PAN AMERICAN NETWORK FOR THE HARMONIZATION OF THE DRUG REGULATION (PANDRH)
(Norms and Procedures)
UPDATE PROPOSAL
November 17 2008
Discussed in Plenary Session

CURRENT VERSION	PROPOSED VERSION	COMMENTS
The Pan American Network for Drug Regulatory Harmonization (PANDRH) is an initiative to support the processes of drug regulatory harmonization throughout the Americas.	The Pan American Network for Drug Regulatory Harmonization (PANDRH) is an initiative that supports the processes of pharmaceutical regulatory harmonization in the Americas, within the framework of national and sub-regional health policies and recognizing pre-existing asymmetries.	Agreed during the Steering Committee Meeting of August 1 2008.
The Pan American Conference on Drug Regulatory Harmonization, the Steering Committee and the Working Groups on as many themes defined as priorities by the Conference, are the main components of PANDRH	The Pan American Conference on Drug Regulatory Harmonization (PANDHR), the Steering Committee (SC), the Technical Working Groups (WGs) in the areas considered as priority by the Conference, and the Secretariat, constitute the components of PANDRH.	Agreed during the Steering Committee Meeting of August 1 2008.

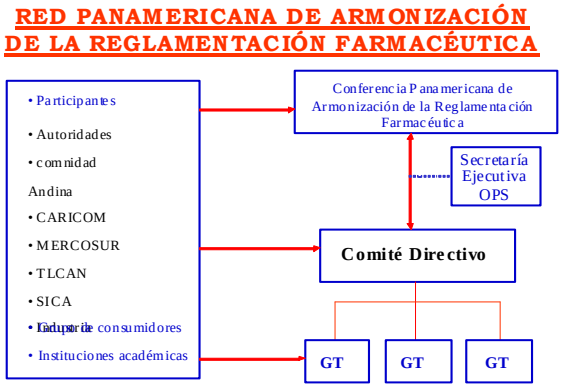
Comments added by CR during the PANDRH session, 17th Nov 08

CURRENT VERSION	PROPOSED VERSION	COMMENTS
	I. PAN AMERICAN NETWORK	
	I.1. Vision	
	That countries from the Region of the Americas implement pharmaceutical policies promoting access to medicines coherent with standards of quality, safety and efficacy, and pharmaceutical harmonization within the Region of the Americas through technical cooperation, contributing to the quality of life and health care of its citizens.	The article was agreed during the Steering Committee Meeting of August 1 2008, however COFEPRIS suggested the current text with the following observations: it is important that the Vision reflect the 'essence' of PANDHR, that it guides us to where we want to go considering the different scenarios that are present within the Region of the Americas.
	I.2 Mission	
	To promote the harmonization of pharmaceutical regulation covering aspects of quality, safety, efficacy and rational use of pharmaceutical products, the strengthening of NRA capacity within the Region of the Americas based on the right of the population to access quality medicines recognizing advances in science and technology and within the context of national and sub-regional realities.	Agreed in the Steering Committee Meeting of August 1 2008.

Comments added by CR during the PANDRH session, 17th Nov 08

CURRENT VERSION	PROPOSED VERSION	COMMENTS
	I.3. Objectives	
	I.3.1 To strengthen regulatory authorities in countries of the Region promoting inter-country cooperation	I.3.1 Agreed in the Steering Committee Meeting of August 1 2008.
	I.3.2. To develop and approve harmonized proposals (technical documents, guidelines, etc.) in medicine's regulation	I.3.2 Agreed in the Steering Committee Meeting of August 1 2008.
	I.3.3. To identify support mechanisms for the implementation, monitoring and evaluation of proposals adopted and approved by NRAs through PANDRH.	I.3.3 Agreed in the Steering Committee Meeting of August 1 2008.
	I.3.4. To promote qualification of the NRAs in the Region in accordance with criteria established by PAHO/WHO and in order to establish reference Regulatory Authorities and contribute actively to the achievement of other objectives.	I.3.4 Agreed in the Steering Committee Meeting of August 1 2008.

Comments added by CR during the PANDRH session, 17th Nov 08

CURRENT VERSION	PROPOSED VERSION	COMMENTS
	I.4. Composition of the Network	
	I.4.1 The PANDRH Network is composed of the Pan American Conference on Drug Regulatory Harmonization, the Steering Committee, the Secretariat, and the working groups.	Remains as in the original version

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CURRENT VERSION	PROPOSED VERSION	COMMENTS
	I.5. Members	
	I.5.1 The members of the PANDRH are the NRAs of PAHO/WHO Member States, one representative from ALIFAR and one from FIFARMA,	
	I.5.2 PANDRH will have observers who are representatives of recognized international and/or national organizations working in the area of pharmaceutical regulation. Members with observer status shall be approved by the Steering Committee of PANDRH.	
1. THE CONFERENCE	**II. THE CONFERENCE**	
1.1 Mission	**II. 1 MISSION**	
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.	To define strategies, programs and decisions in order to promote pharmaceutical regulatory harmonization covering all the aspects of quality, safety, and efficacy of the pharmaceuticals products and contributing to the rational use of the medicines.	

Comments added by CR during the PANDRH session, 17th Nov 08

CURRENT VERSION	PROPOSED VERSION	COMMENTS
1.2 **Objectives**	**III.2. Objectives**	
To promote and maintain a constructive dialogue among regulatory agencies, the pharmaceutical industry, and other sectors, through periodic Conferences.	III.2.1 Same	
•1 To encourage convergence of drug regulatory systems in the Pan American Region	III.2.2 Same	
•2 To adopt recommendations for implementation at national and regional levels	III 2.3.To adopt recommendations that contribute to the implementation both at the national and regional level of harmonized proposals presented by working groups of the PANDRH Network	
To encourage and facilitate technical cooperation among countries	III.2.4 .Same	
To promote harmonization of medicinal drug regulation requirements, and guidelines for specific regulatory issues	III.2.5. Promote the analysis of issues of interest and priority in processes of pharmaceutical regulatory harmonization, technical documents and guidelines addressing specific problems in regulation, and review global regulatory systems.	Canada proposes an additional objective II.2.6 which will be circulated during the morning of the 18th.

Comments added by CR during the PANDRH session, 17th Nov 08

CURRENT VERSION	PROPOSED VERSION	COMMENTS
1.3 Goals	Goals Deleted	
•1 To examine global regulatory systems	Included in Functions	
•2 To develop and adopt proposals for technical/regulatory harmonization	Modified and included in Objectives	
•3 To review existing medicinal drug regulation requirements and guidelines for specific issues.	Same and included in functions	
•4 To identify and discuss medicinal drug regulation implementation issues	Deleted	
	II 3 . Description and Functions	
	II.3.1 The Conferences will be organized every two years at a date and place determined by the Steering Committee	Previously presented as a Goal
	II.3.2 The Conferences will be open forums for discussion for themes of interest in pharmaceutical regulation.	Previously presented as a Goal

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CURRENT VERSION	PROPOSED VERSION	COMMENTS
	II.3.3 Those participating in the Pan-American Conferences for the Harmonization of Pharmaceutical Regulation are the Regulatory Authorities of the countries of the Region of the Americas, Representatives from: Regional associations of the pharmaceutical industry, Consumer groups, Academia, Professional associations, groups of economic integration and global harmonization initiatives in pharmaceutical regulation. Note: The general public and other interested parties can participate in the Conference in accordance with conditions determined by the Steering Committee of the PANDRH	
	II.3.4 The recommendations and conclusions of the conferences will be adopted by consensus in the plenary sessions. If it is not possible to reach a consensus, the different points of view will be stated in the reports.	A more agile mechanism for decision making is to be later defined.

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	II.3.5 Any decision taken at the Conference with regard to the approval of Resolutions, modification of the present norms and procedures of the Network and approval or adoption of the proposals presented by the Working Groups of the PANDRH is at the sole discretion of the PANDHR.	
	II.3.6 The NRA of participating countries will present credentials to the Conference in order to be identified as the competent authority. Representation may be delegated through an official communication issued by the Minister of Health of the country or the maximum authority of the national regulatory authority and presenting credentials to act on its behalf.	

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CURRENT VERSION	PROPOSED VERSION	COMMENTS
	II.3.7 The representatives of the regional associations of the pharmaceutical industry that participate in the review and/or approval of documents presented by the WGs must present credentials to the Conference, identifying themselves as members of the SC of the Network or presenting a written communication issued by highest authority of the association in order to act on its behalf.	
	II.3.8 Decisions regarding proposed resolutions, guidelines, technical documents, regional studies, etc, for approval or adoption by the NRAs accredited by the Conference will be taken by consensus.	
	II.3.9. The Conference will be chaired by the Regulatory Authority of the host country or by a member of the Steering Committee of the Network who has been elected.	

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CURRENT VERSION	PROPOSED VERSION	COMMENTS
	II.3.10. Conferences shall be held every two years at the date and place determined by the Steering Committee	
1.4 Functions (CONFERENCE)		
To promote the participation of all interested parties in the Americas and those invited by the Steering Committee. National and regional medicinal drug regulatory authorities, subregional integration agencies, pharmaceutical industry, pharmaceutical bodies, academia, and consumer associations should be encouraged to attend	Passed to Functions of the Steering Committee	
Conferences shall be held every two years on the dates and place determined by the Steering Committee	Incorporated into the Description of the Conference.	
To adopt all Conference recommendations and conclusions through consensus in plenary sessions. If consensus cannot be reached, the different points of view will be recorded	Incorporated into the Description of the Conference.	

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CURRENT VERSION	PROPOSED VERSION	COMMENTS
1.5 Participants		
Regulatory Authorities from each Member States Representatives from: Regional and national pharmaceutical industry associations (research-based, generic, OTC, other) Consumer groups Academia Professional pharmaceutical associations Regional economic integration groups Global drug harmonization initiatives Other interested groups.	Incorporated into the Description of the Conference.	

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CURRENT VERSION	PROPOSED VERSION	COMMENTS
2. THE STEERING COMMITTEE	**III.STEERING COMMITTEE**	
2.1 Misión The Steering Committee should facilitate advancement between Conferences by coordinating, promoting, facilitating and monitoring harmonization processes in the Americas.	**III.1 Mission** The Steering Committee should facilitate advancement of the work program between Conferences by coordinating, promoting, facilitating and monitoring the processes of harmonization in the Americas, according to the recommendations of the Conferences	
2.2 ***Objectives***	***III. 2 Objectives***	
•1 To ensure the effectiveness of the Conference and the relevance of the topics addressed by the Conference	III.2.1 SAME	
To facilitate and monitor implementation of Conference recommendations	III.2.2 .SAME	
	III.2.3 To identify support mechanisms that will facilitate the implementation of technical documents that have been harmonized and approved by the PANDRH	New

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CURRENT VERSION	PROPOSED VERSION	COMMENTS
To ensure continuity of drug harmonization activities between Conferences .	III.2.4 .SAME	
To facilitate consensus-building and resolutions of issues between and at the Conferences	III.2.5 To facilitate consensus-building in the recommendations of the Conference and in decisions taken by the Network	
2.3 Goals	Deleted	
To identify experts and request broader scientific consultation to facilitate consensus at the Conferences.	Is a function of the WGs	
To develop and maintain an information system to disseminate information on the progress of harmonization processes at national and subregional levels.	Incorporated into Functions	
Identificar mecanismos para fomentar la formación de capacidad y la cooperación científica y técnica.	Incorporated into Functions	
To provide current, accurate information on regulatory systems on a timely manner.	Incorporated into Functions	

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CURRENT VERSION	PROPOSED VERSION	COMMENTS
2.4 Functions	**III.3. Functions**	
	III.3.1. To ensure operational management of the PANDRH	
	III.3.2. To stimulate actions necessary to ensure compliance with the recommendations of the Conference	
	III.3.3. To develop and maintain an information system in order to disseminate information on advances during the process of harmonization at the national and sub-regional level.	
	III.3.4. To identify mechanisms promoting capacity building, and scientific and technical cooperation.	
	III.3.5. To provide in a timely fashion, up-to-date and precise information on regulatory systems.	
	III.3.6. All the members of the SC jointly and separately will promote the participation of all countries in the Conferences urging national and regional regulatory authorities,	

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CURRENT VERSION	PROPOSED VERSION	COMMENTS
	mechanisms of sub-regional integration, the pharmaceutical industry, pharmaceutical groups, academic institutions and consumer associations to attend the conferences.	
	III.3.7 To receive and evaluate requests for the creation of new Working Groups and present for consideration to the Conference for eventual approval	
	III.3.8 To prepare the agenda for the Conference and organize jointly with the Secretariat logistics for the Conference.	
To organize meetings, workshops, and other related activities to carry out the recommendations of the Conference	III.3.9 To request the Secretariat to organize meetings, workshops, and other related activities that the Committee considers necessary for the implementation of recommendations of the Conferences and the decisions of the PANDRH.	
	III.3.10 To identify experts and request additional scientific consultations to facilitate the achievement of consensus in the Conference and any decisions of PANDRH.	

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CURRENT VERSION	PROPOSED VERSION	COMMENTS
To establish study groups on regulatory topics identified by the Conference as relevant	III.3.11. To request the Secretariat to execute studies on pertinent and relevant subjects relating to pharmaceutical regulation the results of which can be presented in the Conferences	
To determine the preparatory activities required for subsequent Conferences	III.3.12.SAME	
Determine the best methods to resolve issues to reach consensus .	III.3.13. To determine appropriate and improved methods for resolving problems in order to achieve consensus within the framework of the PANDRH	
To convene meetings at which a quorum of two thirds of the membership are present. .	Incorporated into the section on the Secretariat	
	III.3.14. The members of the SC as a Committee and as individual members will participate in the mobilization of resources to finance the operation of the PANDRH	New

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CURRENT VERSION	PROPOSED VERSION	COMMENTS
2.5 *Members*	**III.4. Members**	
Five (5) Alternate Members. Regulators from five (5) countries, or their representatives. One from each Sub-Regional Group.	III.4.1. The Steering Committee will be composed of (5) five members: national medicines regulatory authorities, or their representatives. One from each sub-regional block (The Andean Region (including Venezuela), CARICOM, central America (including Cuba and the Dominican Republic), MERCOSUR (including Chile), and NAFTA. One representative from FIFARMA One representative from ALIFAR	
Five (5) Alternate Members. Regulators from five (5) countries, or their representatives. One from each Sub-Regional Group.	III.4.2. Seven (7) alternate members corresponding to five medicines regulatory authorities or their representatives who have been accredited by PANDRH from five countries; one country from each group of countries indicated in the previous numeral, One representative from FIFARMA One representative from ALIFAR All members will retain institutional representation, and not personal.	

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CURRENT VERSION	PROPOSED VERSION	COMMENTS
2.6 Nomination	**III.5. Nomination**	
The Pan American Conference will nominate the members of the Steering Committee.	III.5.1. The members of the Steering Committee will be nominated to the Conference following proposition by the countries in the respective sub-regional block.	
With the exception of the representatives from ALIFAR and FIFARMA, all other Members and Alternates should be regulatory authorities from Member States of PAHO.	To be deleted, is similar to III.4.2	
In order to maintain continuity during each Pan American Conference, up to three of the five Members and Alternates will be changed	III.5.2 .SAME	
Members will serve for a period of four years. Members with more seniority in the SC will change during each Conference	III.5.2 .SAME	
Nomination of members will take into account representation from the different geographical groups, including all countries in the American Region	To be deleted	

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CURRENT VERSION	PROPOSED VERSION	COMMENTS
2.7 Communication and Meetings	**III.6. Communication and Meetings**	
The Steering Committee will meet at least once every year preferably in a place and date on which other activities related to drug regulation take place.	III.6.1 Same	
Video, telephone, and virtual conferences will be promoted as a means to discuss and exchange information among members of the SC. E-mail should also be used by the Secretariat to keep SC members abreast of new developments.	III.6.2. Same	
Regulators from countries not represented in the SC may participate at meetings of the SC	III.6.3. The regulatory authorities of countries that are not part of the Steering Committee can also participate in the meetings of the Committee as Observers	
Representatives from NGOs recognized by PAHO/WHO and other stakeholders invited by the Steering Committee may attend meetings of the SC as observers	III.6.4 Same	

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3. FINANCING	**IV Financing of the Network**	
Financing for the Conferences, the meetings of the Steering Committee and those of the working groups, including preparatory activities, will be sought from the following sources: Pharmaceutical industry associations Professional associations Governments Conference registration fees PAHO contributions NGOs Other	IV.1 The financing of PANDRH including the Conferences, the meetings of the Steering Committee and of the Working Groups, and any activity that is carried out within the framework of the Network will be requested through the Secretariat and may be derived from the following sources • Associations of the pharmaceutical industry • Governments • Contributions from PAHO • Professional associations • Payments by attendance at the Conference and other events • NGOs • Other	
	IV.2. The Secretariat can request financing from other sources in accordance with the principles and established standards of PAHO.	New

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CURRENT VERSION	PROPOSED VERSION	COMMENTS
	IV.3. The acceptance of contributions from sources cited in the previous paragraphs will be subject to the norms and principles that regulate programmed activities of PAHO.	New
	IV.4. The educational activities of the Network will be self-financed in such a way as to support the participation of a limited number of public sector officials in such activities.	New
4. The Secretariat	**V. The Secretariat**	
The Pan American Health Organization will serve as the Secretariat of the Network, the Conference, and the Steering Committee.	V.1 The Secretariat of the Network in all its components: Pan American Conferences, the Steering Committee and the Working Groups will be provided by the Pan American Health Organization, Regional Office of the World Health Organization.	

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CURRENT VERSION	PROPOSED VERSION	COMMENTS
The Secretariat shall	**V.2. Functions**	
	V.2.1. The Secretariat will provide technical and administrative support to the PANDRH	
Provide administrative and technical support to the Network;	V.2.2. The Secretariat will coordinate activities arising from recommendations of the Conference, from the decisions of the Steering Committee as well as all activities related to the PANDRH	
	V.2.3. The Secretariat will organize Conferences jointly with the SC	
	V.2.4. The Secretariat will convene the Conference and all the meetings of the Working Groups and others that are developed within the framework of the Network.	
	V.2.5. The Secretariat jointly with the Steering Committee will prepare the Program for the Conference and is responsible for preparing the final report of the Conference.	

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CURRENT VERSION	PROPOSED VERSION	COMMENTS
	V.2.6. The Secretariat will prepare the agenda of the meetings of the working groups, will convene the meetings and will prepare the reports of those meetings.	
Act as a clearinghouse for information	V.2.7. The Secretariat will act as center for the dissemination of information regarding the Network and as presenter of technical documents that are processed and approved by the PANDRH.	
Arrange for expert advice and consultants to assist regulatory authorities in promoting medicinal drug regulatory harmonization.	V.2.8.Same	
Maintain permanent communication with all members of the Steering Committee	V.2.9 Same	
Act as liaison, whenever appropriate, with similar programs such as ICDRA (organized by WHO), ICH, and other national or regional trade agencies, and others as necessary	V.2.10. Act as liaison and representative of the Network in global and interregional harmonization organizations (ICDRA, ICH, etc)	
Seek financing sources for the operations of the Network	V.2.11.Same	

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CURRENT VERSION	PROPOSED VERSION	COMMENTS
	V.2.12. Create ad-hoc groups for the study of issues and in support of the development of proposals that advance or serve as a complementary activity to the WGs	New
	V.2.13. Identify and approve resource Experts required by the WG's in order to develop work program	New
	V.2.14. Maintain updated WG Member CVs and make them available to coordinators, members of the SC and other entities within PANDRH	New
	V.2.15 Maintain an updated Web page for the PANDRH; promote articulation of the Web page with NRA Web pages within the Region and promote information on the Network within other public health programs (AIDS, Malaria, chronic diseases, etc.)	New

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5. Working Groups (WG)	**VI Working Groups**	
	VI.1. Composition	
Each Working Group (WG) will be established and assigned specific tasks by the SC based on Conference recommendations	VI.1.1.Same	
Members of the Working Group should be experts in the specific area of the WG. Experts are defined as persons with deep theoretical knowledge and verifiable practical experience in the field	VI.1.2. The WGs will be composed of experts on the subject matter of the group, understanding "expert" to mean a person who has a thorough technical knowledge in a field and can demonstrate broad experience in the specialized subject.	
The number of members in each WG will depend on the subject. It is advisable to keep it as small as possible to encourage consultation outside the group as needed. A total of up to 9 members is recommended	VI.1.3. The Working Groups can have up to nine members	
	VI.1.4. A WG may have the following categories of members: **Principle Member**: represents of the NRA of a country in each sub-regional block (five members), the regional Industrial Associations	New

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CURRENT VERSION	PROPOSED VERSION	COMMENTS
	ALIFAR and FIFARMA (up to two members) and those designated by the Secretariat (up to two members) **Alternate or Substitute:** members designated to attend the meetings instead of the principle member. **Observer**: from any country generally nominated by a participating NRA. The observers do not retain voting rights. **Expert Resource:** Every group may avail of up to two experts approved by the Secretariat to support a specific activity of the WG and/or to attend the meetings. Expert resources do not have voting rights.	
	VI.1.5. The NRAs of countries that are not represented in the WGs can designate Focal Points in the WGs of the Network. This designation is voluntary and the professionals thus designated can participate in technical discussions via e-mail on documents and guidelines that the WGs are developing. The Focal Points should be professionals in	New

CURRENT VERSION	PROPOSED VERSION	COMMENTS
	charge or responsible for the subjects of the WG within their respective regulatory. The combination of Members and Focal Points will form Networks of Technical Discussion.	
The Secretariat shall keep a file with the curricula vitae of all WG members	To be deleted	
Any member may, at any time, through written notice to the Secretariat, resign his/her membership from the WG	VI.1.6. Any member can, at any time, withdraw his/her participation in the Working Group, notifying his/her decision to the respective NRA who will communicate with the Secretariat.	
Representation in the WG will be flexible, and vary from WG to WG depending on the subject area. Representation should include stakeholders and technical experts from the public or private sectors. The Steering Committee will encourage representation from subregional groups.	VI.1.7. The Steering Committee will promote the representation of sub-regional groups in the WG. In order to promote broad participation, their will be a balance of representatives in each group and among the groups.	

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To assure the effectiveness of a WG, continuity of its representatives should be encouraged to the extent possible.	VI.1.8. Same	
A member of a WG cannot participate as such in more than two Working Groups.	VI1.9. A member of a WG cannot participate in more than two Working Groups	
5.1 Leader of Expert and Members	**VI.2. Coordinator**	
Each WG will have a Thematic Leader and/or a Coordinator and an Alternate Coordinator	VI.2.1. Each WG will have a Coordinator and an Alternate Coordinator. Both can belong to a single Agency or to two Agencies that share the coordination of the WG.	
Thematic Leaders, Coordinators, and Members of the WG will be appointed/selected by the SC and all shall be representative of national regulatory authorities. The SC can make exceptions to this rule	VI.2.2 The coordination (incumbent and alternate) of any WG is the responsibility of a Regulatory Authority or Agency. The network SC can establish exceptions to this rule with solid scientific justification.	
	VI.2.3. The coordinators will be selected or designated by the Steering Committee from NRAs that offer voluntarily to coordinate the WG. In the case where no NRA has volunteered, the SC will propose	

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	the coordinator from among the NRAs requesting their participation as coordinator.	
	VI.2.4 The coordinators and alternate coordinators will remain in this function for a period of four years renewable for a similar period.	New
	VI.2.5 The coordinator can voluntarily resign by submitting written notice to the Secretariat.	New
	VI.3. Functions of the Coordinator	
	VI.3.1 Lead the development process for technical documents in the Group	New
	VI.3.2. Support the Secretariat in following up on the Work Plan ensuring that members implement within the agreed timeframe.	New
	VI.3.3. Chair and coordinate the meetings of the WG	New

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	VI.3.4. Report periodically to the Steering Committee on progress achieved by the Group through annual written reports or when specifically requested by the Committee.	New
	VI.3.5. The Coordinator will seek and promote consensus among the members of the WG in decisions of the Group.	New
	VI.4.Functions of the Working Groups	
	VI.4.1. The Working Groups are responsible for developing harmonized proposals on priority issues of interest in the area of pharmaceutical regulation	New
The Ministries of Health from participating countries shall confirm the member of the Working Group representing governmental institutions.	DELETED	
Members of the Working Group should be experts in the specific area of the WG. Experts are defined as persons with deep theoretical knowledge and verifiable practical experience in the field	Incorporated into Point 1	
The Secretariat shall keep a file with the	Incorporated into Functions of the	

CURRENT VERSION	PROPOSED VERSION	COMMENTS
curricula vitae of all WG members.	Secretariat	
The number of members in each WG will depend on the subject. It is advisable to keep it as small as possible to encourage consultation outside the group as needed. A total of up to 9 members is recommended	Deleted	
It is unlikely that a country will have a representative in all WG	Deleted	
A member of a WG cannot participate as such in more than two Working Groups	Same as in VI.1.9	
Any member may, at any time, through written notice to the Secretariat, resign his/her membership from the WG	Same as in V.1.6	
Each WG shall develop diagnostic studies, identify differences between countries, formulate harmonized proposals in its area of expertise, and develop cooperation plans between the countries.	VI.4.2.Same	
The WGs shall also ensure follow-up on implementation of Conference	VI.4.3.Same	

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recommendations and approved proposals in its area of work at the regional and national level		
Members who cannot attend two consecutive meetings will forfeit their representation.	Deleted	
Whenever an expert attends two consecutive meetings in representation of another member, that expert will replace the member indefinitely.	Deleted	
Representation in the WG will be flexible, and vary from WG to WG depending on the subject area. Representation should include stakeholders and technical experts from the public or private sectors. The Steering Committee will encourage representation from subregional groups	Deleted	
To assure the effectiveness of a WG, continuity of its representatives should be encouraged to the extent possible	Deleted	
To encourage maximum participation, WG representation will be balanced within the WG and among WGs.	Deleted	

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Proposals for new Working Groups shall be approved and adopted by the Conference	VI.4.4.Same	
5.2 Work Plan	Title Eliminated	
A well-defined, written work plan should be developed by each WG.	VI.4.5. Prepare a work plan and submit it for approval by the Steering Committee	
	VI.4.6. Develop diagnostic studies, identify technical differences between countries, and formulate harmonized proposals in its area of expertise, and plans of cooperation among countries	New
	VI.4.7. Follow up on the recommendations and conclusions of the Conference applicable to their technical group.	New
	VI.4.8. To design training proposals in training and to accompany implementation during the pilot phase.	New, proposal PAHO
	VI.4.9. Develop educational material in areas or issues identified as necessary for a better comprehension and application of	New

CURRENT VERSION	PROPOSED VERSION	COMMENTS
	the proposals	
	VI.4.10. Assist countries in the dissemination, education, and implementation of proposals approved by the Steering Committee of the Network through technical support to countries coordinated by the Secretariat	New
	VI.4.11. Agreements on technical documents will be reached by consensus and in the case where a consensus is not possible, will be submitted to a vote of members of the WG.	New
All work plans will be authorized/approved by the SC	Deleted	
	VI.4.12. Maintain country focal points not represented in the WG informed of the progress in implementation of the Work Plan and continually seek the participation of the countries of the respective sub-region in the work plan. In the situation where a country has not designated a Focal Point in the subject area of the	New

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	Group, the member will ensure that the NRA is informed of progress of the Working Group.	
5.3 **Communication and Meetings**	**Communication and Meetings**	
The use of means of communications such as e-mail, videoconference and teleconference should be encouraged.	VI.5.1. In addition to regular meetings, communication means such as e-mail, videoconference and teleconference will be promoted	
Fifty-one percent (51%) of the members shall constitute a quorum for any meeting of the WGs.	VI.5.2. A quorum for any meeting of the WGs is achieved when half plus one of the members are present	
All meetings of the WGs shall be convened by the Secretariat	VI.5.3.Same	
5.4 Mechanisms for information		
The Thematic Leader or Coordinator shall make periodic updates of WG progress to the SC at designated times.	Incorporated into Coordinator	
The Thematic Leader or Coordinator from each WG will submit a written report to the	Incorporated into Coordinator	

CURRENT VERSION	PROPOSED VERSION	COMMENTS
SC at designated times		
	VII. Final Statement	
	The present Regulations replace in their entirety the first set of Regulations governing the Conferences approved by the II Pan American Conference for the Drug Regulatory Harmonization, November 1999. It thus constitutes the Regulations of the Pan American Network for Drug Regulatory Harmonization entering into force at the time of its adoption by the V Pan American Conference for Drug Regulatory Harmonization.	New

Abbreviations

SC	Steering Committee
WG	Working Group
NRA	National Regulatory Authority
WGs	Working Groups

Comments added by CR during the PANDRH session, 17th Nov 08