VII Conference of the Pan American Network for Drug Regulatory Harmonization (PANDRH)

Sixteen years promoting Good Regulatory Practices in the Region of the Americas

Recommendations and next steps

Government of Canada / Gouvernement du Canada

Pan American Health Organization

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RED PARF PANDRH

Organización Panamericana de la Salud

PANDRH Secretariat

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CONFERENCE AGENDA– FIRST PART

- Regional context, lessons learned and rationale for the PANDRH Strategic Development Plan 2014-2020
- Plenaries and working groups discussions about each of the objectives of the PANDRH Strategic Plan:
    - (SO1): "To promote effective governance of PANDRH and active participation of NRAs towards regulatory convergence and harmonization"
    - (SO 2): "Defining priorities, strategies and mechanisms for regulatory convergence and harmonization, and supporting their dissemination, adoption and implementation by NRAs"
    - (SO3): "To promote the strengthening of competencies in Good Regulatory Practices and Regulatory Science"
    - (SO4): "To promote the exchange of experiences and regulatory knowledge between NRAs inside and outside PANDRH"
- PANDRH Steering Committee meeting

CONFERENCE AGENDA– SECOND PART

- Five thematic sessions:
  - Pharmacovigilance and patient safety
  - Substandard/spurious/falsely-labeled/falsified/counterfeit (SSFFC) medicines: global and regional perspectives
  - Parallel session on biotherapeutic products
  - Round table on medical devices regulation
  - Implementation of bioequivalence regulation - case studies
- Poster sessions – related to the objectives of the PANDRH Strategic Development Plan

RECOMMENDATIONS

STRATEGIC OBJECTIVE 1

OE1: "To promote effective governance of PANDRH and active participation of NRAs towards regulatory convergence and harmonization"

- To adjust PANDRH work to the current regional context and emerging challenges, the Conference proposed that the governance structure of the network should be more flexible and stimulate the prompt response and participation. Therefore, the Conference recommended establishing a new governance structure together revising its operational approach:
    - This new structure should adopt a model that allows flexibility, facilitate the participation of members and guarantee the representation of all sectors,
    - The new structure must be dynamic and must respond efficiently to the needs of the countries,
    - Must integrate PANDRH work to other international initiatives that promote harmonization/regulatory convergence, adapting documents produced by WHO and other initiatives, with a regional focus,
    - Should promote bilateral and sub-regional cooperation among member countries, and take advantage of other international models based on bilateral or regional agreements.

RECOMMENDATIONS

STRATEGIC OBJECTIVE 2

OE2: "Defining priorities, strategies and mechanisms for regulatory convergence and harmonization, and supporting their dissemination, adoption and implementation by NRAs"

- The Conference considered that the network should adopt a systematic mechanism for priority setting based on a periodic analysis of the context and needs of NRAs
    - Use data obtained through the assessment of regulatory functions and institutional development plans (established by Resolution CD50.R9 on Strengthening National Regulatory Authorities for Medicines and Biologicals),
    - Furthermore, NRAs' needs can be established through periodic surveys that explore existing gaps,
    - Work plans, compliance with PANDRH objectives and the adoption and implementation of technical documents should be monitored through the establishment and assessment of indicators to evaluate the efficiency of adopted processes,
    - Develop / use of virtual tools to strengthen communication and socialization of work plans, technical documents, PANDRH products and any other relevant information.

OBJECTIVE 2 (CONT.)

- The working groups should focus on issues that represent fundamental NRAs functions. They should:
  - Be created based on established priorities,
  - Have an specific mandate for a defined period of time,
  - Be evaluated periodically based on results,
  - Have a flexible structure to incorporate diversity of members (including experts from other global harmonization / convergence initiatives),
  - Work beyond the development of guidelines and technical documents, enabling communication, information exchange and practical implementation of PANDRH recommendations.

RECOMMENDATIONS

STRATEGIC OBJECTIVE 3

OE3: "To promote the strengthening of competencies in Good Regulatory Practices and Regulatory Science"

- The Conference considered that to strengthen basic and advance regulatory functions, the Region must renew its efforts on the development of human resources. It should build up Good Regulatory Practices management based on regulatory science progress. Therefore, we must establish a competence based curriculum and a comprehensive development plan for staff I regulatory entities that reflects the different realities and the diversity of the Region. This requires to:
    - Conduct a diagnosis of each country priorities and capabilities through the evaluation process,
    - Development of a regulatory curriculum that addresses the necessary skills for small NRAs and NRAs with broader functions and WHO recommendations and other government leaders in regulatory science,
    - Provide training based on institutional development plan well documented and based on the gaps that arise during the NRA's evaluation process,
    - Inventory of existing training offerings and lean in the regional NRAs strengthen and experience to efficiently leverage existing resources,
    - Monitor the implementation of the development plan to establish cost-effectiveness and sustainability of this investment.

RECOMMENDATIONS

STRATEGIC OBJECTIVE 4

OE4: "To promote the exchange of experiences and regulatory knowledge between NRAs inside and outside PANDRH

- The Conference considered that at present, the cooperation, communication and exchange of information among regional NRAs are key elements for the effective functioning of regulatory agencies to guarantee medicines quality, safety, and efficacy. Therefore, the Conference recommended PANDRH as a network to promote the exchange of information between PANDRH members and other entities leading regulatory science, taking into consideration tools that facilitate communication and knowledge management in support to the PANDRH Strategic Plan and the achievement of its stated strategic objectives. This requires the:
    - Endorsement of bilateral and multilateral agreements that promotes information exchange among NRAs,
    - Use virtual tools that prompt information exchange, including products resulting from the regulatory processes,
    - Creation of repositories with data from NRAs standardized assessments to establish benchmarks that allow the assessment on regulatory agencies' strengths and the establishment of the regional regulatory capacity profile,
    - Use of health technologies that allows the integration of information, the development of databases, and the sharing of products important for the decision making processes of other countries.

PANDRH STEERING COMMITTEE

CONCLUSIONS – NEXT STEPS

PANDRH STEERING COMMITTEEE RECOMMENDATIONS

- Revision of PANDRH statutes to guarantee the flexibility, improved participation and the transparency in governance of the Network through the establishment of a multi participative working group.
- The new statutes will address the needs and priorities of regulatory systems in the Americas while leveraging capacity within the Region, considering other regulatory harmonization initiatives and WHO recommendations.
- Request to the PANDRH technical working groups to present a report to the PANDRH Steering Committee. Reports should include: an analysis of current activity level, current members, achieved results, and when it corresponds a proposal for continuity. The proposal must include a workplan and expected results for its consideration.

PANDRH STEERING COMMITTEEE RECOMMENDATIONS

- Request to PANDRH Secretariat to coordinate and develop a methodology that allows the establishment of priorities, based on a periodic analysis of PRAIS-Observatory data, surveys and consultations.
- In the case of countries needs identified through the survey conducted prior the VII PANDRH Conference(e.g. medical devices), the PANDRH Steering Committee recommended to establish a Regional profile to assist the development and assessment on regulatory systems, based on the countries' evolving needs.
- Establishment of a technical group to develop a proposal of a regulatory curriculum based on NRAs current needs and context , and a methodology for continuing education of NRA personnel. The group will also define a roadmap for the implementation of this proposal that should involve academic institutions, centres of excellence and the support of functional NRAs.

PANDRH STEERING COMMITTEE REPRESENTATIVES *

Sub-region	*Main*	*Alternate*
NAFTA	United States of America	Canada
SICA	El Salvador	Guatemala
CARICOM	Barbados	Suriname
Andean Community	Colombia	Ecuador
MERCOSUR	Uruguay	Paraguay (temporary)
ALIFAR	Rubén Abete	Miguel Maito
FIFARMA	Alberto Paganelli	Ernesto Felicio

**Based on current PANDRH statutes. Steering Committee organization might change in response to a new statute.*

VII PANDRH CONFERENCE CONCLUSIONS (1)

- In general, the PANDRH Strategic Development Plan 2014-2020 was endorsed by the VII PANDRH Conference.
- Request PANDRH Secretariat the revision, edition, publishing and dissemination of the PANDRH Strategic Development Plan by the end of 2013.
- The Conference approved the revision/development of PANDRH statutes to guarantee the flexibility and to improve the functioning of the Network based on the current regional context.
- Establish a working group to develop a proposal that, contemplating the principles outlined during the Conference, will lead to the restructure of PANDRH governance, statutes and functions.

VII PANDRH CONFERENCE CONCLUSIONS (2)

- Request to the Secretariat to finalize and publish the results of the study on adoption, adaption and implementation of PANDRH technical reports.
- The PANDRH Secretariat, in collaboration with experts and the Working Group (WG) , should elaborate a proposal that allows the establishment of priorities, based on a periodic analysis of PRAIS-Observatory data, surveys and consultations.
- Current PANDRH technical groups should submit a detailed workplan within the next 3 months. Workplans should include: an analysis of current activity level, current members, expected results.

VII PANDRH CONFERENCE CONCLUSIONS (3)

- Establishment of a technical group (by PANDRH Secretariat) to develop a proposal of a regulatory curriculum based on NRAs current needs and context , and a methodology for continuing education of NRA personnel. The group will also define a roadmap for the implementation of this proposal that should involve academic institutions, centres of excellence and the support of functional NRAs. The group should also assess the feasibility of creating centers for training in Good Regulatory Practice (GRP).
- Adopt PRAIS within the new PANDRH model of governance and operation, and as a tool to promote the effective information exchange and knowledge management in support of the new strategic development plan.

Support PANDRH work within the leadership of regional National Regulatory Authorities