VII MEETING
PANDRH STEERING COMMITTEE
26-28 June 2006
Washington, D.C.

Participants

Members
Andean Countries: Julio Cesar Aldana (NRA/COL) **(Unable to attend)**
Central America: Maria de Los Angeles Morales (NRA/COR)
Caribbean Countries: Yvette Sylvester (NRA/T&T)
South America: Manuel Limeres (NRA/ARG)
North America: Alberto Frati (NRA/MEX)
Ruben Abete (ALIFAR)
José Manuel Cousiño (FIFARMA)

Alternate Members
USA/FDA: Justina Molzon

Observers
Mike Ward, Health Canada
Angela Acosta, INVIMA, Colombia
Nancy Blum, USP

Secretariat
D'Alessio Rosario
Nelly Marín (Monday and Tuesday)
José M. Parisi (Monday)

AGENDA

The meeting was developed according to the expected agenda (see Annex 1) with modifications in subject order.

1. WELCOMING REMARKS

Dr. José Luis Di Fabio, Area Manager of Technology and Health Systems, welcomed members and observers of the VII meeting of the Steering Committee of the PANDRH, pointing out the importance of the Network and of the meeting of its CD. Expectations regarding SC recommendations are high due to the current situation of PANDRH in which implementation of its agreements is vital, but lack of funding for meetings and other PANDRH activities represents a difficult challenge. Dr. Di Fabio recommended the use of modern means of communication such as SharePoint, which is being applied by PAHO. He also offered a demonstration of the "Iluminate" system, which is being used in the Organization (and which was

presented the following day). Finally, he pointed out the importance of the representation of the countries (subregions) at these meetings as well as the need for increased participation among alternate members and observers.

2. DESIGNATION OF CHAIR AND REPORTERS

Dr. Alberto Frati (COFEPRIS, Mexico) was designated Moderator of the meeting and Prof. José Manuel Cousiño (FIFARMA) as Co-Rapporteur.

3. PANDRH RULES AND REGULATIONS

Meeting participants were requested to review the Rules and Regulations before the meeting, specifically in regard to the functions and responsibilities of the Steering Committee.[1]

4. PANDRH STRATEGIC REVIEWS

Participants reviewed the draft document, making modifications where appropriate (see final document in separate file).

5. FUTURE CHALLENGES FOR PANDRH

This part of the agenda was discussed on the last day of the meeting, after review of all other agenda items, to allow inclusion of more elements. The final document is presented separately (see agenda item 4).

6. WORKING GROUPS

6.1 Follow-Up on Work Plans and Reports

Members of the CD were requested to review reports of the WGs as indicated in Annex 2. In addition, the SC reviewed the following table-report prepared by the Secretariat. The SC made specific recommendations to each WG as indicated in the table.

Situation of the Technical Groups:

[1] http://www.paho.org/english/ad/ths/ev/norms-pandrh.pdf.

Working Group	Achievements	In Progress and Pending Issues According to Conference Recommendations	Comments
1. Good Manufacturing Processes	Adoption of the Guideline for GMP Inspection 1. Some countries have accepted the Guideline: Bolivia (officially) and Venezuela (on official Web page) 2. *Union Aduanera* (CA) is discussing the Guideline	1. They are: a. Implementing, with members of selected academy staff, national seminars open to all sectors (PAHO-WG and faculty) b. Delivering (after national seminar) direct advice to NRAs c. Preparing a document on NRAs to lead GMP implementation 2. In its last meeting, the WG approved for public opinion: a. Decision tree for national discussion with industry on implementing WHO/32 b. GMP for API c. Code of ethics Pending: Liaison between NRAs interested in internships	The WG met in March, cofinanced by PAHO and FDA. The program for the educational seminar on appropriate uses of the Guideline is presented in Agenda: Plan for Educational Activities. Need to know whether FDA will continue to financially support GMP meetings. <u>From the SC Meeting:</u> It is necessary to determine the possible adoption of the Guideline by DRAs. With reference to the ICH document on API, some members commented that it should not be submitted for public opinion. It was explained that this step is necessary so that other NRAs (not represented in the WG) can comment on the proposal before its submission for approval to the Conference. The public opinion step does not necessarily mean modification of the proposal. Supporting the dissemination of all PANDRH documents to all NRAs is also a function of the SC. Access to all PANDRH documents (those under discussion and those already approved) through the Web page should be improved.
2. Drug Regulation	Several countries have reviewed the draft of common requirements for	In progress: 1. Final version of common requirements for drug approval 2. National legislations	The Conference recommended giving high priority to this area. 1. Countries compared their current requirements with the PANDRH proposal (ARN), but the

	drug registration, which is being used by the WG in preparing the final proposal.	in the Web are being incorporated into the Web 3. Preparation of educational seminar on basic functions of NRAs and self-evaluation tool Still not addressed: Verification that marketed products met requirements approved at the time of registration	review lacked the analysis necessary to adopt the proposed requirements. 2. The WG met in March, partially financed by FDA. All but one of the members of the WG are "new" members. 3. The proposal is being reviewed by one member and the resource person (Hope Briceño) who led the development of the proposal. 4. Only a few ARNs have sent their national legislation as recommended by the Conference. They are too few to update the Web page. <u>From the SC Meeting:</u> The need for continuity as well as suitability of WG members was included as one of the agenda items.
3. BE	1. In its last meeting, the WG finalized the PANDRH document on BE. The WG adopted the WHO document and decided to focus the PANDRH document on the strategy for implementation of BE studies. 2. National seminars are being implemented in countries with national legislation in process. So far they have been implemented in Panama and Uruguay with very good	The WG is developing educational material for a BE seminar. Pending: 1. Addressing different issues according to the group's objectives 2. Validating GCP implementation in BE studies 3. Reviewing and participating in educational seminars	The last meeting (May 2006) was cofinanced by PAHO and FDA. It is necessary to determine whether FDA will continue to financially support BE meetings. <u>From the SC Meeting:</u> The coordinator of the WG gave a presentation on the group's progress, reporting that the WG endorsed the WHO document on BE and focused the PANDRH guideline on the implementation of BE studies.

	attendance levels.		
4. Combating Drug Counterfeiting	1. Road map to evaluate the cycle for CDC (adopted) 2. Executing unit to strengthen DRA to CDC (adopted) 3. Set of indicators for the management and criteria for classification of counterfeit drugs	The WG is still attempting to build a Regional network of focal points. Pending: 1. Promoting articulation of NRAs in other sectors 2. Adopting national good practices standards for all of the stages of the chain of drugs 3. Establishing a drug traceability mechanism 4. Developing educational seminars 5. Second survey under way; posted on Web since Conference, but only two countries have responded	The WG/CDC do not work well by mail. Do not activate participation. No report has been made to the Secretariat on the role of members in promoting the approved tool in their own countries A WG meeting and possible changes in membership could help; no funds are available for meetings. <u>From the SC Meeting</u>: Drug counterfeiting is a complex problem that goes beyond the area of NRAs. Can the WG have more focalized objectives? The work of the WG should be clarified. It is necessary to know what the WG is going to do to strengthen efforts to combat drug counterfeiting. There are a few communications of case reports to WHO (database) and PAHO. However, PAHO only was informed on a case (ANVISA). It is known that there are many more that are not reported. It is necessary to promote increases in case reports. IMPACT is an initiative coordinated by WHO. It formulated a Declaration of Rome (2006) and held another meeting in Rome in July. It is important to consolidate efforts between IMPACT and PANDRH through the WG/CDC. INVIMA was believed to be invited to the next IMPACT meeting (July 2007). The SC decided to ask INVIMA to represent PANDRH and to request information on the conclusions.

			Also, ALIFAR may have Miguel Maito (member of the WG/CDC) to participate at the meeting and he also may inform PANDRH on the agreements. The SC will monitor the WG, which should be more operational. The Caribbean countries may finance some activities through the subregional project on drugs.
5. GCP	1. Document of the Americas (adopted and referenced by new WHO norm along with ICH and ISO) 2. Educational material for a seminar on GCP ready for pilot testing. It includes: (a) list of current educational opportunities (regional), (b) all PP, and (c) a CD with reference material from WHO, ICH, EMEA, and other regulatory agencies.	In progress: 1. Discussing GCP for pediatric populations 2. Indicators for GCP inspections Pending: Considering implementation of joint inspections	WG essentially working by mail. Needs to meet. It is recommended that the next meeting be held along with the pilot for the GCP seminar. That pilot will allow the WG to support countries interested in improving national situations in this area. Pilot must be implemented in a country that can ensure self-financing of the activity. <u>From the SC Meeting</u>: FIFARMA will consider financing the pilot and the next WG meeting.
6. Drug Classification	1. Criteria for drug classification (adopted) 2. Criteria for OTC promotion (adopted) 3. Label content for OTC drugs (adopted) 4. Development of a list of API for OTC 5. Work toward	1. The WG is currently developing the list of API susceptible to classification as OTC 2. The WG has been asked to review label information for nutraceutics jointly with Medicinal Plants WG.	There is no active participation of the members by mail as a result of difficulties in responding by this means of communication. See report prepared by former coordinator on proposed actions. A meeting would help members regain action and commitment.

	classifying food- and cosmetic-related drugs		
7. Pharmacovigilance (From III Conference)	New WG	Regional study under development	12 of 30 countries sent back the questionnaire. Two of them indicated that they do not have any pharmacovigilance system. WG working by mail; scheduled to establish working plan and objectives in its first meeting in August (financed by PAHO). They will participate at the workshop on Phv of the FIP. <u>From the SC Meeting:</u> The WG should discuss the approach to the subject: only DRAs? Be more comprehensive: DRAs, quality problems, and drug counterfeiting, or also focus on how to develop a program for quality verification of products in the market (health surveillance)? The WG should discuss the differences and the advantages of each approach and of the quality surveillance systems. The WG should also discuss the following: (a) whether it would be more appropriate to address the approach through sub-regional groups, (b) the establishment of networks and nodes (structure), and scope and impact in terms of rational/adequate use of drugs. It is recommended that this WG analyze the experiences of the WGs on GCP, GMP, and BE. WHO documents on the subject and other experiences in the region should also be considered.
8. Pharmacopoei	Protocol to harmonize new monographs (endorsed)	1. Broaden country participation 2. Prepare monographs of herbal products	The WG is managed by the USP (see report from the coordinator). There is a need to exchange information with WG/MP.

			From the SC Meeting: ALIFAR requests incorporation of a representative in the Pharmacopeia WG.
9. Good Laboratory Practices	1. WG established 2. Educational materials on GLP developed and pilot implemented 3. Continuation of EQCP with support of USP (currently in the sixth phase)	In progress: 1. Evaluation tool for QC labs (pilot in Jamaica and DOR) 2. Procedures for EQCP	USP has increased financial contribution form US$ 10,000 to US$ 40,000 to support this WG. From the SC Meeting: The Secretariat (Dr. Parisi) briefly presented the progress of the WG and acknowledged the technical and financial collaboration of the USP.
10. Medicinal Plants (from III Conference)	The WG has defined its working plan.	Working on: 1. Categorization of medicinal plants 2. Harmonized format for medicinal plants monograph 3. Harmonization of document on GMP for MP 4. Harmonization of common requirements for registration of medicinal plants	WG met in March. The meeting was financed by ANVISA. WG is currently working by mail. Coordinator and funds are needed. From the SC Meeting: FIFARMA and U.S. doubt the priority of this WG. The representative of the Caribbean pointed out the importance of this subject in the subregion. It was recognized that the use of medicinal natural products is generalized throughout the Region of the Americas and that other NRAs are highly interested in this subject.
11. Vaccines	The Conference recommended the establishment of a WG on Biologics, but after considering several factors the SC approved a WG focused on vaccines.	The WG is working on common requirements for vaccine registration (almost completed), and it will address development of GMP for vaccine production, educational seminars, and development of GCP guideline for vaccines	See WG report; no financial problems. From the SC Meeting: The WG is made up of NRAs and expert representatives from the industry, and all of its members should be cited to WG's meetings. All should be kept informed, and all documents of the WG should de accessible to all members. The Secretariat and the coordinator of the WG should guarantee compliance with the standards and inclusive work of all of the

			members of the GW. The works (mainly those that PAHO develops in the field of vaccines) that cannot be developed within the framework of PANDRH are preferably maintained outside PAHDRH. It is recognized that PANDRH is not the only cooperation opportunity. There is need for clarifying what can be done within PANDRH and what would be outside this context. FIFARMA and ALIFAR said that the Vaccines GW has been functioning outside the PANDRH rules. It was agreed to send a note to the Secretariat (Regional Adviser of Vaccines of PAHO, Dr. M. de los Angel Cortés) and to the coordinator of the GT (Dr. Olga Jacobo) to inform them of these comments and request the integration of all members at the meetings and technical discussions of the WG. The SC will follow up next steps of the WG. It is necessary to strengthen communication between WG and SC. It is necessary to establish a link with the WG on Drug registration.
12. Drug Promotion	New WG	The WG was proposed by ANVISA to the Conference, it was approved, and the SC selected members and designated ANVISA as the coordinator. The Conference requested that the WG address the following: 1. Establishment of a regulation to avoid confusion induced by the use of a brand	The WG does not have funds. ANVISA has proposed financing the first meeting and to hold it just before a national event in this subject in September (not final). <u>From the SC Meeting:</u> Some members consider brand use to be territorial to each country. Other aspects are being analyzed by other groups. Differentiation of containers is being addressed by the WG on Drug Classification.

		name 2. Differentiation of OTC packaging 3. Establishment of a code of ethical criteria for drug promotion and publicity and a control system	Drug promotion should be addressed when developing pharmaceutical policy, since it is a central axis for national pharmaceutical policies. The WG includes the use of INN as part of its technical aspects. The DRA has the responsibility of monitoring/authorizing publicity in many sectors, including food (energizing drink). The publicity is linked not only to drugs but also to other areas and should not be isolated from the rest. Health is not alone: Should the WG involve the Office of Defense of Consumers? It is a difficult issue and is handled differently in each country. The SC decided that the issue should be limited to the discussion of drugs (PANDRH). The WG should define its scope in this regard.

6.2 PANDRH Harmonization Processes: A System of Phases and Stages

Presentation of the topic: Considering that the current status of the development of PANDRH indicates that:

1. PANDRH has advanced and that some of the guidelines and technical documents that were adopted or approved by the Pan American Conference have reached an implementation stage;
2. In order to evaluate the process and the impact of PANDRH, it is necessary to establish a monitoring and evaluation system of the productivity and relevance of the products of PANDRH, as well as their acceptance and implementation in the countries;
3. As per today, the operation of the working groups (WGs) encompasses different stages from the preparation of guidelines and/or technical documents to country support in the adoption or implementation of guidelines adopted by PANDRH, including its dissemination in national and international events.

Proposal: To establish a system of phases and stages describing the development of PANDRH, which will lay the basis for the definition of indicators that measure processes and effects of the initiative according to the following:

Harmonization process within PANDRH:

- Phase 1: Development of Draft
  - Stage 1: Draft proposal (draft 1) (by one or more members of the WG)
  - Stage 2: Discussion of the proposal by the WG members and selected professionals
  - Stage 3: Approval of the proposal (draft 2) by members of the WG

- Phase 2: Draft for Public Opinion
  - Stage 1: Web page consultation
  - Stage 2: Consolidation of comments (draft 3)

- Phase 3: Preparation of Final Draft
  - Stage 1: Comments review by the WG
  - Stage 2: Preparation of final draft

- Phase 4: Approval (or Nonapproval) by the PANDRH Conference
  - Stage 1: Review, endorsement by the Steering Committee[2]
  - Stage 2: Decision of the Conference: approval/modification or adoption; the document can be sent to the WG for additional considerations

- Phase 5: Implementation of Proposal
  - Stage 1: Dissemination of the approved proposal at the national or subregional level (by NRA, by selected members, or at WG activities)
  - Stage 2: Document discussion/guideline at the national level with the participation of interested entities
  - Stage 3: Adoption of the proposal at the national and/or subregional level (recognition)

Acceptance of this proposal would generate reports according to the example on WG/GMP presented in Annex 3.

Decision: The SC approved the proposal.

6.3 Working Group Composition

Presentation of the topic: The current composition of WGs indicates that:

[2]The endorsement of the SC of the proposals of the WGs is only for the purpose of presentation to the Conference, which is the maximum authority and the only one that can adopt (or choose not to adopt) the proposed technical documents of the GT. Members of the SC will not have the authority to change the technical content of the works presented by the WGs.

1. The WGs are continuously modified through changes in members' representations, particularly from the Regulatory Authorities;

2. The WG members selected do not always meet the experience and knowledge requirements needed for adequate discussions of the technical material being processed;

3. The Steering Committee, at its meeting in March 2005, decided that new WG would require representation from five regulators, one for each of the five geographical subregions (in addition to the representatives from the pharmaceutical industry), making this group different from the previously established WGs;

4. The first established WGs, in most cases, have met their immediate objectives (some of them only partially), and there have been changes in their structures as a result of changes in NRAs or industry representatives.

Proposal: To reevaluate the composition of the different working groups as currently formed, to formulate a new proposal for the groups' composition that would be presented for consideration by the NRAs affected by the changes, and to adopt the following criteria:

- The number of members should be flexible, according to the complexity of the WG area;
- All WGs should have at least one NRA representative per subregion, along with one alternate representative for each subregion who is from a different country;
- The CD would have the responsibility of selecting the representative of the country in each WG and of safeguarding representation (of the countries) by subregion;
- NRAs would have the responsibility of selecting members;
- NRAs would send the CV of the member to the Secretariat, after which it would be reviewed by the SC and, once approved, made available to the group;
- Members would serve for a given fixed period.

Comments and Decision of the Committee: The subject of WGs prevailed throughout the meeting. In this regard, the CD decided:

1. To create an ad hoc group (sub commission) that would be in charge of preparing a proposal of rules and regulations to complement the existing ones and that would be applied to both the existing WGs and the new ones. The SC will analyze the proposal at its next meeting (November 2006). This sub commission is the same that will address point 6.6.

2. That the ad hoc group will incorporate the following considerations of the SC:

a. The establishment of working groups should be channeled through the SC before presentation to the Conference. Requests to create new WGs should be made formally to the PANDRH Steering Committee and should be accompanied by technical justification, preferably with details on how the required financing would be covered to ensure the operation of the WG and with information on what products (output) would be expected from the WG during the financing period of work.

b. All of the WGs should be able to predict the time needed to reach their objectives (or to conclude works or documents being prepared).

c. Stage of implementation can be a cause of changes in the constitution of the GT, whose members are not necessarily in the same WG that developed the proposal.

d. WG members represent not only countries but also subregions. In this regard, it is necessary to define members' responsibilities within their institution (to their own country) as well as their responsibilities with other countries in the same subregion.

e. It is necessary to establish a more effective member selection process (one that is more appropriate in relation to the needed experience according to the expected discussion levels).

3. To postpone the review of the composition of the WGs until the next meeting, after review of the proposal that the ad hoc group will prepare. The constitution of GTs will be reviewed taking into account the discussed conditions, and the ad hoc group has the responsibility of including in its proposal all aspects discussed here.

4. All of the members of GTs (current and future) should send their updated CVs to the Secretariat. The SC will review all of them and will approve in the selection of members if appropriate.

5. The member of the SC representing the Caribbean showed interest in improving the representation of that subregion in the WGs, which was recognized by the other members of the SC.

6. The SC will reevaluate all WGs based on their functioning and approach to the priority subjects. The SC will closely monitor the operations of the WGs and will analyze the possibility of financing in order to make appropriate decisions.

7. The SC will reevaluate the priority of the area of work of the WGs, taking into account (a) the request of the IV Conference in conferring priority on the WG on Drug Registration; (b) the arrangement of the priorities of subjects established in the I Conference classified as urgent, priority, and important; (c) the progress and possible conclusion of the mission of the

WGs; and (d) the financing of WG operations. Although all of the areas of work of the WGs are of interest in terms of regulatory harmonization, some are more urgent than others, and it is necessary to reorganize the priorities of PANDRH work.

6.4 Communication Network by Technical Subject

Presentation of the topic: Considering that one of the principles of PANDRH is to promote broad country participation and that the operation of the WG has demonstrated that:

1. There are members who participate in a very passive manner, which slows the process of developing guidelines and technical documents, and that they do not enrich group discussions affecting country and subregion representation on the WG's decisions;

2. The SC's previous decision to include in each WG only five NRA representatives (one for each subregion), which was based on the financial limitations associated with WG operations, limits the representation of NRAs, making their participation even weaker;

3. Being a member of the WG is not the only way to participate, and that other modalities to promote broader NRA participation in technical discussions and preparation of documents should be explored;

4. Financial resources for the operation of PANDRH are more and more limited, and financial collaboration from countries is increasingly conditioned. This financial aspect has affected the continuous work of the WGs in that they meet less frequency and work mainly electronically, which is not always the most appropriate mean for technical discussions. Furthermore, the number of PANDRH groups has increased, thus also increasing financial needs as numbers of members rise.

Proposal:

1. To expand country participation of those that are not WG members by establishing communication networks on the different PANDRH areas through participation of focal points for countries that want to participate voluntarily;

2. To establish the following membership categories:
    a. *Members:* Members of a country by subregion and the two regional pharmaceutical industry associations;
    b. *Alternate members:* each sub-region will have an alternate member from a different country than the one of the member. The industry will also have an alternate member;
    c. *Resource persons:* These individuals are recognized experts from the academia, regulatory agency, industry, or other sectors. They would participate in discussions but not in the decision-making process;

d. *Observers:* NRA staff additional to members who, as a result of their experience, can participate in technical discussions but not in the decision-making process;
e. *Focal points:* NRA staff responsible for the technical area in the agency, who can participate in discussions but not in the decision-making process.

Approval of this proposal will officially establish the communication networks of technical discussion, by subject. The table was prepared on the basis of the responses of countries that answered the request for designation of focal points. These communication networks are to participate in the WGs' technical discussions by electronic means.

Decision: Taking into consideration that there are not economic implications in establishing communication networks and that networks will contribute in making more open and participative the PANDRH process of developing technical documents and formulation of regional proposals, the SC approved the constitution of communication networks as presented.

6.5 Coordinators

Presentation of the topic: Considering that the operation of the Network has demonstrated that:

1. The WG coordinators, with the exception of those selected by the Conference, are DRA representatives, and at the same time they are subject to changes and gaps caused by staff rotation at national regulatory agencies (currently these cases are the WGs on Regulation, Classification, and Medicinal Plants);

2. The regulation of PANDRH establishes that the SC is responsible for selecting WG coordinators.

Proposal: To review and complete the designation of the WG coordinators, as indicated in the table below. The definition of the coordinators' responsibilities, the duration of the coordination, and the requirements for the coordinator profile are also addressed.

Group	Institution	Previous Coordinator	Current Coordinator	Reason for the Change
GMP	FDA	Justina Molzon	Justina Molzon	
BE	FDA	Justina Molzon	Justina Molzon	Resignation of the previous

				coordinator from the institution
GCP	ANMAT	Patricia Saidon	Martín Soane	Resignation of the previous coordinator from the institution
Drug Registration	Venezuela	Esperanza Briceño	VACANT	
Pharmacopoeia	USP	Roger Williams	Horacio Papas	Decision of the coordinator institution
Drug Classification	MOH Guatemala	Beatriz Batrez	VACANT	Resignation of the coordinator
Medicinal Plants	Health Canada	Michael Smith	VACANT	Decision of the previous coordinator
Combating Drug Counterfeiting	ANVISA	Antonio Carlos Da Costa Bezerra Maria Graca	José Augusto Simi	Decision of the coordinator institution
Good Laboratory Practices	ISP, Chile		Maria Gloria Olate	
Pharmacovigilance			VACANT	New WG
Drug Promotion	ANVISA		Maria José Delgado	
Vaccines	MOH Cuba		Olga Jacobo	

Decision:

Designation of Coordinators:

- Medicinal Plants: Princess Ousborne, representative of Jamaica and the Caribbean;

- Drug Registration: The Secretariat will ask the MOH of Venezuela whether it is interested in continuing to coordinate this WG. If so, then the MOH should designate its representative. Otherwise, the SC decided that a member representing COFEPRIS (Mexico) and the North American countries will coordinate this WG. The Secretariat will inform the decision made by both national institutions;

- Pharmacovigilance: The representatives of INVIMA, Colombia, and the Andean countries will coordinate this WG;

- Drug Classification: The Secretariat will ask the MOH of Guatemala whether it is interested in continuing to coordinate this WG. If so, then the MOH should designate its representative. Otherwise, the SC decided that a member representing Costa Rica and the Central American countries will coordinate this WG. The Secretariat will inform the decision made by both national institutions.

- It is recommended that the institution/country that assumes responsibility for the coordination of the WG support the group, including presenting to the SC a financing plan for the GT. It is necessary that the coordinators lead the work of the group that they coordinate. To this end, is recommended that the coordinators be expert in the subject of the group.6.6

6.6 Regulation of PANDRH

Presentation of the topic: Considering that the current regulation was established in 1999 and that the Network has advanced and diversified its operation, there is a need for reviewing and making adjustments of its regulation in order to optimize PANDRH operation.

Proposal: To establish a sub commission (ad hoc group) composed of two members of the Steering Committee who jointly with the Secretariat will prepare a proposal that complements and strengthens the current regulation of PANDRH. The proposal would be reviewed by the SC at its next meeting (scheduled for November 2006). The proposal will include, among other aspects, the following:

1. Criteria for selection and WG members;
2. Main functions of the different categories of participation in the working groups (see point 4);
3. Time period for the different categories of membership participation in the WGs;
4. Functions and responsibilities of the coordinators of the WGs, as well as time period and criteria or profile;
5. Other related matters.

Decision:

1. An ad hoc group was established that will prepare the proposal of rules and regulation for PANDRH operations according to the points presented in this report. The group's members are Manuel Limeres (ANMAT Argentina), María de los Ángeles Morales (MS/Costa Rica), Mike Ward (Health Canada), Yvette Silvestre (MS/Trinidad and Tobago), and Rosario D'Alessio (OPS/Secretariat).

2. The timetable approved for this process is the following:
    a. The members of this ad hoc group will send to the Secretariat their proposed rules and regulations before September 2006;

b. The proposals from the different members of the ad hoc group will be consolidated by the Secretariat in September-October;
c. The consolidated document (draft) will be circulated among all members of the Steering Committee in November 2006;
d. The SC will review the draft at its VIII meeting scheduled for November 2006.

7. PLAN OF IMPLEMENTATION OF EDUCATIONAL ACTIVITIES

Presentation of the topic: The plan and level of implementation of educational activities are indicated in the following table. To support the planning stage at the country level, the Secretariat prepared a document to help the country PAHO offices and NRA assist in the organization of national courses. However, the precarious situation involving recovery of seed funds in some cases requires close review by the SC.

	Good Manufacturing Practices: Course on Appropriate Use of the Guideline for GMP Inspections		
	Date	**Location**	**Observations**
1.	9-13 January	Guatemala (pilot)	Implemented. The material was developed by an ad hoc group of university professors and members of the GT. Number of participants: 46 (36 industry, 10 officials); 8 facilitators and 5 additional participants were included to create core group
	20-24 March		Programmed for Honduras and postponed at the request of PAHO (pending new authorities in country)
	17-21 April		Postponed at the request of the country
	2-6 May		Programmed for Colombia and postponed with requirement that the country have a facilitator of FDA
	8-12 May		Programmed for Venezuela and postponed at the request of the country
	8-12 May		Programmed for Mexico and postponed with requirement that the country have a facilitator of FDA
2.	5-9 June	El Salvador	Implemented. Participants: 25. Lack of acceptance on the part of industrial sectors; only 13 participants from the industry
3.	12-16 June	Bolivia	Implemented. 39 participants; 29 paid registration fees
4.	10-14 July	Uruguay	Confirmed. Great support from industry. More than 100 want to participate. Are requesting a second course

	10-14 July		Reprogrammed for Venezuela and changed again (several courses in development). Analyzing new dates
	17-21 July		Paraguay. Postponed with request of NRA review of quota fees. Difficult to obtain the 50 participants from the industry
	24-28 July	Chile	Postponed
	31 Jul-4 August		Canceled again as a result of lack of FDA facilitator's availability
5.	31 Jul-4 August	Chile	Confirmed
	31 Jul-4 August		Brazil (at this time)
6.	8-12 August	Colombia	Reprogrammed for Colombia with facilitator of ANMAT
7.	11-15 September		Mexico. Needs to be confirmed. Conducting the course only for COFEPRIS staff is being considered. Alternatives for financing are being reviewed. Interest in the activity has been confirmed
	11-15 September		Programmed for Argentina. Does not consider it out
8.	18-22 September	Nicaragua	Confirmed
9.	2-6 October	Peru	Confirmed. To be reconfirmed with new authorities
10.	16-20 October	Ecuador	Confirmed
11.	23-27 October	Panama	Confirmed
12.	23-27 October	Venezuela	New proposed date by Venezuela. Availability of professors being requested
13.	6-10 November		Cuba has not confirmed
14.	13-17November	Dominican Republic	Confirmed
15.	4-8 December		Available date (Paraguay?)
16.	11-15 December		Available date (Honduras?)
17.	TBD		Costa Rica?
Good Clinical Practices			
	Date	**Location**	**Observations**
18.	August-September	TBD	Patricia Saidón finalized the material to use in educational seminars on GCP: document of the Americas. The material for the pilot is available. Financing being sought
19.	February 2007	TBD	Second course in GCP
Good Laboratory Practices			
20.	March	Dominican Republic	Carried out. Material developed by the group with the active participation of Prof Alzate. The pilot was successful
21.	28-31 August	Chile	Second course in GLP. Confirmed

22.	November	Río de Janeiro	Third course in GLP. Confirmed
Bioequivalence			
23.	January 2007		The material is being prepared by Dr. Bolaños (GT/BE). It will be implemented in a pilot
Combating Drug Counterfeiting			
24.	TBD	TBD	Materials are being prepared and implemented for the second time as a pilot by ANVISA; will be reviewed by the WG. Two seminars can be implemented in October 2007. The Secretariat is contacting ANVISA and the WG/CDC
Basic Function of NRAs			
25.	TBD	TBD	Materials are being prepared by PAHO and the WG on Vaccines. Materials are based on the basic functions of NRA proposed by WHO and the adaptation of Vaccines educational programs. Two courses may be implemented in October 2007. The Secretariat is contacting WHO in this regard
Other Courses in Negotiation			
26.	February 2007	TBD	Conversation started with ICH in order to implement a regional seminar on GMP for API with simultaneous translation. Possible headquarters: Argentina, Brazil
27.	January 2007	TBD	Conversation started in order to implement a seminar with WHO on evaluation of dossier for HIV products of the program for prequalification. Subject to candidates (experts) of the DRA of the region that want to participate in this initiative. Only in English

The SC was requested to:

1. Analyze the situation of the implementation plan and to make recommendations to the Secretariat:
    a. To improve the participation of the private sector (pharmaceutical industry) in the courses. In particular, the representatives of the pharmaceutical industry in the SC are required to give suggestions to promote (and to guarantee) the participation of this sector in the implementation of all programmed courses.
    b. To promote the commitment of the NRAs in the organization of the course in a way that recovery of funds is guaranteed. If this goal is not achieved, the other countries will be affected.

c. To improve the general directions and recommendation to the Secretariat to ensure the financial support and implementation of the plan.

2. Approve the proposed plan as presented. The plan will be implemented as long as it can be financed.
3. Present suggestions for the implementation of activities 26 and 27 of the plan.

Comments and Decisions:

1. The most troubling aspect is the lack of assurance of recovery of funds in each course, considering that the program of courses works on the basis of a seed fund (revolving fund). Ii is necessary that the host countries of the courses guarantee recovery of funds so that these programs can continue.

2. The course in GCP takes as a basis a necessary seed fund of US$ 25,000. FIFARMA will consider the possibility of financing the course, which will take place in Chile. The Secretariat will estimate the cost and report it to FIFARMA.

3. Course 27, the workshop on evaluation of dossiers for prequalification of products (according to the WHO program), would be financed completely by WHO. Only staff members of NRAs previously selected by WHO and PAHO would participate, and a phase of selection of these professionals should be delimited. Some members of the SC said that this course could not be directly related to the mandates of PANDRH. It is recognized that the plan of courses is very broad and that all of the courses offered within the framework of the Network should be relevant to pharmaceutical harmonization. This course was related to the plan of support of WHO for the local industry in Latin America that Latinpharma presented to PAHO. The participants knew of this proposal through the Secretariat and the interest in combining both initiatives, which involve a specific program of WHO (prequalification of suppliers and products). It was emphasized that in Latin America there are manufacturers certified by FDA but not by PAHO (or by WHO). The importance of having Latin American manufacturers recognized as suppliers of the United Nations system and the important role that the NRAs of the region can have in this initiative were discussed in the meeting; however, some of the participants considered these types of actions not related to drug regulatory harmonization.

4. Training in the area of drug registration should focus on capacity building among regulators in the Americas.

5. Some members of the SC suggested analyzing the possibility of a joint implementation of courses in several subjects at the same time. It was also suggested to study the possibility of implementing courses at the subregional level. It was recognized that this modality has two important limitations: a greater cost of participation (in addition to the registration fees, participants should cover hotel and travel expenses) and a smaller

number of participants, which means that it may not generate the expected impact. However, it was recognized that some subjects are of necessary regional application. When the course is to disseminate PANDRH-approved technical documents, national implementation of the activity is necessary so that countries can compare their specific situations with regard to the proposed document.

6. The course offered through ICH was agreed to be implemented as a first course in Argentina, which would be coordinated jointly with the Secretariat and the ANMAT. The representative of COFEPRIS in the SC requested a second course on that subject for Mexico, and it was agreed it will be also offered to Brazil. These courses will all be implemented regionally. The replication of the first course will depend on what will be agreed on with ICH. The Secretariat will formalize the contacts with ICH in order to organize jointly with ANMAT the first course in Argentina in March 2007.

7. It is necessary to monitor the courses and their reproduction by national professionals. In the GMP courses, it is required that the NRAs and schools of pharmacy replicate the course in the first 12 months after the implementation by the PANDRH. It is necessary to document what is happening in this regard.

8. The SC approved the proposed plan of educational activities presented by the Secretariat.

8. NEW GROUPS

Presentation of the topic: The Secretariat received a request from the representative of FIFARMA on the Steering Committee, Prof. José Manuel Cousiño, to incorporate into the agenda a proposal on the creation of a WG on Biologicals[3].

Request: The Committee is requested to analyze the proposal presented by Prof. Cousiño and to decide whether this proposal will be presented for approval by the next Conference, according to the procedure indicated in the PANDRH regulation.

Dr. Cousiño, in his presentation, pointed out that the creation of a WG in this subject is a need for the NRAs and the industrial sector. These types of products have difficulties in registration, in GMP, and in the need for validating rigorously safety and efficacy due to the high complexity of the macromolecules. It is a current subject in which worldwide concerns exist in terms of knowing what is being made, and the PANDRH could, through a WG, offer proposal tenders on how to approach the subject. Highly developed agencies of regulation and the EMEA are working on the subject as well as the ICH.

Comments:

[3] Doc available by request

- FIFARMA presented the document “Toward a Regulatory Framework Differentiated Between Products of Pharmaceutical Origin and Products of Biological/Biotechnological Origin in Latin America,” based on the creation of a new GT that would deal with the subject of biologics.

- The proposal of establishing a WG on Biologics was analyzed. It was shown that the official document was not read in preparation of this meeting by all of the members of the Steering Committee. The presentation motivated the discussion and several comments. For some the subject is a very difficult matter, pointing out that there is a need for expertise that may not be available in PANDRH; at the same time, there was also opinion that PANDRH cannot be left behind in the discussion of this topic.

- The possibility of establishing a task force or an ad hoc group with a specific assignment was also discussed.

- Having more information on what is being done globally was considered necessary. It was emphasized that the document presented indeed includes important information.

- The fact that the document was available only in Spanish possibly limited its comprehension by members who do not speak that language.

- Another observation was that the document was prepared without the participation/collaboration of DRAs, and it was considered that it should be analyzed and endorsed by some DRAs.

- It was also emphasized that PANDRH should focus its efforts on the current WGs and recognize its financial constraints.

- It was emphasized that this WG as well as all WGs recently created as drug surveillance and drug promotion groups deserved to be regarded as a need of the regulatory agencies of the region.

Decision:

- It was agreed to create an ad hoc PANDRH group on Biologicals that will study all of the background and present a proposal to the SC at the next meeting.

- The group will be composed of representatives of ANMAT, Argentina, COFEPRIS, Mexico, FIFARMA, and ALIFAR. The cited agencies will designate their representative expert in the subject of biologicals in August, informing the Secretariat of the members, and will prepare a document by consensus to be presented at the meeting of the SCD.

- FIFARMA will translate the document into English to allow better understanding on the part of the members of the SC.

9. FINANCIAL SITUATION OF PANDRH

Presentation of the subject: To date, PANDRH has operated with the following resources:

1. Funds allocated by PAHO (regular and/or extra budgetary). In some cases, PAHO funding is total (Vaccines).

2. Funds of the countries through regulatory authorities:

- FDA contributes with partial funds in order to meet the GMP and BE WGs (FDA also contributed to the meeting of the drug registration WG) and financed participation of the PANDRH representative at an ICH meeting (in 2003) and the V SC meeting (Madrid 2004) as a pre-ICDRA activity.
- ANVISA completely financed the meeting of the WG on Medicinal Plants.
- USP finances the WG on Good Laboratory Practices and the Program of External Quality Control. The USP increased its funding from US$ 10,000 to US$ 40,000 for 2006-2007.

3. Country funding through PAHO's BPB. These funds should be approved by PAHO since they correspond to resources being contributed from the countries to the Organization. Canada has been the only one that uses BPB PAHO funds, to support two meetings of the PANDRH Steering Committee (June and December 2006)

4. The associations from the pharmaceutical industry finance the participation of their members at the WG meetings and at the SC, and traditionally, although they have been contributing less lately, they provide funding support for the PANDRH Conference.

The operation of the Network demands a strategy to maintain funds through financing agencies, increased contributions from countries, and other funding strategies. In reference to the first point, the Secretariat prepared a project in 2005 for the operation of the Network that was reviewed by the majority of the NRAs in the Region. The project has a modular character to facilitate agencies' motivation in the financing of areas of interest. The project (Annex 7) was sent to WHO to be channeled to the financing agencies. The members of the WG of the SC requested the dissemination of the proposal to possible financing sources, and it was sent as a preproposal to a staff member of the Gates Foundation. The foundation showed interest but indicated that it requires organizational support as well as from the countries and, especially, a guarantee that concrete results will be obtained in pharmaceutical regulation harmonization.

Request to the Steering Committee: Analyze and recommend to the Secretariat strategies to process the project with the financing agencies and in the meantime suggest possible sources to finance the proposed plan of activities for 2006-2007, as indicated in Annex 8. It is important to point out that the table in the annex has

been sent to different NRAs seeking financial contributions, with partial results to date.

Decision: The SC did not make a decision in this regard, but it formulated some comments:

- It was suggested to seek financing after reviewing the plan of courses, pointing out that there are 19 countries with courses on GMP. Those courses should be concentrated in three countries, with a participation of, for example, 500 people at a cost of registry of US$ 400, which would cover financing of the courses and the operation of PANDRH.
- It was reported that this would imply a modification of the methodology of the courses, since they are highly participatory through workshops and case studies; they are impossible to implement if the number of participants is too high, given that the objective of the educational activity would be lost.

10. SECRETARIAT

10.1 Communication with the Steering Committee and Secretariat Functions

Communications with the SC have been done basically via mail and with the frequency that the Secretariat establishes. Communications (by e-mail) can be informative or of a decision-making variety. In the latter, the opinion of the majority of the members is considered. The functions of the Secretariat have been carried out as indicated in the regulation of the PANDRH

The Steering Committee is requested to review and suggest modalities for the improvement of the participation of the SC members in the decision making of PANDRH as well as the operation of the Secretariat.

Decision: The subject was not discussed in full, but the members suggested using the “Iluminate” model (primarily as a pilot) with the members of the SC for the purpose of improving communication and promoting active participation of the members of the CD in decision making, and, after an evaluation, considering extension of its use to the WGs.

10.2 Representation and Responsibilities

The PANDRH Secretariat is carried out by PAHO in accordance with PANDRH regulation. The technical unit within the Organization in charge of this responsibility is the Essential Drugs, Vaccines and Health Technology Unit (THS/EV). The coordination of the Secretariat is under the responsibility of Rosario D’Alessio. José Maria Parisi collaborates in the WG on GLP Secretariat and Maria de los Ángeles Cortés in the WG on Vaccines. THS/EV has identified a “back-up person” in the different groups of the PANDRH, as follows.

Area	Responsible	Back-up
Pharmaceutical Regulation (PARF Network) Coordination	R. D'Alessio	Juanita Rodríguez
1. Management of the Steering Committee	R. D'Alessio	Nelly Marín
2. WG/GMP	R. D'Alessio	Juanita Rodriguez
3. WG/BE	R. D'Alessio	Nelly Marín
4. WG/GCP	R. D'Alessio	José Luis Castro
5. WG/Combating Counterfeiting	R. D'Alessio	James Fitzgerald
6. WG/Drug Approval	R. D'Alessio	José Peña
7. WG/Pharmacopoeia	USP	D'Alessio Rosario
8. WG/Pharmacovigilance	R. D'Alessio	José Luis Castro
9. WG/Drug Promotion	R. D'Alessio	James Fitzgerald
10. WG/Medicinal Plants	R. D'Alessio	Juanita Rodríguez
11. WG/Drug Classification	R. D'Alessio	Juanita Rodríguez
12. WG/GLP	José María Parisi	D'Alessio Rosario
13. WG/Vaccines	M. Angeles Cortés	Rosario D'Alessio

10.3 Miscellaneous Information

The Steering Committee was informed on:

- Web page: updating and modification.
- Share point: information with demonstration of "Iluminate."
- Directory of NRA (reference document 8): Information is needed from NRAs to update the document.
- Internships in NRAs (need for formalizing this type of collaboration between countries).
- Resolution CD46R5 (possibility of renewal?).

No major decisions were made on these subjects.

11. Representation of PANDRH in International Organizations

Before presenting the specific points, Mike Ward, coordinator of the GCG/ICH, made a presentation on the progress of the GCG. He explained the decisions the group has made, pointing out the recent document on educational programs (training) and the opportunities of ICH members to organize courses through the ICH and to participate in educational activities, which are open to the participation of professionals of NRAs from other regional members of the GCG. The document and the plan of educational activities are available on the Web site of ICH. He also presented the progress of the global study on the regional initiatives of harmonization members of the GCG and presented the case of PANDRH (Annex 4).

11.1 *Representation at the ICH Global Cooperation Group (GCG):* The representative of PANDRH at the GCG is Rosario D'Alessio, who coordinates the PANDRH Secretariat, according to the decision of the Steering Committee at its previous meeting (March 2005).

Decision: Rosario D'Alessio will continue to represent PANDRH at the GCG for the next two years (2006-2008).

11.2 *Representation at the ICH working group Q10:* Given the request of the GCG and the agreement of the ICH Steering Committee, the participation of a representative from each of the five regional initiatives (PANDRH among them) was approved, and these initiatives will designate a representative at the Q10 group. The member represents the regional initiative (PANDRH) and not a particular country. Considering the interest in the participation of non-ICH countries in the technical discussions of the ICH WG, and considering the nature of the thematic area of the group, the PANDRH Secretariat requested that the selected NRAs in the Region represented in the WG/GMP propose candidates for the approval of the PANDRH SC. ANMAT proposed its representative at the WG on GMP (ANMAT), while ANVISA and COFEPRIS proposed various candidates (none of them related to the PANDRH WGs). The PANDRH SC indicated its support of Dr. Rodolfo Mocchetto, who participated in the Q10 group at the meeting. This participation was completely financed by ANMAT.

The Secretariat noted that, considering the high cost of this representation, partial financing is included in the PANDRH project. However, as long as the funding agents of the project have not been identified, funding for this participation should continue to come from the agency of assignment. One of the conditions is that the person that represents PANDRH should know the work of the Network in order to share the advances of the Network at the international level, and at the same time, to provide feedback to the PANDRH group this representative belongs to on information regarding these international groups. This is in addition to the benefit that the member can contribute to the national agency.

The SC took note of this subject presented by both Dr. Limeres (ANMAT) and Mike Ward (GCG Coordinator) and pointed out the importance of having PANDRH and Latin America represented in this working group of ICH.

11.3 *Representative at the International Regulatory Cooperation for Herbal Medicines (IRCH):* The IRCH has requested that PANDRH designate a representative at this group.

Request: The Steering Committee is requested to designate the representative based on the following criteria:

- To be a member of the Working Group on Medicinal Plants;
- To be a regulatory authority;
- To have dominion of the English language;
- To be financed by the organizers of the IRCH, and in the event that this does not occur, PANDRH will not finance this representation.

Decision: The member of the WG on Medicinal Plants, Princess Osborne of the Ministry of Health of Jamaica, was selected as the representative of PANDRH in the IRCH.

11.4 *Representation on other international committees (e.g., USP and CCI):* The CD was informed on two initiatives: one of the USP (prequalification of manufacturers of API) and the second one by the ICC (support for the evaluation of the Latin American pharmaceutical industry to become a supplier of the United Nations).

12. NEXT CONFERENCE

The Steering Committee, after considering that the conferences of PANDRH demand strong country political support, demonstrated primarily by the participation (in the opening) of the Minister of Health, by a high level of participation of the National Regulatory Authority, and by the institutional capacity of the organization and management of the Conference, and after analyzing several options offered by members of the CD (Argentina, Chile, and Costa Rica), made the following decisions:

a) Location: Buenos Aires, Argentina
b) Dates: 8-11 October 2007
c) Subcommittee of logistical support:

- Dr. Manuel Limeres (or a representative from ANMAT)
- Prof. José Manuel Cousiño (or a representative from FIFARMA)
- Dr. Rubén Abete (or a representative from ALIFAR)
- Rosario D'Alessio, PAHO/HQ
- Representative from PAHO country office (Argentina)

This subcommittee of logistical support will be responsible for preparing a budget for the Conference, taking into account (a) that the Conference will be financed through the payment of a registration fee (to be determined by the subcommittee) and that the exceptions of payment of registration include the DRAs of PAHO/WHO member countries, the lecturers, and other exceptions that will be determined; (b) the place where the Conference would be developed; and (c) other direct and indirect expenses. The draft budget will be analyzed by the Steering Committee at its next meeting.

d) A subcommittee for technical matters formed by:

- Dr. Alberto Frati (or a representative of COFEPRIS)
- Ms. Justina Molzon (or a representative of FDA)
- Manuel Limeres (or a representative of ANMAT)
- Rosario D'Alessio, PAHO/WHO Headquarters

This subcommittee will be responsible for preparing a proposed agenda and methodology for the Conference that will be analyzed by the SC at its next meeting.

13. NEXT MEETING OF THE STEERING COMMITTEE

After analyzing meeting costs, the members requested that the Secretariat explore the possibility of holding the meeting in Costa Rica or Panama. A budget comparison will be sent to the members of the CD via mail. The next meeting will also be financed with funds from BPB-Canada and will take place from 27 to 29 November 2006.

ANNEX 1: AGENDA

PAN AMERICAN NETWORK ON DRUG REGULATORY HARMONIZATION (PANDRH)
STEERING COMMITTEE
VII Meeting
Washington D.C.
26-28 June, 2006

Monday 26 8:30 am – 4:00pm[4]

1. Welcome Remarks (PAHO representative)
2. Designation and Selection of Chair and Rapporter
3. Review of the Steering Committee's responsibilities according to current PANDRH Rules & Regulations.
4. PANDRH Strategic Review: Presentation of the discussion paper on Overview. Successes, Opportunities and Challenges
5. Future directions of PANDRH. Recommendations for moving forward. Governance and management structure

6. WORKING GROUPS

a. Work Plan: Review and approval of the work plans and reports from the different working groups,
b. Proposed scheme to follow up PANDRH operation,
c. Current WGs membership,
d. National focal points. Analyze the benefits and problems of establishing a network to increase country participation in technical discussion in each PANDRH subject,
e. Group Coordinators,
f. Rules and Regulations for PANDRH: Review the Rules and Regulations of the PANDRH approved by the II Conference and consider if it is time to update them according to PANDRH 7 year's experience.

7. Plan for Educational Activities. Current Situation

8. **New WG:** SC member will analyze the feasibility of establishing a new WG on Biologics.

9. **Financial situation of PANDRH**
10. The Secretariat: Communications and functions
11. Representation of PANDRH in International Organizations

Wednesday 28 8:30 am – 12:00m

12. **Next Conference**
13. Closing Remarks

[4] AM coffee at 10:00-10:30; Lunch at 12:00 – 1:00 and PM Coffee at 3:00-3:30

ANNEX 2: GTs Reports reviewed by the SC

1. **Good Manufacturing Practices**
   Plan of work (FROM updated Webpage)

2. **Drug Registration**
   Plan of Work (FROM updated webpage)

3. **Bioequivalence**
   Plan of Work (FROM last meeting, May 06)

4. **Good Clinical Practices**
   Plan of Work and last email on this issue

5. **Combat Drug Counterfeiting**
   Plan of Work and last email on this issue

6. **Drug Classification**
   Plan of Work, Report from (former) Coordinator and email on this issue

7. **Pharmacopoeia**
   Report From coordinator

8. **Medicinal plants**
   Plan of Work (FROM updated webpage)

9. **Vaccines**
   Report from Coordinator

10. **Good Laboratory Practices**
    Report from coordinator

11. **Pharmacovigilance**
    Information from the Secretariat (e-mail)

12. **Drug Promotion**
    Information from the Secretariat

***ANNEX 3 (Only Spanish): Ejemplo de Informes de GTs de BPM* según la modalidad de Seguimiento a la Red PARF aprobada por el CD en su VII reunión.**

BPM		
Fase 1: Desarrollo del borrador del documento		
Fase 1, Etapa 1: propuesta de borrador (por uno o mas miembros del GT)	1. Strategy for NRA to lead GMP implementation 2. National legislation and WHO 32 prevision + Guideline	(1) Reviewed in March 06 and reassigned with changes to Elsa Castejón, (2) pending for FIFARMA representative since July 05.
Fase 1, Etapa 2: discusión de la propuesta entre miembros del GT y personal designado		
Fase 1, Etapa 3: aprobación de la propuesta (por miembros del GT)		
Fase 2: Borrador para Opinion Pública		
Fase 2, Etapa 1: Consulta de página web	1. Decision Tree for national discussion with industry on implementing WHO/32 2. GMP for API 3. Code of Ethics	
Fase 2, Etapa 2: Consolidación de comentarios		
Fase 3: Preparación del Borrador Final		
Fase 3, Etapa 1: Revisión de comentarios por el GT		
Fase 3, Etapa 2: Preparación del borrador final		
Fase 4: Aprobación (o rechazo) por la Conferencia de la Red PARF		
Fase 4, Etapa 1: Información al Comité Directivo de la Red		
Fase 4, Etapa 2: Aprobación/adopción por la Conferencia	1. Guideline for GMP Inspection	
Fase 5: Implementación de la Propuesta		
Fase 5, Etapa 1: diseminación de la propuesta nacional o sub-regional (por ARN, por miembros seleccionados o actividades del GT);	1. National Seminars on open to all sectors (PAHO-GT & Faculty) 2. Direct advise to NRA (delivered after national seminar)	See special report on Educational Activities
Fase 5, Etapa 2: discusión del documento/ guía a nivel nacional con participación de entes interesados	1. Discussion at national level por (ARN) 2. Discussion for adoption of the Guide at Sub-regional level (CA)	
Fase 5, Etapa 3: adopción de la propuesta a nivel nacional y/o a nivel sub-regional.	1.Bolivia has accepted the Guideline officially 2.Venezuela incorporated the Guideline in their webpage	

***ANNEX 4: DESCRIPCIÓN DE LA RED PARF* (solo en inglés)**

Regional Harmonisation Initiative (RHI) Profile
PAN-AMERICAN NETWORK FOR DRUG REGULATORY HARMONIZATION (PANDRH)

Established: ***1999, with official recognition by the 42nd Directing Council of PAHO in September 2000.***
Website: http://www.paho.org/english/ad/ths/ev/redparf-home.htm
http://www.paho.org/spanish/ad/ths/ev/redparf-home.htm

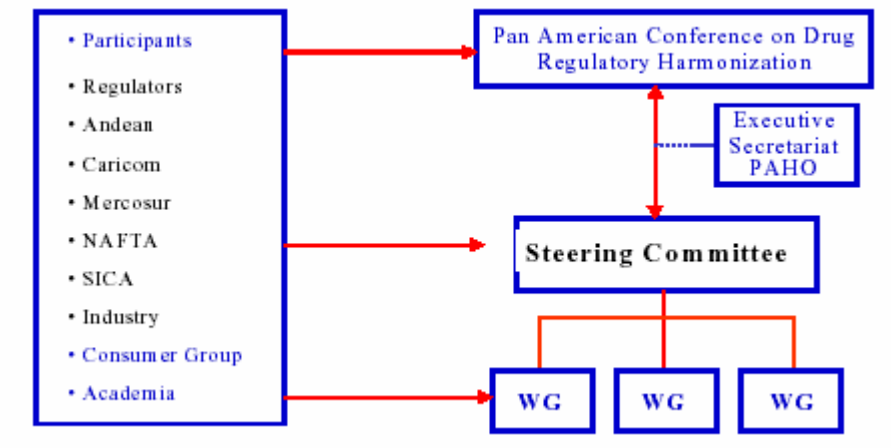
1. MISSION AND SCOPE OF ACTIVITIES

The Conference should promote drug regulatory harmonization for all aspects of quality, safety, and efficacy of pharmaceutical products as a contribution to the quality of life and health care of the citizens of the Member Countries of the Americas.

PANDRH's scope of harmonisation/cooperative activities includes technical guidelines, regulatory processes and the strengthening of national regulatory agencies through harmonization of processes and standards to improve drug quality and quality assurance. Specific drug sectors covered include prescription, over the counter, generics, 'similars', biologics/vaccines and herbal medicines.

2. ORGANISATION

The network consists of four components: biennial Pan American conferences, a steering committee (SC), technical working groups and a secretariat.



The conferences act as the highest level of authority and as such serve to define priority areas for harmonisation and to endorse standards, guidelines and other recommendations, including norms/procedures and steering committee membership. The conferences also provide an open forum for discussing issues of common interest in drug regulation. Participants include the regulatory authorities of all PAHO member states, representatives of the regional pharmaceutical industry associations, academia, consumer groups, professional associations and representatives from the five sub-regional trade integration groups within the Americas.

The SC's primary role is to follow up on conference recommendations by establishing and monitoring the progress of working groups. The SC also establishes the agenda for conferences. The steering committee is composed of 12 members, 10 regulatory authorities (5 main, 5 alternate) representing each of the sub-regional economic groups and two industry

representatives. Regulators from other countries not represented on the SC may participate in SC meeting. Representatives from NGOs recognised by PAHO/WHO and other stakeholders invited by the SC may also attend as observers. Members serve for a period of four years, with staggered rotation.

Steering Committee
Regulatory Authorities from each of the economic groups:

- Andean
- CARICOM
- MERCOSUR
- NAFTA
- SICA

Industry representatives:

- FIFARMA
- ALIFAR

Working groups are formed to address areas that have been identified by conferences as priorities for the drug regulatory harmonisation. Members are selected by the Steering Committee and confirmed by the regulatory authorities of the respective countries. Whenever possible, WG should have at least one representative for each of the five sub-regional blocs of the Americas. Industry and academics can also be members. WGs typically conduct surveys to identify the differences in regulatory requirements, analyse international, regional and/or national guidelines and prepare harmonized proposals.

PAHO serves as the secretariat, providing technical and administrative support and a focal point for the coordination of information to the conference, SC and working groups.

The SC should meet at a minimum of once a year, whenever possible in relation to other events related to drug regulation. WGs may meet separately or in conjunction with SC meetings at a frequency determined by work plans and resourcing. Conferences and SC meetings have usually taken place at PAHO headquarters in Washington, DC.

3. OPERATIONS

Norms and procedures
Objectives, goals and operating procedures and rules have been developed for the conference, SC, working groups and secretariat and are available on the PANDRH webpage: PANDRH Norms and Regulations:
http://www.paho.org/english/ad/ths/ev/norms-pandrh.pdf

Harmonisation process
PANDRH primarily uses WHO documents as the basis for developing regional guidelines. Other international guidelines including ICH, as well as selected regional (e.g., EU, American sub-regional) or national technical documents are also used as basis for harmonisation and as reference material.
After a WG has agreed on a draft harmonized document it is posted on the web site for external comment. Comments are reviewed by the WG to prepare the final version of the document. Final technical documents are intended to be used at the national level, at the discretion of the countries.
PANDRH is developing strategies to follow up implementation processes at national and sub-regional level. Members of the Steering Committee are responsible for monitoring implementation in their sub-region.

Communications:
The Pan American Conferences are forums open to all regulators of the region and representatives from industry, academia, consumers, and economic groups.

An updated Web page is available as the main source for public to get information on PANDRH and to participate in the process of developing technical documents. Information is also communicated through presentations and promotion in national and international congresses or conferences, workshops on specific topics, and meetings with patient organisations, healthcare professionals, industry associations, individual companies and/or the media.

WG documents are also posted to the web site for external comments, which are reviewed by the WG to prepare the final version of the document.

Training:
A central focus of PANDRH has been the training of regulators, industry and other interested parties. In this regard PANDRH has or is developing training courses on GMP inspection, GCP, GLP, bioequivalence and the basic functions of a regulatory authority. A train the trainer approach has been adopted in order to institutionalise training programs and leverage resources. All courses are being implemented nationally and are open to public and private sectors. PANDRH training plans may be found at:

Sources of Funding:
PANDRH has a proposed operational budget supported primarily from PAHO biennial funds. Other sources for financing are:

- Discretional amount by Governments
- Discretional amount by the Pharmaceutical Industry*
- Discretional amount International organizations
- Registration fees from training courses

* FIFARMA and ALIFAR, Latin American pharmaceutical industry associations, have contributed to the financing of the Pan American Conferences.

4. HARMONISATION TOPICS

The following areas of work have been undertaken by PANDRH:

Technical Area	Work Description	Status
Good Manufacturing Practices		
Bioequivalence		
Medical Plants		
Good Clinical Practices		
Pharmacopeia		
Drug Classification		

Combat to Drug Counterfeiting		
Pharmaco Vigilance		
Drug Registration		
Good Laboratory Practices		
Drug Promotion		

Information on Technical Working groups, documents and topics can be found on the PANDRH website: http://www.paho.org/english/ad/ths/ev/RedParf-home.htm