

Advances in the exchange of information in the Region of the Americas on global regulatory convergence initiatives

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The views expressed in this presentation do not necessary reflect those of Health Canada or the Government of Canada.

On behalf of this Project Coordination group including ANVISA/Brazil, FDA/US and Health Canada



PANDRH's Objectives



- ❖ Strengthen the regulatory functions and systems of the countries of the Region, promoting cooperation and sharing among countries, with the Pan American Health Organization (PAHO), and with other regional and international organizations, civil society, industry associations, and academia.
- ❖ Develop and approve common proposals (projects, joint activities, technical documents, guidelines, work plans, etc.) for the regulation of health technologies, taking into account international guidelines and standards for regulatory convergence.

PAHO/WHO

Project Purpose



- ❖ Keep the NRAs of the Americas up to date with strategic information regarding regulatory issues and trends, through the communication and interaction among designated focal points, with the goal of providing tools that might be used nationally to improve regulatory processes.

Project Rationale

- ❖ Since not all NRAs or stakeholders in the Americas have the opportunity to get involved in global harmonization and convergence initiatives involving countries outside of the Americas, they could benefit from the fact that some countries in the region actively participate in such initiatives. These countries can share strategic information with regional partners, advancing their knowledge on global regulatory trends and practices.
- ❖ The sharing of knowledge through communication and interaction among NRA and other stakeholders' focal points provides tools and information that may be potentially applied at a domestic level to improve regulatory processes, in alignment with those from outside of the Americas.

Proposed Activities



- Creating a network of focal points to disseminate strategic information regarding regulatory issues and trends
- Distribution of an electronic list of websites with information on the major fora that elaborate guidelines on medicines and medical devices for regulatory purposes
- Web Seminars to present the main characteristics and updates relating to selected initiatives

Activities Update - 1



❖ Network of focal points:

- It was created and is open to all stakeholders in PRAIS
- ... but has relatively low activity. It currently counts with 22 members (10 NRAs; 5 PAHO)

□ Purpose of the recently created PRAIS Community:

- To provide a platform for keeping NRAs and other stakeholders of the Americas up-to-date with strategic information regarding regulatory issues and trends, through communication and interaction among designated focal points
- The goal is the sharing of tools that might be used nationally to improve regulatory processes



PAHO/WHO

Activities Update - 2

- ❑ PRAIS Community Membership:
 - Employees of NRAs of the region of the Americas (any number of participants); Focal points of other interested organizations, including industry, professional and patient associations and academia; PAHO staff.

- ❑ The Community has a mandate to deal with matters related to the activities of global and regional regulatory convergence initiatives, excluding PANDRH. To avoid duplication of work, unless requested, the Community will refrain from promoting discussions on matters that are under the mandate of other PANDRH approved projects and other networks of focal points led by PAHO for specific purposes.

- ❑ The PRAIS Community is moderated by Brazil and members will be added to the community as long as they comply with the requirements for membership. Focal points might ask to join the Community directly through PRAIS.

Activities Update - 3



- ❖ Distribution of an electronic list of websites with information on the major fora that elaborate guidelines on medicines and medical devices for regulatory purposes
 - Completed and posted in PRAIS (English only)

Activities Update - 4



- ❖ Web Seminars to present the main characteristics and updates relating to selected initiatives (at least one per year)
- ❖ Webinars - Updates on Global Regulatory Convergence Initiatives
 - June 13, 2017 Topics: 1) The PANDRH Project - ANVISA, 2) ICH Reform – HC, and ISO IDMP – FDA. [n=34]
 - April 05, 2018 Topics: 1) The International Pharmaceutical Regulators Program (IPRP) – ANVISA, and 2) ICH: Membership & Participation. [n=about 200]
 - Webinar presentations are available in PRAIS
 - ... **next TBD (Q4 2018?) ... any suggestions?**

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Please do not hesitate to contact us:

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thanks
Dank
mercierBeaucoup grazas
grazieMille
GRACIAS
gracias
esker gràcies



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