



# **VII Pan American Network for Drug Regulatory Harmonization (PANDRH) Conference Report**

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Ottawa, Canada  
5 – 7 September 2013

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# Introduction

The VII Conference of the Pan American Network for Drug Regulatory Harmonization (CPANDRH VII) was held in Ottawa, Canada, 5–7 September 2013, on the theme *Sixteen Years Promoting Good Regulatory Practices in the Region of the Americas*. Participants included representatives from the World Health Organization (WHO), the Pan American Health Organization (PAHO), national regulatory authorities (NRAs), the pharmaceutical industry, and academia, among others.<sup>1</sup>

The conference's main topic revolved around a strategic development plan designed to tackle the unfinished agenda and deal with new challenges faced by the NRAs of the Region of the Americas.<sup>2</sup> The plan was conceived in response to the petition made at VI PANDRH Conference (CPANDRH VI)<sup>3</sup> by the PANDRH Steering Committee and the Region's NRAs, and its preparation was coordinated by the PANDRH Secretariat. The *Strategic Development Plan* contains four strategic objectives:

- 1) To promote effective PANDRH governance and active, strategic participation of NRAs toward regulatory convergence and harmonization;
- 2) To define priorities, strategies, and mechanisms for regulatory convergence and harmonization, and to support their dissemination, adoption, and implementation by NRAs;
- 3) To promote the strengthening of competencies in good regulatory practices and regulatory science;
- 4) To promote the exchange of experiences and regulatory knowledge between NRAs inside and outside PANDRH.

The issues addressed at the conference were grouped by strategic objective. The sessions on the first three strategic objectives were comprised of an introductory plenary session, three working sessions, and a closing plenary session. The introductory plenary sessions were moderated by representatives of NRAs and included presentations by WHO, PAHO, and NRAs. The plenary group was divided into three smaller groups, or working sessions, in order to promote constructive dialogue among participants and generate ideas about how to implement the strategic objectives presented. All working sessions met afterward in a closing plenary session to present the most salient points discussed as well as their conclusions.<sup>4</sup>

The second day of the conference marked the beginning of its thematic sessions, which focused on specific areas of work that the countries identified as priorities. In addition, the conference included a meeting of PANDRH's Steering Committee and a poster session that highlighted the work of technical

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<sup>1</sup> The list of participants for CPANDRH VII can be found in Annex 1.

<sup>2</sup> For more information on the conference agenda, see Annex 2.

<sup>3</sup> More information about VI PANDRH Conference can be found at:

[http://www.paho.org/hq/index.php?option=com\\_content&view=article&id=5101&Itemid=513&lang=en](http://www.paho.org/hq/index.php?option=com_content&view=article&id=5101&Itemid=513&lang=en)

<sup>4</sup> The session to present the fourth strategic objective consisted only of a plenary session.

Working Groups and the efforts and performance of the countries. On the last day of the conference, the most outstanding posters received honorable mention.

The following sections present topics discussed at the conference, recommendations made by the Steering Committee, and conclusions outlining the next steps to be taken following VII PANDRH Conference.

## I. Conference Inauguration and Opening Ceremony

At the beginning of the inaugural event, Mike Ward, Representative of Health Canada on PANDRH's Steering Committee, welcomed the participants to the meeting. Dr. Luiz A. C. Galvão, Assistant Director of PAHO, and Kathryn McDade, Assistant Deputy Minister of the Health Products and Food Branch of Health Canada, gave their inaugural addresses.

Dr. James Fitzgerald, Director of Health Systems and Services at PAHO, continued with the conference's introductory presentation; the theme was *Regional Context, Lessons Learned, and Justification for Creating PANDRH's Strategic Development Plan 2014–2020*.<sup>5</sup> Dr. Fitzgerald highlighted PANDRH's efforts to date and the reason for the current paradigm shift, as well as the conference's objectives and expected results. The topics addressed during his presentation include:

- History of PANDRH's work;
- Recommendations of CPANDRH VI (held in Brasilia, Brazil, in 2011), where the request for a strategic development plan for the Region originated;
- Development of the Region's regulatory systems;
- Examples of regional cooperation initiatives among NRAs, regulators, and cooperation networks;
- Impact of the technical guidelines prepared by PANDRH's Working Groups;
- Regulatory challenges identified by countries of the Region in the survey designed by the Secretariat;
- PANDRH's *Strategic Development Plan*, including its context, purpose, lines of action, and expected results;
- Expected results of CPANDRH VII:
  - 1) Approval of the *Strategic Development Plan*;
  - 2) Development of ideas about how to address and implement the plan's objectives;
  - 3) Agreements among the countries for joint implementation, taking into account each of the plan's four strategic objectives.

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<sup>5</sup> More information on the presentation can be found at the following website:

[http://www.paho.org/hq/index.php?option=com\\_content&view=article&id=8469%3Avii%20-%20conference-of--bread-American-network-for-drug-regulatory-harmonization-cpandr%20h&catid=1156%3Ahss-pan-%20American-network-for-drug-re&Itemid=1685&lang=en](http://www.paho.org/hq/index.php?option=com_content&view=article&id=8469%3Avii%20-%20conference-of--bread-American-network-for-drug-regulatory-harmonization-cpandr%20h&catid=1156%3Ahss-pan-%20American-network-for-drug-re&Itemid=1685&lang=en)

## II. Strategic Objectives

**A. Strategic Objective I: To promote effective PANDRH governance and active participation of NRAs toward regulatory convergence and harmonization.**

### **A.1. Session Scope and Objectives**

Despite current evidence that the NRAs are significantly improving implementation of their control functions, asymmetries in pharmaceutical regulatory capacity persist in the Region. Hence, it is necessary to revise regional strategies in order to bridge existing gaps; and this includes reviewing the concepts expressed in PANDRH's statutes. Given that the network's structure should enable timely responses to the Region's regulatory requirements, PANDRH proposes formulating a proposal for a more appropriate structure that will respond to the different needs and challenges faced by the countries today. This, in turn, will make it possible to promote regulatory convergence in a more agile and flexible way, thus creating space where all NRAs can participate.

### **A.2. Countries Moderating the Session**

Canada and Mexico acted as moderators.

### **A.3. Presentations**

#### ***Governance Models from Other Networks: Lessons Learned from ICH, APEC, IMDRF, and EMA***

ICH = International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use

APEC = Asia-Pacific Economic Cooperation

IMDRF = International Medical Device Regulators Forum

EMA = European Medicines Agency

*Michelle Limoli, United States Food and Drug Administration (FDA)*

*Mike Ward, Health Canada*

*Alexios Skarlatos, EMA*

#### ***WHO Support in Setting up the AMRH Initiative***

AMRH = African Medicines Regulatory Harmonization

*Samvel Azatyan, WHO*

#### **A.4. Summary of the Main Topics of the Session**

- The need to encourage and promote efficient governance and strengthen NRA functions aimed at implementing national legislation promoted by PAHO/WHO and close existing gaps in regulatory asymmetries.
- Existing differences in regulatory capacities and the importance of an environment of harmonization, where reference NRAs can provide support to those still in development.
- Promoting access to medicines by reducing prices paid by families and governments—a basic element common to all countries of the Region.
- The need to review PANDRH's governance mechanism in order to enable immediate response to regulatory changes and develop an inclusive work strategy.
- Closing gaps in different areas of harmonization, for example, biotechnological products. Harmonization will increase availability of these products.
- The need to strengthen research in the countries in order to promote innovation.
- The importance of sharing information and identifying ways for countries to interact, cooperate, and collaborate.
- Knowledge of other countries' harmonization initiatives in order to both implement and maximize successful experiences.
- The level of development of health systems, which has a direct effect on the ability of NRAs to work efficiently.

#### **A.5. Discussions of the Working Sessions**

Canada, Cuba, and Mexico moderated the discussions of the three working sessions. Each session discussed two questions.

- 1) Has the current governance structure met PANDRH's needs?
- 2) What changes could be made to enable PANDRH to face current and future challenges?

Based on their discussions, the working sessions arrived at the following conclusions:

- PANDRH's governance structure has met its initial objectives; however, it must tackle new regulatory challenges before it can update these objectives.
- The structure should incorporate new challenges by redesigning the Working Groups as well as PANDRH's communication and transparency mechanisms.
- The regulatory authorities should promote active participation, seeking a consensus to build products that address current priorities and reflect national circumstances.
- Strengthening PANDRH's work is fundamental, which requires using experiences of other international governance models to avoid duplication of effort.
- PANDRH should aim to be an integral part of the consortium of international regulatory harmonization initiatives.
- PANDRH should take advantage of PAHO's certification process in order to generate Regional Reference NRAs that promote harmonization and convergence, thus increasing access to health inputs and providing support to those NRAs that need it.

- PANDRH needs to form more flexible Working Groups (with specific mandates, deadlines and participation of outside experts) that address the issues facing the Region.
- PANDRH should consider promoting bilateral or subregional cooperation among authorities to achieve greater effectiveness.

## **A.6. Next Steps (Agreements, Actions, and/or Recommendations)**

Based on the points discussed, the working sessions recommended the following actions/activities.

### **A.6.1. PANDRH and Steering Committee**

- Review and edit PANDRH's proposal on network governance prior to submitting it for approval by the Steering Committee.
- Organize a system through which countries receive support in developing an implementation plan based on their different circumstances and on issues they consider priorities.
- Establish tools and indicators to measure the effectiveness of the Working Groups with regard to health objectives, going beyond mere production and adoption of documents/guidelines.

### **A.6.2. National Regulatory Authorities (NRAs)**

- Make a commitment to implementing PANDRH's recommendations.
- Identify subjects of mutual interest to be addressed by Working Groups.
- Participate in evaluation and development processes aimed at strengthening human resource capacity.
- Reference NRAs should provide support to less developed NRAs.

### **A.6.3. Manufacturing Sector**

- Implement the guidelines contained in PANDRH's technical documents.
- Actively participate in processes to build human resource capacity within the industry in order to foster rapid implementation of PANDRH's technical guidelines.
- Participate in evaluation processes.
- Promote innovative research in the Region.

### **A.6.4. PANDRH Secretariat**

- Form an *ad hoc* working group to prepare a governance proposal for PANDRH's operations. This proposal should aim to achieve the following:
  - Adopt a flexible model that facilitates member participation and guarantees the representativeness of all sectors;
  - Show dynamism, and efficiently meet country needs;
  - Integrate PANDRH's work into other international regulatory harmonization/convergence initiatives by adapting documents/guidelines produced by WHO and other initiatives, and by taking a regional approach;

- Promote bilateral and subregional cooperation among countries and take advantage of other international models based on bilateral or regional agreements.
- Develop and maintain a transparent information system that shows the work carried out by PANDRH's Working Groups and Steering Committee.
- Provide technical cooperation and assistance to countries in preparation of: documents, guidelines, and training processes; and continuing education for PANDRH's human resources.
- Promote a system for NRA convergence in implementation of basic functions (taking a regional approach to strategies such as adapting WHO guidelines, among others) and thus empower the countries to make more solid regulatory decisions based on scientific advances.



## **B. Strategic Objective II: To define priorities, strategies, and mechanisms for regulatory convergence and harmonization and support their dissemination, adoption, and implementation by NRAs.**

### **B.1. Session Scope and Objectives**

The guidelines and technical standards formulated and developed by PANDRH over the past 16 years have contributed to a significant increase in regulatory capacity throughout the Americas. Notwithstanding, there are still opportunities for improving the network's response capacity based on regional and national priorities that need periodic review. With this strategic objective, PANDRH aims to step up its dissemination of the technical standards it has developed and adopted, and provide support to the countries of the Region as they adopt these guidelines. The aim here is to strengthen existing regulatory functions and develop new technical standards as needed to tackle new regulatory challenges throughout the Americas. This will eventually enable the countries to create effective regulatory systems that progressively and systematically implement international standards for pharmaceutical regulation, thus contributing to regulatory convergence processes at the regional level.

### **B.2. Countries Moderating the Session**

Brazil and the United States acted as moderators.

### **B.3. Presentations**

***Overview of Regulatory Capacity and NRA Priorities Based on PRAIS Data and NRA Surveys (PRAIS = Regional Platform on Access and Innovation for Health Technologies)***  
*Murilo Freitas, PAHO/WHO*

***Objectives and Development of the Joint Evaluation Tool for Assessing NRA Operations***  
*David Wood, WHO*

### **B.4 Summary of the Main Topics of the Session**

- All NRAs are working on topics that the survey indicated pose regulatory challenges, except in the area of medical devices.
- Connecting information and avoiding duplication of activities have emerged as important issues.
- Various mechanisms and/or information sources exist, which create the need to consolidate and make them available to countries for consultation and use.
- There was consideration of the need to ensure that the most developed NRAs support less developed NRAs to help them meet established objectives and move toward convergence.
- It was determined that there is a need for capacity-building in terms of prioritizing work areas in both technologies and NRA operations and a need for developing a work plan to enable visible progress (by establishing indicators for measuring results).
- A recommendation was made to establish: criteria and elements to support the prioritization process aimed at mapping areas; a specific Working Group charged with developing sustainable mechanisms and related guidelines.
- The experience of various NRAs was mentioned and acknowledged.
- The importance of the Working Groups was highlighted in terms of their roles in producing guidelines and supporting implementation of these guidelines within NRAs.

- There is a need to improve communication within the Working Groups, i.e., between representatives and Member States.
- The importance of transparent evaluation processes was highlighted, with emphasis on taking the necessary precautions whenever confidential data is exchanged.
- Defining NRA responsibilities was also emphasized.
- Emphasis was placed on the need to form Working Groups to deal with new topics of interest to the countries, identify unmet needs while strengthening response to existing needs, and focus on groups with the greatest capacities in order to foster their coordination and integration.
- There was a consensus that the Working Groups should be more flexible, adjust their objectives, and consider the value of including other experts. They should decide on their own adjustment mechanisms in order to adopt PANDRH's new approach and work plans.
- The need to disseminate the technical guidelines widely, with the aim of optimizing their implementation within the NRAs, was noted.
- The need for some existing Working Groups to review and adjust their objectives in order to support the implementation of key processes was discussed.

### **B.5. Discussions of the Working Sessions**

Brazil, Colombia, and the United States moderated discussions during the conference's three working sessions. Each session discussed three questions:

- 1) How can we reach quick, operational agreements on new priorities and lines of work for the Working Groups?
- 2) How can we move forward in disseminating, implementing, and expeditiously approving our guidelines, recommendations, agreements, etc.?
- 3) How can we improve PANDRH's operations?

Based on the discussions of the working sessions, it was decided that PANDRH should:

- Boost its capacities in order to prioritize work on NRA technologies and functions and develop the work plan so progress can be seen by establishing indicators for measuring results; (This should be presented at the next conference in order to improve continuity of topics presented. Established priorities should be examined and ranked.)
- Use results-based management with an institutional development plan to measure and serve country needs;
- Promote the use of multiple information sources—for example, periodic surveys and NRA indicators—to support prioritization;
- Promote and foster sharing experiences and information among the Working Groups, with emphasis on implementation;
- Maximize use of state-of-the-art online tools to further dissemination and approval of PANDRH agreements;
- Advance toward regulatory convergence in order to respond to the social and economic realities of each country, working with core concepts and principles aimed at achieving common results;
- Boost the capacity of Working Groups by modifying membership requirements, ensuring flexible participation, and establishing terms, deadlines, and expected results;

- With a view to supporting Working Groups on specific topics, assign one or more topics to NRAs already evaluated by PAHO;
- Strengthen evaluation processes, because this is fundamental to the progress of PANDRH's new *Strategic Development Plan*;
- Define and disseminate NRA competencies so each country can identify what it must accomplish to have a functional NRA.

## **B.6. Next Steps (Agreements, Actions, and/or Recommendations)**

Based on their discussions, the working sessions recommended the following actions/activities.

### **B.6.1. PANDRH Network and Steering Committee**

- Adopt a systematic, priority-setting mechanism based on periodic review of NRA contexts and needs.
- Use data on regulatory functions derived from evaluation processes, as well as established, agreed-upon institutional development plans as outlined in PAHO Resolution CD50.R9, [\*Strengthening National Regulatory Authorities for Medicines and Biologicals\*](#).
- Determine whether PANDRH's Working Groups will continue their operations. If so, they must:
  - Focus on issues that reflect core NRA functions;
  - Be based on established priorities;
  - Have a specific mandate and time period;
  - Periodically evaluate activities on the basis of the results achieved;
  - Develop a flexible structure that allows a diverse membership (including experts from other global regulatory harmonization/convergence initiatives);
  - Go beyond elaborating technical guidelines; Working Groups need to foster sound communication, exchange information, and implement network recommendations in daily practice.

**B.6.2. Network Secretariat**

- Consult with NRAs about their needs by conducting periodic surveys that assess existing gaps.
- Monitor work plans and the achievement of network objectives, as well as adoption and implementation of PANDRH technical guidelines, by establishing indicators that measure the relative efficiency of the processes followed.
- Develop and use virtual communication tools to strengthen communications and foster wide dissemination of PANDRH's work plans, technical guidelines, products, and any other relevant information.

## **C. Strategic Objective III: To promote the strengthening of competencies in good regulatory practices and regulatory science.**

### **C.1. Session Scope and Objectives**

Developing the essential functions of an NRA calls for qualified personnel who, with professionalism and skill, can implement good regulatory practices and periodically incorporate advances in regulatory science into their activities. Thus, NRAs need to adopt a human resource policy that includes the following practices:

- Defining competencies related to NRAs' regulatory processes and functions;
- Hiring skilled professionals recruited through transparent processes;
- Developing incentives to facilitate professional development of both the individual and the agency.

PANDRH, as a vehicle for regulatory convergence, must provide support to follow up with the Region's NRAs as they develop and apply good regulatory practices. This will in turn facilitate generation and exchange of knowledge, as well as application of advances made in regulatory science.

### **C.2. Countries Moderating the Session**

El Salvador and Peru acted as moderators.

### **C.3. Presentations**

#### ***Good Regulatory Practices***

*Federal Commission for Protection against Health Risks (COFEPRIS, Mexico)*, acting as representative for Regional Reference NRAs

#### ***Approaches for Applying Regulatory Science and Developing Regulatory Curricula***

*Mary Lou Valdez and Carl Sciacchitano, FDA*

#### ***Implementation of Good Regulatory Practices through the Evaluation of Regulatory Capacity***

*Aimée Naarendorp, National Regulatory Authority of Suriname*

### **C.4 Summary of the Main Topics of the Session**

- Access is a key part of regulation. The lack of national training within regulatory agencies creates the risk of making agencies unable to guarantee public access to safe, effective products.
- Common good regulatory practices among the Region's NRAs should include the following:
  - Alignment with national priorities;
  - Coordination of different national entities, interest groups, and civil society;
  - Improvements in the regulatory and legal framework;
  - Adopting international best practices and mandates, with the aim of strengthening regulatory capacity;

- Leadership in risk management;
  - Strengthening institutional capacity for regulatory management.
- The core elements of regulatory policy include:
  - Social and economic benefits that surpass their cost;
  - Good practices based on the principles of transparency and stakeholder participation;
  - Mechanisms to review goals and processes;
  - Confidence in the regulatory agency and its decisions;
  - Establishment of risk models;
  - Regulatory measures that allow for tangible goals.
- Currently, several coordination schemes are used by the Region’s regulatory agencies to achieve good regulatory practices. The model used by Mexico consists of four lynchpins that foster effective access to quality services and disease prevention. One of these lynchpins has resulted in significant benefits for members of the Pacific Alliance, a regional economic integration initiative comprised of Chile, Colombia, Mexico, and Peru. In a groundbreaking move, the alliance incorporated a public health objective, drug regulatory harmonization, into its economic measures.
- Based on current circumstances in the Region, certain tasks have become imperative:
  - Preparing lines of action aimed at strengthening human resource capacity in order to develop a competent regulatory workforce;
  - Developing a curriculum that defines NRA responsibilities;
  - Educating and training professionals in their ethical responsibilities;
  - Working in an environment that encompasses globalization and risk management;
  - Positioning regulators in such a way that their work can be carried out effectively at a high level;
  - Identifying core competencies common to the different agencies.
- Professional development is the foundation of any regulatory system. If NRAs are to achieve long-term impact, they need to identify elements that foster sustainability. Thus, it becomes imperative to define regulators’ core competencies in order to enable them to adequately perform their tasks.
- With support from academia and other sectors, PANDRH should act as a catalyst in efforts to develop a regulatory curriculum aimed at strengthening the regulatory capacities of professionals working in the Region’s NRAs.
- Regulatory science is not limited to medical products; it is also aimed at bridging the gap between research and regulation by developing evidence-based regulatory tools.
- One of the greatest benefits of regulatory science is having safe products. To prevent risks and product contamination, regulators must have up-to-date knowledge of the latest scientific findings and technological advances.
- Small NRAs face their own particular circumstances. Suriname, for example, is a small country that has managed to implement its own regulatory system despite limited resources. The indicators developed by PRAIS are particularly useful to NRAs by virtue of helping them identify current gaps that hinder development of their training systems at all levels—basic, intermediate, and advanced.

### **C.5. Discussions of the Working Sessions**

Costa Rica, El Salvador, and Peru moderated discussion of the three working sessions. Each session discussed four questions.

- 1) Have priorities been set for institutional development of good regulatory practices?
- 2) When developing institutional development plans, what elements should a comprehensive regional training plan include for dealing with supply and demand in the countries?
- 3) What should PANDRH do to develop and support a comprehensive training plan and what elements should such a plan comprise?
- 4) Should there be a consultation with the countries on developing ways to expand the current supply?

Based on the discussions of the working sessions, it was decided that PANDRH should:

- Determine each country's core priorities and capacities, either through self-evaluation or external evaluation; this will in turn act as input for developing a training plan.
- Create a regulatory curriculum that includes core competencies needed by smaller NRAs and/or NRAs with broader functions, incorporating recommendations from WHO and other leaders in regulatory science;
- Offer training based on well-documented, institutional development plans and on gaps identified through NRA evaluation processes;
- Have Working Groups prepare and support a comprehensive training plan following current WHO, ICH, and FDA guidelines;
- Use PAHO's regulatory training tool, which the countries can then use to identify their needs;
- Use PRAIS to implement and interpret techniques or guidelines developed by NRAs;
- Create a school for good regulatory practices involving well-informed professionals and experts in that area. Academia, civil society, and NRAs should be included in this effort.

### **C.6. Next Steps (Agreements, Actions and/or Recommendations)**

Based on the points discussed, the working sessions recommended the following actions/activities.

#### **C.6.1. PANDRH and Steering Committee**

- Strengthen management training in good regulatory practices, based on advances in regulatory science. Subsequently establish both a competency-based curriculum and a comprehensive, capacity-building plan for regulatory agencies that reflect the diversity and varying circumstances of the Region.

#### **C.6.2. PANDRH Secretariat**

- Use evaluation processes to determine each country's priorities and capacities.
- Convene an *ad hoc* working group to formulate a proposal for developing regulatory competencies, training, and curricula, and draw up a roadmap for providing continuing education for regulators, involving academia, centers of excellence, and the strongest of the regional NRAs.
- Conduct an inventory of existing training offers, relying on the strengths and experiences of regional NRAs as a guide for the best use of existing resources.



## **D. Strategic Objective IV: To promote the exchange of experiences and regulatory knowledge between NRAs inside and outside PANDRH.**

### **D.1. Session Scope and Objectives**

Interest in communicating and having instruments to do so, is key in knowledge management. New technologies make it possible to integrate information, develop databases, and share products and results that countries can put to use in their decision-making. PANDRH, with its history of opening up new paths for collaborative work, serves as a natural vehicle for promoting and coordinating the exchange of experiences and regulatory knowledge among NRAs, as well as the use of tools to facilitate dynamic, productive sharing. With this in mind, PANDRH should:

- Facilitate the generation and exchange of knowledge based on priorities set by the network itself;
- Act as a catalyst to meet information needs, promote active member participation, and use resources both efficiently and effectively;
- Promote agreements to facilitate information exchange among NRAs and systematize this information on the PRAIS platform;
- Call on collaborating centers and centers of excellence to complement and expand the information resources needed for decision-making and regulating new and complex health technologies;
- Actively support the creation of secure spaces for the quick exchange of confidential data.

### **D.2. Countries Moderating the Session**

Costa Rica, El Salvador, and Peru acted as moderators.

### **D.3. Presentations**

#### ***Lessons Learned from Effective International Cooperation Agreements on Regulatory Functions (Bilateral and Subregional Case Study)***

*Center for State Control of Drugs and Medical Devices (CECMED, Cuba), acting as representative for the Regional Reference NRAs*

*José Vicente Coto, El Salvador*

*Catherine Parker, Health Canada*

#### ***Mechanisms for Exchanging Regulatory Information: PRAIS and Other Tools for Technical Cooperation among Countries***

*Analía Porrás, PAHO/WHO*

*Catherine Parker, Health Canada*

*José Luis Castro, PAHO/WHO*

#### D.4 Summary of the Main Topics of the Session

- The need to promote the exchange of experiences and regulatory knowledge among NRAs in the Americas, both inside and outside PANDRH.
- The Network to Create Vaccine Regulatory Capacities.
- Importance of the availability of exchange mechanisms for regulatory information: PRAIS and other tools for technical cooperation among countries.
- Lessons learned from effective international cooperation agreements on regulatory functions (bilateral and subregional case studies).
- *Community of Practice for Pharmacovigilance* on the PRAIS platform.
- Lessons learned from TECHPharm's effective international cooperation agreements.

#### D.5. Plenary Discussion

Unlike the discussion sessions for the three preceding strategic objectives, this session did not include working sessions. Rather, a plenary discussion followed the presentations. The following issues were discussed.

- International regulatory cooperation should focus on:
  - Promoting bilateral forums aimed at developing best practices;
  - Sharing knowledge;
  - Adopting and/or fostering international standards and developing approaches compatible with international counterparts.
- Thanks to PAHO's certification of Mexico's COFEPRIS as a Regional Reference NRA for medicines and vaccines, Mexico is now recognized worldwide for its best practices in reviewing quality and safety of health products used and consumed by the Mexican population. Technical regulatory committees among reference NRAs should be created in order to support technology transfer and development processes of interest to the countries.
- Current issues involving policies that regulate health-related products in the international arena should be discussed.
- PANDRH should consider raising the profile of the role played by reference NRAs in decision-making scenarios that involve health regulation.
- It is important to increase multilateral initiatives and surveillance activities in terms of both inspection and marketing.
- Regulatory harmonization initiatives should be expanded and linked.
- Emphasis was placed on the importance of health authorities exchanging information, knowledge, and experiences and, as a result, contributing to Member States' efforts to strengthen their regulatory capacities.
- Knowledge management implies using new technologies to integrate information, provide databases, and share results, all of which optimize decision-making.
- The PRAIS platform is both a challenge and an opportunity for improving cooperation mechanisms among countries through use of computer technologies and their various instruments.

- The regional authorities identified two issues as priorities:
  - 1) Facilitating the exchange of confidential information on regulatory lessons learned;
  - 2) Using the PRAIS platform as a mechanism for information exchange.
- It is important to use information technology to promote priority issues and provide regulatory agencies with training on these issues.
- Cooperation among countries leads to stronger regulatory capacities and safer medical products for the population.
- Greater importance should be placed on human resource training.
- A joint program should be developed with PAHO to disseminate mechanisms that can be used by countries of the Region to benefit from decisions made by the Regional Reference NRAs.
- The regulatory agencies of Mexico, Colombia, and El Salvador made a commitment to provide PAHO with support in preparing PANDRH's *Strategic Development Plan 2014–2020*.
- PANDRH should consider instituting mechanisms to improve Caribbean countries' ability to benefit from the PAHO/WHO Strategic Fund and joint negotiations, especially with regard to access to medicines for the dual epidemic of HIV/AIDS and chronic diseases. There is also a need to construct a subregional regulatory framework for these countries in order to guarantee the quality of medicines, especially generics.
- PANDRH should establish an ongoing and systematic process to ensure sustainability of the NRAs' work and their relationship with PAHO.

#### **D.6. Next Steps (Agreements, Actions and/or Recommendations)**

Based on the items covered in the plenary discussion, the following actions and activities were recommended:

##### **D.6.1. PANDRH and Steering Committee**

- Adopt the PRAIS platform not only as part of PANDRH's new governance and operational model but also as a tool to promote greater fluidity in information exchange and knowledge management. This, in turn, will help meet the proposed objectives of PANDRH's new strategic plan.
- Promote bilateral and multilateral agreements on exchange of confidential information among NRAs.
- Use virtual tools to facilitate information exchange, including products resulting from regulatory processes.

##### **D.6.2. National Regulatory Authorities (NRAs)**

- Regulatory authorities should develop new capacities under a training scheme that includes cooperation aimed at guaranteeing the quality, efficacy, and safety of medicines.
- The regulatory agencies with the greatest knowledge and expertise should assume responsibility for passing on their knowledge, which implies training other regulatory agencies with less capacity.

**D.6.3. PANDHR Secretariat**

- Create and feed databases with information obtained from standardized evaluation processes conducted by the NRAs. This will establish points of reference to evaluate the strength of regulatory agencies and determine the current state of regulatory capacity in the Region.

### III. Thematic Sessions

The CPANDRH VII agenda included five thematic sessions organized jointly by WHO and PAHO under the following headings: Pharmacovigilance and Patient Safety; Bioequivalent Regulation, Medical Devices Regulation; Biotherapeutic Products; and Substandard/Spurious/Falsely-labeled/Falsified/Counterfeit (SSFFC) Medicines. The objectives achieved during these sessions are outlined below.<sup>6</sup>

#### A. Pharmacovigilance and Patient Safety

1. Raise awareness of the strengths, weaknesses, and challenges of monitoring safe use of medicines through the Region's pharmacovigilance systems.
2. Confirm or propose changes in the objectives and lines of action of PANDRH's Working Groups within the framework of its new *Strategic Development Plan*.
3. As the plan progresses, set additional priorities for the Working Groups' future work.

#### B. Bioequivalent Regulation

1. Share countries' experiences with implementation of regulatory guidelines on bioequivalence.
2. Identify strategies to overcome regulatory, logistical, and political obstacles.
3. Determine the results and health impact of access to generic therapeutic equivalents.
4. Define lines of action for implementation in the Region's NRAs, based on lessons learned.

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<sup>6</sup> More information on the topics addressed during each session can be found at the following website: [http://www.paho.org/hq/index.php?option=com\\_content&view=article&id=8469%3Avii%20-%20conference-of--bread-American-network-for-drug-regulatory-harmonization-cpandr%20h&catid=1156%3Ahss-pan-%20American-network-for-drug-re&Itemid=1685&lang=en&limit%20&tst%20art=2](http://www.paho.org/hq/index.php?option=com_content&view=article&id=8469%3Avii%20-%20conference-of--bread-American-network-for-drug-regulatory-harmonization-cpandr%20h&catid=1156%3Ahss-pan-%20American-network-for-drug-re&Itemid=1685&lang=en&limit%20&tst%20art=2)

### **C. Medical Devices Regulation**

1. Clarify the challenges to and opportunities for regulating medical devices in the Region of the Americas.
2. Evaluate how to incorporate regulation of medical devices into PANDRH's activities.
3. Discuss priorities for strengthening the capacity to regulate medical devices in the Region.

### **D. Biotherapeutic Products**

1. Emphasize the importance of having specific, well-defined requirements for evaluating biotherapeutic products/biosimilar products so that they are in line with international requirements and WHO recommendations.
2. Facilitate the implementation of WHO recommendations by regulators and manufacturers (with a focus on clinical assessment).
3. Define the expectations of the Region's Member States concerning the role of WHO in order to improve convergence of regulatory requirements at both the regional and global levels.

### **E. Substandard/Spurious/Falsely-Labeled/Falsified/Counterfeit (SSFFC) Medicines**

1. Bring participants up to date on current debates and actions carried out at the international level, particularly regarding the new mechanism developed by WHO's Working Group of Member States.
2. Assess the activities carried out by PANDRH's Working Groups in the Region and discuss their mission and priorities under the new *Strategic Development Plan*.

## IV. Poster Exhibit

The aim of CPANDRH VII's poster session was to provide a venue for presenting state-of-the-art information on different aspects of health technology regulation in the Region of the Americas. The posters addressed issues within PANDRH's scope, particularly in the following areas:

- Good regulatory practices and regulatory science;
- Interinstitutional and international experiences in technical cooperation;
- Successful experiences in human resource development and/or strengthening national capacities;
- The impact of adopting new regulatory guidelines from an institutional, academic, or industry perspective.

The exhibit was open for the duration of the conference and could be visited during breaks.

During the last day of the conference, an evaluation committee recognized three posters as worthy of honorable mention.

### **1<sup>st</sup> Honorable Mention**

<b>Title</b>	<i>Communication as a Tool for Health Surveillance</i>
<b>Language</b>	Spanish
<b>Author</b>	Luis Piñero Rodrigo
<b>Institution</b>	National Administration of Medicines, Food, and Medical Technology (ANMAT)
<b>Country</b>	Argentina

### **2<sup>nd</sup> Honorable Mention**

<b>Title</b>	<i>Joint Ventures in the Fight Against Illegal Drugs: Cooperation between the National Health Surveillance Agency (ANVISA) and the Ministry of Justice</i>
<b>Language</b>	Portuguese
<b>Author</b>	Lorilei de Fátima Wzorek, Patricia Azevedo Chagas, and Roberto Pontarolo
<b>Institution</b>	ANVISA and the Federal University of Paraná (UFPR)
<b>Country</b>	Brazil

### **3<sup>rd</sup> Honorable Mention**

<b>Title</b>	<i>Developing Clinical Guidelines for Evaluating Therapeutic Cancer Vaccines</i>
<b>Language</b>	English
<b>Author</b>	J.M. Sarjeant, J. Wang, and Agnes V. Klein
<b>Institution</b>	Centre for Evaluation of Radiopharmaceuticals and Biotherapeutics (CERB), Biologics and Genetic Therapies Directorate (BGTD), Health Canada
<b>Country</b>	Canada

## V. Steering Committee Meeting

The Steering Committee met during the second day of the conference. Participation was limited to Committee and Secretariat members. A presentation was made of the conclusions drawn by the working sessions and in the plenary discussion. On this basis, the Steering Committee formulated its own recommendations aimed at promoting PANDRH's work, particularly in terms of implementing the *Strategic Development Plan*. Each of the Steering Committee's recommendations has been incorporated into the sections on strategic objectives included in this report, under the heading *Next Steps*.

The meeting also provided a briefing for committee members on PANDRH's current statutes. It is understood that the composition of the Steering Committee may change with a new statute. The list below shows Steering Committee membership as agreed upon during the conference.

<b>Subregion/ Pharmaceutical Industry</b>	<b>Main Member</b>	<b>Alternate Member</b>
Latin American Association of Pharmaceutical Industries (ALIFAR )	Rubén Abete	Miguel Maito
Caribbean Community (CARICOM)	Barbados	Suriname
Andean Community	Colombia	Ecuador
Latin American Federation of the Pharmaceutical Industry (FIFARMA)	Alberto Paganelli	Ernesto Felicio
Southern Cone Common Market (MERCOSUR)	Uruguay	Paraguay (temporary)
North American Free Trade Agreement (NAFTA)	United States of America	Canada
Central American Integration System (SICA)	El Salvador	Guatemala



## VI. Conclusions

CPANDRH VII provided a forum for the network to present and adopt its *Strategic Development Plan*, thus responding to one of the requests made at the previous conference. The active atmosphere at CPANDRH VII was crucial to stimulating dialogue among countries, institutions, and other participating sectors, which then provided information for future activities that will strengthen both the network and the regulatory structure of the countries of the Americas.

Conclusions drawn at the conference can be summarized as follows.

- The PANDRH Secretariat should review, edit, publish, and distribute the *Strategic Development Plan*.
- Conference participants agree that a review of PANDRH statutes should be carried out to ensure flexibility and improve network operations in keeping with the current regional context.
- Approval was given for the formation of a special working group tasked with preparing a proposal for a new governance structure, statutes, and network operations in line with principles outlined during CPANDRH VII Conference.
- The Secretariat should conclude and publish the results of the study on adopting, adapting, and implementing PANDRH's technical guidelines.
- The Secretariat, in collaboration with experts and network members, should prepare a proposal for adopting a systematic, priority-setting mechanism based on periodic analysis of PRAIS data, survey responses, and other relevant consultations.
- Each of the network's Working Groups should present a report to the Steering Committee that details 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 Secretariat should convene a special working group to prepare a proposal for a competency-based curriculum in line with the NRAs' circumstances. The group also should present a methodology for continuing education for NRA staff and prepare a roadmap for implementation. The roadmap should involve participation of academia, centers of excellence, and the strongest regional NRAs, and it should evaluate the feasibility of creating training centers for good regulatory practices.
- PANDRH should adopt the PRAIS platform as part of its new governance and operations model and as a tool to promote fluid information exchange and knowledge management. In addition, using PRAIS will support PANDRH's new *Strategic Development Plan* and the achievement of its objectives.

## VII. Closure

To end the conference, representatives of Health Canada, WHO, and PAHO shared their thoughts on the meeting and the future of PANDRH's work.

The representative of Health Canada thanked participants for attending, saying it was an honor for Health Canada to host the event. The support and commitment shown by all participating sectors was acknowledged and praised. It was noted that all participants understood a single regulatory language, including key terms such as flexibility, capacity, strengthening, exchange, prioritization, and transparency. Finally, the Health Canada representative thanked the audiovisual staff and interpreters for their hard work.

The WHO representative thanked Health Canada for its hospitality and organization of the event. WHO thanked PAHO for its work at the conference and thanked participants for attending and actively participating. WHO noted that the timing of the meeting was propitious for discussing and specifying recommendations for the *Strategic Development Plan*, with a view toward present and future activities. WHO also highlighted important examples of evaluation instruments mentioned in the course of the event, among them, Mexico's COFEPRIS and the International Conference of Drug Regulatory Authorities.

Dr. Fitzgerald, Director of Health Systems and Services at PAHO, took the floor and pointed out the participants' clear commitment to backing the network's *Sixteen Years Promoting Good Regulatory Practices in the Region of the Americas*. He mentioned that participants' support demonstrated their vision and intention to make improvements in the Region. He emphasized the importance of advancing toward a shift of paradigm and mandate so PANDRH can more efficiently meet the needs of the countries of the Americas. Finally, he thanked the poster evaluation committee, the group that helped prepare the *Strategic Development Plan*, the PANDRH Secretariat, and Health Canada for having made the event possible.<sup>7</sup>

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<sup>7</sup> Details on the presentations and subjects discussed during the conference can be found on PANDRH's website: [http://www.paho.org/hq/index.php?option=com\\_content&view=article&id=8469%3Avii-conference-of--bread-American-network-for-drug-regulatory-harmonization-cpandr h&catid=1156%3Ahss-pan-American-network-for-drug-re&Itemid=1685&lang=en](http://www.paho.org/hq/index.php?option=com_content&view=article&id=8469%3Avii-conference-of--bread-American-network-for-drug-regulatory-harmonization-cpandr h&catid=1156%3Ahss-pan-American-network-for-drug-re&Itemid=1685&lang=en)

## VIII: Annexes

### Annex I: List of Participants

*Ordered alphabetically by last name*  
(The list of PAHO/WHO Secretariat participants can be found below.)

**Mrs. Ivana Abalos**, National Administration of Medicines, Food, and Medical Technology (ANMAT), Argentina

**Dr. Rubén Abete**, ALIFAR, Argentina

**Dr. María Cristina Alonso Alija**, Bayer Healthcare Pharmaceuticals SA, United States

**Ms. Aida María del Carmen Alvarez**, ALIFAR-CIFABOL, Bolivia

**Mr. José Ancalmo Escobar**, ALIFAR-INQUIFAR, El Salvador

**Dr. Alfredo Antia Behrens**, ALIFAR-ALN, Uruguay

**Ms. Ivana Antonacci**, Merck & Co. Inc., United States

**Mrs. Carmen Cecilia Araujo**, ALIFAR-CIFAR-Elmor SA, Venezuela

**Mrs. Elizabeth Armstrong**, Public Health Institute of Chile, Chile

**Mr. Mikel Arriola**, COFEPRIS, Mexico

**Dr. Juan Arriola Colmenares**, Laboratorios AC FARMA; ALIFAR-ADIFAN, Peru

**Dr. Maria Baca-Estrada**, Health Canada/BGTD, Canada

**Mrs. María Cristina Baracaldo Cortés**, Ministry of Health and Social Protection, Colombia

**Dr. Dirceu Barbano**, National Health Surveillance Agency (ANVISA), Brazil

**Mrs. Ana Barravecchia de Dehó**, SERVIER ARGENTINA S.A., Argentina

**Dr. Vanina Barroca Gil**, Sandoz S.A.; ALIFAR-CILFA, Argentina

**Dr. Kimby Barton**, Health Canada, Canada

**Mr. Nelson Belisario**, Presidential Commission on National Pharmaceutical Policy (COPPFAN), Dominican Republic

**Mr. Alejandro Bermudez-Del-Villar**, Drug Information Association (DIA), United States

**Dr. Juan Bidegaray**, Bio Sidus S.A.; ALIFAR-CILFA, Argentina

**Ms. Joan Blair**, Center for Biologics Evaluation and Research/FDA, United States

**Dr. Ron Boch**, BIOTECanada, Canada

**Dr. Ricardo Bolaños**, ANMAT, Argentina

**Ms. Sherri Boucher**, Health Canada, Canada

**Dr. Andrés Brandolini**, ANMAT, Argentina

**Mr. Alberto Bravo Borda**, ALIFAR-ASINFAR, Colombia

**Miss Sofía Bravo Bustamonte**, ALIFAR-ASINFAR, Colombia

**Dr. Sonia Brazales**, Ministry of Public Health, Ecuador

**Dr. Albania Burgos Antezana**, Ministry of Health, Bolivia

**Mrs. María Margarita Bustamante Sánchez**, ALIFAR-ASINFAR, Colombia

**Mr. Damián Cairatti**, U. S. Pharmacopeial Convention (USP), United States

**Ms. Blanca Cajigas de Acosta**, National Institute of Food and Drug Monitoring (INVIMA), Colombia

**Mrs. Gina Carey**, Ministry of Health, Department of Public Health, The Bahamas

**Dr. Lucette Cargill**, Caribbean Public Health Agency (CARPHA), Jamaica

**Dr. Valentina Carricarte**, Gador SA, ALIFAR-CILFA, Argentina

**Miss Laura Castanheira**, ANVISA, Brazil

**Dr. Ricardo Cavazos**, COFEPRIS, Mexico

**Dr. Carlos Chiale**, ANMAT, Argentina

**Dr. Miga Chultem**, Health Canada/BGTD, Canada

**Mrs. Claudia Cilento**, ALIFAR-ALANAC, Brazil

**Mr. John Cockhill**, BIOTECanada (Grifols Canada), Canada

**Mr. Eric Conte**, Ministry of Health, Panama

**Ms. Maria Luisa Correa Abastoflor**, ALIFAR-CIFABOL, Bolivia

**Dr. José Coto**, National Bureau of Medicines, El Salvador

**Mr. José Cousiño**, FIFARMA, Chile

**Mr. Víctor Raúl Crespo Vasquez**, ALIFAR-CIFABOL, Bolivia

**Dr. Rudolph Cummings**, CARICOM Secretariat, Guyana

**Dr. Robert Cushman**, Health Canada/BGTD, Canada

**Dr. Jeannette Daza Castillo**, INVIMA, Colombia

**Ms. Loretta Del Bosco**, AbbVie; Research-Based Pharmaceutical Companies (RX&D), Canada

**Ms. Rocelyn DelCarmen**, AstraZeneca Canada; BIOTECanada, Canada

**Dr. Louise Déry**, Health Canada, Canada

**Mr. Héctor Duarte**, ANMAT, Argentina

**Mr. Douglas Duarte Queiroz Rega**, ALIFAR-ALANAC, Brazil

**Dr. Lindsay Elmgren**, Health Canada/BGTD, Canada

**Ms. Mirta Gloria Escobar Carcamo**, SESAL, Honduras

**Mrs. Ana Amelia Faleiros de Padua**, ROCHE, Brazil

**Dr. Ana Fallas Quesada**, Gutis SA; ALIFAR-ASIFAN, Costa Rica

**Dr. Albert Figueras**, Universidad Autónoma de Barcelona-Instituto Catalán de Farmacología, Spain

**Dr. Eduardo Franciosi Bañon**, ALIFAR, Argentina

**Mr. Carlos Fulcher**, DIA, United States

**Mrs. Ellen Gabriel**, Ministry of Health, Grenada

**Mr. Juan Fernando Gallo Ibañez**, ALIFAR-CIFABOL, Bolivia

**Miss Cammilla Gomes**, ANVISA, Brazil

**Mrs. Samira Gongora**, Ministry of Health, Belize

**Mrs. Luz Angela Grajales Valdivieso**, Trial & Train LTDA, Colombia

**Ms. Vilma Guerrero de Los Santos**, Directorate for Drugs and Pharmacies, Dominican Republic

**Mrs. Stella Harrygin**, Chemistry Food and Drugs Division, Trinidad and Tobago

**Dr. Escarlen Heredia Ovalles**, Presidential Commission on National Pharmaceutical Policy (COPPFAN), Dominican Republic

**Dr. Ileana Herrera**, Ministry of Health, Costa Rica

**Dr. Carl James Hospedales**, CARPHA, Trinidad and Tobago

**Ms. Juana Hughes**, LARKIT; Merck Serono, LATAM

**Dr. María Teresa Ibarz Muro**, National Institute of Hygiene “Rafael Rangel”, Venezuela

**Dr. Olga Lidia Jacobo Casanueva**, CECMED, Cuba

**Dr. Maria Jacobs**, Pfizer Inc., United States

**Mrs. Marie Flaurine Joseph**, Department of Pharmacy, Medicines and Traditional Medicine (DPM/MT)-MSPP, Haiti

**Mrs. Maryam Karga-Hinds**, Barbados Drug Service, Ministry of Health, Barbados

**Dr. Agnes V. Klein**, Health Canada, Canada

**Dr. Nestor Lago**, Gema Biotech S.A.; ALIFAR-CILFA, Argentina

**Mr. Lawrence (Larry) Liberti**, Centre for Innovation in Regulatory Science (CIRS), United Kingdom

**Mrs. Angela Long**, United States Pharmacopeia, United States

**Mr. José López**, National University of Colombia, Colombia

**Mr. Rogelio López**, ANMAT, Argentina

**Ms. Beatriz Luna**, Department of Medicines, Ministry of Public Health, Uruguay

**Mr. Miguel Maito**, CILFA; ALIFAR, Argentina

**Miss Cristina Marinho Ribeiro**, ANVISA, Brazil

**Dr. Luz Martínez**, Department of Public Health, Ecuador

**Mrs. Marcia Martini Bueno**, ALIFAR-ALANAC, Brazil

**Mr. Estuardo Matheu**, ALIFAR-ASINFARGUA-INFASA, Guatemala

**Ms. Kathryn McDade**, Health Canada, Canada

**Mr. Keith McIntosh**, Rx&D, Canada

**Mrs. Karina Mena**, Autonomous University of Santo Domingo (UASD), Dominican Republic

**Dr. Patricia Mena Sturla**, ALIFAR-INFADOMI, Dominican Republic

**Dr. Moisés Mendocilla**, Health and Social Security (ESSALUD), Peru

**Mr. Steve Millington**, Ministry of Health, Wellness and the Environment, Saint Vincent and the Grenadines

**Mrs. Clarice Mitie Sano Yui**, ALIFAR-ALANAC, Brazil

**Mr. Rodolfo Mocchetto**, INAME/ANMAT, Argentina

**Ms. Miriam Naarendorp**, Ministry of Health, Suriname

**Mr. Ricardo Ortiz Mazzella**, ALIFAR-ALN, Uruguay

**Mrs. Princess Osbourne**, Ministry of Health, Jamaica

**Dr. Alberto Paganelli**, FIFARMA, Latin America

**Ms. Silvia Palencia**, ALIFAR-ASINFARGUA-UNIPHARM, Guatemala

**Ms. María Patricia Palomino Vasquez**, ALIFAR-ASINFAR, Colombia

**Mrs. Catherine Parker**, Health Canada/BGTD

**Miss Prisha Patel**, Centre for Innovation in Regulatory Science (CIRS), United Kingdom

**Dr. Rafael Pérez Cristiá**, CECMED, Cuba

**Mrs. Carmen Perez Gomez**, ALIFAR-INQUIFAR, El Salvador

**Mr. Danilo Pineda**, ALIFAR-ASINFARGUA-CHEMINTER, Guatemala

**Dr. Berenice Pinto Vizcardo**, ALIFAR-ADIFAN, Peru

**Miss Marisela del Carmen Poot Grajales**, GlaxoSmithKline México, S.A. de C.V., Mexico

**Mr. José Raúl Ramírez**, COFEPRIS, Mexico

**Ms. Laura Nelida Ramírez**, ALIFAR-CIFARMA, Paraguay

**Dr. Norberto Rech**, ANVISA, Brazil

**Ms. Elizabeth Recinos Cueto de Posadas**, Ministry of Public Health and Social Assistance, Guatemala

**Tarsila Rey**, Pfizer, Mexico

**Dr. Aline Rinfret**, Health Canada/BGTD, Canada

**Mrs. Helen Rosenbluth**, Public Health Institute of Chile, Chile

**Mrs. Lisa Ruiz**, AbbVie, United States

**Ms. Barbara Sabourin**, Therapeutic Products Directorate, Health Canada, Canada

**Dr. Santiago Salguero Garzon**, ALIFAR-ALAFAR, Ecuador

**Mr. Julio Sánchez**, COFEPRIS, Mexico

**Mrs. María José Sánchez**, ANMAT, Argentina

**Miss María Sánchez Herrera**, INVIMA, Colombia

**Mrs. Mercedes Santana**, Venezuelan Chamber of Medicines (CAVEME), Venezuela

**Mr. Thomas Schreitmueller**, Roche, Switzerland

**Mrs. Jewel Sears**, Food and Drugs Department, Ministry of Health, Guyana

**Dr. Sonia Seino**, Eli Lilly and Company, Argentina

**Ms. Nancy Shadeed**, Health Canada, Canada

**Dr. Supriya Sharma**, Health Canada, Canada

**Mr. Carlos Silva**, ALIFAR-Hersil S.A., Peru

**Mrs. Ana Paula Silveira e Silva**, ANVISA, Brazil

**Dr. Karen Tamariz Ortiz**, Pharmacists Foundation for Life, Dominican Republic

**Mr. Elmer Torres Cortes**, ALIFAR–ASILFA, Chile

**Mr. Gustavo Trindade da Silva**, Center for Good Regulatory Practices, ANVISA, Brazil

**Mr. Henrique Uchio Tada**, ALIFAR-ALANAC, Brazil

**Mrs. Mary Lou Valdez**, FDA, United States

**Dr. Ronoldy Valencia**, ROVAL Consulting Inc., El Salvador

**Ms. María Vargas de Dentice**, National Bureau of Health Surveillance, Paraguay

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**Ms. Esmeralda Villagrán**, ASINFARGUA, Guatemala

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**Mr. Mike Ward**, Health Canada, Canada

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**Dr. Pedro Yarasca**, General Directorate of Medicines, Input Materials, and Drugs (DIGEMID), Perú



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***World Health Organization***

**Dr. Samvel Azatyan**, Manager, Medicines Regulatory Support Programme, Department of Essential Medicines and Health Products, WHO, Switzerland

**Mr. Cornelis (Kees) De Joncheere**, Director, Essential Medicines and Health Products, WHO, Switzerland

**Dr. Ivana Knezevic**, Quality Assurance and Safety of Biologicals (QSB), WHO, Switzerland

**Dr. David Wood**, Coordinator of Quality, Safety and Standards: Immunization, Vaccines and Biologicals, WHO, Switzerland

**Pan American Health Organization**

**Dr. Cecilia Acuña Díaz**, Advisor, Health Systems and Services PAHO/WHO, Ecuador

**Ms. Francisca Dalia Castillo Sánchez**, Consultant, PAHO/WHO, Dominican Republic

**Dr. José Castro**, Advisor, Rational Use of Medicines, PAHO/WHO, United States

**Dr. Victoria de Urioste**, Subregional Advisor on Medicines and Health Technology-Andean Region, PAHO/WHO, Bolivia

**Dr. James F. Fitzgerald**, Director, a.i., Health Systems and Services, PAHO/WHO, United States

**Mr. Murilo Freitas Dias**, Regulatory Affairs Specialist-Medicines and Health Technology, PAHO/WHO, United States

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**Mr. Alexandre Lemgruber**, Regional Advisory, Health Technologies, PAHO/WHO, United States

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**Dr. Patricia Saidón**, Consultant, PAHO/WHO, Argentina

**Dr. Amelia Villar**, National Consultant, PAHO/WHO, Peru

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**Annex II: Agenda of the VII Pan American Network for Drug Regulatory Harmonization Conference**

See Link: <http://goo.gl/IHQKsD>