Harmonization of Regulation – Challenges and Benefits

Chair: Mr. Albert Poon  CCE
Co-chair: Dr. Noboru Takamura
Invited Speaker: Dr. Larry Kelly, TGA, Australia

Essential Health Technologies EHT
medicaldevices@who.int
Regulation on Medical Device:

• About 30% of countries has developed framework for regulation
• About 30% of countries are only partly regulated for medical devices
• The Rest – either developing a framework or not yet having regulation.
Challenges in the system:

- Various forms of regulation exist to meet different needs of individual countries.
- High cost and expertise required to meet different requirements of regulation systems
- Require timely availability to patients in need
- Difficult to enforce effective safety and risk management programmes
Some Concerned Areas

- Manufacturers’ desire to simplify/standardize premarket submissions or approval to market
- Patients anticipate timely accessibility for the required MD/technology
- Management Systems such as procurement or donation guidelines and Maintenance Procedures
- One Nomenclature System – for effective market surveillance, safety management and risk management.
Urges Member States:

• (3) to draw up national or regional guidelines for good manufacturing and regulatory practices, to establish surveillance systems and other measures to ensure the quality, safety and efficacy of medical devices and where appropriate participate in international harmonization;
WHO Activities

- Address the interests and needs of the Andean Community in the areas of regulation, surveillance, and harmonization of medical devices.
- Review the development of medical devices regulatory program
- Examine the current state of regulatory program for medical devices
- Develop basic building blocks for the regulation and harmonization of medical devices
WHO resources

- “A Guide for the Development of Medical Device Regulations (2001)” provided a framework to assist member States in establishing regulatory programs for medical devices.

- “Medical Device Regulations: Global overview and guiding principles (2003)” also provided guidance to Member States wishing to create or modify their own regulatory systems for medical devices.
WHO Website and e-Library

www.who.int/medical_devices

Overview

Background
Medical devices are indispensable in health care delivery as tools for prevention, diagnosis, treatment and rehabilitation. However, despite the exponential growth of scientific and technological development, availability of and access to appropriate and affordable health technologies in low- and middle-income countries are still insufficient.

Objectives
One of the goals of the WHO Department of Essential Health Technologies is to help make available the benefits of core health technologies by developing a framework for health technology programmes and by challenging the scientific and business community to identify and adopt innovative technologies to address global health concerns.

The call for innovative technologies aims at identifying and evaluating innovative medical devices, either existing or under development, which address global health concerns and which are likely to be accessible, appropriate and affordable for use in low- and middle-income countries.

Key dates
- 11 September: Opening date for applications
- 31 January 2011: Deadline for submission of applications
- 27-29 April 2011: Selections of applications
- 30 June 2011: Posting of selected technologies on the WHO website

Call for innovative technologies that address global health concerns: 1-2-3-4-5 | Next page

RELATED LINKS
- Brochure (pdf 130kb)
- Fact Sheet (pdf 86kb)
- Applicant form (pdf 21kb)
The Way Forward

• The Way Forward and YOU have a SAY !!

• Your views please !!

Thank you !