

**IV PAN AMERICAN CONFERENCE ON DRUG REGULATORY
HARMONIZATION
Dominican Republic
2-4 March 2005**

CONCLUSIONS AND RECOMMENDATIONS

The Rules & Regulations of the Pan American Network on Drug Regulatory Harmonization (PANDRH) establishes that:

The Mission of the Pan American Conference on Drug Regulatory Harmonization is to 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;

The objectives of the Conference include the adoption of recommendations for implementation at national and regional levels; and the promotion of harmonization of drug regulation requirements, and guidelines for specific regulatory issues;

The goal of the Conference refers to the development and adoption of proposals for technical and regulatory harmonization;

The IV Pan American Conference on Drug Regulatory Harmonization issued the following recommendations and decisions on each one of the proposals submitted by the Working Groups of PANDRH and other subjects:

I. Good Manufacturing Practices

1. Considering that all the elements contained in *Guidelines for the Verification of the Good Manufacturing Practices for the Pharmaceutical Industry* are important and whose application will make quality drugs available to the population, the Conference

recommends the adoption of the Guideline as it was presented by the Working Group of GMP of PANDRH;

2. The Conference also recommends:

The National Drug Regulatory Authorities (DRA)

- 2.1 To verify that the national regulation on GMP considers, but not limited to, what is expected in the Guideline for GMP Verification for the Pharmaceutical Industry;
- 2.2 To prepare a national plan for the implementation of the Guideline for GMP Verification, with the participation of drug manufacturers through : a) public consultations with the participation of all parties involved, in particular with the pharmaceutical industry; b) dissemination of the Guideline in each country and according to the national realities; c) that the plan be part of an industrial policy of local development and of a national health policy; and that d) the plan has time schedules defined for the implementation of the Guideline;
- 2.3 To prepare a decision tree for implementation of the Guideline;
- 2.4 To promote the adoption of the Guideline for GMP Verification proposed by PANDRH in the harmonization processes of the sub-regional economic groups of integration (AA, CA, NAFTA, MERCOSUR and CARICOM);

The Pharmaceutical Industry:

- 2.5 To be committed with the process of GMP implementation according to the requirements of the Guideline for GMP Verification and the national Plan approved by the DRA;

The National Universities:

- 2.6 To promote the adoption of the GMP training modules and the Guideline for GMP Verification in the educational programs for college students and in the development of continuing education courses;

PANDRH, WG/GMP and the Secretariat:

- 2.7 To establish through the Network webpage a mechanism to receive questions and comments for consideration of the WG/GMP;

- 2.8 To continue supporting the development of GMP training programs for inspectors and the industry, specially in regards to use and application of the Guideline for GMP Verification and other specific aspects of interest on GMP, in compliance with a regional plan approved by the PANDRH Steering Committee;
- 2.9 To include inspectors from other countries as a strategy to support the national inspectors in the training programs with the use of the Guideline;
- 2.10 To include in the WG/GMP Work Plan to provide direct advisory services to those countries that require technical support in the processes of adoption of the Guideline for GMP Verification;
- 2.11 To promote opportunities for DRA to share experiences in their process of implementation of the Guideline for GMP Verification;
- 2.12 To develop a guideline for active pharmaceutical Ingredients and a guideline for biologicals, recombinant, blood derivatives and of natural products;
- 2.13 To promote among countries mechanisms of mutual recognition on GMP inspections;
- 2.14 To discuss among members of the WG/GMP all the comments received in the consultation sessions of the IV Conference;
- 2.15 To ask DRA to complete and validate the information contained in the comparative study of implementation WHO Report 32 on GMP, identifying the weaknesses in the national legislations regarding the application of this report and to correct any error that may be identified in the study;
- 2.16 To follow up the processes of adoption and implementation of the Guideline in the national regulation of countries, its adoption by the sub-regional economic integration groups (AA, CA, NAFTA, MERCOSUR and CARICOM); and to prepare a report on the use of the Guideline to be presented in the next Pan American Conference.

II. Bioequivalence and Bioavailability

1. Considering the proposal submitted by the GT/BE and the interest that the countries have shown on the implementation of BE studies, the Conference approves the following Mission and Objectives for the WG/BE:

Mission:

The WG/BE will contribute to the harmonization of the bioequivalence criteria for interchangeability of pharmaceutical products in the Americas.

Objectives:

- a) To develop scientific based criteria for products that require BE studies *in vitro* and/or *in vivo* and for those that do not;
 - b) To develop prioritized lists of pharmaceutical products in which BE studies *in vivo* are necessary;
 - c) To develop a list of pharmaceutical products where BE studies *in vivo* are not necessary;
 - d) To develop a list of comparators for BE studies to be used in the Region of Americas;
 - e) To formulate recommendations and guidelines of interpretation, evaluation, and application of BE scientific principles;
 - f) To promote training in the application of BE principles in countries of the Americas;
 - g) To promote BE on pharmaceutical products that require it, in the Americas;
 - h) To include exchange of experiences in the implementation of BE studies on the training programs in the Americas;
 - i) To develop a set of indicators to evaluate the implementation of BE studies in the Americas.
2. The Conference recognizes that the document "*SCIENCE BASED CRITERIA FOR BIOEQUIVALENCE TESTING (IN VITRO AND IN VIVO), BIO-WAIVERS, AND REGIONAL STRATEGY IMPLEMENTATION*"; presented by the WG/BE is an step in the application of BE studies in the Region, and it recommends to submit the draft document for its discussion this year to review aspects such as bio-waivers, biopharmaceutical classification, GMP for the BE, among others;

3. The Conference also recommends:

The National Drug Regulatory Authorities (DRA)

- 3.1 To send their comments to the Secretariat of PANDRH on the draft of the document *"SCIENCE BASED CRITERIA FOR BIOEQUIVALENCE TESTING (IN VITRO AND IN VIVO), BIO-WAIVERS, AND REGIONAL STRATEGY IMPLEMENTATION"*; for consideration of the WG/BE;
- 3.2 To promote harmonization on a list of active ingredients that require BE testing using the strategy of health risk (high, medium and low) of drugs as reference; with a gradual implementation process, as already being done in some countries and as requested at the regional expert meeting (Caracas, 1999);
- 3.3 To develop a BE training program for the DRA's offices personnel and to promote the participation of suitable personnel in the BE training activities developed by PANDRH;
- 3.4 To validate the application of Good Clinical Practices in BE training centers in countries where BE studies are currently implemented.

To PANDRH, the WG/BE and to the Secretariat:

- 3.5 To complete the document: *"SCIENCE BASED CRITERIA FOR BIOEQUIVALENCE TESTING (IN VITRO AND IN VIVO), BIO-WAIVERS, AND REGIONAL STRATEGY IMPLEMENTATION"*. This is due that BE studies are being under discussion by sub-regional integration initiatives; and in some such as Central America, the documents prepared within the framework of PANDRH are needed for internal discussions.
- 3.6 To consider the following specific recommendations in completing the document:
 - 3.6.1 To analyze the contributions (comments) sent by DRA and the conclusions of the discussions on the document;
 - 3.6.2 To focus the document on the technical aspects of BE and not to include aspects of intellectual property;
 - 3.6.3 To analyze if BE studies can be used as a quality requirement rather than for drug interchangeability;
 - 3.6.4 To broaden the discussion on the strategy for BE implementation based on the criteria of health risk, particularly on aspects related to the score assignment, criteria used, and the classification of the risks. At the same time, to consider other strategies that are being used in some countries for the implementation of BE studies (such as the case of Brazil);
 - 3.6.5 To incorporate in the document all necessary considerations on the efforts of WHO on BE to develop, when possible, a global harmonization of the requirements as of the terms

used, as well. To facilitate this process, the Conference requests that Dr. Sabine Kopp from WHO participates in the WG/BE meetings.

- 3.7 To present the final version of the document "*SCIENCE BASED CRITERIA FOR BIOEQUIVALENCE TESTING (IN VITRO AND IN VIVO), BIO-WAIVERS, AND REGIONAL STRATEGY IMPLEMENTATION*", at the next Pan American Conference of PANDRH;
- 3.8 To prepare a list of critical items that should be supervised during the evaluation of BE studies;
- 3.9 To study the relevance of requiring BE studies to all antiretroviral products and to study it case by case;
- 3.10 To continue the discussion until a proposal is formulated on the development of single comparator (by product) in Latin America, since this approach may help decrease the number of BE studies conducted;
- 3.11 To prepare a report on the advances of the implementation of the BE studies in the Americas and to present it at the next Pan American Conference.
- 3.12 To maintain an functional system of dissemination of country experiences through the Network's webpage in order to receive comments to be considered by the WG/BE.

III. Good Clinical Practices

1. The Conference approves the following Mission and Objectives for the Working Group on Good Clinical Practices:

Mission:

The WG/GCP should promote harmonization of GCP in the Americas

Objectives

- a) To promote implementation of GCP in the Americas;
- b) To disseminate the document *Good Clinical Practices: Document of the Americas* with recommendations to be adopted in national legislations;
- c) To develop and promote educational programs on GCP mainly directed to professionals of regulatory agencies.

2. The Conference recommends the adoption of document entitled: *Good Clinical Practices: Document of the Americas*, developed by the WG/GCP;
3. The Conference recommends:

The National Drug Regulatory Authorities (DRA)

- 3.1 To adopt and incorporate within their regulatory framework the document *Good Clinical Practices: Document of the Americas*;
- 3.2 To promote training of human resources on the inspection of entities that conduct clinical trials and on the authorization of clinical drug studies;
- 3.3 To promote joint inspections on GCP in ongoing researches; and
- 3.4 To promote within the harmonization processes of sub-regional economic integration groups (AA, CA, MERCOSUR, NAFTA and CARICOM) the adoption of the document *Good Clinical Practices: Document of the Americas*.

The National Universities:

- 3.5 To promote continuing education on GCP for investigators, sponsors and regulators. This is to establish the foundations for GCP education in undergraduate programs and in the development of continuing education courses;
- 3.6 To promote joint efforts aimed at establishing GCP educational programs with the participation of all interested sectors.

The Pharmaceutical Industry:

- 3.7 To ensure that clinical drug research carried out in the Region complies with the document *Good Clinical Practices: Document of the Americas*, if allowed by national regulations;
- 3.8 To promote the inclusion of the document *Good Clinical Practices: Document of the Americas* in the educational programs on GCP.

PANDRH, the WG/GCP and the Secretariat:

- 3.9 To review some differences detected between the document and what is proposed by the ICH in the subject of constitution of Ethics Committees, in regard to the requirement that,

as resources be available, the presence of a biostatistics or an expert in research methodology; and that the review of the Ethics Committees be carried out in prudent times;

- 3.10 To encourage members of the WG/GCP that in coordination with the Secretariat of PANDRH, provide technical support to the countries that agree to adopt the document *Good Clinical Practices: Document of the Americas*;
- 3.11 To develop a training program for the inspection of entities that carry out clinical drug research, and for the authorization of drug clinical studies, taking advantage of existing training programs in countries that have had experiences on the subject; and
- 3.12 To ask the WG/GCP to prepare a progress report on the status of the adoption of the GCP document, to be presented at the next Pan American Conference on Drug Regulatory Harmonization.

IV. Pharmacopoeia

1. The IV Pan American Conference on Drug Regulatory Harmonization approves the report presented by the Pharmacopoeia Working Group (PWG);
2. The Conference approves the following Mission Statement of the PWG:

“To create a forum for discussion and information exchange that facilitates the adoption of harmonized procedures, in order to have a harmonized pharmacopoeia for the Americas”.
3. The Conference endorses the *Protocol for the Harmonization of New Monographs* proposed by the GT/Pharmacopoeias and recognizes that it does not imply that all the pharmacopoeias have a single text and that the differences in any case, do not take to different results. This should allow mutual recognition of the procedures of each participant pharmacopoeia;
4. The Conference recognizes that in order to establish a regional pharmacopoeia, the existence of a supranational agency is required to have the legal support needed; and, that the process should involve all countries and not only the ones that have national pharmacopoeias;

5. The Conference recognizes the importance of the GT/Pharmacopeias including the preparation of monographs of herbal products in its work plan.

V. External Quality Control Program (EQCP)

1. The Conference acknowledges the report on the External Quality Control Program which has been implemented with a joint effort between PAHO and the USP; and it recommends to governments in the Americas to strengthen the official quality control laboratories according to the needs found by the EQCP;
2. The Conference recommends:

The National Drug Regulatory Authorities (DRA)

- 2.1 To support the EQCP by participating actively in the selection of samples to be analyzed by the Program.

The Official Quality Control Laboratories

- 2.2 To continue participating in the EQCP providing their infrastructure and specialized personnel for the training workshops on specific analytical techniques, including organization and implementation of training activities;
- 2.3 To assure the involvement of appropriate personnel in the training activities;
- 2.4 To participate in the Network of Official Quality Control Laboratories in the Americas and to designate periodically a coordinator for such Network;

The Pharmaceutical Industry and Universities

- 2.5 To promote update and training on analytical techniques of appropriate personnel from in the industry and the university, in order to support future training workshops and quality improvement of marketed drugs.

USP

- 2.6 To continue providing technical and financial support to the EQCP through an annual plan of operation;

2.7 To produce standardized analysis protocols and common reports

PANDRH and the Secretariat

2.8 To establish a Working Group on Good Laboratory Practice (WG/GLP) which will have the following objectives:

2.8.1 To monitor the EQCP;

2.8.2 To prepare a document on the Procedures of the External Quality Control Program that defines the criteria for product selection to be used by the EQCP, and for result reporting (specially of those referred to tests performed in products available in the market); and for mechanisms to finance this program;

2.8.3 To prepare educational materials on GLP;

2.8.4 To prepare a plan of implementation of educational activities to be approved by the Steering Committee of the PANDRH.

2.9 To follow up GLP implementation in the Region and to present a report in the next Pan American Conference of PANDRH.

VI. Drug Registration

1. The Conference approves the following Mission statement and Objectives for the Working Group on Drug registration:

Mission

“To promote and facilitate the harmonization of regionally recognized and appropriate technical criteria for drug registration to contribute to their quality, safety, efficiency and availability in the Americas”.

Objectives

a) To establish a data base on pharmaceutical legislation in the Region of the Americas and to make it available on the PANDRH web page;

b) To advise countries on the adoption of the harmonized proposal of requirements for drug registration as adopted by PANDRH, and to formulate recommendations to optimize the process of drug registration at country and regional level. This is in coordination with the Secretariat of PANDRH;

- c) To follow up on the implementation of the recommendations of PANDRH to advance in drug regulatory harmonization using selected indicators and preparing updated reports;
 - d) To develop diagnostic studies as necessary to help with the harmonization process, including those directed to measure the impact of having common requirements for drug registration;
 - e) To develop educational tools, documents and guidelines to be used in the processes of registration of pharmaceutical products;
 - f) To promote the assessment of drug regulatory agencies to improve their efficiency;
 - g) To organize and participate in educational activities addressed to regulatory agencies' personnel;
 - h) To promote the establishment of a regional network of drug regulatory authorities.
2. The Conference recognizes that the requirements for drug registration continue to be a subject of high importance to DRA and represent the framework of reference for future surveillance and drug control. In this regard, the Conference considers that the proposal prepared by the GT/Drug Registration on *Common Requirements for Drug Registration in the Americas* be considered as draft until the WG/DR prepares a final document;
3. The Conference also recommends:

The National Drug Regulatory Authorities (DRA):

- 3.1 To analyze the draft proposal on Common Requirements in their offices on given dates and to send their comments to the Network Secretariat for consideration of the GT/DR;
- 3.2 To send the national legislations (or their web page address) to the Network Secretariat in order to complete the database of drug registration legislations in the Americas that is being prepared by the PANDRH Secretariat;
- 3.3 To support and to promote self-evaluations with a common pattern, as it is done in the area of vaccines as a mechanism to optimize its operation and to promote trust among DRA from different countries;
- 3.4 To harmonize the requirements for drug registration taking the draft-proposal as a reference to acknowledge support among countries, specially to under developed countries;

3.5 To discuss the draft-proposal in groups of economic integration (AA, CA, MERCOSUR, NAFTA, CARICOM); and

3.6 To implement control mechanisms to verify that the products in the market meet the approved requirements at the time of their registration.

The Pharmaceutical Industry:

3.7 To notify any changes in the products to what was initially authorized. These should be done by the manufacturers as well as drug seller. The DRA will establish if a new registration is required, according to the regulations;

3.8 To promote human resources training on drug evaluation for drug registration purposes.

PANDRH and Drug Registration Working Group (GT/DR):

3.9 To review and finalize the proposal on common Requirements for Drug Registration in the Americas, considering the following specific issues:

3.9.1 Quality and efficacy requirements; and drug safety. For instance, evidences for verified active pharmaceutical ingredients, characterization of raw material; since in the case of the generic and similar products, these are not requested in the current version of the proposal;

3.9.2 Regulations of abbreviated drug registration for generics and for biologicals. The creation of working groups to discuss these points separately could be considered;

3.9.3 Review the registration requirements presented by the group of classification in order to incorporate them into the document;

3.9.4 Duration of the registration as a requirement for product registration renewal;

3.9.5 Therapeutic life of the product as a requirement to continue in the market;

3.9.6 Request of samples and standards for control and analysis as a requirement for drug registration renewal.

3.10 To establish a mechanism of coordination between the WG/DR and the other working groups of PANDRH that are developing related proposals such as Medicinal Plants, GLP, GMP, Bioequivalence, Biologicals etc. in order to develop a consistent work;

3.11 To include the proposal in the webpage of PANDRH to facilitate its dissemination and comments by interested parties;

- 3.12 To include in the activities of PANDRH strengthening the human resources in charge of reviewing the drug registration processes as a way to improve their capabilities and to perform their functions adequately;
- 3.13 To promote the evaluation of DRA based on the use of a common instrument, as it is done in the area of vaccines;
- 3.14 To include in the proposal a glossary of the terms in order to better understand and harmonize their interpretation;
- 3.15 To prioritize the support to the WG/Drug Registration so that it can consolidate the proposal and present it in the next Conference.

VII. Drug Classification

1. The Conference recommends the adoption of the following definition of Non Prescription Drug or Over the Counter (OTC) as proposed by the Working Group on Drug Classification (WG/DC):

“An OTC is a pharmaceutical product, drug, or medicinal specialty whose dispensing or administration does not require medical authorization, and it can be used by the consumers under its own initiative and responsibility to prevent, relieve or to treat symptoms or mild illnesses and that its use, in the form, conditions and authorized dosages are safe for the consumer”;
2. The Conference recommends the following criteria for the classification of drugs as OTC: OTC drugs are those that comply with the following characteristics:
 - 2.1 Drugs which are effective and safe to be used in the prevention, relief of symptoms, or treatment of mild illnesses, and that are easy to identify;
 - 2.2 Drugs with broad safety range, in such a way that the voluntary or involuntary administration of the dosage higher than that recommended, or where it is not indicated, does not represent a serious danger for the health of the patient;
 - 2.3 Have a broad dosage margin, so it can be adapted to the age and weight of the patient;
 - 2.4 Drugs that do not generate tolerance or dependency when used and that are not susceptible of abuse;

- 2.5 Drugs that when used following the instructions, do not hide serious illnesses, or delay the diagnosis and treatment of a condition that requires of medical care;
 - 2.6 Drugs of safe use for all the age groups of the population;
 - 2.7 Dosage forms usually of oral or topical route, of easy management and storage and that are not of IV or IM administration;
 - 2.8 Drugs whose active ingredient has been marketed under medical prescription for at least 5-10 years, time during which it has demonstrated a favorable index of safety and efficacy through drug surveillance data;
 - 2.9 The adverse reaction reports have not increased during the marketing period.
3. The Conference recommends the following criteria for the promotional material for OTC drugs advertisement:
- 3.1 That OTC drugs are promoted only with the information and definitions approved by the Ministry of Health or Regulatory Authority;
 - 3.2 That they do not suggest that the use of these drugs may delay or avoid seeing the doctor;
 - 3.3 That they do not suggest the permanent use of the drug, but that it should only be administered (used) for the authorized period of time;
 - 3.4 That the words, content or sentences used do not exaggerate the benefits of the product;
 - 3.5 That the content is expressed in colloquial language, without the use of medical or technical terms that may confuse the consumer; and
 - 3.6 Not to use the testimony of people or known entities in the education, research or health sciences, since it can induce to the consumption of the drug.

4 The Conference also recommends:

The National Drug Regulatory Authorities (DRA)

- 4.1 To adopt and incorporate in the national regulatory framework the definition and criteria for drug classification recommended by PANDRH;
- 4.2 To establish the product sale modality during the registration process in compliance with a previously established regulation for all products that contain the same formula and indication; and to avoid taking this decision product by product;
- 4.3 To avoid the use of models from other countries in which sub-dosages of drugs are accepted under prescription as a means to switch them to OTC categories;

- 4.4 To ensure that the information on the labeling, insertion and prospect of OTC products includes the necessary information for the consumer with respect to the use of OTC products and to use it adequately; and that the information is expressed in common language (colloquial); if possible, with the use of visible pictograms and legible letter;
- 4.5 To review all promotional material for OTC drugs, and ensure that these materials meet the criteria recommended by PANDRH. This review should be under the responsibility of the health authority for drug registration and control;
- 4.6 To promote the incorporation of the recommendations of PANDRH in regards to OTC drugs within the regional integration groups (AA, CA, NAFTA, MERCOSUR, CARICOM).

The National Universities

- 4.7 To incorporate in the curricula for related health professionals the drug classification criteria and definition recommended by PANDRH;

The Pharmaceutical Industry

- 4.8 To support DRA with the incorporation of the definition and criteria for drug classification for OTC drugs into the regulatory frameworks;
- 4.9 To adopt the new classification into the drug registration authorization and in the drug promotion and advertisement;

PANDRH, Working Group/Drug Classification and the Secretariat

- 4.10 The Conference approves the establishment of WG on Drug Promotion and Advertisement (WG/DPA) within the framework of PANDRH, which will address the following issues in regards to OTC drugs:
 - 4.10.1 The existence of a regulation to avoid that the brand name of a product induces to error or confusion;
 - 4.10.2 The use of umbrella brands should be used as long as the packaging uses different colors and that its indication or therapeutic action is clearly identified as an extension of the name;
 - 4.10.3 Packaging for OTC drugs are clearly different than those of prescription medicines and drugs with medical prescription (example: color band, logo, information, etc.)

- 4.10.4 A code of ethical criteria for drug promotion and advertisement that allows the establishment of control systems should be agreed by the industry and regulatory authority,
- 4.11 To update the PAHO publication “Glossary of Terms Used in the Evaluation of Medicinal Products”;
- 4.12 To monitor the incorporation of a harmonized criteria for drug classification into the regulatory framework of the countries of the Region and to present a progress report in the next conference;
- 4.13 To formulate a comprehensive proposal that harmonizes the definitions and criteria for classification of: phytopharmaceutical product, dietary supplements and food-drug (nutraceuticals); cosmetic-drugs (cosmeceutics); medical devices; reagents of diagnosis, radioactive drug, and odontological products to be considered by the next Conference.
- 4.14 To prepare a harmonized proposal on categories and active pharmaceutical ingredients (concentration/strengths, dosage, pharmaceutical forms and indications) susceptible to be considered as OTC;
- 4.15 To request the WG/Drug Registration to review the proposal presented by the GT/Classification on the content of information in the labels, packages and inserts of OTC drugs for its detailed harmonization in common requirements for drug registration; and
- 4.16 To continue the discussion on the sale points of OTC drugs since there has not been consensus on the subject.

VIII. Drug Promotion

The subject was presented in the Conference at the request of the Steering Committee of PANDRH. The SC requested that the regulatory Agency of Brazil (ANVISA) prepare a proposal to discuss the subject within the framework of PANDRH. The Conference, considering the recommendations of the WG/Drug Classification and the presentation on this subject delivered by

the Drug National Authority of Brazil, approves the establishment of a Working Group on Drug Promotion and Advertising (WG/DPA) which in addition to the issues requested by the WG/DC, it will address the level of adherence to ethical criteria in Drug Promotion and Advertisement in countries of the Region.

IX. Vaccines

The Conference acknowledged the report submitted by PAHO on the activities of the Organization regarding the area of Vaccines, including the support on assessment of national regulatory authorities through the application of an instrument of self-evaluation. It was recognized the urgency in addressing subjects that are being discussed within the framework of the Network such as ethics committee, authorization of clinical trials, drug surveillance, GMP, registration, etc. The Conference recognizes the importance of the subject and approves the establishment of a Working Group in Biologicals that includes subjects that due to its specificity should be addressed by a special group, but also requests that the work of that WG be coordinated with the other WG of the Network such as Drug Registration, Good Manufacturing Practices and Good Clinical Practices.

X. Drug Counterfeiting

1. The Conference approves the following Mission Statement of the Working Group to Combat Drug Counterfeiting:

“The WG against Drug Counterfeiting will promote, facilitate and motivate implementation of proactive strategies to prevent and combat drug counterfeiting; thus to contribute to the improvement of health care in the countries of the Americas”.

2. The Conference adopts the following Definition of Drug Counterfeit: A counterfeit drug is one that is manufactured deliberately and fraudulently with respect to its identity and origins. It may contain products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.
3. The Conference recommends the adoption of the three components of the proposal made by the GT/Combat Drug Counterfeiting: the *Road-map proposal to evaluate the*

implementation by the focal points of each country; the proposal of *Implementation Unit to carry out the actions of prevention* and combat drug counterfeiting, as a part of the national regulatory/health authority; and the proposal of *Indicators for the management and criteria for the classification of counterfeit drugs*.

4. The Conference recognizes that the application of the Implementation Unit will depend on the possibilities of each country since some still do not have the infrastructure or established regulatory offices, as it is the case of some English-speaking Caribbean countries;
5. The Conference recommends WHO the accomplishment of what was agreed upon at the pre-ICDRA Workshop on Drug Counterfeiting in order to discuss the possibility to create a Global Convention on this subject;
6. The Conference also recommends:

The National Drug Regulatory Authorities (DRA):

- 6.1 To limit the drug marketing to establishments authorized by the DRA;
- 6.2 To promote the articulation of the DRA with other sectors that participate in the effort of combating drug counterfeiting since it exceeds the responsibilities of the DRA; thus it is necessary to have the cooperation of the government agencies (DRA, district attorney's office and taxes, and customs), the industry and wholesale and retail drug distributors;
- 6.3 To promote agreements among collaborating institutions that include punitive sanctions that threaten severely those who incur in the manufacturing or distribution of counterfeit drugs;
- 6.4 To constitute a focal point network on drug counterfeiting in the Region establishing a regional network of communication;
- 6.5 To report on a timely basis to the WHO database and to the PANDRH Secretariat the cases of drug counterfeiting that are detected at the national level and to participate actively in the surveys developed by PANDRH;
- 6.6 To promote collaboration among the DRA of the Region to transfer available technology and to facilitate internships of DRA from other countries;

- 6.7 To adopt national standards of good practices for all the stages of the drugs chain, to adopt the necessary mechanisms and to have skilled personnel for an effective control of accomplishment;
- 6.8 To have mechanism and technologies to trace drugs effectively in the different stages of the drugs chain (from production to dispensing), including the number of batches in the purchase and sale documents (fiscal note, invoice, etc.);
- 6.9 To promote reviewing legal legislations and to include:
 - 6.9.1 Sanctions to crimes related to drug counterfeiting and other illegal actions;
 - 6.9.2 Definition of drug counterfeit as adopted by the PANDRH;
 - 6.9.3 Measures to prevent the use of equipment that have been declared unusable for drug manufacturers;
 - 6.9.4 Measures on wasting of materials of packaging, label, finished products and raw materials non-suitable for utilization, to avoid their used by unauthorized companies and that do not damage to the environment;
- 6.10 To promote the dissemination and implementation of the recommendations contained in the WHO "Guidelines for the Development of Measures to Combat Drug Counterfeiting ";
- 6.11 To strengthen the national programs for drug surveillance of post-marketing;
- 6.12 To preserve the confidentiality in cases of suspicious drug counterfeit.

The Pharmaceutical Industry, National Professional Associations and Universities:

- 6.13 To collaborate with DRA in the dissemination of information on cases of drug counterfeiting;
- 6.14 To contribute with educational activities on the subject;
- 6.15 To inform DRA on any case of drug counterfeiting and to communicate any existence of drug counterfeit;

PANDRH, the GT/CDC, and the Secretariat

- 6.16 To integrate in the GT/CDC experts who address the use of the internet to promote and sell counterfeit drugs in order to collect data, and subsequently develop a proposal to solve or alleviate the problem;
- 6.17 To develop an educational program as presented by the WG/CDC on Drug Counterfeiting within the framework of PANDRH and to incorporate in those programs successful experiences on combating drug counterfeiting. Other methodologies for its implementation should also be explored, such as the internet, CD-ROM, video conferences, etc; to be presented for the approval of the SC of PANDRH;
- 6.18 To conduct a survey to update the data on situation of drug counterfeit and publish the results;
- 6.19 To continue with the development of the proposal of the guideline for inspections in order to confirm the legitimacy of marketed drugs;
- 6.20 To monitor the cases of drug counterfeiting by applying the indicators selected and report the results in the next Pan American Conference.

XI. Training and Education

The Conference approves the following criteria for the educational seminars, workshops and other educational activities (workshops, seminars, course, etc.) organized within the framework of PANDRH:

1. Plans for educational activities within PANDRH should be reviewed and approved by the Steering Committee (SC);
2. The need for educational activities should be prioritized according to the objectives of the Working Group, and a biennial integral plan for all PANDRH educational activities should be prepared for the approval of the SC;
3. All the working groups should review available educational programs that comply with the plans of the working group. When there is no available material on a specific area, the WG should develop them on the aspects of priority;

4. The educational activities of PANDRH should be mainly based on the WHO guidelines and standards. They can also include documents developed by other international harmonization initiatives;
5. The discussion of on WHO technical documents and their application should be encouraged in the educational activities in order to support WHO in the continuous improvement of these materials;
6. Successful national experiences should be presented as case studies in the educational activities of PANDRH;
7. Working Group members should participate as trainers. Each WG should designate those members who will participate as such in each area;
8. DRA and national universities (schools of pharmacy and other specialized national institutions) should be part of the national committee for the organization of the PANDRH educational activities;
9. PANDRH training activities should have a focal point/ national authority to replicate the national courses with the participation of pertinent institutions;
10. All activities should be self financed. The cost of registration fees will depend on the characteristics of each activity;
11. The National Drug Regulatory Authorities (DRA) and / or Universities that host the educational activities should provide local needs such as site, equipment; and share local expenses: coffee breaks, meals and hotel costs for participants;
12. The SC will explore other financing opportunities and sources for the educational activities in the technical areas of interest for PANDRH;
13. PANDRH educational activities may be opened to the private sector;
14. Use of video conferences and other methods of distance learning should be explored by each WG and the SC in order to preserve sources and to decrease the expenses associated with the implementation of future training;

15. PANDRH educational activities should explore the possibility to offer these in English in order to include the English-speaking countries of the Caribbean.

XII. Implementation Strategy

1. The Conference adopts the *Strategy of Implementation of the Technical Proposals for the Drug Regulatory Harmonization* presented by members of the Steering Committee of PANDRH; it recognizes the effort of the different Working Groups in the development of the proposals in various areas; and points out that the time to implement the proposals has arrived so that the DRA can benefit from the process of harmonization effectively.
2. The Conference recognizes three levels in the implementation strategy: dissemination, education and management of the implementation. This also represents a common process to be also applied in the diagnosis in order to identify areas that require corrective actions;
3. The Conference recommends for the application of the strategy:
 - 3.1 The political desire/will is necessary to implement the changes that demand the implementation of the different proposals, and that the convenience of having an autonomous agency for drug regulation should be evaluated;
 - 3.2 That the DRA manifest their interest in implementing the proposals at the national and international level;
 - 3.3 That the countries analyze the possibility of applying the proposals in sub-regional economic blocs;
 - 3.4 That communication and discussion on the proposals remain on a scientific level and be maintained within legal framework, and that it should guarantee a broad participation from all interested parties;
 - 3.5 That the time schedules that demands the complete adoption and implementation of the different proposals be identified for each case;
 - 3.6 That the implementation of the proposals at the national and international levels have the technical support of PANDRH.

Steering Committee Selection (SC)

In compliance with PANDRH rules and regulations, up to three steering committee members should be re-elected at each Conference. Members of the SC will serve for a period of four years. Three of the five members (with their alternate members respectively) from sub-regional groups were re-elected at this Conference: a) Central America, Dominican Republic and Cuba; b) CARICOM; and c) MERCOSUR and Chile.

The new members were elected by consensus within their sub-regional group. The new Steering Committee until the next Conference is as follows:

- 1) *Andean Area*: (from the III Conference to the V Conference)
Member: DRA from Colombia
Alternate: DRA from Bolivia
- 2) *CARICOM*: (from the IV Conference to the VI Conference)
Member: DRA from Trinidad & Tobago
Alternate: DRA from Barbados
- 3) *Central America, Dominican Republic and Cuba*: (from the IV Conference to the VI Conference)
Member: DRA from Costa Rica
Alternate: DRA from Panamá
- 4) *MERCOSUR* (from the IV Conference to the VI Conference)
Member: DRA from Argentina
Alternate: DRA from Chile
- 5) *NAFTA* (from the III the Conference to the V Conference)
Member: DRA from Mexico
Alternate: DRA from USA
- 6) One representative from ALIFAR or the substitute member
- 7) One representative from FIFARMA or the substitute member