



# Medical devices are indispensable for health care

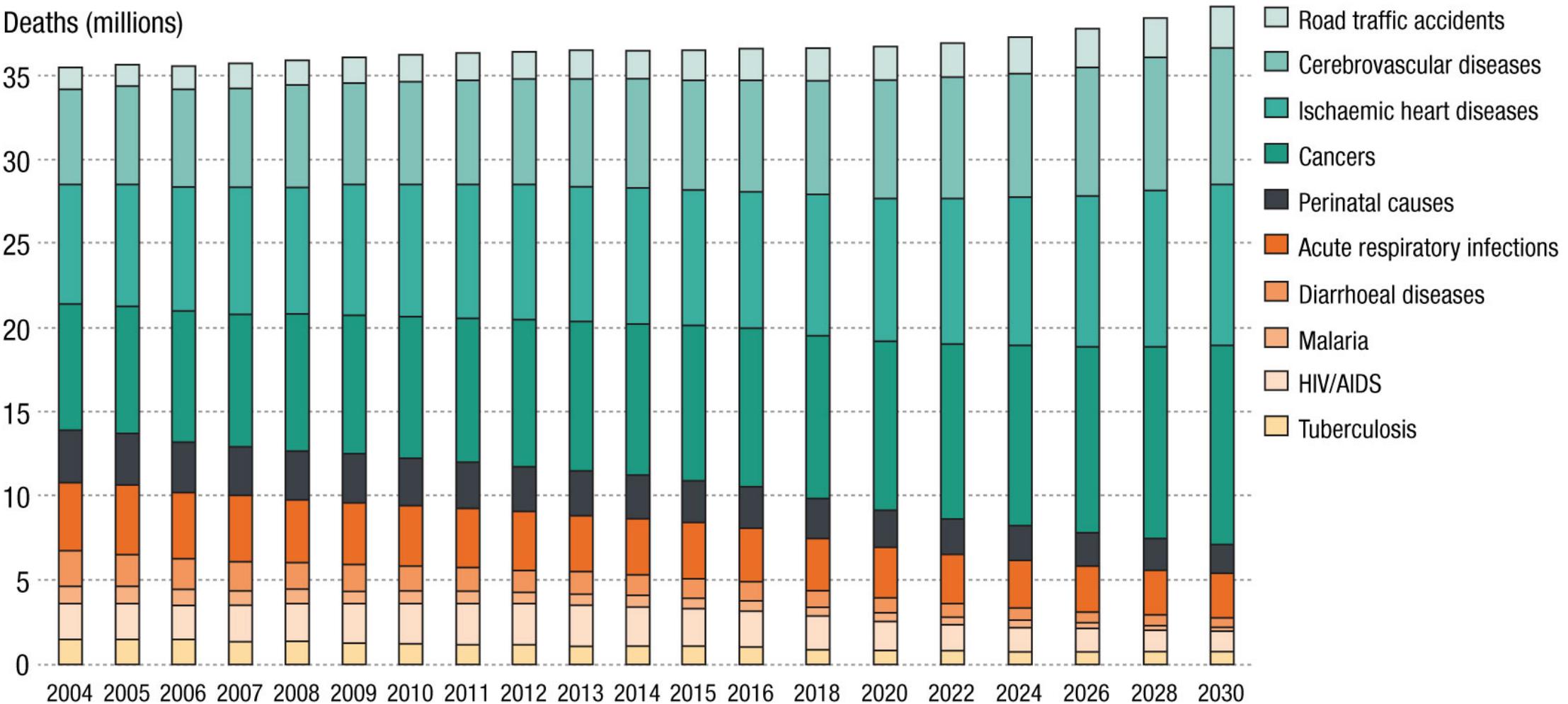


**XXI C. still many have no access to essentials**

**We all can help, what will you do?**



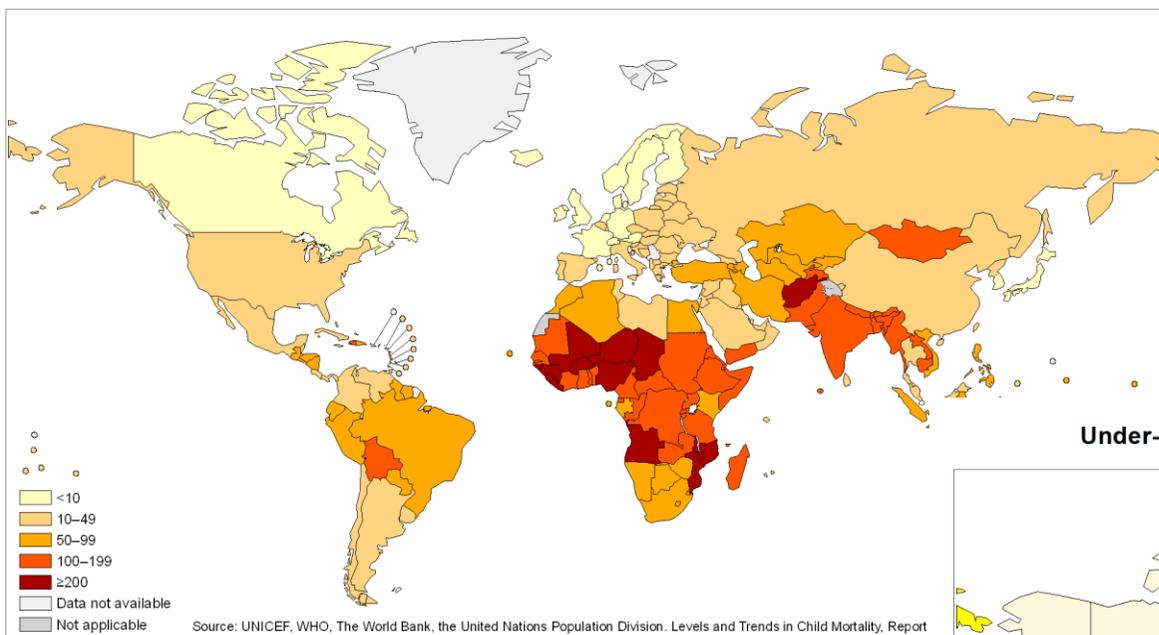
# Epidemiological Changes: increasing NCDs



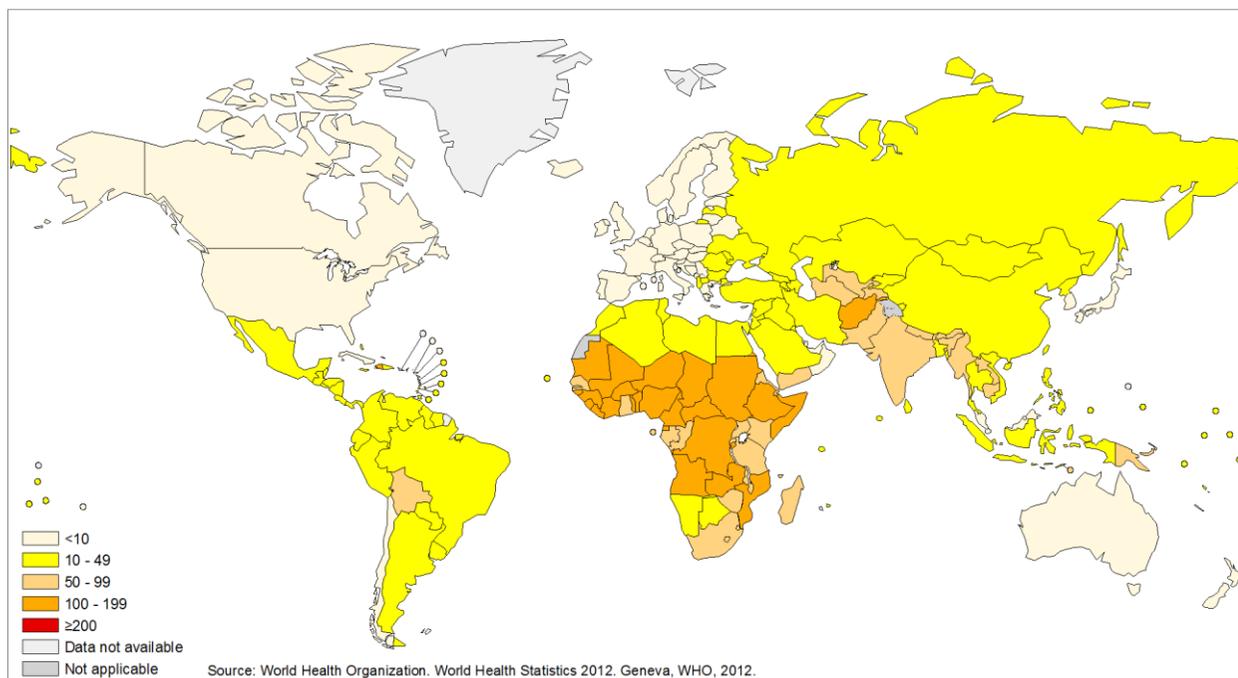
# Child mortality , under five mortality rate.

Under-five mortality rate (probability of dying by age 5 per 1000 live births), 1990

0



Under-five mortality rate (probability of dying by age 5 per 1000 live births), 2010



The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

Data Source: World Health Organization  
Map Production: Public Health Information and Geographic Information Systems (GIS)  
World Health Organization

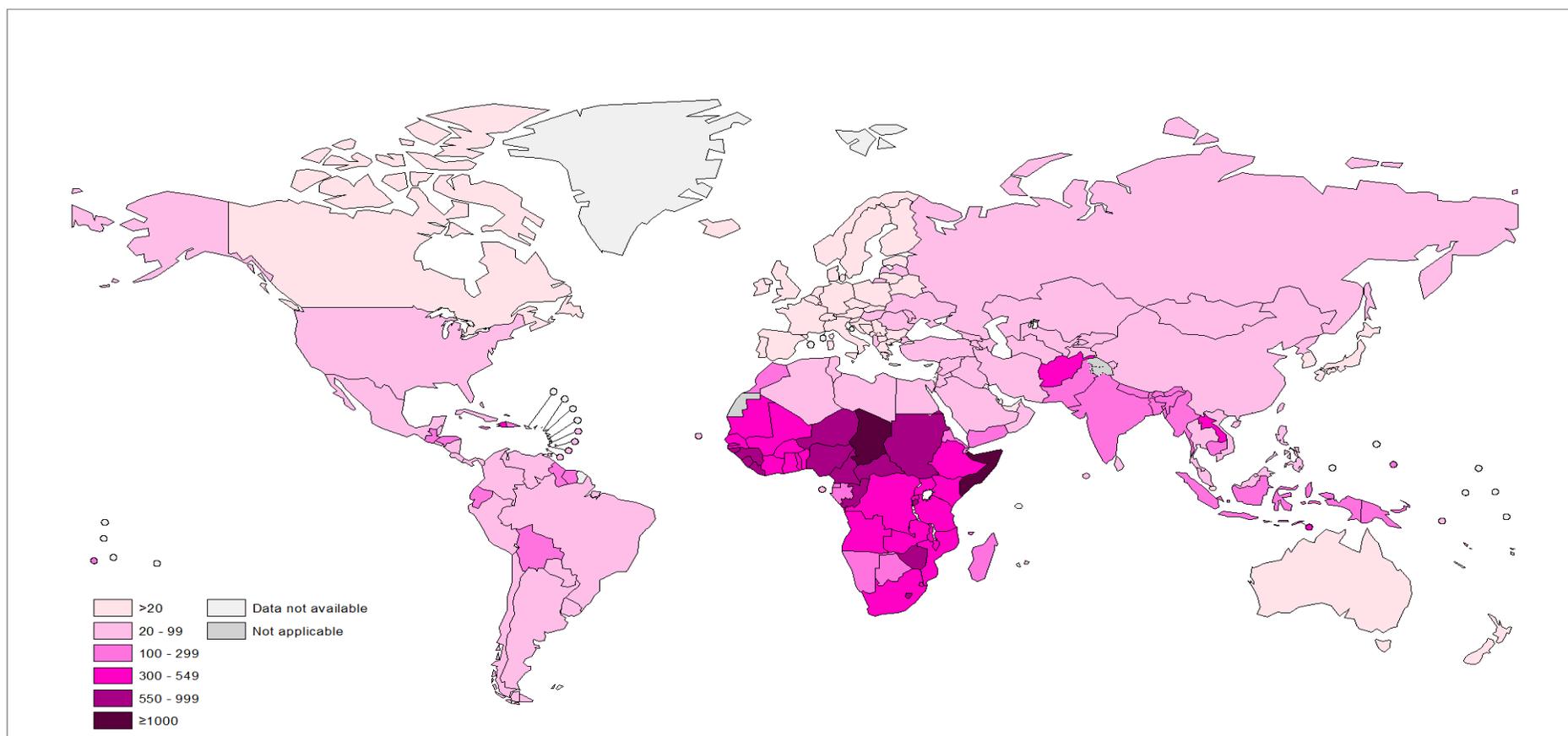
The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

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# Every day 1000 woman die, related to birth

Maternal mortality ratio (per 100 000 live births), 2010



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Data Source: World Health Organization  
Map Production: Public Health Information and Geographic Information Systems (GIS)  
World Health Organization



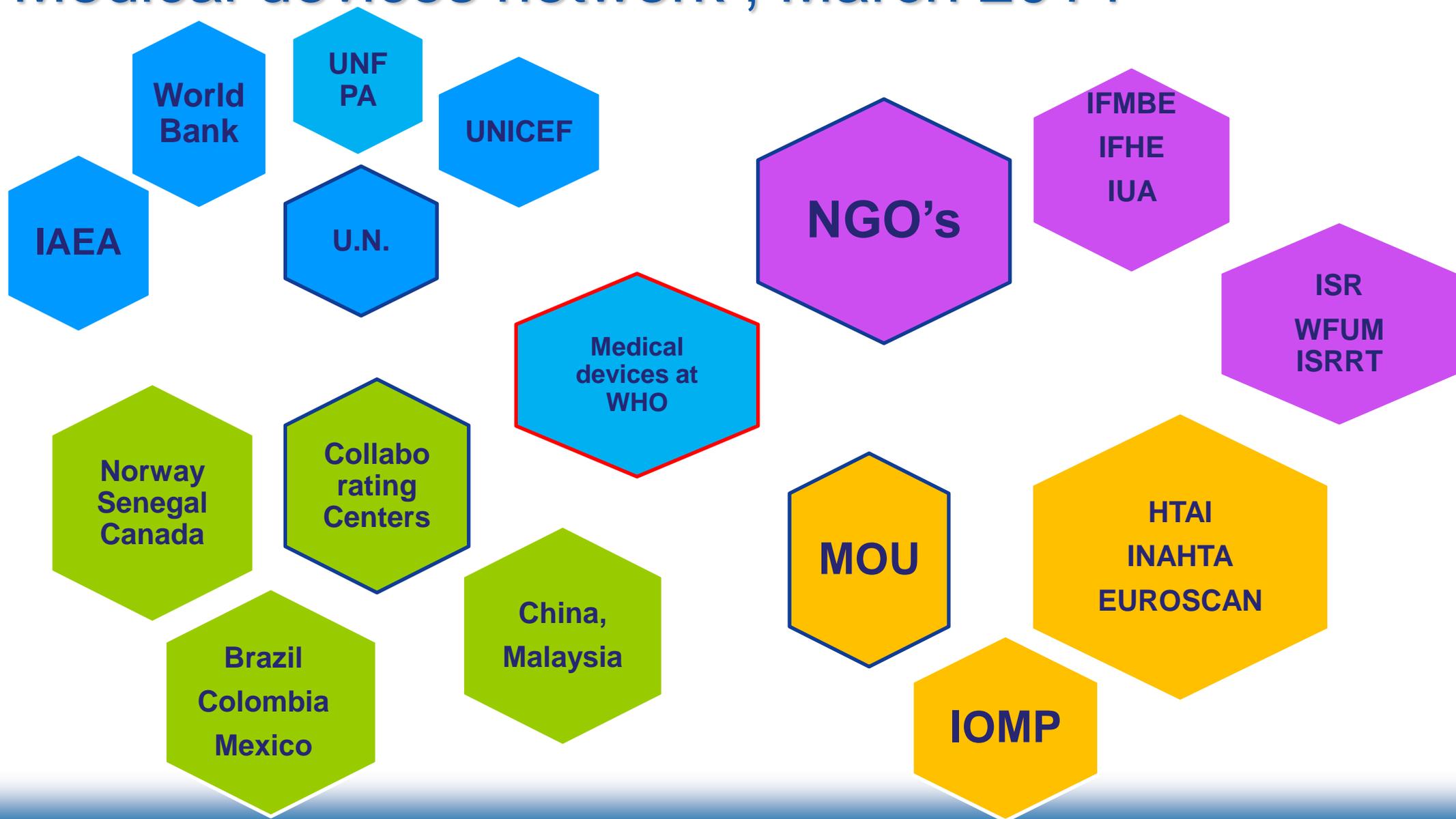
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# Health technologies resolution WHA60.29

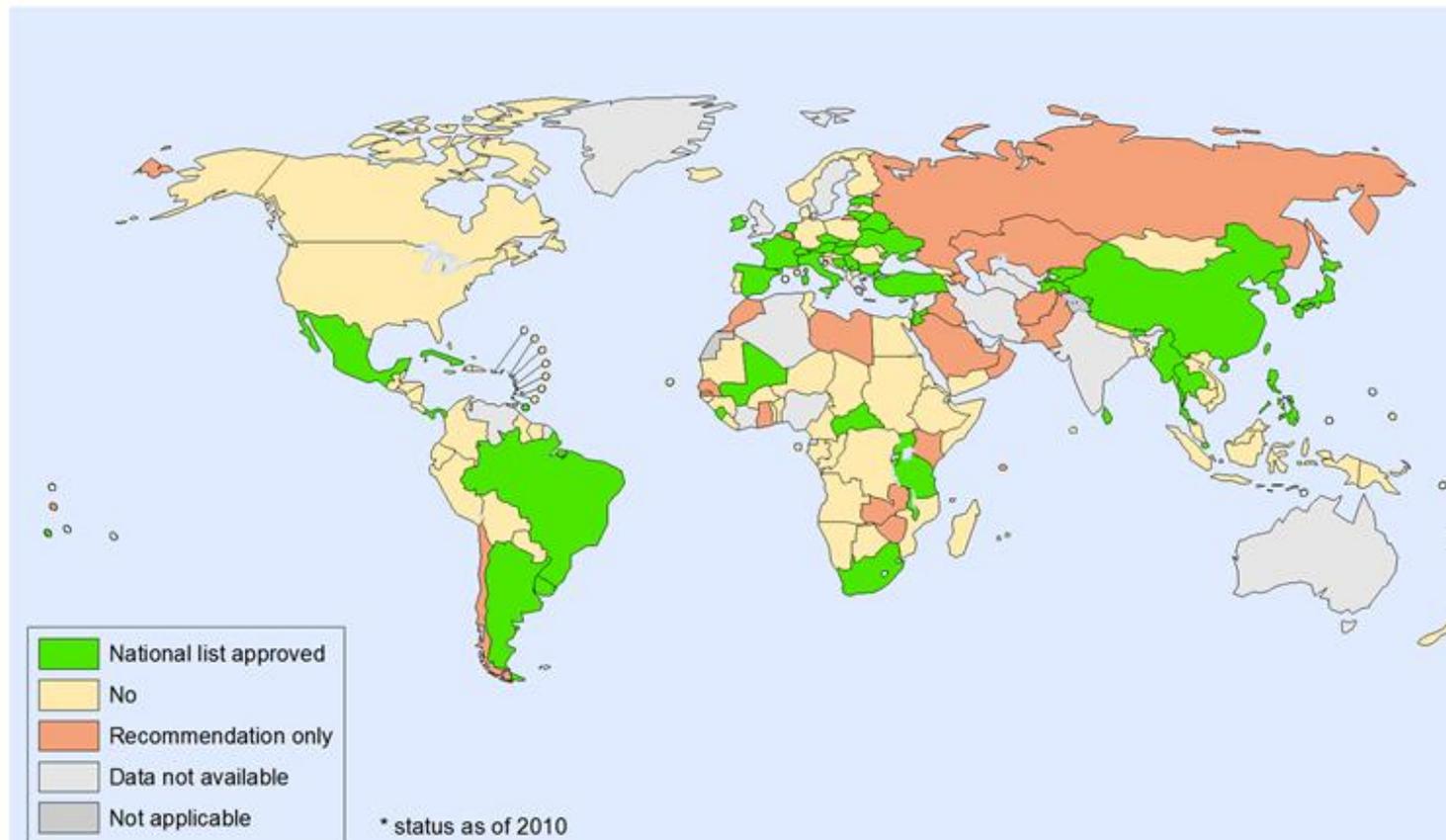
- Approved by all member states in May 2007 ( 5 years!)
- 60 World Health Assembly
- From member states:
  - Information on medical devices
  - Regulations of medical devices, harmonization
  - National units of health technologies / medical devices
  - Policies and strategies on medical devices
- From WHO , secretariat
  - Norms, standards, glossary
  - Clearinghouse on medical devices information for selection.
  - Work with NGO, CC, Academia and all stake holders

# Medical devices network , March 2014



# Approved medical devices for national procurement or reimbursement

National list of approved medical devices for procurement or reimbursement

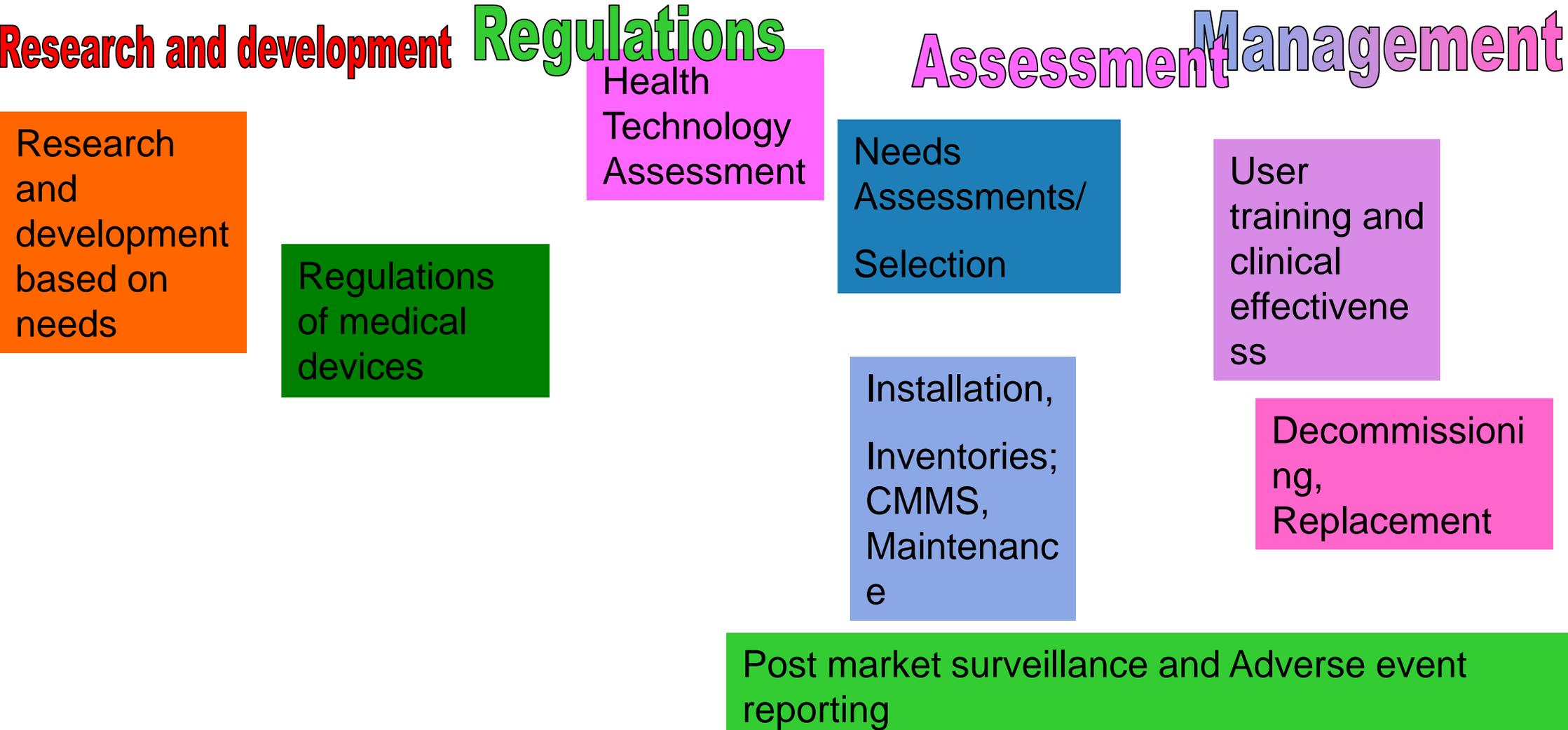


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Data Source: Baseline country survey on medical devices 2010  
Map Production: Public Health Information and Geographic Information Systems (GIS)  
World Health Organization

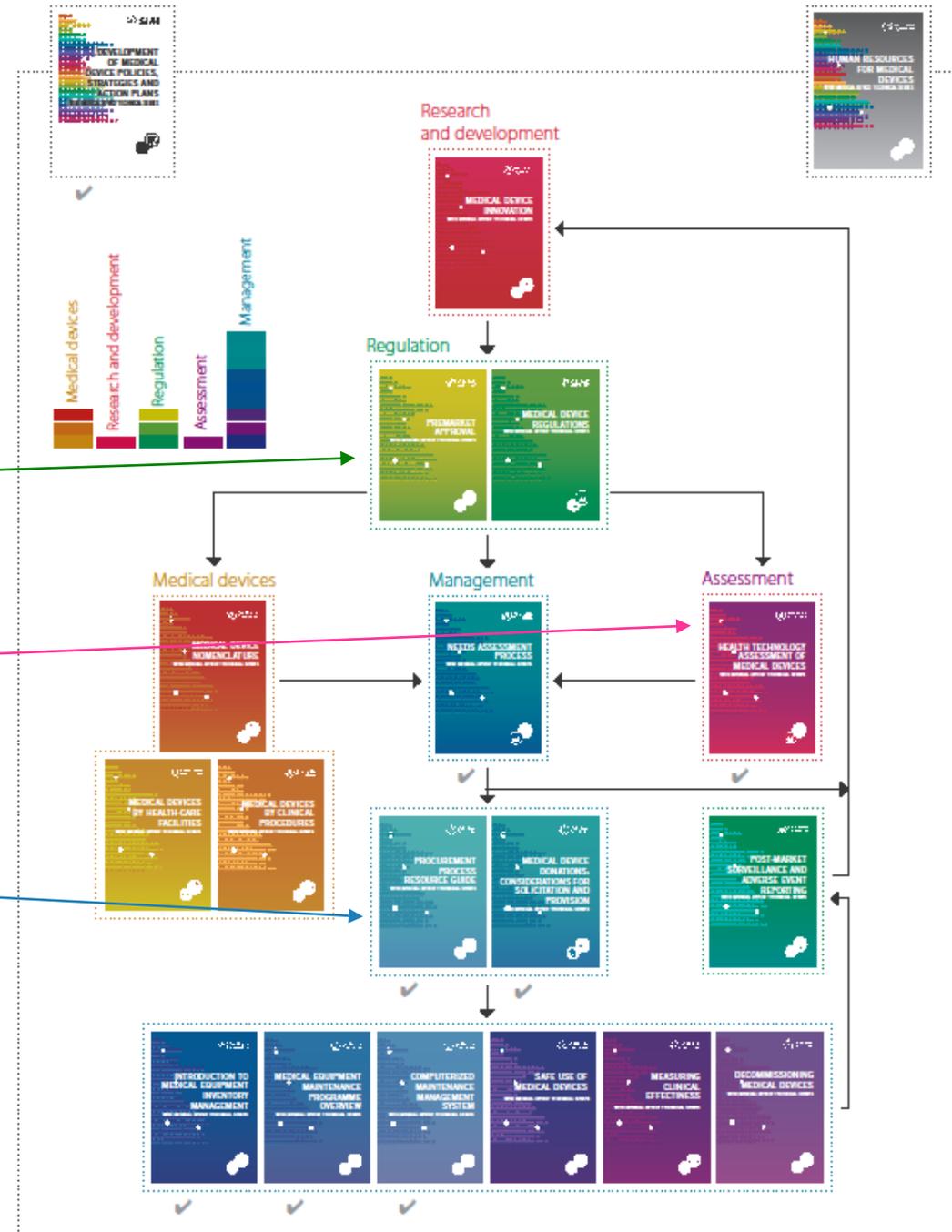
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# To ensure improved access of safe, quality medical devices

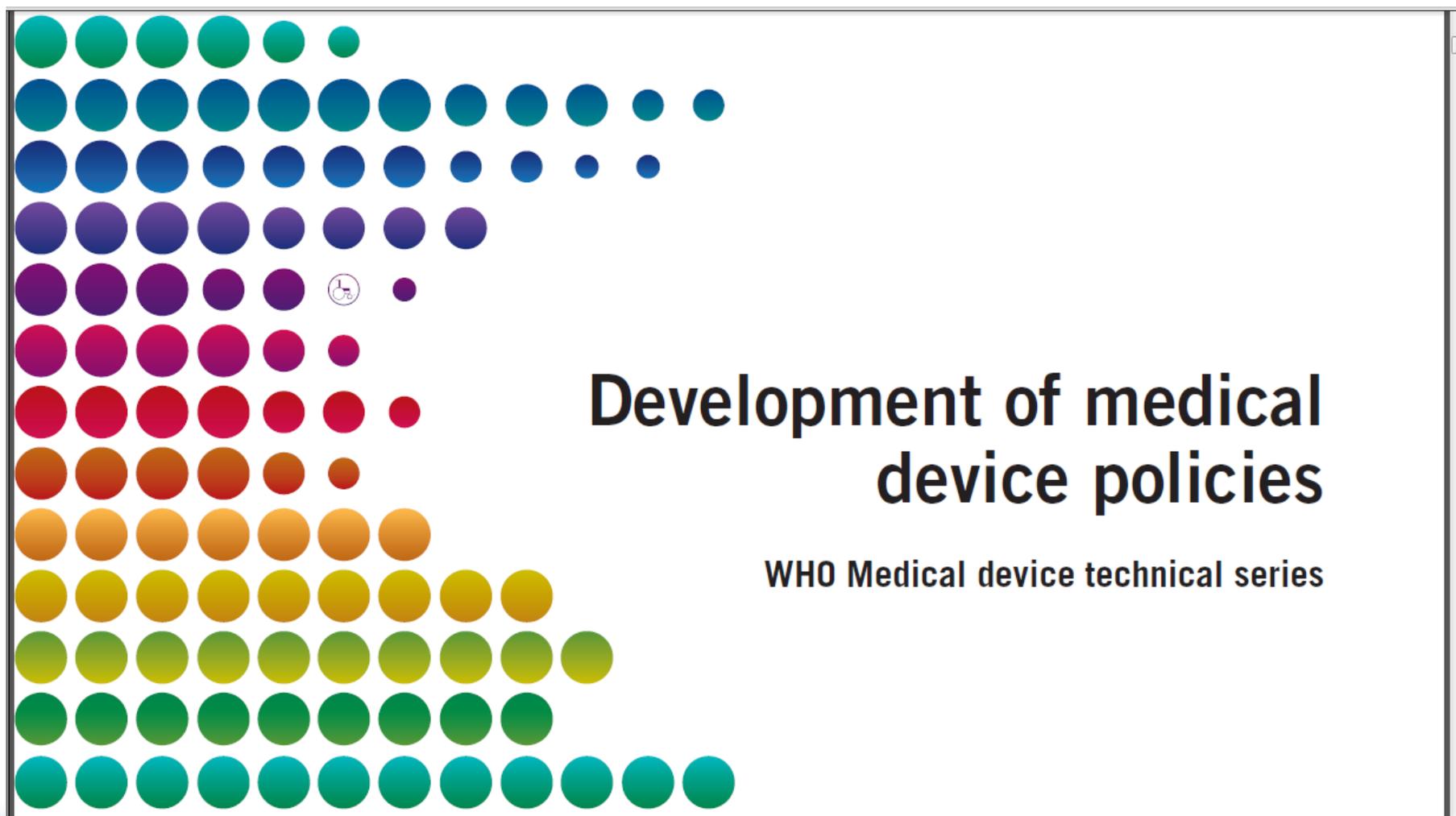


# Medical devices

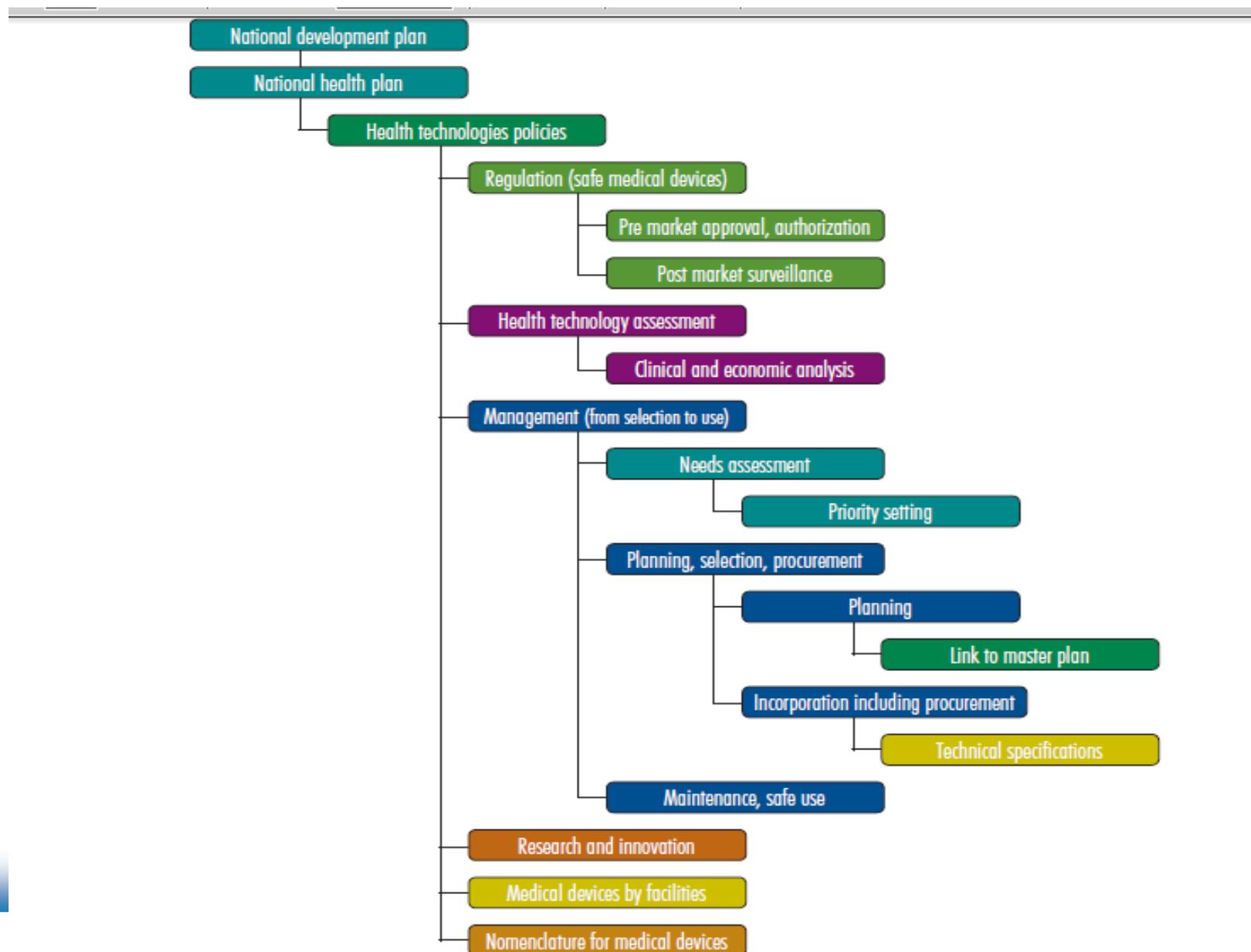
- to ensure improved access, quality and use of medical devices:
- **Regulations**
  - HTR
- **Assessment**
  - HTA
- **Management:**
  - Clinical engineering



# Policies in National Health Plans



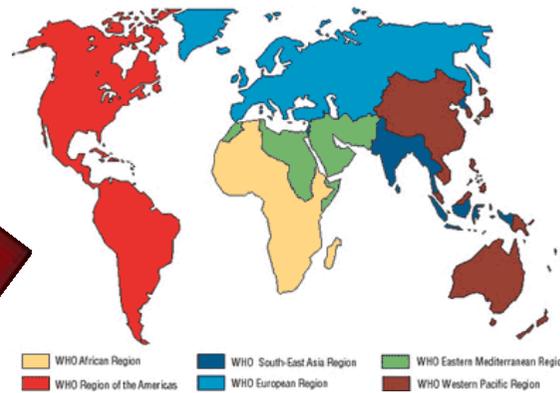
# Medical devices policies at national level



# Partnerships and Productive Collaborations

WHO Medical Devices Reports  
(2008-2011)

Country Publications



WHO Regions





Innovation  
Affordability  
**Safety**  
Effective  
Equity



# Second WHO Global Forum

## on **Medical Devices:** Priority Medical Devices for Universal Health Coverage

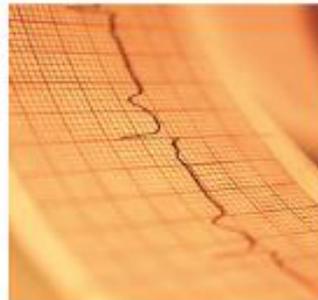
Centre International de Conférences Genève (CICG)  
Geneva, Switzerland  
22–24 November 2013



Improving access to  
safe, effective and  
innovative quality  
medical devices.

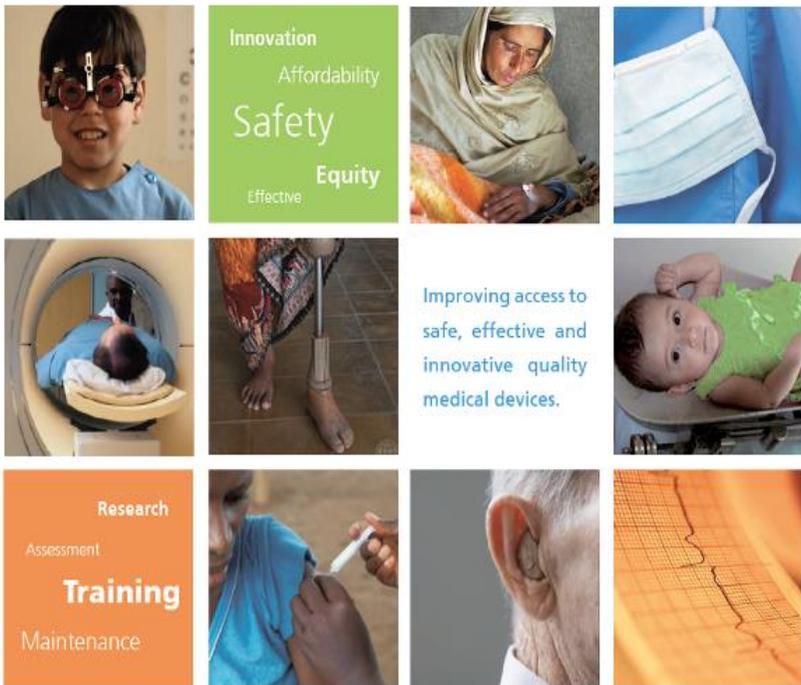


Research  
Assessment  
**Training**  
Maintenance



Adriana Velazquez Berumen

Outcomes of the 2<sup>nd</sup> WHO Global Forum on Medical Devices

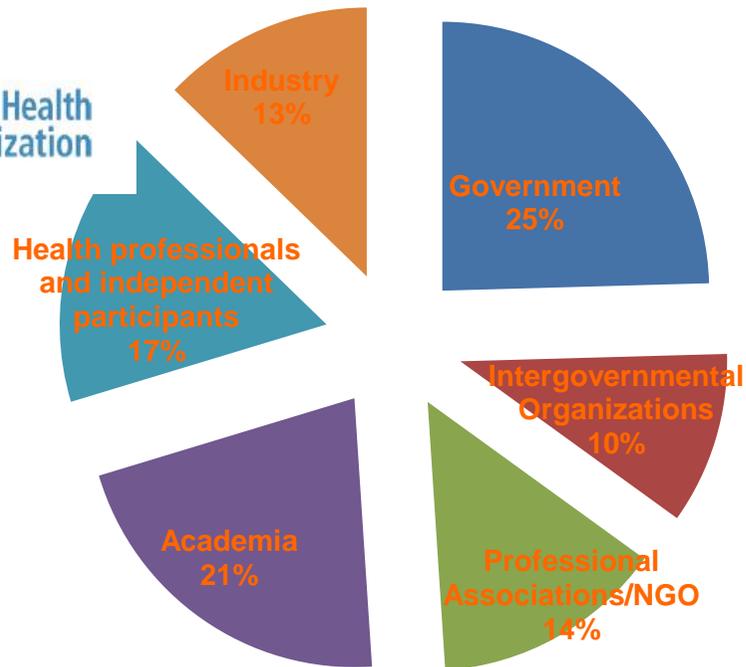


## Second WHO Global Forum

### on **Medical Devices:** Priority Medical Devices for Universal Health Coverage

Centre International de Conférences Genève (CICG)  
Geneva, Switzerland  
22-24 November 2013

**569 participants**  
**108 countries**



- 4 plenary sessions
- 116 posters
- 36 workshops
- 156 oral presentations





# Regulations sessions in 2<sup>nd</sup> GFMD

## ● Regulation Workshops

### Nomenclature, Standards and Regulations

GMDN - a requirement for Unique Device Identification (GMDN Agency)

#### Health break

Partnership on regulatory harmonization (AHWP, APEC)

National Regulatory Assessment tool (WHO)

### Nomenclature, Standards and Regulations

International standards – state of play and future trends in the medical domain (DITTA)

Medical software – regulatory and legal trends (DITTA)

## ● Regulations posters

K. Regulation of medical devices	
K.03	On regulatory policies for medical devices in low-resource countries Khondkar Siddique-e Rabbani, <i>University of Dhaka, Bangladesh</i>
K.05	Consumer health market demands balance and granularity in regulation policy Prof Daidi Zhong, <i>Chongqing University, China</i> ; Xiaolian Duan, <i>Chongqing Academy of Science and Technology, China</i> ; Michael Kirwan, <i>IEEE, United States of America</i>
K.06	Regulations of medical devices in Turkey  Abdullah Ozdemir, <i>Turkish Medicines and Medical Devices Agency</i> ; Olgun Sener, <i>Department of Health Technology Assessment, General Directorate of Health Research, Ministry of Health, Turkey</i>
K.07	Metrology in post market medical devices Diego Schirmer Spall, Renato Garcia Ojeda, <i>Biomedical Engineering Institute, Brazil</i>
K.08	Medical device clinical investigations and performance evaluation studies in Turkey Asim Hocaoglu, Ahmet Gökhan Demir, Cihad Göker, Osman Nacar, Ismet Koksall, Ali Sait Septioglu, <i>Turkish Medicine and Medical Devices Agency, Turkey</i>
K.09	Turkish National Medical Device Database (TITUBB) Mehmet Erden, Funda Özdiler, Esra Demir, Osman Nacar, Ismet Koksall, Ercan Simsek, <i>Turkish Medicine and Medical Devices Agency, Turkey</i>
K.11	Arthroplasty registry and tracking system (ARTS) in Turkey  Serian Doma, Ismet Köksall, Osman Nacar, Saim Kerman, <i>Turkish Medicine and Medical Devices Agency, Turkey</i>
K.12	Worldwide Arthroplasty Registry System (ARS) applications and outcomes Serian Doma, Senay Sat, Ismet Köksall, Osman Nacar, Saim Kerman, <i>Turkish Medicine and Medical Devices Agency, Turkey</i>
K.13	For the standardization of measures performed with IVDs, the need for laboratory accreditation  Semra Koyunoglu, Osman Nacar, Ismet Köksall, Saim Kerman, <i>Turkish Medicine and Medical Devices Agency, Turkey</i>
K.14	Delivering as One UN to strengthen regulatory framework for medical devices in Kenya: The case of condoms regulation in Kenya  Regina Mbindyo, <i>World Health Organization, Kenya</i> ; Geoffrey Okumu, <i>United Nations Population Fund (UNFPA), Kenya</i>
K.15	Brazilian industrial and innovation complex in health: improve domestic standards and harmonize international medical device standards  Marcos Roberto Signori, Marco Aurelio de Carvalho Nascimento, Paulo Henrique Dantas Antonino, Eduardo Jorge Valadares Oliveira, Carlos Augusto Grabois Gadelha, <i>Ministry of Health, Brazil</i>



## Regulation of Medical Devices

Session Chair: Ms. Kimberly Trautman  
Session Co-Chair: Ms. Robyn Meurant

Harmonization and in-country implementation of regulations

Shelley Tang, Australia

Developing a competent regulatory workforce for medical devices in the global environment

Mr. Rainer Voelksen, Regulatory Affairs Professionals Society (RAPS), United States of America; Philippe Auclair, RAPS European Advisory Committee, Belgium; Sherry Keramidas, RAPS, United States of America

IMDRF medical device single audit program pilot program

Ms. Kimberly Trautman, US Food and Drug Administration Center for Devices and Radiological Health, United States of America; Ana Paula Teles Ferreira Barreto, ANVISA, Brazil; Mike Ward, Health Canada, Canada; Larry Kelly, TGA, Australia; Hideyuki Kondo, Ministry of Health, Labour and Welfare, Japan

IMDRF review of the NCAR exchange program: challenges and opportunities

Dr Isabelle Demade, European Commission, Belgium

Best international PMS practice and in-country implementation of PMS systems

Ms. Shelley Tang, Australia

Harmonizing the regulation of in vitro diagnostic (IVD) medical devices in developing countries

Dr. Ruth McNerney, London School of Hygiene & Tropical Medicine, United Kingdom

Single-use medical devices: re-use and re-processing

Mr. Antonio Jose G. Hernandez, American College of Clinical Engineering, United States of America

Codification of medical devices in Portugal

Ms. Emilia Alves Da Silva, INFARMED, National Authority of Medicines and Health Products, IP, Portugal

Japanese approach of nomenclature system

Mr. Tomomichi Nakazaki, Tokyo Women's Medical University, Waseda University Joint Institution for Advanced Biomedical Sciences, Japan

Harmonization of standards and regulations should be addressed through collaboration of government and the private sector

Mr. Anil Nanubhai Patel, Abel Torres, UL (Underwriters Laboratories), United States of America

# Regulation sessions

## Regulation of Medical Devices: Country Initiatives

*(Spanish translation available)*

Session Chair: Mr. Rainer Voelksen  
Session Co-Chair: Ms. Irena Prat

Medical devices regulations in Cuba. Progress, challenges and opportunities for regulatory strengthening in the region of the Americas

Ms. Dulce María Martínez Pereira, Lic. Silvia Delgado Ribas, Centro de Control Estatal de Equipos y Dispositivos Médicos (CECMED), Cuba

Moving towards harmonization of medical devices in Peru

Ms Lida Esther Hildebrandt Pinedo, Headquarters of Medicines Inputs and Drugs, DIGEMID, Department of Health, Peru

Post market surveillance in Saudi Arabia

Dr. Saleh Al Tayyar, Saudi Food and Drug Authority, Abdullah Thabit, Medical Devices Sector of Saudi Food and Drug Authority, Saudi Arabia

Regulation on changes to registered medical devices and challenges faced in Singapore

Dr. Huiling Debbie Ko, Health Sciences Authority, Singapore

Regulation of medical devices in Tanzania

Ms. Agnes Sitta Kijo, Tanzania Food And Drug Authority, United Republic of Tanzania

A new horizon for the medical device sector in South Africa

Ms. Debjani Mueller, CMeRC, University of Witwatersrand, South Africa

Regulatory affairs of medical devices in Africa; The Nigeria scenario

Dr. Charity Ilonze, National Agency for Food And Drug Administration and Control, Nigeria

Towards the implementation of medical devices regulation based on the WHO model in Malaysia and its challenges

Mr. Zamane Abdul Rahman, Medical Device Authority, Malaysia



# Suggestions Regulation

## Regulation

### Regulation of Medical Devices

1	X	WHO to provide a platform for harmonization of taxonomy and nomenclature of safety reporting and Learning systems across different disciplines in health care (e.g. radiation safety, blood safety, techno-vigilance, etc.)
2	X	Global bodies Develop and offer training for users about AE and near miss reporting
3	X	WHO and IMDRF build a/invest in a Solid PPP to far more comprehensively organize capacity building training services for regulators
4		Increase the list of international valid standards and promote them

### Regulation of Medical Devices: Country Initiatives

1	X	WHO should assist low resource countries to establish effective systems for regulating medical devices
2	X	1) medical devices should not be regulated the way drugs are regulated for efficacy but for bringing a disciplined approach to manufacturing and for ensuring safe performance 2) transition period of 5 years should be minimal
3		In order to best serve all developing countries the use of the GHTF guidelines would assist and give more than a foundation for any country without the relevant expertise in place to start a regulatory office for Medical Devices with some confidence
4		It is brilliant to see many countries establishing a medical devices regulatory framework, I hope from the outset emphasis is also placed on sharing information globally



# Re-organization of Essential Medicines and Health Products Department in WHO

Irena Prat and Adriana Velazquez

Essential Medicines and Health products Department

World Health Organization



# WHO new Programme of work 2014

- 6 priorities:
  - Advancing universal health coverage
  - Achieving health related MDG
  - Addressing NCD and mental health
  - Implementing international health regulations
  - **” Increasing access to essential, high quality and affordable medical products”**
  - Reducing health inequities.



n Medical Devices





# Reorganization: single PQ programme for further impact & restructured regulatory units

- Consolidated prequalification team aiming at:
  - Enhanced management & operations
    - e.g. quality management system
    - e.g. administrative efficiencies, incl. financial management
  - Better relationship with stakeholders
    - e.g. single voice when dealing with national regulatory authorities
    - e.g. increased transparency around processes and outcomes
  - Cross-product stream learning
    - e.g. extension of ERP process to new product categories
    - e.g. bigger pool of external experts and testing laboratories
    - e.g. PQDx benefit from medicines and vaccines experience to improve efficiency

# ICDRA 16 International Conference of Drug Regulatory Authorities

“The role of a Drug Regulatory Authority in  
an efficient National Health System”

Rio de Janeiro  
26 to 29 August, 2014

2 sessions proposed for medical devices: 11:00 to 12:30

28 August: plenary 6: New trends in regulating medical devices  
Regulation global landscape  
Harmonization initiatives: IMDRF, AHWP,  
PQDx update  
Country initiative

29 August: Workshop: current topics and future developments.  
Combination products, UDI, reuse medical devices

[http://www.who.int/medicines/areas/quality\\_safety/regulation\\_legislation/icdra/en/](http://www.who.int/medicines/areas/quality_safety/regulation_legislation/icdra/en/)



ANVISA  
Agência Nacional de Vigilância Sanitária

Ministério da  
Saúde



# International Conference of Drug Regulatory Authorities

## ICDRA 15. Workshop M.

### How should medical device products be regulated

- The challenge of regulating medical devices is further compounded by the huge complexity and variety of products. Due to increasing interest in this area, this was **the first time that an ICDRA session was devoted to the topic.** **Recommendations:**
- Medical devices should be regulated to protect public health and promote their proper use.
- Nomenclature systems for medical devices should be harmonized for better understanding by regulators and to better protect public health.
- WHO should encourage collaboration between medicines regulatory authorities with well established regulatory systems for medical devices and countries with less developed systems.
- The 15th (ICDRA) took place in Tallinn, Estonia, 23–26 October 2012. had 300 participants from 100 member states ICDRA is closed to regulators only.



	Tuesday / 26 August	Wednesday / 27 August	Thursday / 28 August	Friday / 29 August
08:00 - 09:00	Registration			
09:00 - 10:30	<b>Plenary 1</b> Opening Ceremony	<b>Workshop A</b> Best Practices in Pharmacovigilance  <b>Workshop B</b> How to ensure the safety of traditional and complementary medicines in national healthcare systems	<b>Plenary 5</b> Regulators role in Access/availability (shortages etc.)	<b>Workshop I</b> Current status and future vision of regulating advanced therapies  <b>Workshop J</b> Managing decentralized GMP inspection systems
Coffee				
11:00 - 12:30	<b>Plenary 2</b> Update on 15th ICDRA recommendations Global context – WHO	<b>Workshop C</b> Regulatory models for minimizing risks in blood and blood products  <b>Workshop D</b> Approaches to educating regulators to meet country needs	<b>Plenary 6</b> New trends in regulating medical devices	<b>Workshop K</b> Current challenges and transparency in clinical trials regulation  <b>Workshop L</b> Current Topics and Future developments
Lunch				
14:00 - 15:30	<b>Plenary 3</b> The role of drug regulatory authorities in national health systems	<b>City Tours</b>	<b>Workshop E</b> Challenges of vaccines regulation and safety monitoring  <b>Workshop F</b> Collaboration for ensuring the quality and safety of Active Pharmaceutical Ingredients	<b>Plenary 7</b> Recommendations Closing remarks
Coffee				
16:00 - 17:30	<b>Plenary 4</b> Strengthening regulatory systems for medical products		<b>Workshop G</b> Preventing and reducing the risk to public health from SSFFC medical products  <b>Workshop H</b> Biosimilars	



# 67<sup>th</sup> World Health Assembly, May 2014

## Regulatory system strengthening

Report by the Secretariat

- Moreover, where areas regulations of medicines and vaccines is now scientifically well developed, there are **important gaps concerning regulation of other classes of products, for example medical devices**, which in many countries are not regulated at all.
- an estimated 1.5 million different medical devices
- more than 10 000 generic device groups are available
- of the 161 countries responding to the 2010 Baseline country survey on medical devices:
  - 55 did not have a regulatory authority for medical devices,
  - 87 did not have a national health technology policy and
  - 93 did not have national lists of approved medical devices for procurement or reimbursement.





# Conclusions:

1. WHO re-organization needs staff/ resources/ information on: standards and norms, strengthening regulatory authorities, safety and vigilance of medical devices.
2. 2<sup>nd</sup> Global Forum on Medical Devices, recommends to assist low resource countries to establish effective systems for regulating medical devices. Follow up: MIMS, Medical Devices regulation book, capacity building and convergence.
3. 16<sup>th</sup> ICDRA, to increase medical devices regulations awareness, harmonization and development .
- 4.. EB resolution to regulatory systems strengthening, for World Health Assembly in May 2014.

**Thank  
you.**



n Medical Devices