

Series

17

Essential Drugs and Technology

CONSULTATION ON REGULATION OF MEDICAL DEVICES

*20-22 October 1999, Washington, DC
Final Report*

Division of Health Systems and Services Development



Pan American Health Organization
World Health Organization

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OF MEDICAL DEVICES**

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December 1999

Program on Essential Drugs and Technology (HSE)
Division of Health Systems and Services Development (HSP)



Pan American Health Organization
World Health Organization

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LIST OF ACRONYMS

ANMAT	Administración Nacional de Medicamentos, Alimentos y Tecnología Médica
DD/OPS	Deputy Director/Pan American Health Organization
ECRI	Emergency Care Research Institute
FDA	Food and Drug Administration
FDA - CBER	Food and Drug Administration, Center for Biologics Evaluation and Research
FDA - CDRH	Food and Drug Administration, Center for Devices and Radiological Health
GHTF	Global Harmonization Task Force
MDB	Medical Devices Bureau - Health Canada
MERCOSUR	Mercado Común del Sur
WHO	World Health Organization
WHO-BCT	World Health Organization, Blood Safety and Clinical Technology
WHO-DCT	World Health Organization, Devices and Clinical Technologies
WHO-HTP	World Health Organization, Health Technology and Pharmaceuticals
PAHO	Pan American Health Organization
PAHO-CPC	Pan American Health Organization, Caribbean Program Coordinator
UMDNS™	Universal Medical Device Nomenclature System

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1. OBJECTIVES

- To revise the reference documents "A Guideline for the Regulation of Medical Devices" and "A Model Program for Medical Devices" that will be used for the development of Member State programs for the regulation of medical devices.
- To present to the participants in the meeting an overview of the programs and topics of regulation of the Collaborating Centers of WHO/PAHO in medical devices (USA-FDA, Medical Devices Bureau-Health Canada, ECRI).
- To exchange information on high-priority topics on legislation of medical devices.
- To promote the participation in the meetings and work groups of the Global Harmonization Task Force (GHTF) by the countries of Latin America and the Caribbean.
- To identify areas for future technical cooperation of the PAHO/WHO in coordination with the Collaborating Centers in Medical Devices.
- To launch the electronic discussion group "MED-DEVICES" for the communication and the exchange of information regarding medical devices.

2. MEETING AGENDA

The Consultation on the Regulation of Medical Devices was held at PAHO Headquarters in Washington, DC from the 20th through the 22nd of October 1999.

The meeting agenda is attached to this report.

3. PARTICIPANTS

Twenty-five officials from the following organizations participated in the Consultation on Regulation of Medical Devices:

PAHO/WHO Collaborating Centers: USA-FDA; Medical Devices Bureau (MDB) of Canada; Emergency Care Research Institute (ECRI)

Regulatory Agencies of Argentina, Brazil, Canada, Cuba, Mexico, Panama and United States of America

Official from WHO's Headquarters.

Officials from PAHO's Headquarters.

Officials of PAHO's Caribbean Programs Coordination (PAHO-CPC) and PAHO's Dominican Republic Office.

The list of participants is annexed to the report

4. INAUGURATION

In his introductory speech, Dr. David Brandling-Bennett, Deputy Director of PAHO/WHO, emphasized that "initiatives like those that bring us together today, are a new challenge for the Pan American Health Organization and the World Health Organization. We should feel proud that we will soon complete 100 years of service. We were born to combat measles and yellow fever and to reduce obstacles to trade by integrating the efforts of all countries to combat those illnesses."

Dr. Brandling-Bennett remarked that we are seeing a decline in infant mortality and an increase in life expectancy; positive signs regarding non-transmissible diseases. Technological advances present us with two dilemmas: how to use them and how to establish standards. Here we apply the concept of Pan Americanism, the meeting of countries in search of consensus regarding standards and regulations. A common perspective will help us to implement regulations and to facilitate the use of appropriate technologies. It is important to create alliances with governments, agencies, multilateral organizations and to create common positions to solve problems."

5. PRESENTATIONS

5.1 *The Steering Role of Ministries of Health in Health Sector Reform*

Dr. Daniel López Acuña, Director of the Division of Health Systems and Services Development of PAHO, through his videotaped message, presented the Steering Role of the Ministries of Health in Health Sector Reform. He indicated that "in the framework of transformation of the health sector that each one of the countries in the region are taking and with the transitions that the sectorial reforms represent, profound changes are occurring in the operating environment of the health authorities and in the environment in which they exercise their regulatory functions."

He added, "There are important and significant advances in the decentralization of the State that are bringing us to redefine the responsibilities of the different levels of central, state or provincial authorities and the local, municipal and county authorities in each country. This is happening for all of the functions that the State carries out, not only in the health sector. As

regards the delivery of health services, there is a great tendency toward the decentralization of public health services and of other services offered to individuals."

He said that PAHO promotes the reorganization of health systems to achieve a higher level of equity, quality, efficiency and universal access to healthcare.

5.2 PAHO's Essential Drugs and Technology Program

In the initial session Dr. Enrique Fefer, Coordinator of PAHO's Program for Essential Drugs and Technology, described the technical areas that are integrated by the program under his coordination, emphasizing their highly specialized nature: Essential Drugs, Clinical Laboratories and Blood Banks, Radiological Health, Radiation Protection, Engineering and Technology Management and Information Technology.

He emphasized that all the aforementioned areas have as their common objective the assurance of the readiness and quality of healthcare supplies, as well as the efficiency of the services that use those products; for example, pharmaceutical services and those of the clinical laboratories and radiology. The program aims for the safe and effective use of the pertinent technologies through effective regulation at the national level, taking into consideration the current context of reformation of the health sector and the processes of subregional and regional integration.

He remarked that the experience acquired by the countries and PAHO in pharmaceutical product regulation is relevant to the development of medical device regulation programs. Similarly, each country's healthcare policies and regulations reflect these items. Authorities should consider them when establishing the necessary mechanisms for their implementation and compliance according to their level of development and technological capacity.

5.3 PAHO's Role in Medical Device Regulation

Engineer Antonio Hernández, Regional Advisor of PAHO's Engineering and Maintenance of Health Services, remarked that "the agenda for this meeting incorporates the role of the Ministries of Health in the process of reform health sector as the regulatory authority that should be exercised to guarantee the security, effectiveness and quality of medical devices used for the people of each country."

He pointed out that regulation is a high priority for PAHO, which has been working in this field for more than five years. The purpose is to support to countries in structuring their regulatory programs. In Latin America and the Caribbean, there are approximately 16,566 hospitals with more than 1,100,000 hospital beds: 44.5% of these hospitals are located in the public sector. Approximately 50% of the medical equipment in the public hospitals is out of service or functioning at a level that is out of compliance with manufacturer safety specifications.

PAHO has added medical device regulation to its technical programs for the strengthening and development of technical cooperation activities in engineering and maintenance and technology management (planning, procurement and management). In medical device regulation, PAHO has been working since 1995 with its collaborating centers in medical devices, the MDB of Canada and the ECRI. One of the objectives of the meeting is the review and presentation of the regulation program developed by PAHO to the countries as well as the 1996 WHO Report prepared by the U.S. FDA.

It is important to highlight that we are seeking to support the development of a group of countries in Latin America and the Caribbean to participate in the meetings of the GHTF and its Study Groups, and to prepare an action plan that serves as a basis for PAHO's support of this activity. We will examine the work to be performed by PAHO's new electronic discussion group on medical devices as a mechanism for communication and exchange for regulatory activities among countries of the Region.

Eng. Hernandez noted that the consultation meeting include the participation of Dr. Gerald Verollet, recently assigned to the WHO as an advisor on Devices and Clinical Technologies, which includes the topic of medical device regulation. This appointment is an indication of the commitment by WHO to this program area and its interest in projecting knowledge about medical devices to all countries.

5.4 *The New Canadian Approach for the Regulation of Medical Devices*

Mrs. Beth Pieterston, Director of the MDB, presented the Canadian regulatory system for medical devices has been evolving since February 1991. The system includes recommendations to ensure that the regulatory program is based on risk assessment, risk management, a risk-based classification system, a system of post-market surveillance, including requirements for a quality system, and lastly with an interrelated Canadian approach with international approaches.

The Canadian system of quality, evaluation and acceptance of medical devices was presented. Norms and regulations were also presented including registration, licensing and authorization.

The MDB has been working continuously with PAHO since 1995 to stimulate countries in the Region in the organization of regulatory programs. The activities have been oriented towards the training of professionals and to the support of the organization of the programs. As a result of the increase in the demand for technical cooperation, it was agreed to prepare a basic document that presents and outline and a guide for the organization of regulatory programs.

5.5 Presentation of the Document: "A Guideline for the Development of Medical Devices Regulations"

The document "A Guideline for the Development of Medical Devices Regulations", written by Dr. Michel Cheng, in coordination with the MDB and PAHO was prepared with the purpose of having an orientation guide for the establishment of programs that ensure the safety, effectiveness and quality of medical devices. The guide is designed for non-technical readers. It explains the essential terms/concepts in device safety and common government regulatory methods. It is also a supporting instrument for regulatory program training and information sessions that are being developed in the countries within the cooperation program established between the MDB and PAHO.

In his presentation, Dr. Cheng indicated that the guideline was a synthesis of a large amount of information in a didactic form to introduce the readers to the topic. He summarized the contents of four key sections and also explained his technique of using diagrams and tables to facilitate the understanding of the material. He showed how the details relate to the overall system that is in place.

The guideline illustrates that medical device safety is a risk management issue: the task is to maximize benefit and minimize risk. Potential hazards exist in each phase in the life span of a medical device from conception to disposal. The optimal safety and effectiveness of a device requires shared responsibility and co-operation among all those involved (the stakeholders). The guideline describes the current global trend toward harmonizing medical device standards (works of GHTF), and urges Member States to take advantage of this development in order to optimize the use of their regulatory resources.

The guideline concludes that the two critical determinants of device safety and effectiveness are PRODUCT and USE. To help these two critical aspects, the guideline made specific recommendations for international organizations.

The participants in the consultation meeting believed that the document was an important instrument, necessary for all of the countries in the region. It will facilitate the process of promotion of regulation and the negotiation with the health authorities of the countries. It contains the information to begin a basic regulatory system, and, if necessary, to develop progressively into a comprehensive system with the help of detailed reference to the Canadian Medical Devices Regulations. It offers flexible alternatives and provides suggestions for priority setting in countries with very limited resources. The document obtained the consent and the acceptance of the participants, with the recommendations to add a glossary of terms and to revise the vocabulary. Specific comments were given to the author to be incorporated in the final version.

PAHO and the WHO are making every effort to help member countries to assign a high priority to ensure the safety, effectiveness and quality of medical devices used on their people. To this end, the actions are directed to support them in the organization of mechanisms that allow the exercise of some form of regulation or control of medical devices, the great majority of which are imported by the countries.

Additionally, a consensus was achieved on the following points:

- the primary goal of a regulatory system is to protect the public health;
- it is necessary to have a document of this nature to provide regulatory system concepts to governments;
- it is necessary to adapt the document to the specific regulatory needs and resource capacities of each country;
- we need to keep in mind that the regulatory systems of each country are at different levels of development;
- it is essential to know how to verify the compliance of medical equipment with the norms of the FDA, Health Canada, and the European Union; and
- it is important that countries share their experiences related to the regulation of medical devices.

5.6 WHO Activities in Medical Devices

Dr. Gerald Verollet presented the reorganization of the WHO, its corporate strategy, and its structure of eight "Clusters". The program for Blood Safety and Clinical Technology (BCT) which includes the Devices and Clinical Technologies (DCT) component, is in the sector of Health Technology and Pharmaceuticals (HTP). Dr. Verollet also discussed the mission, form of operation, and interrelations with other programs and Clusters.

We were also informed that in this new work area, the WHO is preparing an action plan for next few years. He noted that this meeting was held at an opportune time since that information from the consultation could be incorporated into the plan. He also offered the possibility to sponsor events like this one in other WHO regions.

5.7 Information Resources of the FDA

Mr. John Stigi, Director, Division of Small Manufacturers Assistance (DSMA), focused his presentation on the international activities of the FDA and the Center for Devices and Radiological Health (CDRH) and the interaction with the countries of the Americas. He informed us that in the USA, in contrast to the pharmaceutical industry, the medical device industry is composed of a great number of relatively small companies of which approximately 60% have less than 50 employees. FDA has registered 41,077 medical device companies.

The main functions of the DSMA international group include the negotiation of international recognition agreements, and promotion of harmonization and technical assistance to device companies and governments.

Technical assistance includes support via electronic communication systems: telephone, fax and access to the CDRH's web-site. The presentation included a demonstration of the web-site and an information search.

5.8 Special Issues: FDA Device Export Requirements and FDA Regulations of Biological Devices

Mr. Steven Niedelman, Director, Division of Enforcement III CDRH, presented the requirements for the export of medical devices. He indicated that products marketed in the United States can be exported to other countries. He also outlined the conditions under which medical devices that are not approved for sale in the USA can be exported to other countries.

The presentation included the topic of the export certificates for governments of other countries and access to the "COMSAT" database, where one can find up to date information on inspections and pending compliance actions by manufacturers.

He also discussed the issue of export certificates and the new security measures taken by FDA to avoid their falsification. He demonstrated the security measures implemented with the new paper used to print the certificates.

Dr. Jerome Donlon, Deputy Director, Center for Biologics Evaluation and Research (CBER), indicated that his center regulates and licenses biological products and that this category includes some medical devices, mainly related to the security of blood and blood products. The license includes software used in blood banks. The same occurs with medical devices depending on their specific use.

5.9 Presentation of the Document: "A Model Program for Medical Devices"

The document, "A Model Program for Medical Devices", together with a proposal for an action plan for "The Role of the WHO in Assuring Medical Devices Safety and Quality", which were prepared for WHO under a consultation assignment with FDA, were presented. These documents were prepared in 1996 by Mr. Robert Eccleston, Assistant to the Director in FDA's CDRH.

The model program document, in particular, was included in this consultation so that it could receive comments from experts in this field. Participants considered the document an important reference instrument to support countries in instituting medical device regulatory programs.

Ms. Linda Horton, Director of International Policy at FDA, presented the document on behalf of Mr. Eccleston, emphasizing the principles and essential characteristics that should be contained in a medical device regulatory program. She stated that the fundamental goal is to protect health and public safety.

The main feature of the document is its modular approach to establishing a device regulatory program in addition to technical information in support of specific program components. This allows flexibility in the development and implementation of device regulatory programs. Aspects of definition, legislation and the necessity of post-market surveillance by the regulatory authority were presented.

The model program also addresses public participation, confidentiality of information, and cooperation between governments. A section is dedicated to the GHTF for the promotion of worldwide harmonization of regulatory requirements.

In summary, the document is a model that presents all appropriate elements required to build a system of medical device regulation including legislation, inspection and manufacturing controls, reuse of devices and disposables, agreements and documents from the GHTF. The principal characteristic of the model is its modular organization that permits its implementation while allowing for the needs and resources for each country to adopt and develop the components required for their regulatory programs.

Participants in the consultation agreed that the document provides a useful reference framework with specific program elements necessary to allow countries to organize their regulatory programs to meet their individual needs and circumstances. It was also agreed that its flexibility to adapt to the different levels of development in each country was particularly important.

Because of the time that has passed since the creation of the document, it was considered necessary to revise and update it. This point has been raised in previous meetings between FDA, WHO, and PAHO. Updating will primarily focus on those sections for which GHTF guidance is now publicly suitable. Re-use of disposable devices and remanufactured devices will also be included. PAHO will translate the document into Spanish and circulate it for comments.

Other recommendations, similar to those of the Cheng document were used at the consultation meeting. Basically, they were the addition of a glossary of terms and the revision of the vocabulary. Specific comments will be given directly to the author to be incorporated in the final version of the document.

The following points were presented in the discussion of the document:

- Implementation of programs should be made according to the regulatory needs as resources of each country.
- The following sections will have priority to be translated into Spanish: Essential Principles, Monitoring, Auditing and Surveillance.
- The reuse of medical products and the necessity for regulation of remanufactured products needs to be addressed.

5.10 ECRI and Information Products to Assist Regulatory Agencies

Engineer Jonathan Gaev, Director of International Programs for ECRI, introduced his organization as a non-profit health services research agency and a WHO Collaborating Center for Healthcare Technology.

After describing ECRI and its mission, the presentation focused on the information products and services that are used today by healthcare professionals throughout the world to solve problems regarding medical device regulation.

The products include the Universal Medical Device Nomenclature System (UMDNS™), which is an international standard for medical devices. It facilitates access to the world's largest databases of medical technology problems, e.g., hazards and recalls. The nomenclature is translated and published in several languages including Spanish.

Other products include the Health Devices Sourcebook that contains the addresses of medical device manufacturers and a directory of healthcare standards (Healthcare Standards Directory).

5.11 Global Harmonization Task Force

The presentation was made by Mrs. Elizabeth Pieterse, current Chair of the GHTF. She announced that the next meeting will take place on September 17, 2000 in Ottawa, Canada.

The principles that govern the GHTF are: collaboration, consensus, and transparency. General information and GHTF harmonization documents are available on the Organization Web-site (www.ghtf.org).

The following points were also made:

- Any country or organization with an expert level of competency in a relevant field can be a member of GHTF. Presently, the requirements for membership include attendance to the meetings and contribution to the work of a Study Group (even if the participant comes from a country that has just begun or not yet begun its medical device regulatory system). Further requirements for membership have not yet been defined.
- The GHTF will contribute to the regulation topic for re-manufactured equipment and the reuse of disposables. It is also working on the definition of a global nomenclature.
- It was recommended to standardize certifications.
- It was recommended that PAHO and WHO representatives attend all future GHTF meetings.

- It was suggested that an association be made between the GHTF and MERCOSUR. MERCOSUR could benefit from the experience, organization, information and other work of the GHTF.

5.12 "MED-DEVICES", *Electronic Discussion Group Medical Devices*

Engineer Antonio Hernández indicated that PAHO has already begun a private list-server to facilitate communication and the exchange of information via e-mail between professionals of the sector of regulation of medical devices. The list-server discussion group will not be moderated. The participants of this meeting have already been registered in the group. The discussion group is called MED-DEVICES.

PAHO is a leader in the organization of electronic discussion groups. It currently maintains of 20 groups in different healthcare topics. It has three groups in the area of Physical and Technological Infrastructure of Health Services:

- INFRATECH, for infrastructure and technology
- EQUIPMENT-DONATION, for donation of medical equipment
- MED-DEVICES, for the regulation of medical devices.

The first activity of MED-DEVICES will be the revision and distribution of comments on the reference documents presented in this meeting.

6. CLOSING

The closing words were made by Dr. Fefer who made reference to the messages by Dr. Brandling-Bennett and Dr. López Acuña regarding the program and commitment of the WHO and PAHO to support efforts in this important area. We urge each country to work to promote the introduction of medical device regulation.

7. CONCLUSIONS

It was recognized that the regulation of increasingly complex medical devices is a vitally important component of health care. 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 exceptions, 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, effectiveness 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, the demand for equipment and technology is driven both by health 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. There are not 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 bases 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.

8. 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 the 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.

The 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.

The area of the regulation of organs and human tissues is becoming more important every day. Canada has an advanced regulatory system in this area and offers support and information to countries in the Region.

9. PROPOSED PLAN OF ACTION

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

- Develop a regional project proposal to strengthen the capacity 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 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 Study Groups.

ANNEX A: AGENDA

Consultation on the Regulation
of Medical Devices
20-22 October 1999
PAHO Headquarters, Room B
Washington D.C.

Wednesday, 20 October

8:30 - 9:00	Registration
9:00 - 9:15	Opening Remarks <i>Dr. A. David Brandling-Bennett, DD</i>
9:15 - 9:30	Agenda and Objectives <i>Mr. Antonio Hernández, HSP-HSE</i>
9:30 - 10:00	The Steering Role of the Ministries of Health in the Health Sector Reform <i>Dr. Daniel López Acuña, D-HSP</i>
10:00 - 10:30	PAHO's Essential Drugs and Technology Program <i>Dr. Enrique Fefer, CP-HSE</i>
10:30 - 10:45	Coffee
10:45 - 11:30	PAHO's Role in Medical Devices Regulation <i>Mr. Antonio Hernández, HSP-HSE</i>
11:30 - 12:30	New Canadian Approach for the Regulation of Medical Devices <i>Mrs. Beth Pieterston, Health Canada</i>
12:30 - 2:00	Lunch
2:00 - 2:45	Presentation of the Document: "Guidelines for the Development of Medical Devices Regulations" <i>Dr. Michael Cheng</i>
2:45 - 3:30	Discussion of the Document
3:30 - 3:45	Coffee
3:45 - 5:00	Continue discussion of the Document

Thursday, 21 October

9:00 - 9:45	Medical Devices in WHO activities <i>Dr. Gerald Verollet, WHO</i>
9:45 - 10:30 <i>Mr. John Stigi, FDA</i>	Information Resources from FDA
10:30 - 10:45	Coffee
10:45 - 11:30	Special Issues: FDA Device Export Requirements and Regulations on Biological Devices <i>Mr. Steven Niedelman, FDA</i> <i>Dr. Jerome Danlon, FDA</i>
11:30 - 12:30	Presentation of the Document: "A Model Program for Medical Devices" <i>Ms. Linda Horton, FDA-WHO</i>
12:30 - 2:00	Lunch
2:00 - 3:30	Discussion of the Document
3:30 - 3:45	Coffee
3:45 - 5:00	Information Products to Help Regulatory Agencies <i>Mr. Jonathan Gaev, ECRI</i>

Friday, 22 October

9:00 - 9:45	The Global Harmonization Task Force <i>Mrs. Beth Pieterston, Health Canada</i>
9:45 - 10:30	"MED-DEVICES" Electronic Discussion Group in Medical Devices <i>Mr. Antonio Hernández, HSP-HSE</i>
10:30 - 10:45	Coffee
10:45 - 12:30	Proposed Action Plan for Latin America and the Caribbean Countries
12:30 - 2:00	Lunch
2:00 - 2:45	Conclusions and Recommendations
3:00	Closing

ANNEX B: LIST OF PARTICIPANTS

Collaborating Centers:

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PUBLICATIONS OF THE DIVISION OF HEALTH SYSTEMS AND SERVICES DEVELOPMENT

ORGANIZATION AND MANAGEMENT OF HEALTH SYSTEMS AND SERVICES SERIES

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