ANVISA
Reliance – Medical Devices Experience in Brazil

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International Affairs Office
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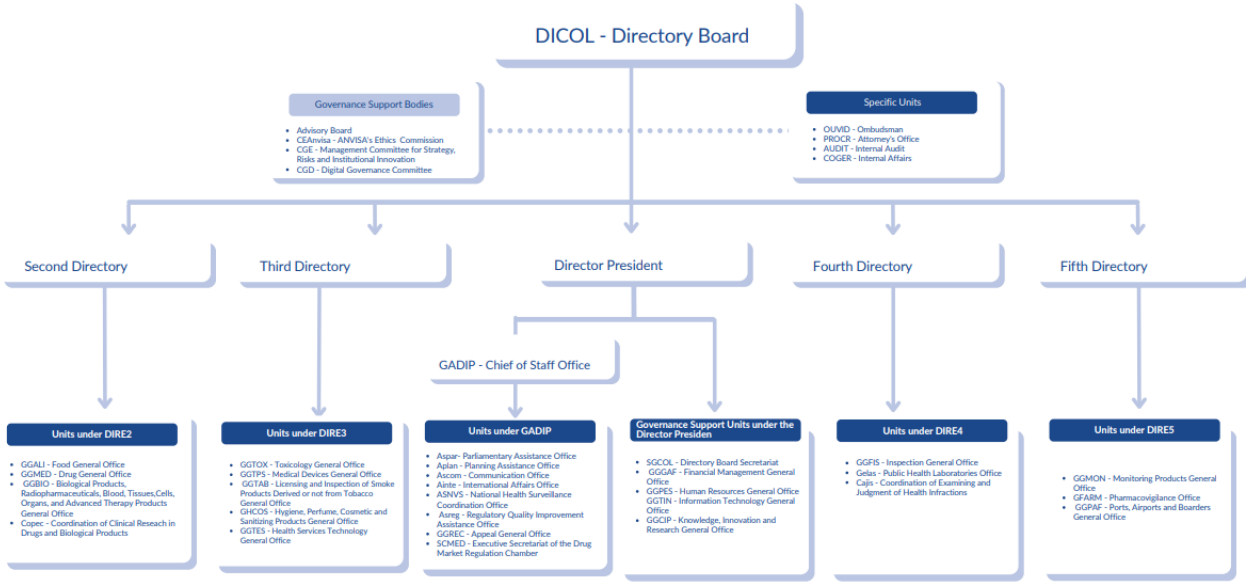
Webinar - Inter-American Coalition for Regulatory Convergence

ANVISA
Agência Nacional de Vigilância Sanitária

Brazilian Health Regulatory Agency

Mission: "To **promote and protect the health of the Brazilian population**, acting with scientific excellence in the regulation of products, services, and environments subject to health surveillance, promoting **access**, reducing **risks**, and supporting the development of the country in integrated action with the **Brazilian Unified Health System**."



Vision:
To be an innovative and reliable health authority for the entire society.

Values:
Systemic, articulated, and integrated vision with SUS;
Transparency, communication and integrity;
Excellence in service provision;
Knowledge as a source of action;
Innovation and Sustainability.

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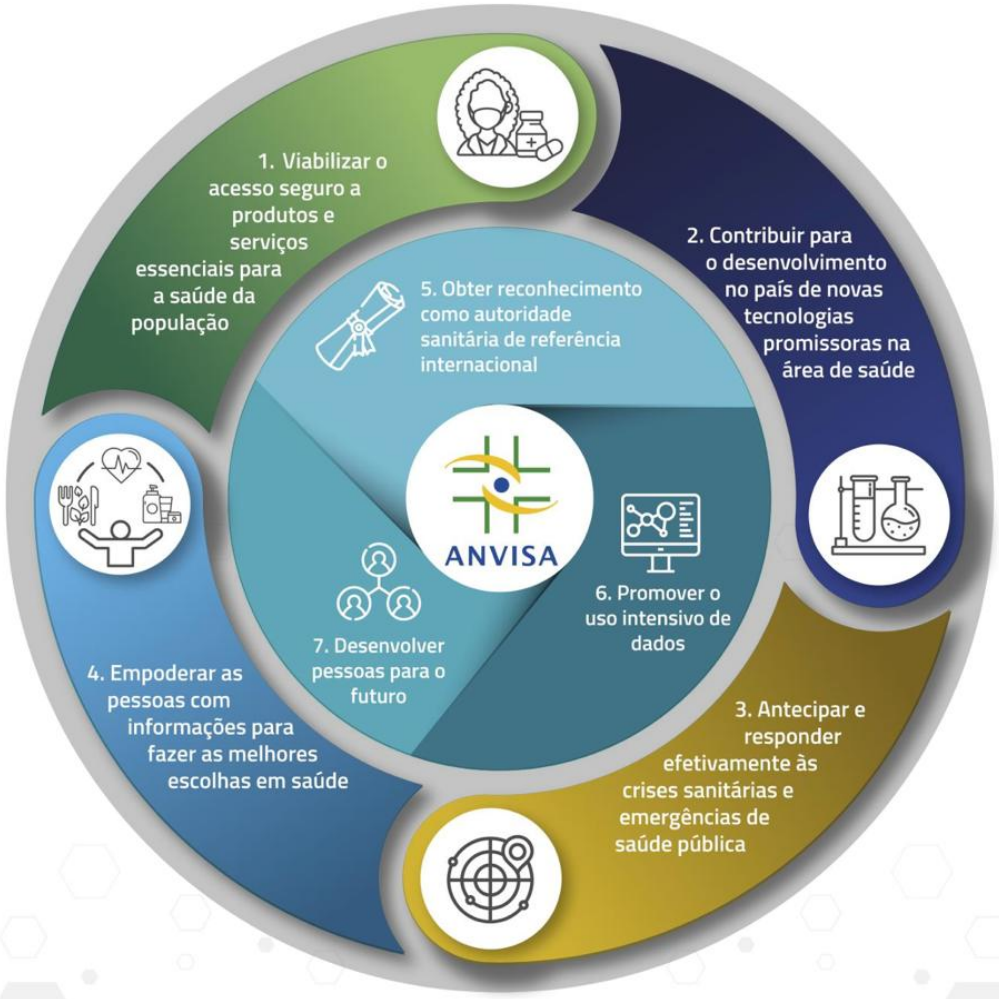
Brazilian Health Regulatory Agency
Strategic Plan and Value Chain



- The Anvisa's actions are guided by its institutional strategic planning.
- Its objectives are aligned with promoting health, innovation and development, and improving public management.
- The focus is on generating value for society and strengthening the regulatory environment.

Anvisa's Strategic Planning and KR 5.2

1	Colombia	Instituto Nacional de Vigilancia de Medicamentos y Alimentos (INVIMA)	Registration	Medicines
2	Colombia	Instituto Nacional de Vigilancia de Medicamentos y Alimentos (INVIMA)	GMP Inspection	Medicines
3	Mexico	Comisión Federal para la Protección contra Riesgos Sanitarios (COFEPRIS)	Registration	Medicines
4	Mexico	Comisión Federal para la Protección contra Riesgos Sanitarios (COFEPRIS)	GMP Inspection	Medicines
5	Peru	Dirección General de Medicamentos, Insumos y Drogas (DIGEMID)	GMP Inspection	Medicines
6	Chile	Instituto de Salud Pública (ISP)	Registration	Medicines
7	Chile	Instituto de Salud Pública (ISP)	GMP Inspection	Medicines
8	Australia	Therapeutic Goods Administration (TGA)	Registration	Medical devices
9	Egypt	Egyptian Drug Authority (EDA)	Registration	Medical devices
10	Malaysia	Medical Device Authoriry (MDA)	Registration	Medical devices
11	Mexico	Comisión Federal para la Protección contra Riesgos Sanitarios (COFEPRIS)	GMP Inspection	Medical devices
12	United Kingdom	Medicines and Healthcare Products Regulatory Agency (MHRA)	Registration	Medical devices

Strong Commitment to Good Regulatory Practices

- Anvisa adopts instruments such as Regulatory Impact Analysis (RIA), public consultations and Regulatory Result Assessment (RRA)
- Promotes the periodic review of standards based on evidence.
- Seeks transparency and constant dialogue with society.
- Works towards convergence with international standards.

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National and International Relevance

Anvisa is an integral part of the SUS, ensuring access to safe and effective products.

The sectors regulated by the Agency represent more than 25% of Brazil's industrial GDP.

Active role in forums such as ICMRA, ICH, IMDRF, ICCR promoting international convergence and cooperation.

ICH harmonisation for better health

ICMRA International Coalition of Medicines Regulatory Authorities

IPRP International Pharmaceutical Regulators Programme

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MERCOSUL

World Trade Organization

CODEX ALIMENTARIUS International Food Standards
Food and Agriculture Organization of the United Nations
World Health Organization

ICCR International Cooperation on Cosmetics Regulation

Pan American Health Organization

Organização dos Estados Americanos

World Health Organization

IMDRF International Medical Device Regulators Forum

MDSAP Medical Device Single Audit Program

Food and Agriculture Organization of the United Nations

PIC/S Pharmaceutical Inspection Co-operation Scheme

International Cooperation

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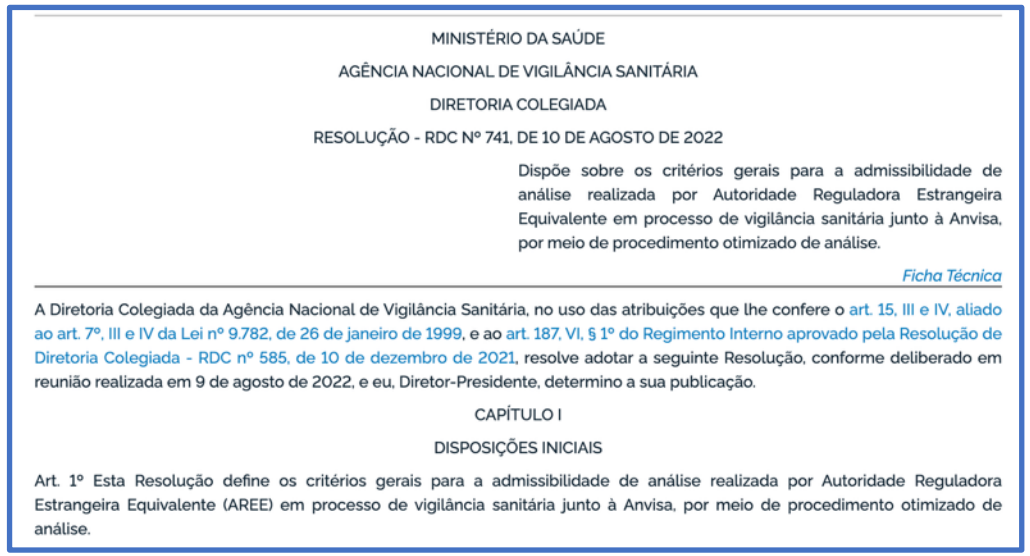

MINISTÉRIO DA SAÚDE

AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA

DIRETORIA COLEGIADA

RESOLUÇÃO - RDC Nº 741, DE 10 DE AGOSTO DE 2022

Dispõe sobre os critérios gerais para a admissibilidade de análise realizada por Autoridade Reguladora Estrangeira Equivalente em processo de vigilância sanitária junto à Anvisa, por meio de procedimento otimizado de análise.

Ficha Técnica

A Diretoria Colegiada da Agência Nacional de Vigilância Sanitária, no uso das atribuições que lhe confere o art. 15, III e IV, aliado ao art. 7º, III e IV da Lei nº 9.782, de 26 de janeiro de 1999, e ao art. 187, VI, § 1º do Regimento Interno aprovado pela Resolução de Diretoria Colegiada - RDC nº 585, de 10 de dezembro de 2021, resolve adotar a seguinte Resolução, conforme deliberado em reunião realizada em 9 de agosto de 2022, e eu, Diretor-Presidente, determino a sua publicação.

CAPÍTULO I

DISPOSIÇÕES INICIAIS

Art. 1º Esta Resolução define os critérios gerais para a admissibilidade de análise realizada por Autoridade Reguladora Estrangeira Equivalente (AREE) em processo de vigilância sanitária junto à Anvisa, por meio de procedimento otimizado de análise.

- Anvisa adopts reliance mechanisms to optimize regulatory processes based on decisions of Equivalent Foreign Regulatory Authorities (AREEs).
- Maintains bilateral and multilateral agreements for inspections and recognition of good manufacturing practices.

Recognition of FSC and CFG

Bilateral Agreement – Argentina

- Agreement on the recognition of Free Sale Certificates and Certificates for Foreign Government for classes I and II medical devices and class A and B in vitro diagnostic medical devices between ANVISA and ANMAT

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anmat

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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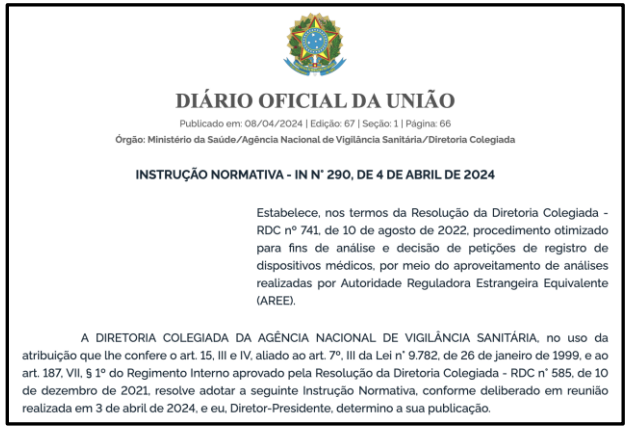
Reliance mechanism for pre-market authorizations

General regulation on reliance – RDC 741/2022

- Pathway for abridged review process
- Normative Instruction for MD and IVD MD – **IN 290/2024**
- Product registration certificates from Equivalent Foreign Regulatory Authorities may be used as a trigger for abridged reviews
  - Australia Therapeutic Goods Administration (TGA)
  - Health Canada (HC)
  - US Food and Drug Administration (US FDA)
  - Japan Ministry of Health, Labour and Welfare (MHLW)



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INSTRUÇÃO NORMATIVA - IN Nº 290, DE 4 DE ABRIL DE 2024

Estabelece, nos termos da Resolução da Diretoria Colegiada - RDC nº 741, de 10 de agosto de 2022, procedimento otimizado para fins de análise e decisão de petições de registro de dispositivos médicos, por meio do aproveitamento de análises realizadas por Autoridade Reguladora Estrangeira Equivalente (AREE).

A DIRETORIA COLEGIADA DA AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA, no uso da atribuição que lhe confere o art. 15, III e IV, aliado ao art. 7º, III da Lei nº 9.782, de 26 de janeiro de 1999, e ao art. 187, VII, § 1º do Regimento Interno aprovado pela Resolução da Diretoria Colegiada - RDC nº 585, de 10 de dezembro de 2021, resolve adotar a seguinte Instrução Normativa, conforme deliberado em reunião realizada em 3 de abril de 2024, e eu, Diretor-Presidente, determino a sua publicação.

Reliance mechanism for pre-market authorizations

Normative Instruction – IN 290/2024

- Classes III and IV Medical Devices (according to RDC 751/2022 and RDC 830/2023)
- Product must be essentially identical
  - *“the documentation proving registration or authorization issued by AREE must refer to the medical device essentially identical to the one intended to be registered in the national territory, and include the information related to the indication(s) of use/intended use and manufacturer(s)”*

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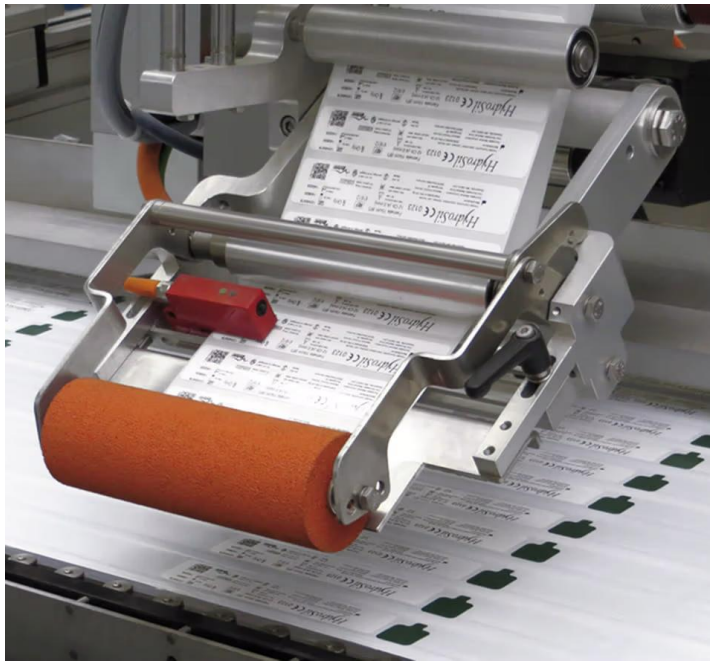
Reliance mechanism for pre-market authorizations

Normative Instruction – IN 290/2024

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



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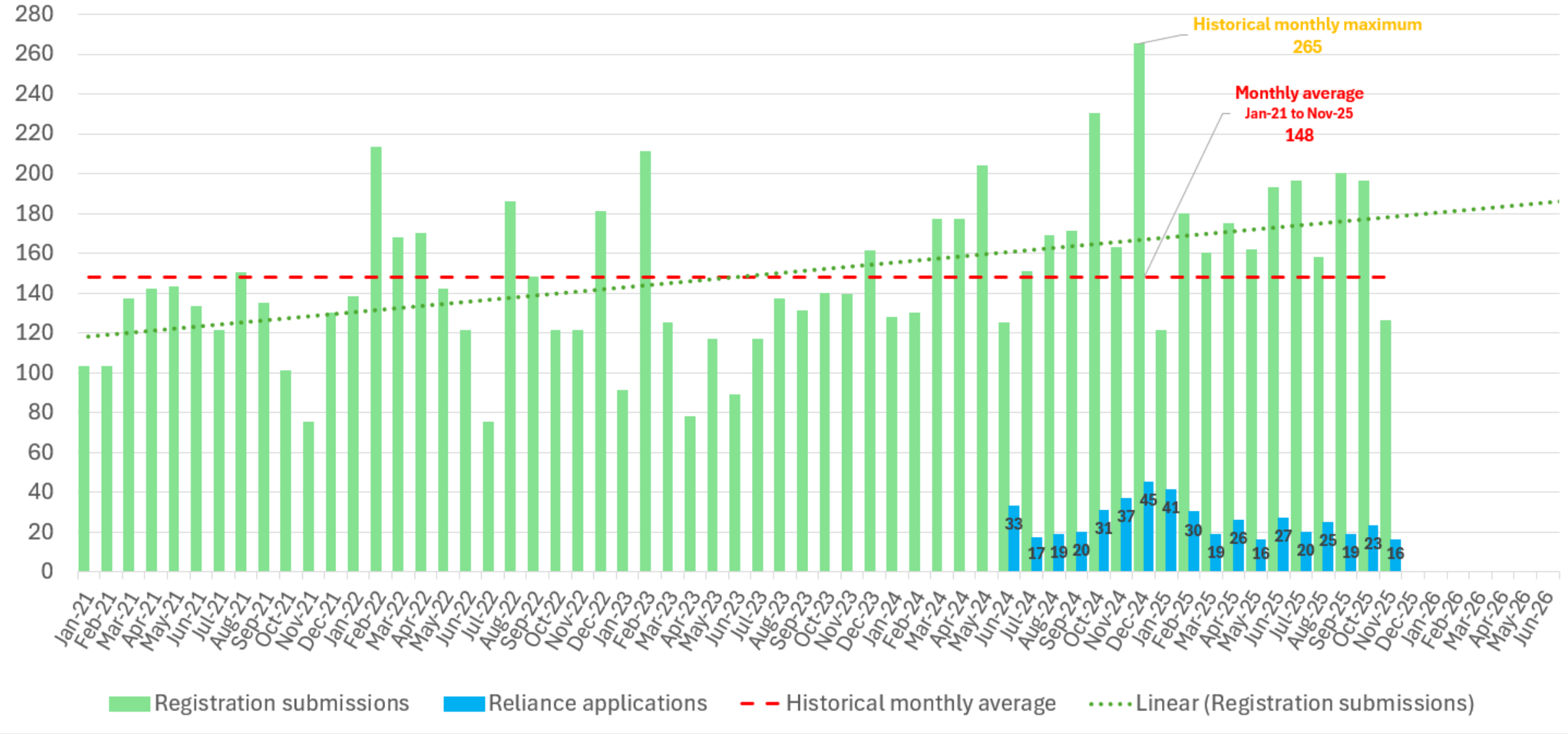
Submissions for optimized review procedure by reliance



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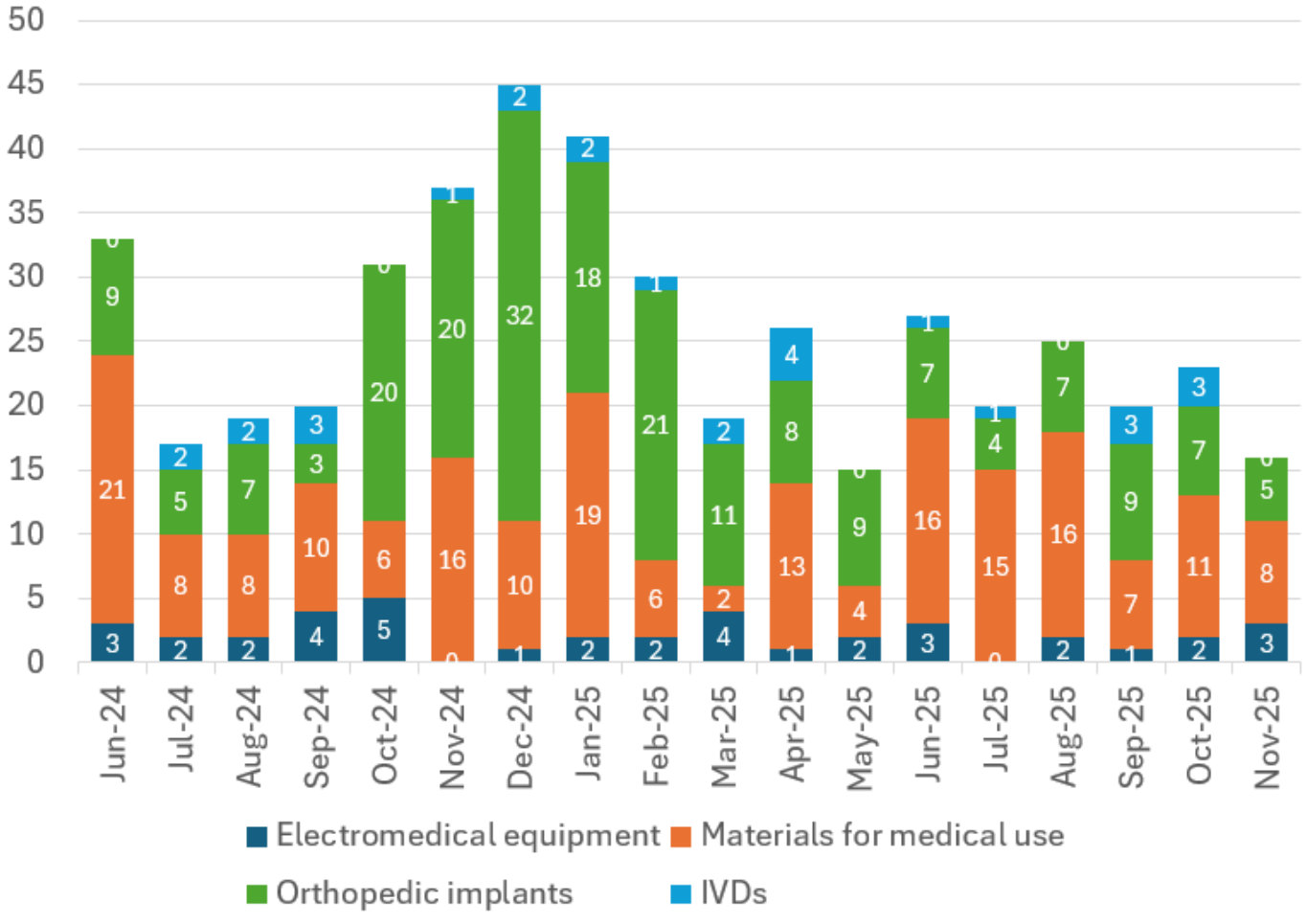

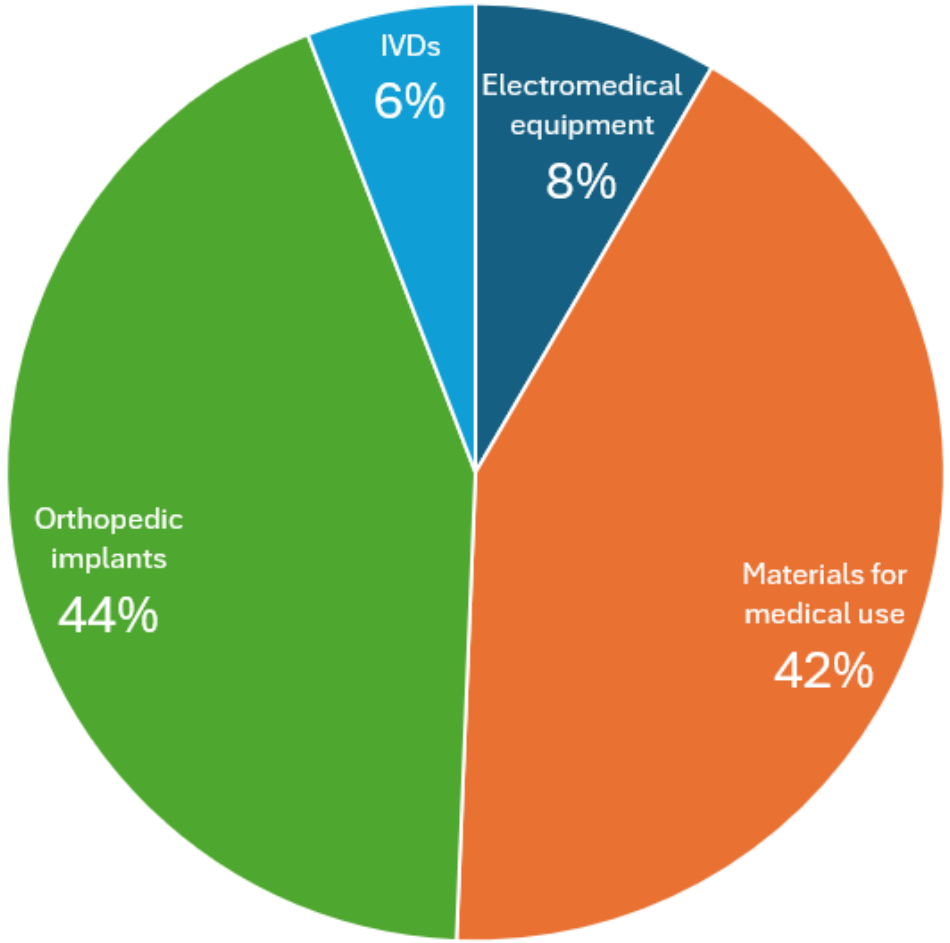

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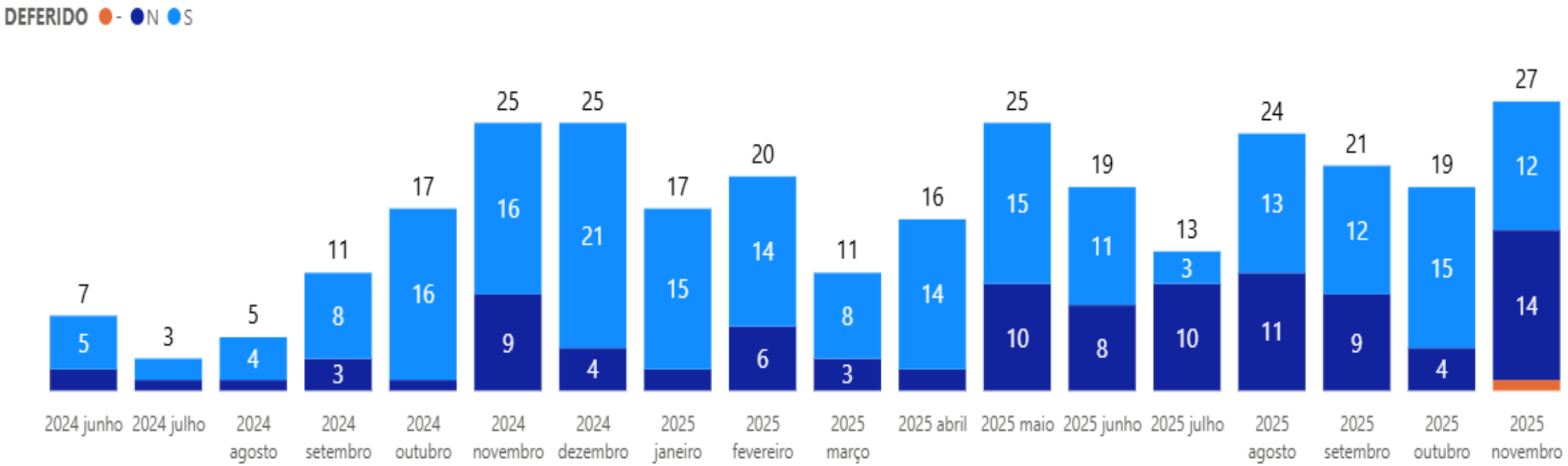
Submissions for optimized review procedure by reliance



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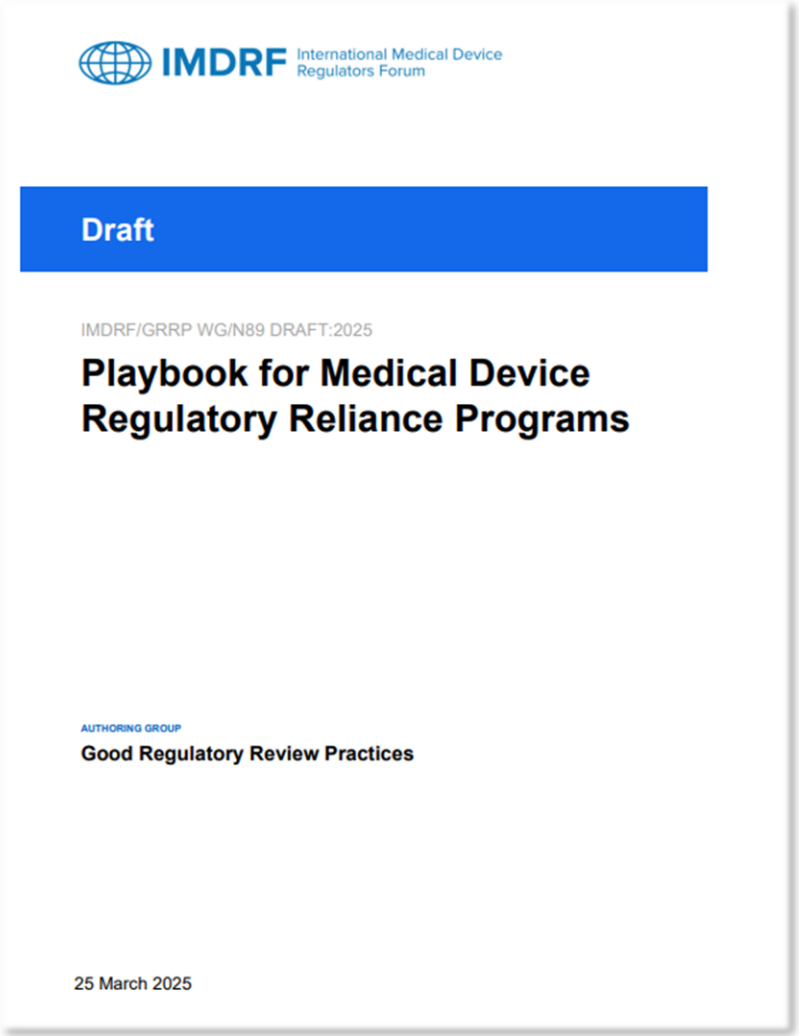
IMDRF Reliance Playbook



- The GRRP Working Group completed the development of the *Reliance Playbook* in December 2025, providing a structured and harmonized approach for regulatory authorities to implement reliance practices.
- Key principles, definitions, operational models, and practical examples to support regulatory decision-making based on assessments performed by trusted authorities, enhancing efficiency, convergence, and regulatory capacity.
- The document has been submitted to the IMDRF Management Committee, which is expected to consider its formal adoption in January 2026.

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Anvisa Project to become WHO Listed Authority (WLA)

- Anvisa is implementing strong efforts to become recognized as World Health Organization Listed Authority (WLA).
- This recognition will attest that the Agency operates at maturity level 4 and based on international standards of quality and independence.
- The project involves a robust WHO assessment of Anvisa's systems, practices, and governance.
- Inclusion in the WLA will strengthen Anvisa's international credibility and expand possibilities of reliance and mutual recognition.
- It is a strategic step to consolidate Anvisa's position as a global reference in health regulation.

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Anvisa works every day to protect the health of the Brazilian population.

It operates with technical excellence, institutional responsibility and focus on results.

Our commitment is to the life, health and sustainable development of the country.

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Obrigado!!!

Gracias!!!

Thank you!!!

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