"Enabling the Use of Regulatory Reliance in the Americas"

Webinar

Organized by PANDRH's Technical Secretariat

Thursday, November 17, 2022 / 9:00 am to 11:30 am EST

Purpose

Reliance is a critical efficiency for regulatory systems that can be used across a variety of regulatory functions in pre- and post-market stages. It helps reduce workload so that resources can be prioritized elsewhere in all regulatory systems, regardless of their size and/or existing resources. The practice of regulatory reliance is encouraged by PAHO and PANDRH, following current guidelines[1] and principles.[2] Despite recent progress made by several National Regulatory Authorities (NRAs) in adopting reliance mechanisms, there are still opportunities for further strengthening this practice. This webinar aims to identify those opportunities, discuss major remaining obstacles, and recommend a path forward to expand the use of reliance. The PANDRH's Technical Secretariat is pleased to host this event, seeking to promote the exchange of information and experiences towards greater regulatory convergence in the Region.

Audience

PANDRH Members, and related actors from the public and private sectors involved in advancing regulatory efficiencies through convergence, harmonization, and reliance.

PRELIMINARY AGENDA

As of 27-Oct-22

8:45 – 9:00	**Sound and image tests on Zoom**
9:00 – 9:10	**Opening remarks, and PANDRH updates** *James Fitzgerald, Director, Health Systems and Services, PAHO/WHO*
9:10 – 10:10	**SESSION 1: Adoption of Regulatory Reliance Mechanisms in the Region of the Americas** *Objectives:* Discuss the context and value of regulatory reliance in promoting a more efficient approach to regulation of medical products; and review lessons learned from National Regulatory Authorities of Regional Reference (NRAr) and other organizations on inter-institutional collaboration towards the adoption and implementation of reliance mechanisms. *Moderator*: *Maria Baca Estrada, Manager, Clinical Evaluation Division: COVID, Center for Vaccines, Clinical Trials and Biostatistics, Health Canada* *PAHO Introductory Video:* **Regulatory systems for universal health: Regulatory reliance** • **Principles of an effective regulatory reliance** *Maria Luz Pombo, Advisor, Vaccines and Biotechnological Products, Health Systems and Services, PAHO/WHO* • **The role of NRAr in the advancement of reliance: Lessons learned** *Speaker tbc, ANVISA*

	• **Promoting collaboration to enable information sharing between authorities** *Richard Siggers, Acting Manager, Bacterial and Combination Vaccines, Health Canada* • **Case study: Leveraging reliance to improve management of post-approval changes (variations) during the lifecycle of a vaccine** *Thierry Gastineau, Global Head, Quality Innovation, Culture & Engagement, Vaccines, Sanofi* *Q&A*
10:10 – 11:25	**SESSION 2: Challenges and Opportunities for Increasing Use of Reliance** *Objectives:* Reflect on challenges and opportunities to enable the effective use of reliance throughout the product life cycle, and the role that regulated parties and other stakeholders in the system can play in achieving an efficient regulatory environment. *Moderator: Murray Lumpkin, Deputy Director, Regulatory Affairs, Bill & Melinda Gates Foundation* • **Panel discussion: Potential approaches and tools to help overcome barriers in implementing regulatory reliance more broadly** *Maria Cristina Mota Pina, Regulatory Policy and Intelligence Head, Emerging Markets at AbbVie on behalf of FIFARMA* *Ruben Abete, General Secretary, ALIFAR* *Danielle Craig, Regulatory Affairs Lead for the Americas, CEPI* *Heriberto García Escorza, Director, Public Health Institute of Chile* *Samvel Azatyan, Team Lead, Regulatory Convergence and Networks, Regulation and Prequalification, WHO* *Q&A*
11:25 – 11:30	**Closing remarks: Main takeaways, and next steps** *PANDRH Secretariat Host/s*

References:

1. World Health Organization. Good regulatory practices: guidelines for national regulatory authorities for medical products. Geneva: WHO; 2016.

2. PANDRH. Regulatory reliance principles: concept note and recommendations. Washington, DC: Pan American Health Organization; 2018.