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

110 1902 - 2012

RED PARF PANDRH

Organización Panamericana de la Salud

PANDRH Secretariat

September 7th, 2013

CONFERENCE AGENDA– FIRST PART

- Regional context, lessons learned and rationale for the PANDRH Strategic Development Plan 2014-2020
- Plenary discussions and working groups on the Plan strategic objectives:
    - (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 session based on PANDRH strategic objectives

RECOMMENDATIONS: STRATEGIC OBJECTIVE 1

TO PROMOTE EFFECTIVE GOVERNANCE OF PANDRH AND ACTIVE PARTICIPATION OF NRAS TOWARDS REGULATORY CONVERGENCE AND HARMONIZATION

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

- To adapt PANDRH operational work to the current regional context and new emerging challenges, the Conference proposed to restructure the network governance structure to allow flexibility and stimulate the prompt response and participation. Therefore, the Conference recommended the establishment of a new governance structure reconsidering PANDRH operation. The new governance structure:
  - Should be a flexible model that facilitate the participation of members and guarantee the representation of all sectors.
  - 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 countries, and use other international models based on bilateral or regional agreements

RECOMMENDATIONS: STRATEGIC OBJECTIVE 2

DEFINING PRIORITIES, STRATEGIES AND MECHANISMS FOR REGULATORY CONVERGENCE AND HARMONIZATION, AND SUPPORTING THEIR DISSEMINATION, ADOPTION AND IMPLEMENTATION BY NRAS

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 priority setting mechanism based on a periodic analysis of NRAs context and needs.
    - Resulting data from the assessment processes of regulatory functions and institutional development plans (established by Resolution CD50.R9 on *Strengthening National Regulatory Authorities for Medicines and Biologicals*) should be used
    - Furthermore, NRAs' needs should be consulted through periodic surveys that reflect 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 communication tools to strengthen communication and socialization of work plans, technical documents, PANDRH products and any other relevant information

Strategic 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 the achieved results
  - Have a flexible structure that allows the incorporation 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

TO PROMOTE THE STRENGTHENING OF COMPETENCIES IN GOOD REGULATORY PRACTICES AND REGULATORY SCIENCE

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

- The Conference considered that to achieve the strengthening of basic and advance regulatory functions, the Region must renew efforts on its human resources. The management of Good Regulatory Practices should be strengthened based on advances of regulatory science. Therefore, a curriculum based on competencies and the development of a comprehensive plan should be established. Both the curriculum and plan should seek the development of regulatory organizations staff capacity reflecting the different realities and the diversity of the Region. This requires to:
    - Identify countries' priorities and capacities through evaluation processes,
    - Develop a regulatory curriculum that addresses the necessary skills for small NRAs and NRAs with broader functions, taking into account recommendations from WHO and other government leaders in regulatory science field,
    - Provide training based on institutional development plans based on the gaps arising from NRA's evaluation processes,
    - Identify existing training offers and lean in NRAs strengthens and experiences to efficiently leverage existing resources,
    - Monitor the implementation of the development plan to establish cost-effectiveness and sustainability of this investment.

SUMMARY: STRATEGIC OBJECTIVE 4

TO PROMOTE THE EXCHANGE OF EXPERIENCES AND REGULATORY KNOWLEDGE BETWEEN NRAS INSIDE AND OUTSIDE PANDRH

OBJETIVO 4: 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 strategic objectives. This requires the:
  - Endorsement of bilateral and multilateral agreements that promotes information exchange among NRAs,
  - Use of virtual tools to prompt information exchange, including the products resulting from 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 a 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 STREERING COMMITTE CONCLUSIONS – NEXT STEPS

PANDRH STEERING RECOMMENDATIONS

- Proceed to the revision of PANDRH statutes and develop a proposal to ensure flexibility, inclusiveness, improved participation and transparency in PANDRH governance.
- The new statutes will address the needs and priorities of regulatory systems in the Americas while leveraging capacity within the Region, in other regulatory harmonization initiatives and the recommended by WHO.
- Request existing PANDRH WGs to present a report to the Steering Committee. Reposts should include: their activity level, members of WG, workplan, defined expected results from workplans and a proposal with a justification for the longevity of the WG (if necessary, complemented by workplan).

PANDRH STEERING COMMITTEE RECOMMENDATIONS (CONT.)

- Request the secretariat to coordinate and develop a methodology for the prioritization of network activities based on surveys and PRAIS-Observatory systematized information.
- Develop a diagnostic matrix (a regional profile) to assist the development and assessment on regulatory systems, based on the countries' evolving needs (e.g. medical devices) identified through the survey conducted prior the VII PANDRH Conference.
- Establish a new Technical Group to define a proposal that will lead to the improvement of regulatory competencies, training and regulatory curriculum with participation of academic institutions, centres of excellence and strengthened NRAs.

RENEWAL OF PANDRH STEERING COMMITTEE MEMBERS *

Sub-region	*Main*	*Alternate*
NAFTA	United States of America	Canada
SICA	El Salvador	Guatemala
CARICOM	Barbados	Suriname
Comunidad Andina	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.*

PANDRH STEERING COMMITTEE CONCLUSIONS

- In general, the PANDRH Strategic Development Plan 2014-2020 was endorsed by the VII PANDRH Conference.
- Plan will be revised, edited, published and disseminated by PANDRH Secretariat 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 Technical Group to develop a proposal that, contemplating the principles outlined during the Conference, will lead to the restructure of PANDRH governance, statutes and operation.

PANDRH STEERING COMMITTEE CONCLUSIONS (CONT.)

- Request to PANDRH Secretariat to finish and publish the results of the study on adoption, adaption and implementation of PANDRH technical reports
- PANDRH Secretariat, in collaboration with experts and WG actual members, will elaborate a proposal to adopt a systematic mechanism that allows regulatory priorization, based on a periodic analysis of PRAIS-Observatory data, surveys and consults
- Existing PANDRH WGs should elaborate a detailed workplan within the next 3 months and present it to PANDRH Steering Committee. Workplans should include: their activity level, members, defined expected results from workplans and a proposal with a justification for the longevity of the WG.

PANDRH STEERING COMMITTEE CONCLUSIONS (CONT.)

- PANDRH Secretariat will establish a technical group to develop a proposal of a regulatory curriculum based on NRAs realities, and a methodology of continuing education of NRA personnel. The group will also define a regional roadmap that will lead the development of regulatory curricula with participation from regional universities, centres of excellence and strengthened NRAs. The group will assess the feasibility of creating Good Regulatory Practice (GRP) training centers.
- 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 to the new PANDRH strategic development plan.

Support PANDRH work within the leadership of regional NRAs