Laboratorio di Tecnologie Biomediche

Introduction to Medical Devices

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What 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
  - …

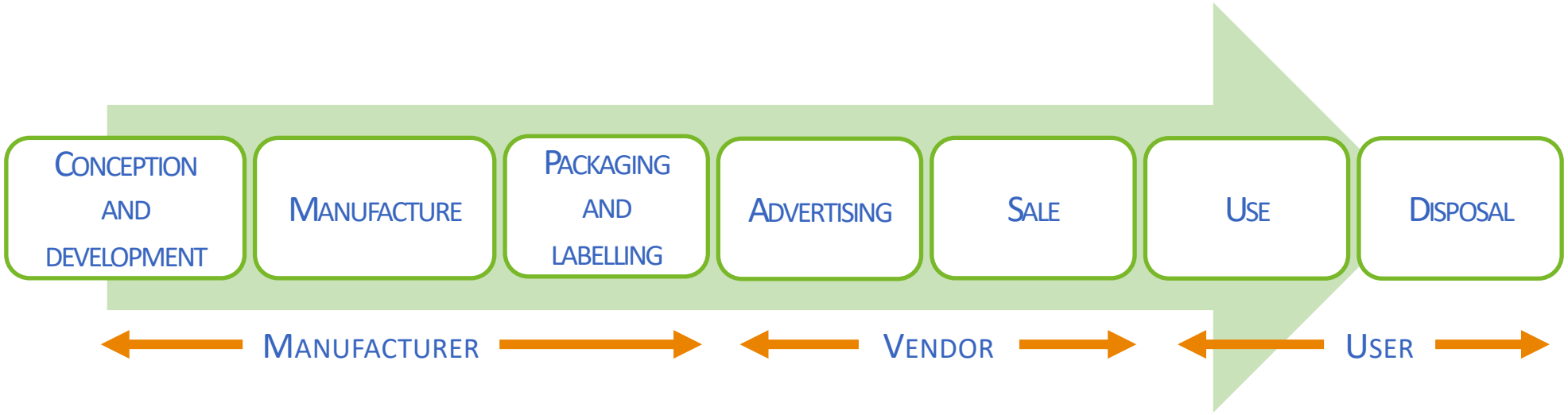
SOME EXAMPLE OF MEDICAL DEVICE

- 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)

LIFE CYCLE OF A MEDICAL DEVICE



- **Stakeholders**: Manufacturer, Vendor, User, Public/Patient, Government

Medical Device Safety

- Ensuring safety of patients, users, bystanders, healthcare providers, environment
- 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

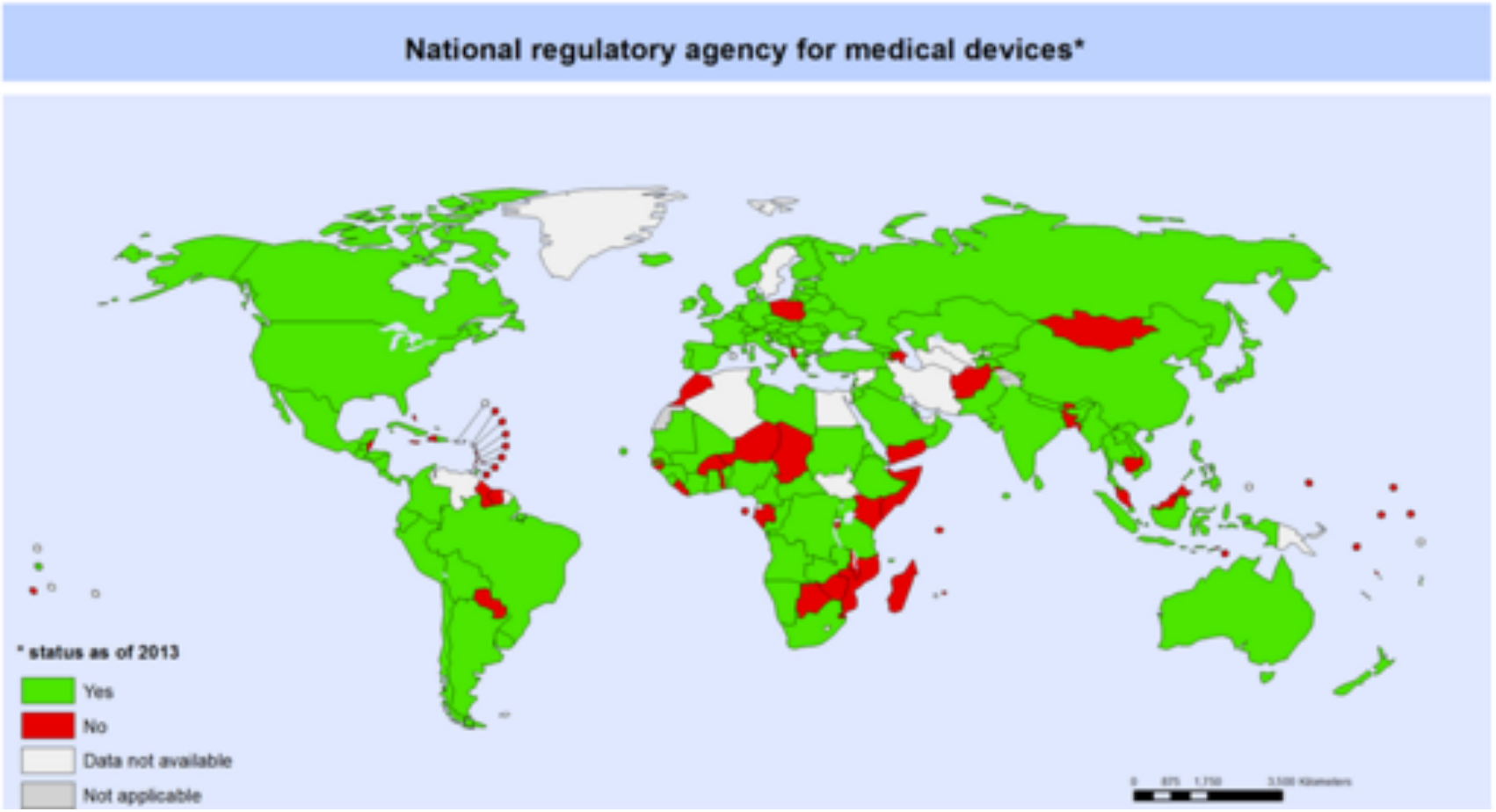
Standards & Regulations

- **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

- Efficient regulation system means:
  - Safety for patients and workers
  - Higher quality of devices
  - Reliability in diagnostic exams
  - Healthcare for the whole community
  - Fair competition in healthcare industries

Standards & Regulations



STANDARDS & REGULATIONS

International regulation agencies for global harmonization

World Health Organization

Global Harmonization Task Force

International Medical Devices Regulatory Forum

World Health Organization

GHTF

IMDRF

Standards & Regulations

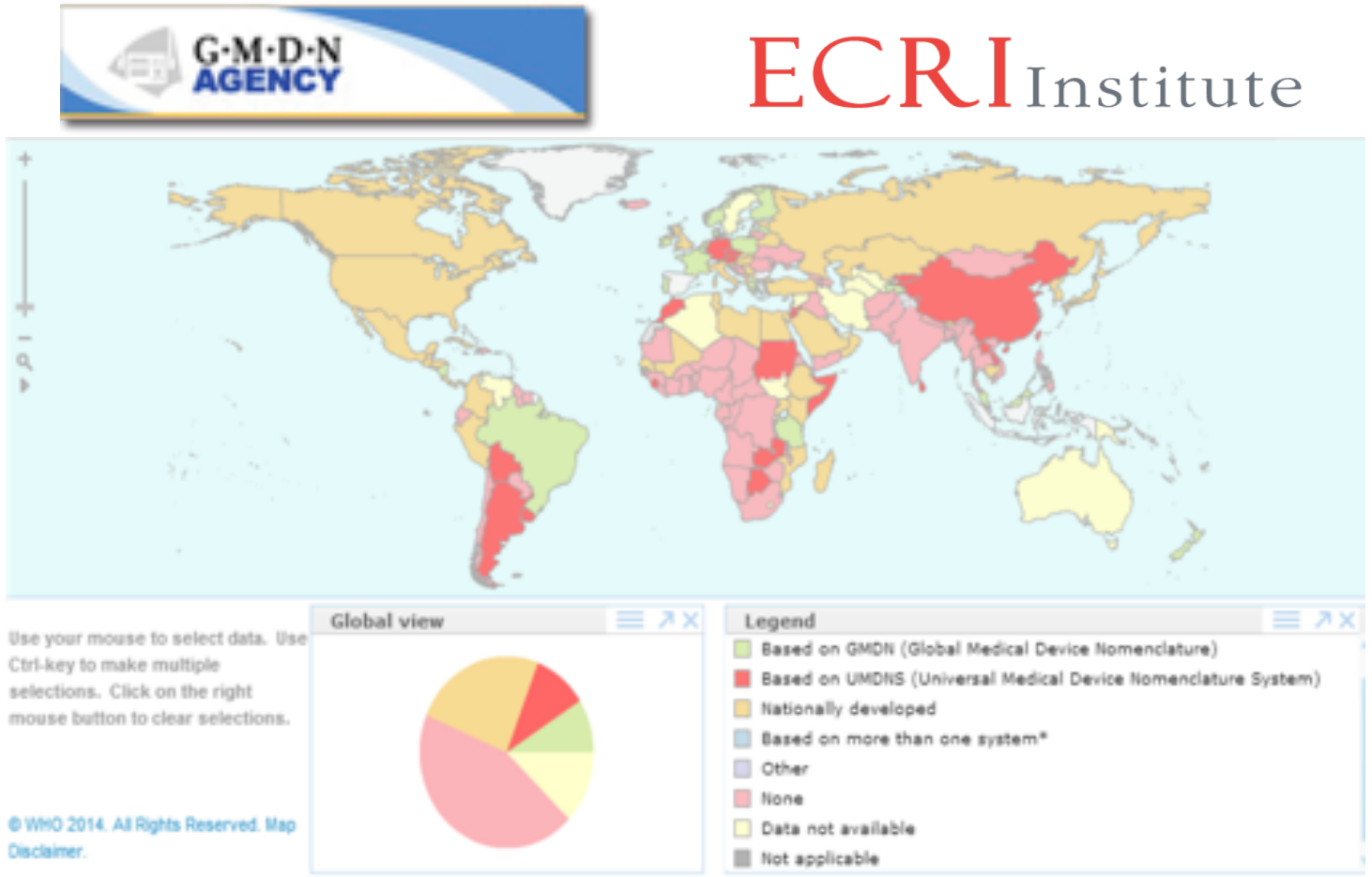
International regulation agencies for regulatory harmonization in a specific area

- Europe
  - European Committee for standardization (CEN)
- USA
  - Food and Drug Administration (FDA)
- South America Asia
  - 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 and 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)



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

International Organization for Standardization

ISO STANDARDS

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

SUGGESTED READINGS

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

Safe innovation: On medical device legislation in Europe and Africa

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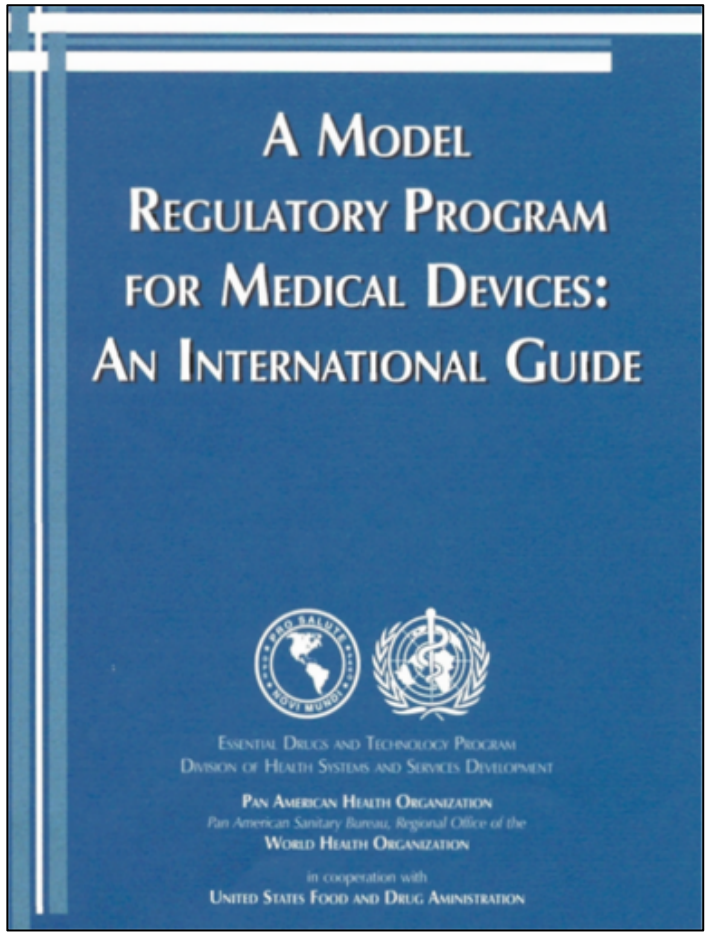
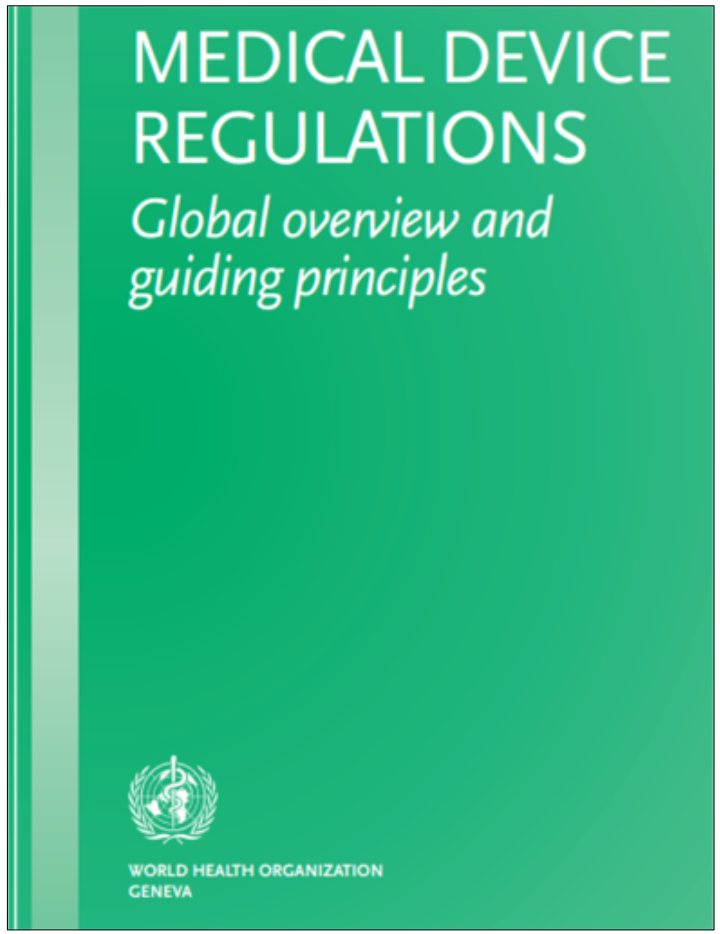
SUGGESTED READINGS

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





SUGGESTED READINGS

Global Atlas of Medical devices

https://www.who.int/medical_devices/publications/global_atlas_meddev2017/en/