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

Regulatory Convergence for Universal Health

Strengthening capacities, expanding access, and facilitating regulatory cooperation in the Region of the Americas

Recommendations and next steps

Secretariat
21 October 2016

CONFERENCE PROGRAM

- Plenary sessions for thematic discussions:

  ST 1: Harmonization, convergence, cooperation, sharing of experiences, and “reliance”

  - Conceptual discussions
  - National and global experiences

  ST 2: Essential regulatory functions and innovative operational models

  - Implementation of Resolution CD 50.R9
  - Regional experiences

CONFERENCE PROGRAM

ST 3: Competencies in best regulatory practices and regulatory science

- Implementation of the prioritization system
- Regulatory CV and global discussions

ST 4: Investment in regulatory systems

- National experiences
- Contributions of industry associations

CONFERENCE PROGRAM

- Technical Panels:

  PANEL A: Medical Devices

  PANEL B: Access and Rational Use

  PANEL C: Human Drugs and Other Biologicals

  PANEL D: Market Surveillance

  PANEL E: Quality Management

  PANEL F: Emergency Preparedness

CONFERENCE PROGRAM

- Meeting of the Network's Steering Committee:
  - Discussion of the projects presented
  - Nomination of representatives for the next period, based on geographical/cultural division

RECOMMENDATIONS OF THE PANDRH STEERING COMMITTEE

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✓ Five proposals were received in response to the call for proposals issued before the VIII Conference:

- **Non-prescription drugs: From the traditional model to new regulatory feedback scenarios (ANMAT/Argentina)**
- **Strengthening of capacities for regulation of medical devices in the Region of the Americas (INVIMA/Colombia and CECMED/Cuba)**
- **Regional network for exchange of information concerning global initiatives on regulatory convergence (ANVISA/Brazil)**
- **Development of an online system for the identification of registered drugs to support post-marketing surveillance activities and efforts to combat counterfeit, fraudulent, and contraband drugs (INHRR/Venezuela and INVIMA/Colombia)**
- **Development of a platform of courses using the distance learning (DL) model, for the education of professionals in the Region's national regulatory authorities (Racine Institute) – no funding source defined.**

RECOMMENDATIONS OF THE STEERING COMMITTEE

- ✓ The Steering Committee took note of the projects and decided to issue observations and questions on them prior to 11 November.
- ✓ The Secretariat will transmit the comments and/or questions received to the projects' authors, who will have until 25 November to respond and revise the projects.
- ✓ Once revised, the projects will be sent to the members of the SC to evaluate and decide upon at a virtual meeting (week of 12 December).
- ✓ The recommendations of the SC should indicate the value added for PANDRH, as well as the specific activities to be carried out. The projects should address the priorities of the Region and meet the criteria defined by the Network in the document "Procedure for Prioritization of Areas and Selection of Projects."
- ✓ Following the recommendation of the SC, the Secretariat should share the proposals with the rest of the members of PANDRH in order to identify and enlist the participation of all members in the specific activities to be carried out.
- ✓ Dissemination will occur via ListServ and PRAIS, as well as through direct communications with the main stakeholders.
- ✓ New proposals will be received starting 1 January 2017, and thereafter all new proposals will be evaluated in the six months following receipt of the proposals.

RECOMMENDATIONS OF THE STEERING COMMITTEE

2. Revision of Steering Committee membership, based on the new bylaws:

Subregion	Title	Alternate
North America	CANADA	UNITED STATES
Central America + Cuba + Dominican Republic	EL SALVADOR	COSTA RICA
Caribbean	SURINAME	BAHAMAS
Andean Region	CHILE	COLOMBIA
Southern Cone	ARGENTINA	BRAZIL
CRS	TBD	TBD
NRAr	TBD	TBD
ALIFAR	RUBEN ABETE	MIGUEL MAITO
FIFARMA	ALBERTO PAGANELLI	LUIS VILLALBA

RECOMMENDATIONS OF THE VIII PANDRH CONFERENCE

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- Develop a concept note on *reliance* for the Region, following the general concepts of harmonization and convergence described in the PANDRH Strategic Development Plan. Emphasize the advantages and disadvantages of *reliance* activities for the development of regulatory systems, taking into account the contributions of the discussion groups emanating from PANDRH VIII.
- Promote the use of platforms such as REPs for secure exchange of information among the NRAs, and the PRAIS platform for non-confidential information.
- Promote the use of PAHO and WHO evaluation findings in order to facilitate decision-making by NRAs.

RECOMMENDATIONS OF THE VIII PANDRH CONFERENCE

- Through PANDRH, carry out activities to facilitate implementation of the WHO guidelines on Best Regulatory Practices once the guidelines are completed, urging members to review and share their observations on the guidelines.
- Evaluate activities that can be carried out to meet the specific education and training needs of regulators, within the context of regional needs.
- Between conferences, review the priorities of the Network so that a new set of priorities can be approved by the Steering Committee with respect to periodic submission and review of proposals. PAWG will function as the technical advisory committee for the prioritization process.

RECOMMENDATIONS OF THE VIII PANDRH CONFERENCE

- Implement projects on the basis of the Network's prioritization model and its Strategic Development Plan, with a view to developing synergy with international initiatives and to obtaining specific products and monitoring their progress.
- Urge members to become involved and prepare a communications plan to ensure maximum member participation in the projects to be carried out during the next biennium, taking steps to ensure that the results will benefit the countries.
- The recommendations of the VII Conference were reiterated with regard to intensifying and expanding PANDRH participation in global initiatives for regulatory harmonization and convergence, and establishing effective links with these global initiatives.
- Promote programs in which the health system and industry can achieve efficiency through regulatory activities that are transparent and predictable, and that provide accountability.

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Expositores: por favor, nos deben enviar un correo electrónico a parf@paho.org con su autorización para difundir las presentaciones de la VIII Conferencia de la RedPARF.

Una vez autorizadas, estarán disponibles en el sitio web de la Red PARF y en la plataforma PRAIS

www.paho.org/redparf

Speakers: Please send an email to parf@paho.org with your written consent to disseminate the presentations made at CPANDRH VIII .

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