

9TH GHTF Conference

Role of PAHO/WHO on Medical Devices Issues in Latin America and the Caribbean

ANTONIO HERNANDEZ
PAHO/WHO

Singapore
12-16 May 2002



Pan American Health Organization 2002



Pan American Health Organization

Regional Office for the Americas for the
World Health Organization





Celebrating 100 Years of Health

PAHO Technical Cooperation on Medical Devices

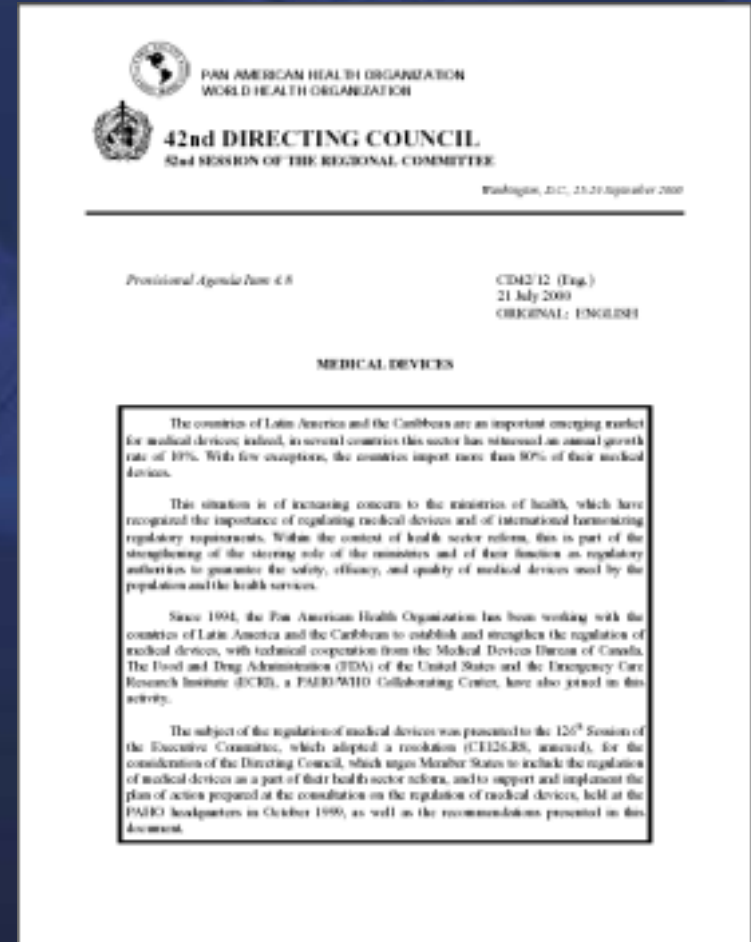
To Collaborate with the Member States
in the
Development and Strengthening
Medical Devices Regulation
to Guarantee
Safety, Efficacy and Quality
of the Devices Used
by the Population
an in the Health Services



42nd PAHO Directing Council

Document CD42/12 on Medical Devices

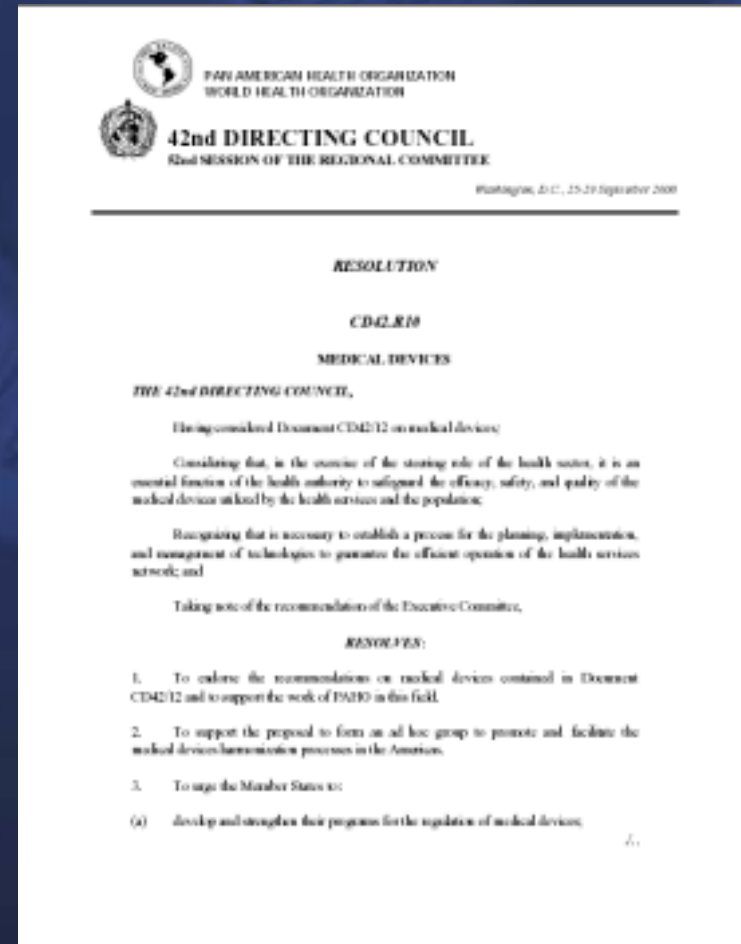
- PAHO Initiative on LA&C
- Consultation on MedDev
- Collaborating Centers
 - US-FDA
 - MDB-Canada
 - ECRI
- Regional Plan of Action
- Recommendations



42nd PAHO Directing Council

Resolution CD42.R10 on Medical Devices

- Endorse Document CD42/12
- Support Ad-hoc Group
- Urge Member States to:
 - Develop Regulation
 - Promote the GHTF
- Request PAHO Support



Regional Plan of Action

- To Organize Five Sub-Regional Workshops
- To Prepare a Country Status on Medical Devices and Regional Profile
- To Promote LA&C Participation in GHTF Conference and Study Groups
- To Attend Pan American Cooperation Medical Equipment (PACME) Meetings
- To Promote the Use of MED-DEVICES List
- To Produce and Disseminate Technical Information and Publications
- To Provide Technical Expertise to the Countries



Regional Economic Integration Groups



Sub-Regional Workshops

- International Workshop on Regulation of Medical Devices - Andean Region - Cartagena, Colombia - July 2001
 - Chile, Colombia, Ecuador, Peru, Venezuela
 - US-FDA, MDB-Canada, ANMAT-Argentina, ECRI
 - Panama (Observer)
- International Workshop on Regulation of Medical Devices - Central American Region - Scheduled October 2002
- International Workshop on Regulation of Medical Devices - South Cone Region - Scheduled 2003



Country Program Information

LATIN AMERICAN CARIBBEAN REGULATORY PROGRAMS

COUNTRY	COLOMBIA	IMPORT REQUIREMENTS	Import license not required, but the importer must register the transaction with the Ministry. Sensitive products on Decree 861 must be pre-inspected and cleared
REGULATORY AUTHORITY	Instituto Nacional de Vigilancia de Alimentos y Medicamentos (INVIMA)	COMMENTS	Andean Community of Nations Economic Initiative
LAWS/REGULATIONS/STANDARDS	Decreets 1292, 1298and 1999; Resolutions 2092 and 5039.		
REGISTRATION	Imports & exports are registered through the Colombian Ministry of Foreign Trade. ICONTEC sets the product standards.		



Status of Regulatory Programs in LA&C

- 21 of 43 Countries & Territories without Legislation for Medical Devices
- 7 of 22 with Legislation Effectively Enforce it
- 27 without Import Requirements
- 12 Have Attended GHTF Conferences
- Weak Areas:
 - Surveillance Systems
 - Human Resources
 - Training
 - Budget




MED-DEVICES List

INTERNET Discussion Group for the Americas

- Regulatory Authorities
- 53 Members
- 14 Countries
- Information Exchange
- English/Spanish
- Private Non Moderate List

MED-DEVICES membership <http://lists.paho.org/archives/1008/CONFIRMATION.html>

welcome - bienvenida

 Washington D.C.

MED-DEVICES membership

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* Total number of users subscribed to the list: 50
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Publications

- Consultation on Regulation of Medical Devices Final Report - October 1999
- Workshop on Regulation of Medical Devices - Andean Region - Final Report - July 2001
- A Model Regulatory Program for Medical Devices: An International Guide - 2001
- A Guide for the Development of Medical Devices Regulations - 2002
- GHTF Overview : FDA - ANVISA - PAHO (**Videoconference**) - May 2001
- Universal Medical Device Nomenclature System - ECRI - Spanish/English (CD-ROM) - 2000
- GHTF : SG1 - SG3 - SG4 Documents - Spanish Translation - Colombia - 2002



PAHO WEBSITE

<http://www.paho.org>

