Pan American Network for Drug Regulatory Harmonization

2nd Steering Committee Meeting

March 23-34,2001

Overview of the Pan American Network

for Drug Regulatory Harmonization

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Introduction

- Harmonization will reduce unnecessary and duplicative requirements
- Harmonization will expedite the availability of pharmaceutical products and reduce the costs of their development

Current Situation

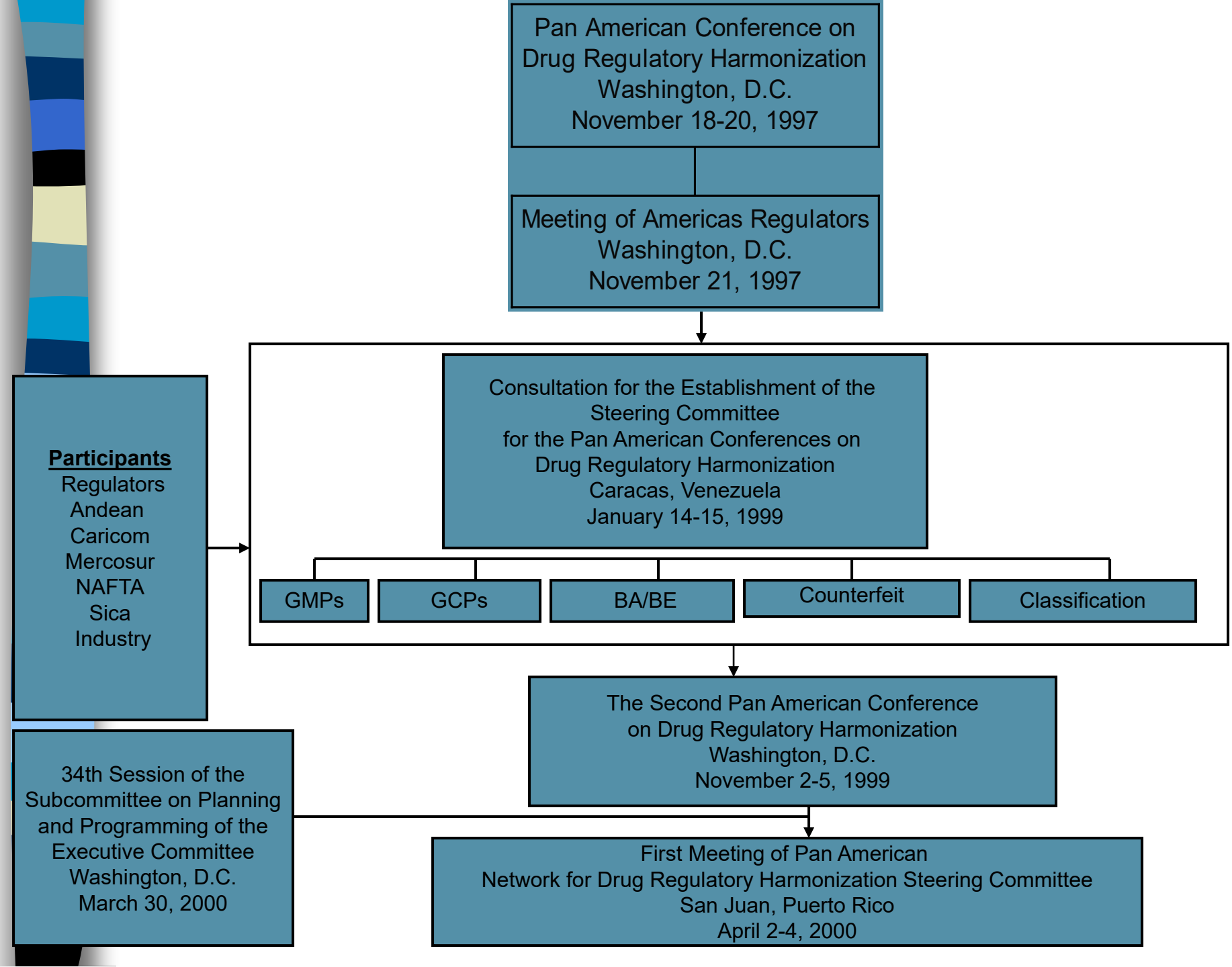
- **Global Harmonization: WHO and ICDRA**
  - **WHO: 1946** "…to develop, establish, and promote international standards with respect to food, biologics, and pharmaceuticals and similar products."
  - **ICDRA** Convened every two years by WHO, and promotes harmonization, exchange of information, and development of collaborative approaches to problems of common concern.
- **European Harmonization**
  - **EU** Harmonizes laws and regulations of member countries to promote public health and free circulation of pharmaceuticals within European trade areas.
  - **EMEA 1995** to oversee, coordinate, and facilitate European harmonization of pharmaceutical requirements.

Current Situation

- **ICH**
  - Established to improve through harmonization, the efficiency of the process for developing and registering new medicinal products in the European Union, Japan, and the United States
  - To ensure that quality, safe and effective pharmaceuticals are developed and registered in the most efficient and cost-effective manner
  - Over 40 guidelines developed in first 10 years
  - A subcommittee to on global cooperation was established

PAHO Activities Related to Drug Regulatory Harmonization in the Americas

- Region of the Americas
  - Promoting harmonization in the Americas will improve the health of the Region by facilitating the availability of safe, effective, and quality pharmaceuticals
- PAHO convened a series of three conferences
- Harmonization activities recognized as important


Pan American Conference on Drug Regulatory Harmonization
Washington, D.C.
November 18-20, 1997
Meeting of Americas Regulators
Washington, D.C.
November 21, 1997
Participants
Regulators
Andean
Caricom
Mercosur
NAFTA
Sica
Industry
Consultation for the Establishment of the Steering Committee for the Pan American Conferences on Drug Regulatory Harmonization
Caracas, Venezuela
January 14-15, 1999
GMPs
GCPs
BA/BE
Counterfeit
Classification
The Second Pan American Conference on Drug Regulatory Harmonization
Washington, D.C.
November 2-5, 1999
34th Session of the Subcommittee on Planning and Programming of the Executive Committee
Washington, D.C.
March 30, 2000
First Meeting of Pan American Network for Drug Regulatory Harmonization Steering Committee
San Juan, Puerto Rico
April 2-4, 2000

Pan American Conference on Drug Regulatory Harmonization

Washington, D.C., 17-20 November 1997

- Hemispheric forum be established
- PAHO as Secretariat
- Steering Committee
- Stakeholders

Consultation for the Establishment of the Steering Committee for the Pan American Conferences on Drug Regulatory Harmonization

Caracas, Venezuela, 14-15 January 1999

- Continuity
- Officially recognized
- Government endorsement

The Second Pan American Conference on Drug Regulatory Harmonization

Washington, D.C., 2-5 November 1999

- Harmonization--search for common ground
- Mission--to promote regulatory harmonization
- Pan American Network for Drug Regulatory Harmonization
- Steering Committee formed

First Meeting of Pan American Network for Drug Regulatory Harmonization Steering Committee

San Juan, Puerto Rico, 3-4 April 2000

- Structure
  - Canada; Guatemala; Jamaica; Brazil; Venezuela
  - FIFARMA; ALIFAR
- Developed a two-year work plan based on conclusions & recommendations from the November 1999 conference

Pan American Network for Drug Regulatory Harmonization

Work Plan 2000 - 2001

- **Priorities Approved by the Steering Commitee**
  - **First:Urgent Issues**
    - GMP
    - BA/BE
    - GCP
    - Counterfeit
  - **Second:Important Issues**
    - Classification
    - Drug Regulatory Agency
  - **Third: Recommended Issues**
    - Pharmacopoeia

Pan American Health Organization
Governance

- **The Subcommittee on Planning & Programming**
  - March 29-31, 2000
- **The Executive Committee**
  - June 26-30, 2000
- **The Directing Council**
  - September 25-29, 2000

42nd Directing Council Considerations

- Took into account that drug regulatory harmonization processes are fundamental for guaranteeing the safety, efficacy, and quality of drugs
- Recognized efforts in the Americas towards drug regulatory harmonization
- Aware that the Pan American Network for Drug Regulatory Harmonization will represent a concrete regional option for this process

42nd Directing Council Resolved

- **To urge Member States to:** Support national implementation of the agreements and recommendations arising out of the Pan American Network for Drug Regulatory Harmonization
- **To request the Director to:** Support the establishment of the Pan American Network for Drug Regulatory Harmonization and strengthen the role of PAHO as its Secretariat