**AIDE-MEMOIRE**

**Meeting of the Steering Committee of the Pan American Network for Drug Regulatory Harmonization (PANDRH)**

Venue: Washington, D.C.

Date: 27 and 28 May 2015

The Steering Committee of the Pan American Network for Drug Regulatory Harmonization (PANDRH) met at the Headquarters of the Pan American Health Organization (PAHO) in Washington, DC, on 27 and 28 May 2015. Other Authorities from the Region participated both in person and virtually. The agenda items were as follows:

**TOPICS DISCUSSED**

1. **Monitoring of implementation of the PANDRH Strategic Development Plan 2014-2020**

The Secretariat of the Network presented progress made in implementation of the PANDRH Strategic Development Plan 2014-2020, approved during the VII Conference. Said progress included the following:

* Web publication of the following documents: Report on Functionality of the Working Groups, Strategic Development Plan 2014-2020, and Report of the VII Conference.
* Establishment of ad hoc groups to deal with the following:
* New statutes and model of governance;
* Regulatory curriculum and use of best regulatory practices
* Methodology for prioritizing Network activities
* The Network’s participation in other global harmonization initiatives and progress in developing the Network’s communications strategy
1. **Proposals for new PANDRH Statutes and Model of Governance**

The Secretariat presented the background information and proposals for new PANDRH statutes and model of governance. The presentation included observations received in advance of the meeting.

After an exchange of ideas among the members present, the Steering Committee recommended:

1. That representation of the regulatory authorities of the countries on the Steering Committee be according to the geographical division proposed by the Secretariat (North America, Central America + Cuba + the Dominican Republic; Caribbean; Andean Region, and Southern Cone) according to the attached table;
2. That the regional reference authorities be represented on the Steering Committee by their Secretariat and that other multilateral regulatory initiatives from the Region also participate in the Steering Committee;
3. To expand PANDRH participation to other associations of health technology producers (in addition to FIFARMA and ALIFAR), under criteria defined by the PANDRH Steering Committee and after issuing a call for applications. The participation of these associations should be open to all Network activities (Conference, priority areas, projects, activities) and when the Network holds discussions, sets priorities, and establishes relevant topics, with the exception of the reserved space for regulatory authorities as stated below;
4. That the Steering Committee comprised of representatives of the regulatory authorities (as established in items 1 and 2) with the participation of other stakeholders, have times reserved for closed discussion and decision-making restricted to the regulatory authorities.
5. **Procedure for the Prioritization of Topics**

The Secretariat presented the work and prioritization methodology used by the PAWG (PRAIS Analytics Working Group) as one of the inputs that will be used by the Network’s Steering Committee for decision-making on the priority areas of work. The Steering Committee received and approved the PAWG’s work. As for the internal procedure, the Steering Committee decided to ask the Secretariat to prepare a document describing this procedure and identifying priorities for its consideration. This procedure should consider the following:

1. The work and recommendations of the PAWG (PRAIS Analytics Working Group);
2. The results of the evaluations of regulatory systems conducted under Resolution CD 50.R9, an analysis of the data stemming from those evaluations and from the observatory of the Regional Platform on Access and Innovation for Health Technologies (PRAIS), as stated in the Bulletins; and
3. Inputs contributed by the Steering Committee, the countries, the 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.

The prioritization procedure should include Terms of Reference to support eligible projects, including components to monitor the implementation of those projects.

1. **Good Regulatory Practices, Regulatory Curriculum, and Continuing Education**

The Secretariat presented the results of the working group that was established to work on this, and summarized the training being offered regionally and globally.

1. **Regional Work on Medical Devices**

Pursuant to the decisions of the VII Conference, the Secretariat presented the work being done regionally, as well as the prospects of this group providing support for PANDRH projects that may arise regarding medical devices.

The members of the Steering Committee stressed the importance of the work being done to strengthen regulatory capacity for this area of health technology. They also reiterated that this field is quite relevant for the NRAs of the Region, and therefore should be included in PANDRH’s discussions. This should be part of the regional efforts to develop indicators to support an assessment of capacity regarding medical devices, so that the Region can contribute significantly to global discussions on the subject avoiding duplication of efforts.

Additionally, it was informed that CECMED – Medical Devices Division was assigned as a Collaborative Center for PAHO/WHO on Health Technologies.

1. **PRAIS Report and Bulletin**

The Secretariat gave a presentation on the updates being made to the PRAIS Platform, and the two Bulletins generated from the analysis of regulatory data in the Platform’s observatory. This was also mentioned during the session on the methodology for prioritizing PANDRH topics.

1. **Preparation for the VIII Conference PANDRH—2016**

The delegation of Canada, as host of the VII Conference held in Ottawa in 2013, described the challenges and opportunities of organizing such an event. It was then announced that Mexico will host the next Conference of the Network to be held in 2016. It was pointed out that the Steering Committee and the Secretariat of the Network will need to support the host country during preparations for the VIII Conference, together with COFEPRIS.

1. **Other Business**

At the end of the meeting, it was announced to the Steering Committee and other countries present that Health Canada, after undergoing the evaluation process based on the mechanism established pursuant to Resolution CD50.R9, was recognized as a Regional National Reference Regulatory Authority.

Annex I. Meeting Agenda, including its objectives

Annex II. List of Participants

Annex III. Table of Geographical Divisions

Annex IV. Presentation