PAWG
1st Meeting 2016

HSS/MT
March 3rd, 2016

Pan American Health Organization

World Health Organization
REGIONAL OFFICE FOR THE Americas

Universal health
Access and coverage for all

Agenda

1) Role of PAWG in the framework of implementation of PANDRH projects and
2) PRAIS Webinars/Discussion Good Regulatory Practices

Role of PAWG in the framework of implementation of PANDRH projects

- PANDRH Steering Committee meeting (Dec 16th, 2015
  - Each PANDRH thematic area will be coordinated by defined NRAs
  - Development of Quality Management System (QMS): PAWG proposed project approved (Brazil and USA as coordinators)

- PRAIS Webinars/Discussion Good Regulatory Practices

Background information: Relevant indicators from PAWG 1st round

Order	Non-Ach Basic Indicators for 35 countries
1st	0906 - Existence of legal provisions requiring the NMRA to publish the Summary Product Characteristics (SPCs) of the pharmaceuticals registered
2nd	0919 - Existence of routine and crisis communication strategies
3rd	0916 - Existence of legal provisions requiring the sponsor and investigator to comply with Good Clinical Practices (GCP)
4th	0905 - Existence of legal provisions that require the NMRA to make publicly available information of registered pharmaceutical products with a defined periodicity
5th	0914 - Existence of legal provisions requiring NMRA authorization for conducting clinical trials

Background information
Relevant indicators from PAWG 2nd round by main regulatory areas

1st - Development of Quality Management System
5011 - The NRA has implemented a Quality Management System (QMS) for the regulatory functions.
5012 - The QMS is based on or recognizes reference standards (WHO, PIC/S, ISO, etc.).
5013 - The documentation system needed to establish, implement, and maintain the QMS has been defined (quality manual, record keeping, policies, quality procedures, operating procedures).

2nd - Management of conflicts of interest
5020 - A written policy/procedure is in place for identifying and appointing outside experts. Candidates are chosen by a selection panel/jury and the final decision is made public.
5021 - There is a general policy governing potential conflicts of interest that may affect ad hoc outside experts or members of the advisory committee.
5029 - There is a mechanism/internal policy governing conflicts of interest that may affect staff.

3rd - Monitoring and Evaluation / Evaluation of Regulatory Impact
5033 - Regulatory functions or processes are regularly and systematically monitored and reviewed to identify problems, gaps, weaknesses, and inconsistencies in the NRA.

4th - Transparency
5026 - Information on decisions is publicly available. This includes timely information on negative decisions in specific cases (when the legislation so permits).

5th - Participation of Stakeholders
5005 - The development of legislation and regulations brings various mechanisms into play that involve sectors of civil society, such as NGOs, health sector representatives, industry representatives, consumers, patients and other stakeholders.

PAWG 2016 proposal work plan

- Monthly Teleconference (follow-up)
  - March 3rd
  - April 20th
  - June 8th
  - July 13th
  - August 10th
  - September 14th
  - October 13th (preparation for VIII PANDRH Conference, October 19-21, Mexico City)
  - November 9th
- Definition of sub-groups of countries in charge of planning webinars by thematic areas

- Four webinars
  - May 5th
  - June 30th
  - August 25th
  - October 6th

Thank you!
!Muchas gracias!
Muito obrigado!

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