Reliance in Premarket Setting

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CECMED

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IMDRF International Medical Device Regulators Forum

Transparence in regulatory process

Regional reliance mechanisms

Mutual recognition agreements

Effective regulatory system

PAHO/WHO Collaborating Center CUB-26 Regulation of Health Technologies

QMS Certification

Reference Regulatory Authority by PAHO

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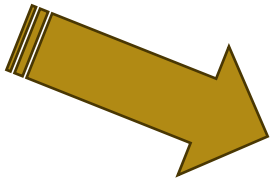
INTERNATIONAL INSTRUMENTS

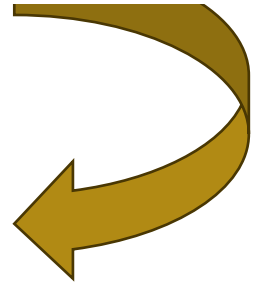
AUTHORITIES AND ORGANIZATIONS

- Agreements
- Memorandums of understanding
- Letters of intent



with an important group of regulatory authorities

- 36 instruments subscribed
- 28 regulatory authorities and organizations
- 9 belong to the Region of the Americas



facilitate exchanges,
increase **trust**
Speed up products assessments

https://www.cecmed.cu/acerca-de/instrumentos-internacionales

working together
MEDICAL DEVICES REGULATION

- **Regional Working Group on Medical Device Regulation**
- **Exchange of reports on adverse events of medical devices – REDMA Program**
- **Research projects – PANDRH**
  - ✓ Strengthening of regulatory capacity on medical devices in the Region of the Americas
- **IMDRF Affiliate members**
  - ✓ IMDRF WG/QMS
  - ✓ IMDRF WG/AI & ML
- **GHWP member**
- **WG WHO**
  - ✓ GBT+MD
  - ✓ GMRF

LATIN AMERICA REGION

The National Regulatory Authorities of Colombia, Mexico and Cuba signed the ¨Acapulco declaration on April 26th, which formalizes negotiations for the creation of the Regulatory Agency for Medicines and Medical Devices of Latin America and the Caribbean (AMLAC).

Purpose*:* Achieving convergence and recognition of regulatory decisions to optimize processes, human and physical resources, facilitating timely access of people to safe, effective and quality medical products

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LEGAL BASIS FOR RELIANCE

National Law

2020

- Decree Law 10/2020 of the Council of State & Decree 17/2020 of the Council of Ministers.
  Objective: *promoting trust among regulatory authorities.*

Regulation

2023

- Resolution 69/2023. "Principles and Policy of Good Regulatory Practices of CECMED".

International exchange and regulatory convergence mechanisms will be strengthened, expanding the use of regulatory decisions from recognized international authorities and organizations.

RELIANCE FOR ALL REGULATORY FUNCTIONS

Resolution 78/2023

- **will consider the decisions** of other regulatory authorities or international entities when making its own regulatory decisions, maintaining independence and responsibility for the decisions made
- **will apply the Regulatory Reliance** to the decisions and processes of the National Regulatory Authorities of Regional Reference certified by PAHO, the Authorities Listed by WHO, as well as those Authorities with which there are bilateral agreements that establish this
- Medical products prequalified by WHO **will be recognized** by CECMED, so expedited assessment will be applied for their approval

BUILD TRUST – MEDICAL DEVICES

Evidences for Sanitary Register applications for Risk Class I non-sterile that do not require approval of the measuring instrument model in Cuba, other than electromedical devices or novels:

- **Sanitary Register Certification in the country of origin or in another country that has a regulatory system based on compliance with the essential principles of safety and performance, recommended internationally, such as members countries of the IMDRF Management Committee**

Exempt from presenting evidences:

- Software validation reports

- Biological preclinical evidences

- Basis safety test reports

- Certificates of analysis of raw materials

- Stability study reports

PREMARKET APPROACH – COVID 19

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- Issuance of Emergency Use Authorizations / Exceptional Use Permits
- Extension of validity periods of current certifications
- Regulatory Audit certificates / reports from prestigious NRAs accepted
- Review of documentation outside the production site
- Periodic review of NRAs Security Alerts and Notifications

PREMARKET APPROACH

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Registered medical devices	Country of origin
52	7

Thermometers	5
Ventilation devices	3
Ventilation accesories	4
Monitoring and life support	8
Disinfectants	3
Disinfection/sterilization devices	7
IVDMD	14
Oxygen concentrators	8

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REGULATORY POLICY FOR MEDICAL DEVICES

2024

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ANEXO ÚNICO

REPÚBLICA DE CUBA
MINISTERIO DE SALUD PÚBLICA
CENTRO PARA EL CONTROL ESTATAL
DE MEDICAMENTOS, EQUIPOS Y DISPOSITIVOS MÉDICOS
CECMED

POLÍTICA NACIONAL REGULADORA DE DISPOSITIVOS MÉDICOS

202X

adopt the internationally recommended principles and elements for harmonization and convergence

STRENGTHEN REGULATORY CAPACITY

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WHAT WE DO

- Recognition of certifications
- Recognition of testings
- Accelerated assessments of manufacturers, suppliers an medical devices

WHAT WE DON´T DO

- Recognition of marketing authorizations

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FUTURE CONSIDERATIONS

INCREASE TRUST LEVELS

- Creation of multidisciplinary work groups – Share work
- Availability of documentary evidence for reliable and timely decision making. Updated websites
- Promote the use of an international nomenclature system for medical devices
- Consultation mechanism on borderline products
- Development of regulatory pathways for innovative medical devices

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Thank you/Questions

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2024