PAN AMERICAN NETWORK ON DRUG REGULATORY HARMONIZATION (PANDRH)
V STEERING COMMITTEE MEETING

Washington, D.C.
9-10 December 2004

REPORT

I. PARTICIPANTS

Members
Andean Area (AA):
1. Julio Cesar Aldana, INVIMA Colombia (Confirmed)
2. Victoria de Urioste, MOH Bolivia (Cancelled)

CARIBBEAN:
3. Princess Thomas Osbourne, Jamaica (Confirmed)

Central America:
4. Marta de Alvares. MOH Guatemala (Confirmed)

MERCOSUR:
5. Davi Rumel ANVISA-Brazil (Confirmed)
6. Manuel Limeres, ANMAT/Argentina (Cancelled)

NAFTA:
7. Albero Frati, SS-Mexico (Confirmed)
8. Justina Molzon, FDA-USA (Confirmed)

ALIFAR:
9. Miguel Maito, *in liú of* Rubén Abete (Confirmed)

FIFARMA:
10. Loreta Marquez, *in liú of Jose Manual Cousiño* (Confirmed)

Other Regulators:
11. CAN: Mike Ward (Confirmed)
12. Julio Valdez, MOH Guatemala

Observers/WG Members:
13. Roger Williams, USP (Confirmed, Dec 9)
14. Horacio Pappas, USP (Confirmed)
15. Hector Bolaños, ILAR / Drug Classification WG (Confirmed)

Secretariat:
PAHO/WHO
16. German Velasquez, WHO/EDM
17. Jorge Bermudez. Unit Chief THS/EV (Confirmed)
18. Rosario D'Alessio (Confirmed)

II. OPENING

The meeting was opened by German Velasquez (WHO/EDM) and Jorge Bermudez (PAHO/Unit Chief, THS/EV).

G. Velasquez stressed the current interest in the application of the DOHA declaration, particularly in the use of compulsory licensing as a mechanism for effective improvement of drug access.

J. Bermudez pointed out PAHO principles of Panamericanism and equity as well as main strategies for PAHO technical orientations: priorities countries, vulnerable populations, and inconclusive health agenda. He also talked about the four lines of work for the Unit of Essential Medicines: Access, Policy and Regulation, Health Technology and Management. He stated the importance of PANDRH's work as the most comprehensive conference programmed by the EV Unit; and, as a main component for the analysis of regulations, concepts and documentations of national experiences on generic policies and programs in the Region.

III. MINUTES

The meeting followed the approved Agenda (attached); and decisions were made in regards to each one of the items as indicated below.

IV. DECISIONS AND COMMENTS BY THE SC

GENERAL:

1) To explain at the IV Conference the PANDRH origin and development. It can be done during the report of the Secretariat;
2) It is necessary to establish how new documents are to be included in national legislations, adopted by countries, etc. It is important to consider "public hearings' in such processes;
3) It was confirmed that, according to PANDRH's rules, all Plan of Work of the WGs are to be approved by the SC and not by the Conference.
4) National and sub-regional representations at the WGs will be reviewed at the next meeting of the SC, which will be held right after the conclusion of the IV Conference (4 March after 2 p.m.);
5) Some of the future activities of the WGs will be discussed in an inter-working group approach;
6) All proposals will make emphasis in the need of intra and inter institutional collaboration in the implementation phase of all PANDRH proposals.

Goof Manufacturing Practices (GMP):

7) To include in the background of the Proposal: a) sub-regional and national references about their experiences in GMP inspection. It is important to make clear that the development of this guideline is not a "new" activity in the Region; b) to include a "political" component; c) to strengthen the need for mutual recognition among countries; d) to strengthen that the Guideline is not to be used as a check-list;
8) To include as a recommendation to the WG to work on Good Distribution Practices and pre-qualification of API suppliers (or certification mechanisms);
9) There is no conflict of interest with the participation of the industry in training workshops on the use of the Guideline; so training activities should be open to all: public and private sectors. Inspectors may have sessions in which the industry will not participate. But, training in GMP should mainly remain open to all sectors;

10) Training for Guideline inspections should be focused to those countries that are committed to adopt the Guideline.

Bioequivalence (BE):

11) The document on BE is being reviewed by the same WG. It is assumed that it will be ready for the Conference. At this moment, it is being aligned with new global criteria in some aspects included in the document.
12) Training modules 1 & 2 should focus on the document developed by the WG. Module 3 & 4 should be organized as specified in the training program developed initially.
13) To include the endorsement of the WG mission and objectives in the proposal;
14) The proposal should point out that the concept of "health risk" is an innovative strategy that will be very useful to countries for the harmonization of the list of drugs that require BE studies;
15) To help harmonization processes, it will be helpful to have harmonized analytical methods for BE studies. Some discussion rose around if the analytical methods are for BE WG or not, for the Pharmacopoeia WG, or for a sub-group. It may be helpful to have compendia. This case should be discussed by both WGs;
16) It was suggested to include in the plan of work: a)requirements for GMP in cases of changes in manufacturers of AFI (changes post-marketing).

Good Clinical Practices (GCP):

17) To include more information in each activity of the plan of work;
18) To recommend the implementation of joint inspections on GCP in ongoing researchers.

Drug Registration:

19) To use the term "to adopt" rather than "to approve" (this is valid for all proposals);
20) To use the term "national legislations" rather than "national regulations"
21) To eliminate # 9 of the recommendations since the subject is not a matter of integration in some sub-regional integration groups such as NAFTA. This number was referred to: *To monitor the adoption of the proposal by the countries of the Region and submit a report prior to the next Pan American Conference on Drug Regulatory Harmonization*; and

Classification

22) To eliminate # 8 of the proposal (OTC can be sold in pharmacies and other stores for general products) since in some countries, it could be considered as promoting to sell drugs outside the pharmacies.
23) To integrate the part on "additional criteria" to the general criteria (of the proposal).
24) To recommend that the IV Conference establishes a WG on Drug Promotion to address the following points: a) To establish a regulation to prevent that the use of names for medicines induce to error or confusions; b) the use of umbrella brands to be used in packages along with different colors and to clearly identify indication or drug therapeutic use as an extension of the name; c) to use a clearly identifiable difference between OTC and prescription drugs such as color, logo, information, etc. and d) in agreement with NRA and the industry, to define an ethics code for drug publicity to allow the implementation of a surveillance system.

    The Representative form Brazil at the SC (Davi Rumel) is responsible to prepare a background to support the establishment of a WG on Drug Promotion.

25) To eliminate reference to Herbal product since PANDRH has a WG on that subject
26) That the WG on Drug Classification, with participation of an specific expert, addresses the subjects of: dietary supplements; cosmetics; medical devises, diagnostic reagents, and dentistry products;
27) That PANDRH, either through the WG on Drug Classification or any other WG prepare a harmonized proposal on categories and active pharmaceutical ingredients (strengths, pharmaceutical forms and indications) susceptible of being considered OTC.

Pharmacopeia:

28) The WG under the responsibility of Horacio Papas will prepare a proposal document (with background and proposals) similar to those prepared by the Secretariat for the other WGs, in regard to the work being done by the WG on Pharmacopoeia and its proposal to the IV Conference;

External Quality Control Program (EQCP)

29) Important to identify the advantages and those aspects that are being harmonized;
30) To include as a recommendation to PANDRH the establishment of a WG on Good Laboratory Practices. The WG will develop a guideline for GLP and follow up the EQCP;
31) To include the preparation of a manual of procedures and protocols for the operation of the EQCP, including the use of samples from national pharmaceutical market as part of the Program;

Counterfeit

32) To include in the document the opinion of the WG on the drafted WHO document on Drug Counterfeiting;
33) To include in the background reference the experience developed by some countries since the previous Conference (Venezuela, Paraguay)
34) The cost of training activities for this WG should be included for the SC to analyze different options for implementations;
35) Drug counterfeiting is an area in which DRA collaboration is essential
36) The WG prepared a proposal to execute unit to work under the DRA to deal prevention and to combat drug counterfeiting. Layers, police, intelligence personnel and inspectors are key staff for this unit.
37) To include in the recommendation to the industry: to ask the pharmaceutical industry to inform DRA of any suspicion they may have on possible drug counterfeiting cases.

SURVEYS

38) Three WGs developed diagnostic studies: BE, Classification and Registration. The studies are not final since there are parts that are still missing. However, it is expected to have them ready by the Conference;
39) The Level of responses of all surveys was presented

Training Activities

40) Training will continue to be an important part of PANDRH activities;
41) Training activity will consider national capacity in adopting harmonized proposals and new guides;
42) Educators should participate at training seminars and workshops to promote the use of educational materials developed by the WG in their educational programs. This is considered part of the vision for the future. It may be useful to sign agreements with educational institutions;
43) New strategies should be explored to finance training activities;
44) New methodologies such as video conferences and other distant learning

ICH GCG

45) Davi Rumel participated in the GCG/ICH as substitute member for PANDRH representation at the GCG. He presented a brief report (presentation attached). He explained how a non ICH can participate, the objective of the GCG;
46) Mike Ward, GCG Coordinator, thanked Davi for his presence at the meeting. He explained that GCG is a harmonization solution; the type of work is a double way of communication to better understand the role and advantages of harmonization and training. It is everybody's responsibility including other initiatives (Asia, Africa, etc).

IV PAN AMERICAN CONFERENCE

47) **Agenda**:

a. The Conference will focus on the work being done by the WG
b. Members of the WG will present their proposals;
c. No other conferences will be included, other that the opening and the key note speaker. In this regard, the Conference on Combating Counterfeit Drugs: WHO Concept Paper was cancelled;
d. On Day 3, the focus will be on implementation. Justina Molzon and Mike Ward will prepare a PROPOSAL ON IMPLEMENTATION STRATEGIES AND PANEL OF REACTION of NRA from each sub-Region will follow.
e. The summary of the agenda is (order may change to adjust estimated time):

DAY 1
Opening
Keynote from speaker
Global harmonization initiatives (ICDRA and ICH)
Report from the Secretariat
GMP proposal
Pharmacopoeia
EQCP (Report)

DAY 2
BE study (Silvia Giarcovich, TBC)
Proposal on BE
Registration study (Esperanza Briceño, TBC)
Proposal registration

Classification study (B. Jimenez, TBC)
Proposal Classification
Other proposals: training, new WG: drug promotion, GLP)
Counterfeit
GCP

Election of new SC members

DAY 3
PROPOSAL ON IMPLEMENTATION STRATEGIES (Mike & Justina) AND PANEL OF REACTION of NRA from each sub-Region
Conclusions and recommendations
Closure

48) **List of participants**

a. National Regulatory Authorities from all PAHO Member States shall be invited (and financed);
b. Members of the WGs with responsibilities of presentations should be also invited (and financed).
c. Representation of the industry was proposed to be no more than 15 per regional association. Concerned was expressed by both associations requesting increase of industry representatives;
d. Representative members from FIFARMA and ALIFAR in active WGs may attend the Conference (in addition to the 15 previously agreed);
e. There will be few invitations to external organizations and/or institutions (self-financed)
f. To promote PAHO support to all PANDRH activities more effectively; the annual coordination meeting of PAHO essential medicines group will be held in conjunction with the Conference. All PAHO participants will be financed by PAHO.

49) **Finance**

a. The estimated cost of the Conference is US$118,013.00 not including associated costs such as translation of documents, editing services, photocopy and cost of materials;
b. Since the financial support form ALIFAR and FIFARMA are only of 25,000 each (total of 50,000.00), it was decided to send the detailed cost of the Conference to each organization. Both organizations will review their support and reconsider their financial contribution.
c. PAHO will seek other variable financial sources; otherwise, will review the list of participants and adjust it to the available funds.

V. Next Meeting of the SC

50) It was decided that the next meeting will be right after the closure of the Conference. **FRIDAY, 4 MARCH in the afternoon**

51) The main agenda will be:

a. Welcome new members
b. Review, adjust and approval of the plan of work of the WGs
c. Implementation strategies for each WG
d. Review and re-structure of the WGs (representation of countries, and sub-Region)

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Provisional Agenda
(Simultaneous translation available)

Welcome remarks
Jorge Bermudez, Unit Chief, PAHO/HQ-THS/EV

Nomination of Chairperson

Review and comments on the proposals to be presented at the IV Conference for their adoption, approval or recommendation [1]

1. Doc IV -1: Regional Guideline for GMP Verification
2. Doc IV -2: Science Based Criteria for Bioequivalence Testing (*in vitro* and *in vivo*), Bio-waivers and Strategy Framework for its implementation
3. Doc IV -3: Good Clinical Practices: Document of the Americas
4. Doc IV -4: Drug Registration Requirements in the Americas
5. Doc IV -5 Working Group on Combating Drug Counterfeiting
6. Doc IV -6 Classification of Drugs
7. Doc IV -7: External Quality Control Program of Official Control Laboratories

Regional studies implemented by PANDRH:

2.1 Bioequivalence
2.2 Registration requirements for Drug Registration
2.3 Classification of drugs

Review of the WGs' plan of activities for approval of the Conference

- GMP, BE, Registration, GCP, Counterfeit,
- Training: Plan of activities

4. PANDRH participation at the GCG of ICH
   Report by Davi Rumel

5. PANDRH Website

6. IV Pan American Conference on Drug Regulatory Harmonization
   AGENDA: Review and selection of Speakers
   DATE: 2-4 March 2005
   PLACE: Dominican Republic
   Financing - Estimated Budget

7. Closure
   Jose Luis Di Fabio, Area Manager, PAHO/HQ, THS

[1] The review it is not intended to refer to the content of the technical document but on what is to be requested to the Conference (Resolution type).