



Terms of Reference

PRAIS Community for the project “Network for sharing information in the Americas on global regulatory convergence initiatives”

I. Purpose of the Community

Provide a platform for keeping 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.

II. Rationale

As stated in the PANDRH Strategic Development Plan 2014-2020, the current environment of global health requires the renewal of international cooperation to develop national, regional, and global health surveillance systems for medicines and technologies under the coordination and leadership of the NRAs.

PANDRH Member States are required to work together towards the common goal of strengthening regulatory capacity, through collaborative processes, with the purpose of reaching further convergence in their processes, functions, and regulatory results. This regulatory convergence requires stepping up the cooperation between the countries and the NRAs for developing regulatory systems, sharing experiences and information on health regulatory processes.

Given that not all NRAs in the Americas have the opportunity to be involved in global harmonization and convergence initiatives involving countries outside the Americas, they could benefit from the fact that some countries in the Region actively participate in these initiatives, which 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 focal points provides tools and information that potentially may be applied at a domestic level to improve regulatory processes, in alignment with updated regulation and practices of NRAs from outside the Americas.

III. Membership

- Employees of NRAs of the region of the Americas (any number of participants)
- PAHO staff



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. PANDRH Secretariat will give information on how to join PRAIS whenever requested (PARF@paho.org).

IV. Role of Project Leaders

The Project Leaders for this activity, as approved by the PANDRH Steering Committee, are: ANVISA (Brazil), Health Canada and FDA (USA).

Their role is to organize opportunities for sharing strategic information regarding regulatory issues and trends, in consultation with other NRAs of the region or PANDRH Steering Committee, as appropriate.

Project Leaders might send reference information / documentation (when the topic only demands communication) or might propose the organization of meetings via web (when the topic requires interaction / discussion among NRAs). Also, Project Leaders might disseminate information to promote the participation of representatives of NRAs of the Americas in face-to-face or virtual activities organized by / within global initiatives.

V. Activities

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 (i.e. substandard and falsified medical products).

Sharing of information and documentation	
Purpose	Provide updated information on the activities of global and regional regulatory convergence initiatives. Encourage the participation of NRAs of the region of the Americas in activities promoted by global and regional regulatory convergence initiatives. Disseminate information about the technical products / documentation approved by global and regional regulatory convergence initiatives with the objective of, as appropriate, promoting their leverage and the alignment of NRAs of the region of the Americas to these references.
Methodology	Exchange of information via PRAIS Community (subject to moderation).
Issues to be	Upcoming meetings and training activities open for participation; documents approved or available for public consultation; educational material developed



addressed	by global and regional regulatory convergence initiatives.
Initiator	Any member of the Community. Typically, will be done by Project Leaders.
Periodicity	Whenever necessary.
Limitations	Confidential information and copyright documentation should not be exchanged.

Seminars	
Purpose	Provide updated strategic information and promote the discussion of matters related to the activities of global and regional regulatory convergence initiatives.
Methodology	Virtual meetings.
Issues to be addressed	Any update on governance, structure and scope of work of global and regional regulatory convergence initiatives; presentation of documents approved or available for public consultation that might benefit from a joint discussion among NRAs of the Americas.
Initiator	Project Leaders (based on their decision or on request by other NRAs or PANDRH Steering Committee).
Periodicity	At least once a year.
Limitations	Confidential information should not be exchanged.