPANDRH in November 1999.

Mission

To harmonize application criteria for the classification of non-prescription, over-the-counter (OTC) drugs in the countries of the Americas.

Objectives

1. Conduct a diagnostic study on medicines classification criteria in the Americas.
2. Formulate a harmonized proposal on criteria for medicines classification.

II. Group Members until 2005

Coordinator

At its first meeting, held in Puerto Rico in 2000, the group's Steering Committee designated Mexico as group Coordinator. However, in 2003 Mexico withdrew from the group, whereupon the members designated Guatemala's representative, Ms. Beatriz Batres de Jiménez, as group Coordinator.

Titular Members

MERCOSUR: Tatiana Lowande, Brazil

SICA: Beatriz de la Cruz Pérez, Cuba

CARICOM: Pamela Payne-Wilson, Barbados

ALIFAR: María Angélica Sánchez, Chile

FIFARMA: Héctor Bolaños, Mexico

Alternate Members

MERCOSUR: Maria Rosa Papale, Argentina

SICA: Luis Palma, Panama

CARICOM: Mary Louis, Trinidad and Tobago

FIFARMA: Marisa Carcione: Argentina

Secretariat (PAHO/WHO)

Juanita Rodríguez, Guatemala

III. Work Plan to date

The table below shows results obtained to date; for any original objective as yet unmet, the table specifies any limiting factors.

Objective and Activity carried out	Results obtained
Conduct a comparative study on criteria classifying medicines sold over the counter without a prescription, as well as medicines requiring a prescription.	Comparative study conducted and presented at III CPANDRH.
Develop a position paper on promotion and advertisement of medicines.	At IV CPANDRH, proposal submitted and accepted defining: OTC medicines; medicines designated for free-sale, or medicines sold without a prescription; as well as criteria for classifying OTC medicines and criteria for promoting and advertising medicines.
Analyze national legislation with regard to requirements for registration and labeling.	Criteria and definitions incorporated by several countries of the Region into their legal framework and procedures.

Group mandates emerging during CPANDRH IV

1. Monitor the incorporation of harmonized criteria for medicines classification into the medicines regulations enacted by the countries of the Region, and submit a report on it at the next conference.
2. Formulate a comprehensive proposal to harmonize definitions and criteria for classifying herbal (phytotherapeutic) products, dietary supplements (nutraceuticals or pharmaceutical products related to nutrition), cosmetic products with biologically active ingredients (cosmoceuticals), medical devices, diagnostic agents, radioactive drugs, and dental products for consideration at the next conference.
3. Prepare a harmonization proposal for medicines categories and active ingredients (concentration, dosage, dosage form, and indications) likely to be regarded as free-sale, OTC medicines
4. Ask the Working Group on Medicines Registration to review the proposal presented by the Working Group on Medicines Classification on the content of information provided on labels, containers, packaging, and "Drug Facts" for free-sale, OTC medicines, with a view to detailed harmonization of common requirements for medicines registration.
5. Continue to discuss the topic of points of sale for OTC medicines where consensus is still pending.

However, IV CPANDRH approved the establishment of a Working Group on Medicines Promotion and Advertisement to henceforth monitor topics dealt with by the Working Group on Medicines Classification.

IV. Continuity Proposal

Continuity is not applicable in this case, since monitoring functions have been taken over by the Working Group on Medicines Classification.

Annex 13: Operations Report, Working Group on Medicines Promotion (WG MP, also known as Drug Promotion and Advertisement / WG DPA)

I. Original Mission and Objectives

Date of creation

The Working Group on Medicines Promotion, also referred to as the Working Group on Drug Promotion and Advertisement, was created in 2005 at V CPANDRH.

Mission

To promote and harmonize criteria for drug promotion and advertisement as a contribution to their rational use within the scope of health policy in the Americas.

Objectives

1. Provide mechanisms and criteria for identifying irregularities and demonstrate the market strategies most commonly used to promote and advertise medicines in the countries of the Americas.
2. Provide information and analysis on regulation, implementation, and monitoring as it relates to medicines promotion and advertisement.
3. Promote educational activities and programs related to medicines promotion and advertisement aimed at health professionals and current and potential consumers.
4. Evaluate the group's operations and the impact of its activities.

Group Members (group currently inoperative and inactive)

Titular Members

MERCOSUR: Brazil, Vacant (Coordinator)

Andean Community: Elvira Tincopa, Peru

SICA: Digmara Barban Lores, Cuba

CARICOM: Heather E. Carter

NAFTA: Margarita Contreras, Mexico

ALIFAR: María Angélica Sánchez, Chile

FIFARMA: José Manuel Cousiño, Chile

PAHO/WHO: Carlos Fuentes, Nicaragua

Alternate Members

Andean Community: Wilma Terán, Bolivia

SICA: Edgar Domínguez, Panama

CARICOM: Mary Louis, Trinidad and Tobago

NAFTA: Margarita Contreras, Mexico

ALIFAR: Laura Castellanos, Dominican Republic

FIFARMA: Héctor Bolaños, Mexico

Secretariat (PAHO/WHO)

José L. Castro, Washington D.C.

III. Work Plan to date

The table below shows results obtained to date; for any original objective as yet unmet, the table specifies any limiting factors.

Objective	Limiting factors (if applicable)	Activity carried out	Result obtained	Date
Evaluate and consolidate information on regulation, implementation and monitoring of regulations related to medicines promotion and advertisement.		Developing a questionnaire and sending it to the countries.	Partial responses obtained.	2007
		Developing a document with ethical criteria for medicines promotion and advertisement.	Document approved and published.	2012
Promote activities and educational programs on medicines promotion and advertisement aimed at health professionals and consumers.		Identifying educational products and their content.	Some common content partially identified.	2008
Evaluate group operations and the impact of group activities.				

IV. Continuity Proposal

Due to the absence of representation on the part of the coordinating country, the group has not convened for some time. Therefore, the Steering Committee will have to decide on the relevance of its continuity.

Justification

There is a current need to: disseminate and discuss ethical criteria; provide training in the critical evaluation of medicines promotion and advertisement; exchange information on that topic; and provide a framework for sanctions. All these needs could receive support from the Working Group on Medicines Promotion/Drug Promotion and Advertisement. The Steering Committee should evaluate the justification for and desirability of continuing the group's operations, as well as its restructuring in the event that the Committee decides in favor of its continuity.



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