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WORLD HEALTH ORGANIZATION



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PHARMACEUTICAL REGULATORY HARMONIZATION IN THE AMERICAS

Political and economic development in the Americas has resulted in a renewed interest in regional economic integration. The regulation of pharmaceuticals and the harmonization of technical standards have emerged as an important component of the economic integration discussion. The degree of progress in the area of harmonization of technical standards varies from one subregion to another and from one country to another.

In view of their similar needs, other regions and a multiregional group of countries are working toward drug regulatory harmonization. In fact, the European Union developed a structure and system for harmonizing the laws and regulations of its member countries to promote both public health and the free circulation of pharmaceuticals within the European trade areas. The United States, Europe, and Japan formed the International Conference on Harmonization and Technical Requirements for Registration of Pharmaceuticals for Human Use, which is working toward drug regulatory harmonization.

In the Americas there is a need to promote harmonization to facilitate the availability of safe, effective, and good quality pharmaceuticals and thereby protect public health. PAHO, in collaboration with the pharmaceutical industry, has held two conferences on drug regulatory harmonization in the Region, aimed at facilitating communication and the exchange of information in this area among all interested parties.

This document is submitted for the consideration of the Directing Council to apprise its Members of the implications of the drug regulatory harmonization initiative in the Region of the Americas as a way of assuring drug quality in a globalized pharmaceutical market, and to obtain their support for the Pan American Network for Drug Regulatory Harmonization and its Steering Committee. The 126th Session of the Executive Committee, held in June, discussed this item and adopted a resolution (see CE126.R9, annexed) for the consideration of the Directing Council.

CONTENTS

	<i>Page</i>
1. Introduction.....	3
2. Current Situation.....	3
2.1 Global Harmonization: World Health Organization and the International Conference of Drug Regulatory Authorities.....	3
2.2 European Harmonization.....	4
2.3 International Conference on Harmonization and Technical Requirements for Registration of Pharmaceuticals for Human Use.....	4
2.4 Harmonization Activities in the Region of the Americas	5
3. PAHO Activities Related to Drug Regulatory Harmonization in the Americas	7
3.1 First Pan American Conference on Drug Regulatory Harmonization	7
3.2 Center for Drug Evaluation and Research, FDA: Meeting of Americas’ Regulators	8
3.3 Consultation for the Establishment of the Steering Committee for the Pan American Conferences on Drug Regulatory Harmonization	8
3.4 Regional Working Group on Bioequivalence.....	9
3.5 Regional Working Group on Good Clinical Practice	9
3.6 Second Pan American Conference on Drug Regulatory Harmonization.....	9
3.7 First Meeting of the Steering Committee of the Pan American Network for Drug Regulatory Harmonization	10
4. Proposed Action to Improve the Drug Regulatory Harmonization Processes	10
5. Budget	11
Annex A: Pan American Network for Drug Regulatory Harmonization. Work Plan 2000/2001, Ranked by Priorities Approved by the Steering Committee	
Annex B: Estimated Biennial Budget for the Proposed Plan of Work 2000-2001 for Drug Regulatory Harmonization	
Annex C: Resolution CE126.R9 - Drug Regulatory Harmonization	

1. Introduction

Access to pharmaceutical products (drugs and biologicals) requires national drug policies that are part of the overall health policy. As a social good associated with justice and equity, they are directly linked to the quality of care. Moreover, since the purpose of drugs is to diagnose, prevent, or treat diseases or ailments in humans, they are products intimately linked with the advances in research and national policies on research and regulation. The pharmaceutical industry, while pursuing a multinational market, is obliged to comply with national regulations. The harmonization of technical norms for the development and registration of pharmaceuticals in the countries of the Region has many advantages: it will reduce unnecessary regulations for registering drugs that represent a duplication of efforts without compromising the standards of safety and effectiveness; and it will permit the development of pharmaceutical products at lower cost—products that can be placed on the market rapidly. Harmonization has a direct influence on the quality of drugs and optimizes the quality of the domestic and international markets while facilitating the expansion of the international market. This, under the aegis of the international integration and trade organizations, thereby safeguarding the sanitary aspects of products with high commercial value and extraordinary sanitary value.

2. Current Situation

There are three international harmonization movements in progress with serious implications for the Region of the Americas:

2.1 *Global Harmonization: World Health Organization and the International Conference of Drug Regulatory Authorities*

The Constitution of the World Health Organization explicitly states that one of its functions will be "...to develop, establish, and promote international standards with respect to food, biologics and pharmaceuticals and similar products." This is accomplished through the work of the various Expert Committees, which issue recommendations concerning the standards, policies, and reference materials that should be accepted internationally. Experts from both the developed and the developing countries participate in this exercise, which covers essential, but not necessarily new, drugs of sanitary interest to the developing countries, as well as products whose therapeutic efficacy and cost have kept them from being replaced by other, newer drugs. WHO has convened the International Conference of Drug Regulatory Authorities (ICDRA) every two years since 1980 to promote harmonization and the exchange of information and criteria in the search for a solution to problems common to all

agencies

in the world charged with regulating drugs and biologicals. These meetings represent a unique opportunity for the regulatory authorities of the developed and developing countries alike.

2.2 *European Harmonization*

The European Union, which to date includes the full participation of 15 European countries, and observer status for others, developed a structure and system for harmonizing the laws and regulations of its member countries to promote public health and the free circulation of pharmaceuticals within the European trade areas. European Council Regulation EEC No. 2309/93 of 22 July 1993 established the European Agency for the Evaluation of Medicinal Products (EMA) to specifically oversee, coordinate and facilitate European harmonization of pharmaceutical requirements. The creation of the EMA was in large part due to the multinational focus of the pharmaceutical industry and the increasing cost and time involved in the development of new medicines. Pharmaceutical companies needed an effective and efficient regulatory environment within the European Union to be fully competitive when developing products to promote public health. The EMA offers a centralized alternative for the registry of products that the pharmaceutical companies wish to market in the member countries of the Union. At the same time, when companies wish to market a product in a particular country, they can select the registration modality of the country in question.

2.3 *International Conference on Harmonization and Technical Requirements for Registration of Pharmaceuticals for Human Use*

In 1990 a unique project was initiated through the cooperative effort of the pharmaceutical regulators and research and development industry of three regions: the European Union, Japan, and the United States. The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) was established to improve the efficiency of the process for developing and registering new medicinal products in the three regions through harmonization. This effort is aimed at ensuring that good quality, safe and effective pharmaceuticals are developed and registered in the most efficient and cost-effective manner. These activities, as stated in the ICH's 1990 Terms of Reference, "...are pursued in the interest of the consumer and public health to prevent unnecessary duplication of clinical trials in humans and to minimize the use of animal testing without compromising the regulatory obligations of safety and effectiveness". The ICH sponsors wanted to ensure the transparency of its harmonization process and recognized the importance of the presence of observers from other regulatory authorities as a means of

ensuring that the benefits of harmonization would be felt worldwide. To that end, the representatives of WHO, Canada, and the European Free Trade Area (EFTA) were made permanent "observers" in the Steering Committee. WHO is also an observer in the ICH. Expert working groups of the ICH, including observers, were charged with the task of harmonizing the technical requirements identified as priorities by the ICH sponsors.

Recognizing the growing use and adoption of more than 40 guidelines developed in the first 10 years of ICH harmonization activities, in March 1999, the ICH Steering Committee created a subcommittee to focus specific attention on global cooperation. Of paramount importance, is the recognition by the ICH sponsors that close cooperation with WHO and support for WHO efforts is critical to ensure that the ICH achievements are readily available to all.

2.4 *Harmonization Activities in the Region of the Americas*

Political and economic development in the Americas has resulted in a renewed interest in regional economic integration. The regulation of pharmaceuticals and the harmonization of technical standards have emerged as an important component of the economic integration discussion. The degree of progress in the area of harmonization of technical standards varies from one subregion to another. Hence, the need to promote harmonization in the Americas and promote the health of the Region by facilitating the availability of safe, effective and quality pharmaceuticals. In addition, both the national authorities and the pharmaceutical industry recognize that in order to participate in the world market, the Region, as a prerequisite, must meet international standards on the quality of pharmaceuticals, as well as have effective registration (licensing) processes.

2.4.1 *North American Free Trade Agreement*

To date in the North American Free Trade Agreement (NAFTA), established in 1994, the topic of the regulation of pharmaceuticals has focused on information exchange such as regulatory matters, Good Clinical Practice (GCP), postmarketing surveillance and adverse event reports, approval of new products, and joint reviews. These discussions are supportive efforts in the development of harmonization within the current regulatory requirements in each of the three NAFTA countries (United States, Canada, and Mexico). NAFTA has still not established a specific technical group to deal with the topic of pharmaceuticals.

2.4.2 *MERCOSUR*

The Mercado Común del Sur (MERCOSUR), established in 1991 by Argentina, Brazil, Uruguay and Paraguay, reflects the most structured effort among the trade groups for regulatory harmonization of pharmaceuticals. The technical work is carried out through

working subgroups, one of which focuses on technical standards. PAHO is an official adviser to the meetings of this subgroup. There has been important progress such as the establishment of work mechanics at the technical level, the definition of priority subjects, and the acceptance of certain common standards, some of which are based on WHO recommendations, for example, Good Manufacturing Practice (GMP). Among the current priorities identified by the technical group from these countries is the development of a common pharmaceuticals policy. The most significant problem noted by the group is the difficulties encountered by the participating countries in incorporating MERCOSUR agreements, conventions, and resolutions into their national legislation.

2.4.3 *Andean Group*

The Andean Group, established in 1969 and which includes Bolivia, Colombia, Ecuador, Peru and Venezuela, has been attempting with limited success since the 1970s to develop a common market, despite several agreed upon proposals. Drug policy, drug regulation and common registration have been topics openly and widely discussed by national drug regulators. Organizations such as the Convenio Hipólito Unanue and the Secretariat of the Andean Community (formerly Cartagena Agreement) promote and sponsor the harmonization process through meetings and technical workshops in which the pharmaceutical industry also participates on occasion. The supranational nature of the agreements reached within the framework of the Andean Community should be noted. PAHO/WHO has long provided technical and financial support for this process through a variety of activities in this subregion, and many of the technical agreements are used for the discussions held within the framework of the other organizations. In this subregion the bilateral agreements between countries, such as the one between Colombia and Venezuela on GMP, are of particular interest.

2.4.4 *Caribbean Community*

In the Caribbean Community (CARICOM) established in 1973, a legal or administrative framework for pharmaceutical regulatory harmonization has yet to be created. However, the Caribbean Regional Drug Testing Laboratory is responsible for analyzing drug quality in the subregion, and its Technical Committee meets twice a year. Last year (1999), CARICOM hosted a meeting on regulatory issues sponsored by PAHO. This year, also under the auspices and with the financing of PAHO, compliance with the agreements of the first meeting will be monitored and a proposal will be prepared for a common pharmaceuticals policy for the countries of the area.

2.4.5 *Central America Integration System*

Economic integration in the Central America area is being sought by the Central America Integration System (SICA), established in 1961 with Costa Rica, El Salvador, Guatemala, Honduras and Nicaragua as members. There have been several attempts to establish a free trade in pharmaceuticals, but without success. Drug regulatory harmonization in this subregion began in 1985 as part of several projects on essential drugs. In 1993, the need for harmonization and the protection of consumer health were recognized in the Protocol of Economic Integration, signed by the presidents of Central America. However, since there is no subregional legal or administrative framework for participating countries to adopt the decisions of subregional technical meetings, the implementation of those agreements depends on the interest and political capacity of the regulatory authorities. Pharmaceutical regulatory harmonization processes are, for the most part, supported by PAHO and during recent years, some activities are further being supported by the pharmaceutical industry. Harmonization efforts have focussed on pharmaceutical registration, GMP inspections and quality control.

3. PAHO Activities Related to Drug Regulatory Harmonization in the Americas

PAHO has convened two conferences on drug regulatory harmonization in the Americas. These conferences have served as an open forum for representatives of the drug regulatory authorities, the pharmaceutical industry, consumer groups, academia, regional professional associations, and other interested groups from all regions of the Americas, which has facilitated communication and the exchange of information on this topic of common interest.

As a result of these conferences, harmonization activities were recognized as important areas to be focused on to ensure that national authorities in the Region have access to state of the art information. The summary of these meetings and their outcomes follow:

3.1 *First Pan American Conference on Drug Regulatory Harmonization* *(Washington, D.C., 17-20 November 1997)*

Conference participants acknowledged the necessity of continuing harmonization processes under way through the specific agencies and mechanisms currently operating in the Region, such as CARICOM, LAIA, MERCOSUR, NAFTA, and the Andean Community.

It was unanimously recommended that a hemispheric forum be established, with PAHO as its Secretariat, to facilitate communication among the different subregional blocs in

the area of drug regulation and to make room in the process for countries not represented in the current integration blocs, such as Cuba, the Dominican Republic, and Chile, although this latter country is considered part of the MERCOSUR discussions. The Conference stressed the importance of having a Steering Committee in which the subregional groups active in the regulatory harmonization process are represented. It was felt that the conference or forum should include all stakeholders involved in addressing the problems connected with pharmaceuticals: the regulatory authorities, industry (domestic and multinational), representatives of the integration blocs, consumers, academia, and professional associations.

Further recommendations suggested that terms of reference for the forum and the Steering Committee could be developed by mutual agreement and could cover the following areas: 1) structure and operations; 2) legal/administrative/policy regulatory topics; 3) information exchange and communications, focusing on Internet access and translations; 4) training to build expertise; and 5) other general topics of mutual interest.

3.2 *Center for Drug Evaluation and Research, FDA: Meeting of Americas' Regulators (Washington, D.C., 21 November 1997)*

Taking advantage of the Pan American Conference on Drug Regulatory Harmonization, in November 1997, the FDA's Center for Drug Evaluation and Research, with PAHO's assistance, arranged a meeting of Americas' Regulators.

The intent of the meeting was to discuss further harmonization strategies for selected science/technical topics in the Americas (continuation of discussion from PAHO meeting) and to consider 'doable' short-term activities on selected science/technical topics that could support long-term regulatory harmonization efforts in the Americas.

Attendees determined a series of science, technical and general strategy topics worthy of cooperative efforts. The topics included bioavailability and bioequivalence (BA/BE), GMP, control laboratories/surveillance, and enhanced communication between the Regulators and countries of the Americas.

3.3 *Consultation for the Establishment of the Steering Committee for the Pan American Conferences on Drug Regulatory Harmonization (Caracas, Venezuela, 14-15 January 1999)*

Participants analyzed the importance of continuing and strengthening regulatory harmonization processes aimed at ensuring the quality, efficacy, and safety of drugs in the

Americas. The recommendation of the first Pan American Conference on the Drug Regulatory Harmonization was deemed to be of great importance for giving continuity to the process, and the formation of a Steering Committee was considered strategically necessary for this purpose. It was also considered very important that the Steering

Committee, once established, be officially recognized by the authorities of the countries in order to ensure the support and endorsement of the governments for the fulfillment of its responsibilities.

3.4 *Regional Working Group on Bioequivalence (BE) (Caracas, Venezuela, 13-15 January 1999)*

Distinguished experts in bioequivalence from different countries of the Region participated in this meeting and analyzed the situation in the Americas. They noted that bioequivalence studies are a requisite to ensure the interchangeability of pharmaceutical products; also a requisite is the implementation of these studies, which should be prioritized by type of product, in line with the WHO proposal in this area. The recommendations of this group are being widely disseminated at the national level.

3.5 *Regional Working Group on Good Clinical Practice (Buenos Aires, Argentina, May 1999)*

The working group was organized jointly with the National Drug, Food, and Medical Technology Administration (ANMAT). Technical representatives from several countries analyzed the current legislation on the conducting of clinical trials in the Americas and on the areas requiring regulation. The group used the Guidelines published by the ICH as a reference and, making the necessary adaptations, issued its recommendations, which are being widely disseminated.

3.6 *Second Pan American Conference on Drug Regulatory Harmonization (Washington, D.C., 2-5 November 1999)*

The Second Pan American Conference on Drug Regulatory Harmonization recognized that progress had been made since the first Conference on drug regulatory harmonization in the Region, although it also suggested that a greater, more continuous effort should be made. Pharmaceutical topics discussed at the Conference included: bioequivalence, good clinical practice, good manufacturing practice, counterfeit products, and categorization

of drug classes. Further work on these topics was recommended with harmonization efforts considered, where feasible.

Among the conclusions issued by the Conference are the following:

- Harmonization should be understood as the search for common ground within the framework of recognized standards, taking into account the existence of different political, health, and legislative realities among the countries of the Region.
- The mission of the Conferences is to promote 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 countries of the Americas.
- A “Pan American Network for Drug Regulatory Harmonization” with biennial Pan American conferences should be established to provide an open forum for interested parties.
- A steering committee should be formed to enable progress between Conferences by coordinating, promoting, facilitating and monitoring harmonization processes in the Americas.
- The harmonization processes should encompass regulations governing not only the registry of drugs but their marketing as well, and these processes should be analyzed from the standpoint of their impact on access to drugs.

3.7 *First Meeting of the Steering Committee of the Pan American Network for Drug Regulatory Harmonization (Puerto Rico, 2-3 April 2000)*

The main objective of this meeting was to develop a two-year plan of work based on the recommendations of the Second Pan-American Conference on Drug Regulatory Harmonization, presented in the order of priority identified by the Committee (see Annex A).

4. Proposed Action to Improve the Drug Regulatory Harmonization Processes

- Every effort should be extended by PAHO and the countries to endorse and assure the success of the Pan American Network for Drug Regulatory Harmonization and the biennial Pan American Conferences in their efforts towards pharmaceutical harmonization. Providing an open forum for interested parties (e.g., regulators,

industry, consumer representatives), to discuss the progress of harmonization will ensure the successful adoption and implementation of harmonized outcomes.

- It is of utmost importance that the country authorities at the highest level officially endorse the establishment of the Pan American Network and its Steering Committee to ensure support for the work of the Committee and its working groups.
- PAHO should provide administrative support for the Network, the Conference and the Steering Committee. Resources should be allocated to enable this activity.
- PAHO should increase support to the countries of the Region by strengthening the capacity of the regulatory authorities involved in the harmonization process to participate, adopt and implement the recommendations. For those countries with less developed regulatory infrastructures, PAHO should promote the adoption of procedures that facilitate regulation, the organization or restructuring of the agencies responsible for regulation, and opportunities for upgrading the skills of the human resources involved—all of which should be accomplished by the strengthening of national capacities and the exchange of support and expertise among the countries.
- The health authorities of the Americas should make a commitment to move forward with the implementation of scientific standards, at the normative level, approximating international recommendations. Work schedules should be established to expedite the regional goals for harmonization with initiatives for cooperation in pharmaceutical regulatory harmonization in the subregional blocs supported within the framework of the economic integration processes. The participation of academia and the private sector should be promoted to provide the infrastructure with the necessary human resources (Annex A).

5. Budget

Drug regulatory harmonization presupposes the participation of the public and private sectors. In the public sector, this would involve the administrative structures of the ministries of health, trade, and finance, and in the private sector, the pharmaceutical industry. Also necessary is the participation of the education sector, consumer protection agencies, and, in general, representatives of stakeholders in the pharmaceutical field. This participation by interested sectors is spearheaded by the ministry of health, through the drug regulatory authority.

The renewal and amendment of laws and regulations, the strengthening of existing structures in terms of their organization, administration, and financing, the renovation and

modernization of their facilities, and the upgrading of their personnel are among the commitments that governments and the private sector assume to move forward the harmonization process. In the pharmaceutical field, these processes are not new in the Americas, nor is the participation of PAHO. In fact, for many years PAHO has lent its technical and financial support to the governments in their efforts to improve the quality component of the pharmaceutical market, especially the harmonization processes themselves.

The activities in that context have been included in the plans of work of the Regional Program on Essential Drugs and Technology for activities of a regional nature. For national activities, the support is provided through drug projects with extrabudgetary resources and national technical cooperation programs. The proportion of the resources varies with the size of the projects but is estimated at 25% to 30% of the budget in each case. Historically, approximately US\$ 50,000 annually in PAHO regular and extrabudgetary funds have been allocated to drug regulatory activities. The Pan American Conferences on Drug Regulatory Harmonization have cost \$100,000 each. The resources for the two conferences held have come from the Latin American associations of the pharmaceutical industry, FIFARMA and ALIFAR. The FDA of the United States has also contributed, as has Argentina's ANMAT.

Financing to support the Pan American Network for Drug Regulatory Harmonization, its Steering Committee, and its technical working groups is necessary if harmonization efforts are to progress. Financing could come from government, the pharmaceutical industry, conference registration fees (the ICH model), and other sources. PAHO and WHO may be able to provide resources, but given the general resource constraints, such financing should always be considered supplementary, supplied through extra budgetary resources. The budget required to implement the plan of work proposed by the Steering Committee for the biennium 2000-2001 is presented in Annex B. In order to implement this regional plan of work, an estimated \$430,000 in extrabudgetary funds will be required. This financing includes funding for all the working groups, the realization of the study and reports, together with their translation, publication, and dissemination, and the holding of the next Conference, proposed for November 2001, to adopt the recommendations issued by the working groups through the Steering Committee.

From the budgetary standpoint, it should be noted that the real cost of the plan of work includes the following elements:

For the Governments

- The assignment of staff (man/hours) from the respective institutions, depending on the specific area.

- The cost of national implementation of the regional harmonization agreements, which imply an improvement in structures, the training or updating of human resources and equipment, and operating costs.

For the private sector

- The participation of its representatives at technical meetings.
- The cost of adapting to the specific requirements (physical structure, human resources).

For PAHO

- The participation of its personnel (staff member/hours) to meet its responsibilities as the Secretariat of the Network, of the Steering Committee, and of the Conference.
- Technical assistance in the areas identified as priorities for the regional, subregional, and national harmonization processes.
- The reproduction and dissemination standards, guidelines, reports, and agreements.

For other stakeholders

- Participation of representatives at the meetings of the technical groups.

Annexes

**PAN AMERICAN NETWORK FOR DRUG REGULATORY HARMONIZATION
WORK PLAN 2000/2001, RANKED BY PRIORITIES APPROVED BY THE STEERING COMMITTEE**

Topics	Coordinator / Participants	Members	Scope	Timeframe	Outcomes/Indicators Suggested
GOOD MANUFACTURING PRACTICE (GMP)	Coordinator: FDA Contact person: Justina Molzon Participants: GUT: Esmeralda Villagran ARG: Carlos Chiale CAN: France Dinasarau BRA: Antonio Bezerra FIFARMA: ALIFAR:	Regulators Academia Industry	<ul style="list-style-type: none"> - Training program design - Implementation of training programs - Mechanism for Monitoring GMP implementation - Identify standard under development in other Forum (ICH) (Consultation GMP) - Joint inspection/observation (Sharing documents) - Working Group meeting (WG) 	<p>June 2000 Sep-Oct 2000 Long Term goal June 2000 May 2000</p>	<ul style="list-style-type: none"> - Training material developed - Implementation of the Training Program (regional and national) - Proposal/work plan - Number of trained professionals - Report of the WG
BIOEQUIVALENCE (BE)	Coordinator: USA/FDA Contact Person: Justina Molzon Participants: USP: Roger Williams Univ. TEXAS: Salomon Stavchansky (To be confirmed) JAM: Eugene Brawn ARG: Ricardo Bolaños VEN: INH (To be announced) CAN: Norman Pound FIFARMA: (To be announced) ALIFAR: Silvia Gercovich	Regulators Academia Industry	<ul style="list-style-type: none"> - Assessment on BE in Countries - Selection of Team Members - Consolidation of the questionnaire - Selection of materials - USP¹ Public meeting - I Regional Seminar - Evaluation (at Pharmacy Congress) <p>Pending possibility:</p> <ul style="list-style-type: none"> - National Seminars - II Regional Seminar - WG meeting 	<p>May-June 2000 April 2000 July 2000 July-Aug 2000 Sept 2000 Nov-Dec 2000 March 2001</p> <p>---</p> <p>Jan-July 2001 May 2001</p>	<ul style="list-style-type: none"> - Training material developed - Training Seminars (Regional and national) - Number of trained professionals - Report of the WG
GOOD CLINICAL PRACTICE (GCP)	Coordinator: ARG (ANMAT ²): Patricia Saidon Participants: BRA: Elizabeth MEX: Alberto Frati CARICOM: Henry Freisal COR: Guillermo Rodriguez VEN: INH USA: FDA. David Lepay (To be confirmed) FIFARMA: (To be announced) ALIFAR: (To be announced)	Academia Regulators Industry	<ul style="list-style-type: none"> - Situation analysis on GCP in the Americas - Mechanism to follow up on the implementation of GCP (Buenos Aires) - Identify training programs in the Americas - Two DIA³ events (ARG and Central America) - Follow- up mechanism for GCP - WG meeting 	<p>Sept 2000</p> <p>Oct 2000</p>	<ul style="list-style-type: none"> - Report on the Study on GCP - Training programs being developed in the Americas - Number of events on clinical practice - Number of trained professionals - Report of the working group

CD42/13, Rev. 1 (Eng.)
Annex A

¹ US Pharmacopoeia

² Administración Nacional de Medicamentos, Alimentos y Tecnología Médica

³ Drug Information Association

Topics	Coordinator / Participants	Members	Scope	Timeframe	Outcomes/Indicators Suggested
CLASSIFICATIONS	Coordinator: Mexico Contact person: Rafael Garcia Participants: COR: Ileana Hess GUT: Beatriz de Jimenez CAN: Dorothy Walker (Tto be confirmed) ARG: Ines Bignone VEN: INH (To be announced)	Regulators USP Industry	<ul style="list-style-type: none"> - Comparison study including a matrix on classification criteria of all countries. (including other regions - Australia, France, Japan, USA) - Inventory of existing guidelines - Recommendations - Proposed framework for classification - WG meeting 	Sept. 2000 March 2001	<ul style="list-style-type: none"> - Report on the study - Existing Guidelines Identified and available - Proposal criteria to be applied in the countries - Number of countries with reviewed criteria - Report of the WG
COUNTERFEIT DRUGS	<ul style="list-style-type: none"> - Coordinator: Brazil Marcelo Itagiba - Participants: CAN Sultan Ghani ARG: Silvia Bonis CARICOM: Francis Burnet ALIFAR: To be announced CUMCIG: To be announced 	Regulators Industry Consumer groups	<ul style="list-style-type: none"> - Proposal on network and strengthening of communication mechanism - Presentation of the proposal - Identify existing mechanism to help combat the problem (Laboratory) - Working group meeting 	October 2000 Next Steering Committee (SC) meeting	<ul style="list-style-type: none"> - Document on Proposal - Work plan for implementing mechanism - Report of the WG
DRUG REGULATORY AGENCY	<ul style="list-style-type: none"> - Coordinator: VEN Francisco Griffin - Study by an STC (PAHO) 	Regulator	<ul style="list-style-type: none"> - Identify & circulate useful existing doc. - Study on DRAs (including France, Spain, CARICOM) 	Sept. 2000 May2000—April 2001	<ul style="list-style-type: none"> - Report on the study - Regional Meeting - Number of countries with reviewed system
PHARMACOPOEIA (USP)	Coordinator: USP Contact: Roger Williams Participants: MEX: Carmen Becerril BRA: Celso Bethancurt ARG: Carlos Chiale	Regulatory entities Pharmacopoeia members Industry	<ul style="list-style-type: none"> - Develop work plan for communication network to share information (ARG, BRA, MEX, USP) - Expand work with control laboratories (validation, analysis) - Working group meeting 	Next Pharmacopoeia Meeting: São Paulo, May 2000	<ul style="list-style-type: none"> - Network established with a plan of work - Plan of Work for Drug - Laboratories Network - Report of the working group
GOOD PHARMACY PRACTICE	FARMACEUTICAL FORUM FOR THE AMERICAS	Regulators Academia Prof. Associations	<ul style="list-style-type: none"> - Presentation from Pharmaceutical Forum of the Americas at the III Conference - No WG needed. Highly related to Pharmacy care. Postponed until next SC meeting - USP will send information on e-mail and mail selling of drugs 	To be considered at the Next SC meeting May 2000	
REGIONAL ENTITY		Regulators	<ul style="list-style-type: none"> - Develop work plan for a feasibility study for a regional / subregional entity. 	To be considered at the next SC meeting	

**ESTIMATED BIENNIAL BUDGET FOR THE PROPOSED PLAN OF WORK
2000-2001 FOR DRUG REGULATORY HARMONIZATION
(In US Dollars)**

Good Manufacturing Practice	- Preparation of Training Courses (FDA/UPR ⁴) - Two Training Courses - Two Working Groups (WG) meetings	15,000 40,000 30,000	85,000
Bioequivalence	- Preparation Courses (FDA/UT ⁵) - Two Regional Seminars - Three National Seminars - Two WG meetings	15,000 54,000 30,000 30,000	129,000
Good Clinical Practice	- Assessment (ANMAT ⁶) - Central America meeting - Argentina Meeting - One WG meeting	5,000 4,000 3,000 15,000	27,000
Classifications	- Comparative study - One WG meeting (Mexico)	6,000 10,000	16,000
Counterfeit Drugs	- One WG meeting (Brazil)	15,000	15,000
Drug Regulatory Agency	- Study	25,000	25,000
Pharmacopeia	- One WG meeting	8,000	8,000
Good Laboratory Practice	- Validation course	25,000	25,000
III Pan American Conference on Drug Regulatory Harmonization	- Conference	100,000	100,000
Total			\$430,000

⁴ University of Puerto Rico

⁵ University of Texas

⁶ Administración Nacional de Medicamentos, Alimentos y Tecnología Médica, Argentina



PAN AMERICAN HEALTH ORGANIZATION
WORLD HEALTH ORGANIZATION



126th SESSION OF THE EXECUTIVE COMMITTEE

Washington, D.C., 26-30 June 2000

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Annex C

RESOLUTION

CE126.R9

DRUG REGULATORY HARMONIZATION

THE 126th SESSION OF THE EXECUTIVE COMMITTEE,

Having considered the Director's report (Document CE126/15) on drug regulatory harmonization in the Americas,

Taking into account that the drug regulatory harmonization processes are fundamental for guaranteeing the safety, efficacy, and quality of drugs;

Recognizing that other regions and subregional groups of countries in the Americas with different levels of development are making efforts at the global level to move forward with drug regulatory harmonization;

Aware that, through its plans of work, the Pan American Network for Drug Regulatory Harmonization will represent a concrete regional option for this process; and

Observing that drug regulatory harmonization offers health, economic, and technical advantages for the countries committed to its implementation,

RESOLVES:

1. To thank the Government of the United States of America for presenting the topic at the 34th Session of the Subcommittee on Planning and Programming.
2. To recommend that the Directing Council adopt a resolution in the following terms:

THE 42nd DIRECTING COUNCIL,

Having considered the Director's report (Document CD42/13, Rev. 1) on drug regulatory harmonization in the Americas;

Taking into account that the drug regulatory harmonization processes are fundamental for guaranteeing the safety, efficacy, and quality of drugs;

Recognizing that other regions and subregional groups of countries in the Americas with different levels of development are making efforts at the global level to move forward with drug regulatory harmonization;

Aware that, through its plans of work, the Pan American Network for Drug Regulatory Harmonization will represent a concrete regional option for this process; and

Observing that drug regulatory harmonization offers health, economic, and technical advantages for the countries committed to its implementation,

RESOLVES:

1. To urge the Member States to:
 - (a) review the current drug policies, with a view to adopting new policies that will ensure access to drugs that are safe, effective, and of acceptable quality;
 - (b) strengthen the infrastructure currently in place for regulating drugs to permit regulation that is expeditious but technically acceptable;
 - (c) support national implementation of the agreements and recommendations arising out of the Pan American Network for Drug Regulatory Harmonization.
2. To request the Director to:
 - (a) support the establishment of the Pan American Network for Drug Regulatory Harmonization and strengthen the role of PAHO as its Secretariat;
 - (b) promote progress toward technical agreements on drug regulation among the Member States, including multilateral, bilateral, and subregional agreements, with the participation of all sectors and interest groups;
 - (c) promote the search for sources of financing for this process and the plan of work.

(Sixth meeting, 28 June 2000)