Laboratorio di Tecnologie Biomediche

Introduction to medical devices

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What do they have in common?

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
- Software for surgical planning
- 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
  - Aesthetic 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)

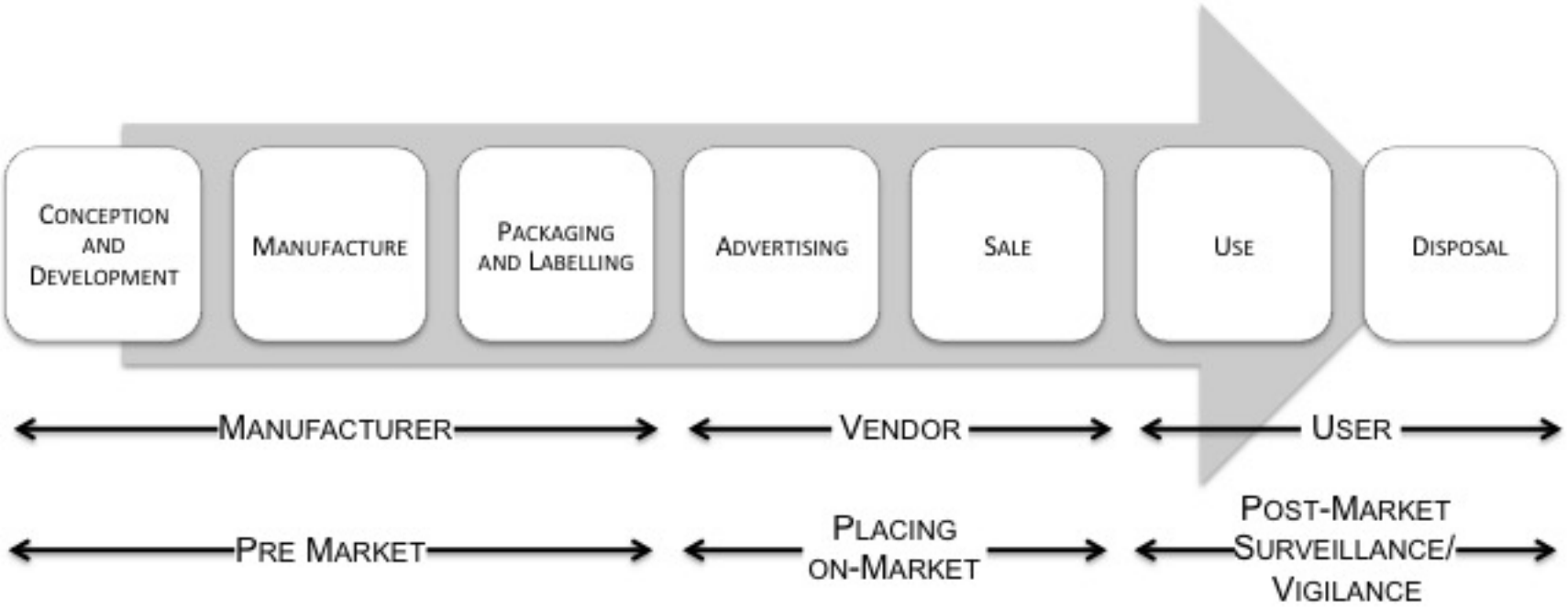
Medical Device Safety

- 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

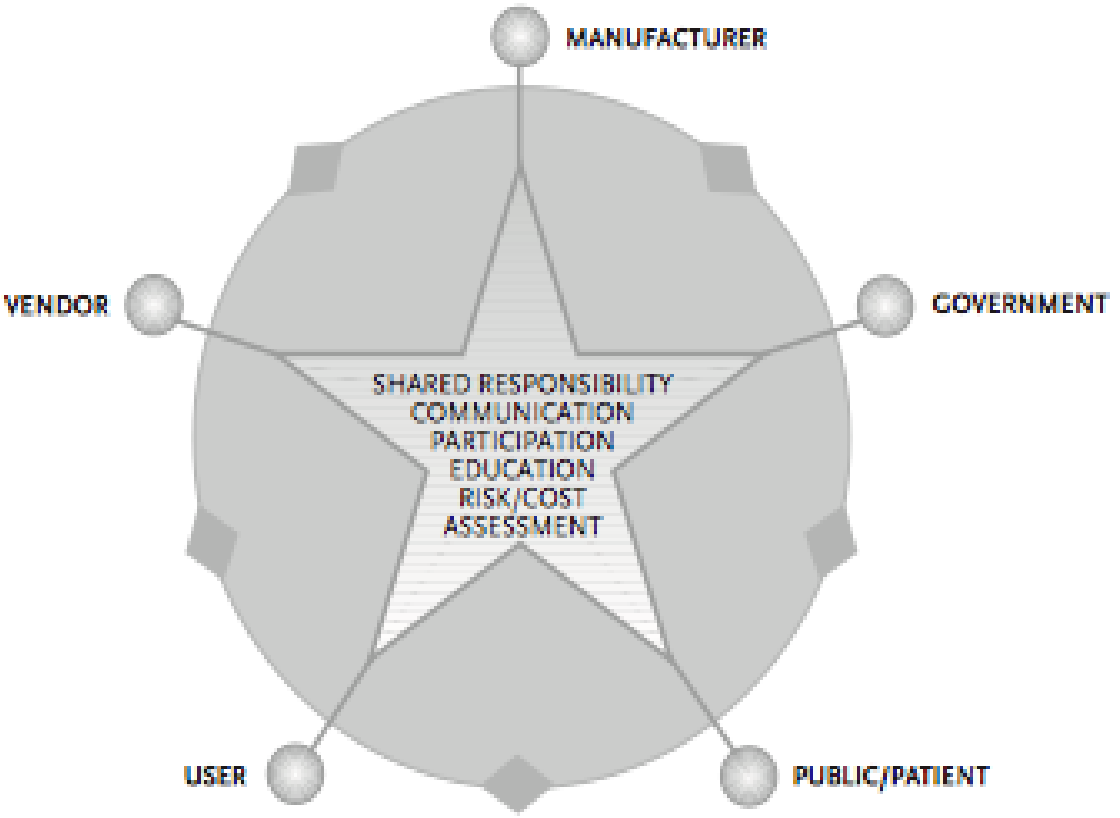
- Risk assessment
  - Potential risks associated with the devices
- Criteria
  - applied to a vast range of different medical devices and technologies
  - combined in various ways in order to determine classification
- Risk management
  - Higher for higher risk classes
  - From self- declaration to comprehensive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

Life cycle of a medical device



Stakeholders

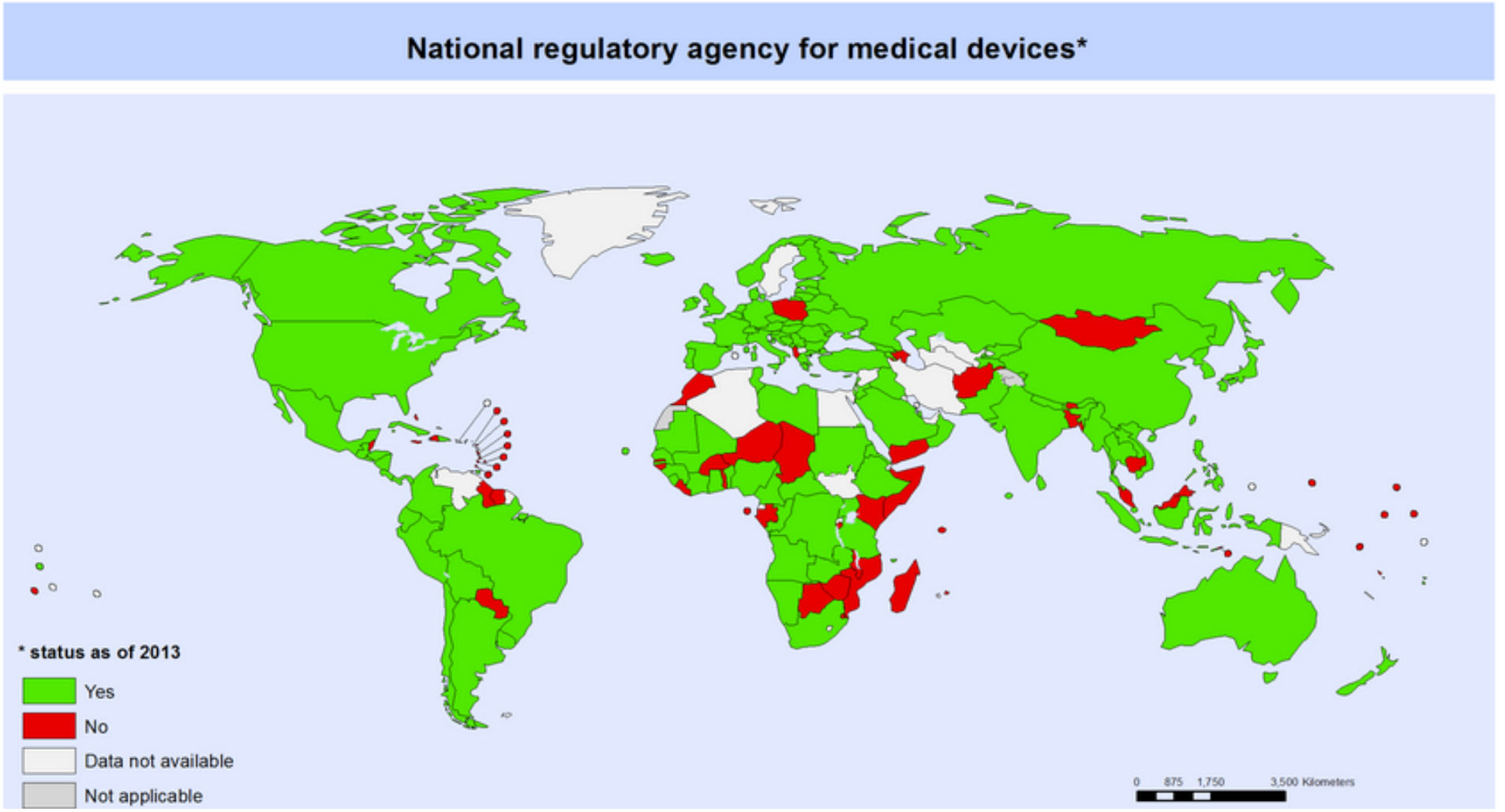
- Manufacturer
- Vendor
- User
- Public / Patient
- Government



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**

World Health Organization

GHTF

Global Harmonization Task Force
(disbanded in 2012)

IMDRF

International Medical Devices
Regulatory Forum

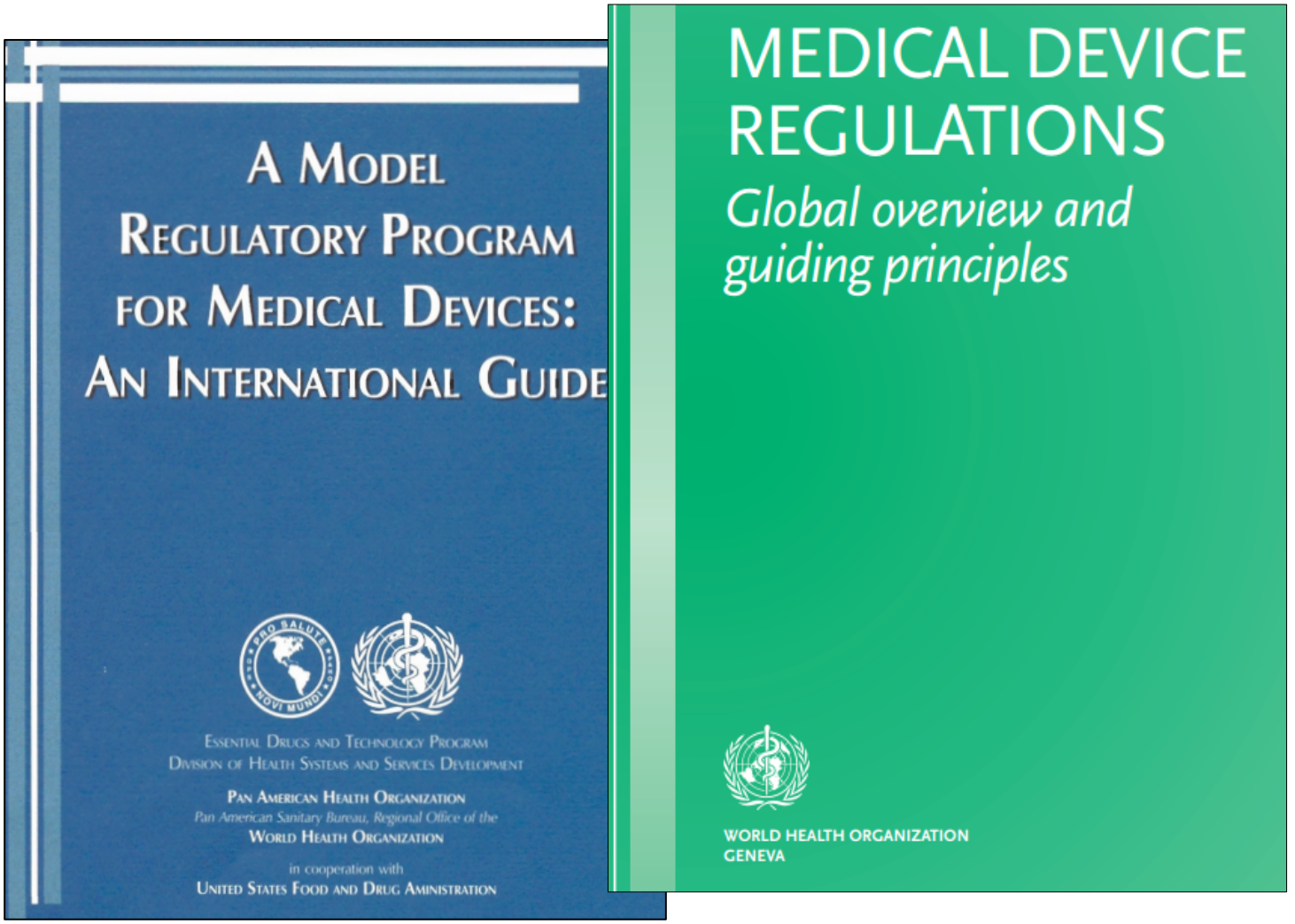
Standards & regulations

Regional agencies for harmonization

- Europe:
  - European Community
- 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

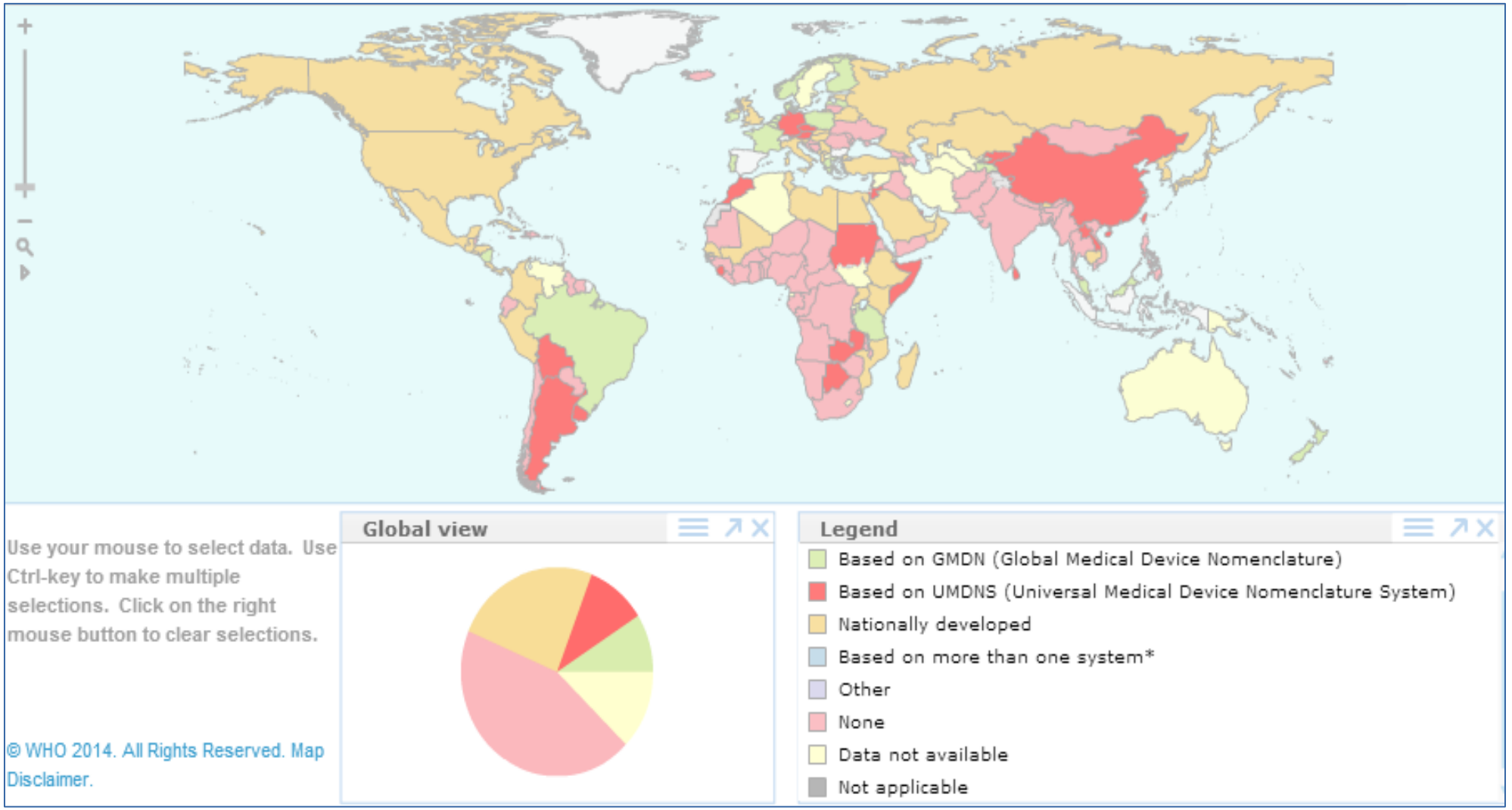
- A nomenclature system is also useful to classify devices and harmonize regulations.
  - GMDN agency: Global Medical Device Nomenclature (www.gmdnagency.com)
  - ECRI institute: Universal Medical Device Nomenclature System (UMDNS) (www.ecri.org)

G·M·D·N AGENCY

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

Standards & regulations

Nomenclature distribution

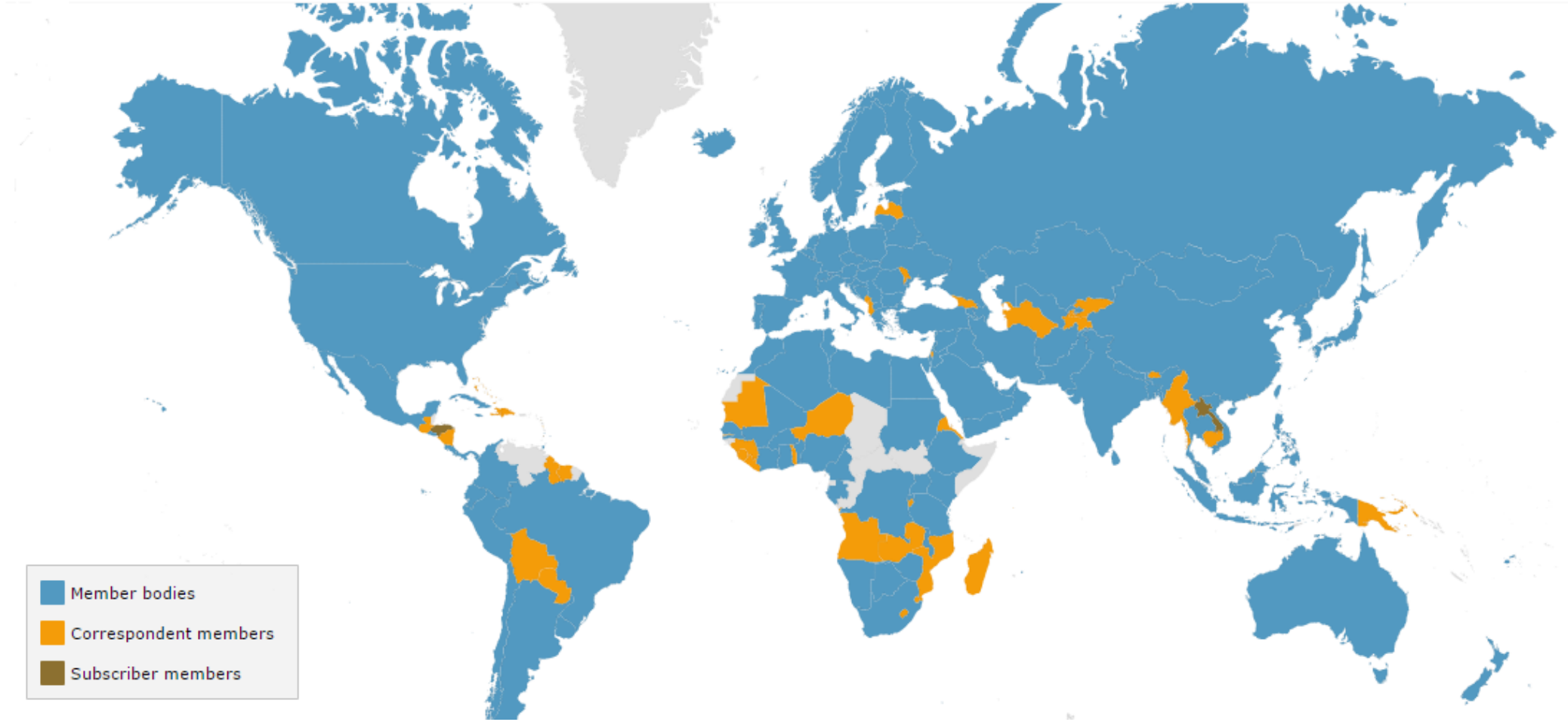


ISO standards

- 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 2017/745 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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