WHO and International Regulatory Harmonization Activities for the Regulation of Medical Devices and IVDs

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Prequalification / Policy Access and Use/Regulatory System Strengthening /Technologies Standards & Norms

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www.who.int/medical_devices/

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Regulating Medical Devices

Bridging gaps on a global scale

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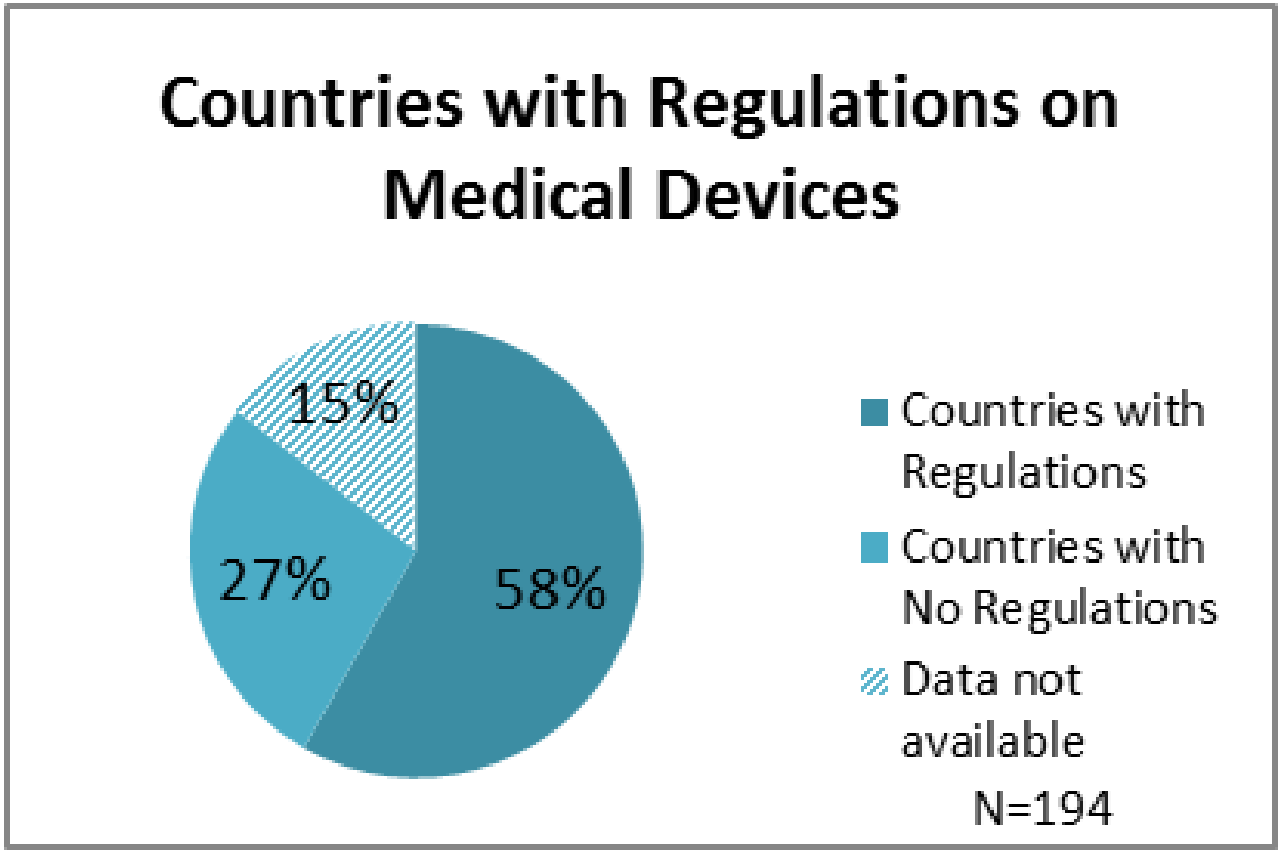
Outline of WHO Regulatory Activities

- Introduction
- WHO Activities – support of harmonisation initiatives
- WHO Activities – promoting harmonisation through regulatory science
- WHO Global Regulatory Model

Regulation of medical devices: global perspective



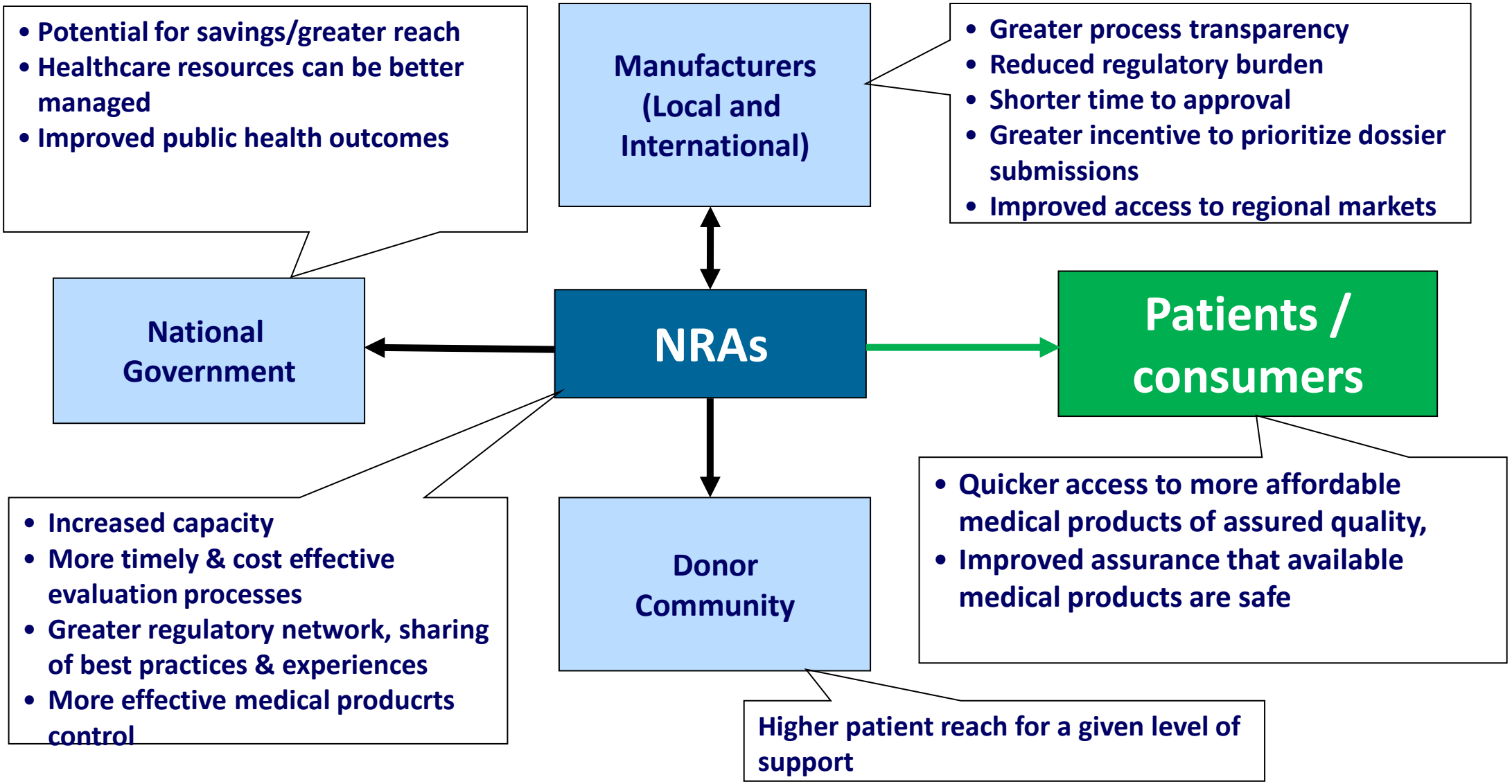
WHO mandate on regulating medical devices

- WHA 67.20 Regulatory System Strengthening for medical products

> ... 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***;

http://apps.who.int/gb/ebwha/pdf_files/WHA67/A67_R20-en.pdf

Why WHO Supports Harmonisation



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Global

IMDRF International Medical Device Regulators Forum

- Home
- About IMDRF
- Work items
- Consultations
- Documents
- Meetings
- Stakeholders
- Recent updates
- GHTF Archive

International Medical Device Regulators Forum

A- A+

The International Medical Device Regulators Forum (IMDRF) was conceived in February 2011 as a forum to discuss future directions in medical device regulatory harmonization.

It is a voluntary group of medical device regulators from around the world who have come together to build on the strong foundational work of the Global Harmonization Task Force on Medical Devices (GHTF), and to accelerate international medical device regulatory harmonization and convergence.

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Global

- International Generic Drug Regulators Programme (IGDRP)

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Global

- International Conference of Drug Regulatory Authorities (ICDRA)

Global

- **WHO Blood Regulators Network**
  - comprised of leading international regulatory authorities that have responsibility for the regulation of blood, blood products and related IVDs
  - forum for the exchange of information and opinion among members on blood-related issues.
  - Focus
    - scientific assessment of current and emerging threats to the safety and availability of blood and blood products,
    - assessment of the impact of new blood-related technologies, and
    - explores opportunities for regulatory cooperation and collaboration, where possible.

Regional

- Latin American Alliance for Development of IVDs (ALADDIV)

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Regional

- Asian Harmonization Working Party (AHWP)
  - Increasing support for WG2 (Premarket IVDD)
    - WHO technical guidance development
    - AHWP guidance
  - Review of legislation
  - Training

Regional

- Pan African Harmonization Working Party
  - Founding nations
    - EAC and EAC partner states, Ethiopia, Nigeria and South Africa
    - Housed under AU-NEPAD (AU's partnership for African development)
    - Project facilitated by LSHTM, supported by WHO, ASLM, GIZ, GCC
  - Working groups
    - Risk classification
    - Registration Files
    - Auditing quality management
    - Avoiding duplication in clinical Performance Studies
    - Post marketing surveillance
    - Classification
  - Training

Regional

- Association of Southeast Asia Nations (ASEAN)
  - 10 nations: Brunei Darussalam, Cambodia , Indonesia, Laos People's Democratic Republic, Myanmar, Malaysia, Philippines, Singapore, Thailand, Viet Nam
  - Pharmaceutical Product Working Group (PPWG)
    - Common technical document format & requirements
    - Harmonized technical guidelines for pharmaceutical products
      - Quality, efficacy and safety guidelines
    - Harmonized technical guidelines for biotherapeutic products in-progress
      - Vaccines first priority
  - WHO to establish a joint assessment program that has been accepted by heads of agency

Regional

- **African Vaccine Regulatory Forum (AVAREF)**
  - Developing mechanisms and clear pathways for expedited regulatory review of clinical trials and approval of products
  - agreement on timelines and joint review by regulators and ethics committees of clinical trial applications by AVAREF countries
  - endorsement of a panel of safety experts to review safety data of new products and relevant communication with National Regulatory Authorities

Regional

- APLMA
  - Asia Pacific Leaders' Malaria Alliance
  - APLMA is an initiative of Asia Pacific Heads of Government. It was established in response to the East Asia Summit Leaders' call for coordinated action to fight malaria.
  - Supported by WHO
    - Essential medicines
    - Prequalification
  - WHO PQDx working with APALMA
    - requirements for IVDs to detect deficiencies of G6PD

Subregional

- East Africa Community Medicines Regulatory Harmonization (EAC-MRH)
  - 5 partner states and 6 NRAs
  - Technical working groups (TWG's) with WHO involvement:
    - Medicine Evaluation & Registration, GMP Inspection, Quality Management Systems (QMS), Information Management System
  - EAC harmonized guidelines for medicine evaluation & registration, GMP and QMS
    - All approved at EAC level
    - Different stages of implementation
  - Collaborative assessment for registration of medicines (WHO PQ and Swiss Medic in pilots)
  - Development of framework for medical device and IVD regulation

Subregional

- ZAZIBONA Collaborative Process PQ
  - **Za**mbia, **Zi**mbabwe, **Bo**tswana, **Na**mibia of SADC region
  - Collaborative assessments for registration of priority medicines submitted to some/all of the four NRA's
  - ~100 products reviewed, 40% completed of which ~2/3 positive decision
  - Future: to share reports and decisions to NRA's of SADC
  - Open to other SADC NRA's as participant or observer

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Other WHO Regulatory Activities

- Norms and Standards
  - Intended to assist WHO Member States in ensuring consistent quality and safety of biological medicines and related IVDs worldwide.
  - WHO Expert Committee on Biological Standardization (ECBS)
    - commissioned by WHO to establish detailed recommendations and guidelines for the manufacturing, licensing, and control of blood products, cell regulators, vaccines and related IVDs.

Other WHO Regulatory Activities

- International Biological Reference Materials
  - **"To define an internationally agreed unit to allow comparison of biological measurements worldwide"**
  - WHO provides International Biological Reference Preparations which serve as reference sources of defined biological activity expressed in an internationally agreed unit.
  - These preparations are the basis for a uniform reporting system, helping physicians and scientists involved in patient care, regulatory authorities and manufacturers to communicate in a common language for:
    - designating the activity or potency of blood derived products used in prophylaxis or therapy
    - ensuring the reliability of *IVD s* used for diagnosis of diseases and treatment monitoring

WHO Regulatory Strengthening Activities

- NRA Assessment Tool
  - Designed to be applied by WHO or for self-assessment
  - Can be used as a benchmarking tool when building harmonisation groups
  - The tool is aimed at facilitating the conduct of a comprehensive assessment for medicines including vaccines or assessments targeted at selected product categories (vaccines or medicines separately).
  - In the future, it is expected that the tool will be revised to address also blood products, medical devices including diagnostics and traditional medicines.

WHO Regulatory Strengthening Activities

- Capacity-building workshops
  - Organized as follow-up for specific institutional development plans for NRA's
  - Workshops :
    - QMS in Thailand in June 2016
    - GMP inspection in India in June 2016 and in Russia in July 2016
    - PV inspection in Malaysia in Aug 2016

Other WHO Regulatory Activities

- Prequalification Activities
  - PQ requirements
  - PQ guidance
  - PQ requirements training
  - Sample dossiers
  - Assessment meetings
  - PMS
  - WHO Collaborative Procedure
  - WHO Joint Assessment
  - Rotational Fellows
  - Observers: PQ Inspections

diagnostics@who.int

http://www.who.int/diagnostics_laboratory/evaluations/en/

Other WHO Regulatory Activities

- Reviews of draft medical device and IVD legislation
  - Provides an opportunity to ensure that the legislation is
    - Aligned internationally
    - Maximises potential for reliance or recognition
    - Strong PMS activities

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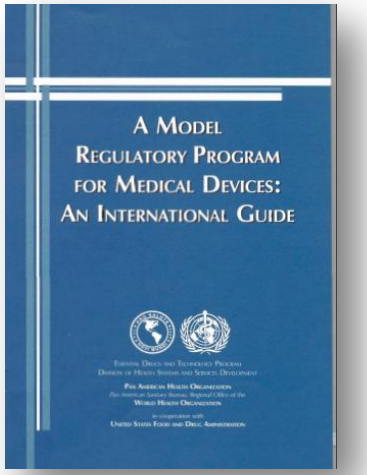
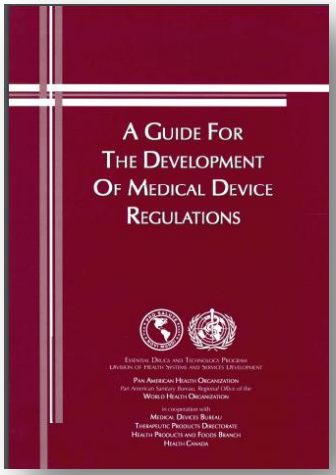
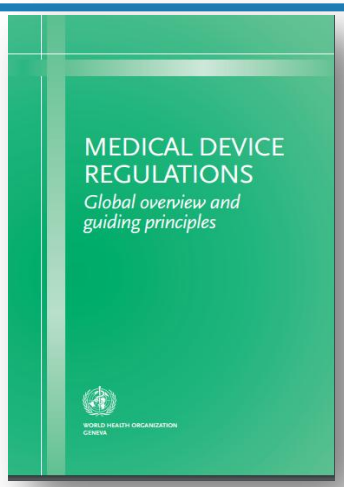
Regulating medical devices - challenges

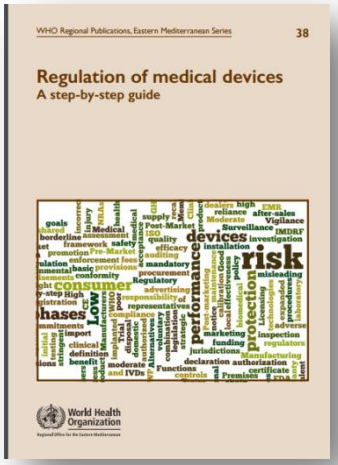
- Less developed regulatory systems than for vaccines and medicines, particularly in LIMC's
  - Lack of awareness
  - Characteristics of medical devices as a product group
  - Regulating in an existing market
  - Lack of specialized knowledge and resources to draft and implement medical devices regulations
  - Lack of resources

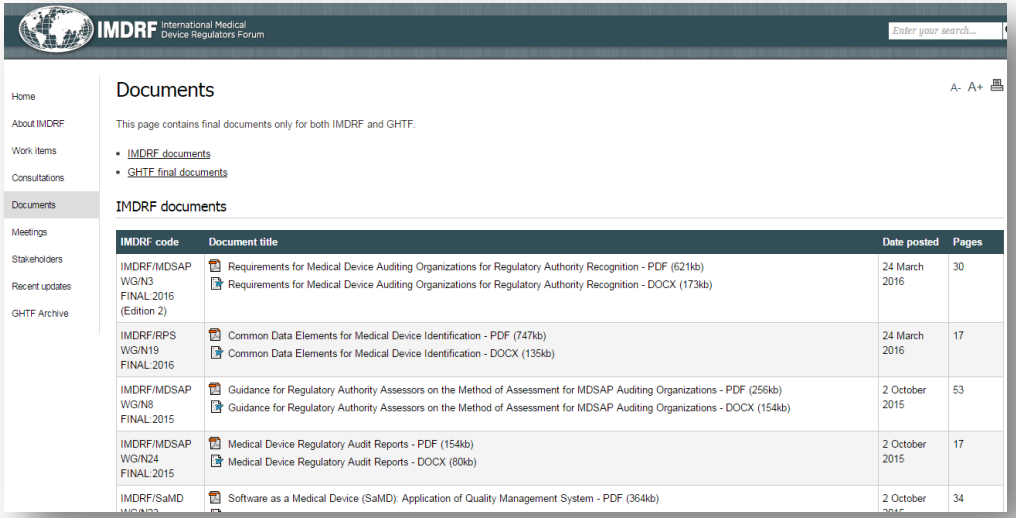
Current guidance

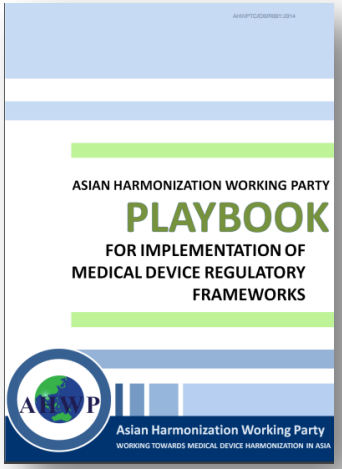


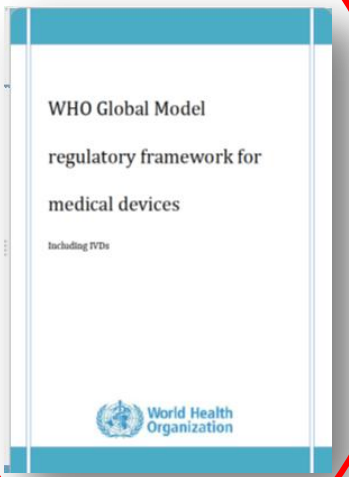












http://www.who.int/medical_devices/en/

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Two steps approach

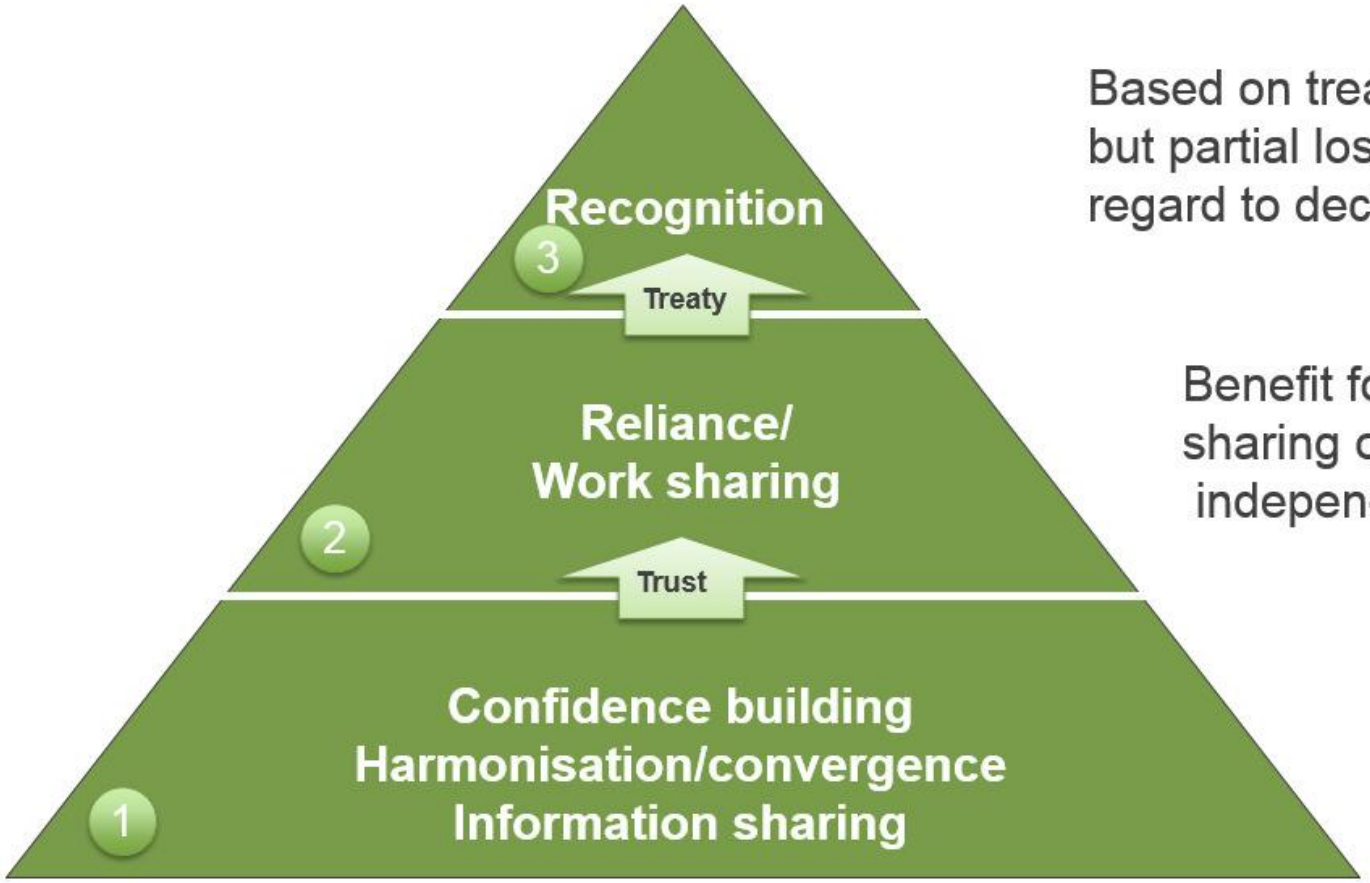
- Basic level controls and enforcement
  - Legal framework
  - Market oversight
  - Reporting system

- Expanded level controls and enforcement
  - regulatory controls depending on the priorities of the country

Convergence and harmonization

- Convergence and harmonization
  - Definition of a medical device
  - Classification of medical devices
  - Essential principles of safety and performance
  - QMS
  - Standards
  - …
- Confidence building and Information sharing
- Reliance and recognition

Reliance and recognition



Based on treaties; «maximal benefit» but partial loss of sovereignty with regard to decision-making

Benefit for regulators; sharing of workload, but independent decisions

«Foundation», Equivalence of requirements

Source: Swissmedic

Good regulatory practices

- Critical elements for regulating medical devices
  - Political commitment
  - Legal framework
  - Implementation plan
  - Competent authority with enforcement power
  - Involvement of stakeholders
  - Transparent and impartial
- Importance of convergence, harmonization, reliance and recognition

Steps

- Public Consultations June and September 2016
  - *http://www.who.int/medical_devices/en/*
- October 2016: WHO Model Regulatory Framework for Medical Devices adopted by Expert Committees
- 2016-2017: Regional workshops
- 2017: Training workshops on regulating medical devices

Acknowledgements

- Mike Ward
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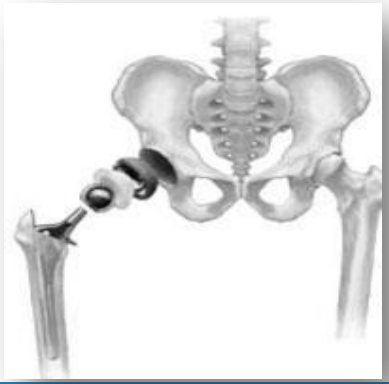

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