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MEDICAL DEVICES

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The Latin American and Caribbean countries are significant emerging markets for medical devices and several of them have an annual rate of growth of 10%. With few exceptions, the countries imported more than 80% of their medical equipment and devices.

The ministries of health have become increasingly concerned about this situation and have recognized the importance of the regulation of medical devices and the international harmonization of regulatory requirements. Under the Health Sector Reform this is part of the strengthening of the steering role of the ministries of health in its function as a regulatory authority in order to guarantee the safety, effectiveness and quality of the medical devices used by the population.

Since 1994, PAHO has been working with the Latin American and Caribbean countries in the developing and strengthening of regulation of medical devices with the technical cooperation of the Medical Devices Bureau of Canada. The United States Food and Drug Administration and ECRI, a PAHO/WHO Collaborating Center, have joined this effort.

The Medical Devices Regulation issue is being submitted to the Subcommittee on Planning and Programming to urge the Member States to include medical devices regulation as part of their health sector reform, and to support and implement the Plan of Action prepared in the Consultation on Medical Devices, held at PAHO in October 1999, and the recommendations presented in this document.

TABLE OF CONTENTS

	<i>Page</i>
1. Introduction	3
2. PAHO Initiatives to promote Medical Device Regulation in Latin American and Caribbean Countries	3
3. PAHO Consultation on the Regulation of Medical Devices	4
3.1 Conclusions	4
3.2 Recommendations	5
3.3 Proposed Plan of Action	6
4. Model Program for Medical Devices	7
5. Guideline for the Development of Medical Devices Regulations	7
6. The Global Harmonization Task Force	7
7. Status of Regulatory Systems in Latin America and the Caribbean Countries	9
8. Recommendations to the Subcommittee on Planning and Programming	11
Annex A	
Annex B	

1. Introduction

Health care technology is a critical component of any health care system. While the costs of new medical technology continue to increase, so do the benefits that new technologies can provide. Several Latin American countries are significant emerging markets for medical devices where the growth rate in the market is about 10% annually. Health authorities are confronted with a bewildering array of choices related to increasing sophistication and complexity of medical devices, and emerging technologies. In addition to the increase in choices, health authorities are experiencing an increased expectation by the population for new technologies and are facing challenges in the provision of quality and cost-beneficial treatments.

The steps involved in the planning, procurement and management of healthcare technology are complex but essential for effective utilization of limited resources and effective use of technology. Government regulation of medical devices as a mechanism to ensure the safety, efficacy and quality of products can add significant benefit to technology management. Promotion of regulatory programs is consistent with PAHO's goals of health sector reform and strengthening the leadership of the ministries of health in relation to monitoring and regulating the medical device sector in order to guarantee the use of safe, effective and high quality products throughout a country.

Guiding regulatory principles for any country should include the use of international standards for safety and effectiveness, utilization of a quality systems approach to medical device manufacturing, and the adoption of a harmonized approach to regulation using internationally accepted guidelines and practices.

Harmonization should be understood and the search for common ground within the framework of recognized standards, taking into account the existence of different political, financial, health and legislative realities among the countries of the Region. The advantages of adopting a harmonized approach are many: increased access to new technologies; efficient use of available regulatory resources; facilitates trade among countries in the Region; and sets a common and high standard for products throughout the Region.

2. PAHO Initiatives to Promote Medical Device Regulation in Latin American and Caribbean Countries

PAHO's objective is to collaborate with the Member States in the development and strengthening of medical devices regulatory systems to guarantee safety and effectiveness of the products used by the population. Since 1993 several countries have been requesting PAHO technical cooperation in the area of regulations for medical

devices. In 1995 the Medical Devices Bureau of Health Canada presented to PAHO an overview of the proposed new approach to regulation in Canada. These regulations have since become law; they were developed using both the United States' and Europe's regulations as models.

In 1996 PAHO began fostering harmonization of regulatory requirements in selected countries, including Colombia, Cuba, Mexico and Panama. PAHO sponsored presentations of the Canadian model in national and international seminars.

Technical information, advice and expertise on medical devices has also been provided to Member States. For example, workshops on the impact of electromagnetic interference on medical devices have been provided in Cuba, Mexico and Peru. In addition, technical workshops were held in Canada on various aspects of the regulatory system such as the classification system, cost recovery practices, and management of medical device databases. These workshops have varied in length from two days to one week and were given to Colombia, Costa Rica and Cuba.

More recently, PAHO held a consultation on medical devices in October 1999 in Washington, D.C. Representatives of the health ministries of several Member States, the US Food and Drug Administration (FDA), the Medical Devices Bureau of Canada, WHO, and PAHO officials participated. The agenda included presentations on: The Steering Role of Ministries of Health in Health Sector Reform; PAHO's Essential Drugs and Technology Program; PAHO's Role in Medical Device Regulation; The Canadian Approach for the Regulation of Medical Devices; Medical Devices in WHO Activities; Information Resources from the FDA; Information Product to Help Regulatory Agencies (ECRI); The Global Harmonization Task Force; the documents *A Guideline for the Development of Medical Device Regulations* and *A Model Regulatory Program for Medical Devices: An International Guide*; and the PAHO initiative "MED DEVICES" Electronic Discussion Group in Medical Devices.

3. PAHO Consultation on the Regulation of Medical Devices

3.1 Conclusions

It was recognized that the regulation of medical devices is an increasingly important component of health care that is growing in complexity. As a result, there is an expanding and competitive market with manufacturers and agents very actively marketing their products through the Region without adequate provision of after sales service and maintenance.

With few expectations, the countries of the Americas imported more than 80% of their medical equipment and devices. However, only a few countries have functional systems to regulate medical devices to assure their safety and effectiveness or the technical capacity to implement these.

As technology and information becomes more widely available, many ministries of health have become increasingly concerned about this situation and have recognized the importance of initiating such programs. This is in keeping with Health Sector Reform and the strengthening of the leadership role of ministries of health in relation to monitoring and regulating the sector in order to guarantee the safety, efficacy and quality of health care.

However, the problem is complex and involves issues such as the capital and recurrent cost of equipment and the "explosion" in the availability of information from various agencies, as well as the lack of technical capacity of the ministries in this area and the consequent cost and feasibility of setting up new programs.

A significant body of information exists to assist medical device regulation but there is a need to improve accessibility and understanding of these resources.

In addition to demand for equipment and technology is driven both by professionals (particularly when exposed to new technology through training programs) and by the clients whose expectations are raised by the media and exposure to the same information. PAHO doesn't have the mechanisms in place that satisfy this demand while permitting access to training, maintenance and the procurement of supplies. All those elements must be present to ensure that the technology will improve patient care.

The draft documents, *A Guideline for the Development of Medical Device Regulations* and *A Model Program for Medical Devices: An International Guide* were well received and considered important inputs for the preparation of final documents following the meeting.

WHO and PAHO, individually and together, have undertaken relatively little work in this area in recent years and there is potential to become more active and for closer collaboration.

3.2 Recommendations

The ministries of health should assign appropriate priority to the regulation of medical devices as part of their new leadership role in the reformed health sector.

In order to achieve a measure of consensus on the way forward, WHO (and PAHO in the Americas) should increase their participation in and promote greater country inputs in major international activities and initiatives in this area. WHO should evaluate PAHO experience in this area and its applicability to other Regions.

The ministries of health are invited to utilize the updated draft documents presented at the meeting as a reference for the development of guidelines and programs within their respective countries. Special attention should be given to the education of professionals and consumers.

Full use should be made of existing and emerging communication technologies to encourage the sharing of information between countries and agencies, for example, the "MED-DEVICES" Electronic Discussion Group and the Web pages maintained by the regulatory authorities and the collaborating centers.

Latin American and Caribbean countries should be represented at meetings and work groups of the Global Harmonization Task Force.

Technical cooperation between countries in the Region should be stimulated including the development of specific projects as appropriate.

3.3 *Proposed Plan of Action*

The following is suggested as a preliminary plan of action for the next two years to be coordinated by PAHO with the support of WHO:

- Develop a regional project proposal to strengthen the capacity of a range of countries in the area of medical device regulation. A preliminary activity will be to collect information on the present status of medical device regulation programs and issues in the countries of the Region.
- Circulate the draft documents for comments and updating by the end of March 2000.
- Publish a glossary of terms and a non-technical guide to medical device regulation as the first phase of the development of comprehensive guidelines.
- Implement a series of workshops to address specific issues for countries selected according to their level of development of regulatory capability.

Promote the identification of information sources for medical device regulation including the "MED-DEVICES" Electronic Discussion Group.

- Promote and support the participation of Latin American and Caribbean countries in the Global Harmonization Task Force and its work groups.

4. *Model Regulatory Program for Medical Devices*

The document *A Model Regulatory Program for Medical Devices: An International Guide* was prepared in 1996 by the FDA under contract for WHO. It has been revised to include comments received at the October 1999 consultation meeting and a glossary of terms has been added. This document outlines the principles and essential characteristics that should be contained in a model medical device regulatory program (Annex A).

5. *Guideline for the Development of Medical Devices Regulations*

This guideline was jointly developed by Canada and PAHO as an orientation guide for the establishment of regulatory programs in developing countries. It explains in non-technical language the essential terms and concepts in device safety, and common government regulatory methods. The document promotes the use of risk management principles throughout the life span of a medical device and the concept of shared responsibility amongst the stakeholders. The document is being revised based on comments received from the participants at the October Consultation meeting and a glossary of terms will be added. The document was endorsed by participants at the meeting (Annex B).

6. *The Global Harmonization Task Force*

The Global Harmonization Task Force (GHTF) is a voluntary international consortium of public health officials responsible for administering national medical device regulatory systems, in partnership with representatives from the regulated industry. Since its inception in 1993, the GHTF has been comprised of representatives from five founding members (Australia, Canada, Japan, United States, and the European Union), representing three geographical areas, and of representatives from many other countries, including many Latin American and Caribbean countries, with regulatory systems at various stages of development. The GHTF has not had any formal operating policies or procedures but is currently developing these. The goal is to have draft policies and procedures for the organization to discuss, with the aim of endorsing them, at the GHTF Conference in September 2000 in Ottawa, Canada. PAHO sponsored several member

countries attendance at last year's conference and will again this year sponsor attendance at the September 2000 meeting.

The objectives of the GHTF are: to promote a high level of public health; to encourage the development of a flexible regulatory environment that allows for better protection of public health, and thereby facilitate the availability of important new medical technologies; to voluntarily reduce regulatory differences and eliminate any unjustified duplicate controls that are not necessary to ensure medical device safety, efficacy and quality, resulting in greater global access to new devices; to facilitate the development of an international post-market and vigilance system that will reduce the likelihood of repeated adverse events; and to foster international cooperation between countries with developed regulatory systems and those with developing systems.

The goals of the GHTF are: to provide a forum for representatives of national regulatory authorities and industry representatives to work together to encourage convergence of regulatory practices regarding medical device safety, efficacy and quality; and to provide a forum for information exchange between countries with developing medical device regulatory systems and those with existing regulatory systems. Harmonization is to be accomplished by consensus among the GHTF members on the technical requirements that underpin regulatory practices.

It is noteworthy that the objectives and goals of the GHTF are consistent with PAHO's goal of promoting harmonized regulations in its Member States through consultation and consensus.

The GHTF consists of four study groups (SGs) that produce documents on various topics of medical device regulation:

- SG1 has been charged with comparing operational medical device regulatory systems around the world and from that comparison, isolating the elements/principles that are suitable for harmonization and those that may present obstacles to uniform regulations. In addition, the group is also responsible for developing a standardized format for pre-market submissions and harmonized products labeling requirements.
- SG2 is charged with the task of reviewing current adverse event reporting, post-market surveillance and other forms of vigilance for medical devices and performing an analysis of different requirements amongst countries with developed device regulatory systems with a view to harmonizing data collection and reporting systems.

- SG3 is responsible for the task of examining existing quality system requirements in countries having developed device regulatory systems and identifying areas suitable for harmonization.
- SG4 has been charged with the task of examining quality system auditing practices (initially among the founding members of the GHTF) and developing guidance documents laying harmonized principles for the medical device auditing process.

Each study group is made up of representatives from member countries who are technical experts in that area of expertise. Documents are produced through consensus and undergo significant consultation with groups and individuals outside the study group prior to being recommended for endorsement by the GHTF.

The GHTF has produced to date, 12 final documents and 9 proposed documents, on various aspects of medical device regulations and at least one from each of the four Study Groups. Founding member countries have committed to implementing the guidelines, where there is not conflict with existing regulation or legislation. A survey of founding member countries will be conducted in the near future to determine the status of each of the 12 final documents in their respective country. Additionally, each member that registers for the GHTF Conference this year will be asked to complete a survey about their regulatory system and how or if they are using GHTF documents. This information will be made available on the GHTF Web site www.ghtf.org.

7. Status of Regulatory Systems in Latin America and the Caribbean Countries

Latin American and the Caribbean countries have regulatory programs at various stages of development.

ARGENTINA: New medical device regulations are in the process of being developed. Existing regulations accept Country of Origin Certificates for Foreign Governments (from the FDA), legalized CE Mark Certificates from the European Union (EU), or legalized Certificate of Free Sale for marketing products in the country. Imported products must comply with specified standards, including Spanish labeling and the provision of importer information. Requirements for conducting clinical trials in Argentina are similar to those in the Canada, EU, and USA.

BRAZIL: Brazilian regulations are in the process of renewal also. User fees have been implemented (i.e. the manufacturers pay to have products registered). The registration procedure in Brazil requires all non-Brazilian manufacturers to register products using a Brazilian representative or distributor. In addition, Certificates of Free Sale must come

from the country of origin. A Good Manufacturing Guide, adopted by MERCOSUR will be implemented, following an inspection training program.

CHILE: New medical device regulations were developed in Chile in 1998. The regulations include a risk-based categorization scheme and require testing of the devices by a Chilean authorized testing facility, according to Chilean and/or international standards.

COLOMBIA: The Colombian government is updating the legislation for the regulation of medical devices. The new legislation includes quality control and product surveillance for goods imported, exported or commercialized. Medical devices produced, imported, exported or commercialized in the country must be registered with INVIMA (Instituto Nacional de Vigilancia de Medicamentos y Alimentos). The Ministry of Health has developed a norm for the acquisition of biomedical technology.

CUBA: Cuba's National Control Center for Medical Devices is the regulatory agency for medical devices in Cuba. Regulations for medical devices have been implemented and include pre-market, post-market, and quality system components.

MEXICO: All medical devices sold in Mexico must be registered with the Secretariat of Health and must comply with labeling, quality standards, certificates of origin, and import permits. Product applications must contain information to support the safety and efficacy of the product, including, but not limited to: raw material data, description of product and its uses, sterilization method, labeling, clinical information to support safety, and information on the physical, chemical and biological specifications of the product.

PANAMA: The Ministry of Health of Panama has started to develop a medical device regulatory program oriented to guarantee the safety, effectiveness, and quality of the medical devices used by the population. The Medical Devices Bureau of Health Canada and PAHO are providing technical support for this program.

PERU: A medical device regulatory program is in process of being developed. The medical devices sold in the country must be registered with the Ministry of Health and there is a limited surveillance of the products in the market. DIGEMID (Dirección General de Medicamentos, Insumos y Drogas) at the Ministry of Health is the regulatory authority and is preparing the norms for medical devices regulations.

Argentina, Brazil, Paraguay and Uruguay, and more recently Bolivia and Chile, as associate members, have formed a trading alliance under what is known as the MERCOSUR Agreement. This multi-national pact entails a harmonized regulatory

approach for medical devices that is presently in the developmental stage. In broad conceptual form, the new system will regulate medical devices according to their risk potential. Products will be assigned to one of three risk-based categories, with Class 3 being the highest risk group. Regulatory programs are to be phased in, starting with product registration and followed by quality system inspections.

8. Recommendations to the Subcommittee on Planning and Programming

Member States should be encouraged to consider regulatory development for medical device regulation as part of their health sector reform activities.

Member States should be encouraged to use "needs based" health technology assessment early in their health technology management plans. In this way, medical technology purchased, and regulated, will meet the needs of the country's health care system.

- PAHO should give consideration to the effects of medical device technologies on specific populations, such as women and aboriginals, to determine the proper use and management of risk. Through regulation, manufacturers can be required to provide information on the use of devices in a specific population group. Where possible, new and innovative approaches to the use of technologies should be considered for use in Member States. For example, telemedicine is a promising approach to provide health care in remote areas.
- PAHO should host workshops, every two years, to promote the development of harmonized regulations amongst its Member States. All aspects of regulation and/or technical aspects of medical devices should be considered for topics. Recommendations on regulatory matters should be an output of the workshops. For example, workshops could be used to discuss in detail GHTF documents to develop its understanding and to recommend their implementation in the countries, as applicable. The objectives of the workshop could include: to promote and maintain constructive dialogue among regulatory agencies, the medical devices industry, and other sectors, through periodic workshops; to encourage the convergence of regulatory systems in the Region; to adopt recommendations for implementation at national and regional levels; to encourage and facilitate technical cooperation between countries; and to promote harmonization of medical device regulation requirements, and guidance document for specific regulatory issues.
- PAHO should establish a Steering Committee on medical devices, to include representatives from regulatory authorities from Member States, representatives

from WHO Collaborating Centers, medical device industry associations, and others as PAHO and the Steering Committee may identify. The role of the Steering Committee would be to enable progress between workshops by coordinating, promoting, facilitating, and monitoring harmonization processes in the Americas. The recommendations of the workshops would be used to develop the workplan of the Steering Group. The objectives of the Steering Group could include: to ensure the effectiveness of the workshops and the relevance of the topics addressed at the workshops; to facilitate and monitor implementation of workshop recommendations; to ensure continuity of device harmonization activities between workshops; and, to facilitate consensus building and resolution of issues between and at the workshops.

- PAHO should promote and facilitate access to a significant body of information exists to assist medical device regulators but accessibility and understanding of these resources should be enhanced through workshops and continuous dialogue. Full use should be made of these existing and emerging communication technologies to encourage the sharing of information and use of existing information. For example: Web pages maintained by most regulatory authorities such as Canada and the US; the "MED-DEVICES" Electronic Discussion Group; and ECRI's (a non-government, non-profit organization and WHO Collaborating Centre) variety of information products on medical devices.
- PAHO should promote the use of international standards, where they exist, to be used in the regulation of medical devices. Use of international standards could be included as a topic for the proposed workshops.
- PAHO should promote the participation of the member states in the GHTF and promote the use of GHTF documents when developing regulatory systems. It is also recommended that PAHO participate in GHTF to provide dialogue on how best GHTF can provide the countries with opportunities to share information on topics of interest. If PAHO adopts the recommendations, a representative from the GHTF should be considered for the proposed Steering Committee.
- PAHO should continue to provide technical advice and expertise on topics of particular concern to member countries, as they have in the past for Y2K and electromagnetic interference. These topics should be included on the agendas of workshops as much as possible, rather than providing training to individual countries.

MODEL PROGRAM FOR MEDICAL DEVICES

The main feature of this document is its modular approach to establishing a regulatory program to allow for flexibility in the development and implementation of regulations according to each country's needs and resources. There are four major modules of the document: market entry notification, post-market vigilance, manufacturing controls and inspections, and safety and efficacy performance assessments.

- **Market Entry Notification**

Overall, a critical baseline requirement of any medical device program, irrespective of its complexity, is the acquisition of information about an establishment seeking to commercially distribute a product. Equally important is the availability of information describing the performance history of the product and adverse events or performance trends associated with its use. These dual objectives can be accomplished by requiring manufacturers of devices to submit premarket notifications to the national regulatory body.

- **Post-Market Vigilance**

No amount of rigor in any Market Entry Notification process can predict all possible device failures or problems arising from product misuse. Thus, the ability to monitor the performance of marketed devices is an essential component of a device regulatory system. How elaborate a system is for tracking device performance, documenting problems and imparting vital information about device-related incidents with other users is, of course, a function of available resources and other local and national considerations.

- **Manufacturing Controls and Inspections, and Safety and Efficacy/Performance Assessment**

The final two levels of a device regulatory program, perhaps more than any other, are ones that must be adapted to the socioeconomic conditions, infra structural capacities and unique needs of individual countries. There is a broad spectrum of available mechanisms for regulating product safety, which can be selectively adopted, incrementally applied, or instituted en bloc. This menu of regulatory controls gives countries broad discretion in designing systems that are best suited for them and the constituencies they represent, as follows:

- (a) site inspection of manufacturing facilities and the practices used in the mass production of medical devices;
- (b) required manufacturer conformance with national or international consensus standards developed by third parties that address product safety, quality, effectiveness, performance and sterility of finished devices;
- (c) pre-market testing of devices, either by the regulatory body, or the manufacturer or an independent testing entity, that demonstrates conformance with applicable standards and other performance and marketing requirements;
- (d) mandatory pre-market evaluation of new devices and market clearance to attest that safety, effectiveness and performance requirements are met;
- (e) controls under which devices can be marketed; that is, specifications on the conditions under which devices can be offered for sale, in addition to who may use particular devices and under what conditions.

GUIDELINE FOR THE DEVELOPMENT OF MEDICAL DEVICES REGULATIONS

Section 1 Describes the nature of medical device safety as a risk management process that must be continued throughout the life span of medical devices from conception to disposal. The safety and effectiveness of medical devices demands co-operation among the people who actively manage the different phases in the life span of medical devices. The responsibilities must be shared among the stakeholders.

Section 2 Considers the role of the government. The stages of pre-market, on-market and post-market control are described with their commonly used regulatory tools. An example on the use of these tools in the Canadian Medical Devices Regulations is also presented.

Section 3 Introduces the work of the Global Harmonization Task Force (GHTF) which has a mission to harmonize standards and procedures for medical device regulation, as well as address other issues related to medical devices in different countries.

Section 4 Provides suggestions for governments seeking to establish an affordable program for ensuring the safety and effectiveness of medical devices. Such a program requires that the government increases its knowledge of the medical device sector, and shares this understanding among the stakeholders. This will lead to the establishment of a clear policy on medical device management on which legislation and enforcement can be brought in when necessary and, as resources are available. Governments are urged to take advantage of the current development of the GHTF and the worldwide Quality Movement to reduce the local regulatory burden for the program.

Section 5 Describes the different intentions of existing "export certificates" from Canada and the United States. Member are urged to exercise caution when interpreting these certificates.

Section 6 Concludes that this research suggests that a recommendation be made to the Global Harmonization Task Force. There is a need to establish a uniform format so that different countries can certify that medical devices being exported comply with their domestic regulatory requirements. This certification can greatly help the importing countries to control medical devices.

