Laboratorio di Tecnologie Biomediche

Introduction to medical devices

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Medical Device

- A Medical Device is identified by means of its INTENDED PURPOSE
- Intended to treat, prevent or control physiological characteristics of a living being
  - Disease
  - Handicap
  - Conception
  - Anatomy
  - ...

Some example of medical device

- Band aids
- Incontinence pads
- ECG
- RMI
- Heart valves from bovine or porcine tissue
- Knee joints
- Hearing aids
- Vessel mesh
- Bone fillers
- Dental implants
- Bone screws both removable or permanent
- Defibrillators
- IV sets
- Syringes
- Eye drops (artificial tears)
- ....and on

Comments

- Use on humans (or animals on a lower grade of regulation)
- Intended to have a MEDICAL purpose, excluding devices intended for
  - Esthetical purposes
  - Research not aimed to marketing of the device
- Multiple ways of interacting with the human body
  - Implant to NO corporeal interaction (medical SW)
  - Temporary or permanent
  - Acute or chronic
  - Energy or substance exchange
- Clinical effectiveness vs efficacy
- Performance: technical performance + clinical effectiveness (SAFE and EFFECTIVE)

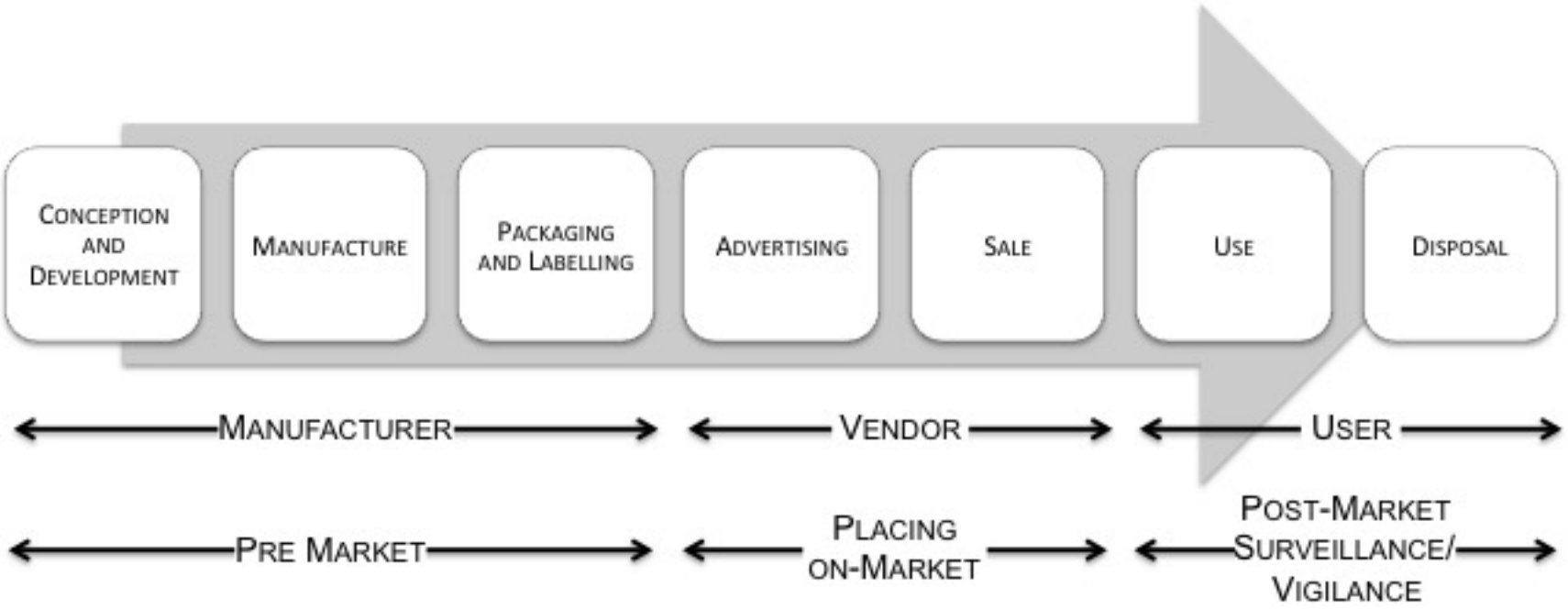
Medical Device Safety

- Absolute safety cannot be guaranteed
- It is a risk management issue
- It is closely aligned with device effectiveness/performance
- It must be considered throughout the life span of the device
- It requires shared responsibility among the stakeholders

Medical Device Safety

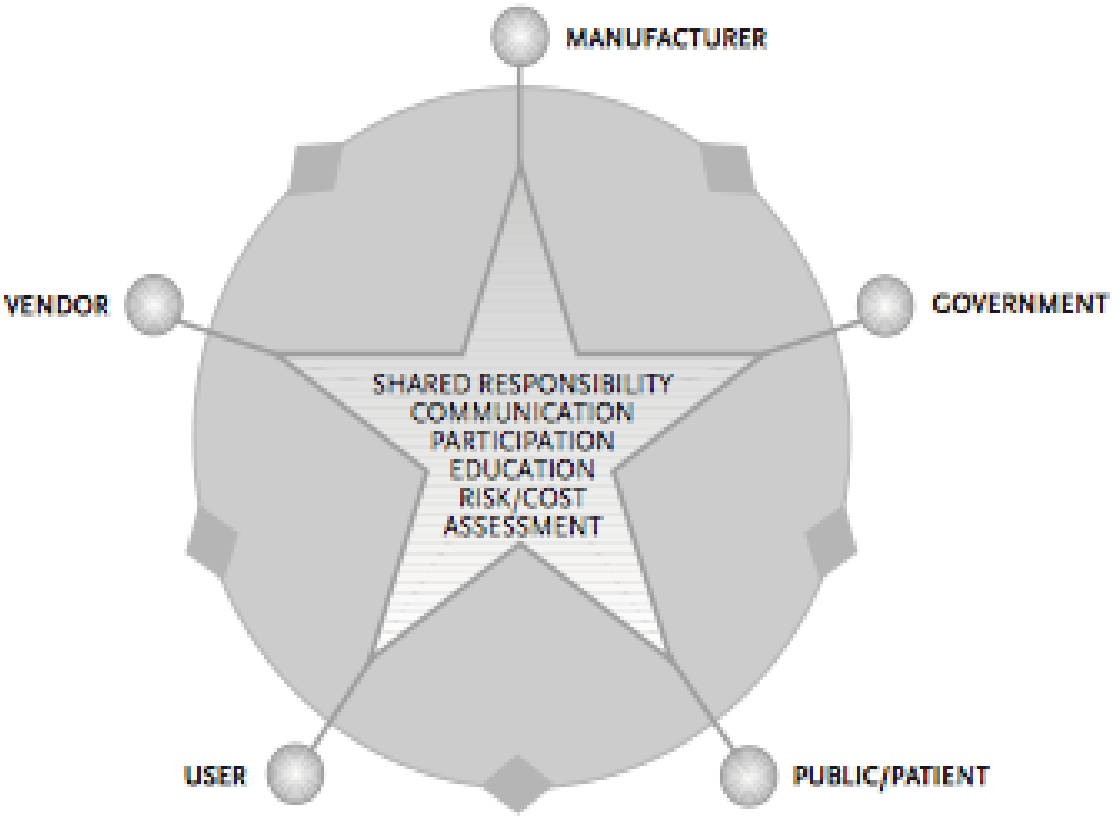
- Risk assessment
  - Potential risks associated with the devices
- Criteria
  - applied to a vast range of different medical devices and technologies
  - combined in various ways in order to determine classification
- Risk management
  - Higher for higher risk classes
  - From self- declaration to comprehensive device and company audit by Notified Body

Life cycle of a medical device



Stakeholders

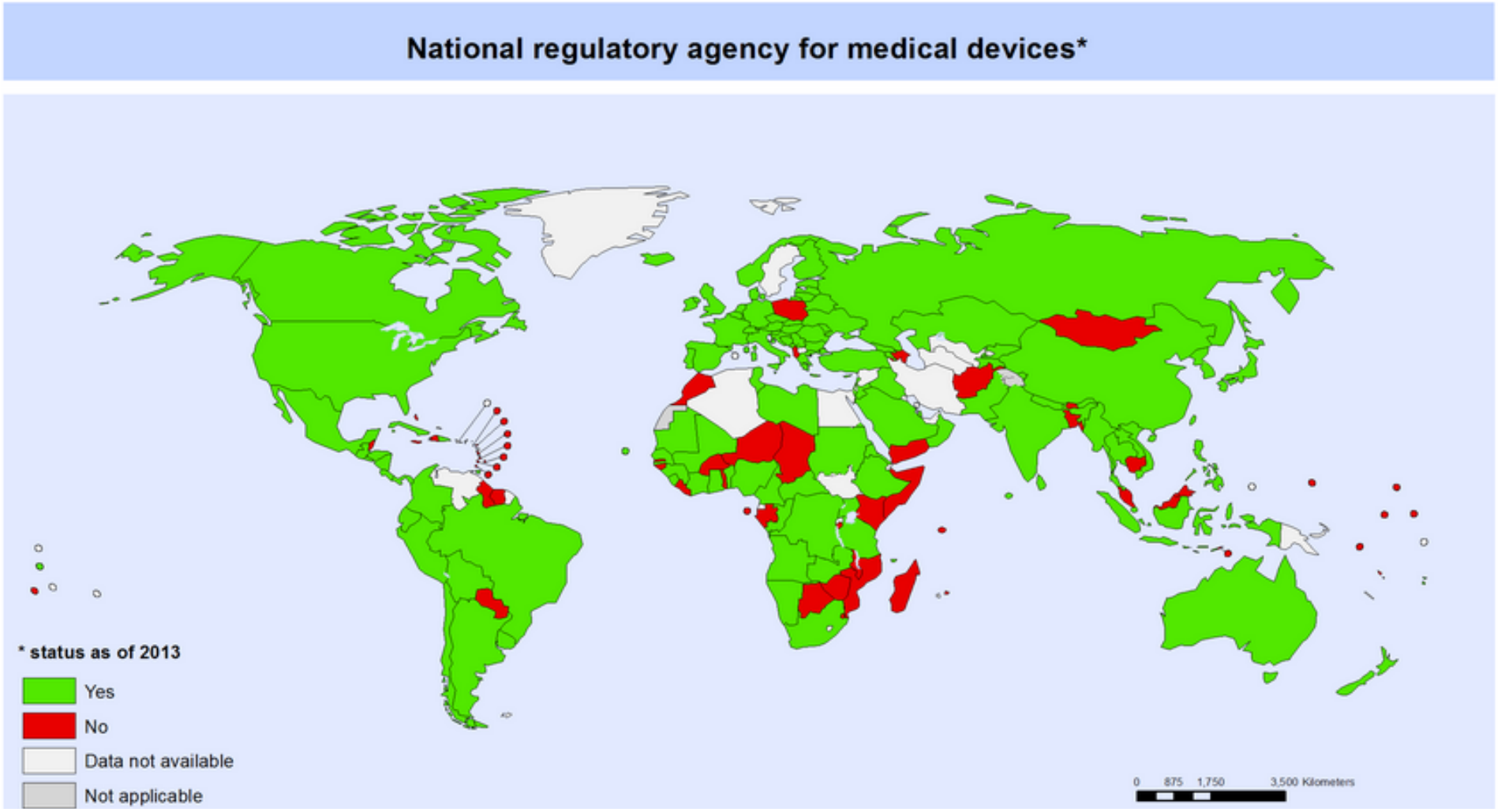
- Manufacturer
- Vendor
- User
- Public / Patient
- Government



Standards & regulations

- Standards
  - Recommendations
  - Use is voluntary
  - Available to the public
  - Established by consensus of all parties concerned
  - Based on consolidated results of science, technology and experience
  - Approved and published by recognized standardisation body
- Regulations
  - Legislation
  - Use is mandatory
  - Available to the public
  - Developed by an authority under public observation
  - Provide technical specifications either directly or by reference, e.g. to standards
  - Adopted by an authority

Standards & regulations



Standards & regulations

- Efficient regulations system means:
  - Safety for patients and workers
  - Higher quality of devices
  - Reliability in diagnostic exams
  - Healthcare for the whole community

Standards & regulations

- International regulation agencies for global harmonization
  - WHO, Harmonization Task Force (GHTF, no more active) , International Medical Devices Regulatory Forum (IMDRF)
- International regulation agencies for regulatory harmonization in a specific area
  - Europe, Africa, Asia, …
- National regulation agencies

Standards & regulations

- WHO promotes and recognizes the guidance provided by the 5 study groups of the Global Harmonization Task Force (GHTF) during the last 20 years.
- WHO is an official observer in the management committee of the International Medical Devices Regulatory Forum (IMDRF).

World Health Organization

Standards & regulations

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

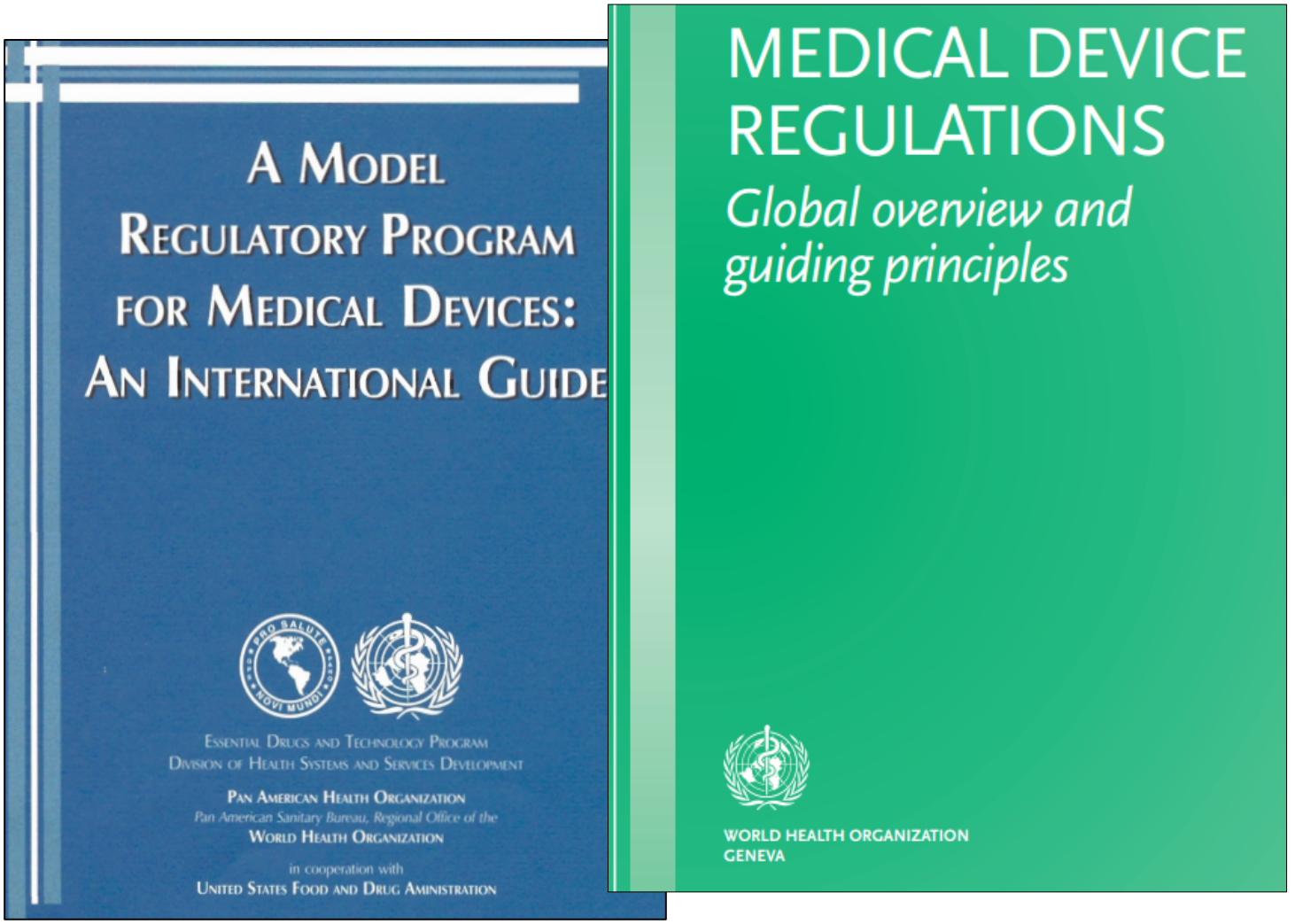
IMDRF International Medical Device Regulators Forum

Standards & regulations

- Europe:
  - European Committee for standardization (CEN)
- USA
  - Food and Drug Administration (FDA)
- South America
  - Latin American Harmonization Working Party (LAHWP)
- Asia
  - Asian Harmonization Working Party (AHWP)
- Africa
  - Pan African Harmonization Working Party on Medical Devices and Diagnostics (PAHWP)
  - NEPAD with African Medicines Regulatory Harmonization Programme

Standards & regulations

Available in a free pdf version on the WHO website, www.who.int



Standards & regulations

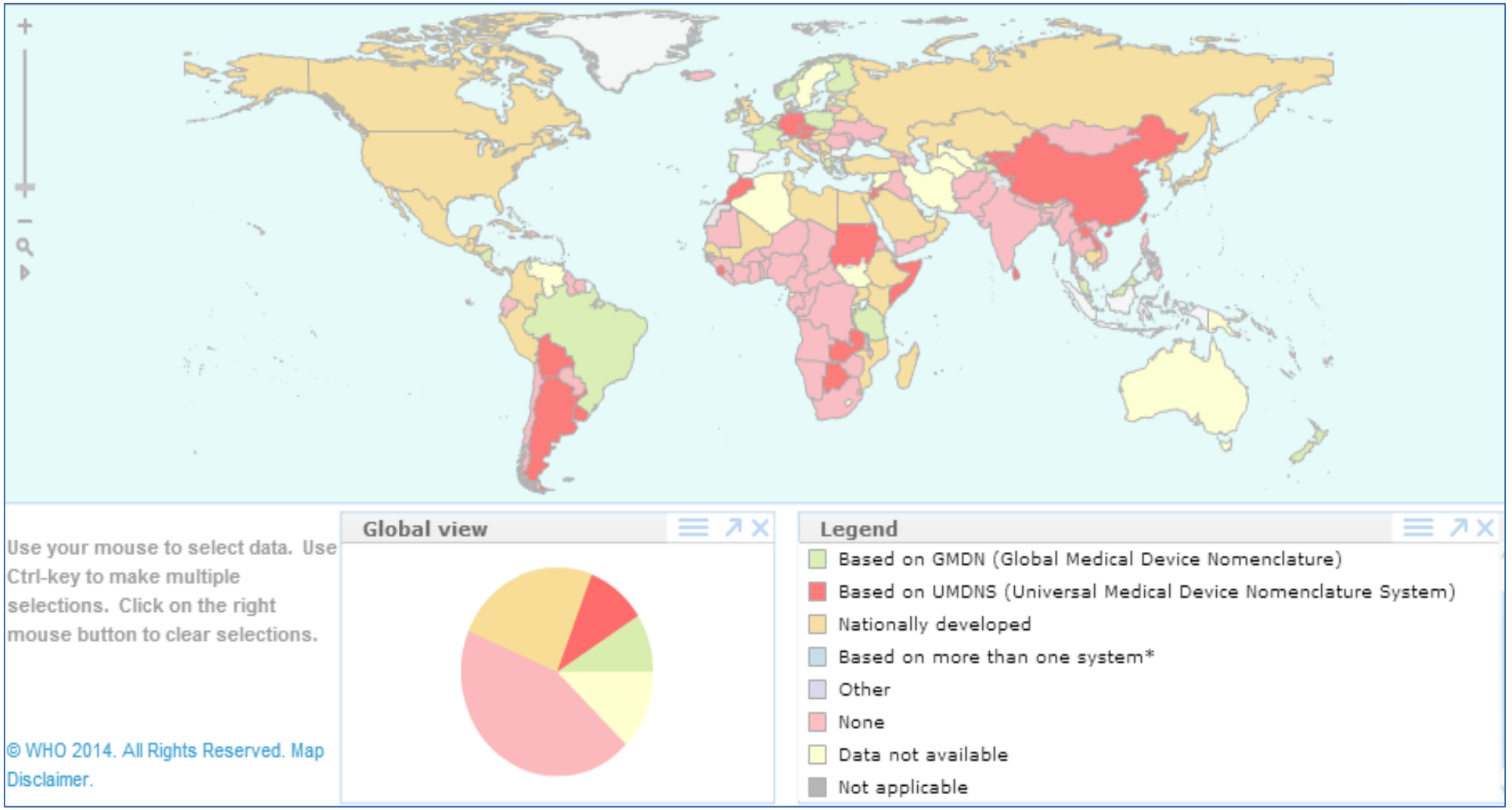
- A nomenclature system is also useful to classify devices and harmonize regulations.
  - GMDN agency: Global Medical Device Nomenclature (www.gmdnagency.com)
  - ECRI institute: Universal Medical Device Nomenclature System (UMDNS) (www.ecri.org)

G·M·D·N AGENCY

ECRI Institute
The Discipline of Science. The Integrity of Independence.

Standards & regulations

Nomenclature distribution

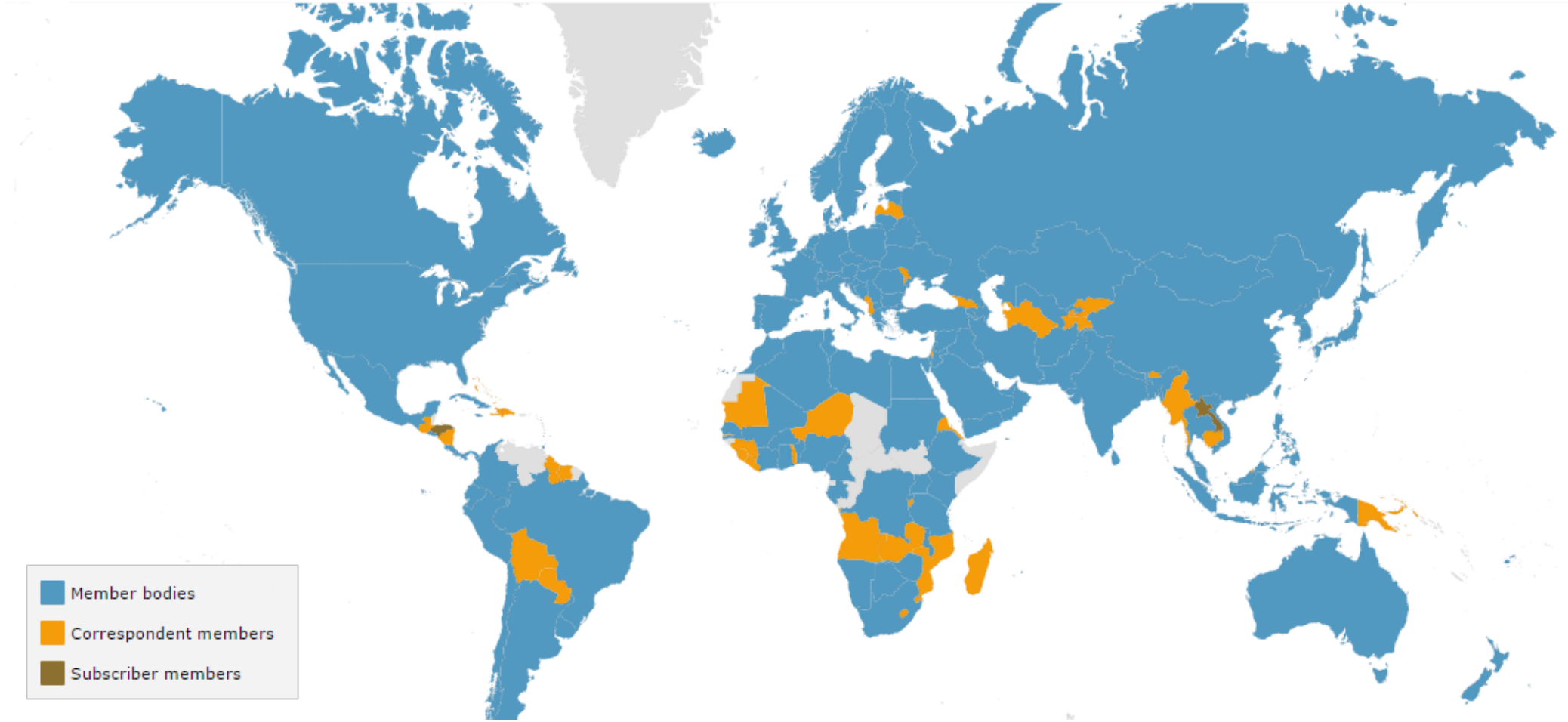


ISO standards

- Non-governmental membership organization
- The world's largest developer of voluntary International Standards
- Members from 165 countries and 3,368 technical bodies to take care of standard development

ISO standards

ISO Members



Other standardization agencies

- International Electrotechnical Commission (IEC)
- ASTM international
- World Wide Web Consoritum (W3C)

Medical Device Regulation (MDR)

- The MDR is a law that regulates the marketing of Medical Devices in the European Community
- Details the device identification
  - Classification
  - Application
- Defines manufacturers responsibilities and duties
  - Safety and performance requirements
  - Surveillance
- Gives powers to the Local Authorities to control the putting on the market of the devices

Suggestion

https://www.sciencedirect.com/science/article/pii/S2211883718300303

Available online at www.sciencedirect.com

ScienceDirect

journal homepage: www.elsevier.com/locate/hlpt

Safe innovation: On medical device legislation in Europe and Africa

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