Second Meeting of the Working Group on Good Manufacturing Practices

Mexico City, Mexico
5-7 May 2003

Pan American Health Organization
Regional Office of the
World Health Organization
PAN AMERICAN NETWORK ON DRUG REGULATORY HARMONIZATION
(PANDRH)

SECOND MEETING
WORKING GROUP ON GOOD MANUFACTURING PRACTICES

Mexico City, Mexico
5-7 May 2003

PARTICIPANTS

Elsa Castejón, MSDS Venezuela
Stephen McCaul, Health Canada (in lieu of France Dansereau)
Suzana Machado Avila, ANVISA
Magdalena Reyes, Instituto de Salud Pública de Chile
Rodolfo Monchetto, ANMAT (in lieu of Carlos Chiale)
Marisela Benaim, ALIFAR (in lieu of Miguel Maito)
Justina A. Molzon, FDA, Coordinator
Marco A. Vega, FIFARMA
José Luis Aguilar, MSPAS Guatemala (arrived a day later)

Resource Persons
Rebeca Rodríguez, FDA
Mildred Barber, FDA

Others
Suleta García, COFEPRIS
Rosa María Morales, COFEPRIS

Secretariat
Rosario D’Alessio, PAHO/WHO
AGENDA

1. Overview of PANDRH and background information on the activities of the WG/GMP: Justina Molzon (Annex 1)

2. Past and Future Educational Activities
Justina Molzon presented details on the educational activities and the participants made several comments:

- There is a need to increase educational activities
- The WHO modules were considered less demanding than the WHO-1992 standards requirements
- It is recommended to combine the content of both educational modules / programs: WHO education modules and FDA documents.
- While some countries replicated national seminars, there are some that need more support and involvement of schools of pharmacy of universities to implement more educational activities
- The GW/GMP recognized that the educational activities should be self-financed
- Regional seminars and national seminars promoted by PANDRH should be primarily addressed to those that can replicate the activity at a national level
- There is a need for a more appropriate and accurate selection of the participants to the regional and PANDRH courses
- The ideal team to replicate the activities are universities, official inspectors and the industry
- The next courses need to be focused on a specific area of GMP such as validation, water, etc. It was noted that WHO has recently prepared special modules.

3. The III Pan American Conference on Drug Regulatory Harmonization: Review of the Recommendations and Decisions made to the WG/GMP: Justina Molzon


- Emphasis was made on the responsibility of members to participate in the WG meetings, the membership continuity and the need to receive confirmation from the Ministry of Health regarding the members representing governments. The members were urged to send their CV to the Secretariat.

5. Guideline for GMP Inspection

- The group reviewed the draft guideline previously distributed to all members. A. Monchetto, in lieu of C. Chiale (member from Argentina), presented the guideline.
- The guideline has 12 chapters and is based on the WHO-92 requirements
- The group acknowledges that the guideline is being discussed at MERCOSUR and that so far they have reached consensus until chapter 8. Even though it was noted that the draft guideline is under discussion, the guideline will be considered from this moment as a draft for the WG work.
- The final draft of the guideline will include recommendations from each member of the group.
- Some of the main discussions included:
  - **Validation**: The guideline should have a separate chapter on this subject which should include validation of water, of processes and of information systems
  - **Segregation Areas (penicillin - cephalosporin)**: Even though the majority of members agreed on the idea of having segregation areas for manufacturing avoiding cross-contamination, it was recognized that the requirements of WHO needed to be more clear and to include examples to avoid confusion and contradictory criteria on this subject.
  - R. Monchetto from Argentina was designated responsible for including the comments and recommendations of the members in the final version of the draft and for sending it to the Secretariat by the end of May 2003.
  - Major concerns regarding risk factors, flow and a possible need for inspectors training were expressed.

- General requirements should be considered previous to the inspection. Only manufacturers in operation should be inspected. The manufacturer should have:
  - A list of products with registration number and pharmaceutical forms
  - A quality control system in place
  - A continuous training program
  - Updated documentation (ISO 2000)
  - Statistical analysis of problems related to quality
  - Organizational structure with a clear separation of quality control from production and a clear definition of the staff responsibilities
  - A professional responsible of quality assurance with direct relation to the management of the company
  - An architectural design of its facilities (water / air equipment location)
  - An official authorization to operate (national/local)

6. **Process to validate the GMP Guideline**
   There will be two processes in parallel:
   - A pilot phase for validating the use, comprehensiveness of the GMP guideline for inspections as it will be in its final draft (to be sent to PAHO by R. Monchetto by the end of May).
   - The guideline will be tested by a group of three inspectors.
- No member of the WG/GMP will be part of the team of inspectors. Two will be inspectors from regulatory offices and one from PAHO/WHO who will lead the team.
- The two inspectors from the regulatory offices should not be from the country where the inspection takes place. No representative from the industry will be part of the inspector team.
- The members of the team to perform the pilot will be hired by PAHO/WHO.
- The pilot’s objective is to validate the guideline. Thus, it should focus on what in the guideline is not relevant; what is needed and not included; what is contradictory; what is a priority and what is complementary; and what needs to be supported by a national legislation.
- The information gathered during the pilot is confidential. The documents obtained from the inspections will be filed in the PAHO/WHO office.
- It was suggested to validate the guideline in manufacturers of at least two different lines of products.
- The inspection will take five days at least.
- The countries and the site for the inspections will be determined by FIFARMA and ALIFAR. It was recognized that since this is a validation of the guidelines, the manufacturer should volunteer for inspections.

- As recommended by the III Conference (see Report), the guideline will be accessible to all interested parties through PAHO’s webpage which will include an Internet address where comments can be sent to.
- There will be a post-pilot evaluation of the guideline.
- In May 2003, R. Rodriguez (FDA) will send the questionnaire used by the FDA to all members. S. Machado (Brazil) will consolidate comments.

Schedule of Implementation:

<table>
<thead>
<tr>
<th>DATE</th>
<th>ACTION</th>
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<tbody>
<tr>
<td>30 May 2003</td>
<td>A. Mochetto will send the final draft of the guideline</td>
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<td>30 May 2003</td>
<td>R. Rodriguez will send the questionnaire to evaluate the guideline</td>
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<td>June 2003</td>
<td>PAHO will conform the inspectors team</td>
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<td>June 2003</td>
<td>FIFARMA &amp; ALIFAR will send names of manufacturers (site of inspections)</td>
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<tr>
<td>July 2003</td>
<td>Guideline in PAHO’s webpage</td>
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<tr>
<td>July-September 2003</td>
<td>Guideline receiving comments through PAHO’s webpage</td>
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<tr>
<td>August-September 2003</td>
<td>Inspections in place</td>
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<tr>
<td>October-December 2003</td>
<td>PAHO will consolidate comments</td>
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<tr>
<td>January 2004</td>
<td>Next meeting</td>
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Note: On 7 May 2003, the Steering Committee approved the proposal presented by the WG/GMP on the validation of the guideline.

7. **National Quality Assurance Systems presented by Venezuela**
   - NRA should implement a Quality Management System.
   - E. Castejo (Venezuela) will incorporate the requirements from Canada in the proposal.
   - The final proposal will be presented and submitted for approval at the Conference.

8. **Next Meeting**
   Date: January
   Place: To be determined
   Subjects:
   - Results from the pilot
   - Review of the comments received through PAHO’s webpage
   - Possible training of inspectors for appropriate application of the guideline
   - Quantitative qualification of the guideline (ponderation)
3rd Meeting of the PANDRH Steering Committee 7-8 of May 2003 Mexico City

Report

GMP Working Group

Justina A. Molson, M.S. Pharm., J.D.
Associate Director for International Programs Center for Drug Evaluation and Research
U. S. Food and Drug Administration


- Priorities Approved by the Steering Committee
  - First: Urgent Issues
    - Good Manufacturing Practices
    - Good Clinical Practice
    - GCP
    - Counterfeit
  - Second: Important Issues
    - Classification
    - Drug Regulatory Agency
  - Third: Recommended Issues
    - Pharmacopeia

GMP WORKING GROUP WORKPLAN 2000–2001

- Training program design
- Implementation of training programs
- Mechanism for monitoring GMP implementation
- Identify standard under development in other Forum (ICH) (Consultation GMP)
- Joint inspection/observation (sharing documents)
- Working Group meeting

GMP WORKING GROUP TEAM MEMBERS COORDINATOR: FDA/USA

- Contact Person: Justina Molson
- Tech Leads: Millie Barber, Rebeca Rodriguez
- ALIFAR: Miguel Mauro/Mauroisela Benaím
- Argentina: Carlos Chialio/Rodolfo Mochetto
- Brazil: Antonio Bezerra Suzana Machado de Avila
- Canada: France Darsenne/Stephen McCaul
- Chile: Magdelena Royes
- FIFARMA: Marco Antonio Vega
- Guatemala: Emeralda Vitalgajoj Jose Luis Aguilar
- Venezuela: Elsa Castellón

The Second Pan American Conference on Drug Regulatory Harmonization Washington, D.C., 2-5 November 1999

Recommendations on GMPs

- The training program for GMPs that the FDA proposes to carry out with the UPR and PAHO/WHO should be institutionalized
- The program should rely on contributions from government and industry in the interested countries, include distance learning, and take advantage of the installed capacity of the Region.

SURVEY ON GMP

- To progress the topic, a survey concerning pharmaceutical GMP training was developed and sent to Latin American Regulators
- Responses from 12 countries
- Used to prepare for a meeting of interested parties to the pharmaceutical activities under the FDA/USDA and University of Puerto Rico Partnership
- Latin American regulators invited to attend
SURVEY QUESTIONS

- Are GMPs legally required of drug manufacturers?
- Are these spelled out in laws or regulations?
- How many manufacturing sites in the country and how many full time inspectors perform inspections and enforce compliance?
- Are certificates of GMP compliance issued?
- Is there a legal requirement for imported pharmaceuticals to be manufactured under GMP?
- How is compliance determined?
- What kinds of GMP training would be useful for your country?

FDA SYSTEMS-BASED cGMP INSPECTION PROGRAM

- Concept adapted to UPR GMP training program as it represents state of the art
- More efficient use of resources
- More cGMP inspections in less time
- Coverage of 2 or more systems with mandatory coverage of Quality System
- Inspect minimum number of systems to provide basis for overall CGMP decision

National GMP Workshops Based on WHO Educational Modules

- Based on the WHO report 32 on GMPs
- First workshop in Jamaica, April 2000
- Translated into Spanish and implemented in all Latin American countries
- “Road Show” taught by Professors
  - University of Costa Rica
  - National University of Colombia
  - the Central University of Venezuela

The Pan American Network for Drug Regulatory Harmonization's GMP Working Group

First Meeting
Caracas, Venezuela
3-4 March, 2002

Mission of Working Group

To promote the knowledge and implementation of GMPs as a strategy for improving the quality of medications in the countries of the Americas.

Promover el conocimiento y la implementación de las Buenas Practicas de manufactura, como una estrategia para el mejoramiento de la calidad de los medicamentos, en los países de las Americas.

Prioritized Objectives

Through individual and collective exercises the participants proposed for the GMPWG the following objectives, listed in order of priority:
- Knowledge--Education/Training
- Development of a Harmonized Guideline for GMP inspection
- Monitoring GMP implementation
- Support to Regulatory Authorities
The Pan American Network for Drug Regulatory Harmonization
2nd GMP Working Group
Mexico City
May 5-7, 2003

RESUMEN
Buena Discussion
Mucho Trabajo y Esfuerzo

2nd Meeting of the Working Group
Good Manufacturing Practices
AGENDA

- III Pan-American Conference recommendations and decisions.
- Guide for Inspection of GMP, approval of a final proposal "SC"
- Strategies to implement Guide for Inspection of GMP "SC"
  - Responsibilities of the group
  - Selection of countries
  - Inspectors and places for the test pilot

2nd Meeting of the Working Group
Good Manufacturing Practices
AGENDA

- Education/Training Activities
  - Strategies for the second round of courses
- Review a proposal from Venezuela on strategies to implement/pursue GMP
- Revision of the plan of work
  - Present state
  - Responsibilities of each member

III Pan-American Conference
Report of GMP Working Group

- Please refer to the reports distributed in English and Spanish
- Highlights
  - Mission (endorsed by the Conference)
  - Objectives and Work Plan (endorsed)
  - Report of Educational Activities
  - Initial Diagnostic Study (Spanish)

III Pan-American Conference
Recommendations and Conclusions
HIGHLIGHTS

- Continue training activities
- Encouraged adoption of WHO GMP 92
- Recognized GMP prior condition to BE
- Harmonized Guide for GMP Inspections
  - Post on PANDRH Web to facilitate accessibility/obtain comments
- Disseminate information on WGs efforts
- Indicators for implementation of GMPs
Guide for Inspection of GMP
- WG spent past two days discussing proposed document
  - Drafted by ANMAT
  - Follows WHO GMP 92
  - 12 chapters/areas of focus
  - 61 pages long
- WG proposed additional language and revisions to be incorporated into Guide
- Integrate WG recommendations by 5/30

Strategies to Implement Guide for Inspection of GMP
- Post on PAHO Web for Comments
  - 2 months
- PAHO to collect comments from Web
  - 4 months
- Anticipated sources of comments
  - Members of GMP WG
  - Drug Regulatory Authorities
  - Sub Region
  - Industry
  - Other interested groups and persons

Strategies to Implement Guide for Inspection of GMP
- Consolidate acceptable comments
  - 1 month
- Final Draft used for Pilot of Guide
- Review PIC/S SOP and apply to Guide
- Develop SOP for Guide
  - June 2003
- Evaluate Guide post Pilot
  - Possible use of FDA questionnaire used in Quality Systems Pilot

Pilot Plan Guide for Inspection of GMP
- Scheduled for July – September 2003
- 3 participants
  - 2 DRA Inspectors + PAHO/WHO
- Confidentiality 100% guaranteed
- At least 3 inspections
- Recommended
  - 2 types of dosage forms/production lines
- Duration of inspection will be 5 days

Next Meeting of Working Group
- December 2003 or January 2004
- Discussion of impact of comments on the Guide from interested parties
- Quantify value of Guide based on Pilot
- Planning of training/education efforts

Wrap up and Action Items
- Elaborar metas a largo plazo.
  - Resp: M. Vega, S. Maccaul
  - Fecha: Julio 2003
**Entrenamiento**
- Curso Avanzado en GMP, basado en Curso FDA, comparado con Reporte 32, 34 y 37 de la OMS.
  - Incluye: agua, aire, esterilización
  - Mayo: Enviar CD (R. Rodríguez)
  - Julio: Revisar comentarios
  - Agosto: Consolidar comentarios (Susana)
  - Septiembre: Teleconferencia

**Gestión de calidad**
- Se recomienda implementar por parte de las autoridades regulatorias de cada país un sistema de gestión de calidad.
  - Se recomienda que el Steering Committee solicite a la conferencia la implementación de dicha gestión de calidad con los diferentes gobiernos

**Comparación de Regulaciones**
- Cada país revisará como comparan sus propias regulaciones contra la guías 32,34 y 37 de la OMS
  - Se sugiere que por medio de PAHO se solicite dicha revisión a los países.
  - FIFARMA coordinará este esfuerzo, recopilara y organizará la información.

**Cuestionario Armonizado**
- Integrar el G.T. Mayo 30. (R. Monchetto)
  - En Web. 1-2 meses
  - Comentarios: 4 meses
  - Consolidar: 1 mes (Rosario)
Guía técnica armonizada

- Prueba Piloto
  - 3 Cías (S. Comité proponer nombres)
  - 3 auditores y 1 observador del grupo.
  - Fechas: Julio – Sept.
- Procedimiento para auditoria
  - Elaborar PNO para uso de la guía,
  - Basada en PIC y WHO
  - Resp: E. Castrejón y M. Vega

- Cuestionario de evaluación de guía.
  - Basado en cuestionario de FDA
  - Resp: G. Safeta

Muchas gracias
Muito obrigada
Merci

Thank you
THE PAN AMERICAN NETWORK ON DRUG REGULATORY HARMONIZATION.

Working Groups Pan American Network for DRH

1. Good Manufacturing Practices (FDA) 12
2. Bioequivalence and Bioavailability (FDA) 16
3. Good Clinical Practices (ANMAT) 16
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 Pharmacopoeia)
• Members are selected by the SC
• Members are experts in the field (theoretical/practical)
• Members represent government or institutions. (The MOH shall confirm govt. representatives)
• Members are not remunerated
• Each WG has been number up to 8
• 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 encouraged 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:
   - Objectives and conference recommendations
3. Plan of Work:
   - To approve the Plan of work
   - To follow up on plan implementation
   - To address new issues
4. Impact on processes and results (Group Indicators):
   - National
   - At sub-regional levels

GMP (FDA)

- Members: EUA, ARG, BRA, CAN, GUT, CHI, MEX, VEN, ALIFAR, FIARMA
- Assessment on GMP
- Workshops: two in UPR (FDA); one in CARICOM (WHO); and 19 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 GMP inspection developed and implemented in at least three countries using the harmonized guideline
- Developed a proposed Plan to follow up GMP 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: EUA, ARG, BRA, CAN, CHI, JAM, VEN, ALIFAR, USP, U. Texas, ALIFAR, FIARMA
- 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; study and a proposal formulated
- Risk criteria for prioritize BE studies for low risk drugs
- Definitions of Generic drug and non-registered drug in countries of the Americas identified
- A harmonization of the proposal formulated
- Indicators for BE implementation identified
- Implementation of a new diagnostic study with quantitative data and changes from the previous study implemented in 2006 identified
- Training material (Module 1, 2 & 3) finalized by the FDA
- Training Seminars (Module 1 & 2) in Mercosur, Mexico and Caricom (40 part)
- Advance Training Seminar (Module 3) in at least one subregion (25 part)
- National seminars in BE in at least three countries (90 part)
- Report of the WG

GOOD CLINICAL PRACTICES (GCP)
ANMAT, Argentina

- Members: ARG, BRA, CARICOM, COR, CHI, CUB, EUA, VEN, ALIFAR, FIARMA
- Assessment on GCP
- Status of GCP: Mission and objective of the WG
- TWO National Seminars on GCP (GUT, PER)
- Approved harmonized proposal on:
  - Ethics Committee
  - Proposal on informed consent
  - Plan of work
- The III Conference suggested:
  - Meeting (Americans - Europeans) 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) Elderly; d) Indigenous; e) Handicapped
- Training programs being developed in the Americas identified
- 3 National seminars on GCP implementation (Peru, Y. T)
- Proposal on Use of Phases discussed and formulated
- Proposal on evaluation of clinical protocols defined
- Guidance for GCP implementation 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, COI, 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 nutraceuticals, cosmeceuticals, etc. In this regard, the WG will limit its actions to gathering information (jointly with Med. Planta)
- Harmonised 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)
(2002 - 2004)
- Members (9): ARG, BRA, CAN, COI, 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 implementation 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 guidelines for notification of counterfeit drugs developed
- Network of national focal point on Combatting drug Counterfeiting established
  - Work plan for implementing mechanism
- Report of the WG

PHARMACOPEIAS
(2002 - 2004)
- Members (5): USA, BRA, MEX, ARG, COI
- Agreements:
  - Extranet development (USP)
  - Database of Monographs (BRA)
  - Regional Format for Monographs (ARG)
  - Compendium "Pharmacopeia of the Americas"
  - New pub 2005
- Approved proposals on
  - Plan of work
  - Establishment of an Expert Body (PAHO, USP, CANADA)

Pharmacopeia & EQCP
(2002 - 2004)
- Standardised format of database
- Standardised format for drug monograph
- Steering Committee of the Pharmacopeia Group established
- Expert Group to support the PH WG established
- External Quality Control Program
  - Second and third phases of the program implemented
  - Cuba and the Caribbean official drug quality control laboratories participating in the Program
  - Plan of training seminars formulated
  - Training seminars implemented in at least three countries (40 participants)
  - National Oficial Drug Quality Control Laboratories, established and a coordinating program among them formulated
- Report of the WG
MEDICINAL PLANTS (CANADA)

- Members: 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 GACP
- Strategies for implementation of GACP
- The Mission and objectives will be established
- A plan of work will be prepared and initiated

PHARMACOVIGILANCE (2002 - 2004)

- Members: 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 initiated
- Criteria for immediate report and annual report of DRA (FDA, WHO)
- Strategies for improving DRA reporting from physicians
- Strategies to improve communication to people on the DRA
- Strategies to strengthen already existing (WHO) International networks
- Training activities in the Region on pharmacovigilance will be initiated and their programs reviewed

DRUG REGISTRATION 2002 - 2004

- Members: 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 - Raw 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 pharmacist in community pharmacies developed by a regional Group and tested in at least six countries: Advanced Report
- Protocol for a diagnostic study on Good Distribution and Good Dispensing Practices defined and tested in at least two countries: Advanced Report
- A review plan for a feasibility study for a regional or 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/GMPD, D Class % SC
COST OF IMPLEMENTED ACTIVITIES (May 2002 - May 2003)

- II Pan American Conference: 130,000 (75,000)
- GMP National Seminars: 221,000 (66,300)
- Special Studies on DNA: 5,000
- WED page: 29,000
- EQCP: 29,000 (9,000)
- TRM & WG: Medicinal Plants: 36,000 (36,000)
- GMP, D Class % SC: 45,000
TOTAL: 477,000 (196,300)

WORKING GROUP MEETINGS

- Pharmacopoeia not included
- Once/year: GMP
- Twice/year: BE
- Med. Plants: GCP
- Pharmacovigilance: Counterfeit
- Classification: GCP
- Drug registration: Counterfeit

UNTIL THE IV PAN CONFERENCE NOV 2004

- MAY 03: GCP
- AGO 03: GCP
- NOV 03: GCP
- FEB 04*: GCP
- AUG 04: GCP
- BE
- Class
- Vigil
- Coop
- SC

WORKING GROUPS Pan American Network for DRH

1. Good Manufacturing Practices (FDA) 12
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3. Good Clinical Practices (ANNMAT) 10
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TOTAL WORKING DRUG MEMBERS: 82

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)
- 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)