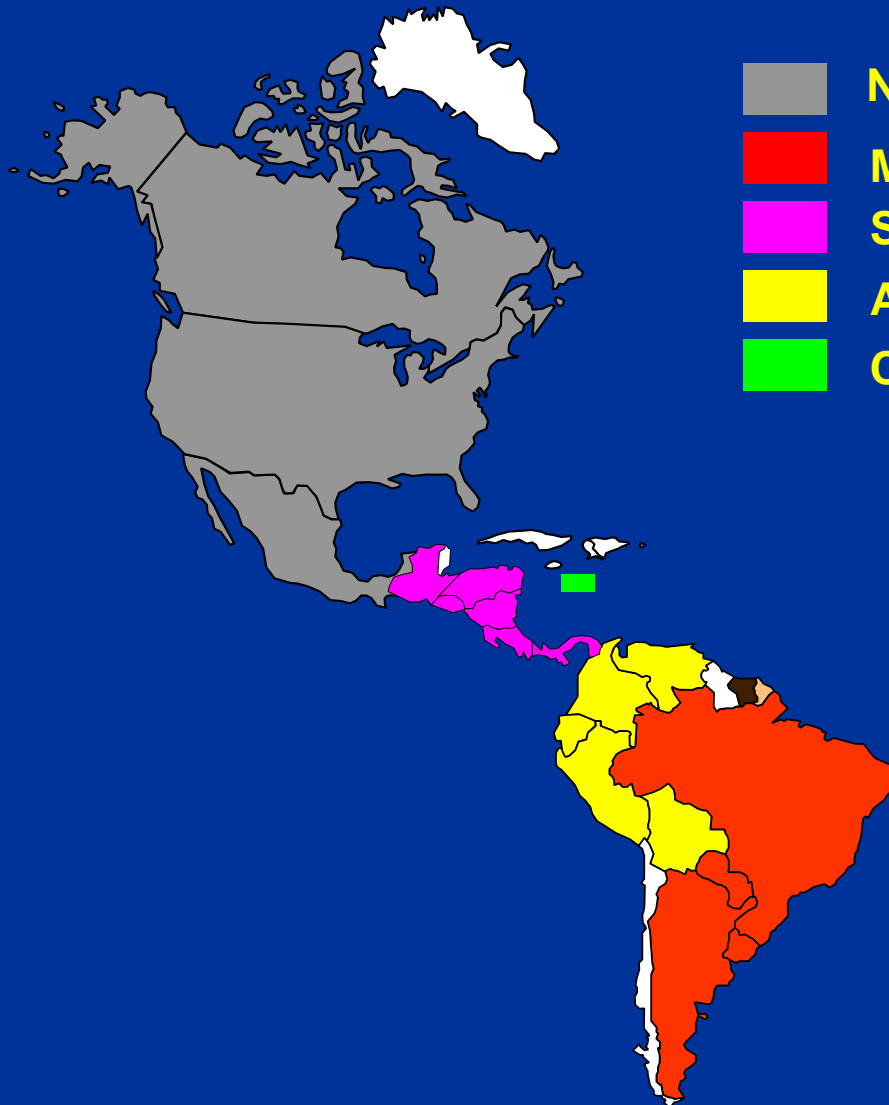




**PAN AMERICAN NETWORK FOR
DRUG REGULATORY
HARMONIZATION (PANDRH)**



Groups of Economic Integration in the Region of the Americas

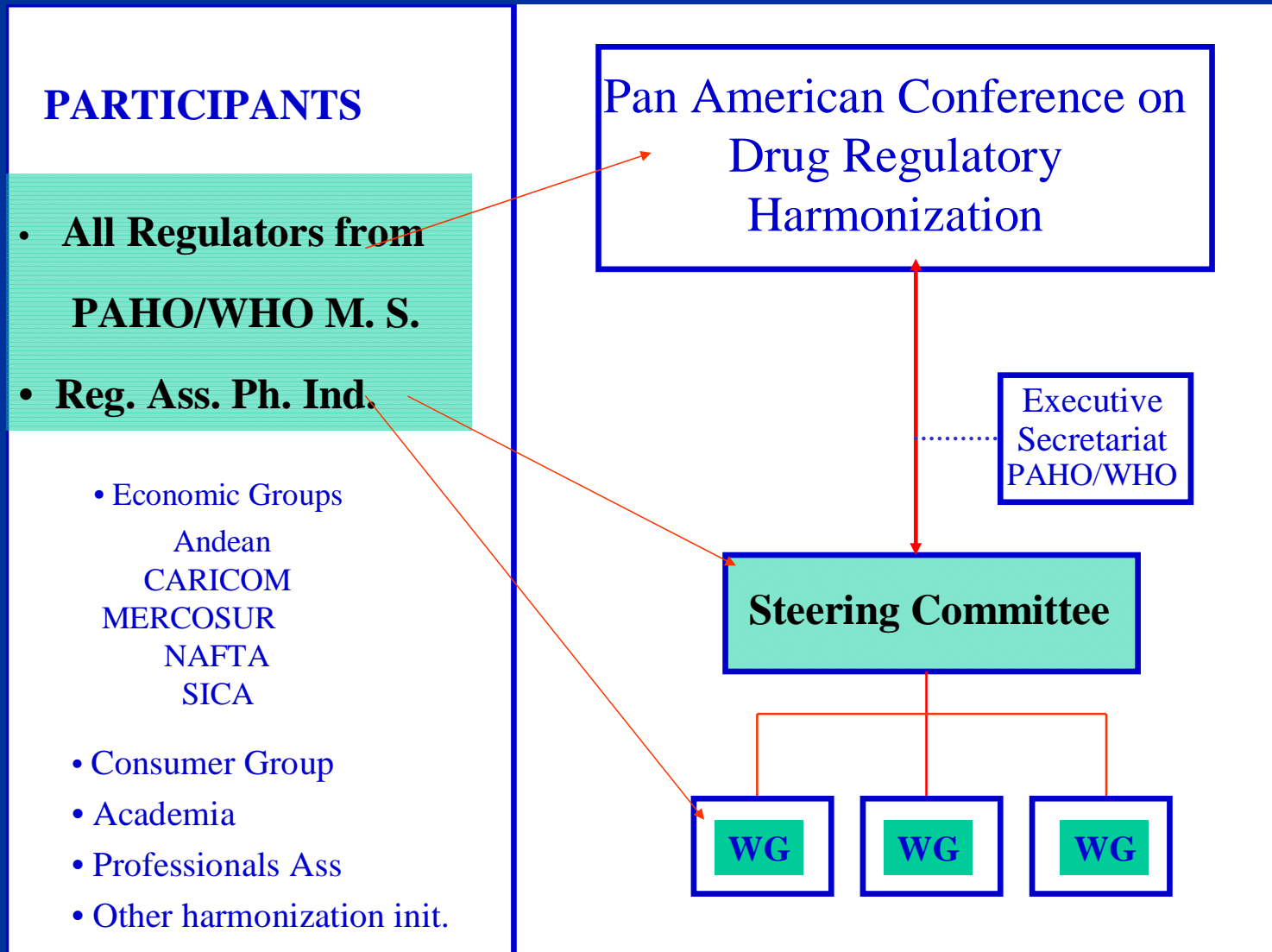


- NAFTA
- MERCOSUR
- SICA
- ANDEAN COMMUNITY
- CARICOM

BILATERAL &
MULTILATERAL:
REGIONAL
INTERREGIONAL
ALADI
HISPANOAMERICA
ICDRA
ICH

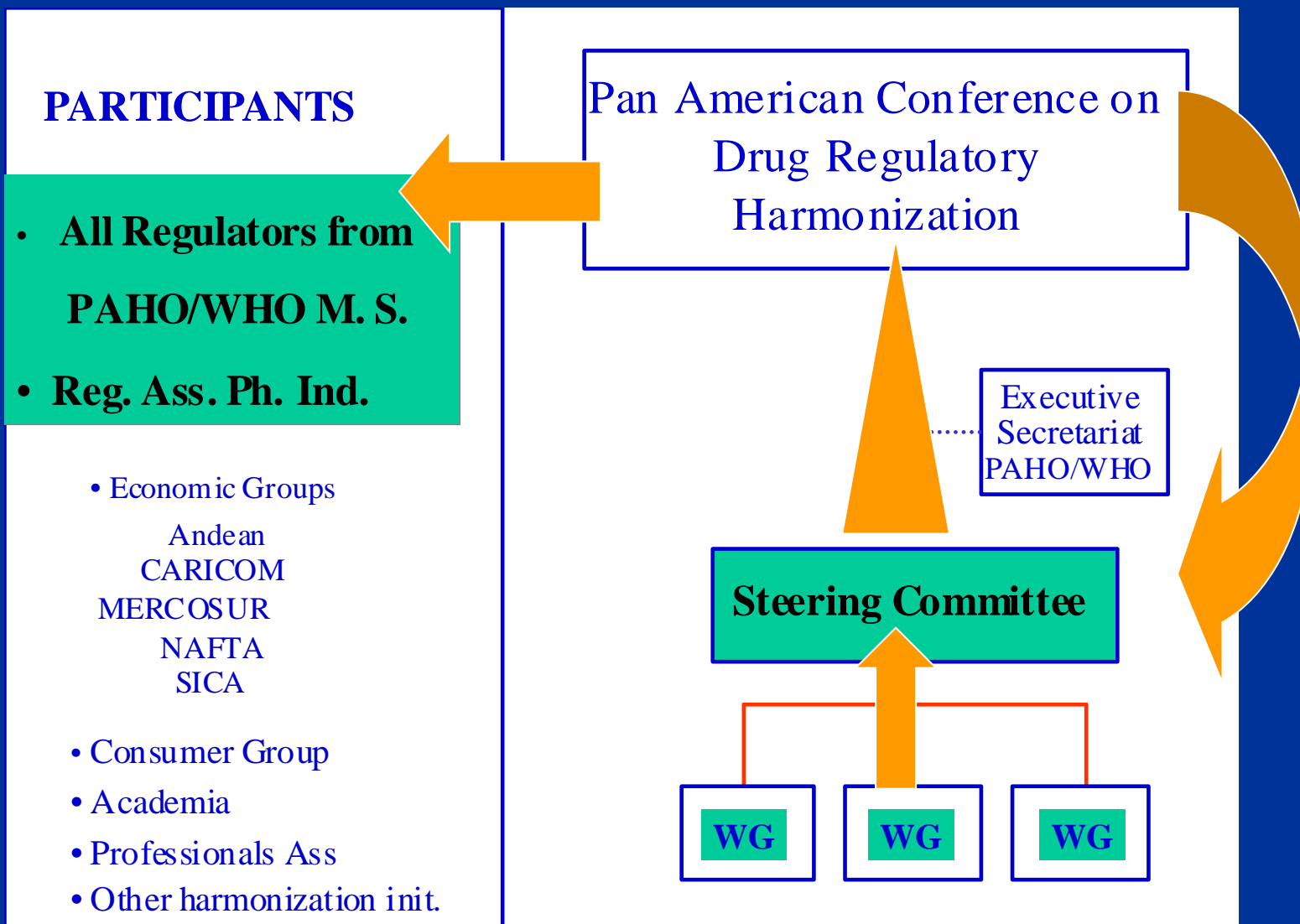


Pan American Network for Drug Regulatory Harmonization





Pan American Network for Drug Regulatory Harmonization





CONFERENCE: MISSION

The Conference should promote drug regulatory harmonization for all aspects of quality, safety and efficacy of pharmaceutical products as a contribution to the quality of life and health care of the citizens of the Member Countries of the Americas.

Mission

Objectives

Goals

Operation

www.paho.org



Steering Committee 2002-2004

□ 5 Regulatory authorities

Members

- Mexico
- Guatemala
- Jamaica
- Brazil
- Colombia

Altern

- * USA
- * Costa Rica
- * Trinidad & Tobago
- * Argentina
- * Bolivia

□ A representative of FIFARMA

□ A representative of ALIFAR

NGOs in the area of drugs and with official relations with PAHO can participate at the SC meetings as OBSERVERS



PANDRH / Working Groups

1. **Good Manufacturing Practices** (FDA/USA)
2. **Bioequivalence and Bioavailability** (FDA/USA)
3. **Good Clinical Practices** (ANMAT/ARG)
4. **Drug Classification** (MH/Guatemala)
5. **Counterfeit Drugs** (ANVISA/BRA)
6. **Pharmacopoeia** (USP)
7. **Medicinal Plants** (Health Canada)
8. **Drug Registration** (MH/Venezuela)
9. **Pharmacovigilance**



PANDRH: Education and Training (1)

- Integration of Universities and NDR
- Open to all sector: regulatory, academia and industry
- Translate into Spanish WHO training modules (based Report #32)
- Develop educational material based on FDA (GMP/BE)
- Implementation of:
 - GMP: 22 courses (665 participants)
 - BE: 2 sub-regional seminars (60 participants)
 - GCP: 2 national seminars (80 participants)
 - EQCP (HPLC/Dissolution Test): 2 sub-regional workshops (24 participants)



PANDRH: Proposals under development (2)

Regional Guideline for GMP Inspections based on WHO Report #32 and updated addendum's

Scientific criteria to apply in BE studies implementation

Methodology to establish common list of priority drugs to require BE studies

Regional Reference Products for BE studies

Standardization of drug monographs in pharmacopoeias in the Region

Implementation of the External Quality Control Program

Document of the Americas in GCP



PANDRH: Studies under development (3)

REGISTRATION: To identify differences and similarities in drug registration requirements of pharmaceutical products; to analyze possible effects of differences in the Q,S & E; to establish priorities of differences and to propose strategies to advance in the harmonization processes

BIOEQUIVALENCE: To study and compare national legislation on BE studies implementation and to establish priorities in harmonization processes

CLASSIFICATION: To compare national criteria and formulation of a harmonized proposal of criteria to classify OTC and prescription drugs



PAHO/WHO INVOLVEMENT IN PANDRH

1. **WHO MANDATE:** to act as directing and coordinating authority on international health work; and to develop, establish and promote international standards with respect to biological, pharmaceutical and similar products;
2. **PAN AMERICAN SANITARY CONFERENCE** supports the development of essential drug policies that include drug legislation and registration; drug manufacturing and marketing; and drug use and drug financing; that promotes the establishment of pharmaceutical services and drug information for health workers and public education promoting the rational use of medicines



ADVANTAGES OF PANDRH

1. It establishes a Pan American Forum to discuss common problems

- To strengthen NRA at individual level
- To promote constructive participation of all sectors
- To facilitate the establishment of a NDR network

2. Strengthens health issues prioritization in the process of economic integration

- To establish priorities in drug regulatory harmonization processes
- To facilitate continuity of technical agreements
- To encourage convergence of drug regulatory systems in the Region

3. Improves access to Q, S & E drugs

- To reduce unnecessary and duplicated requirements for drug registration which help the speed drug registration and marketing
- To harmonize acceptance of international standards of Q, S & E , which improve the quality of pharmaceutical markets



ADVANTAGES OF PANDRH II

4. DRA lead and participate in the process

- WGs are composed by technical staff of DRA, academia and representative from the industry. PAHO & WHO staff, and other experts participate as resource persons

5. It promotes technical cooperation

- Among countries: more developed DRA share knowledge and experiences with less advanced DRA
- Among interested parties: regulators, academia, industry and between the public and the private sector

6. It is a permanent opportunity for professional development

- Training is a major component of the initiative
- Improve the knowledge of international guidelines: WHO, ICH, Other region (EMEA), as well as national regulatory issues in the Region
- Pre or post PANDRH WGs meetings may include scientific national or international events to facilitate members participation



THANK YOU