



PAN AMERICAN HEALTH ORGANIZATION  
WORLD HEALTH ORGANIZATION



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### **MEDICAL DEVICES**

The countries of Latin America and the Caribbean are an important emerging market for medical devices; indeed, in several countries this sector has witnessed an annual growth rate of 10%. With few exceptions, the countries import more than 80% of their medical devices.

This situation is of increasing concern to the ministries of health, which have recognized the importance of regulating medical devices and of international harmonizing regulatory requirements. Within the context of health sector reform, this is part of the strengthening of the steering role of the ministries and of their function as regulatory authorities to guarantee the safety, efficacy, and quality of medical devices used by the population and the health services.

Since 1994, the Pan American Health Organization has been working with the countries of Latin America and the Caribbean to establish and strengthen the regulation of medical devices, with technical cooperation from the Medical Devices Bureau of Canada. The Food and Drug Administration (FDA) of the United States and the Emergency Care Research Institute (ECRI), a PAHO/WHO Collaborating Center, have also joined in this activity.

The subject of the regulation of medical devices was presented to the 126<sup>th</sup> Session of the Executive Committee, which adopted a resolution (CE126.R8, annexed), for the consideration of the Directing Council, which urges Member States to include the regulation of medical devices as a part of their health sector reform, and to support and implement the plan of action prepared at the consultation on the regulation of medical devices, held at the PAHO headquarters in October 1999, as well as the recommendations presented in this document.

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## 1. Introduction

Health care technology is an essential component of every health services system. The costs of new medical technology continue to increase, as do the benefits that it can provide. Several Latin American countries constitute important emerging markets for medical devices, whose growth rate in local markets is nearly 10% annually. Health authorities face an overwhelming variety of options with regard to increasingly sophisticated and complex technologies and new medical devices. In addition to having more options, authorities must also consider a population that expects more from the new technologies, as well as the challenge of delivering good quality services and beneficial treatments as a function of costs.

The steps that involve planning, procurement, and the management of health care technology are complex but essential to the effective utilization of technology and limited resources. Government regulation of medical devices as a means to safeguard the safety, efficacy, and quality of the products can in turn be very beneficial for the utilization of technology. The promotion of regulatory programs is compatible with the goals of the Pan American Health Organization in terms of health sector reform and the leadership of the ministries of health insofar as concerns the monitoring and regulating of the medical devices sector to guarantee the use of safe, effective, and high-quality products in a given country.

Areas in which there is a need to establish programs to regulate medical devices include: the technological complexity of the devices; more global and competitive markets; increases in the marketing of used and refurbished equipment; donation of devices; reuse of single-use devices; ever-increasing use of devices in physician's offices and at the household level; patients with greater access to information; weak post-sale technical support services; need to track adverse events and recalls with devices, and increased use of *in silico* testing.

The guiding principles driving regulation in any country should include the enforcement of international guidelines (standards) for safety and efficacy systems, the utilization of quality systems in the manufacture of medical devices, and the adoption of a criterion for harmonization of regulations based on internationally accepted guidelines and practices.

The need for harmonization is to be understood (and points of agreement within the context of recognized guidelines should be sought) by taking into account that the countries of the Region of the Americas are marked by differing political, financial, health, and legislative realities. The advantages of adopting a criterion for harmonization are many, namely: increased access to new technologies; effective use of available

regulatory resources; facilitation of trade among countries of the Region; and establishment of a common, optimal guide for products from the entire Region.

## **2. PAHO Initiatives to Promote the Regulation of Medical Devices in the Countries of Latin America and the Caribbean**

The objective of PAHO is to collaborate with the Member States in the creation and strengthening of systems for regulation of medical devices in order to guarantee the safety and efficacy of products used by the population. In 1995, the Medical Devices Bureau of Canada presented the Organization with a summary of the new proposed approach for regulation in that country. Since then, the Canadian regulation has become law. This was done using regulations from the United States and Europe as a model.

PAHO has promoted the harmonization of the regulatory requirements of several countries (Colombia, Cuba, Mexico, and Panama) and sponsored the presentation of the Canadian model at national and international seminars.

PAHO has also provided technical information, advisory services, and specialists in medical devices to the Member States. For example, workshops have been conducted in Cuba, Mexico, and Peru on the effects of electromagnetic interference on medical devices. Technical workshops have also been held in Canada on various aspects of the regulatory system, such as the classification system, cost recovery practices, and the management of databases on medical devices. The length of these workshops has ranged between two days and a week. Colombia, Costa Rica, and Cuba have participated.

In October 1999, PAHO held a consultation on medical devices in Washington, DC, joined by representatives of the ministries of health of several Member States, the Food and Drug Administration (FDA) of the United States, the Medical Devices Bureau of Canada, the World Health Organization/HQ, and staff members of PAHO. The agenda included presentations on the steering role of the ministries of health in sectoral reform; PAHO's Program of Essential Drugs and Technology; the function of PAHO in the regulation of medical devices; the Canadian strategy for regulation of medical devices; medical devices in the activities of WHO; FDA information resources; information products for support of regulatory agencies (ECRI); the Global Harmonization Task Force (GHTF); and the documents: *Guidelines for Development of Medical Device Regulations*, and *A Model Regulatory Program for Medical Devices*; and the *Electronic Discussion Group on Medical Devices*, MED-DEVICES initiative of PAHO.

### **3. PAHO Consultation on the Regulation of Medical Devices**

#### **3.1 *Conclusions***

The participants of the consultation recognized that the regulation of medical devices is a component of growing complexity, which is increasingly important in the delivery of health services. Furthermore, the market is highly competitive and expanding, as manufacturers and distributors actively market their products throughout the Region. This market is characterized by poor post-sale technical support service and maintenance.

With very few exceptions, the countries of the Americas import more than 80% of their medical devices. However, only a few countries have systems to regulate devices to ensure their safety, quality, and effectiveness, or have the technical capability to set up this type of program.

To the extent that technology and information become ever more accessible, many ministries of health have manifested their growing concern in this area and have recognized the importance of launching regulatory programs. This is perceived as a function of health sector reform and strengthening of the steering role of the ministries of health with regard to monitoring and regulation of the sector in order to guarantee equity, safety, effectiveness, and quality in health services.

Nevertheless, the problem remains complex: it involves aspects such as capital costs and equipment operating costs; the “explosion” of information available from agencies and organizations; the lack of technical capabilities of the ministries in this field; and the cost and the feasibility of establishing a program of this kind.

A considerable amount of information is available to support the regulation of medical devices, but it is necessary to improve access to it, as well as the understanding of the information from these sources.

Furthermore, the demand for devices and technologies is promoted by health professionals (particularly those exposed to new technologies during training programs) and by users whose expectations are rising on account of advertising and exposure to the same sources of information. Efforts to meet this demand have not been accompanied by mechanisms to provide staff training, maintenance service, or procurement of supplies.

The draft documents *Guidelines for Development of Medical Device Regulations* and *A Model Regulatory Program for Medical Devices* were very well received and considered; during the consultation important inputs were made for the preparation of the final versions.

WHO/HQ and PAHO, whether individually or jointly, have done little work in the area of regulation; however, there is considerable potential to become more active and to engage in closer collaboration, jointly with the Collaborating Centers.

### **3.2 *Recommendations***

- As part of their steering role in the process of sector reform, the ministries of health should assign an appropriate priority to the regulation of medical devices.
- WHO (globally) and PAHO (in the Americas) should increase their participation and promote greater participation of the countries in international activities and initiatives in this field, with a view to establishing a consensus to facilitate the harmonization of regulations on medical devices. WHO/HQ should evaluate PAHO's experience in this field and should analyze its possible application in the other Regions.
- Once the documents presented at the consultation are updated, the ministries of health can use them as references for the development and organization of guidelines and programs in their respective countries. Special attention should be given to the education of professionals and consumers.
- Increased use of current and emerging communication technologies, such as the electronic discussion group MED-DEVICES and the Web pages of the regulatory agencies and the collaborating centers, should be facilitated for the exchange of information between agencies and countries.
- The countries of Latin America and the Caribbean should be present or represented at the meetings and working groups of the GHTF for medical devices.
- Technical cooperation among the countries of the Region should be stimulated, including the development and implementation of specific projects.

### **3.3 *Proposal for 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/HQ:

- Prepare a project profile of Regional scope to strengthen the capacity to regulate medical devices for a group of countries of the Region, one of the initial activities being the collection of data on the situation and on the current state of regulatory programs in the countries of the Region.

- Circulate, for comments, the two draft documents presented at the consultation and update them.
- Publish a glossary of terms and a nontechnical guide on the regulation of devices as the first phase of the development of more detailed guidelines.
- Organize and hold workshops on specific regulatory subjects for groups of countries consistent with the degree of development of their regulatory capacity.
- Promote the identification and use of sources of information on medical devices, including the electronic discussion group MED-DEVICES.
- Promote and support the participation of the countries of Latin America and the Caribbean in the GHTF meetings and study groups.

#### **4. A Model Regulatory Program for Medical Devices**

In 1996, the Food and Drug Administration prepared, under contract to WHO, a document titled *A Model Regulatory Program for Medical Devices*. The document has been reviewed and now includes comments that were made at the consultation held in October 1999, and a glossary has been added. This document outlines the essential principles and characteristics that a program of this type should have (see Annex A).

#### **5. Guidelines for the Regulation of Medical Devices**

This guide was crafted with PAHO and Canada in order to help establish regulatory programs in developing countries. It explains in simple language the essential terms and concepts of medical devices safety and common methods of governmental regulation. The document promotes the application of the principles of risk management throughout the shelf life of a medical device and the concept of sharing responsibility among the directly interested parties. It is being reviewed, in order to factor in the opinions of participants at the consultation held in October 1999 and a glossary will be added. The document was supported by the participants at the meeting (see Annex B).

#### **6. Global Harmonization Task Force**

The Global Harmonization Task Force (GHTF) is a voluntary international consortium made up of public health officials in charge of administering national systems for the regulation of medical devices, in association with industry representatives. From its inception in 1993, the GHTF has been comprised of delegates of the five founding members (Australia, Canada, the European Union, Japan, and the United States), who

represent three geographical areas, as well as by representatives of many other countries, including Latin America and the Caribbean, whose regulatory systems are in differing stages of development. The GHTF has not had any formal operating policy or procedures but is currently preparing them. The goal is to have draft guidelines and procedures for the Organization to review (in order to provide support) at the GHTF conference to be held in September 2000 in Ottawa, Canada. PAHO sponsored the attendance of representatives of several Member States at last year's conference, and will again sponsor attendance at the meeting in Ottawa.

The objectives of the GHTF are as follows: to promote a high level of public health; to promote the development of a flexible regulatory context that makes better protection of public health possible, and to facilitate access to important new technologies; to reduce regulatory differences voluntarily and to eliminate any unjustifiable duplication of controls that are not necessary to guarantee the safety, efficacy, and quality of medical devices, and in order to lead to enhanced global access to new devices and equipment; to facilitate the creation of an international marketing surveillance system that would make it possible to reduce the probability of recurring adverse impacts; and to promote international cooperation among countries that have already prepared regulatory systems and those which are preparing them.

The goals of the GHTF are as follows: to provide a forum for representatives of the regulatory authorities and of national industries to collaborate in promoting the convergence of regulatory practices with a view to the safety, efficacy, and quality of medical devices; and to provide a forum for the exchange of information among countries that are preparing systems for regulation of medical devices and those which already have those systems. Harmonization will be conducted as a function of GHTF member consensus on the technical requirements on which to base their regulatory practices.

It should be noted that the objectives and goals of the GHTF are compatible with PAHO's goal to promote the harmonization of regulations in its Member States through consultation and consensus.

The GHTF consists of four study groups (SG) which prepare documents on various subjects concerning the regulation of medical devices:

- SG1 has been in charge of comparing the regulatory systems for medical devices utilized worldwide and, based on these comparisons, to identify appropriate elements or principles for harmonization and elements which might be an obstacle to the establishment of uniform regulations. The group is also in charge of preparing a standardized form for filing registration applications and for harmonized product labeling requirements.



- SG2 is in charge of examining current reports of adverse effects, surveillance during marketing, and other ways of monitoring medical devices, and of analyzing requirements that differ among countries which have prepared systems for regulation of devices, with a view to harmonizing data collection and reporting systems.
- SG3 is in charge of reviewing existing requirements of quality systems in the countries that have prepared systems for regulation of devices and to determine areas appropriate for harmonization.
- SG4 is in charge of examining the practices for auditing quality systems (initially among the founding members of the GHTF) and preparing orientation documents that set forth harmonized principles for the auditing of medical devices.

Each study group is made up of representatives of the Member States that are technical experts in that specialized field. The documents are produced by consensus and before they are recommended for endorsement by GHTF are subjected to in-depth consultations with groups and individuals who are not part of the study group.

To date, the GHTF has produced 12 final documents and 9 proposal-phase documents on various aspects of the regulation of medical devices. Of these documents, at least one has been prepared by each of the four study groups. The founding Member States are committed to implementing the directives to the degree that they do not conflict with existing regulation or legislation. A survey of the founding Member States will be conducted in the near future to determine the state of each of the 12 final documents in the respective country. Furthermore, members registered for the GHTF Conference this year will be asked to fill out a questionnaire related to the regulatory system of the respective country, if they are using the GHTF documents, and if so, how they are being used. This information will be provided on the GHTF Website at [www.ghtf.org](http://www.ghtf.org).

## **7. Current Situation of the Regulatory Systems of the Countries of Latin America and the Caribbean**

The regulatory programs of the countries of Latin America and the Caribbean are in various stages of development. Those of Argentina, Brazil, Chile, Colombia, Cuba, Mexico, Panama, and Peru are described briefly below.

*Argentina:* Regulation of new medical devices is currently being developed in this country. Existing regulations accept country-of-origin certificates from foreign governments (from the FDA), notarized certificates with the EC label (of the European Union), or notarized unrestricted sale certificates to market products in the country.

Imported products must comply with specific guidelines, including Spanish-language labeling and the provision of information on the importer. The requirements to conduct clinical trials in Argentina are similar to those of Canada, the European Union, and the United States.

*Brazil:* Brazilian regulation is also being updated. User tariffs have been implemented (that is, manufacturers pay to register their products). The registration process requires all non-Brazilian manufacturers to register through a representative or Brazilian distributor. Furthermore, the unrestricted sale certificates must come from the country of origin. A set of good manufacturing practices guidelines, as adopted by MERCOSUR, will be used, following an inspection training program.

*Chile:* New regulations on medical devices were prepared in 1998. These include a classification scheme based on risk. An authorized Chilean facility must conduct the tests in accordance with Chilean or international guidelines.

*Colombia:* The Colombian government is updating legislation for the regulation of medical devices. New legislation includes quality control and product monitoring for imported, exported, or marketed articles. Medical devices produced, imported, exported, or marketed in the country must be registered with the INVIMA (National Institute of Drugs and Food Surveillance). The ministry of health has prepared guidelines for the acquisition of biomedical technology.

*Cuba:* The Center for State Control of Medical Equipment, created in 1992, is the agency that regulates medical devices in Cuba. Regulation of medical devices has been implemented and includes components both prior to and during marketing, as well as quality systems. The program is based on the risk classification of the device.

*Mexico:* All medical devices sold in the country must be registered with the ministry of health and must comply with guidelines on labeling, quality, certificate-of-origin, and importation permits. The product registration applications should contain information that corroborates the safety and efficacy of the product, including the following: data on raw materials, description of the product and its uses, sterilization method, labeling, clinical information to corroborate safety, and information on physical, chemical, and biological specifications of the product.

*Panama:* The ministry of health of Panama has begun to prepare a program of regulation of medical devices aimed at guaranteeing the safety, efficacy, and quality of medical devices used by the population. The Medical Devices Bureau of Canada and PAHO are both providing technical support for this program.

*Peru:* A program for regulation of medical devices is being prepared. Medical devices sold in the country must be registered with the ministry of health; surveillance of the products on the market is limited. The DIGEMID (General Bureau of Medicine, Supplies, and Drugs) in the ministry of health is the agency in charge of the regulation.

Argentina, Brazil, Paraguay, and Uruguay (and, recently, Bolivia and Chile as associated members) form the trade alliance known as the MERCOSUR Agreement. This multilateral pact includes a criterion for regulatory harmonization with regard to medical devices that is currently being prepared. Generally speaking, the new system will regulate medical devices as a function of their level of risk. Products will be assigned to one of three risk categories, with class 3 being the high-risk group. Regulatory programs will be tiered, beginning with the registry of products and leading to quality system inspections.

## **8. Budgetary Implications for the Program of Medical Devices**

PAHO has included the area of regulation of medical devices within its technical cooperation program in order to support the countries of the Region in developing and strengthening programs to guarantee the quality, efficacy, and safety of medical devices utilized by the population and the health services.

PAHO earmarked approximately US\$ 100,000 of its regular funds for the 1998-1999 biennium to finance consultancy activities for the programs of the countries, personnel training, production and dissemination of information, and the consultation on medical devices. To this should also be added the time dedicated to this program by personnel of the Collaborating Centers, the Medical Devices Bureau of Canada, the Food and Drug Administration of the United States of America, ECRI, and staff members of PAHO, including 30% of the time of the Regional Adviser in charge of this Program.

Based on the consultation of October 1999, the demand for technical cooperation in this field has increased significantly. In order to respond appropriately to the recommendations of the document on medical devices, approximately \$300,000 will have to be mobilized over the next two years.

The funds will be applied to the following activities:

- prepare a diagnosis on the state of regulatory programs for each country and consolidate a regional profile;
- hold five training workshops at the subregional level for the health regulatory authorities of the countries;

- finance the participation of the regulatory authorities of the countries at the meetings of the GHTF;
- strengthen the MED-DEVICES communications and information exchange network;
- provide consultancies to the countries for the organization of programs for the regulation of medical devices;
- produce, translate, publish, and distribute documents and technical information on the regulation, safety, quality, and effectiveness of medical devices.

#### **9. Recommendations for the Consideration of the Directing Council**

- Member States should be encouraged to consider the preparation of a system for the regulation of medical devices as part of their health sector reform activities.
- Member States should be encouraged to use a “needs based” health technology assessment in the early stage of their health technology management plans. Medical technologies acquired and regulated can thus meet the needs of the health care system of each country.
- PAHO should take into account the impact of medical devices on certain populations, such as women and indigenous groups, in order to evaluate proper usage and management of risk. Regulations can be used to require manufacturers to provide information on the use of devices in a specific population group. Whenever possible, new and innovative approaches to the use of technologies in the Member States should be considered. For example, telemedicine is a promising approach to the delivery of health care in remote areas.
- PAHO should sponsor workshops every two years to promote the harmonization of regulations in the Member States. All regulatory or technical aspects of medical devices should be on the agenda. The workshops should draft recommendations on regulatory issues. These could be used, for instance, to consider the GHTF documents in detail in order to include them and recommend their application in the Member States, as appropriate. The objectives of the workshops could include the following: to promote and support a constructive dialogue among regulatory agencies, the medical devices industry, and other sectors, through regularly-scheduled workshops; to promote the convergence of regulatory systems in the Region of the Americas; to adopt recommendations for their execution at the national and regional levels; to support and facilitate technical cooperation among

- the countries; to promote the harmonization of requirements for regulation of medical devices; and to promote a document to provide guidance on specific regulatory issues. The workshops would be organized based on the stage of the development of regulation in the countries. This includes countries that would start the programs, countries with some degree of development, and countries with regulatory programs in place.
- PAHO should establish an ad hoc group on medical devices, that includes representatives of the regulatory authorities of the Member States, representatives of the WHO Collaborating Centers, associations of the medical devices industry of the Member States, and such other entities as PAHO and the ad hoc group may select. The function of the ad hoc group would be to facilitate progress between workshops by coordinating, promoting, facilitating, and monitoring the processes of harmonization in the Americas. The workshop recommendations would be used to prepare the work plan of the ad hoc group. The objectives of the ad hoc group could include the following: revise the propose activities for the plan of action, ensure that the workshops are effective and that the subjects they address are pertinent; facilitate and monitor the implementation of workshop recommendations; ensure the continuation of harmonization activities between workshops; and facilitate consensus-building and resolution of problems between workshops and during workshops.
  - PAHO should promote and facilitate access to the growing body of pertinent information to help regulators of medical devices; furthermore, access to and understanding of these resources must be improved through workshops and a continuing dialogue. Existing and emerging communication technologies should be utilized fully to promote the exchange and use of information. Examples include Web pages of regulatory authorities in Canada and the United States, the MED-DEVICES electronic discussion group, and the considerable information on medical devices of ECRI.
  - PAHO should promote the use of existing international guidelines in the regulation of medical devices. The use of international guidelines could be included as a subject of the proposed workshops.
  - PAHO should promote the participation of the Member States in the GHTF and encourage them to use the documents of the Study Groups when they prepare regulatory systems. It is also recommended that PAHO participate in the GHTF in order to start a dialogue and determine the best way for it to provide the Member

States with opportunities to share information on subjects of interest. If PAHO adopts the first two recommendations presented above, the appointment of a GHTF representative to the proposed consultation committee should also be considered.

- PAHO should continue to provide technical advisory services and the support of specialists on subjects of particular interest to the Member States, as it did it in the past concerning the year 2000 computer problem (Y2K) and electromagnetic interference. Insofar as possible, these subjects should be included in the agendas of the workshops, instead of training being provided to each country.

#### Annexes

## **A MODEL REGULATORY PROGRAM FOR MEDICAL DEVICES**

The main feature of this document is its modular approach to establishing a regulatory program that permits flexibility in the preparation and application of regulations consistent with the needs and resources of each country. The document consists of four principal modules, namely: market entry report, post-marketing surveillance, manufacturing controls, inspection and safety audits, and efficacy or operational evaluation.

### **Market Entry Report**

In general, obtaining information on the entity that seeks to place a product on the market is an essential requirement of any program of medical devices, whatever its complexity. Equally important is the availability of information describing the operational background of the product and any adverse impact or operational characteristics associated with its use. This double objective can be achieved by requiring that manufacturers of devices present a pre-marketing report to the national regulatory agency.

### **Post-marketing Surveillance**

However rigorous the process or reporting on market entry may be, it can never predict all the shortcomings or problems a device might have due to inappropriate usage. As a result, the capacity to monitor the operation of the devices being marketed is an essential component of a system for regulation of devices. The degree of complexity of a system for monitoring the operation of devices, the documentation of problems, and the dissemination of vital information concerning incidents experienced by other users of the devices all depend, on available resources and local and national considerations.

### **Manufacturing Controls, Inspection and Safety Audits, and Efficacy or Operational Evaluation**

The last two levels of a program for the regulation of devices, perhaps more than any other levels, must be adapted to the specific socioeconomic conditions, infrastructure characteristics, and needs of every country. There is a broad array of mechanisms for the regulation of product safety; these can be adopted selectively, applied gradually, or established all at once. This range of possibilities give the countries broad discretion in the design of the system that is best for them and the people they represent:

- (a) factory inspection, and inspection of practices used in the mass production of medical devices;
- (b) manufacturer compliance with national or international consensus guidelines prepared by third parties for addressing safety, quality, efficacy, operation, and sterility of end devices;
- (c) testing prior to marketing of devices, either by the regulatory organ, the manufacturer, or an independent testing entity, to demonstrate compliance with applicable guidelines and other operational and marketing requirements;
- (d) compulsory pre-marketing evaluations of equipment and new devices, and commercial approval to verify that safety, efficacy, and operational requirements are met;
- (e) controls for marketing of devices; that is, specifications related to conditions under which devices can be sold, who may use the devices, and under what conditions.



## **GUIDELINES FOR THE REGULATION OF MEDICAL DEVICES**

Section 1 describes medical device safety as a risk management process that should continue throughout the life cycle of medical devices, from the moment they are manufactured up to the moment they are discarded. The safety and the efficacy of medical devices require cooperation among the people who administer the various stages of the life of medical devices. The parties directly interested should share these responsibilities.

Section 2 considers the function of government. The stages of control prior to, during, and after marketing are described, along with commonly used regulatory instruments. Canada's Regulation of Medical Devices is provided as an example.

Section 3 describes the task of the Global Harmonization Task Force (GHTF), whose mission is to harmonize the guidelines and procedures for regulation of medical devices and to address other related aspects in different countries.

Section 4 provides suggestions for governments that wish to establish an attainable program to guarantee the safety and effectiveness of medical devices. Such a program requires that the government better understand the medical devices sector and that it share this knowledge with the directly interested parties. This will lead to the establishment of a clear policy on the management of medical devices, in terms of which sort of legislation and compliance should be sought consistent with the available resources. Governments are urged to take advantage of ongoing efforts of the GHTF and the worldwide movement towards quality, in order to reduce the local regulatory burden of the program.

Section 5 describes the diverse intentions of "export permits" currently existing in Canada and the United States. Members are recommended to proceed with caution in interpreting these certificates.

Section 6 concludes that this research shows that a recommendation should be made to the GHTF. It is necessary to establish a uniform format for the different countries to certify that exported medical devices comply with their national regulatory requirements. This certification would be of enormous help to the importing countries in controlling medical devices.



PAN AMERICAN HEALTH ORGANIZATION  
WORLD HEALTH ORGANIZATION



## 126th SESSION OF THE EXECUTIVE COMMITTEE

Washington, D.C., 26–30 June 2000

CD42/12 (Eng.)  
Annex C

### ***RESOLUTION***

#### ***CE126.R8***

#### **MEDICAL DEVICES**

##### ***THE 126th SESSION OF THE EXECUTIVE COMMITTEE,***

Having considered the Director's report (Document CE126/14) on medical devices;

Considering that, in the exercise of the steering role of the health sector, it is an essential function of the health authority to safeguard the efficacy, safety, and quality of the medical devices utilized by the health services and the population; and

Recognizing that it is necessary to establish a process for the planning, implementation, and management of technologies to guarantee the efficient operation of the health services network,

#### ***RESOLVES:***

1. To thank the Government of Canada for preparing the document and presenting the topic to the 34th Session of the Subcommittee on Planning and Programming.
2. To recommend that the Directing Council adopt a resolution in the following terms:

##### ***THE 42nd DIRECTING COUNCIL,***

Having considered Document CD42/12 on medical devices;

Considering that, in the exercise of the steering role of the health sector, it is an essential function of the health authority to safeguard the efficacy, safety, and quality of the medical devices utilized by the health services and the population;

Recognizing that it is necessary to establish a process for the planning, implementation, and management of technologies to guarantee the efficient operation of the health services network; and

Taking note of the recommendation of the Executive Committee,

***RESOLVES:***

1. To endorse the recommendations on medical devices contained in Document CD42/12 and to support the work of PAHO in this field.
2. To support the proposal to form an ad hoc group to promote and facilitate the medical devices harmonization processes in the Americas.
3. To urge the Member States to:
  - (a) develop and strengthen their programs for the regulation of medical devices;
  - (b) promote and support the participation of their regulatory authorities at the general meetings of the Global Harmonization Task Force (GHTF) and those of its four study groups, while promoting the use of GHTF documents in their programs for the regulation of medical devices.
4. To request the Director to continue his support to the governments for the development and implementation of programs to regulate medical devices and to support the search for sources of financing for the activities of the proposed program of work for the biennium 2000-2001.

*(Sixth meeting, 28 June 2000)*