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

Orlando, Florida
23-24 March

REPORT

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a) Report from the Secretariat (Pan American Network on Drug Regulatory Harmonization)
b) PANDRH Overview (Overview of the Pan American Network on Drug Regulatory Harmonization)

During the discussion, the following comments and recommendations were made:

a) The SC recommended the dissemination of the document on Drug Policy recently approved by Mercosur
b) There is a need to promote videoconference among SC members and WG members using PAHO facilities at the country level
c) The analysis of export and import certificates should be included in future meetings of drug regulatory authorities
d) GMP is still of interest to all countries
e) GCP are important to countries with clinical studies phase II and also for development of clinical studies of herbal medicines (efficacy)

f) BE is a subject of importance, mainly to those countries that have already defined their drug generic policy based on drug interchangeability such as Brazil and Mexico. All other countries should define their drug generic policy first. BE is also important to the academia of all countries.

NEW WORKING GROUPS:

a) Herbal Medicine: the SC members decided the establishment of this WG be proposed at the Conferences.
b) Transparency is not an issue for a WG. Transparency and ethics should be considered as part of the study of the drug regulatory agencies and as part of other WGs.

GOOD MANUFACTURING PRACTICES (Report on the GMP Working Group)
The content of the course is presented, according to the agreements of the SC, FDA and the staff of the University of Puerto Rico (April 2000). The FDA is organizing the course.
Duration: One week
Number of courses this year: Two

1. 29 May – 2 June
2. July

Language: Spanish
Place: San Juan, Puerto Rico. UPR (Pharmacy School)
Number of participants: 25
Cost: It is still under consideration. To facilitate country participation, the organizers have arranged 20 rooms at a facility of the university at the cost of approximately $20/day, which is close to the university cafeteria. It is estimated that the cost for housing and room will be $250. Final information about housing, registration fees and number of participants from the government, university and the industry that can be accepted at both courses will be sent to PAHO before 15 April. PAHO will disseminate this information to the countries.
Final date for application: 8 May

GMP Course using WHO modules:
Place: Jamaica
Date: 17-27 April
Organizers: WHO and PAHO
Language: English
Professors: WHO staff and two other selected professors
Participants: Inspectors from the CARICOM
Professors from Latin America (responsible for replicating the same course in other countries) and from the Jamaican Pharmacy School to facilitate the replication of the course in the Carabbean.
Industry

BIOEQUIVALENCE (Bioequivalence of the Working Group)

(A): Report of the Working Group Meeting (14 September 2000)
(B): List of observers invited to the 1rst meeting of the WG
(C): Content of the modules for BE seminars
(D): Result of the survey: BE in the Americas

Seminars on BE to be implemented in each sub-Region
Number of seminars for this year: Two

1. San Jose, Costa Rica (Central America)

2. Caracas, Venezuela (Andean Community)

Date: September and November-December
Professors: FDA staff and local professors
Language: Spanish
Teaching materials: official FDA documents that are being translated into Spanish
Number of participants per seminar: 25
Participants: from countries of the sub-Region; and two professors from the next sub-Region.
Profile: Government, educators, and industry
Cost: There will be a registration fee which is still under consideration. Government officials will be waived from the registration fees.

PHARMACOPOEIA (Pharmacopeias Working Group)
The USP coordinator of this group presented the report.

It was also informed about the joint PAHO – USP Program on Drug Quality, which includes:

a) An assessment of the official drug quality control laboratory in each country. Central America official laboratories have been already assessed.
b) Identification of quality control laboratory of reference (WHO and PAHO)
c) Implementation of an external drug quality control program. USP will send through PAHO, selected drugs to be analyzed by quality control laboratories to evaluate their performance and results.
d) Products will be selected from the market and their quality will be evaluated by the quality control laboratories
e) Courses on Good Laboratory Practices will be organized
f) A regional activity on Good Procurement Practices focused on Drug Quality will be organized

CLASSIFICATION
New authorities from Mexico should be contacted in regards to this group.

DRUG REGULATORY AGENCY STUDY
The drug regulatory authority of Venezuela (Esperanza Briceño) will review the questionnaire used by WHO in a similar study. The Secretariat will organize the visit to selected agencies in the Region. It is expected that the results of this study be presented at the next Pan American Conference.

ICDRA
The SC analyzed the overlap (in year and month) of the ICDRA and the Pan American Conferences. Due to the importance of both activities and the need for promoting drug regulatory authorities from the Americas to participate at the ICDRA, the SC decided to postpone the III Pan American conference to APRIL 2002.

Reviewing the preliminary agenda, the following authorities compromised their participation at the next ICDRA in November, in Hong Kong:

Argentina:	Access to drugs (economic, political, prices), health sector reform and regulatory authorities
Brazil:	Counterfeit new dimensions, and Access to drugs (economic, political, prices)
Canada:	Herbal medicines and

Homeopathics
Venezuela: Health sector reform and regulatory authorities

According to the ICDRA preliminary agenda, AMRO has to still confirm the following presentations:
Update on the harmonization process
Update in biological (Cuba)
Antimicrobial Resistance

III Pan American Conference on Drug Regulatory Harmonization
Place: Washington DC
Date: April 2001
Agenda:

- Keynote speaker: Regulatory harmonization promoting access and rational use to quality drugs
- Report from the PANDRH Secretariat
- Regional and global integration: Implications of ALCA / FTAA
- ICH implications for the Americas
- Update on sub-regional harmonization (Mercosur, Nafta, Andean Community, Central America and Caricom)
- Report from ICDRA
- Presentation on EAMI and other initiatives on international cooperation on drug regulation
- Helsinki Declaration and Good Clinical Practices
- Regulatory implication of Drug Classification (BCS)
- Self Medication
    - Regulatory consideration of drug advertising trough the Internet. The European experience
    - Ethical criteria for drug promotion
- Implication on drug access of WTO-TRIPS

Financing:
ALIFAR and FIFARMA confirmed their support to the III Conference. PAHO will send a revised budget to finance the Conference and the working groups for a period of two years. The WSMI expressed interest in receiving the proposed budget to evaluate their participation to this process.

LATIN FARMA:
None of the members of the SC will be able to attend the meeting. It was recommended that available information be sent to the organizers.

EAMI-PANDRHA
After analyzing the objectives of the two initiatives EAMI and PANDRHA, the SC considered that both initiatives have different focuses and that can be complementary in their work. EAMI focuses on technical support, and the work of PANDRHA has a strong component of harmonization of drug regulation. Both are important for the regulatory work in the Americas. It was recommended that information on each initiative should be included in the agenda of the main activity (Conference) of the other. PAHO will inform EAMI on this recommendation.