Organización Panamericana de la Salud
Oficina Regional de la Organización Mundial de la Salud

RED PANDRH PARF

EXECUTIVE SUMMARY

Memories of PANDRH Steering Committee Meeting

Place : Bogotá, Colombia

Date : April 27 and 28, 2011

This document is a summary of the PANDRH Steering Committee meeting, which was held in Bogota, Colombia on April 27 and 28, 2011.

TOPICS

I- DISCUSSION OF VI CONFERENCE AGENDA

The approach of the VI Conference is the role of the national sanitary authorities in the framework of the health systems; therefore, it is exposed that the subjects for discussion must have this framework and that for this the instances of discussion will be the round tables.

The Steering Committee approves the agenda that was raised with anticipation.

The work proposal of the conference includes: work tables, work groups, conferences about relevant emerging topics and the presentation of new experiences of the Regulatory Agencies.

This matter is discussed and established how the work of the panels will be and who will be the participants:

		OBJECTIVE	PARTICIPANTS	DURATION
1	Strengthening of the NRAr (Resolution CD 50 R.9)	Share with the regulatory authorities of the region the challenges and strategies that the NRAs faced in the process of preparation to be submitted to the evaluation on behalf PAHO within the process of certification. The purpose is to serve as a support to other NRAs in the accomplishment of the missional functions in the framework of the health systems and encourage them for submission of evaluation on behalf PAHO.	Moderator: PAHO Presentations: MERCOSUR: Argentina, Brazil CAN: Colombia ALBA: Cuba	1hr 30 minutes Each presentation will last 15 minutes
2	International Cooperation	Knowledge of the initiatives of regional, bilateral and sub regional cooperation, from the point of view of the applicants and the providers of the cooperation and debate the most efficient strategies for the purpose	Moderator: Brazil Presentations: Cuba (offerer) CAN: Peru SICA: Salvador (demand) MERCUSUR: Paraguay (demand) NAFTA:	1hr 30 minutes Each presentation will last 10 minutes
3	Implementation of the guidelines of PANDRH in the sub regions	To know the degree of implementation of the guidelines of the Network in the sub regions (for example, the documents and brochures, training and promotion of human resources, internships and exchange, investigations, generation of projects and specific plans, among	Moderator: PAHO/WHO Presentations: Representative of the sub regions: SICA: CAN: MERCOSUR: CARICOM:	2 hours Each presentation will last 15 minutes

		others)	ALBA: Cuba (for this panel, ALIFAR and FIFARMA are invited to participate, if considered convenient)	
4	Systems of information and communication	To know and document the successful experiences of how these systems contribute to optimize the performing of the NRA, as well as the process of intra and inter communication of the NRA	Moderator: Peru Participants: CAN: Colombia MERCOSUR: Uruguay PAHO/WHO:	1 hour Each panelist will have 5 minutes for their presentation
	Transparency	To know about experiences in the transparency from the point of view of Good Practices of Regulation, addressing the spaces for the citizen participation and the subjects of regulation	Moderator: Cuba Participants: NAFTA: CAN: Peru (META project and Medicine Price Observatory) MERCOSUR: Brazil and Argentina SICA:	1 hour Each presentation of 10 minutes
6	Future challenges of PANDRH The dynamic of this panel is different since no introductory presentation is required. Each panelist expresses their topics for debate with the	To debate about the future challenges of PANDRH with the purpose to identify the strategies that generate great positive impact for the member countries; as well as to give an opportunity to the countries to meditate about the fitting of the structure and instruments of the PANDRH in order to reach its goals.	Moderator: PAHO/WHO Papers: CAN: MERCOSUR: NAFTA: SICA: CARICOM: ALIFAR:	1 hour 30 minutes Each panelist will have 5 minutes

	auditorium. Desirably DO NOT bring slides		FIFARMA Cuba TOPICS TO DISCUSS: Agenda, operation, institutions, people in charge. **OBSERVATIONS:** It is required that the representatives of the sub regions take contact with each one of the countries, in order to consolidate the perceptions of the different participants. As well, in order to strengthen the work of PANDRH, it is proposed to establish goals and indicators for each one of the group and for the Steering Committee, and also to evaluate the structure of the network and the amount of the work groups. It is suggested that only the new topics of the WG remain. An invitation is made so the PANDRH is institutionalized, that the works done here are more binding and change the environment of the actions of the recommendations of PANDRH. PAHO refers that due to the diversity of the work groups, there is a loss of opportunity in the response required for transversal topics that are relevant for the countries. Concerning the institutionalization, there is diversity in the NRA and its empowerment and capacity to adopt recommendations. In this matter there should be a search	

			for mechanisms to elevate level/possibility of commitment of the weakest NRA. On the other hand, the steering committee members propose that there should be an evaluation of the representation of the Network so that in addition it is technical as well as political. It is suggested that the network takes into account for the agenda the topics of importance of every agency. An observation is made where it shows the results and progress of the network and that this starting point for this panel. PAHO refers that this suggestion will be taken into consideration for the panel of implementation of the guidelines. Also, it refers that the secretariat will do a survey in order to know about the perception of each one of the countries toward the network. This will be sent to each one of the countries for its acknowledgement. It is estimated that it will be sent to the countries in approximately 20 days so there is time for a response.	
7	Pharmaceutical Policy: Strategies for generic products	Share experiences and perspectives of relevant actors in the implementation of the strategy of generic medicines and know the role and reach of the Authorities of the NRAs in this strategy.	Moderator: PAHO/WHO (to perform an overall presentation about the topic) Participants: ALIFAR: FIFARMA: MERCOSUR: Argentina (presentation of the approved	1 hour 30 minutes

			policy by the ministers) CAN: Peru NAFTA: Brazil: Panamá: **OBSERVATIONS:** It is proposed to share beforehand the strategy of generic medicines and the regulatory frame of BE. Panelists: it is suggested that they express the different perspectives of regulation, according to the sub regions.	Locate it at the end of day 3

It is established that the participation of Chile will be as a member of the Andean Community.

II – PANDRH WORKING GROUP SESSIONS

The Working Groups will have two instances of participation in the VI Conference: during the plenaries, where it is intended to know the results of the WG and the work plan for the immediate future. Also, there will be the work rooms in which it is expected a closer interaction with the focal points and relevant actors.

With the purpose to achieve better effectiveness of the working rooms and avoid confusions in goals and objectives, the participants must do a previous sign up. There will be a maximum capacity for the work tables.

The groups will have a space in the work rooms and for that it is necessary a definition of an orientation for them. In work room 1 the work groups will be working (it cannot be simultaneous) and in work room 2 the specific topics will be treated.

The objective of the working tables of the WG is exclusively of discussion and not decision. It is suggested that there are work tables of all the WGs, regardless if there are results or not.

The capacity will be established for each participant (Industry, NRA) at the tables where it is expected more interest/assistants.

In addition, it is requested that the work tables have an explanatory text about work methodology of the same.

It is estimated a period of 30 minutes for the realization of the presentations of the documents and for the reception of comments. It is expected that the presentations will be held in a period no longer than 15 minutes and the rest of the time will be for opinions/observations of the plenary. The work plan of each group must be presented until the next conference, for its approval.

It is suggested that the recommendations be discussed for its real implementation and that there is an elaboration of a document of all the recommendations as a position of the conference.

PAHO informs that it is relevant that by June 15th, as deadline, all the documents must be sent to the Steering Committee for its approval. ALIFAR suggests that the documents must be sent before May 30th and that those that may have an exception by June 15th. Finally, it is agreed that the documents must be sent to the Steering Committee by May 30th and as a final deadline by June 15th.

As well, it is referred that it is important that the presentation of documents for public consultation and its approval is documented.

PLENARY

The tables of the WGs will have as a moderator a PAHO Focal Point and the presenters will be indicated by the focal point and/or by consensus with the coordinator (according to the group, it could be the coordinator or another member)

It is estimated a period of time of 30 minutes to do the presentations of the documents and receive comments. Additionally, the work plan of each group must be presented for its approval.

It is suggested that the recommendations should be discussed for the true implementation, as well as considering the recommendations and make a document as a position of the conference.

WG- Good Clinical Practices

Moderator : Dr. José Peña
Participants : Group members
María Amparo Pascual
María Vargas
Ileana Herrera.

Documents to be presented at the Conference:

- Clinical trials in pediatric: it was presented at the V Conference. It was adjusted and is now posted for public consultation (only until mid may)
- Investigators brochure: it was already submitted for public consultation. A version with the comments received is in preparation.
- Considerations of the use of placebo: it is posted for public consultation (until the second week of may)

The group has given a deadline of a month maximum to realize all the adjustments to the documents for the approval at the VI Conference. NAFTA has requested that this topic should be worked on day 2 or 3 of

the meeting in order to guarantee the presence of its representative, since his agenda does not allow his participation for day 1. The request is accepted.

WG - Pharmacovigilance

Moderator: Dr. José Luis Castro

Presenter: Claudia Vacca

1. In April 2011 was validated, the guide approved in the V Conference of GPP during the years 2009 and 2010. The final version of the guide was published.
2. Pharmacovigilance network document (which is now in discussion with the WG)
3. Pharmacovigilance diagnosis in the Andean sub region.
4. Workshop for technicians.
5. Algorithm of therapeutic failure manufactured and validated, following the recommendations of the V Conference of taking the therapeutic failure with a notifiable event.

Members of the WG are supporting the implementation of programs of PV in Ecuador, Paraguay and Chile.

Participation of COL in the Committee of WHO Experts in medicine safety.

Challenges: consolidate the network of focal points, strengthen the process of training, articulation of the responsibles and activities of ESAVIS, encounter of PV of the region (may it rotate among other countries); articulation with other actors working in the subject (CAN,EAMI).

WG - Prevention and Combating of Medicines Counterfeiting:

Moderator : Dr. José Luis Castro

Presenters : Tiago Rauber

Eric Conte

The WG will present at the conference:

1. Document of presentation of the workshops days that were held at Panama, Bolivia, Costa Rica. This document does not require previous approval from the Conference, since it is only for information.
2. Document of focal points networks; this document is posted for public consultation. A draft was previously presented at the V Conference for its approval.
3. Document of guidelines and inspections: it requires the approval on behalf the Conference.

WG – Medicines Promotion:

The document of Promotion, Publicity or Propaganda will be presented. A meeting is established for the closure of the definition and of the document to be presented at the conference. FIFARMA requested that the topics of publicity should be included and presented at the same time a document to the WG. AIS has recently also sent contributions of ethical promotion.

WG – Medicines Registration:

Until today, there is no consensus within the group about the acceptance of the last version of the direct document for the generic medicine registration. Therefore, the SC does not recommend that it should be presented for the approval of the Conference and it is suggested that there is a meeting only of the group to review the work done and the next steps previous to the work rooms, since that is where people outside the group but that are interested will be participating.

The document was posted for public consultation, and 80 contributions were received. ALIFAR informed that they do not agree in the inclusion of some topics that the document contains in the last version, such as the topic of polymorphism of the multi source medicaments and the editing of the topic of clinical essays to request, referred to principal known actives with new concentration, new indications, new pharmaceutical way and new association of principal known actives, to approve a new registration and authorization of commercialization of a new product.

At the moment, there is no position of ANMAT whether they accept or not this version due to the fact that in the last meeting of approval of changes of the document, the group coordinator (ANMAT) presented excuses and was unable to participate. The participant of MERCOSUR, informed during the meeting, to not have the opportunity to consult the coordinator of this group about the position of the sub-region.

The secretariat will explore the real and constructive possibilities for the participation of this WG at the VI Conference. The options of proposals will be promptly presented to the SC.

WG – Biotechnological Products:

Moderator : Maria Luz Pombo
Presenter : Marcelo Moreira

CAN: A first work report has been elaborated, as well as a document with the work group. Within the work plan, 6 objectives have been defined, workshops have been performed in the use of informational tools to implement systems of communication and a discussion was generated among the members.

The translation of the document of recommendations of WHO is being reviewed in relation to bio-similar products.

ALBA: The country adopted the guide of WHO will not have affordable bio similars, therefore, it is better to work with the recommendations of guidelines and not adopt guides.

There is a perception that the group is active and that there is an important participation of many members.

In this particular group, the work room will be interesting and challenging since it is foreseen a great interest in participating, therefore the proper guards will be taken with the final purpose that the coordination will not be overwhelmed and it will be able to move on. It is considered recommendable that Maria Luz Pombo will moderate, that Marcelo and Patricia Aprea coordinate the work room for which is required the full support and attention of the members.

It is requested to the Secretariat to do all efforts so that in the work rooms are all the members of the group, due to the fact that there can be many technical questions that maybe the coordinators cannot answer. The two members of ALIFAR guarantee their presence and it is foreseen that FIFARMA will also be present with their integrants.

WG – Good Laboratory Practices:

GLP has been able to reach an agreement with the Network with a common objective. A translation of a GLP of WHO has been made to english, spanish and portuguese. It is referred that the objective of the group has been achieved, and it has been concluded to implement the GLP of WHO. The main objective was achieved with harmonization. There are 22 integrants, there has been held 7 meetings. In the last elluminate session, 15 laboratories participated with 35 participants of the region.

Within the GLP network, there are 3 laboratories pre qualified by WHO that are a world wide reference. The idea is that the 4 NRAs of Regional Reference (ARG, BRA, COL and CUB), reach the level of pre qualification in GLP. About this, it is informed that FUNED laboratory of Brazil have been recently evaluated by WHO, and the results will be known in upcoming days.

General comments for all the groups:

- ✧ The moderator of the WG will be the PAHO Focal Point. The participants will be the people that have worked with each one of the documents that will be presented in the Conference.

- ✧ It is agreed that the documents must be sent to the SC by May 30th and as a final deadline by June 15th . It is established that the importance of the presentation of documents be documented, whether it is a public consultation, for approval, etc.

- ✧ It is important to evaluate how the WG works, to see the possibility of hiring a third person with the purpose of realizing the uprising of the information and give a proposal within a better margin of time. Therefore, it is suggested to combine methodologies for better results.

- ✧ It is clear that one of the major weaknesses of the WG is that the representative members of the sub regions do not communicate or integrate with the fellow country members.

- ✧ A recurring theme in the meetings of the SC has been the convenience of reactivating the WG of GMP. In this way, there are two major topics that would justify this option: the manifest need of the state members of PAHO concerning the training and knowing the degree of implementation of recommendations issued from the developed documents and approved by the network.

  In this matter the participants expressed:

- ALIFAR: A training and diagnosis of the situation of the implementation of the document is required " Verification of the GMP for the Pharmaceutical Industry" approved by the IV Conference of Pharmaceutical Regulatory Harmonization (on the base of recommendations of WHO of 1992) and the studies of bioequivalence of the region established in the document "Settings for the execution of the requirements of equivalence for the pharmaceutical products" approved at the V Conference of Pharmaceutical Regulatory Harmonization.

- That the Steering Committee instructs the GMP in regard to the diagnosis about the previous line and to develop a survey or some mechanism of diagnosis designed to request the information required with the support of PAHO and the diagnosis support for the group of bio equivalence and establish what is needed to be done today in relation to training.

- NRAs of Reference: they are in process of development of training proposal along with PAHO for the region in topics mostly required by the country members. It is expected to know the initiative during the VI Conference.

III - PUBLICATIONS / NRAs SUCCESSFUL EXPERIENCES

The conference foresees the presentation of 6 successful experiences during the plenary. These will be published in a book along with other articles that will be previously evaluated and edited by the Committee established for this purpose only. If received enough articles, a document will be elaborated and distributed during the VI Conference.

Until today, we have only received three articles: 2 from Brazil and 1 from Chile. We insist on the existence of successful experiences that can be a model that will serve and support other countries. It is requested that the representatives of the SC stimulates their countries to send the publications before April 30 or as a final deadline by May 10.

IV - CONFERENCES

Each one of the presentations will have a period of time between 30 to 40 minutes. These are programmed according to the following conferences:

1. **Bacterial Resistance: Lecturer:** Dr. Fernando Otaíza, Chile
2. **Disregarded Diseases:** Lecturer**:** Dr. Isabela Ribeiro. Presentation of specific efforts in the development of medicines and therapeutical schemes. Ex.: specially chagas.
3. **Economic Regulation:** It is referred that Brazil and Chile have experience in the use of economic regulation for medicines access.
4. **Results of the World Health Assembly**
5. **Nanotechnology and Regulation**
6. **Medicine sale by internet**

PAHO requests for support with the recommendation of lecturers for the topics that do not have a designation.

It is proposed to change the name that is proposed for advances in nanotechnology or nanotechnology in medicines.

It is also proposed that besides treating the topic of medicines sale delivery, knowing that there are medicines that must be sold with the prescription. For the development of this topic, Peru will share the result of a survey concerning the current legislation among some country members.

Independent to the topic mentioned above, it is established that there will be a conference for the topic of medicine sale on the internet. The speaker will be from FDA.

PAHO requests that the missing names of the speakers, is ready as soon as possible in order to optimize the resources and guarantee the participation of featured experts in the announced topics.

V – LOGISTICS

It is informed that the capacity for the Conference is for 300 people and that it will be held at the facilities of ANVISA (Brasilia, Brazil). PAHO will finance transportation and lodging of 60 of the guests approximately, among them are:

- Steering Committee members
- Working Group members
- Regulatory Authorities
- Academics / panelists

A reminder of the importance to confirm assistance of the members no further than June 15. In order to begin the relevant logistics aspects, it is requested that the members of the Steering Committee do a follow up of the invitations already sent.

The guests will have guaranteed the transportation from the hotel to ANVISA (location of event). All the assistants of the conference will be provided with lunch and coffee.

Each one of the assistants will receive a certificate of attendance and a memory stick with all the documents of the Conference.

It is informed that the approximate cost of the event is between US$320,000 to 330,000, which will be financed by PAHO, the Pharmaceutical Industry and ANVISA.

VI – OTHERS

- It is proposed and established that once the Conference is finalized, the Steering Committee will have a meeting for 1hour and 30 minutes, approximately.

- Brazil proposes that the National Regulatory Agencies of Reference become a part of the Steering Committee of PANDRH. For this matter, they are informed that a formal request must be done for the submission to the evaluation on behalf the Committee. It is agreed that Brazil will lead this initiative.

- It is informed that within the Conference, a certificate that assures the qualification of National Regulatory Authorities of Reference to the countries that have reached that level.

- The possibility of doing a publication that consolidates the existing information of PANDRH is requested, for example; history, impact, results, among others.

- Web Site: people do not have easy access to the information of PANDRH through PAHO web site, due to problems of search on the page. Improvement of the page is suggested so in this matter, users may have the opportunity of knowledge and use of material available on the site. The idea is the existence of a link that says PANDRH with easy access to publications, news, meetings, etc. It

- Dynamic of the conference: a computer tool will be established for the regulation of the time designed for presentations, comments and questions. There is a search for a quick conference, productive and participative therefore the proposal is for guidelines for the presentations, for example, number of slides, structure of the presentation.

- Election of main and alternate members for the Steering Committee: according to the statutes of the Network, it is moment for the renewal of some Steering Committee members. Attached is the list of the representatives of past periods.

VII – CONCLUSIONES

It was boarded in satisfaction the proposed agenda for the VI Conference of PANDRH. It was pointed out the structure of the same. At the same time, the panels with topics and strategies that are binding with the Health System and Public Health were organized. Additionally to the agenda, relevant topics that were discussed in order to orient the work of the Network.

It is informed that once the report is sent, the Steering Committee will have 10 days to do any pertinent observations.

To finish, the Steering Committee makes a special recognition to Dr. José Peña, for his commitment, leadership and work done in the coordination of PANDRH.

VIII – PARTICIPANTS

MERCOSUR	:	Teresita Traverso
CAN	:	Victor Dongo
SICA	:	Eric Conte
NAFTA	:	Margarita Contreras
ALIFAR	:	Miguel Maito
ALBA	:	Rafael Pérez Cristiá
BRAZIL	:	Renata Carvalho
MPS	:	Claudia Vacca
INVIMA	:	Clara Rodríguez
		Martha Suárez
		Carolina Gómez

		Verónica Vergara
		Natalia Giraldo
PAHO	:	José Luis Castro
		Christophe Rerat
		José María Parisi
		Adriana Mendoza
		José Peña