Reliance in Premarket Setting

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CECMED
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Transparency in regulatory process

Regional reliance mechanisms

Effective regulatory system

Mutual recognition agreements

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

QMS Certification

Reference Regulatory Authority by PAHO

Regional reliance mechanisms
INTERNATIONAL INSTRUMENTS
AUTHORITIES AND ORGANIZATIONS

- Agreements
- Memorandums of understanding
- Letters of intent

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

facilitate exchanges, increase trust
Speed up products assessments

with an important group of regulatory authorities

https://www.cecmed.cu/acerca-de/instrumentos-internacionales
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
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.
LEGAL BASIS FOR RELIANCE

National Law

2020
**Objective:** promoting trust among regulatory authorities.

Regulation

2023
*International exchange and regulatory convergence mechanisms will be strengthened, expanding the use of regulatory decisions from recognized international authorities and organizations.*
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.
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

- 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

<table>
<thead>
<tr>
<th>Registered medical devices</th>
<th>Country of origin</th>
</tr>
</thead>
<tbody>
<tr>
<td>52</td>
<td>7</td>
</tr>
<tr>
<td>Thermometers</td>
<td>5</td>
</tr>
<tr>
<td>Ventilation devices</td>
<td>3</td>
</tr>
<tr>
<td>Ventilation accessories</td>
<td>4</td>
</tr>
<tr>
<td>Monitoring and life support</td>
<td>8</td>
</tr>
<tr>
<td>Disinfectants</td>
<td>3</td>
</tr>
<tr>
<td>Disinfection/sterilization devices</td>
<td>7</td>
</tr>
<tr>
<td>IVDMD</td>
<td>14</td>
</tr>
<tr>
<td>Oxygen concentrators</td>
<td>8</td>
</tr>
</tbody>
</table>
adopt the internationally recommended principles and elements for harmonization and convergence
WHAT WE DO

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

WHAT WE DON´T DO

- Recognition of marketing authorizations
FUTURE CONSIDERATIONS

- 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

INCREASE TRUST LEVELS
Thank you/Questions

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