Pan American Health Organization

Regional Office of the World Health Organization

V Conference of the Pan American Network for Drug Regulatory Harmonization (PANDRH): Information and propositions of 9 working groups presented for consideration

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Introduction

The Pan American Network for Drug Regulatory Harmonization (PANDRH) was created in 1999 during the II Pan American Conference on Drug Regulatory Harmonization in Santo Domingo, Dominican Republic. Its goal is to support drug regulatory harmonization processes in the Region. National regulatory authorities in the Americas (NRAs) participate in the effort, as do various interest groups concerned with pharmaceuticals, such as the drug industry, patient/consumer groups, and members of the academic community. The Pan American Health Organization (PAHO/WHO) became the Secretariat of the network as facilitator of its various working groups.

Public/private-sector collaboration was essential in developing the harmonization of the regulatory process necessary for improving drug management in the Region. Only effective collaboration among all stakeholders can ensure a successful response to the universal challenges posed by a globalized world.

The ministries of health, responsible for national public health and thus, for drug regulation as part of that responsibility, must spearhead and monitor this process at the national level through national health regulation and control agencies, actively participating in subregional, regional, and global forums for enhanced and improved drug regulatory harmonization. Other state institutions, such as the ministries of trade, industry, or education, participate with the ministries of health in the harmonization processes.

The private sector is represented chiefly by the pharmaceutical industry. Pharmaceutical representatives are those who ultimately must adopt and implement the majority of the requirements to guarantee and improve the quality, efficacy, and safety of the drugs and vaccines produced, and to ensure the veracity of the information associated with those products. The participation of the academic community is also essential in the drug regulatory harmonization process. Analysts, professors, students, and experts have the responsibility of coordinating the dissemination of up-to-date information with its practical application in the professional context.

Consumer protection organizations and other interest groups in the field of drugs and pharmaceuticals also play a key role in regulatory processes through ongoing surveillance and specific proposals aimed at optimizing these processes.

Beyond the stakeholders, government commitment is essential to successfully advance the harmonization needed, not only because of the decisions that must be made along the way, but because of the possible changes in laws and regulations needed to adopt the norms,

[1] Information from the document: *Red Panamericana para la Armonización De La Regulación Farmacéutica (RED PARF): Resumen elaborado por Rosario D'Alessio (2005)* ["Pan American Network on Drug Regulatory Harmonization (PANDRH): Summary prepared by Rosario D'Alessio (2005)"]

standards, and guidelines agreed upon. It is equally important to support institution building and a thorough analysis of administrative and financial alternatives to improve the efficiency and effectiveness of existing structures. Maintaining and adapting the infrastructure and providing continuing education for personnel are also commitments that governments and the private sector need to make as part of their support for the harmonization processes.

The PANDRH network has four working/decision-making components: the Pan American Conference, the Steering Committee, the working groups, and the Secretariat. Each has functions established in the network's standards and regulations.

In addition to its own internal activities, the network has been participating in other international regulatory forums. Since November 2003, PANDRH has been a member of the Global Cooperation Group (GCG) of the International Conference on Harmonization (ICH), a joint initiative of Europe, the United States, and Japan focusing on the study of requirements for evaluating the quality, safety, and efficacy of new drugs.

To date, PANDRH has held four conferences and formed 12 working groups. At this V Conference, nine working groups will each present their mission, objectives, and documents, as indicated below:

1. Working Group on Bioequivalence and Bioavailability

1.1. Mission

The Working Group on Bioequivalence and Bioavailability helps harmonize the criteria for bioequivalence to promote the interchangeability of pharmaceutical products in the Americas.

1.2. **Objectives**

a) Develop science-based criteria for products that require *in vitro* or *in vivo* bioequivalence studies and for those that do not require it;
b) Develop lists of priority pharmaceutical products that require *in vivo* bioequivalence studies;
c) Compile a list of pharmaceutical products that do not require *in vivo* bioequivalence studies;
d) Make a list of comparators for bioequivalence studies to be used in the Region of the Americas;
e) Formulate recommendations and guidelines for interpreting, evaluating, and applying the scientific principles of bioequivalence;
f) Provide education and training support in the countries of the Americas for applying the principles of bioequivalence;
g) Promote the bioequivalence of pharmaceutical products, for those requiring it, in the countries of the Americas.
h) Include the sharing of experiences in the conduct of bioequivalence studies in the Americas in training programs.
i) Prepare indicators for evaluating the implementation of bioequivalence studies in the Americas.

1.3. Members

- USA: Justina Molzon, Coordinator. Center for Evaluation and Research. FDA.
- Argentina: Ricardo Bolaños, National Drugs, Food, and Medical Technology Administration (ANMAT)
- Brazil: Tatiana Lowande, General Manager of Drugs, National Health Surveillance Agency (ANVISA)
- Chile: Alexis Aceituno. (ISP)
- Venezuela: Maggi Kabbad, National Institute of Hygiene Rafael Rangel (INHRR)
- The United States Pharmacopeia (USP): Vinod Shaw. Consultant.
- Solomon Stavchansky, College of Pharmacy, Division of Pharmaceutics. USA
- Canada: Conrad Pereira. Therapeutic Products Directorate, Health Canada
- Costa Rica: Graciela Salazar Vargas. Ministry of Health
- The Latin American Association of Pharmaceutical Industries (ALIFAR): Silvia Giarcovich, Argentina
- Resource Support: Aida Sanchez. Division of Bioequivalence. FDA. USA

Secretariat

Rosario D'Alessio and Nelly Marín. Pan American Health Organization. (PAHO/WHO). USA.

Former group members who participated in the preparation of the document to be presented

- Brazil: Silvia Storpirtis. Associate Professor, School of Pharmaceutical Sciences, University of São Paulo
- Canada: Norman Pound and John Gordon. Health Canada
- Chile: Ana Maria Concha, Pamela Milla, and Regina Pezoa Reyes. ISP
- Costa Rica: Marcela Rodriguez and Lidiette Fonseca. Pharmaceutical Research Institute, INIFAR. School of Pharmacy. University of Costa Rica
- USP: Roger Williams and Margareth Marques. USA
- Venezuela: Irene Gonçalves. Chief Pharmacist, Department of Forensic Evaluation. INHRR
- FIFARMA: Vivian Trespalacios and Loreta Marquez

1.4. Document to be presented at the V Conference

Framework for Implementing Equivalence Requirements for Pharmaceutical Products**.**

2. Working Group on Vaccines

2.1 Mission

Promote vaccine regulatory harmonization to ensure quality, safety, and efficacy, establishing more efficient mechanisms that help improve vaccine availability in the countries of the Americas.

2.2. Objectives

a) Harmonize the requirements for authorizing clinical vaccine trials in the various phases and monitor implementation.

b) Harmonize the requirements for sanitary registry of vaccines in the Americas and monitor implementation.

c) Promote information exchange and the convergence and recognition of vaccine regulation systems among the NRAs in the Region.

d) Generate and organize tools and training activities for NRA personnel.

e) Harmonize good manufacturing practice requirements specific to vaccines and monitor implementation.

f) Promote the establishment of surveillance systems for Events Supposedly Attributable to Vaccination or Immunization (ESAVI).

g) Identify other vaccine regulation issues requiring specific treatment and develop work plans to address them.

2.3. Members

- Cuba: Olga Jacobo Casanueva, Assistant Director of the State Center for Drug Quality Control (CECMED). Head of Health Authorizations and the Biologicals Group. Coordinator

  Alternate: Mr. Rolando Dominguez, Head of Drug Department. Expert in Biologicals
- Venezuela. Maria Teresa Ibarz, Chief, National Division for the Control of Biologicals (INHRR)
- Argentina: Marine Rossi, Chief, Immunology Service. ANMAT
- Brazil: Sergio Nishioka, Manager, Office of New Drugs, Research & Clinical Trials, and Granville Garcia de Oliveira. ANVISA
- Canada: Elwyn Griffiths, Associate Director General of the Biologics and Genetic Therapies Directorate

  Alternate: Barbara Benning
- FIFARMA: Marisela Poot, GlaxoSmithKline

  Alternate: Tarsila Rey, Wyeth

Secretariat

Maria de los Angel Cortes. Pan American Health Organization (PAHO/WHO). USA

2.4. Documents to be presented at the V Conference

- Proposal for Harmonization of Sanitary Registry of Vaccines Requirements in the Region of the Americas
- Guidelines for Preparing the Application for Sanitary Registry of Vaccines in the Region of the Americas

3. Working Group on Drug Promotion

3.1. Mission

Promote and harmonize the criteria for drug promotion in support of rational use, within the scope of health policies in the Americas.

3.2. Objectives

a) Provide mechanisms and criteria for identifying irregularities and demonstrate the most widely used market strategies in drug promotion in the countries of America.
b) Provide information and analysis on the regulation, implementation, and monitoring of drug promotion.
c) Promote educational activities and programs related to drug promotion for health professionals and potential and current consumers.
d) Evaluate the operations and impact of the Working Group's activities.

3.3. Members

- Brazil: Maria Jose Delgado Fagundes–ANVISA. Coordinator
- Ecuador: Luis Reyes - Ministry of Health
- Costa Rica: Danilo Arrones - Ministry of Health
- Barbados: Ersie Chase – Chief Pharmacist - Barbados Drug Service (BDS)
- Mexico: Sonia Zamudio Alonso - Executive Director for the Authorization of Products and Establishments. Federal Commission for Protection against Health Risks (COFEPRIS)
- FIFARMA: Jose Manual Cousiño - Chamber of the Pharmaceutical Industry of Chile
  Substitute: Fabiana Lacerca
- Alternate: Analia Perez – Coordinator, Commission on Health Product Advertising, ANMAT. Argentina

Secretariat

Rosario D'Alessio Pan American Health Organization (PAHO/WHO). USA

3.4. Documents to be presented at the V Conference

- Ethical Criteria for Drug Promotion, Advertising, and Publicity

- Proposed Questionnaire on Drug Advertising Legislation

4. Working Group on Pharmacovigilance

4.1. Mission

Develop and strengthen pharmacovigilance through the harmonization of regulatory activities and proposals that promote the safety and rational use of drugs as an essential component in public health policy in the Americas.

4.2. Objectives

a) Promote development and dissemination of the knowledge, criteria, and methodologies used in pharmacovigilance that should be employed in training and education activities for all stakeholders concerned with drugs.

b) Analyze and promote the development of harmonization tools to support pharmacovigilance in the Region.

c) Develop and promote a network that supports knowledge sharing, communication, and sound decision-making on pharmacovigilance.

d) Promote the integration of pharmacovigilance as a building block of medical programs and public health policies.

e) Promote research on pharmacovigilance and its dissemination, and analyze the impact of pharmacovigilance on public health, especially on patient safety.

4.3. Members

- Colombia: Martha Rodriguez, Assistant Director for Drugs, INVIMA. Coordinator
- Barbados Maryan Hinds. BDS
- Cuba: Julian Perez Peña. Pharmacoepidemiology Center
- Uruguay: Cristina Alonso, Ministry of Health
- FIFARMA: Ronoldy Valencia. Leo Pharma USA

Alternates

- Canada: Heather Sutcliffe
- Brazil: Murilo Freitas. ANVISA

Resource Support

- Spain: Albert Figueras. Catalan Institute of Pharmacology. WHO Collaborating Centre
- Argentina: Mabel Valsecia. Northeast University
- Colombia: Claudia Vacca. National University of Colombia

Secretariat

Rosario D'Alessio and Jose Luis Castro. Pan American Health Organization (PAHO/WHO) USA and Argentina

4.4. Document to be presented at the V Conference

Good Pharmacovigilance Practices in the Americas

5. Working Group on Drug Counterfeiting

5.1. Mission

Promote, facilitate, and encourage the implementation of proactive strategies for preventing and combating counterfeiting, thus helping to improve health care in the countries of the Americas.

5.2. Members

- Brazil: Tiago L. Rauber, ANVISA (Coordinator)
- Argentina: Maria Jose Sanchez, ANMAT
- Colombia: Carolina Contreras. INVIMA
- St. Lucia: Francis Burnett, OECS
- Dominican Republic: Marilyn Soto de Lugo, Ministry of Health
- Canada: Linsey Hollet, Health Canada
- Paraguay: Maria Auxiliadora, Ministry of Health
- FIFARMA: Rodolfo Vincent. Argentina
- ALIFAR: Miguel Maito. Argentina

Observers

- Mexico: Eduardo Jaramillo, COFEPRIS
- Costa Rica: Juan Carlos Álvaro Arias
- Brazil: Cammilla Horta, ANVISA

Secretariat

Rosario D'Alessio and Jose Luis Castro. Pan American Health Organization (PAHO/WHO). USA and Argentina.

5.3. Documents to be presented at the V Conference

- Model Network of Focal Points to Combat Drug Counterfeiting
- Proposed Workshop on Tools and Generation of Proposals for Preventing and Combating Drug Counterfeiting

6. Working Group on Good Manufacturing Practices

6.1. Mission

Promote awareness and implementation of good manufacturing practices as a strategy for improving drug quality in the countries of the Americas.

6.2. Objectives

a) Promote universal awareness of good manufacturing practices (GMPs) through coordinated publicity and training programs for health authorities, the industrial sector, academia, and other key sectors for GMP implementation.
b) Obtain a harmonized inspection guide or checklist to verify adherence to good manufacturing practices in the countries of the Americas, based on WHO Report 32.
c) Support regulatory authorities in monitoring the implementation of good manufacturing practices.
d) Raise the level of awareness and assist regulatory authorities in exercising leadership in each country in the implementation and monitoring of good manufacturing practices.

6.3. Members

- USA: Justina Molzon. Center for Drug Evaluation and Research. FDA. Coordinator
- Argentina: Rodolfo Mocchetto. ANMAT
- Brazil: Marcelo Vogler Moraes. Inspection and Control of Medications. ANVISA
- Canada: France Dansereau. Head Inspector Unit.
- Guatemala: Esmeralda Villagran de Diaz. Ministry of Health.
- FIFARMA: Anthony Ventura
- ALIFAR: Marisela Benaim, Venezuela

Resource Support

- Cardigan Rodriguez (SJ-DO/ORA/FDA, District Director)
- Millie Barber (SJ-DO/ORA/FDA)

Secretariat

Rosario D'Alessio and Juana Mejia de Rodriguez. Pan American Health Organization, World Health Organization (PAHO/WHO). USA and Guatemala

6.4. Documents to be presented at the V Conference

Decision Tree for Implementing Verification Guide for Good Manufacturing Practices

7. Working Group on Good Laboratory Practices

7.1. Mission

Improve the performance of official quality control laboratories (OQCLs) in the countries in the Region through the implementation of good laboratory practices (GLPs) to assure the quality of test results and facilitate mutual acceptance of the results.

7.2. Objectives

7.2.1. General objectives

a) Support implementation of GLPs in the OQCLs

b) Promote the creation of an OQCL network

7.2.2. Specific objectives

a) Prepare and disseminate educational material for implementing GLPs, based on the WHO document "Good Practices for National Pharmaceutical Control Laboratories" (Annex 3 of WHO Technical Report Series, Nº 902 – Thirty-sixth Report, 2002)

b) Prepare a plan for training and continuing education (PCEC in Spanish)

c) Provide technical support for countries committed to implementing GLPs

d) Formalization of the PCEC

e) Harmonization of outcome reports

7.3. Members

Principal members

- Maria Gloria Olate, Public Health Institute of Chile, Coordinator
- Rosario Vega Huanca, National Institute of Health, Peru
- Nilka M. Guerrero, Specialized Research Institute, University of Panama
- Lucette Cargill, Caribbean Regional Drug Testing Laboratory. Jamaica
- Damian Cairatti, USP, USA

Alternates

- Silviania Vaz de Melo Mattos, GLAS, ANVISA Brazil

Technical advisers/ facilitators

- Rosalba Alzate, University of Antioquia, Colombia
- Ruben Szyszkowsky, University of Buenos Aires, Argentina
- Carlos Saldarriaga Alzate, University of Antioquia, Colombia
- Milagros Royal Perez, National Institute of Health, Peru

- Catalina Massa, University of Cordoba, Argentina
- Antonio Hernandez-Cardoso, USP, USA

Observers

- Carina Pilatti, National Administration of Drugs, Food, and Medical Technology - ANMAT, Argentina

Secretariat

- José M. Parisi, Pan American Health Organization (PAHO/OMS).Washington, D.C.

7.4. Documents to be presented at the V Conference

- Annex 3 of *WHO Technical Report Series, Nº 902,Thirty-sixth Report, 2002, "Good Practices for National Pharmaceutical Control Laboratories*" (Spanish and Portuguese versions)
- Self-evaluation Guide for Good Practices for National Quality Control Laboratories
- Complete Curriculum for GLP Certification and Workshops on Application

8. Working Group on Good Clinical Practices

8.1. Mission

The Working Group on Good Clinical Practices will promote the harmonization of good clinical practices in the Americas.

8.2. Objectives

a) Promote the implementation of good clinical practices in the Americas.

b) Disseminate the document *Buenas prácticas clínicas: Documento de las Américas* ["Good Clinical Practices: Document for the Americas"] with recommendations that the practices be adopted in national regulations.

c) Develop and implement education programs on good clinical practices especially geared to regulatory agency personnel.

8.3. Members

- Argentina: Analia Perez, ANMAT Coordinator
- Brazil: Jorge Taveira Samaha. ANVISA
- Chile: Eduardo Johnson
- Costa Rica: Ileana Herrera
- CARICOM: Henri Fraser, University of the West Indies

- Cuba: Maria Amparo Pascual
- Venezuela: Maria Aguilar, INH
- FIFARMA: Pablo Virad, Argentina
- ALIFAR: Walter Figueira

Secretariat

Rosario D'Alessio and Jose Luis Castro. Pan American Health Organization (PAHO/WHO), USA and Argentina.

8.4. Document to be presented at the V Conference

Guidelines for Clinical Trials in Pediatric Populations

9. Working Group on Drug Registration

9.1. Mission

Promote and facilitate the regional harmonization of established technical criteria for registering drugs to help ensure their quality, safety, effectiveness, and availability in the Americas.

9.2. Objectives

a) Establish an online database on pharmaceutical legislation in the Region of the Americas and make it available on the PANDRH website.

b) Advise countries on adoption of the harmonized proposal for Drug Registration Requirements adopted by the PANDRH network and formulate recommendations to optimize the drug registration process at the national and regional level, in coordination with the PANDRH Secretariat.

c) Monitor execution of the recommended actions for PANDRH to move toward the harmonization of drug registration systems using selected indicators and preparing updated reports.

d) Undertake diagnostic studies as needed to assist the harmonization process, including an assessment of the impact of having universal drug registration requirements.

e) Create educational tools, documents, and guidelines for use in the pharmaceutical product registration process.

f) Promote the evaluation of regulatory agencies and bureaus to improve their efficiency.

g) Organize and participate in educational activities for regulatory agency personnel.

h) Help establish a regional network of drug regulatory authorities.

9.3. Members

- Venezuela: Maria Teresa Ibarz. Coordinator
- Bolivia: Ana Maria Cardozo. Ministry of Health
- Brazil: Antonio Becerra. ANVISA

- Chile Victor Hugo Estrada. Institute of Public Health
- El Salvador: Pillar Lagos. Ministry of Health
- ALIFAR: Miguel Maito. Argentina
- FIFARMA: Eunice Rojas. Ecuador

Secretariat

Rosario D'Alessio and Jose Daniel Peña. Pan American Health Organization. (PAHO/WHO). USA and Chile

9.4. Document to be presented at the V Conference

Proposal for the Harmonization of Drug Registration Requirements in the Region

Acknowledgment

The Pan American Health Organization commends Dr. Rosario D'Alessio for her dedication in consolidating the Pan American Network for Drug Regulatory Harmonization in the Americas.