THE PAN AMERICAN NETWORK ON DRUG REGULATORY HARMONIZATION

WORKING GROUPS

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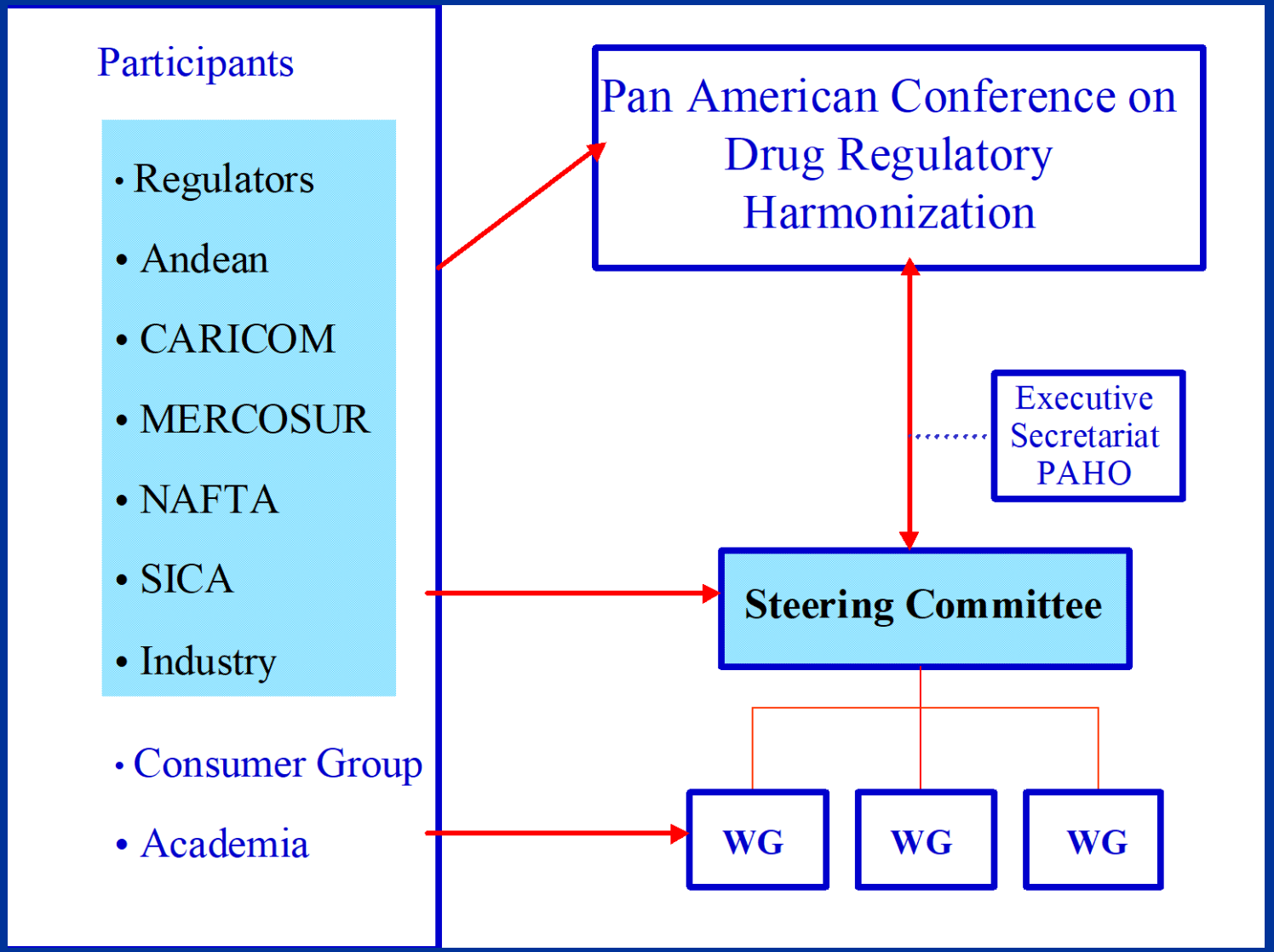
Pan American Network for Drug Regulatory Harmonization



Working Groups
Pan American Network for DRH

1.	Good Manufacturing Practices (FDA)	12
2.	Bioequivalence and Bioavailability (FDA)	10
3.	Good Clinical Practices (ANMAT)	10
4.	Drug Classification (BRA)	7
5.	Counterfeit Drugs (ANVISA)	9
6.	Pharmacopoeia (USP)	6
7.	Medicinal Plants (CAN)	10
8.	Pharmacovigilance	10
9.	Drug Registration	8
TOTAL WORKING DRUG MEMBERS		82

WORKING GROUPS I

- WGs are established by the SC based on Conference recommendations
- WG plans of work shall be approved by the SC
- WGs are coordinated by DRA (except from the GW on Pharmacopoeias)
- Members are selected by the SC
- Members are experts in the field (theoretical/practical)
- Members represent government or institutions (The MOH shall confirm gov. representatives)
- Members are not remunerated
- Each WG has even number up to 9
- Outside experts can participate as observers
- The meetings are jointly organized with other activities

WORKING GROUPS II

- The Secretariat keeps a CV of WG members
- Members who cannot attend two consecutive meetings are no longer members
- A substitute member in two consecutive meetings, become the member of the group
- No one can be member of more than two WG
- Continuity of WG members are encourage to assure effectiveness
- WG representation will be balanced within and among countries
- All WG meeting shall be convened by the Secretariat
- Proposals for NEW WG should be approved by the Conference

WORKING GROUPS OBJECTIVES

- To assess comparative studies and identify gaps;
- To develop harmonized proposals to be approved by the Conference;
- To identify strategies to implement approved proposals;
- To follow up at national and/or sub-regional level;
- To plan cooperation between countries;
- To develop a working plan between Conferences;
- To disseminate knowledge as the advantages of regulatory harmonization.

WG Aspects to review by the Steering Committee

1. **Member:**
   - Selection (also coordinators)
   - Expertise, sub-regional representation
   - Member performance and continuity
2. **Mission and Objectives**
   - Relevance to Conference recommendations
3. **Plan of Work**
   - To approve the Plan of work
   - To follow up plan implementation
   - To recommend issues to be addressed
4. **Impact on processes and results (Group Indicators)**
   - At National
   - At sub-regional levels

GMP (FDA)

- Members (10): EUA, ARG, BRA, CAN, GUT, CHI, MEX, VEN, ALIFAR, FIFARMA

- Assessment on GMP
- Workshops: two in UPR (FDA); One in CARICOM (WHO); and 18 in LA (WHO/GMP)
- GMP/WG work:
  - Harmonized guideline for GMP inspection
  - Indicators to follow up GMP implementation
  - Plan of work

WG/GMP
(2002 - 2004)

- Harmonized Guideline for GMP inspection developed and tested in two countries
- Joint inspection developed and implemented in at least three countries using the harmonized guideline
- Designed a proposed Plan to follow up GPM implementation by the industry
- Identified the minimal requirement for Drug Regulatory Agencies
- Training material for specific areas of GMP developed jointly with WHO / FDA
- Implementation of at least six educational activities with at least 180 professionals trained and updated in specific areas of GMP
- Report of Activities

WG/BE (FDA)

- Members (12): EUA, ARG, BRA, CAN, CHI, JAM, VEN, ALIFAR, USP, U. Texas, ALIFAR, FIFARMA
- Assessment on BE
- Designed and structured BE seminars (FDA)
- Sub-regional seminars: AA , CA
- Upcoming meetings: Mercosur, Mexico and Caribbean
- Approved proposals on:
  - Product of reference
  - Prioritization of BE studies
  - Indicators

BE Plan of Work 2002 - 2004)

- Criteria for prioritizing categories of drugs for BE testing and testing methodology analyzed and a proposal formulated
- Defined criteria for prioritize BE studies for low risk drugs
- Definitions of Generic drug and multisource drug in countries of the Americas identified and a harmonization proposal formulated
- Indicators for BE implementation identified
- Implementation of a new diagnostic study with quantitative data and changes from the previous study implemented in 2000 identified
- Training material (Module 1, 2 & 3) finalized by the FDA
- Training Seminars (Module 1, 2) in MERCOSUR, Mexico and Caricom (80 part.)
. Advance Training Seminar (Module 3) in at least one Subregion (35 part.)
- Nationals seminars in BE in at least three countries (90 partic.)
- Report of the WG

GOOD CLINICAL PRACTICES (GCP)
ANMAT, Argentina

- Members: (10) ARG, BRA, CARICOM, COR, CHI, CUB, EUA, VEN, ALIFAR, FIFARMA
- Assessment on GCP
- Status of GCP: Mission and objective of the WG
- TWO National Seminars on GCP (GUT, PER)
- Approved harmonized proposal on:
  - Ethic Committee
  - Proposal on Informed Consent
  - Plan of work
- The III Conference suggested:
  - Meeting (Americas - Europe) on use of placebo
  - Sub-group on pediatric

GOOD CLINICAL PRACTICES (GCP)
Plan of Work 2002 - 2004

- Responsibilities of Researchers and of sponsors, developed
- Guidelines of GCP for vulnerable groups: a) Pediatrics; b) Patients in emergency services; c) Illiteracy; d) Indigenous; e) Handicapped.
- Training programs being developed in the Americas identified
- 3 National Seminars on GCP implemented (PER, X, Y)
- Proposal on Use of Placebo discussed and formulated
- Proposal on evaluation of clinical protocols defined
- Identified Clinical Research on Medicinal Plants (w/ WG-Med. Plants)
- Guideline for GCP inspection developed and tested in two countries
- Mission and objectives for the GCP group reviewed
- Indicators of GCP implemented
- Report of the Group

DRUG CLASSIFICATION (2002 - 2004)

- **Members (7): ARG, BRA, COR, COL, CAN, GUT, FIFARMA**
- Comparison study including a matrix on Drug Classification criteria of all countries (Including other regions), identifying common criteria
- Different expertise are required to address classification between nutraceutics cosmeceutics, etc.in this regard, the WG will limit its actions to gathering information (Jointly w/Med. Plants)
- Harmonized Proposal on definition and criteria for drug classification (prescription vs OTC)
- Ethical criteria for drug promotion emphasizing OTC and prescription drugs
- Report of the WG

COUNTERFEIT (ANVISA, Brazil)

- Members (9): ARG, BRA, CAN, COL, PAR, VEN, CARICOM, ALIFAR, FIFARMA
- Regional Assessment
- Approved proposal
  - Definition
  - Action Plan: regional and national strategies

COUNTERFEIT (ANVISA, Brazil) (2002 - 2004)

- Budget proposal for implementing the Plan of Action developed
- Data Base design and implemented in at least three countries linked with the WHO database
- Educational modules for seminars on How to Combat counterfeit drugs developed
- Educational national seminars implemented in at least three countries
- Standard guideline for notification of counterfeit drugs developed
- Network of national focal point on Combating drug Counterfeit, established
  - Work plan for implementing mechanism
- Report of the WG

PHARMACOPEIAS

- Members (5): USA, BRA, MEX, ARG, COL
- Agreements:
  - Extranet development (USP)
  - Database of Monographs (BRA)
  - Regional Format for Monographs (ARG)
  - Compendium “Pharmacopoeia of the Americas”
    - New pub 2005
  - Approved proposals on
    - Plan of work
    - Establishment of an Expert Body (PAHO,USP, CANADA)

Pharmacopoeia & EQCP (2002 - 2004)

- Standardized format of database
- Standardized format for drug monograph
- Steering Committee of the Pharmacopoeia Group established
- Expert Group to support the Ph WG established
- External Quality Control Program:
  - Second and third phase of the program implemented
  - Cuba and the Caribbean official drug quality control labs participating in the Program
  - Plan of training seminars formulated
  - Training seminars implemented in at least three countries (40 parts)
  - Network of Official Drug Quality Control laboratories, reestablished and a collaborating program among them formulated
- Report of the WG

MEDICINAL PLANTS (CANADA)

- Members (11) CAN, BOL, BRA, MEX, COR, GUT, PER, JAM, BOL Univ. Chicago, Uni PAN
- The group will be officially established and operational
- Network for information exchange
- Harmonization of Glossary of terms
- Strategies for implementation of GACP
- The Mission and objectives will be established
- A plan of work will be prepared and initiate

PHARMACOVIGILANCE (2002 - 2004)

- Members (10) ARG, BRA, CHI, COL, COR, USA, GUT, PAR, CUB, FIF
- The group will be officially established and operational
- The Mission and objectives will be established
- A plan of work will be prepared and initiate
  - Criteria for immediate report and annual report of DRA (FDA, ICH, WHO)
  - Strategies for improving DAR reporting from physicians
  - Strategies to improve communication to people on risk products from DRA
  - Strategies to strengthen already existing WHO international network
  - Training activities in the Region on pharmacovigilance will be identified and their programs reviewed

DRUG REGISTRATION
2002 - 2004

- Members (8) BRA, JAM, BAR, BOL, ELS, VEN, ALI, FIF
- The group will be officially established and operational
- The Mission and objectives will be established
- A plan of work will be prepared and initiated
- Drug registration requirements is the first issue to be addressed by the Group

PENDING SUBJECTS TO BE ADDRESSED BY WGs

- Countries of reference- Manufacturer certification - Row materials - WHO GMP Certificate
- Pre-qualification of products for international market
- Pharmacological Norms
- Antimicrobial resistance
- Consumer / Patient Advocacy
- DRA Evaluation and Accreditation
- Transparency, Ethics & Conflict of Interest
- Drug marketing network & Pharmacy location and property
- Impact of Health Sector Reform in Drug Regulation

SPECIAL STUDIES

- Protocol to identify the impact of the pharmacists in community pharmacies developed by a regional Group and tested in at least two countries. Advance Report
- Protocol for a diagnostic study on Good Distribution and Good Dispensing Practices defined and tested in at least two countries. Advance Report
- A work plan for a feasibility study for a regional / subregional entity, developed

FROM THE III PAN CONF

(May 2002- May 2003)

- III Pan American Conference
- GMP National Seminars
- Conclusion of Special Studies on DRA
- WEB page
- WG/GCP Meeting
- WG/BE
- Regional TRM & WG/Medicinal Plants
- WG/ GMp, D Class % SC

COST OF IMPLEMENTED ACTIVITIES (May 2002- May 2003)

• III Pan American Conference:	130.000 (75.000)
• GMP National Seminars:	221.000 (66.300)
• Special Studies on DRA:	5.000
• WEB page	
• EQCP	
• WG/GCP Meeting:	20.000
• WG/BE:	20.000 (9.000)
• TRM & WG/Medicinal Plants:	36.000 (36.000)
• WG/ GMp, D Class % SC	45.000
•TOTAL:	477.000 (186.300)

WORKING GROUP MEETINGS

- (Pharmacopoeia not included)

once/year	twice/year
Med. Plants	GMP
Pharmacovigilance	BE
Classification	GCP
Drug registration	Counterfeit

UNTIL THE IV PAN CONFERENCE NOV 2004

•--MAY 03	AGO 03	FEB 04*	AUG 04
•GCP	GCP	GCP	GCP
•MPI	----	MPL	----
•BE	BE	BE	BE
•Class ----		Class	----
•-----	Vigil	----	Vigil
•GMP	-----	GMP	GMP
•----	Count	Count	Count
•----	Regist	-----	Regist
•SC	----	SC**	----

•*Meet before ICDRA Madrid

•** Meet as pre-ICDRA (TBC)

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To be financed: Not included WG/P, FIFARMA, ALIFAR, and including a rep from the Secretariat:		64

EDUCATIONAL ACTIVITIES

UNTIL THE IV PAN CONFERENCE

NOV 2004

- **SIX GMP National Educational Seminars (20.000 each)**
- **TWO GCP (jointly w/WG meeting. No additional cost)**
- **Three BE (Caribbean, Argentina) (35.000)**
- **One BE (MEX) (10.000)**
- **One BE Statistics (TBD) (35.000)**
- TOTAL FUNDS: 100.000

PANDRH BIENIAL OPERATING COST

- WG/meetings (90.000 x 2/year: 180.000)
  (360.000/biennium)
- Annual SC meeting (20.000 x 2: 40.000)
- Educational Seminars (100.000)
- Studies / GMP inspections (50.000)
- Conference (150.000)
- TOTAL: US$ 680.000/ biennium
  (500.000 2003-2004)