Good Reliance Practices in Medical Device Regulation

Medical Device Regulatory Convergence Project (MDRC)

Africa Medical Devices Forum (AMDF)

FDA Workshop

9 November, 2023

Nairobi, Kenya

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Medical Devices Office
Brazilian Health Regulatory Agency

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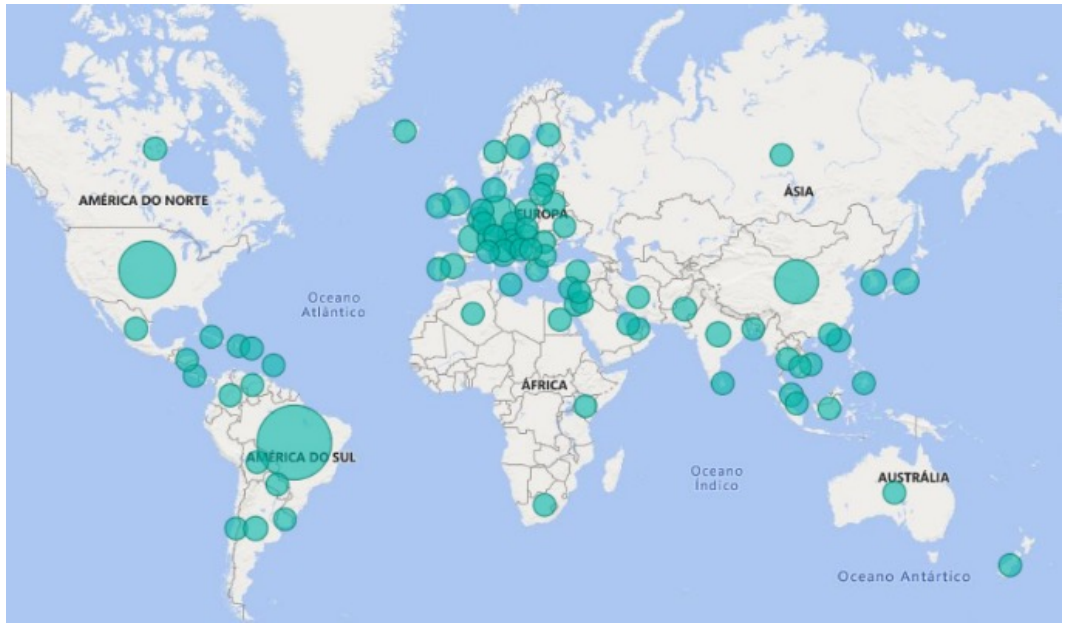
Origin of Licensed MD in Brazil

Position	Country	Reg. / Notif.	%
0	Brazil	27.308	30,87%
1	USA	15.623	17,66%
2	China	13.518	15,28%
3	Germany	8.501	9,61%
4	Italy	2.245	2,53%
5	France	2.226	2,51%
6	South Korea	1.660	1,87%
7	Switzerland	1.587	1,79%
8	India	1.477	1,67%
9	UK	1.448	1,63%
10	Japan	1.265	1,43%
11	Spain	1.061	1,19%
12	Argentina	810	0,91%
13	Pakistan	775	0,87%
14	Taiwan	687	0,77%
15	Ireland	671	0,75%
16	Sweden	638	0,72%
17	Denmark	582	0,65%
18	Turkey	502	0,56%
19	israel	485	0,54%
20	Malaysia	463	0,52%



National	30,87%
Imported	69,13%

(September, 2023)

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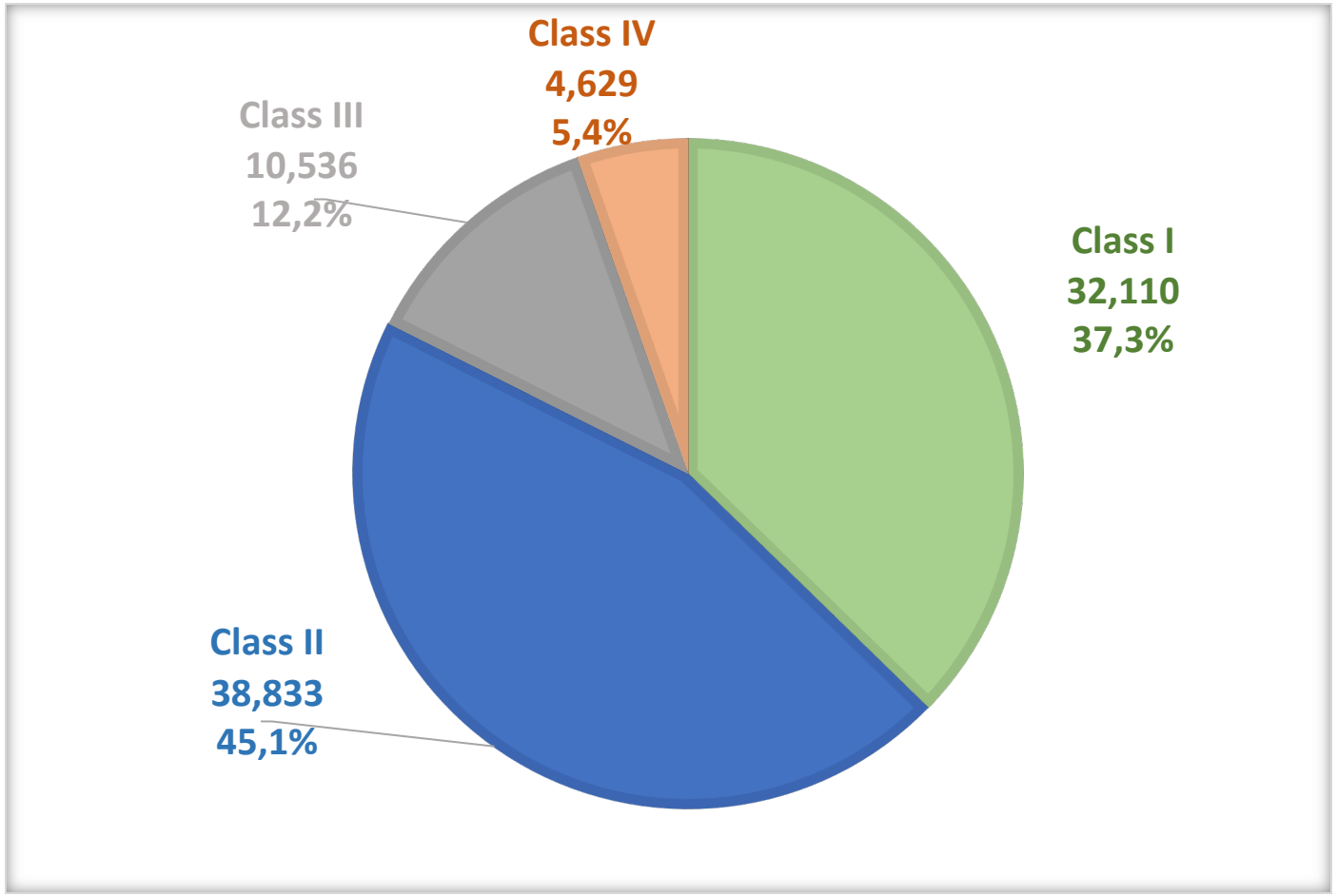
Distribution of Licensed MD by Risk Class



Total
86.108
Active licenses
of Medical Devices
(September, 2023)

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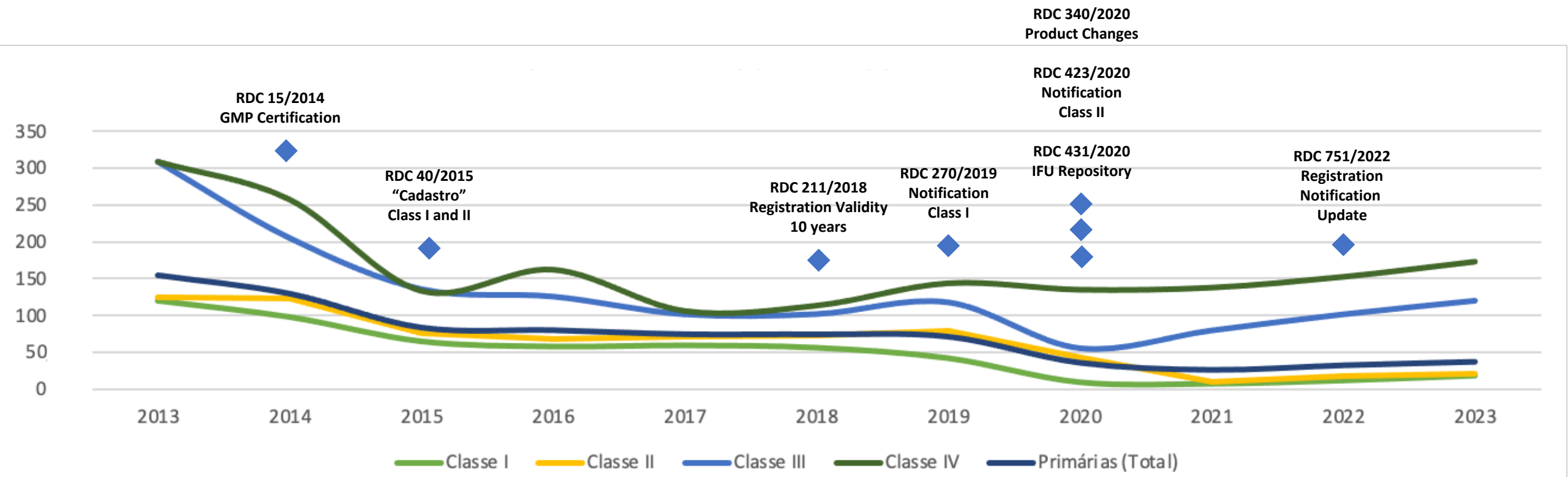
Medical Device Market Authorization



Average Time to Final Decision from ANVISA per Risk Class (days)

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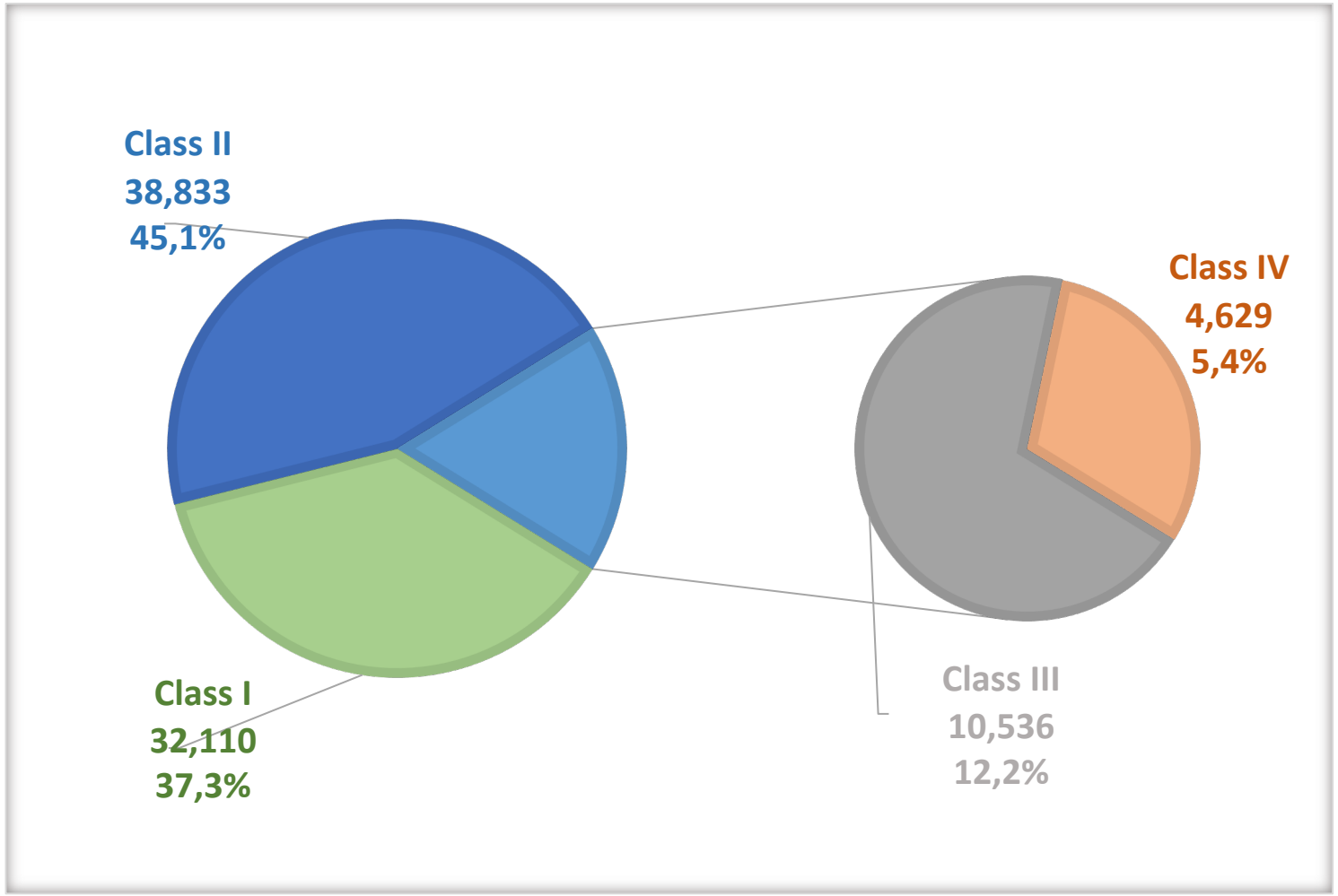
Regulatory Effort



Smallest portion of the universe of medical devices

BUT

Heaviest part of the regulatory pre-market effort

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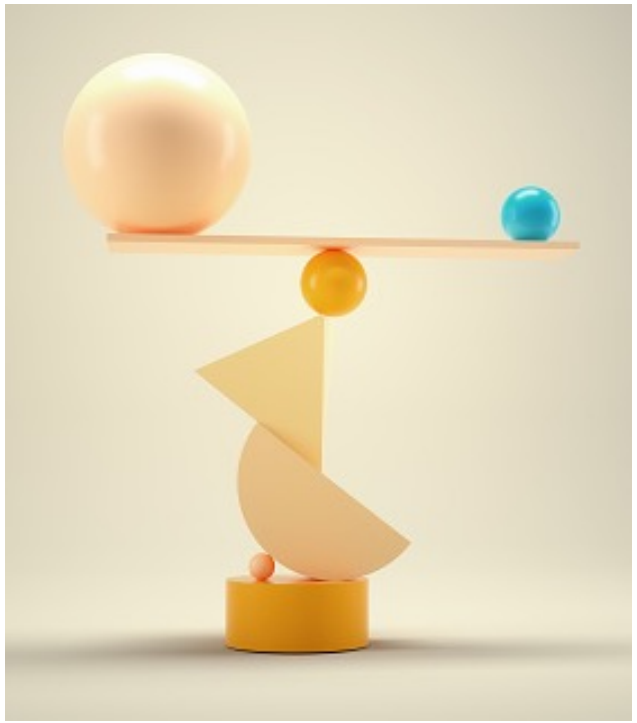
Regulatory Effort



Simplification of work processes for lower risk products

AND

Better use of the workforce

Regulatory Convergence

A voluntary process whereby the regulatory requirements and approaches across countries and regions become more similar or aligned over time as a result of the adoption of the same technical documents, standards and scientific principles (harmonization) and similar regulatory practices and procedures.

The process of convergence represents an important form of regulatory cooperation which in turn makes possible additional, enhanced forms of cooperation and collaboration between regulatory authorities.

IMDRF/MC/N1FINAL:2023

Regulatory Convergence

IMDRF International Medical Device Regulators Forum

MERCOSUL

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

World Health Organization

Bilateral agreements

ISO

IEC

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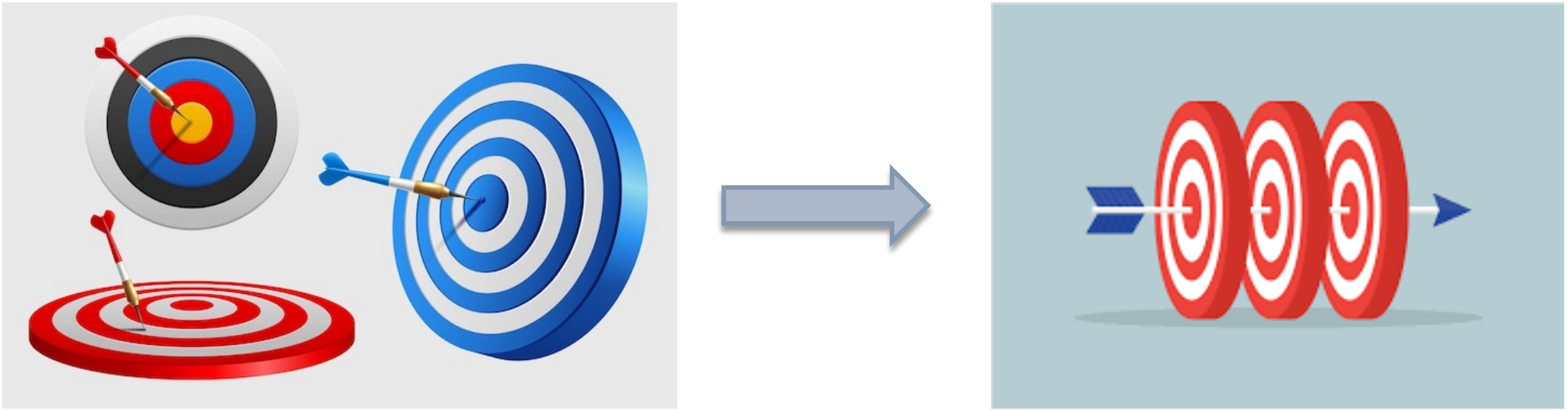
Regulatory Convergence



- ✓ Build an efficient regulatory framework;
- ✓ Strengthen regulatory capacity globally;
- ✓ Converge to International Best Practice;
- ✓ Accelerate patient access to new technologies.

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Implementation of IMDRF Documents

Unique Device Identification (UDI)

RDC 591/2021

Update of the Essential Requirements of Safety and Performance

Final text approved by the Mercosur Sub-Commission of Medical Devices in May 2023, after internal Public Consultations (IMDRF/GRRP WG/N47FINAL:2018)

Update of Medical Devices Risk Classification Rules

GHTF/IMDRF basis – RDC 751/2022

Adoption of the IMDRF ToC as an option of submission format

Regulated Product Submission (RPS)

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Implementation of IMDRF Documents

Regulation of Software as a Medical Device (SaMD)
RDC 657/2022

Regulation of Personalized Medical Devices
RDC 305/2019

Clinical Investigation, Clinical Evidence and Clinical Evaluation
Guidance 29/2019; 30/2019; and 31/2021

Medical Device Cybersecurity Guide
Guidance 38/2020

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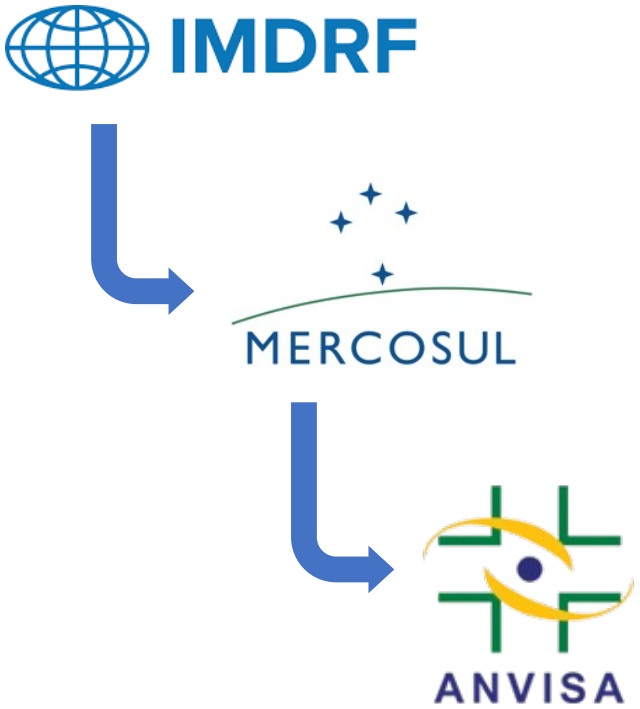
Implementation of IMDRF Documents



Regulation for the Essential Principles of Safety and Performance
RDC 546/2021

Harmonized Regulation in Mercosur

Same requirements applied among the Mercosur member states

Final text approved by the Mercosur Sub-Commission of Medical Devices in May 2023, after internal Public Consultations

Internalization in progress - Expected to be published by Anvisa until November 2023

Reliance Mechanism for Pre-Market Authorizations

reliance. *The act whereby a regulatory authority in one jurisdiction takes into account and gives significant weight to assessments performed by another regulatory authority or trusted institution, or to any other authoritative information,* ***in reaching its own decision****.* ***The relying authority remains independent, responsible, and accountable for the decisions taken****, even when it relies on the decisions, assessments, and information of others.*

(WHO Global Model Regulatory Framework)

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Reliance Mechanism for Pre-Market Authorizations

abridged pathways. *Regulatory procedures facilitated by reliance, whereby a regulatory decision is solely or widely based on the application of reliance. This usually involves some degree of work by the relying agency.*

(WHO Global Model Regulatory Framework)

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Reliance Mechanism for Pre-Market Authorizations

Structure regulation on reliance – RDC 741/2022

- Pathway for abridged review process
- Normative Instruction for MD and IVD MD under public consultation
- Public Consultation 1200/2023

http://antigo.anvisa.gov.br/consultas-publicas#/visualizar/509352

- Open for contributions until 25 October 2023
- Product registration certificates from Equivalent Foreign Regulatory Authorities will be used as a trigger for expedited review
- Initially from the same founding members authorities of MDSAP

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Reliance Mechanism for Pre-Market Authorizations

Conditions that will apply:

- Agreement on the exchange of confidential information with the relied NRA
- Classes III and IV – Registration processes
- Product must be essentially the same
  - ✓ Same indications for use
  - ✓ Same manufacturing sites and legal manufacturer
  - ✓ Same “regulatory version”

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Reliance Mechanism for Pre-Market Authorizations

Conditions that will apply:

- Brazilian labelling and specific requirements must be fulfilled
  - The information on the labels and instructions for use must be written in Portuguese;
  - Medical devices with compulsory certification must meet the requirements of specific regulations.
- Anvisa may choose to perform the full assessment of the Technical Dossier
- Anvisa may request clarification regarding the documents submitted for review

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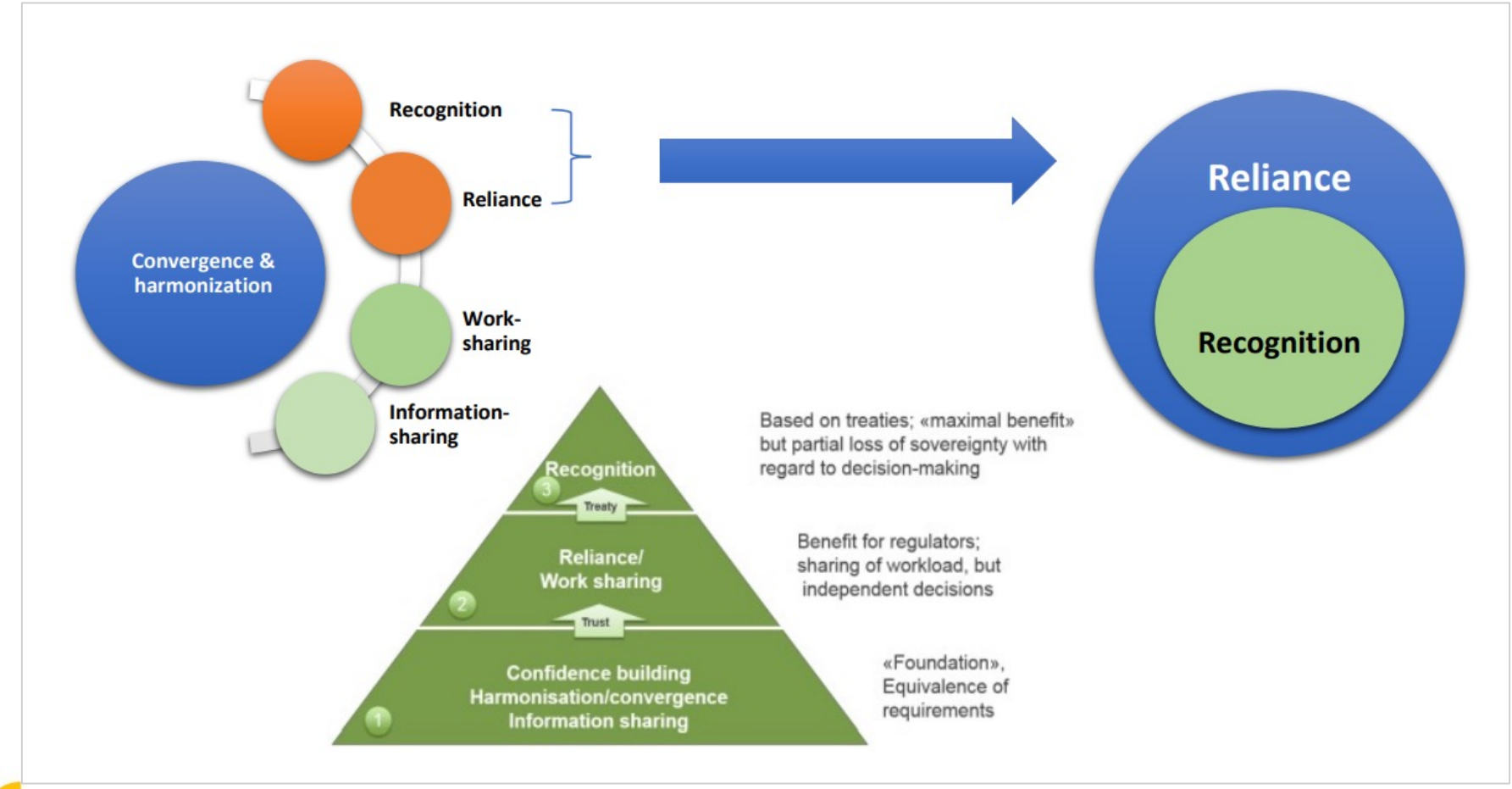
Views on Regulatory Cooperation



(WHO Presentation)

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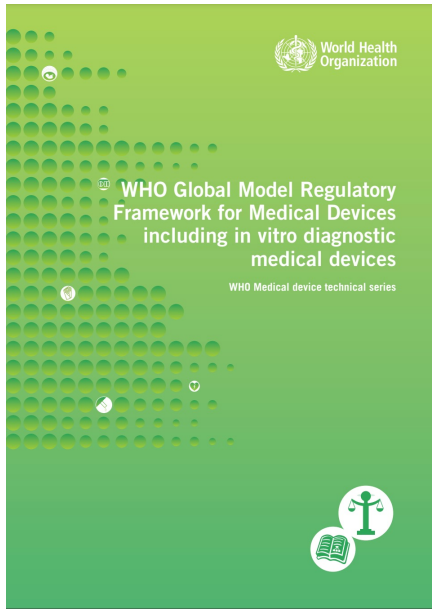
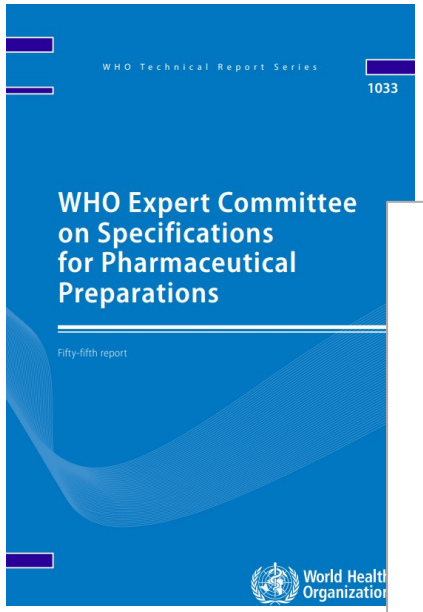
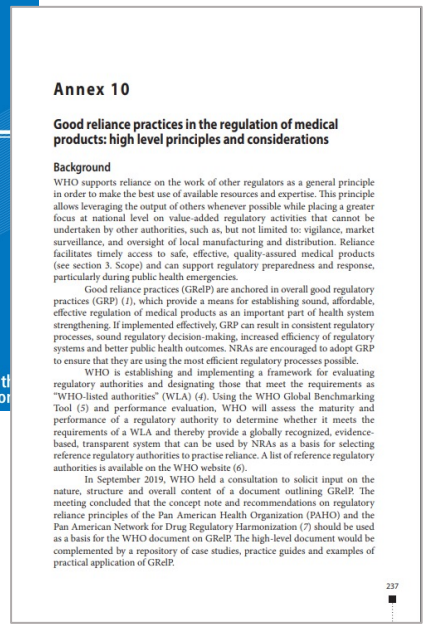
Good Reliance Practices

Good reliance practices (GRelP) are anchored in overall good regulatory practices (GRP)







Annex 10

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

Background

WHO supports reliance on the work of other regulators as a general principle in order to make the best use of available resources and expertise. This principle allows leveraging the output of others whenever possible while placing a greater focus at national level on value-added regulatory activities that cannot be undertaken by other authorities, such as, but not limited to: vigilance, market surveillance, and oversight of local manufacturing and distribution. Reliance facilitates timely access to safe, effective, quality-assured medical products (see section 3. Scope) and can support regulatory preparedness and response, particularly during public health emergencies.

Good reliance practices (GRelP) are anchored in overall good regulatory practices (GRP) (*1*), which provide a means for establishing sound, affordable, effective regulation of medical products as an important part of health system strengthening. If implemented effectively, GRP can result in consistent regulatory processes, sound regulatory decision-making, increased efficiency of regulatory systems and better public health outcomes. NRAs are encouraged to adopt GRP to ensure that they are using the most efficient regulatory processes possible.

WHO is establishing and implementing a framework for evaluating regulatory authorities and designating those that meet the requirements as "WHO-listed authorities" (WLA) (*4*). Using the WHO Global Benchmarking Tool (*5*) and performance evaluation, WHO will assess the maturity and performance of a regulatory authority to determine whether it meets the requirements of a WLA and thereby provide a globally recognized, evidence-based, transparent system that can be used by NRAs as a basis for selecting reference regulatory authorities to practise reliance. A list of reference regulatory authorities is available on the WHO website (*6*).

In September 2019, WHO held a consultation to solicit input on the nature, structure and overall content of a document outlining GRelP. The meeting concluded that the concept note and recommendations on regulatory reliance principles of the Pan American Health Organization (PAHO) and the Pan American Network for Drug Regulatory Harmonization (*7*) should be used as a basis for the WHO document on GRelP. The high-level document would be complemented by a repository of case studies, practice guides and examples of practical application of GRelP.

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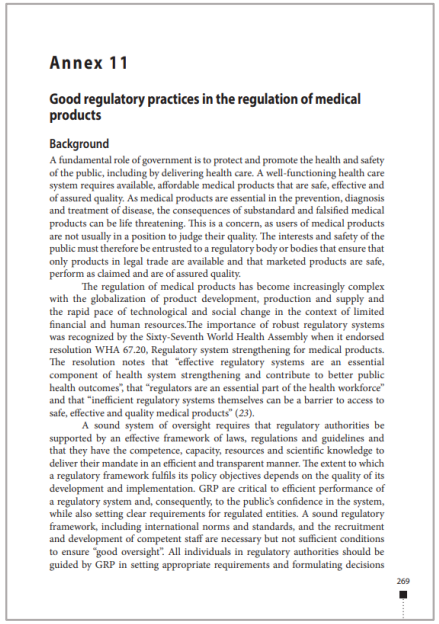

Annex 11

Good regulatory practices in the regulation of medical products

Background

A fundamental role of government is to protect and promote the health and safety of the public, including by delivering health care. A well-functioning health care system requires available, affordable medical products that are safe, effective and of assured quality. As medical products are essential in the prevention, diagnosis and treatment of disease, the consequences of substandard and falsified medical products can be life threatening. This is a concern, as users of medical products are not usually in a position to judge their quality. The interests and safety of the public must therefore be entrusted to a regulatory body or bodies that ensure that only products in legal trade are available and that marketed products are safe, perform as claimed and are of assured quality.

The regulation of medical products has become increasingly complex with the globalization of product development, production and supply and the rapid pace of technological and social change in the context of limited financial and human resources.The importance of robust regulatory systems was recognized by the Sixty-Seventh World Health Assembly when it endorsed resolution WHA 67.20, Regulatory system strengthening for medical products. The resolution notes that "effective regulatory systems are an essential component of health system strengthening and contribute to better public health outcomes", that "regulators are an essential part of the health workforce" and that "inefficient regulatory systems themselves can be a barrier to access to safe, effective and quality medical products" (*23*).

A sound system of oversight requires that regulatory authorities be supported by an effective framework of laws, regulations and guidelines and that they have the competence, capacity, resources and scientific knowledge to deliver their mandate in an efficient and transparent manner. The extent to which a regulatory framework fulfils its policy objectives depends on the quality of its development and implementation. GRP are critical to efficient performance of a regulatory system and, consequently, to the public's confidence in the system, while also setting clear requirements for regulated entities. A sound regulatory framework, including international norms and standards, and the recruitment and development of competent staff are necessary but not sufficient conditions to ensure "good oversight". All individuals in regulatory authorities should be guided by GRP in setting appropriate requirements and formulating decisions

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Good Regulatory Practices

Good reliance practices (GRelP) are anchored in overall good regulatory practices (GRP)

Legality	Consistency	Independence
Impartiality	Proportionality	Flexibility
Clarity	Efficiency	Transparency

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Principles of Good Reliance Practices

Universality

- Reliance applies to all NRAs, irrespective of their levels of maturity or resources. Lack of resources or capacity are not the exclusive drivers for reliance. Different NRAs use reliance for different reasons

Sovereignty of decision-making

- NRAs maintain independence, sovereignty and accountability in regulatory decision-making.

Transparency

- NRAs should be transparent about the standards, processes and approaches they adopt in implementing reliance measures.

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Principles of Good Reliance Practices

Respect of national and regional legal bases

- Reliance practices should be coherent with national and regional legal frameworks and policies on medical products.

Consistency

- Reliance on an assessment or decision from another authority should be established for specific, well-defined categories of products and processes.

Competence

- Implementation of reliance approaches requires that NRAs have the necessary competence for critical decision-making. NRAs should maintain the appropriate scientific expertise of their staff for activities in which they do not apply reliance.

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Reliance

- ✓ In developing a strategy on the use of reliance in regulatory functions and activities, an NRA should consider the needs and characteristics of the national health and regulatory systems.
- ✓ A decision to practice reliance should consider existing capacity, regulatory systems' needs, the availability of an authority on which the NRA can rely with confidence and how reliance could complement the capacity to increase efficiency and make optimal use of resources.

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Thank you!

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