PAN AMERICAN NETWORK ON DRUG REGULATORY HARMONIZATION

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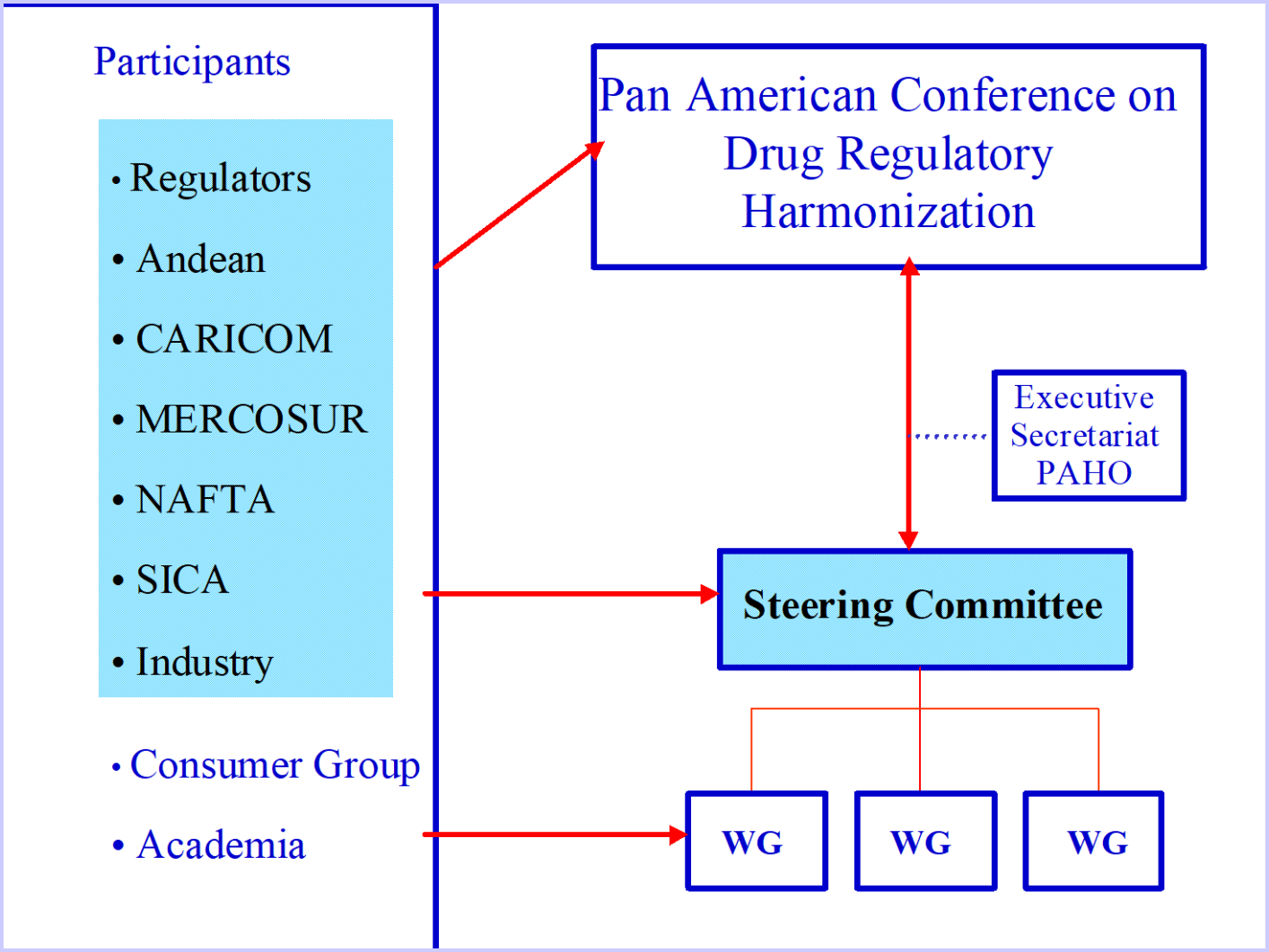
Pan American Network for Drug Regulatory Harmonization



PAN AMERICAN NETWORK ON DRUG REGULATORY HARMONIZATION (PANDRHA)

- PAN AMERICAN CONFERENCE ON DRUG REGULATORY HARMONIZATION
- STEERING COMMITTEE
- WORKING GROUPS
  - GMP
  - GCP
  - PHARMACOPEIAS
  - DRUG REGULATORY AGENCIES STUDY
  - BE
  - COUNTERFEIT
  - DRUG CLASSIFICATION

Secretariat

1. The Secretariat of the Network, the Conference and the Steering Committee will be provided by the Pan American Health Organization.

2. The Secretariat shall:

- Provide administrative and technical support to the Network
- Coordinate actions deriving from recommendations made by the Conference
- Act as a clearing house for information
- Arrange for expert advice and consultants to assist regulatory authorities in promoting drug regulatory harmonization, and
- Provide liaison, with similar programs such as ICDRA (organized by WHO), ICH and other national or regional trade agencies, and others as necessary

SUMMARY OF ACTIVITIES

- As agreed by the Conference & the SC
- Additional activities performed as Regional Program

RESOLUTION APPROVAL PROCESS

PAHO Director Request

USA Gov. Representative
January, 2000

I DRAFT (USA & PAHO)

PAHO Subcommittee
of Planning & Programming
February 2000

II Draft (PAHO)

PAHO 126 Executive Committee
June 2000

Final Proposal

PAHO 42 Directing Council
September, 2000

RESOLUTION

WG/BE I Meeting

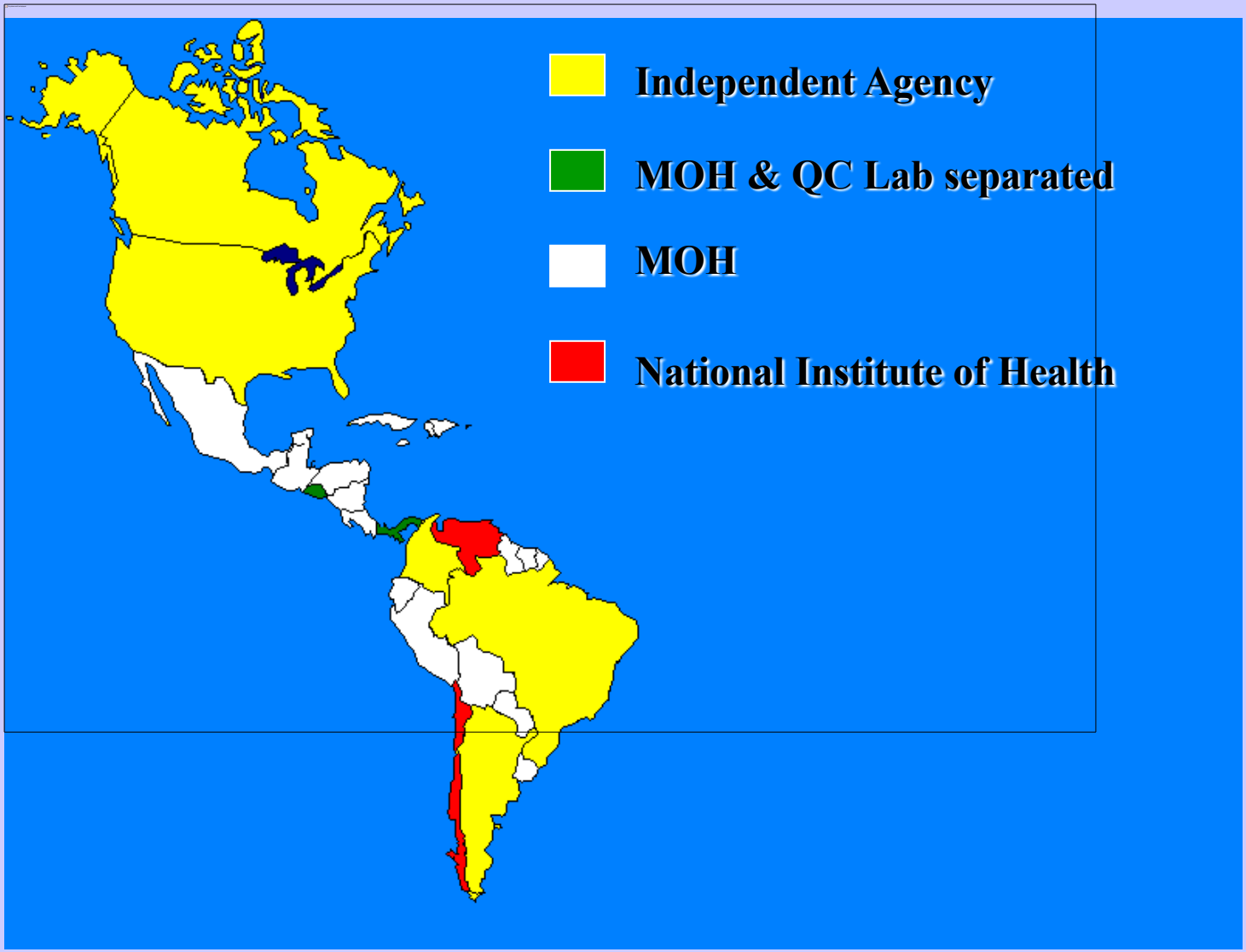
September, 2000

- Previous activity: AAPS Workshop on Biopharmaceuticals
- BE experts were invited to the workshop and to the meeting (observer)
- 37 Participants from 12 countries
  - 20 from 11 LA countries
- DRA/FDA, USP, University of Texas
- USP contributed with 1/3 of total cost

DRUG REGULATORY AGENCY STUDY

- Review on WHO doc. on DRA evaluation
- Informal agreement with CHI, COR, BRA / Pending for agreement HON/GUT, COL/PER
- Alternative options: University of Philadelphia or Two PAHO Consultants
- Present Status: pending

REGION OF THE AMERICAS
DRA MODELS



GOOD CLINICAL PRACTICES WG

March, 29-30

- Preliminary activity:
  - AAPS Congress of Pharmacy
- Objective:
  - Review the status of GCP
  - Define the Mission and objective of the WG
  - Prepare a two year Work Plan
- Coordinated by ANMAT/ ARG

RELATED ACTIVITIES

- Letters to Ministries of Health requesting confirmation of SC and WG Members (done)
- Memos to PWRs requesting support from Country PAHO offices
- Communications requesting funds (in process)
- Request response of the BE questionnaire (done)
- Documents on Legislation and criteria for drug classification (done, need up dating)
- Response of the GCP questionnaire (need updating)
- Proposal on Procedures for Member election of the SC (in process). Need for PS
- Develop a join work plan PAHO-USP in Quality Assurance (in process)

Regulation of Medicinal Plant
Regional meeting, Jamaica, November, 2000

- Organized jointly with TRM / WHO/HQ
- Experts, representative from selected regulatory offices and the industry participated
- Preliminary activity: background document
- Objectives:
  - Analyze medicinal plants and natural products regulation
  - Develop recommendations
  - Follow up recommendations:
- **Request for establishing a WG on Medicinal Plants**

Regulation and Use of Narcotic Drugs
Subregional meeting, Ecuador, December, 2000

- PAHO inter-programmatic activity: ED & NCD and organized jointly with CC Chicago and FIFE
- Participants included:
  - Representative form DRA
  - Responsible of National Palliative Care Program (Cancer Program) & National Cancer Institute
  - PAHO national consultants for ED
  - Representatives of NGOs
- Objectives:
  - To analyze the relevance of narcotic use in palliative care
  - To review the strengths and weaknesses of the availability and access to narcotic drugs in each participant country
- **Replication of the activity in other subregions. Next Step: Southern cone countries. Dec 2001**

Drug National Authorities CA&DOR Subregional meeting, Guatemala, February, 2001

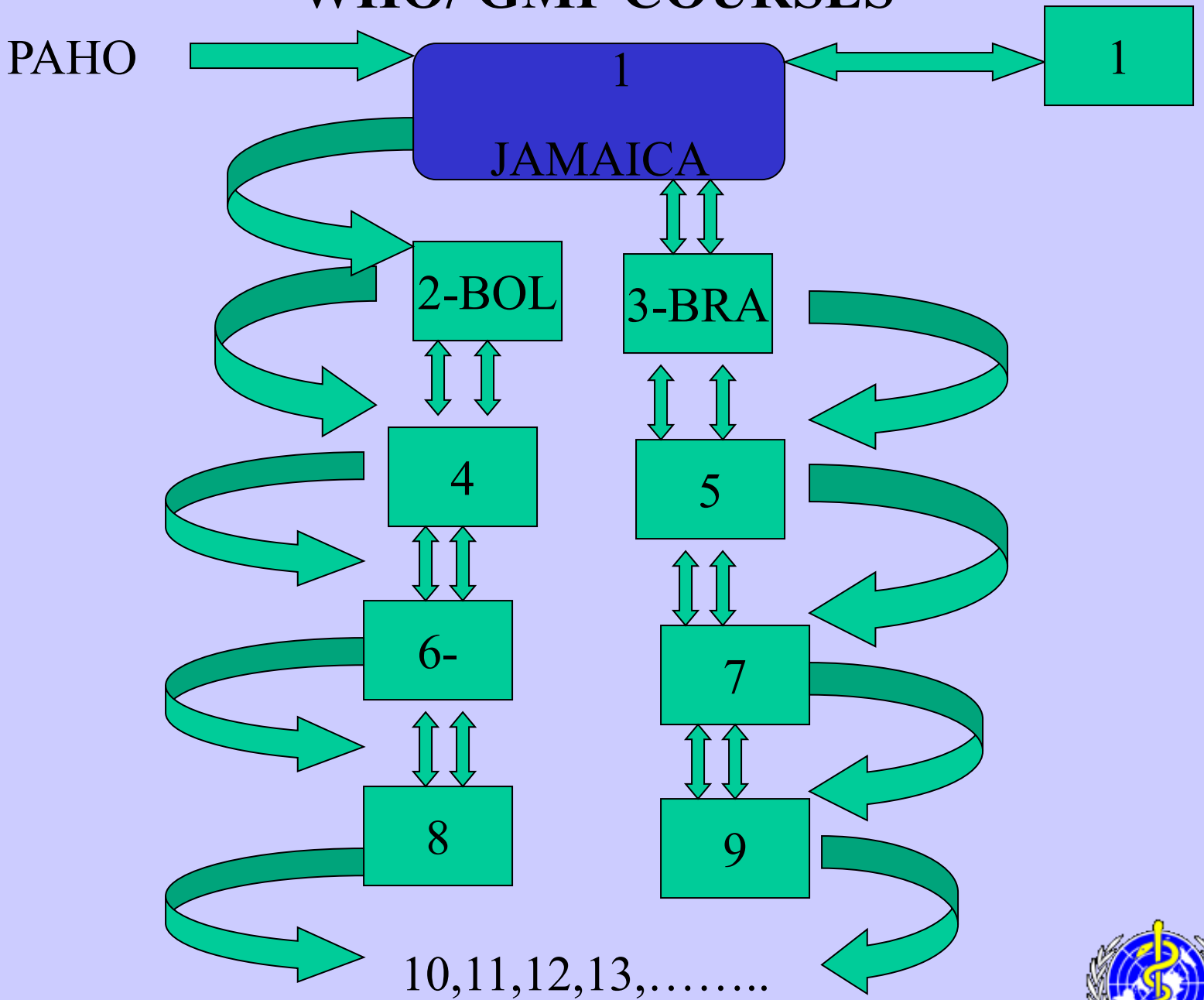
- PAHO inter-programmatic activity with support from the DRA
- Objectives:
  - Follow up to PANDRHA recommendations
  - Vaccine registration harmonization
  - Drug donation
  - Medical device registration
  - Follow up to Subregional project on drug programs
- Representatives from interested parties
- **To be replicated in other subregions. Next step: AA (May - June)**

WHO' GMP COURSE

Subregional Course. April, 2001

- Organized by PAHO/WHO & WHO/HQ
- Based on WHO modules and methodology
- Two International professors and two WHO Staff
- 14 Participants from CARICOM countries
- Trainer's from LA, from BRA and from Jamaica School of Pharmacy (2each)
- Intended to replicate the course (methodology and modules) throughout the Americas

WHO/ GMP COURSES



REQUIREMENTS TO REPLICATE THE COURSES

- Have at least two professors from a national pharmacy school train in the course
- Support from the Drug National Authority and the Pharmacy School (Political & Academic will)
- Support from two international professors
- A national organizer team:
  - Academic Committee
  - Planning Committee
  - Secretariat: PAHO (Local and HQ Office)

PHARMACEUTICAL CLEARINGHOUSE

MODULES

1.Industry and Market

2. Public Health Regulations and Quality

3. Economic Regulations

4. Drug Management

5. Drug Prices

6. Drug Utilization

PUBLIC HEALTH REGULATION AND QUALITY

1. DIRECTORIES
2. REGULATORY DECISIONS
3. LEGISLATION
4. REGULATORY HARMONIZATION
5. CURRENT ISSUES & STUDIES

REGULATORY HARMONIZATION

- PAN AMERICAN NETWORK ON DRUG REGULATORY HARMONIZATION (PANDRHA)
- MERCOSUR
- ANDEAN COMMUNITY
- CARICOM
- CENTRAL AMERICA INTEGRATION SYSTEM (SICA)
- NAFTA
- INTERNATIONAL CONFERENCE ON HARMONIZATION (ICH)
- EUROPEAN UNION MEDICINE AGENCY (EMEA)

OBJECTIVES OF WGs

- Examining existing regulations
- Identify differences gaps
- Setting up action plans
- To develop collaboration between countries
- Develop harmonized instruments
- Analysis of current issues

MAIN STREHGTH & DIFICULTIES

- High cooperation from PAHO Country Offices
- Low and slow response from countries
- Weak national institutional involvement
- Language meeting
- Communications
- Financing