References for Medical Device NRAs

Alexandre Lemgruber, PAHO/WHO

Medical Devices Webinar Series USAID – IACRC – FDA

Utilization of Voluntary Consensus Standards and Conformity Assessment

3 March 2022

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REGIONAL WORKING GROUP ON MEDICAL DEVICES REGULATION

Created in 2012, with the aim of strengthening the regulatory capacity of medical devices in the Region of the Americas - 25 NRAs

Argentina	Belize	Bolivia	Brazil	Canada
Chile	Colombia	Costa Rica	Cuba	Dominican Republic
Ecuador	El Salvador	Guatemala	Guyana	Honduras
Jamaica	Mexico	Nicaragua	Panama	Paraguay
Peru	Trinidad and Tobago	Uruguay	USA	Venezuela

ACTIVITIES OF THE REGIONAL WORKING GROUP

- **REGIONAL MEETINGS**
  - Annual face-to-face meetings
  - Open sessions with the stakeholders
- **VIRTUAL MEETINGS**

Regional Working Group

Training

- Annual Virtual Courses in collaboration with CECMED and INVIMA
- Annual face-to-face workshops on defined priority topics

Participation in IMDRF

- Regional Meetings in conjunction with the IMDRF Meetings
- Pparticipation in the IMDRF meetings
- Participation in the Working Groups
- Creation of Mirror Working Groups
- Translation of technical documents

Technical Groups

- Reuse and Reprocessing of Medical Devices
- National Implant Registry

Medical Device Indicators

- Development of Basic Indicators
- Advanced indicators draft
- Participation in the meetings of the Global Benchmarking Tool + medical devices

Communities of Practice

- Medical Devices Regulation
- REDMA Program

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NEXT MEETING OF THE REGIONAL WORKING GROUP

April 2022

VIRTUAL MODE

Session of the Regional Working Group
September 6, 2019 | Bogota, Colombia

Open session with Stakeholders
September 5, 2019 | Bogota, Colombia

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CAPACITY BUILDING IN 2021

VIRTUAL MODULE ON TECHNOVIGILANCE IN COLOMBIA

In collaboration with **INVIMA**	**2021**	**Spanish** Edition

125
participants registered

14
beneficiary countries

Bolivia, Chile, Costa Rica, Cuba, Ecuador, El Salvador, Guatemala, Honduras, Mexico, Nicaragua, Paraguay, Peru, Uruguay and Venezuela

Modules

1. Introduction to Medical Devices and international overview of Technovigilance
2. Progress, challenges and projection of the Colombian Technovigilance Program
3. Steps to implement a Technovigilance Program in Colombia
4. Strengthening Technovigilance in the Context of the COVID-19 Pandemic

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PROGRAM ON EXCHANGE OF REPORTS ON ADVERSE EVENTS OF MEDICAL DEVICES - REDMA PROGRAM

OBJECTIVES

→ Exchange reports of medical devices adverse events or incidents among National Regulatory Authorities of the Americas Region

→ Promote the development of Surveillance Systems

2014

The Mirror Group was established

Secretariat:

- CECMED
- ANVISA
- INVIMA

2015 → 2017

Baseline documents were prepared and approved

- Criteria and Forms
- Declaration of Conformity
- Functioning of the Secretariat
- REDMA Web System User Manual

2016

Technical Meeting for the implementation of the REDMA Program in Havana

2017

REDMA Web System developed by **CECMED**

PILOT STUDY
ARG, BRA, CHI, COL, CUB, MEX, ELS, PAN, DOR, URU.

2018

Technical Meeting for the REDMA Program in Havana

2019

Integration of the **REDMA Web System** within **PRAIS**

Full implementation of the Program on March

CoP REDMA Program
44 members

Updated versions of the program documents are located in the CoP

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REDMA PROGRAM

11

Associate members

BOL | ECU | HND | NIC | PRY | ELS | URY | PAN | DOR | VEN

6

Full members

ARG | BRA | COL | CUB | CHL | MEX

37

Reports

24 Confidential - 13 public

- 86% of the reports are confidential.
- Health institutions reported 50% of the events, manufacturers 37% and users 13%.
- Risk level of the reported equipment: 38% Low-Moderate; 29% High; 21% Moderate-High; 12% Low.
- The most reported medical specialty was cardiovascular with 21%.

REDMA PROGRAM – REDMA WEB SYSTEM

- Secure exchange of adverse event reports of medical devices.
- Integrated into the Regional Platform on Access and Innovation for Health Technologies (PRAIS).
- Access for NRAs members of the REDMA Program.
- Access to the Web System through a unique contact designated by each NRA.

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COLLABORATION WITH THE INTERNATIONAL MEDICAL DEVICE REGULATORS FORUM (IMDRF)

- Regional Meetings of the Working Group in conjunction with the meetings of the IMDRF.
- Participation in face-to-face and virtual meetings of the Forum.
- Participation in IMDRF Working Groups
  - Clinical evaluation of medical devices (represented by ANMAT, Argentina)
  - Personalized medical devices (represented by ANMAT, Argentina)
  - Good regulatory practices (represented by INVIMA, Colombia)
  - **NEW WORKING GROUP** Clinical evidence for In Vitro Diagnostic Medical Devices (represented by CECMED – Cuba, Ministry of Health – Uruguay and PAHO)
- Creation of Mirror Working Groups

COLLABORATION WITH IMDRF

MIRROR GROUPS OF IMDRF WORKING GROUPS

	REDMA Program	Good regulatory review practices	Personalized medical devices	Adverse events terminology
COORDINATOR	CECMED, CUBA	INVIMA, COLOMBIA	ANMAT, ARGENTINA	MINISTRY OF HEALTH, URUGUAY

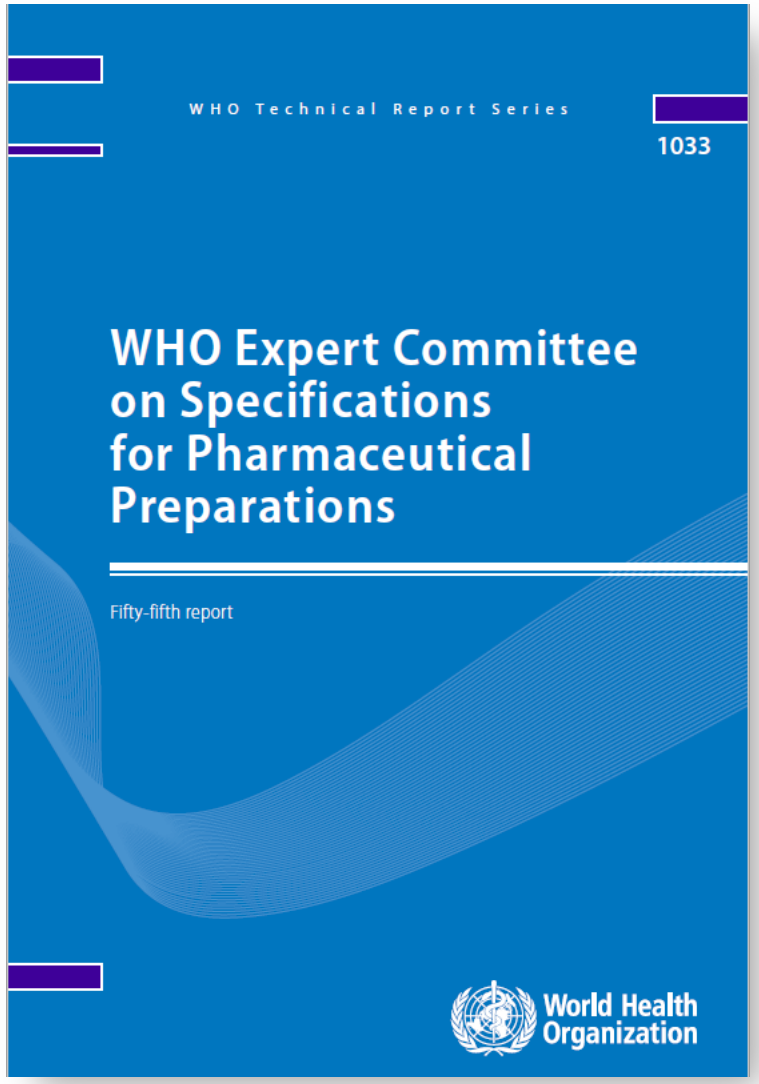
COLLABORATION WITH IMDRF

6
documents
translated
into Spanish

COLLABORATION WITH IMDRF

12 documents are already in the process of being translated

1. Principles of In Vitro Diagnostic (IVD) Medical Devices Classification
2. Requirements for Regulatory Authority Recognition of Conformity Assessment Bodies Conducting Medical Device Regulatory Reviews
3. Personalized Medical Devices - Regulatory Pathways
4. Clinical Investigation
5. Clinical Evaluation
6. Tools for Assessing the Usability of Registries in Support of Regulatory Decision-Making
7. Common Data Elements for Medical Device Identification
8. Software as a Medical Device (SaMD): Key Definitions
9. UDI Guidance. Unique Device Identification (UDI) of Medical Devices
10. Principles of International System of Registries Linked to Other Data Sources and Tools
11. Unique Device Identification system (UDI system). Application Guide
12. Post-Market Clinical Follow-Up Studies



WHO Expert Committee on Specifications for Pharmaceutical Preparations

Fifty-fifth report, 2021

Annex 10

Good reliance practices in the regulation of medical products: high level principles and considerations

Annex 11

Good regulatory practices in the regulation of medical products

Link to the document:
https://www.who.int/publications/i/item/55th-report-of-the-who-expert-committee-on-specifications-for-pharmaceutical-preparations

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ANNEX 11. GOOD REGULATORY PRACTICES

PURPOSE

- Present the **high-level principles** of Good Regulatory Practices.
- Guide Member States in **prioritzing regulatory functions** according to their resources, national objectives, public health policies, medical product policies, and the medical product environment.

SCOPE

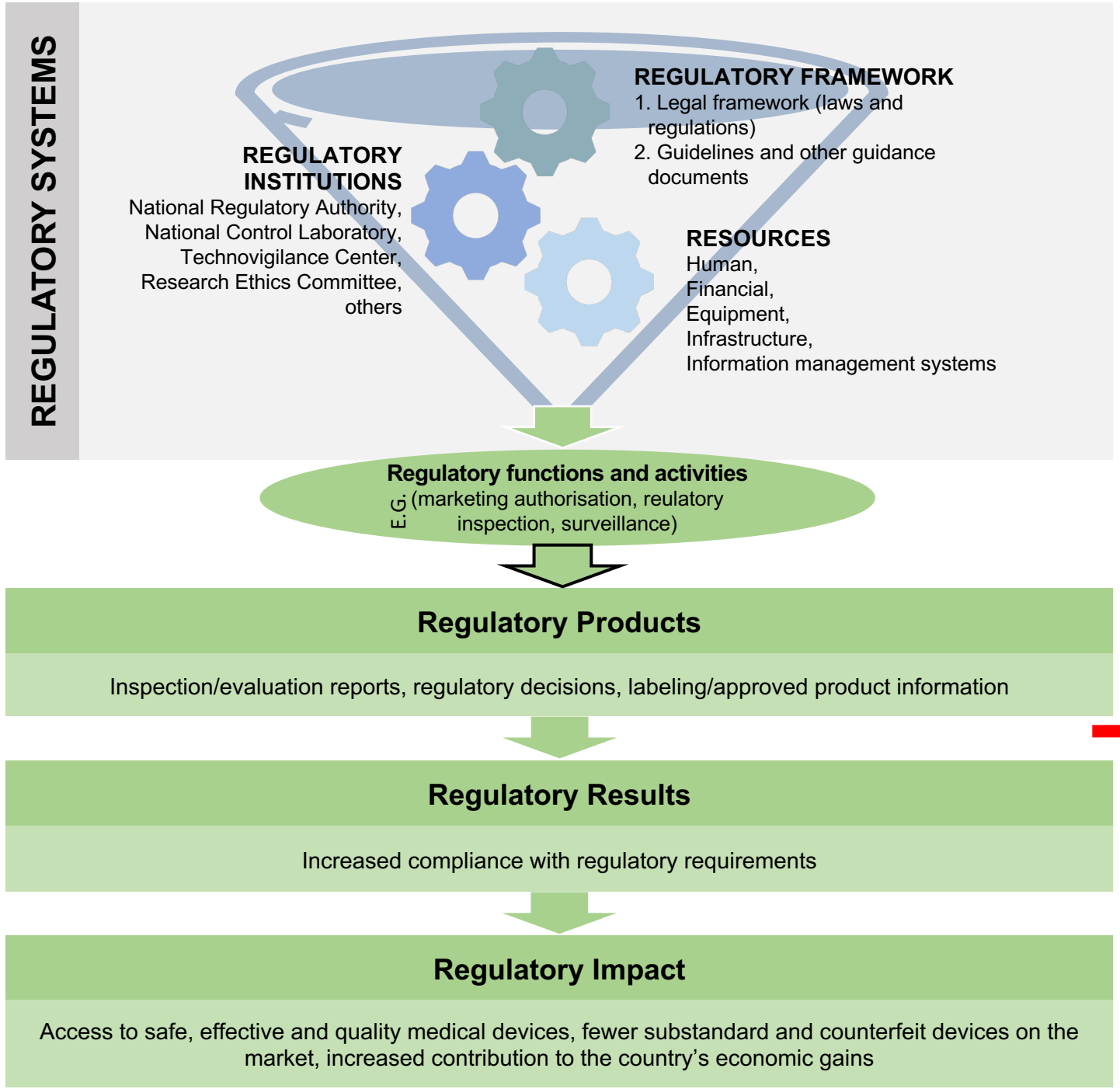
- **Regulatory authorities**, regardless of their resources, maturity or regulatory model;
- **Supranational**, national and subnational regulatory systems;
- Health **institutions and policymakers**, laws, regulations and guidelines;
- **Regulatory networks**;
- **Parties affected or interested** in regulatory frameworks, such as industry.

OBJECTIVES

- Ensure **robust and effective regulation** of medical products,
- Improve **quality, decision-making and regulatory compliance**,
- More **efficient regulatory systems and better** public health **outcomes**,
- **Updated regulatory systems** as the technologies and systems in which they are used continue to evolve,
- Promote **reliance** between regulatory authorities and other stakeholders
- Facilitating **international cooperation**
- Facilitate the **adoption of effective and efficient approaches** to ensure the quality, safety and performance of medical products in the global regulatory community.
- **Serve and protect public health** and the interests of parties.

This document is complemeted by the following guides:

- Good Governance Practices
- **Good Reliance Practices**
- Good Review Practices
- Quality Management System for National Regulatory Authorities



Good Regulatory Practices

Facilitators

- Political and government support
- Good organization, governance and leadership
- Effective communication, collaboration and coordination
- Robust and functional Quality Management System
- Sufficient and sustainable financial resources
- Competent human resources
- Ethics and pre-established organizational values
- Regulatory decision-making process based on science and data

Principles

1. Legality
2. Consistency
3. Independence
4. Impartiality
5. Proportionality
6. Flexibility
7. Clarity
8. Efficiency
9. Transparency

Adapted from Fig. 2 Principles and enablers of good regulatory practices (GRP) and components of a regulatory system. WHO Expert Committee on Specifications for Pharmaceutical Preparations: Fifty-fifth report. Geneva: World Health Organization; 2021 (WHO Technical Report Series, No. 1033). Licence: CC BY-NC-SA 3.0 IGO.

ANNEX 11. GOOD REGULATORY PRACTICES

HIGH-LEVEL PRINCIPLES

These are practices that must be adopted by all institutions responsible or involved in the regulation of medical products.

The nine high-level principles of Good Regulatory Practices are connected to the Global Benchmarking Tool.

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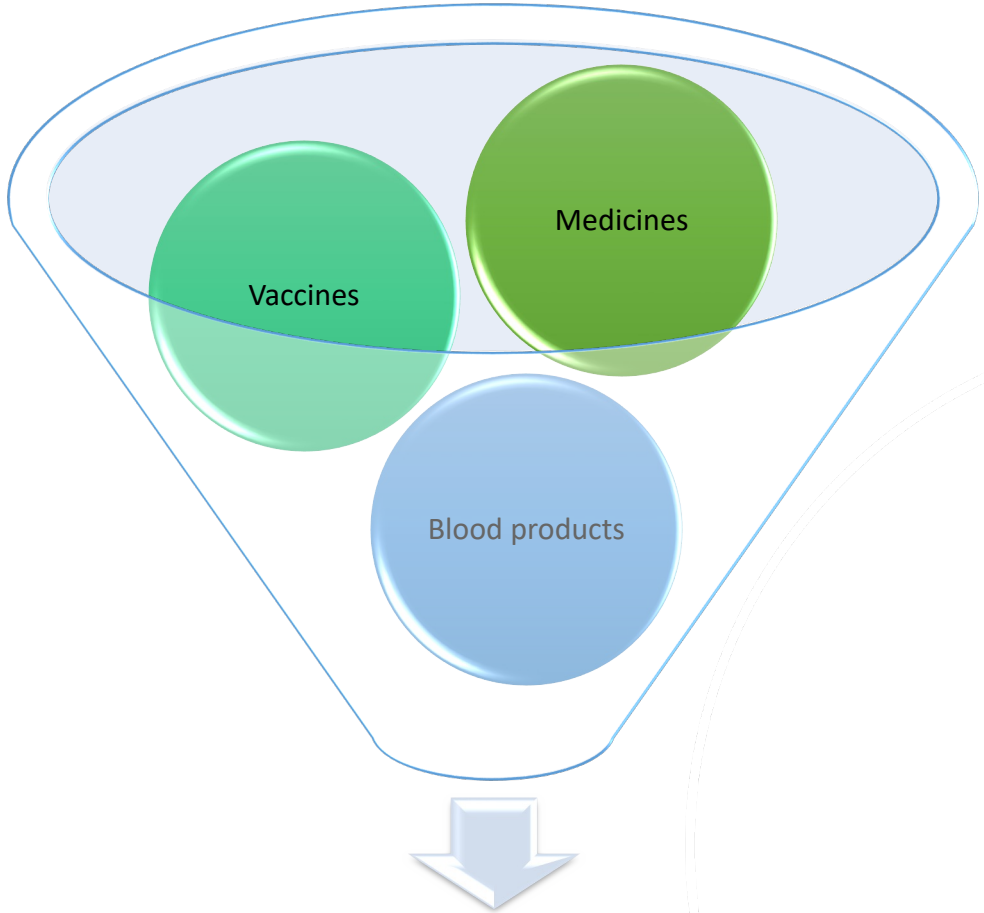
GLOBAL BENCHMARKING TOOL (GBT)

The Global Assessment Tool is the means by which WHO objectively evaluates regulatory systems, as provided in WHA 67.20 on strengthening the regulatory system for medical products.

Link: https://www.who.int/tools/global-benchmarking-tools



GBT +

REGULATORY FUNCTIONS OF THE GBT

Latest version of GBT+ comprises 10 regulatory functions

1. National Regulatory System
2. Registration and marketing authorization
3. Vigilance
4. Market surveillance and control
5. Licensing establishments
6. Regulatory inspection
7. Laboratory testing
8. Clinical Trials Oversight
9. NRA Lot Release
10. Authorization of blood products

WORKING GROUP FOR THE INTEGRATION OF MEDICAL DEVICE INDICATORS, INCLUDING IN VITRO DIAGNOSTIC INDICATORS IN GBT+

OBJECTIVES

- Integration of medical devices, including IVD, into WHO GBT+,
- Identify new functions, indicators and sub-indicators specific to medical devices, including IVD, considering their particularities.

EXPECTED RESULTS

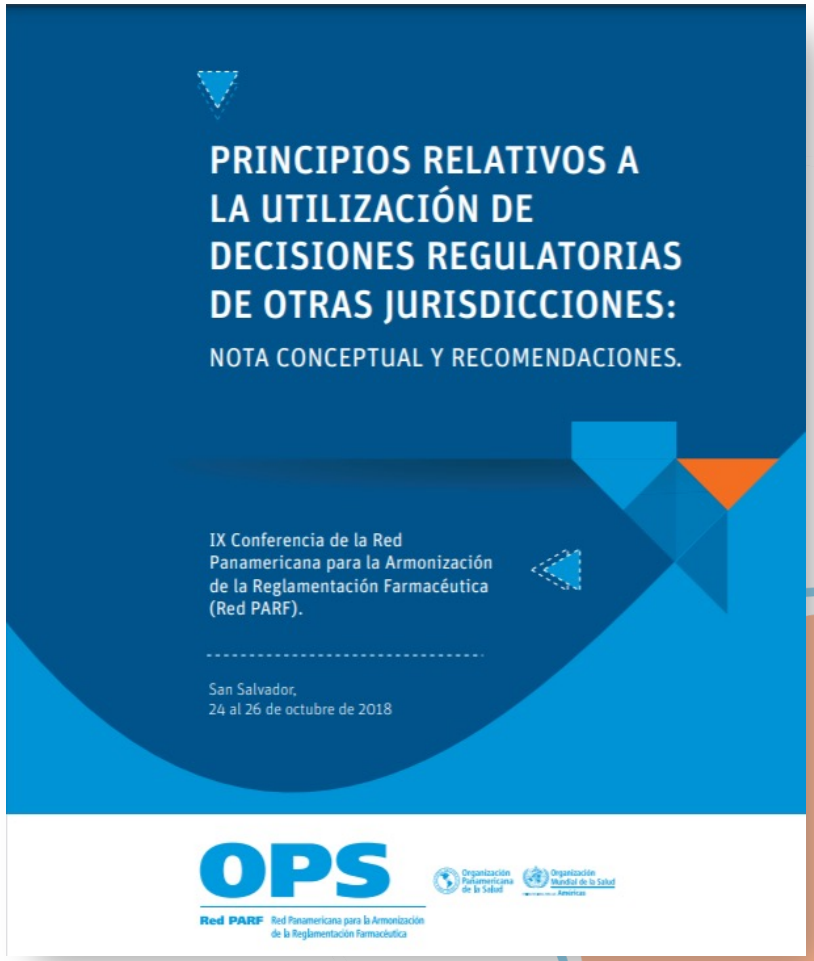
- GBT + Medical Devices, with evaluation criteria for medical device regulatory systems including IVDs.
- Agreed next steps, including piloting the GBT + medical devices.

WORKING GROUP FOR THE INTEGRATION OF MD, INCLUDING IVD INDICATORS IN THE GBT+

- WHO
  - HQ
  - EURO
  - PAHO
- Singapore - HSA
- Kingdom of Saudi Arabia - FDA Saudi
- France - HAS
- <u>Region of the Americas:</u>
  - Argentina - ANMAT
  - Brazil - ANVISA
  - Canada - Health Canada
  - Cuba - CECMED
  - Colombia - INVIMA
  - USA - FDA
  - Mexico - COFEPRIS

DOCUMENT REGULATORY RELIANCE PRINCIPLES: CONCEPT NOTE AND RECOMMENDATIONS

- The purpose of the document is to present examples and key principles of reliance.
- The principles of this document were used as the basis for the WHO Good Practices in Reliance document.
- **Link:** https://iris.paho.org/handle/10665.2/51550



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ANNEX 10. GOOD PRACTICES OF RELIANCE IN THE REGULATION OF MEDICAL PRODUCTS

REGULATORY CHALLENGES

- Globalization of markets
- Sophisticated health technologies
- Rapid evolution of regulatory science
- Increased complexity of supply chains

STRATEGIES TO ADDRESS CHALLENGES

- ✓ Improve international collaboration to ensure the safety, quality and performance of locally used medical products.
- ✓ Make the most of the resources and technical knowledge available, avoid duplication, and concentrate regulatory efforts and resources where they are most needed.
- ✓ Formulation and implementation of strategies consistent with GRP to strengthen regulatory systems, including the search for cooperation and regulatory convergence, as well as reliance.

ANNEX 10. GOOD RELIANCE PRACTICES IN THE REGULATION OF MEDICAL PRODUCTS

PURPOSE

- Promote an **efficient approach to regulation**.
- Improve **access to safe, effective and quality** medical **products**.
- Present the **general principles** of regulatory review.
- Provide **high-level guidance, definitions, key concepts and considerations** to guide reliance mechanisms and activities.

SCOPE

- Reliance activities in the regulation of **medical products**.
  - Drugs
  - Vaccines
  - blood and blood products, and
  - **Medical devices**, including in vitro diagnostic devices.

Addresses **every regulatory function** defined in the GBT throughout the product **lifecycle**

- It is intended for **all NRAs**, regardless of their level of maturity or resources, and policymakers, governments, industry and other stakeholders.

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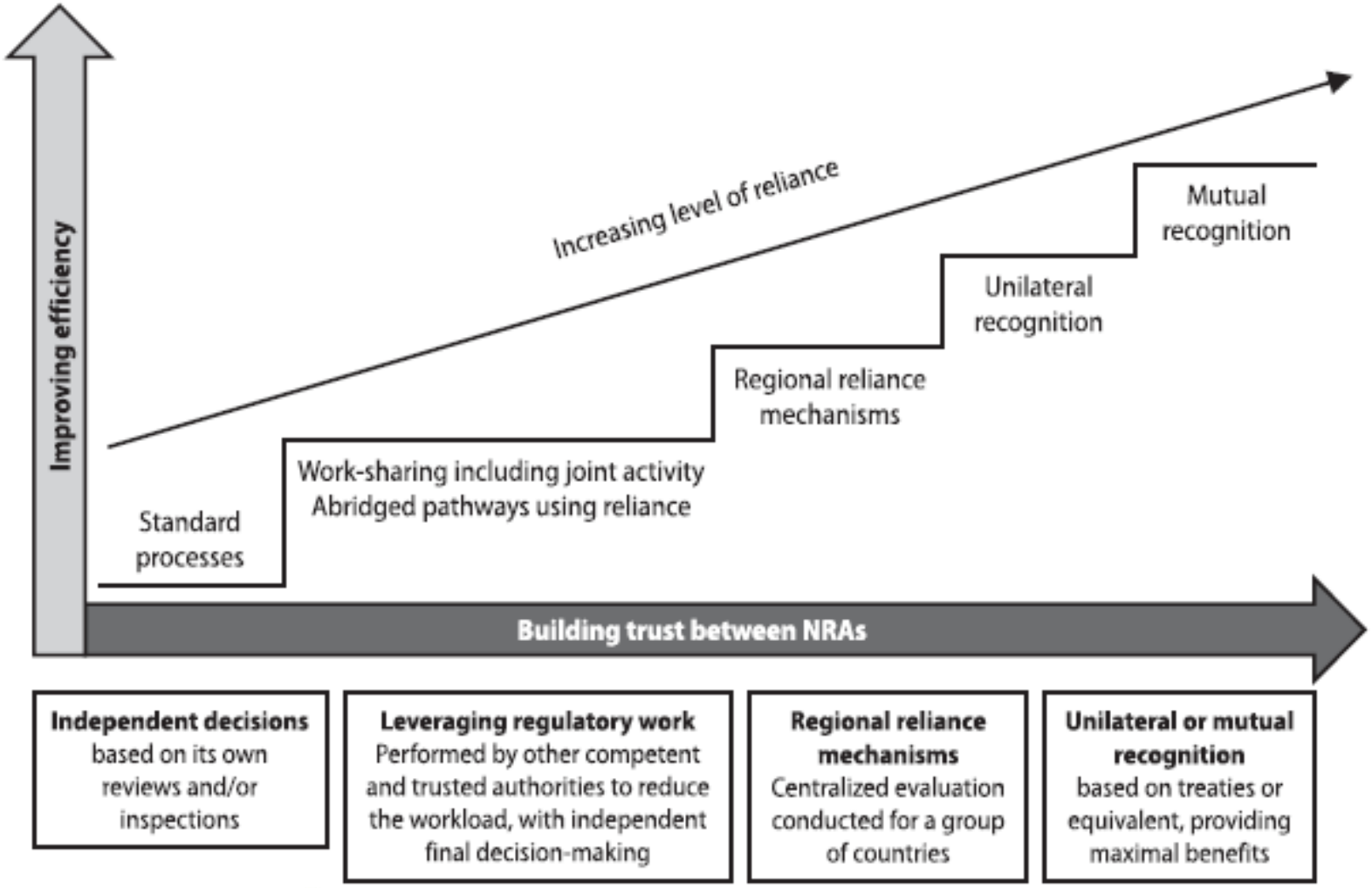
ANNEX 10. GOOD RELIANCE PRACTICES IN THE REGULATION OF MEDICAL PRODUCTS



Taken from Fig. 1 Key concepts of reliance. WHO Expert Committee on Specifications for Pharmaceutical Preparations: Fifty-fifth report. Geneva: World Health Organization; 2021 (WHO Technical Report Series, No. 1033). License: CC BY-NC-SA 3.0 IGO.

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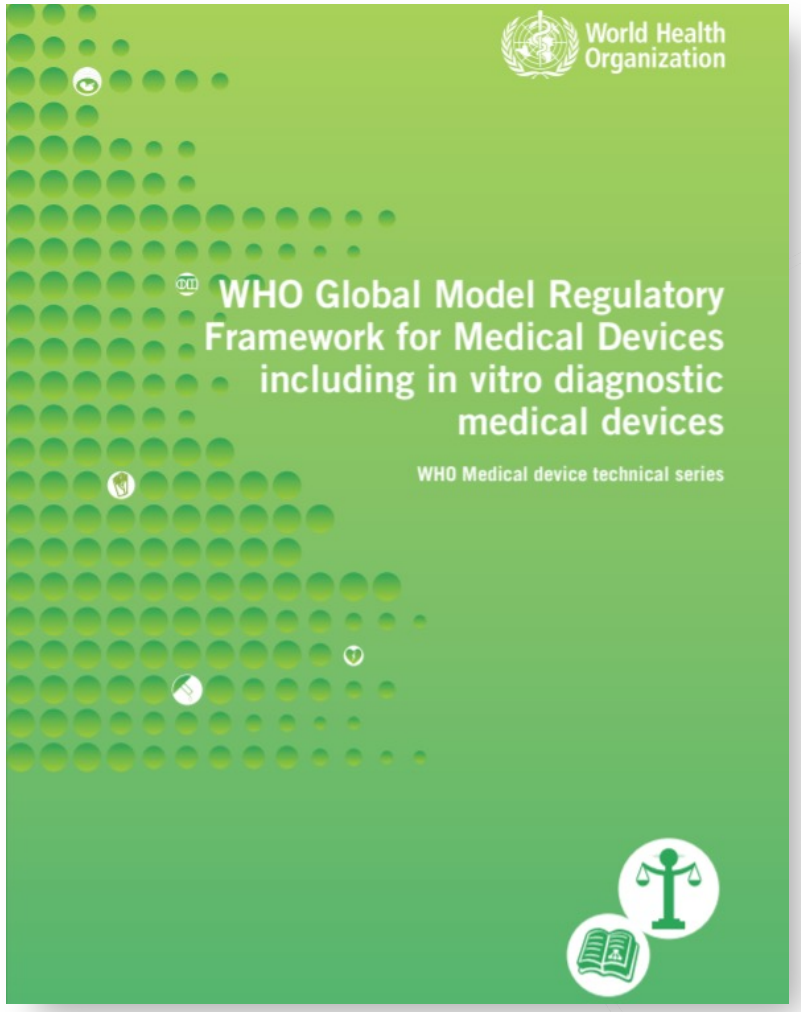
ANNEX 10. GOOD RELIANCE PRACTICES IN THE REGULATION OF MEDICAL PRODUCTS

PRINCIPLES

UNIVERSALITY	Applicable to all NRAs, regardless of maturity level or resources
SOVEREIGNTY OF DECISION-MAKING	NRAs maintain their independence, sovereignty and responsibility in decision-making
TRANSPARENCY	NRAs should be transparent about the standards, processes and approaches they adopt for the implementation of reliance
RESPECT OF NATIONAL AND REGIONAL LEGAL BASES	Consistent with national or regional policy and regulatory frameworks
CONSISTENCY	For specific and well-defined product categories and processes
COMPETENCE	Develop and maintain appropriate scientific skills and knowledge

WHO GLOBAL MODEL REGULATORY FRAMEWORK FOR MEDICAL DEVICES, INCLUDING IN VITRO DIAGNOSTIC MEDICAL DEVICES

- The Model recommends a **stepwise approach**, according to the **resources available** in each country, to regulate the quality, safety and performance of medical devices, and provides guidance for developing **progressively a regulatory system**.
- The approach starts with **basic controls** and then moves to **expanded controls**.
- It states that the **regulatory controls** that must be applied to each device are based on a **risk-based classification system**.
- It recommends reliance and recognition.
- **LINK**: https://apps.who.int/iris/handle/10665/255177



2017

DOCUMENT UPDATE

The Working Group started activities in 2021 and continues with the review process

WHO GLOBAL MODEL REGULATORY FRAMEWORK FOR MEDICAL DEVICES

EXPANDED LEVEL CONTROLS AND ENFORCEMENT		
Premarket	**Placing on the market**	**Postmarket**
• Create oversight of clinical investigations • Appoint and have oversight of conformity assessment bodies • Recognize standards • Adopt a medical device nomenclature system • Control advertising and promotion	• Perform in-country quality management systems audits • Perform review of submissions for compliance with Essential Principles	• Establish within the regulatory authority a postmarket surveillance and vigilance reporting system • Require mandatory reporting by manufacturersof adverse events • Inspection of registered establishments • Provide for testing laboratories

BASIC LEVEL CONTROLS AND ENFORCEMENT		
Premarket	**Placing on the market**	**Postmarket**
• Publish law, including definition, and regulations, with transition period • Establish medical devices classification for regulatory purposes • Establish Essential Principles of safety and performance • Establish basis for reliance and recognition • Establish requirements for declaration of conformity • Establish requirements for manufacturers for a QMS • Establish requirements for labels and labelling • Prohibit deceptive, misleading and false advertising • Establish provisions for exceptional premarket situations	• Registration of establishments • Listing of medical devices • Import controls	• Establish a system for vigilance reporting • Require mandatory notification by the manufacturer of field safety corrective actions • Establish a procedure to withdraw unsafe medical devices from the market • Establish procedure to issue safety alerts to users • Undertake market surveillance

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Figure taken from WHO global model regulatory framework for medical devices including in vitro diagnostic medical devices. Geneva: World Health Organization; 2017. License: CC BY-NC-SA 3.0 IGO.

Thank you for your attention!

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