

ANVISA Reliance: Revolutionizing Medical Device Registration in Brazil

Understanding the Optimized Registration Analysis for Health Products

The Brazilian health regulatory landscape has undergone a significant transformation with the implementation of **ANVISA's reliance mechanism**. This innovative approach represents a paradigmatic shift in how medical devices are registered in Brazil, offering manufacturers a streamlined pathway to market entry.

What is ANVISA Reliance?

Reliance is a regulatory strategy that allows ANVISA to utilize analyses and approvals already conducted by recognized international regulatory authorities. This mechanism aims to accelerate the registration process for health products in Brazil while maintaining the highest safety and efficacy standards.

The reliance approach is strongly supported by the **World Health Organization (WHO)**, which proposes and encourages this strategy due to widespread challenges with human resource limitations and difficulties in keeping pace with rapid technological advances in the medical device sector.

The adoption of reliance addresses critical needs to:

- Optimize human and financial resources
- Accelerate population access to new medical technologies
- Align with international best regulatory practices
- Reduce regulatory burden on manufacturers

Regulatory Framework: IN 290/2024

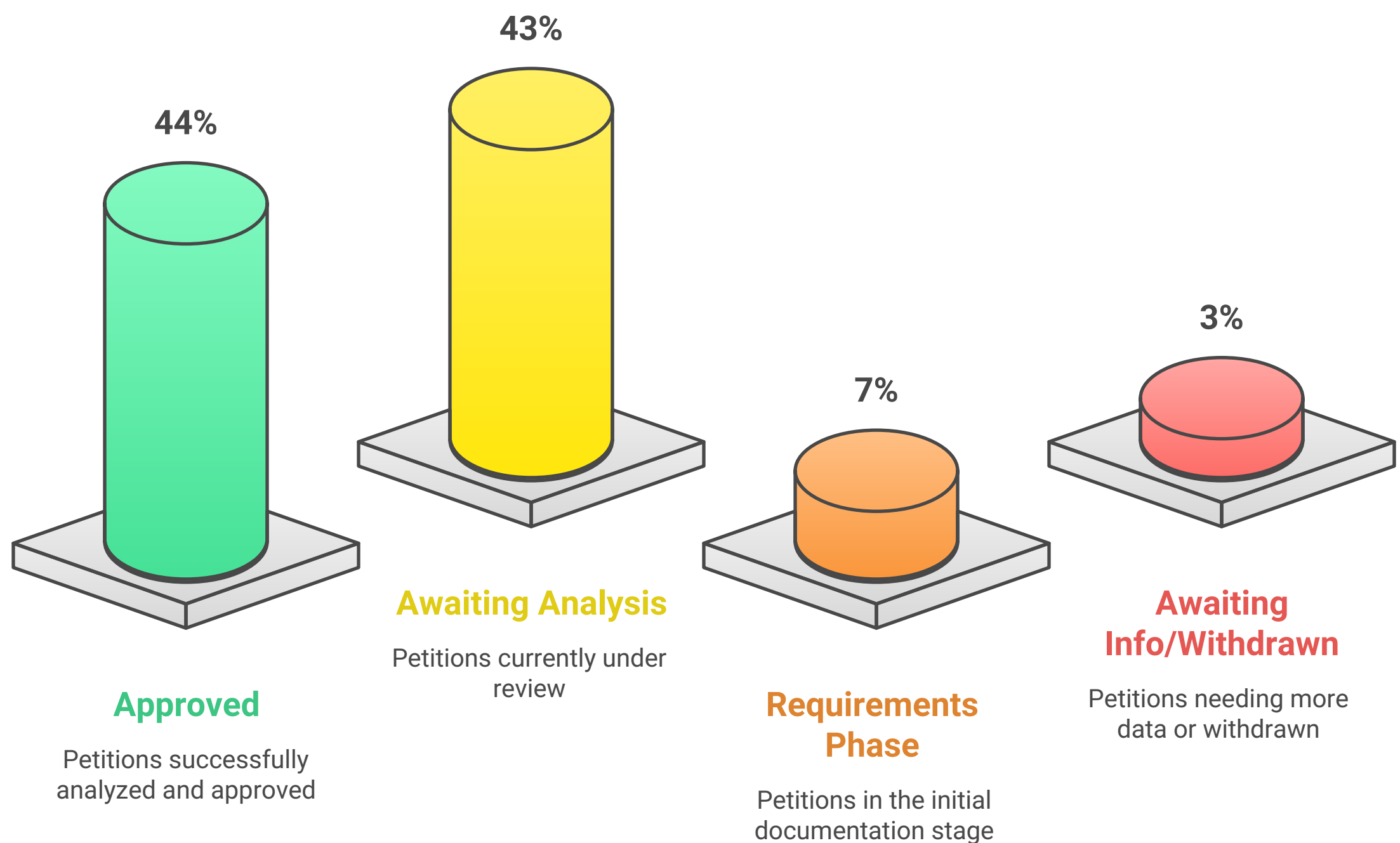
Normative Instruction 290/2024, which came into effect in June 2024, established the legal framework for abbreviated analysis of **Class 3 and 4 medical devices** that have already been registered by founding agencies of the **MDSAP** program:

- **Therapeutic Goods Administration (TGA)** – Australia
- **US Food and Drug Administration (FDA)** – United States
- **Japan Ministry of Health, Labour and Welfare (MHLW)** – Japan
- **Health Canada (HC)** – Canada

Documentation Requirements and Geographic Distribution

Since the implementation of the reliance mechanism, **ANVISA has received 382 reliance petitions** with encouraging results:

Status of ANVISA Reliance Petitions



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According to ANVISA data, the majority of documentation received through reliance comes from:

1. **United States (FDA registration requirements)** - Leading the number of petitions
2. **Australia** [TGA approvals] - Second highest volume
3. **Canada** [Health Canada certifications] - Third in petition volume
4. **Japan** [MHLW authorizations] - Smaller but growing participation

This geographic distribution reflects the robust regulatory frameworks of these **medical device authorities** and their alignment with international **GMP** standards.

Leading Product Categories in Reliance Applications

The reliance mechanism has shown particular success in four main product categories:

1. **Orthopedic Implants** - Leading the number of applications
2. **Medical Materials** - Significant adoption rate
3. **Medical Equipment** - Growing utilization
4. **In Vitro Diagnostic Products** - Emerging category

Essential Requirements for Reliance Eligibility

For the reliance process to be applicable, the medical device must be **essentially identical** to the product approved abroad. This means the device must have the **same intended use indication** as in the country of origin - the indication registered in Brazil must exactly match that approved in the reference country. This requirement ensures consistency in:

- **UDI** [Unique Device Identification] compliance
- Technical specifications
- Intended use and indications
- Risk classification alignment

Strategic Benefits for Medical Device Manufacturers

The reliance mechanism offers multiple strategic advantages:

Accelerated Market Access

- Reduced review timelines
- Faster patient access to innovative technologies

- Streamlined regulatory pathway

Cost Optimization

- Reduced **medical device consulting** expenses
- Minimized documentation requirements
- Efficient resource allocation

Quality Assurance

- Leveraging international regulatory expertise
- Maintaining high safety standards
- Enhanced regulatory confidence

Implementation Considerations

When considering reliance for your medical device registration, several factors should be evaluated:

Product Eligibility Assessment

- Classification verification (Class 3 or 4)
- Foreign approval status confirmation
- Essential similarity documentation

Documentation Preparation

- Foreign regulatory dossier compilation
- Technical file harmonization
- **GMP** compliance verification

ANVISA's Evaluation Flexibility

It's important to note that **ANVISA retains full discretion** in the reliance process. The agency may choose to:

- Perform a **complete evaluation of the Technical Dossier** even when reliance is requested
- **Request additional clarifications** on submitted documents during analysis
- Apply standard review procedures if deemed necessary for public health protection

This flexibility ensures that ANVISA maintains oversight while benefiting from international regulatory work.

The Role of Professional Consulting

Given the complexity of international regulatory requirements and the nuances of the reliance mechanism, engaging with specialized **medical device consulting** services becomes crucial. Professional consultants can:

- Navigate regulatory requirements across multiple jurisdictions
- Ensure compliance with **MDSAP** standards
- Optimize documentation strategies
- Provide insights on **medical products agency** expectations

Future Perspectives and Industry Impact

The reliance mechanism represents a significant step toward regulatory harmonization in the medical device sector. As ANVISA continues to refine and expand this program, we can expect:

Enhanced International Cooperation

- Stronger partnerships with international regulatory bodies
- Improved information sharing mechanisms
- Streamlined global market access strategies

Market Dynamics

- Increased competition through faster market entry
- Enhanced innovation incentives
- Improved patient access to cutting-edge medical technologies

Contact our medical device regulation specialists and ensure your company stays updated on these regulatory advances. Our specialized team can guide you through the reliance process and maximize your success opportunities in the Brazilian market.