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

Deaths (millions)

- Road traffic accidents
- Cerebrovascular diseases
- Ischaemic heart diseases
- Cancers
- Perinatal causes
- Acute respiratory infections
- Diarrhoeal diseases
- Malaria
- HIV/AIDS
- Tuberculosis

World Health Organization

Tmedical devices . March 2014
Child mortality, under five mortality rate.

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

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 be full agreement.
Every day 1000 women die, related to birth

Maternal mortality ratio (per 100 000 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 and dashed 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

© WHO 2012. All rights reserved.
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 stakeholders
Approved medical devices for national procurement or reimbursement

National list of approved medical devices for procurement or reimbursement

* status as of 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: Baseline country survey on medical devices 2010
Map Production: Public Health Information and Geographic Information Systems (GIS)
World Health Organization
To ensure improved access of safe, quality medical devices

Research and development

- Research and development based on needs
- Regulations of medical devices

Regulations

- Health Technology Assessment
- Needs Assessments/Selection
- Installation, Inventories; CMMS, Maintenance

Assessment

- User training and clinical effectiveness
- Decommissioning, Replacement

Management

Post market surveillance and Adverse event reporting
Medical devices

- to ensure improved access, quality and use of medical devices:
  - Regulations
    - HTR
  - Assessment
    - HTA
  - Management:
    - Clinical engineering
Policies in National Health Plans

Development of medical device policies

WHO Medical device technical series
Medical devices policies at national level

- National development plan
- National health plan
- Health technologies policies
  - Regulation (safe medical devices)
    - Pre market approval, authorization
    - Post market surveillance
  - Health technology assessment
    - Clinical and economic analysis
  - Management (from selection to use)
    - Needs assessment
      - Priority setting
    - Planning, selection, procurement
      - Planning
        - Link to master plan
        - Incorporation including procurement
          - Technical specifications
    - Maintenance, safe use
  - Research and innovation
  - Medical devices by facilities
  - Nomenclature for medical devices
Partnerships and Productive Collaborations

WHO Medical Devices Reports (2008-2011)

Country Publications

WHO Regions
Outcomes of the 2nd WHO Global Forum on Medical Devices
4 plenary sessions
116 posters
36 workshops
156 oral presentations
Countries with 2 to 4 participants in 2nd GFMD

AFRO region
- Benin
- Burkina Faso
- Burundi
- Cameroon
- Central African Republic
- Comoros
- Congo
- Cote d'Ivoire
- Democratic Republic of the Congo
- Ethiopia
- Gambia
- Guinea
- Guine-Bissau
- Mauritius
- Nigeria
- Rwanda
- Senegal
- Sierra Leone
- Swaziland
- Togo
- Uganda
- United Republic of Tanzania
- Zimbabwe

EURO region
- Bosnia and Herzegovina
- Bulgaria
- Croatia
- Czech Republic
- Estonia
- Finland
- Greece
- Hungary
- Israel
- Kyrgyzstan
- Lithuania
- Poland
- Portugal
- Republic of Moldova
- Republic of Montenegro
- Russian Federation
- Slovakia
- Sweden
- The Former Yugoslav Rep of Macedonia
- Ukraine

AMRO region
- Argentina
- Chile
- Colombia
- Cuba
- Ecuador
- El Salvador
- Haiti
- Panama
- Peru
- Suriname
- Uruguay

SEARO region
- Bangladesh
- Indonesia
- Myanmar
- Nepal
- Sri Lanka
- Thailand

WPRO region
- Cambodia
- Fiji
- Lao People’s Democratic Republic
- Malaysia
- Singapore
- Viet Nam

Countries >5 participants

- Argentina
- Bangladesh
- Brazil
- Canada
- China
- Egypt
- France
- Germany
- Greece
- India
- Indonesia
- Italy
- Japan
- Kenya
- Korea
- Mexico
- Netherlands
- Pakistan
- Philippines
- Russia
- South Africa
- Spain
- Switzerland
- Turkey
- United Kingdom of Great Britain and Northern Ireland
- United States of America
- Vietnam
- WHO
- World Health Organization
Regulations sessions in 2nd GFMD

- Regulation Workshops

<table>
<thead>
<tr>
<th>National Regulatory Assessment tool (WHO)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health break</td>
</tr>
<tr>
<td>Partnership on regulatory harmonization (AHWP, APEC)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Nomenclature, Standards and Regulations</th>
</tr>
</thead>
<tbody>
<tr>
<td>GMDN - a requirement for Unique Device Identification (GMDN Agency)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Nomenclature, Standards and Regulations</th>
</tr>
</thead>
<tbody>
<tr>
<td>International standards – state of play and future trends in the medical domain (DITTA)</td>
</tr>
</tbody>
</table>

| Medical software – regulatory and legal trends (DITTA) |

- Regulations posters

<table>
<thead>
<tr>
<th>K. Regulation of medical devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>K.03 On regulatory policies for medical devices in low-resource countries</td>
</tr>
<tr>
<td>Khondkar Siddique-e Rabbani, University of Dhaka, Bangladesh</td>
</tr>
</tbody>
</table>

| K.05 Consumer health market demands balance and granularity in regulation policy |
| Prof Daidi Zhong, Chongqing University, China; Xiaolian Duan, Chongqing Academy of Science and Technology, China; Michael Kirwan, IEEE, United States of America |

| K.06 Regulations of medical devices in Turkey |
| Abdullah Ozdemir, Turkish Medicines and Medical Devices Agency; Olgun Sener, Department of Health Technology Assessment, General Directorate of Health Research, Ministry of Health, Turkey |

| K.07 Metrology in post market medical devices |
| Diego Schirmer Spall, Renato Garcia Ojeda, Biomedical Engineering Institute, Brazil |

| K.08 Medical device clinical investigations and performance evaluation studies in Turkey |
| Asim Hocaoglu, Ahmet Gökhan Demir,Çihad Gökler, Osman Nacar, Ismet Koksal, Ali Sait Septioğlu, Turkish Medicine and Medical Devices Agency, Turkey |

| K.09 Turkish National Medical Device Database (TITUBB) |
| Mehmet Erden, Funda Özdiler, Esra Demir, Osman Nacar, Ismet Koksal, Ercan Simsek, Turkish Medicine and Medical Devices Agency, Turkey |

| K.10 Arthroplasty registry and tracking system (ARTS) in Turkey |
| Serian Doma, Ismet Koksal, Osman Nacar, Saim Kerman, Turkish Medicine and Medical Devices Agency, Turkey |

| K.12 Worldwide Arthroplasty Registry System (ARS) applications and outcomes |
| Serian Doma, Senay Sat, Ismet Koksal, Osman Nacar, Saim Kerman, Turkish Medicine and Medical Devices Agency, Turkey |

| K.13 For the standardization of measures performed with IVDs, the need for laboratory accreditation |
| Semra Koyunoglu, Osman Nacar, Ismet Koksal, Saim Kerman, Turkish Medicine and Medical Devices Agency, Turkey |

| K.14 Delivering as One UN to strengthen regulatory framework for medical devices in Kenya: The case of condoms regulation in Kenya |
| Regina Mbinyo, World Health Organization, Kenya; Geoffrey Okumu, United Nations Population Fund (UNFPA), Kenya |

| 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 Nazareno, Marco Aurelio de Oliveira, Valadares Oliveira, Carlos Augusto Grabois Gadelha, Ministry of Health, Brazil |
### Regulation of Medical Devices

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

<table>
<thead>
<tr>
<th>Topic</th>
<th>Presenter(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Harmonization and in-country implementation of regulations</td>
<td>Shelley Tang, Australia</td>
</tr>
<tr>
<td>Developing a competent regulatory workforce for medical devices in the global environment</td>
<td>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</td>
</tr>
<tr>
<td>IMDRF medical device single audit program pilot program</td>
<td>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</td>
</tr>
<tr>
<td>IMDRF review of the NCAR exchange program: challenges and opportunities</td>
<td>Dr. Isabelle Demade, European Commission, Belgium</td>
</tr>
<tr>
<td>Best international PMS practice and in-country implementation of PMS systems</td>
<td>Ms. Shelley Tang, Australia</td>
</tr>
<tr>
<td>Harmonizing the regulation of in vitro diagnostic (IVD) medical devices in developing countries</td>
<td>Dr. Ruth McNerney, London School of Hygiene &amp; Tropical Medicine, United Kingdom</td>
</tr>
<tr>
<td>Single-use medical devices: re-use and re-processing</td>
<td>Mr. Antonio Jose G. Hernandez, American College of Clinical Engineering, United States of America</td>
</tr>
<tr>
<td>Codification of medical devices in Portugal</td>
<td>Ms. Emilia Alves Da Silva, INFARMED, National Authority of Medicines and Health Products, IP, Portugal</td>
</tr>
<tr>
<td>Japanese approach of nomenclature system</td>
<td>Mr. Tomomichi Nakazaki, Tokyo Women’s Medical University, Waseda University Joint Institution for Advanced Biomedical Sciences, Japan</td>
</tr>
<tr>
<td>Harmonization of standards and regulations should be addressed through collaboration of government and the private sector</td>
<td>Mr. Anil Nanubhai Patel, Abel Torres, UL (Underwriters Laboratories), United States of America</td>
</tr>
</tbody>
</table>

**Regulation of Medical Devices: Country Initiatives**  
*(Spanish translation available)*

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

<table>
<thead>
<tr>
<th>Topic</th>
<th>Presenter(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical devices regulations in Cuba. Progress, challenges and opportunities for regulatory strengthening in the region of the Americas</td>
<td>Ms. Dulce María Martínez Pereira, Lic. Silvia Delgado Ribas, Centro de Control Estatal de Equipos y Dispositivos Médicos (CECMED), Cuba</td>
</tr>
<tr>
<td>Moving towards harmonization of medical devices in Peru</td>
<td>Ms. Lida Esther Hildebrandt Pinedo, Headquarters of Medicines Inputs and Drugs, DIGEMID, Department of Health, Peru</td>
</tr>
<tr>
<td>Post market surveillance in Saudi Arabia</td>
<td>Dr. Saleh Al Tayyar, Saudi Food and Drug Authority, Abdullah Thabit, Medical Devices Sector of Saudi Food and Drug Authority, Saudi Arabia</td>
</tr>
<tr>
<td>Regulation on changes to registered medical devices and challenges faced in Singapore</td>
<td>Dr. Huiling Debbie Ko, Health Sciences Authority, Singapore</td>
</tr>
<tr>
<td>Regulation of medical devices in Tanzania</td>
<td>Ms. Agnes Sitta Kijo, Tanzania Food And Drug Authority, United Republic of Tanzania</td>
</tr>
<tr>
<td>A new horizon for the medical device sector in South Africa</td>
<td>Ms. Debjani Mueller, CMeRC, University of Witwatersrand, South Africa</td>
</tr>
<tr>
<td>Regulatory affairs of medical devices in Africa; The Nigeria scenario</td>
<td>Dr. Charity Ilonze, National Agency for Food And Drug Administration and Control, Nigeria</td>
</tr>
<tr>
<td>Towards the implementation of medical devices regulation based on the WHO model in Malaysia and its challenges</td>
<td>Mr. Zamane Abdul Rahman, Medical Device Authority, Malaysia</td>
</tr>
</tbody>
</table>
# Suggestions

## Regulation

### Regulation of Medical Devices

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td>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.)</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>Global bodies develop and offer training for users about AE and near miss reporting</td>
</tr>
<tr>
<td>3</td>
<td></td>
<td>WHO and IMDRF build a/invest in a solid PPP to far more comprehensively organize capacity building training services for regulators</td>
</tr>
<tr>
<td>4</td>
<td></td>
<td>Increase the list of international valid standards and promote them</td>
</tr>
</tbody>
</table>

### Regulation of Medical Devices: Country Initiatives

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td>WHO should assist low resource countries to establish effective systems for regulating medical devices</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>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</td>
</tr>
<tr>
<td>3</td>
<td></td>
<td>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</td>
</tr>
<tr>
<td>4</td>
<td></td>
<td>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</td>
</tr>
</tbody>
</table>
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.
Reorganization of Department of Essential Medicines & Health Products

- To better address priority areas, achieve synergies, concentrate resources, and streamline operations, in line with the WHO reform.

- **Three functional units in the new EMP structure**
  - **Policy, Access and Use**
    - access to medicines and other health technologies (e.g. selection, pricing and supply, rational use)
  - **Public health, Innovation and Intellectual property**
    - Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, on transfer of technology and local production of medicines, vaccines and other technologies.
  - **Regulation of Medicines and other Health Technologies**
    - Technologies' Norms and standards
    - Regulatory systems strengthening
    - Prequalification of medicines, vaccines, diagnostics and devices
    - Safety and Vigilance
New Structure of the Department of Essential Medicines & Health Products in WHO
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

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.
<table>
<thead>
<tr>
<th>Time</th>
<th>Tuesday / 26 August</th>
<th>Wednesday / 27 August</th>
<th>Thursday / 28 August</th>
<th>Friday / 29 August</th>
</tr>
</thead>
<tbody>
<tr>
<td>08:00 - 09:00</td>
<td>Registration</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>09:00 - 10:30</td>
<td>Plenary 1</td>
<td>Workshop A: Best Practices in Pharmacovigilance</td>
<td>Plenary 5: Regulators role in Access/availability (shortages etc.)</td>
<td>Workshop I: Current status and future vision of regulating advanced therapies</td>
</tr>
<tr>
<td></td>
<td>Opening Ceremony</td>
<td>Workshop B: How to ensure the safety of traditional and complementary medicines in national healthcare systems</td>
<td></td>
<td>Workshop J: Managing decentralized GMP inspection systems</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Workshop C: Regulatory models for minimizing risks in blood and blood products</td>
<td>Plenary 6: New trends in regulating medical devices</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Workshop D: Approaches to educating regulators to meet country needs</td>
<td></td>
<td>Workshop K: Current challenges and transparency in clinical trials regulation</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Workshop L: Current Topics and Future developments</td>
</tr>
<tr>
<td></td>
<td>Coffee</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11:00 - 12:30</td>
<td>Plenary 2</td>
<td>Workshop C: Regulatory models for minimizing risks in blood and blood products</td>
<td>Plenary 6: New trends in regulating medical devices</td>
<td>Workshop K: Current challenges and transparency in clinical trials regulation</td>
</tr>
<tr>
<td></td>
<td>Update on 15th ICDRA recommendations Global context – WHO</td>
<td>Workshop D: Approaches to educating regulators to meet country needs</td>
<td>Plenary 6: New trends in regulating medical devices</td>
<td>Workshop L: Current Topics and Future developments</td>
</tr>
<tr>
<td></td>
<td>Lunch</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14:00 - 15:30</td>
<td>Plenary 3</td>
<td>City Tours</td>
<td>Workshop E: Challenges of vaccines regulation and safety monitoring</td>
<td>Plenary 7: Recommendations Closing remarks</td>
</tr>
<tr>
<td></td>
<td>The role of drug regulatory authorities in national health systems</td>
<td></td>
<td>Workshop E: Challenges of vaccines regulation and safety monitoring</td>
<td>Plenary 7: Recommendations Closing remarks</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Workshop F: Collaboration for ensuring the quality and safety of Active Pharmaceutical Ingredients</td>
<td>Workshop G: Preventing and reducing the risk to public health from SSFPC medical products</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Workshop G: Preventing and reducing the risk to public health from SSFPC medical products</td>
<td>Workshop H: Biosimilars</td>
<td>Workshop I: Current status and future vision of regulating advanced therapies</td>
</tr>
<tr>
<td></td>
<td>Coffee</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16:00 - 17:30</td>
<td>Plenary 4</td>
<td></td>
<td>Workshop G: Preventing and reducing the risk to public health from SSFPC medical products</td>
<td>Workshop I: Current status and future vision of regulating advanced therapies</td>
</tr>
<tr>
<td></td>
<td>Strengthening regulatory systems for medical products</td>
<td></td>
<td>Workshop G: Preventing and reducing the risk to public health from SSFPC medical products</td>
<td>Workshop I: Current status and future vision of regulating advanced therapies</td>
</tr>
</tbody>
</table>
Moreover, whereas 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.
Executive Board, January 2014
B134-R17, Requests the director General WHO:

(3) to prioritize support for establishing and strengthening regional and subregional networks of regulatory authorities, as appropriate, including strengthening areas of regulation of health products that are the least developed, such as regulation of medical devices, including diagnostics;

(4) to promote the greater participation of Member States in existing international and regional initiatives for collaboration, harmonization and convergence in accordance with WHO principles and guidelines;
Conclusions:

1. WHO re-organization needs staff/ resources/ information on: standards and norms, strengthening regulatory authorities, safety and vigilance of medical devices.

2. 2nd 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. 16th 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.