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WORLD HEALTH ORGANIZATION

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**INTERNATIONAL WORKSHOP
ON THE REGULATION OF
MEDICAL DEVICES
Andean Region**

FINAL REPORT

Cartagena de Indias – Colombia

31 July – 3 August, 2001

INTERNATIONAL WORKSHOP ON THE REGULATION OF MEDICAL DEVICES
Andean Region
31 July-3 August 2001 - Cartagena, Colombia

FINAL REPORT

COMMITTEE OF RAPORTEURS

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Dr. Elizabeth Garrido, MSDS. Venezuela.
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OBJECTIVES

- Address the interests and needs of the Andean Community in the areas of regulation, surveillance, and harmonization of medical devices by taking advantage of the progress made in other countries of the Americas, the advances achieved in the United States and Canada, and the experience of institutions such as ECRI.
- Review the development of medical devices regulatory program in Argentina and examine related initiatives under way within MERCOSUR.
- Examine the current state of development of regulatory programs for medical devices in the participating countries
- Develop basic building-blocks for the regulation and harmonization of medical devices.
- Study specific aspects of the reuse of single-use devices and equipment donation and introduce the International Basic Safety Standards for Radiological Equipment.

AGENDA

The International Workshop on the Regulation of Medical Devices for the Andean Region was held at the Hotel Almirante in Cartagena de Indias (Colombia) from 31 July to 3 August 2001.

The agenda is annexed to this report.

PARTICIPANTS

Forty-three staff members from the following organizations participated in the workshop:

- PAHO/WHO Collaborating Centers: USA-FDA, MDB-Health Canada, ECRI
- Regulatory agencies and programs from Argentina, Chile, Colombia, Ecuador, Panama (observer) Peru, and Venezuela
- The National University, the School of Pharmaceutical Chemists, and ANDI of Colombia
- PAHO/WHO Staff

The list of participants is annexed to this report.

DAY ONE: 31 July 2001.

OPENING CEREMONY

The opening ceremony was presided over by Dr. Gustavo Adolfo García, Director of the Departmental Health Office of the Department of Bolívar, as the representative of the Minister of Health, Dr. Sara Ordoñez. Sharing the podium with him were Dr. Deny Sanjuan of the Health Office of the District of Cartagena and Antonio Hernández of PAHO/WHO. Dr. García conveyed the Minister's welcome to the participants and emphasized the importance and impact of this subject on the health service operations.

Mr. Hernández indicated that the event was being held in compliance with Resolution CD42.R10 of the Directing Council of PAHO (September 2000), which assigns priority to the regulation of medical devices in Latin America and the Caribbean. He thanked the Organizing Committee for its work and the delegations for attending the conference.

DEVELOPMENT OF THE AGENDA

1. PAHO's Role in the Regulation of Medical Devices.

Mr. Antonio Hernández, PAHO Washington.

PAHO presented a historical overview of the physical infrastructure and technology of health services in Latin America and the Caribbean, followed by a diagnosis of the current situation and the challenges of rehabilitating them and ensuring their continued operation. The function of regulatory programs in ensuring the effectiveness, safety, and quality of medical devices used by health services and population in general was reviewed. The work plan for 2001–2003, as approved by the 42nd Directing Council of PAHO, was explained. It includes the following activities: preparation of country and regional profiles in the area of regulatory programs for medical devices, the organization of subregional training workshops, efforts to promote participation in meetings and study groups of the Global Harmonization Task Force (GHTF), facilitated access to technical information and exchange of experts, and support for the implementation of regulatory programs.

2. The New Canadian Approach to the Regulation of Medical Devices

Dr. Roland Rotter, Medical Devices Bureau (MDB), Health Canada.

The representative of Health Canada gave an overview of the history of this area in Canada. He covered the administrative and operational structure of monitoring and control, the criteria for the design of regulations, the classification of products according to the risks associated with their use, and the structure of the document that regulates various aspects of the control and monitoring of medical devices.

In recent years, Health Canada has reorganized its administrative and operational structure. The monitoring and control of medical devices, previously handled by an independent body, now comes under the Therapeutic Products Directorate. Nevertheless, medical devices that can affect human health or the practice of physicians are still regulated and cannot be sold without technical instructions on how they are to be handled.

In Canada, regulations are not seen as being carved in stone, but as living organisms that must be adapted to changing needs. Since most medical devices (80%) are imported, regulations are oriented chiefly toward importation, distribution, sale, and advertising and are based on two criteria:

- The level of risk of the product, measured on a scale of I (lowest) to IV (highest). Class I products do not require a marketing permit.
- The safety and effectiveness of the medical device, determined with consideration given to both compliance with quality standards and the results of pre- and post-marketing monitoring.

Canada also has a Special Access Program whereby a physician can request authorization to use an as-yet unauthorized product for a specific patient under special circumstances.

3. Requirements and Regulations for the Export of Biological Equipment.

Dr. Roland Rotter, Medical Devices Bureau (MDB), Health Canada.

This was a presentation on the principles and criteria governing the issuance of Export Certificates, with consideration given to whether or not the product is marketed domestically, the monitoring of marketing, standardization, and the quality standards employed.

4. The Center for Devices and Radiological Health (CDRH) of the U.S. Food and Drug Administration (FDA).

Ms. Linda Horton, FDA.

The representative of the FDA presented a historical overview of the regulations governing medical devices in the United States, covering the constitutional principles on which they are based, the criteria taken into account in their design, the component elements, and the process of evaluating a request to market products of this type in the United States.

Regulation is based on the classification of medical devices, recognition of international standards, verification of "Good Manufacturing Practice (GMP)", pre-marketing approval, information provided for users and the public in general, the complaints and claims filed by users and bodies that work in this field, and the pertinent legal framework.

The Web page of the FDA was also introduced, with an explanation of the paths to follow to find information on organizational structure, personnel, current legislation, research findings for cases in which products presented problems, and public information documents.

5. FDA Requirements and Regulations for the Export of Medical Devices.

Ms. Linda Horton, FDA.

In regard to the export of medical devices, the FDA can issue the following certificates:

- Certificate to foreign governments, which confirms that the product in question is marketed in the United States
- Pharmaceutical Product Certificate
- Exportable Product Certificate, which indicates that the product in question complies with legislation, but is not sold in the United States. It is recommended that the importing country take this as a warning sign.

One of the most common problems is the forgery of certificates. In regard to the export of medical devices, the various certificates were explained, along with the mechanisms that help reduce the risk of forgery; the quality standards in place; and the strategies used to monitor these products.

QUESTION AND ANSWER SESSION

The participants' interest centered on the period of validity of certificates issued by the FDA and Health Canada, the strategies used to prevent the forgery of documents submitted to health authorities with the application for registration, the criteria used to classify medical devices, the strategies used to monitor imported and domestically-made products, and the criteria used to establish the useful life of medical devices. Both Canada and the United States require expiration dates for these products. The maximum time period granted is clearly defined and depends on nature of the product, the strengths and weaknesses of the FDA and Health Canada with regard to regulation and control of medical devices, and strategies to ensure the free marketing of medical devices between countries.

DEVELOPMENT OF THE AGENDA

1. Regulation of Medical Products in Argentina.

Mr. Carlos A. Parodi, Director of Medical Technology, ANMAT.

ANMAT is an agency under Argentina's Ministry of Health and Social Action. Its responsibilities include the authorization, monitoring, and registration of drugs, cosmetics, diagnostic reagents, food, devices and other items used in health and home care.

Within ANMAT, the Office of the Director of Medical Technology is in charge of monitoring and guaranteeing the quality of medical products. The system is based on a risk classification scheme based on the guidelines of the European Union. Monitoring and surveillance strategies focus on the manufacture, import, export and marketing of medical products and on investigation of any adverse event. Both the private sector and academia offer support for these efforts.

The control of medical products in Argentina currently relies on the support of the private sector and academia, due to the technical limitations of the oversight body.

Approval of medical products: ANMAT's risk classification system for medical products is similar to that of the European Union. Class I products require a sworn declaration to receive a marketing permit. Class II, III and IV products have to meet basic safety and effectiveness requirements. Complex products, such as those falling into Class IV, must undergo clinical trials.

An Adverse Events Monitoring System, known as "Tecnovigilancia", has been set up for the early detection of any adverse and/or unexpected events. In this way, actual use is monitored.

2. Information Products to Help Regulatory Agencies.

Mr. Jonathan A. Gaev, Director of International Programs, ECRI.

ECRI is a non-profit organization with laboratories especially designed for the evaluation of medical devices. It has an information system that makes it possible to produce reliable and relevant reports on problems arising in the use of medical products. A presentation was made on the various information products that provide support to regulatory programs, with emphasis on the warning system. There was also a presentation of the Universal Medical Devices Nomenclature System (UMDNS), which is the basis for any search for information on devices and has been translated into several languages, including Spanish. A copy of the Spanish/English version of the UMDNS CD-ROM was given to participants.

3. Presentation of the document "A Model Regulatory Program for Medical Devices"
Ms. Linda Horton, FDA.

The document "A Model Regulatory Program for Medical Devices" was distributed to participants. In the presentation it was explained that the document contains a proposal for a modular regulatory program whose purpose is to safeguard health and public safety. A series of basic principles is laid out for auditing the inspection of medical devices. This also facilitates evaluation of device safety and effectiveness. Mention was also made of the documents prepared by the Study Groups of the Global Harmonization Task Force.

4. Regulation of Medical Devices in MERCOSUR
Mr. Carlos A. Parodi, Director of Medical Technology, ANMAT.

The MERCOSUR common framework for the marketing, control, and monitoring of goods and services as applied to medical products was presented. Within this framework it is necessary to implement and maintain operational quality systems for process verification.

5. "MED-DEVICES": Electronic Discussion Group on Medical Devices
Mr. Antonio Hernández, PAHO Washington.

In order to facilitate communication and an exchange of information among regulatory authorities of the countries of the Region, PAHO/WHO has established a discussion group called "MED-DEVICES." This Internet discussion group is open only to health authorities working in the regulation of medical devices.

6. Global Harmonization Task Force (GHTF)
Ms. Linda Horton, FDA.

The origins and historical evolution of the GHTF as an international volunteer organization were covered, as were the objectives and activities of each of its four Study Groups (regulation, quality system, post-marketing monitoring, and auditing). The goal is to work toward the harmonization of national regulatory requirements. The GHTF Web site was presented. It offers access to summaries of previous meetings and to both adopted and working documents of the four Study Groups. The 9th GHTF Conference is being convened in Barcelona (Spain) on 10 to 17 October 2001. During the conference, a session on Latin America and the 3rd Pan American Cooperation in Medical Equipment (PACME) meeting will be held.

7. Presentation of the Document "A Guideline for the Development of Medical Device Regulation"
Dr. Roland Rotter, MDB.

This document, prepared for people who are not well-versed in the subject, covers the concepts of safety, effectiveness, and quality of medical devices within the context of risk management and introduces interest groups involved in the field of product effectiveness and safety. It also offers an introduction to the regulatory systems of Canada, the United States,

and the European Union. Prepared for PAHO/WHO, this document will be published at the end of year.

8. Reuse of Single-Use Medical Devices

Representatives of the FDA, MDB, ECRI, and ANMAT.

The various speakers referred to the risks involved in the reuse of medical devices. Moreover:

- ANMAT made a presentation on the regulations governing the reuse and donation of medical products.
- The FDA indicated that although it is known that in the United States reuse is practiced in approximately 30% of hospitals, there is no clear information that makes it possible to detect risks associated to the use of these products or to determine whether the procedures in place to do so are the most appropriate.
- MDB applies the same regulatory standards it uses for manufacturers to institutions that reuse medical devices, which makes the issuance of new licenses mandatory. Thus, any adverse events that may occur with these new products are the responsibility of the institutions that carried out their modification. In addition, issues related to the re-manufacture of medical equipment were discussed;
- ECRI identified reuse as a way hospitals can reduce costs, but also as a practice that increases the risks to patients. In this regard, clearly defined criteria for reuse and the identification of products for which reuse can be developed are indispensable.

9. International Basic Safety Standards for Radiological Equipment

Dr. María Esperanza Castellanos, PAHO.

The International Basic Safety Standards for Protection against Ionizing Radiation and the Safety of Radiation Sources were developed in order to harmonize basic requirements for protection against radiation and the safety of radiology practices, stressing control of exposure as use increases. These standards include both design and use aspects. The Standards follow the 1990 recommendations of the International Commission on Radiological Protection. The various topics included in the International Basic Safety Standards for Radiological Equipment were covered, and the importance of incorporating them into regulatory, medical device monitoring, and control systems was underscored. The Standards grew out of the joint efforts of several international agencies, among them PAHO and WHO. They were endorsed by the 24th Pan American Sanitary Conference in 1994.

QUESTION AND ANSWER SESSION

In general, the participants showed interest in the recommendations of institutions such as the FDA, MDB and ECRI in regard to specific aspects of the reuse of medical devices; the incidence on product cost of the studies that manufacturers must conduct to determine reuse

procedures, and the number of times a medical device can be reused; intellectual property rights issues related to the remodeling of equipment, and the position of the Canadian and U.S. environmental agencies on the reuse of medical devices.

DAY THREE: 2 August 2001.

DEVELOPMENT OF THE AGENDA

1. Donation of Medical Equipment.

Representatives of PAHO, ECRI, and ANMAT.

PAHO raised the question of the donation of medical equipment and its impact on health facilities when no clear decision-making guidelines are in place regarding the appropriateness of the donation. The World Health Organization has prepared draft guidelines on the donation of medical equipment based on an American College of Clinical Engineering (ACEE) document on the subject. It was recalled that, according to the studies of Dr. Yadin David of the Texas Children Hospital, "The purchase of equipment is only 20% of the investment during its useful life."

From the perspective of ECRI, any donation of equipment, regardless of the reasons justifying it (economic savings or political reasons, for example), must be subject to a careful assessment of the technology and the availability of funds for operating and maintaining the equipment. In this regard, guidelines for making a decision to accept or refuse a donation of equipment were presented.

The representative of ANMAT covered the experience in Argentina and actions taken there in regard to equipment donation when the donation responds to a country's desire to get rid of a certain technology or waste.

2. Regulation of Medical Devices In Ecuador, Chile, Colombia, Peru, and Venezuela.

Dr. Marco Ortega, National Director MPH. Ecuador.

Dr. Nancy Fernández, Institute of Public Health. Chile.

Mr. Napoleón Ortiz, Ministry of Health. Colombia.

Dr. Jeaneth Solano, Ministry of Health. Colombia.

Mr. Luis Vilcahuaman, Pontifical Catholic University. Peru.

Dr. Elizabeth Garrido, MSDS. Venezuela.

Each speaker covered the following topics for the country in question:

- The current situation in the field
- The definition of "medical device"
- The legal regulatory framework

- Classification criteria and aspects related to standardization of the quality of devices
- Surveillance and pre- and post-marketing monitoring
- Available infrastructure in this area, and
- Current and future challenges.

CONCLUSIONS AND RECOMMENDATIONS

The following conclusions and recommendations put forward by delegates and participants were reached within the framework of compliance with Resolution CD42.R10 on medical devices of the 42nd Directing Council of PAHO.

- All countries should prepare documents on medical devices in order to provide comprehensive information on resources, professionals, infrastructure, and specific needs in the area of regulation. Comparing and analyzing such information will make it possible to carry out a diagnosis and prepare a common plan of action. Strengths and weaknesses need to be highlighted.
- Priority should be given to developing and organizing programs for training human resources. Training should be geared to the specific groups involved: health authorities, healthcare professionals, insurers, suppliers, and community (re-use). Such training should also include undergraduate and post-graduate university programs.
- Permanent networks for virtual communication among countries should be put in place in order to facilitate the exchange of information.
- An inter-country, interinstitutional, multidisciplinary working group devoted exclusively to medical devices should be established in order to ensure the continuity and sustainability of efforts over time.
- National legislation should be reviewed and compared with GHTF documents. Definitions, requirements, quality systems, monitoring, and audits.
- Active participation in GHTF activities and study groups is recommended, including attendance at the ninth Meeting of the GHTF to be held in Barcelona, Spain from 10 to 17 October 2001.
- The information, documents, and databases of Collaborating Centers (FDA, MDB, ECRI and others) should be used as a reference. Insurers and professional associations should become involved in order to strengthen pre- and post-marketing monitoring.
- Every country shall prepare a brief summary of its regulatory program, including the legislation currently in force, pertinent institutions, requirements for registration and importation, monitoring activities, etc.

- The various national Working Groups on Medical Devices are to be convened in Colombia during the first half of 2002 for the First National (Latin American) Symposium on the Re-Use of Medical Devices.
- The harmonization of regulations on medical devices among the countries of the Andean Community of Nations is to be incorporated into the Hipólito Unanue Agreement.

**INTERNATIONAL WORKSHOP
REGULATION OF MEDICAL DEVICES
ANDIAN REGION**

Date: July 31 to August 2, 2001
City: Cartagena de Indias
Place: Hotel Almirante

PROGRAM

Tuesday, July 31

8:00-8:30 Registration.

8:30-9:00 Opening Ceremony.

9:00-10:00 PAHO's Role in the Regulation of Medical Devices.
Eng. Antonio Hernandez, PAHO Washington.

10:00-10:30 Break.

10:30-11:30 New Canadian Approach for the Regulation of Medical Devices.
Dr. Roland Rotter, Medical Devices Bureau (MDB), Health Canada.

11:30-12:30 MDB Export Requirements and Regulations on Medical Devices and Biological.
Dr. Roland Rotter, MDB

12:30-14:00 Lunch.

14:00-15:00 The Food and Drug Administration (FDA) and the Center for Devices and Radiological Health (CDRH)
Ms. Linda Horton, FDA.

15:00-16:00 FDA Export Requirements and Regulations on Medical Devices and Biological.
(Video)
Ms. Linda Horton, FDA.

16:00-16:30 Break.

16:30-17:30 Panel of questions

Wednesday, August 1

8:00-9:00 National Administration for Food, Drugs and Medical Technologies (ANMAT) of Argentina.
Eng. Carlos Parodi, AMNAT.

9:00-10:00 Information Products to Help Regulatory Agencies.
Eng. Jonathan Gaev, ECRI. (Emergency Care Research Institute)

10:00-10:30 Break

10:30-11:30 The "Global Harmonization Task Force" (GHTF)
Ms. Linda Horton, FDA & Dr. Roland Rotter, MDB.

11:30-12:00 Medical Devices Regulation in MERCOSUR.
Eng. Carlos Parodi, AMNAT.

12:00-12:30 "MED-DEVICES," Electronic Discussion Group on Medical Devices
Eng. Antonio Hernandez, OPS Washington.

12:30-14:00 Lunch

14:00-14:15 Presentation of the Document: "A Model Regulatory Program for Medical Devices."
Dr. Linda Horton, FDA

14:15-14:30 Presentation of the Document: "A Guideline for the Development of Medical Device Regulation"
Dr. Roland Rotter, MDB

14:30-15:30 Reuse of Single-Use Medical Devices.
Perspective of the FDA.
Perspective of the MDB.
Perspective of the ECRI.
Perspective of ANMAT.

15:30-16:00 Medical Equipment Donation
Eng. Antonio Hernandez, Eng. Jonathan Gaev & Eng. Carlos Parodi

16:00-16:30 Break.

16:30-17:30 International Basic Safety Standards for Radiological Equipment
Dr. Maria Esperanza Castellanos, PAHO

Thursday, August 2

8:00-8:30 Medical Devices Regulation in Bolivia.

8:30-9:00 Medical Devices Regulation in Ecuador.

9:00-9:30 Medical Devices Regulation in Chile.

9:30-10:00 Medical Devices Regulation in Colombia.

10:00-10:30 Break.

10:30-11:00 Medical Devices Regulation in Peru.

11:00-11:30 Medical Devices Regulation in Venezuela.

11:30-12:30 Panel of Questions

12:30-14:00 Lunch.

14:00-15:00 Proposed Action Plan for the Andean Region.

15:00-15:30 Conclusions and Recommendations.

15:30-16:00 Break.

16:00-16:30 Closing.

**NATIONAL TECHNICAL MEETING
COLOMBIAN MINISTRY OF HEALTH AND NATIONAL INSTITUTE FOR FOOD AND
PHARMACEUTICAL VIGILANCE AUTHORITIES –INVIMA–**

**Date: Friday August 3, 2001
City: Cartagena de Indias
Place: Hotel Almirante**

PROGRAM

THE SGSSS AND THE MEDICAL DEVICES REGULATION.

8:00-9:00 Analysis of the Steering Role of the Ministry of Health of Colombia in the process of Medical Devices Regulation.

9:00-10:00 Analysis of the Role of Inspection, Surveillance, and Enforcement of the INVIMA in the Regulation of Medical Devices.

10:00-10:30 Break.

10:30-11:00 Revision of Legal Framework for the Regulation of Medical Devices in of Social Security in Health General System

11:00-12:00 The Role of the National Industry of the Regulation of Medical Devices.

12:00-14:00 Lunch.

**14:00-16:00 INTERNATIONAL EXPERT COMMENTARIES WITH RESPECT TO THE
ROLE OF THE SGSSS AND THE REGULATION OF MEDICAL
DEVICES IN COLOMBIA.**

16:00-16:30 Recess.

16:30-17:30 Conclusions and Recommendations.

INTERNATIONAL WORKSHOP ON THE REGULATION OF MEDICAL DEVICES

Cartagena de Indias, 31 July - 3 August, 2001

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