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) **Biologics:** Since the term “biologics” 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 (nutracetics and cosmecuticals). 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 acknowledgeable 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

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