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XI Conferencia Panamericana para la Armonización de la Reglamentación Farmacéutica (CPARF)

Conclusions and Adoption of Recommendations

PANDRH Secretariat

Mexico City, Mexico
August 23, 2024

XI CPANDRH AGENDA

9

- The role of the State as a promoter of regional innovation and production
- The role of the pharmaceutical industry in health self-sufficiency
- Strengthening regulatory systems in the oversight of production
- Building and strengthening efficient regulatory systems
- Training initiatives and tools
- Challenges of regulatory systems for medical devices
- Digitization
- Artificial Intelligence
- Digital sales

4

A- Regulatory preparedness for epidemics and pandemics
B- Clinical trials
C- Integrated approaches to strengthening regulatory systems: funding, technical assistance, and partnerships
D- Post-marketing surveillance

2

Political-strategic forums promoted by the host country:
- Ministerial dialogue
- Keynote conference

Plenary Sessions

Thematic Panels

1st In-person Meeting (post COVID-19) of the PANDRH Steering Committee

Representatives of

NRAs from 24 countries and territories

Industry

Strategic partners

Audience

400+

100+

ONGOING INITIATIVES COMMUNICATED AT THE XI CPANDRH

1. Guidance for defining roadmaps to strengthen regulatory capacities of countries with productive capacity

2. Situation analysis of the regulatory preparedness for pandemics and epidemics

3. REGTEC Learning Itinerary

4. Regional School of Health Regulation (ERRS)

5. Forum of regulators on clinical trial supervision

6. Financing mechanism for Cooperation between countries to strengthen post-market surveillance of medical devices in the Region of the Americas.

7. Digital sales of medical products

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Ministerial Dialogue: Key aspects

Mexico City, Mexico
August 23, 2024

- Consensus on the importance of health diplomacy in contributing to access and the development of health technologies in the region.
- Reiterating high-level political commitment toward regulatory strengthening, convergence, and harmonization.
- Harmonization as a contributing factor to the development of productive/industrial ecosystems.
- Need for increased coherence among health, industrial, and regulatory policies.
- Relevance of regional and subregional cooperation and integration.

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General Recommendations

Mexico City, Mexico
August 23, 2024

Steering Committee (SC)

- Provide continuity to the current SC to guide the strategic and operational management of the Network during its transition to a new strategic plan and the evaluation of a governance model that effectively addresses the current needs of the Network's members.
- Include representatives from other national regulatory authorities, as well as new actors and perspectives from the different subregions of the Americas in the SC to inform and support this process.
- Emphasize the responsibilities of subregional representatives on the SC to ensure that the collective opinions of members from their subregion are represented and that continuity is upheld.

Steering Committee (SC)

Members	Main	Alternate
North America	MEXICO	CANADA
Central America + Cuba + Dominican Republic	HONDURAS	GUATEMALA
Caribbean	BARBADOS	tbc
Andean Region	ECUADOR	tbc
Southern Cone	URUGUAY	PARAGUAY
Observer Members		
NRAr (pro tempore chair)	UNITED STATES	
CRS	CARPHA	
ALIFAR	Rubén Abete	Eduardo Franciosi
FIFARMA	Yaneth Giha	Diego Salas

The Secretariat will ensure the inclusion of additional regulatory authorities and new stakeholders and perspectives from various subregions of the Americas, to discuss the transition to a new work plan.

Statutes and Strategic Plan

- Evaluate the current statutes and strategic development plan to determine if revisions are needed to ensure compliance with the objectives of the PANDRH Network.
- In this analysis, consider the new regional challenges outlined by the recent mandates of the PAHO Member States and the recommendations of the XI CPANDRH.
- Ensure that timely and equitable access to health technologies remains at the center of the Network's activities.

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Recommendations from Plenary Sessions and Panels

Mexico City, Mexico
August 23, 2024

PLENARY 1: The role of the State as a promoter of regional innovation and production of health technologies through its regulation

- Improve regulatory efficiency.
- Value peer-to-peer work and stimulate the industry to create collaborative opportunities.
- Explore the role of the PANDRH Network as a forum for discussing pharmaceutical policies.
- Integrate the academic and innovation sectors into these discussions.
- Link the PANDRH Network with other international forums.
- Foster dialogue between regulators and regulated parties from the conception of the development plan and throughout the early stages of research.

PLENARY 2: The role of the pharmaceutical industry in self-sufficiency in health matters and pharmaceutical market integration

- It is recommended that the State, Industry, and other key stakeholders take concerted and collaborative action to strengthen the regional production capacity of health technologies.
- Coordination between NRAs and the local pharmaceutical industry is recommended to promote the regional production of biosimilars and biotechnological medicines.

PLENARY 2: The role of the pharmaceutical industry in self-sufficiency in health matters and pharmaceutical market integration (2)

- Collaboration to strengthen the capacity for producing essential medicines, improve regional competitiveness, and attract investments for technology transfer.

- Development of a roadmap that includes diagnosing current capacities and specific needs in the region, to design public policies aligned with health and economic development goals.

PLENARY 3: Strengthening regulatory systems in the oversight of local production of medical products

- Effective regulatory systems are crucial for the success of local production.
- Establishing a regulatory system capable of overseeing local production requires high-level support.
- Countries aiming to build regulatory systems for local production should promote international collaboration and strategic alliances to enhance their capabilities.
- Strengthening local production of medical products is recognized as a key strategy for ensuring access to essential medicines and health technologies in our Region.

PLENARY 4: Building and strengthening efficient regulatory systems for medicines and other health technologies

- Continue strengthening regulatory systems for medicines and vaccines to ensure they are efficient and integrated into health systems.
- Leverage existing capacities to promote the exchange of experiences among peers and contribute to the strengthening of other countries.
- Establishing a roadmap for regulatory strengthening enables the prioritization and identification of gaps, and progress based on an institutional development plan.
- The mechanism for evaluating and strengthening NRAs is inclusive of all Member States and has helped reduce regulatory asymmetries in the Region.

PLENARY 4: Building and strengthening efficient regulatory systems for medicines and other health technologies (2)

- Reliance is recognized as a necessary instrument for all NRAs, regardless of their installed capacity.
    - Promote the adoption of reliance mechanisms throughout the life cycle of medical products by adapting regulatory frameworks and implementing the principles advocated by the PANDRH Network.
    - Strengthen the implementation of reliance in the region by addressing the following: how, with whom, what, and for what purpose?

PANEL A: Regulatory preparedness for epidemics and pandemics

- The need for countries to maintain updated frameworks to address potential emergency situations is reiterated.
- Within the activities of the PANDRH Network, adopting risk-based criteria is recommended for establishing procedures for the authorization, monitoring, and surveillance of medical products, including vaccines, in the context of emergency situations.
- The importance of adopting mechanisms for regulatory recognition/reliance for medical products, including vaccines, acquired through reliable sources is also reiterated.

PANEL B: Clinical trials

- Strengthen the NRA's technical capacities by promoting continuous training for human resources.

  Establishing a forum of regulators is recommended to exchange experiences on performance indicators related to this regulatory function and to facilitate updates on crucial topics inherent to the role.

PANEL B: Clinical trials (2)

- Enhance the efficiency of NRAs in overseeing clinical trials, avoiding duplication of efforts with other entities.
- Establish flexible regulatory frameworks that can adapt to unforeseen situations and ongoing technological advancements, in line with international standards.

PLENARY 5: Initiatives and tools for competency-based continuing professional development of human resources in the regulatory field

- The need for competency-based training for regulators of medicines and other health technologies is reiterated to address current and future challenges, with specialized educational programs and resources tailored to the Region's needs, in line with WHO recommendations for strengthening regulatory systems.
- The importance of technical cooperation within the PANDRH Network – among regulatory authorities, PAHO, and other stakeholders– is highlighted to strengthen training opportunities for human talent, including through the Regional School of Health Regulation and the REGTEC Training Itinerary.

PLENARY 5: Initiatives and tools for competency-based continuing professional development of human resources in the regulatory field (2)

- The critical support of NRArs is acknowledged in the design of specific competency-based training proposals. Countries are invited to actively engage in these proposals, facilitating access and promoting participant involvement.
- It is recommended to create spaces for the recognition of certifications granted by academia, regulatory authorities, PAHO/WHO, and other relevant entities.

PANEL C: Integrated approaches to strengthening regulatory systems: funding, technical assistance, and partnerships

- Leverage successful public-private partnerships and South-South collaborations to strengthen regulatory systems and avoid duplication of efforts.
- Develop mechanisms to promote coordination among stakeholders, ensuring active participation and alignment with the objectives of the PANDRH Network.

PANEL D: Post-marketing surveillance

- Strengthen the model of cooperation among regulatory networks in the region for pharmacovigilance and falsified products, which has been successful and continues to build capacities in new areas within these functions.
- Countries are urged, with the support of PAHO and the PANDRH Network, to create national multisectoral task forces to address substandard and falsified products from a public health perspective.
- The global mechanisms for incident vigilance information (PIDM for safety and GSMS for quality) have been crucial in enhancing national and regional vigilance. NRAs should contribute their data to these unique global platforms, thereby strengthening their own information systems.

PANEL D: Post-marketing surveillance (2)

- Industry sectors reaffirm their interest to enhancing transparency and access to product safety information (including PSURs and RMPs) for regulators within the PANDRH Network by facilitating the necessary legal mechanisms.
- Collaborative strategies involving regulators, industry, and pharmacopeias are essential to address complex impurities, such as nitrosamines. The relaxation of contaminant limits should consider the implications for access to strategic products.

PLENARY 6: Challenges of regulation systems for medical devices

- Provide technical cooperation for the **adoption** of **international recommendations** (GBT, IMDRF, WHO Global Model). Support for the **updating** of **regulatory frameworks** for medical devices (MD).
- Encourage greater **participation** of **countries** in **international harmonization mechanisms** to better position the region's needs.
- Emphasize the importance of **post-market surveillance** of MD and the shared responsibility with the industry.

PLENARY 6: Challenges of regulation systems for medical devices (2)

- Promote **collaboration between countries**, including mechanisms for **information exchange** between regulatory agencies and **joint training** of human resources, to foster regulatory trust.

- Encourage countries to participate in the **South-South Cooperation Mechanism to strengthen post-market regulatory controls for medical devices in the Region of the Americas**.

PLENARY 7: Digitization for more efficient regulatory processes

- **Transparency and Products**: It is recommended to promote transparency in regulatory processes and response times. Additionally, adopting a product-focused approach is advised to accelerate the delivery of value.
- **Agile Methodologies**: It is recommended to encourage the use of agile models with prioritized tasks. Additionally, training internal staff and updating regulations, including those related to digital signatures, is advised.
- **Cybersecurity**: It is recommended to design a secure infrastructure and update systems. Continuous training and raising public awareness are also advised.

PLENARY 7: Digitization for more efficient regulatory processes (2)

- **Collaboration and Usability**: It is recommended to promote regional and global cooperation to support the transition to web-based tools and formats.
- **Experiences and Processes**: It is recommended to establish regional cooperation with similar institutions to optimize processes in the use of new technologies, including the training of specialized personnel.

PLENARY 8: Digital sales of medicines and medical devices

- In collaboration with criminal investigation offices, NRAs should contribute to monitoring social networks, online commerce platforms, and the deep dark web, and take the corresponding coordinated actions.
- Countries in the region are encouraged to consider or adopt the roadmap published by PAHO to develop a regulatory and oversight framework for online sales: https://iris.paho.org/bitstream/handle/10665.2/57444/v47e812023.pdf?sequence=1&isAllowed=y
- The request is for the NRAs to conduct active surveillance of online publications on a permanent basis.

PLENARY 8: Digital sales of medicines and medical devices (2)

- National agreements can be established between NRAs, e-commerce platforms, and social networks to formalize procedures for removing publications of unauthorized, substandard/falsified, or stolen products.
- The approach from e-commerce platforms and social media should extend beyond traditional definitions of medical products to include all items marketed with false or misleading identities (e.g., supplements, cosmetics, foods that actually contain APIs).

PLENARY 9: Artificial Intelligence and its impact on the regulation of health technologies

- Reach a consensus on key terms, definitions, and concepts.
- Multidisciplinary teams, healthcare providers, patients, and health authorities require the appropriate knowledge, skills, and resources to understand the risks and benefits, ensuring the safe and ethical use of AI.
- Promote a collaborative approach to continue involving all stakeholders in the AI ecosystem (i.e., academia, industry, biotechnology, international regulators, etc.).

PLENARY 9: Artificial Intelligence and its impact on the regulation of health technologies (2)

- Regulatory frameworks for AI in public health should address concerns about data privacy, ethical considerations, and ensure transparency in algorithmic decision-making.
- The evolution of regulations should focus on balancing innovation with protection, fostering trust in AI technologies, and promoting the responsible deployment of AI in health systems.
- Regulatory frameworks play a fundamental role in establishing standards for governance, accountability, and AI compliance to maintain the integrity and safety of public health practices.

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Reflections of the audience

Mexico City, Mexico
August 23, 2024

The industry's perspective

How relevant is the governance model in developing and executing a multisectoral agenda?

Vital for development

- ✓ The governance model is crucial for boosting the region's capabilities, identifying needs, and establishing effective priorities and actions.

Key to driving change

- ✓ Ensure technical autonomy of the NRA.
- ✓ The model should be plural and inclusive, aligning with existing initiatives and collaborating with other organizations.
- ✓ Identify gaps and join efforts to strengthen the effectiveness of governance in the regulatory sector.

Being at the forefront

- ✓ From the industry, it is expected that the NRAs will be consistent with advances in technological innovation.

Building trust

- ✓ Provide security and promote rapprochement among the different stakeholders in the sector.

A pillar of transparency and communication

- ✓ Transparent, clear, risk-based, and science-based regulatory frameworks.
- ✓ Early communication between the industry and NRA evaluators to provide guidance on the authorization of research and/or innovative drugs.

The regulatory perspective

What best regulatory practices can be highlighted as part of this articulation*?

*Articulation/coordination among national governmental institutions such as ministries of science and technology, of industry, regulatory systems, among others.

Transparency

- ✓ Clear and open access to information between regulators and those regulated to foster trust.
- ✓ Unified platforms for sharing information

International networks

- ✓ Use of networks such as ICH, ICMRA, and PANDRH to promote the application of quality standards
- ✓ Joint work between regulators and those regulated

Reliance, harmonization and convergence

- ✓ to ensure common standards and better communication between regulators and those regulated
- ✓ Good documentation practices and quality management systems as pillars to ensure the reliability of regulatory processes.

Legal and regulatory framework

- ✓ Risk-based regulations that allow for flexibility and adaptability according to local needs, and that adapt to innovations and changes in the regulatory environment.

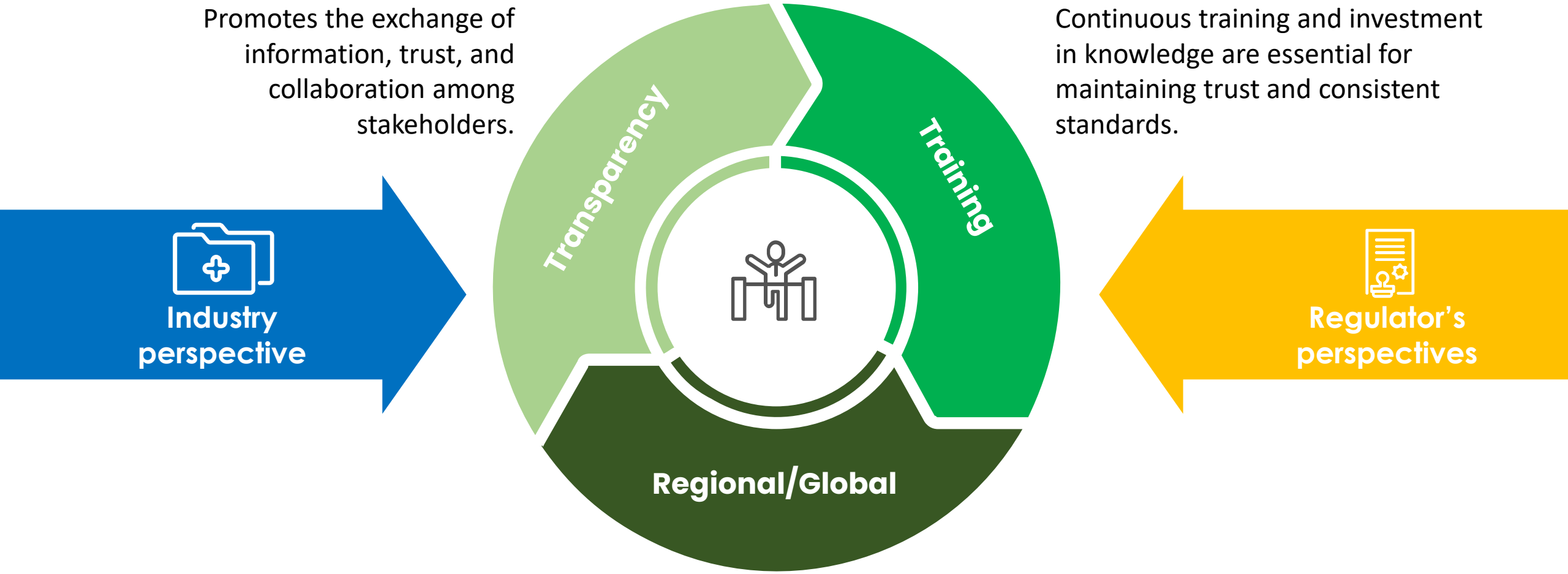
Training and knowledge

- ✓ Continuing education for regulatory staff and the industry to maintain consistent standards
- ✓ Focus regulatory decisions and investments on addressing the unmet needs of the population

The convergence of comments among the audience members

Promotes the exchange of information, trust, and collaboration among stakeholders.

Continuous training and investment in knowledge are essential for maintaining trust and consistent standards.



Key to staying at the forefront and fostering collaboration between regulators and those regulated.

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