



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

**Santo Domingo, Dominican Republic
4 March 2005**

REPORT

PARTICIPANTS

Members

Andean Area:

Julio A. Aldana (ARN/COL)

Victoria de Urioste (ARN/BOL) (Alternate)

Central America

Maria de Los Angeles Morales (ARN/COR)

Pablo Solís (ARN/PAN) Alternate

CARICOM

Yvette Sylvester (ARN/T&T)

Maryan Hinds (ARN/BAR) Alternate

MERCOSUR

Manuel Limeres (ARN/ARG)

Pamela Milla (ARN/CHI) Alternate

NAFTA

Federico Miexueiro (ARN/MAX)

Justina Molzon (ARN/USA)

Ruben Abete (ALIFAR)

José Manuel Cousiño (FIFARMA)

Other Participants

Mike Ward (ARN/CAN)

Rafael Perez Cristia (ARN/Cuba)

Zoila Navarrete (ARN/ECU)

Marta de Alvares (ARN/GUT)

Gustavo Almada (ARN/PAR)

Lourdes Galvan (ARN/URU)

Horacio Papas (USP/USA)

Miguel Maito (Substitute member for ALIFAR)

Loreta Marquez (Substitute member for FIFARMA)

MINUTES

1. **Report on the IV Pan American Conference:** The Secretariat informed that the report on Conclusions and Recommendations will be ready by the end of March and all documents will be posted in PAHO web page by April.

2. Working Groups:

New WG Composition: In selecting membership for new WG it was agreed that, whenever possible, only one member from regulatory offices from each sub-regional group will be financed to participate at the groups meetings. Regulatory offices of other countries may participate; however, their participation at the WG meeting will be self financed. Each WG may have one representative from ALIFAR and one from FIFARMA as both regional organizations may wish to participate.

- a) Biologicals: Since the term “biologicals” requires a wide range of expertise for a single WG, in order to make the group operational, the SC agreed by consensus to start with a WG on Vaccines products (WG/V). This WG/V will analyze among its members if they can also cover the subject of Recombinants. The group will not address issues on blood and bio-molecular products. Members of this WG/V: Regulatory staff from Cuba (Coordinator), Argentina, Brazil, Venezuela and the FDA.
- b) Promotion: As approved by the Conference, a WG on drug promotion and advertisement was conformed by: Brazil (Coordinator), Costa Rica, Ecuador, Paraguay, Mexico, ALIFAR and FIFARMA.
- c) Good Laboratory Practices: Members of this group are from Official Quality Control Laboratories. The coordinator will be selected among its members, taking into account that (by PANDRH’s rules) only a QCL which structure depends from the Minister of Health can coordinate the Group. WG/GLP members are a representative from the OQCL of Peru, Jamaica, Panama, Chile, the USP and one representative from FIFARMA.
- d) Ad-Hoc WG: a special WG will be established to discuss drug classifications (nutraceuticals and cosmeceutics). The Secretariat will identify existing expertise in the Region.

Other Working Groups:

- a) Medicinal Plants: This WG was re-organized and the new members are: regulatory staff from Bolivia, Brazil, Canada, Jamaica (Trinidad and Tobago as alternate), Mexico, Panama, one representative from ALIFAR and one from FIFARMA. The WG/MP will address the issues of classification and registration of natural products, among others;
- b) Pharmacovigilance: Members of the WG/PhV are: regulatory staff from Barbados, Uruguay, Cuba, Colombia, USA (and Canada as alternate or the sub-Region), and one representative from FIFARMA.

Changes on existing WGs:

It was decided that, whenever possible, an existing WG such as GMP, BE, Counterfeit and GCP should not be changed to facilitate the implementation process of their proposals.

- a) Drug Registration: Colombia will substitute Chile in the WG/DR;
- b) GMP: To discuss the strategy and format of educational seminars to implement the Guideline for GMP Verification, professor from the Universities will be invited along with selected members of the WG/GMP.
- c) Drug Classification: Cancellation of this WG was discussed; however, it was decided that the WG should complete the new task recommended by the Conference.
- d) Combat Drug Counterfeiting: The Secretariat will identify an ad-hoc expert to discuss the use of the Internet as a way to spread drug counterfeiting.

Representation by sub-Region: Members of the WG should represent the five sub-regional blocks.. The current representation is presented in the attached table.

Secretariat:

Since WGs are becoming more numerous demanding various expertise available at PAHO/HQ and at country level, the Secretariat in each WG will be performed by different PAHO staff under the general coordination of Rosario D'Alessio.

3. **Representative of PANDRH at the GCG/ICH**

The SC considering that the person selected will represent PANDRH and not any individual country, and that the person should be knowledgeable on the work being developed by all WGs of PANDRH, it was agreed that Rosario D'Alessio will represent PANDRH at the GCG of ICH.

**PAN AMERICAN NETWORK ON DRUG REGULATORY HARMONIZATION
REPRESENTATION BY SUB-REGION**

AREA / Inst.	Country	Steering Committee	BE	GMP	D. Counterf.	GCP	WGP	Medicinal Plants	D. Classf	Pharmacovigilance	D. Registration	Vaccine	Drug Promotion	GLP
AA	VEN		I. Goncalves	E. Castejon	E. Briceño	M. Aguilar					E. Briceño Coord.	TBA		
	COL	J. C. Aldana							TBC	TBA	TBA			
	ECU												TBA	
	BOL	V. Urioste						TBD			V. Urioste			
	PER													R. Vega
SA	BRA		S. Storpitis	S. Machado	M. Graca Coord.	S. Nishioka	C. Bittencourt	E. Machado	Davi Rumel	TBA	I. Chinchilla	TBA	TBA	TBA
	ARG	M. Limeres	R. Bolanos	R. Mochetto		P. Saidón Coord.	C. Chiale		I. Bignone			TBA	TBA	<i>Alternate</i>
	URU									TBA				
	PAR				M. A. Gamarra								TBA	
	CHI	P. Milla	R. Pezoa	M. Reyes		E. Jhonson								TBA
CA	PAN	P. Solís						TBA						N. de Solís
	COR	M. Morales	L. Fonseca			G. Granados			G. Rodriguez				TBA	
	HON													
	GUA			N. Pinto					B. Batres Coord.					
	ELS										P. Alfredo Lagos			
	DOR													
	CUB					A. M. Pascual				TBA		TBA Coord.		
	NIC													
NA	MEX	A. Frati		S. García			C. Becerril	F. Meixuero TBC					TBA	
	USA	J. Molzon	J. Molzon Coord.	J. Molzon Coord.		S. Woollen				TBA	J. Molzon	TBA		

	CAN		C. Pereira	L. Jodoin	P. Maynard			TBA <i>Alternate</i>	M. Ho	TBA <i>Alternate</i>	TBD	TBA		
CARICOM	JAM							TBD (Jamaica)			V Lockhart (Bahamas)			TBA
	SLU				F. Burnett (S Lucia)									
	BAR	M. Hinds								TBA				
	TRT	Y. Sylvester						TBA <i>Alternate</i>						
FIFARMA		J. M. Cousiño	L. Marquez	M. Poot	T. Hechmer	C. Arabetti		TBA	H. Bolaños	TBD	R. De Sario		TBA	TBA
ALIFAR		R. Abete	S. Giarcovich	M Benaim	M. Maito	M Ruiz		TBA			M. Maito		TBA	
UNIV			S. Stavchansky											
USP			R. William				H. Pappas Coord.							TBA
TOTAL		7 Miembros 5 Alternos	11	10	7	9	4	9	7	8	10	6	8	7