

AIDE-MEMOIRE

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

Date: 16th December 2015

The Steering Committee of the Pan American Network for Drug Regulatory Harmonization (PANDRH) met virtually on 16 May 2015 and had personal participation of some Members, Authorities and Observers of the Region at the Headquarters of the Pan American Health Organization (PAHO) in Washington, DC. The agenda items were as follows:

TOPICS DISCUSSED

I. General Report on Activities since the last Meeting of the Steering Committee (May/2015)

The Secretariat of the Network presented documents approved and progress made since the last meeting of PANDRH Steering Committee, held on May, 2015. The subjects reported and presentations distributed with SC Members and observers included the following:

- Statutes of PANDRH Network
- Procedures for Selection of Areas and Prioritization of Projects at PANDRH
- Progress made at PAWG (PRAIS Analytical Working Group) on the elaboration of a pilot project based on the procedures for prioritization approved.
- Report on work done at the Networks of Focal Points on Pharmacovigilance and Prevention and Combat of Falsified Medical Products.

The Steering Committee noted the information provided and reaffirmed the approval of the documents mentioned above, specially, the “Statutes of the Network” and “Procedure for Selection of Areas and Prioritization of Projects at PANDRH”. Final versions of the documents are attached to this aide-memoire.

II. Related activities, Prioritization of Areas and Definition of Projects

The Secretariat presented the results of the prioritization of cross-cutting areas and suggested subjects for future projects under these areas, that was made under the basis of data resulted from the VII PANDRH Conference (Canada/2013), countries’ pharmaceutical profile and data resulted from the analysis of performance on the indicators of the evaluations through the mechanism of Resolution CD50.R9. The Secretariat presented to the Steering Committee a list of Authorities that had previously volunteered to assume the role of coordinators of the cross-cutting areas, as follows:

- Good Regulatory Practices and Regulatory Sciences (ANVISA/Brazil and FDA/US);
- Post-Marketing Surveillance and Activities for Monitoring and Control (ANMAT/Argentina);
- Authorization, Registration and Licensing of products and facilities (COFREPRIS/Mexico and CECMED/Cuba);
- Medical Devices (INVIMA/Colombia and CECMED/Cuba);
- Relationship with other global harmonization and regulatory convergence initiatives (ANVISA/Brazil, HC/Canada and FDA/US).



The Steering Committee expressed the approval of the suggested countries for the coordination of the cross-cutting areas and at this opportunity officially nominates the countries that will act as coordinators accordingly to the abovementioned list, following the mandates of the PANDRH Strategic Development Plan 2014-2020. Next steps will include the definition of priority projects under each of the areas and call for Members to participate on each of the approved projects.

It was presented under the area of “Good Regulatory Practices and Regulatory Sciences” the project on “Quality Management Systems capacity building for National Regulatory Authorities in the Americas” as a result of PAWG discussions. The Secretariat presented the project, its objectives, proposed methodology for its implementation, timeframes and resources needed. This was presented as an example for the future work of PANDRH and the Terms of Reference are subject to further modifications by the Authorities that will be in charge of this project. The coordinators of the cross-cutting area (Brazil and United States) will make, with the support of the Secretariat, the call for Members to be part of the project.

III. Preparation for the VIII Conference PANDRH—2016

During the meeting it was officially announced that the next PANDRH Conference will be held in Mexico City, Mexico, on October, 19 to 21st, 2016. Based on the suggestion made by the host country, the Steering Committee agreed that the Conference will happen in two different moments: on the first day open to the participation of Governmental representatives only and on the following days open to all Members of the Network, including representatives from the private sector and civil society.

It was also agreed that the Secretariat will support COFEPRIS on the elaboration of the draft agenda for the Conference taking into consideration all the suggestions presented by SC Members. The draft agenda will be circulated to PANDRH Members in the future.

IV. PRAIS Report and Bulletin

The Secretariat gave a presentation on the updates and new functionalities of the new version of PRAIS Platform. The new version of the Platform will serve as an important support to the work of PANDRH Network on cross-cutting areas and projects.

V. Other Business

The Steering Committee will keep actual representation until the VIII Conference, while will be announced the nominees for the representatives of each geographical area based on the table attached to the Statutes.

Annex I. Meeting Agenda, including its objectives

Annex II. List of Participants

Annex III. Statutes of PANDRH Network

Annex IV. Procedures for the Selection of Areas and Prioritization of Projects on PANDRH

Annex IV. Presentations