Proposal Submission Deadline Procedure
VIII PANDRH Conference

During the VII Conference, in 2013, countries approved a PANDRH Strategic Development Plan for the period 2014-2020, where the need for development of a systematic mechanism for priority work areas based on a periodic analysis of the context and the needs of National Regulatory Authorities (NRAs) of each country is expressed.

The procedure should be applied by the Steering Committee of PANDRH for defining the biannual strategic thematic areas, where projects that include activities at achieving the aimed outcome of each of the subject areas defined as priority/strategic will be implemented. These areas should express regulatory functions or cross-cutting themes.

The strategic areas will be defined using the approved prioritization methodology and will be coordinated preferably by a national regulatory authority already designated as NRAs of regional reference (NRAr) based on Resolution CD 50.R9. Each of these areas will be made up of projects that will be proposed by any of the Members of the Network whose approval and implementation will be under responsibility of the components of the strategic areas.

Participants in each of the strategic areas prioritized include other RNAs of the Region as long as they are interested in the subject, and representatives of manufacturer associations, civil society and academia, as appropriate, according to the defined area. Each of the projects approved within the priority areas will be coordinated by one of the RNAs participating. An average of nine (9) participating Members by subject area (including RNA and other representatives) and the presentation of projects preceded by terms of reference presented to the Steering Committee which will consist justification, activities, deadlines, resources and expected results.

On this basis, the Steering Committee is going to monitor the development of these projects through regular reports by the leaders of the priority areas during face meetings of the PANDRH Steering Committee.

For more information: www.paho.org/pandrh

General Information

1. We will only accept proposals submitted using the form "**Project Proposal",** available on page 8 of this document.
2. Proposals must be aligned with the strategic areas prioritized by the PANDRH Steering Committee, particularly:
    - Good Regulatory Practices and Regulatory Science
    - Post-market surveillance and enforcement activities
    - Authorization, registration and licensing of products and establishments
    - Regulation of medical devices
    - Relationship with other global initiatives for harmonization and regulatory convergence
3. Proposals must contain:
    a. Title of the project;
    b. Initiator, according to Rule #1 of this document;
    c. Purpose;
    d. Rationale and objectives aligned with the goals of the Strategic Development Plan;
    e. Scope, including issues to be addressed and opportunities for regulatory convergence;
    f. Work plan, timelines and expected results;
    g. Project leader;

h. Source of resources.

4. Only proposals with identified funding sources will be considered.

5. Proposals received after the deadline will not be considered.

6. The deadline for the execution of project should not be more than two (2) years.

Rules and Deadlines:

1. Any participant registered to the VIII CPANDRH may submit the proposal. However, initiatives from non members should be endorsed by a member duly indicated in the "Initiator" specific proposal form;
2. Projects must have identified funding proposals. Projects without identified funding sources will not be considered.
3. Proposals should be submitted to parf@paho.org no later than **31 August 2016, 11 pm EST**. Proposals received after this date will not be considered.
4. The Steering Committee members will receive the proposals for individual assessment up to 1 September 2016 and have until 9 September 2016 to express their comments on these projects. Comments received after this date will not be considered.
5. The PANDRH Secretariat will receive comments until 9 September 2016 and will consolidate them into one document.
6. During the Steering Committee meeting at the VIII CPANDRH (19 October 2016), members will receive the consolidated comments and will have the opportunity to discuss on proposals and define which will be implemented.
7. Proposals will be evaluated according to their potential contribution to improve convergence and regulatory harmonization objecting to strengthening regulatory capacities towards universal health according to the PANDRH prioritization of thematic areas.

8. During the VIII CPANDRH the Steering Committee shall elect a representative to announce proposals that will be implemented throughout the two (2) years and whose results will be presented at the next Conference (IX CPANDRH).

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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 questions[1]:

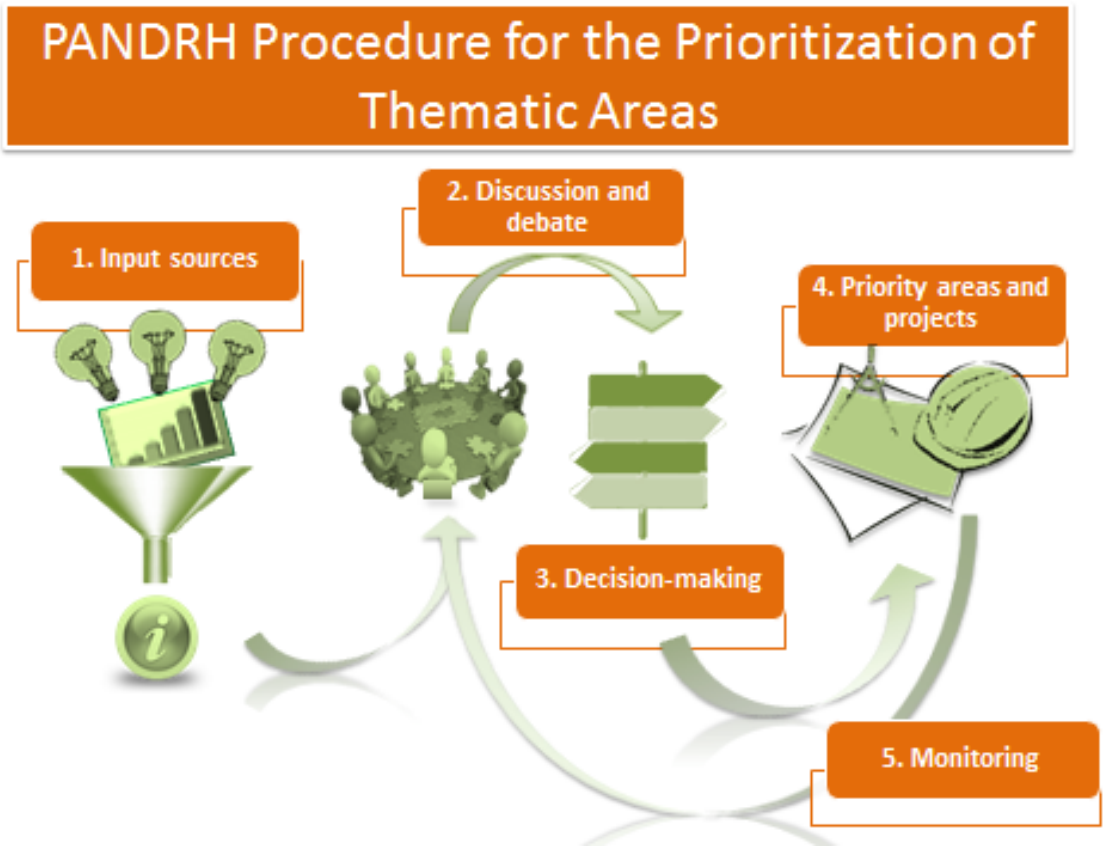
    a. Does the issue address or encompass a significant risk or situation that requires immediate regional support?
    b. Is it focused on implementing a new function with a positive impact needed for the regulation of health technologies (innovation)?
    c. Does it improve the implementation, quality, or capacity of the regulatory function, enhancing efficiency or competences?

[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.

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?
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


PANDRH Procedure for the Prioritization of Thematic Areas
1. Input sources
2. Discussion and debate
3. Decision-making
4. Priority areas and projects
5. Monitoring

ANNEX I

Project Proposal

For Steering Committee consideration

(Please submit to PANDRH Secretariat – PAHO parf@paho.org)

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)	Purpose Rationale Alignment with goals/objectives
Scope (including outline of issues to be addressed and opportunities for regulatory convergence)	Issues to be addressed Opportunities for regulatory convergence
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.	