



Terms of Reference

Procedure for the Prioritization of Areas and Selection of Projects

PANDRH

Background

At the 7th Conference of the Pan American Network for Drug Regulatory Harmonization (PANDRH), held in 2013, the member countries approved the Strategic Development Plan 2014-2020, which states the need to develop a systematic procedure for prioritizing areas of work, based on a periodic analysis of the context and needs of the national regulatory authorities (NRAs).

Rationale

The procedure should be used by the PANDRH Steering Committee to establish biannual strategic areas for the implementation of projects that include activities geared to achieving the end goals in each of the prioritized thematic areas. These areas should express regulatory functions or cross-cutting issues.

The strategic prioritized areas will be approved by the Steering Committee and led preferably by recognized NRAs of regional reference (NRAR) in accordance with the established criteria in support of Resolution CD 50.R9. Each of these areas will be formed by projects that will be decided among the participants of each of the strategic areas.

The participants of each of the prioritized strategic areas will include other NRAs of the Region interested in the issue, as well as representatives of producers' associations, civil society, and academia, as appropriate to the defined area. Each project approved by the participants will be coordinated by one of the participating NRAs. It is recommended that an average of nine (9) Members (including NRAs and other stakeholders) should participate in each area. Furthermore, the Terms of Reference should be presented to the Steering Committee before the projects are presented, in accordance with the model provided (see annex), stating the rationale, activities, terms, source of funding, and expected results.

On this basis, the Steering Committee will monitor project implementation and the leaders of the priority areas will present periodic reports during the face-to-face meetings of the Committee.

Components

The prioritization procedure should consider the following:

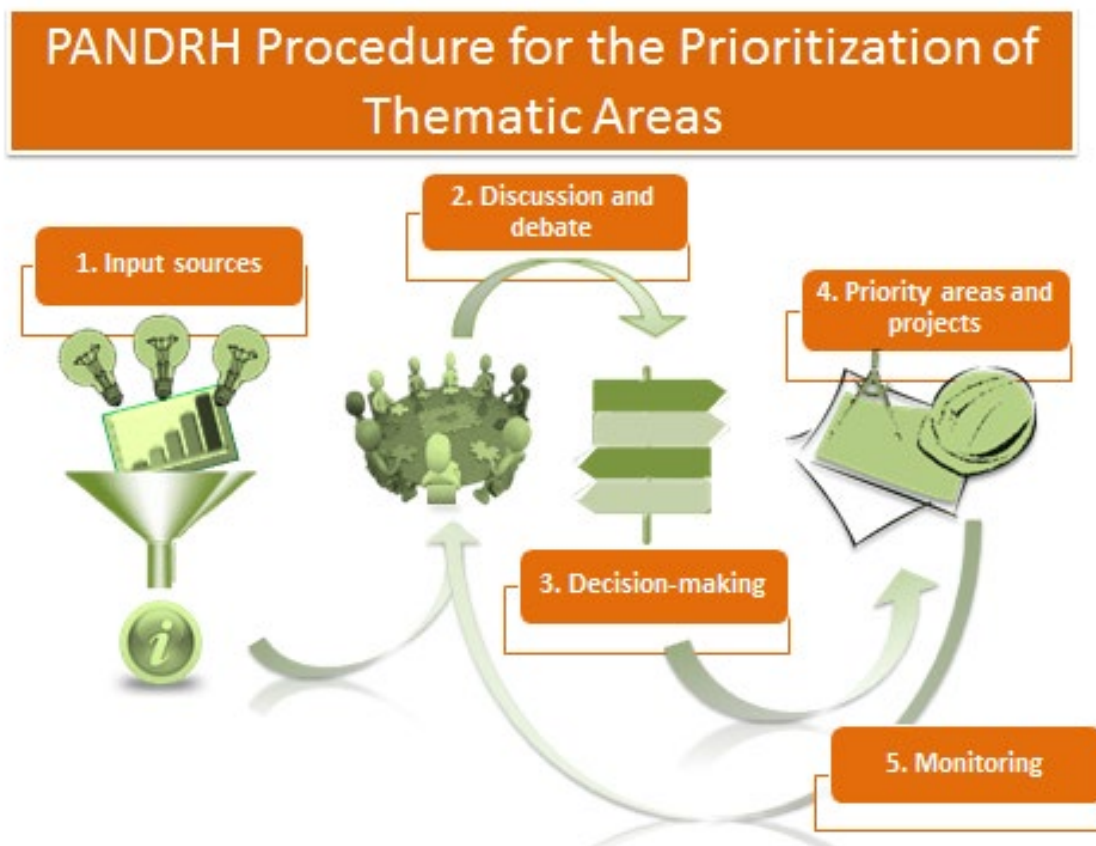
1. Input/information from the following sources:
 - a. The recommendations of the PAWG (PRAIS Analytics Working Group);

- b. The results of the evaluations of regulatory systems conducted in support of Resolution CD 50.R9, the analysis of the available data from those evaluations and from the observatory of the Regional Platform on Access and Innovation for Health Technologies (PRAIS), as stated in the PRAIS Bulletins; and
 - c. Inputs from the Steering Committee, countries, sub-regions, the Secretariat, industry associations, and other stakeholders regarding the priorities to be set according to regulatory and/or cross-cutting functions, and which will be developed through projects, following the structures approved by the Network.
2. Discussion and debate: This process will take place during the (face-to-face or virtual) meetings of the Steering Committee, with the participation of the NRAs, producers' associations, observers, and other stakeholders, as appropriate. Priorities will be discussed on the basis of the information received (see point 1, above). Discussions may touch on some of the following questions¹:
- a. Does the issue address or encompass a significant risk or situation that requires immediate regional support?
 - b. Is it focused on implementing a new function with a positive impact needed for the regulation of health technologies (innovation)?
 - c. Does it improve the implementation, quality, or capacity of the regulatory function, enhancing efficiency or competences?
 - d. Can it be used to enhance any already established practices?
 - e. Is the project proposal formulated based on evidentiary studies, assessments or requests?
 - f. Can the initiative be replicated/expanded/maintained by several countries or can it only be used on a limited basis or in only one or a few countries?
 - g. What is its scope (regional/sub regional/national)?
 - h. How long will it take to plan, implement, and complete it (immediately, available solution, one year, two years, more than 2 years...)?
 - i. How long is it expected to take to obtain positive results/impact; and will impact be maintained over time, after the project ends: short-, medium-, long-term?
 - j. Can it be implemented at the regional level (available solution) or are other participants required at the global level?
 - k. Are the costs involved acceptable? Are financial resources available? Are there offers or possible financing from countries or other acceptable sources?
 - l. Are the uncertainties and potential operational difficulties involved in the implementation of the proposed solutions manageable and acceptable?
 - m. Is it possible to define the indicators for monitoring the implementation and achievement of the objectives?
 - n. Is the action supported by the relevant government and state bodies and authorities?
 - i. Is this support expressed by specific inputs (financial, infrastructure, etc.) or by ways of a specific commitment?
 - o. Are the results sustainable over a longer time frame?

¹ These elements are meant to serve as guidance to proposals but are not exhaustive, Projects do not have to comply with all elements listed.

- p. Does the end result of the projects lead to or supports regulatory convergence
 - q. Does the project support the availability and accessibility of quality health products on a regional, sub regional or national level?
 - r. Does the project support/ address an expressed Public Health Need?
3. Decision-making: The PANDRH Steering Committee will make the final decisions concerning the priority issues for specific time periods.

Diagram of the Procedure





ANNEX I

New Area/Project Proposal/Project Extension Proposal

For Steering Committee consideration

(Please submit to PANDRH Secretariat - PAHO)

Proposed title of the area/project	
Initiator	
Purpose and Rationale (including a reference to one or more of the goals or objectives of the PANDRH Strategic Development Plan)	<u>Purpose</u> <u>Rationale</u> <u>Alignment with goals/objectives</u>
Scope (including outline of issues to be addressed and opportunities for regulatory convergence)	<u>Issues to be addressed</u> <u>Opportunities for regulatory convergence</u>
General Work Plan and Timelines	
Proposed Leader of Project	
Proposed sources of necessary expertise / Funding needs	
Relevant existing documents at national level, as well as in international bodies.	