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MARKET INSIGHT
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INDUSTRY NEWS

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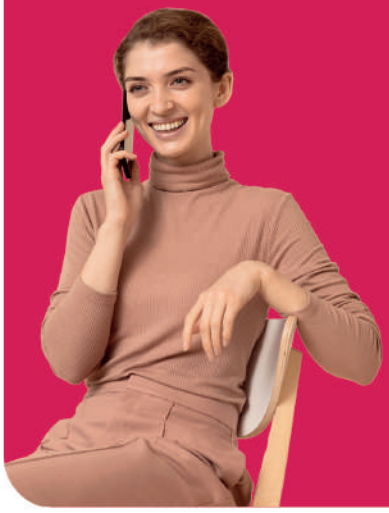

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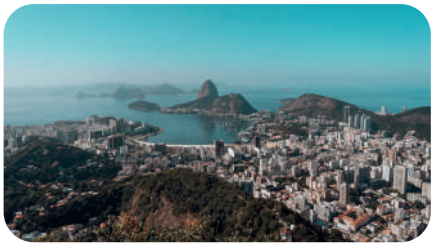

Global Winners, Losers, And The Fragile System Exposed By The Iran War

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The conflict involving Iran is producing economic effects far beyond the Middle East, from rising household energy costs in Europe to emergency measures in parts of Asia. More importantly, it is exposing a structural weakness in the global economy. For decades, globalization has been built around efficiency and interdependence, with countries relying on tightly connected systems to move energy, goods, and capital. While this model reduced costs, it also created major vulnerabilities, especially because global trade depends heavily on a few strategic chokepoints such as the Strait of Hormuz, the Strait of Malacca, the Panama Canal, and the Bab el-Mandeb. These routes are essential for global commerce, but disruptions can quickly produce worldwide consequences.

Recent events demonstrate this fragility. Drought has limited traffic through the Panama Canal, while insecurity in the Red Sea has forced ships away from the Bab el-Mandeb, increasing transport costs and delays. The escalation involving Iran has intensified concerns around the Strait of Hormuz, one of the world's most important energy corridors. Shipping activity there has fallen sharply, while reduced air cargo capacity across the Gulf has added pressure to global logistics networks. Because the Gulf region, with hubs such as Dubai, links trade flows between Asia, Europe, Africa, and the United States, disruptions are spreading beyond energy markets into sectors such as pharmaceuticals, where delays and rerouting are raising costs and creating new inflationary risks.

At the same time, rising energy prices are reshaping the balance between economic winners and losers. Countries exporting oil, gas, or alternative fuels are benefiting from tighter supply. Producers such as Norway and Canada are well positioned to meet demand from countries seeking to reduce dependence on the Middle East, but Russia appears to be gaining the most. As markets adjust, it has increased exports, particularly to India, and could see a significant rise in revenues. Other exporters, including coal producers like Indonesia, may also benefit as some economies turn toward more accessible fuels.

In contrast, energy-importing regions face growing pressure. The United States illustrates this complexity: although its energy sector may benefit, the broader economy remains vulnerable because of high consumption, exposure to global prices, and disruptions affecting companies operating in the Middle East. Europe and the UK are similarly exposed due to their dependence on imported energy, leaving them vulnerable to inflation and slower growth, especially in energy-intensive industries.

Asia faces some of the most immediate challenges because many countries rely heavily on Middle Eastern oil. South Korea, for example, depends on the region for much of its energy supply, raising concerns for industries such as semiconductor manufacturing. Countries including Sri Lanka, Bangladesh, and the Philippines have already introduced fuel rationing and reduced working weeks to cope with rising costs. Larger economies such as China and India are better protected because of energy reserves and diversified suppliers, including Iran and Russia, though these measures mainly provide short-term relief.

Overall, these developments highlight a broader transformation in the global economy. The current system remains efficient but overly dependent on limited routes, regions, and resources, making it increasingly fragile in an unstable geopolitical environment. Governments and businesses are now being pushed to prioritize flexibility and resilience over pure efficiency, shifting from a "just-in-time" to a more cautious "just-in-case" model. In this context, the Strait of Hormuz symbolizes the limits of globalization itself: the point where regional conflict and global economic stability intersect.

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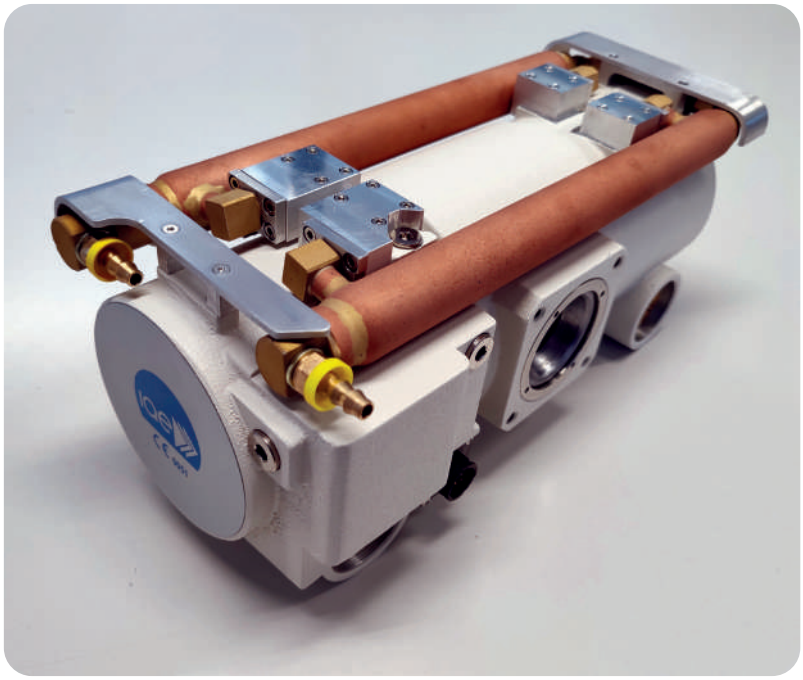

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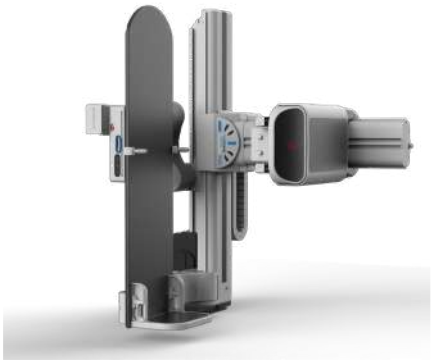

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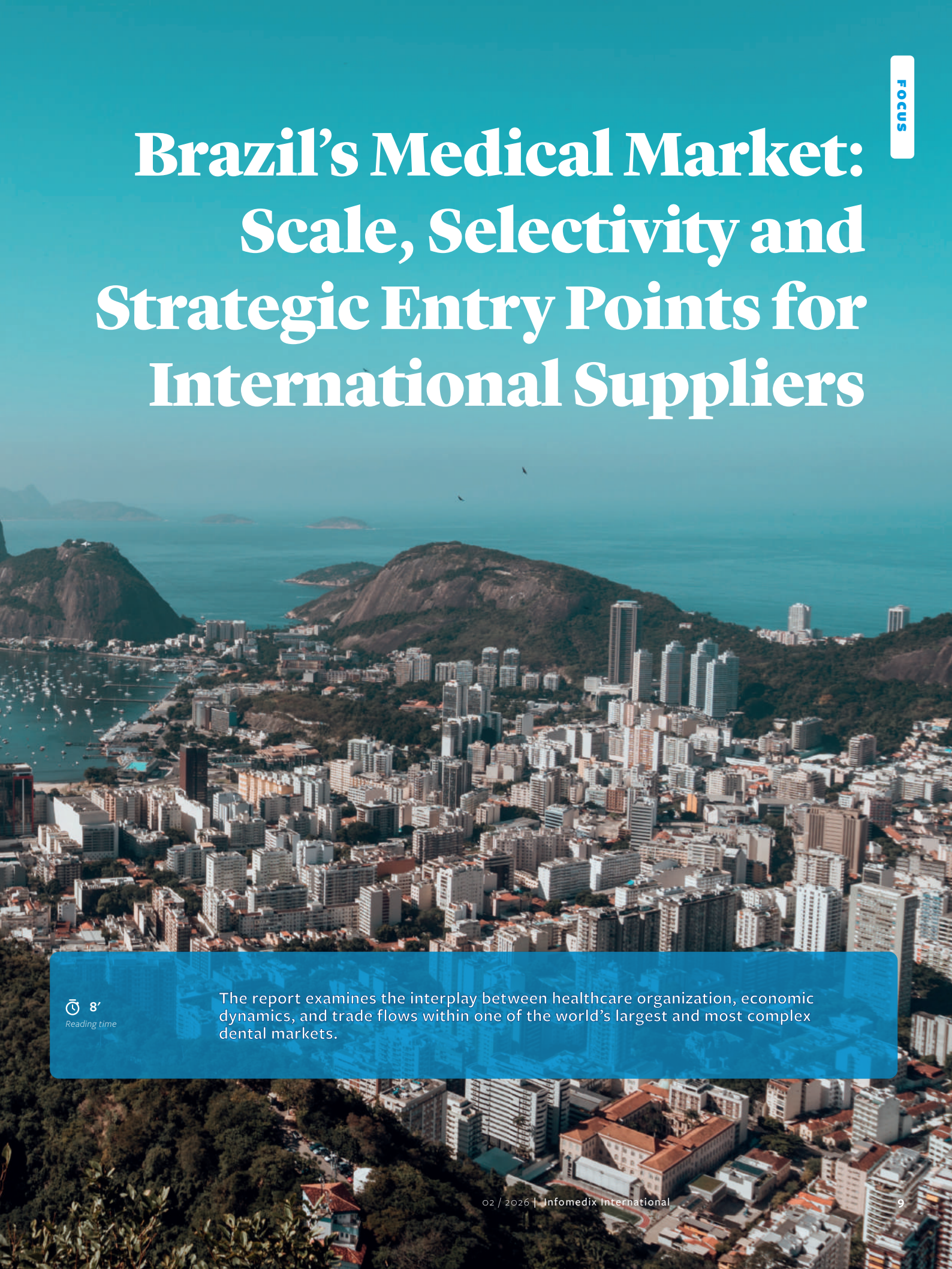
Brazil's Medical Market: Scale, Selectivity and Strategic Entry Points for International Suppliers



8′
Reading time

The report examines the interplay between healthcare organization, economic dynamics, and trade flows within one of the world's largest and most complex dental markets.

1. The numbers that immediately matter

For any manufacturer, distributor or healthcare supplier approaching Brazil, the first element that stands out is scale — but scale alone does not tell the full story.

Brazil remains the largest economy in Latin America, and over the past few years it has shown a level of resilience that is particularly relevant for long-term industrial planning. After the contraction of 2020, the country returned to solid growth, with GDP increasing by 3.2% in 2023 and 3.4% in 2024. Projections for 2025–2026 suggest a more moderate pace, generally in the range of 2–2.5%, reflecting a phase of stabilization rather than expansion.

At the same time, the macroeconomic environment remains disciplined. Inflation has been contained, closing at 4.83% in 2024 and 4.26% in 2025, while the Central Bank has maintained a restrictive monetary stance. The Selic rate, hovering around 15% into early 2026, continues to shape investment decisions across all capital-intensive sectors.

What does this mean in practical terms? It means that Brazil is not a "fast and loose" growth market. It is a market that still invests, but increasingly demands justification. Buyers — whether public or private — are more selective, more analytical, and more focused on long-term efficiency.

And this is exactly where healthcare comes into play.

Unlike many other sectors, healthcare in Brazil does not move strictly with economic cycles. It is structurally resilient. Demand is driven by demographics, by chronic diseases, by access expansion, and by the ongoing need to modernize infrastructure and technologies.

Brazil's healthcare system is built on a dual foundation: a universal public system (SUS) that guarantees access to the entire population, and a large private sector that operates alongside it. Around 51 million Brazilians are covered by private health plans, creating a parallel layer of demand that is dynamic, investment-oriented and increasingly sophisticated.

This dual structure is not just a feature of the system — it is the key to understanding the market.

2. A dual system means a dual market

Looking at Brazil as a single healthcare market is one of the most common — and most costly — mistakes international companies can make.

In reality, Brazil operates as two interconnected but very different markets.

On one side, there is the public system: large, structured, driven by tenders, compliance and institutional priorities. On the other, a private ecosystem composed of hospital groups, clinics, diagnostic networks and insurers, where competition, differentiation and performance play a much stronger role.

These two worlds often coexist within the same facilities, sometimes even within the same hospital groups, but they respond to different logics.

For suppliers, this distinction is critical.

Public-sector access is typically longer, more procedural and highly regulated. It requires patience, strong local partners and deep understanding of procurement mechanisms.

Private-sector access, instead, is more direct — but also more demanding. Decisions are faster, but expectations are higher. Hospitals and clinics look for technologies that can improve efficiency, reduce operational costs, enhance clinical outcomes and strengthen their competitive positioning.

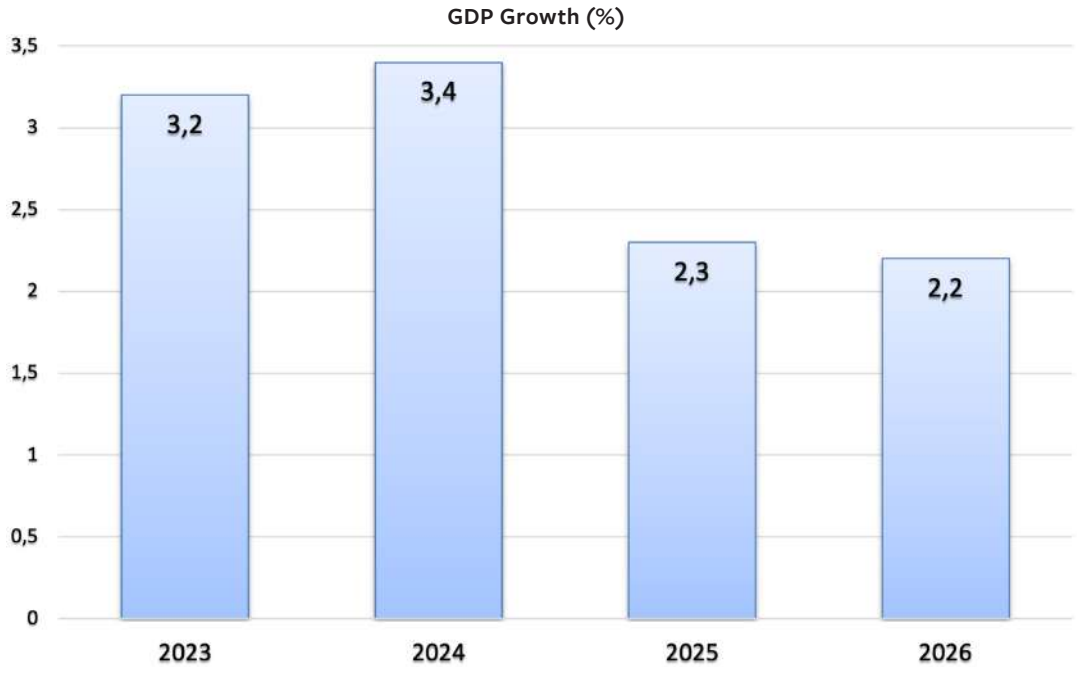
This is where the real question for a B2B reader emerges: not whether Brazil is large — that is already clear — but whether it is a market that can be effectively entered and developed.

The answer is yes, but not universally.

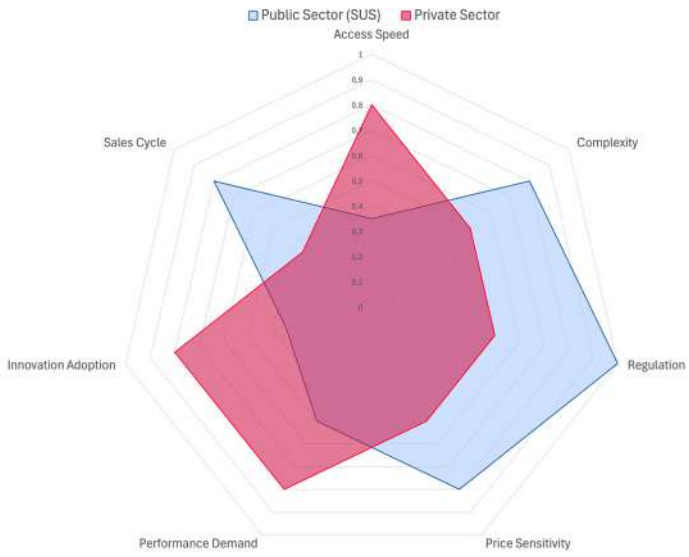
Brazil rewards alignment. Companies that understand which segment they are targeting — and why — tend to succeed. Those that approach the market with a generic strategy often struggle.

In high-volume segments, price competition is intense. In high-complexity areas — imaging, ICU, surgical technologies, rehabilitation, specialized devices — the equation changes completely. Here, reliability, service, training and clinical support often matter more than initial cost.

For many international suppliers, this is precisely where Brazil becomes attractive.



Dual Market Comparison



3. Why the hospital and medtech opportunity remains real

If there is one structural characteristic that defines Brazil's healthcare market, it is its reliance on imported technology — especially in advanced segments.

While the country has a solid domestic industry in certain areas, high-complexity medical technologies continue to depend heavily on international suppliers.

Over the past three years, imports of medical devices have grown steadily, moving from around USD 4 billion in 2023 to over USD 5 billion in 2025. This is not a temporary spike; it reflects a deeper trend: the progressive modernization of the healthcare system.

But numbers alone don't capture what is really happening.

Brazil's hospital sector is evolving. It is not simply expanding — it is upgrading.

Hospitals are investing in:

- more advanced diagnostic systems
- better-integrated clinical workflows
- ICU capacity and monitoring technologies
- laboratory automation
- surgical efficiency and precision

In other words, the focus is shifting from capacity to quality.

This transformation is visible both in the public and private sectors, although it is particularly pronounced among private hospital groups, which are increasingly competing on service quality, specialization and technological differentiation.

For suppliers, this has a clear implication: the opportunity is not in selling more equipment, but in selling better solutions.

Competing on scale against larger global players is difficult. Competing on specialization, engineering quality and flexibility is far more realistic — and often more profitable.

In Brazil, the companies that win are not necessarily the biggest ones, but those that manage to integrate product, service and long-term support into a coherent value proposition.

4. Pharmaceuticals: large, growing, but more complex than it appears

The pharmaceutical sector follows a similar logic, but with its own complexities.

Brazil is one of the largest pharmaceutical markets in the world and by far the largest in Latin America. Current estimates place the market in the range of USD 35–40 billion, with a strong growth trajectory driven by demographics, access to care and increasing demand for advanced therapies.

But this is not a simple market to read.

It is structured across three main pillars:

- public procurement through SUS
- private healthcare providers
- an extensive retail network of pharmacies

Each of these channels operates differently, both in terms of pricing and product positioning.

One of the most important structural characteristics is Brazil's dependency on imports, particularly for APIs and high-complexity drugs. More than 90% of raw materials used in pharmaceutical production are sourced from abroad, and advanced therapies rely heavily on international supply chains.

This creates opportunities — but also responsibilities.

For international companies, entering the Brazilian pharmaceutical market means engaging with a highly regulated environment. ANVISA plays a central role, overseeing registration, compliance, quality standards and post-market surveillance.

Regulation here is not just a hurdle; it is a selection mechanism.

Companies that approach Brazil with a long-term perspective, solid regulatory preparation and consistent quality standards are far more likely to succeed than those looking for short-term export opportunities.

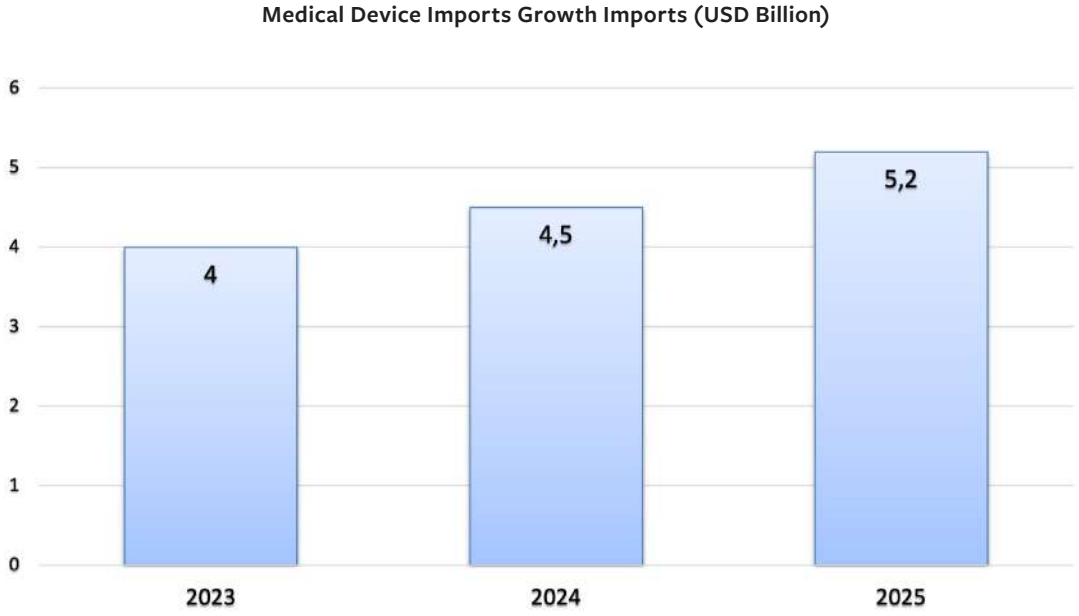
5. Market access: where opportunity meets reality

If Brazil offers significant opportunities, it also demands a high level of execution.

Market access is not only about having the right product — it is about building the right structure around it.

Three elements are particularly critical.

The first is the tax and customs system. Brazil's fiscal framework is complex, with multiple layers of taxation that depend on product classification, state



regulations and import conditions. Understanding this system is not optional — it is fundamental.

The second is regulatory compliance. Certification, documentation, technical standards and local requirements all play a central role in determining whether a product can enter — and remain in — the market.

The third, and often underestimated, is local presence.

In Brazil, after-sales service is not an added value. It is expected.

Hospitals and clinics require:

- fast technical support
- availability of spare parts
- local teams capable of intervention
- continuity of service

In many cases, the purchasing decision is influenced as much by the service structure as by the product itself.

This is why companies that invest in local partnerships, technical teams and service infrastructure tend to outperform those that rely solely on export models.

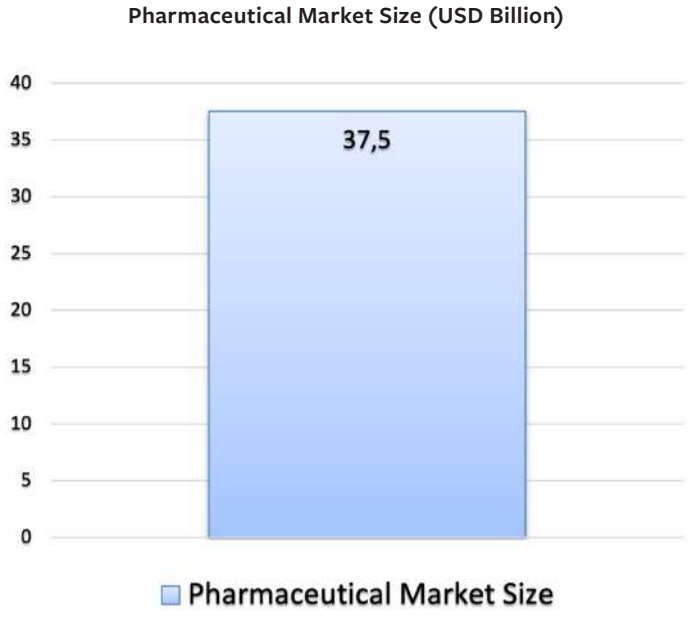
6. What does this mean?

Brazil represents a market of opportunity — but not of shortcuts.

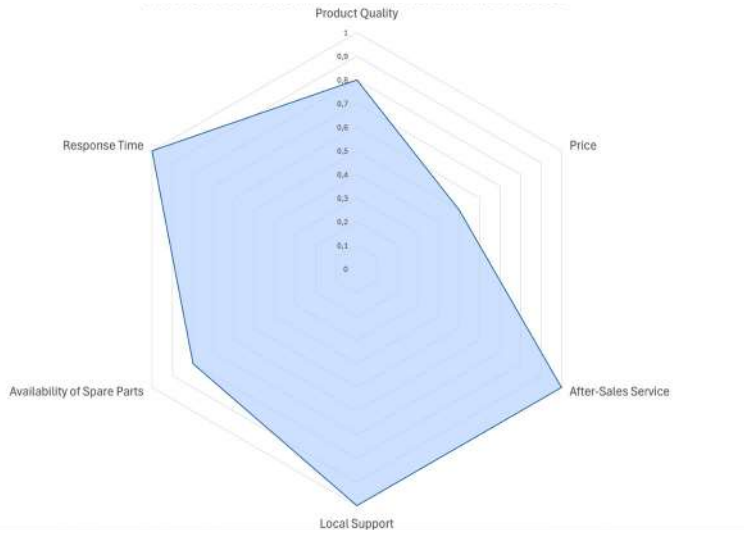
The macroeconomic environment is stable but selective. Growth continues, but capital remains expensive. Investments are made, but only when clearly justified.

This favors companies that can demonstrate:

- operational efficiency
- reliability over time
- measurable value beyond initial cost



Impact on purchasing decision impact level



At the same time, the geopolitical landscape is evolving. The EU–Mercosur framework, now moving toward implementation, could gradually improve trade conditions and reduce barriers, reinforcing Brazil's role as a strategic long-term market for European companies.

However, success will not come from broad, undifferentiated expansion.

The most effective strategy is targeted:

- focus on high-value segments
- build strong local partnerships
- invest in service and support
- approach the market with a medium- to long-term perspective

In Brazil, market entry is only the first step. The real challenge — and the real opportunity — lies in staying relevant over time.

7. Conclusion

Brazil's healthcare market is, in many ways, a paradox.

It is large, but not easy.

It is open, but highly regulated.

It is growing, but increasingly selective.

For companies that approach it superficially, it can be frustrating.

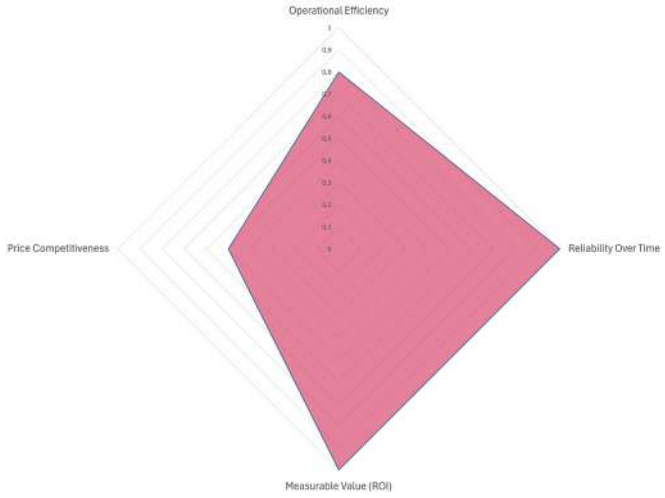
For those that understand its structure, its dynamics and its expectations, it can be one of the most rewarding markets in the global healthcare landscape.

The combination of scale, technological demand, import dependency and system evolution creates a unique environment — one where quality, reliability and long-term commitment are not just appreciated, but required.

Brazil is not the easiest market to enter.

But for the right companies, it is one of the most strategic to build.

Success factors in Brazil importance level



Flexibility as a Strategic Resource in Exporting Medical Devices to Africa

5′
Reading time
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The article analyzes the role of flexibility as a strategic competence for medical device companies operating in African markets. In a context characterized by strong regulatory fragmentation, cultural diversity, and logistical complexity, the ability to adapt processes, documentation, and business models becomes a determining factor for market access and growth. Through an overview of the continent's main geographic areas, the article highlights how differences in regulatory systems, healthcare infrastructures, and payment dynamics require highly customized approaches. This highlights the vital role of flexibility not only as a competitive advantage, but as a structural element of international operations in the medical sector.

Flexibility as a Strategic Resource in Exporting Medical Devices to Africa

The internationalization of medical device companies requires much more than a solid product and competitive pricing. In highly regulated and culturally diverse markets, success often depends on a key capability: flexibility.

In the healthcare sector, exporting companies must constantly adapt to regulatory frameworks, cultural contexts, and logistical dynamics. A rigid strategy can slow market entry, reduce competitiveness, and complicate regulatory compliance.

In international business, flexibility does not mean accommodating every request, but rather adapting processes, documentation, and strategies to different markets while maintaining quality and compliance standards.

In this sector, this capability is essential: requirements vary across countries and demand a constant balance between internal procedures and market needs.

Success in international healthcare markets depends more on the ability to adapt to regulatory, cultural, and logistical constraints than on company size or technology. It is no coincidence that well-organized SMEs can successfully operate even in complex markets often considered inaccessible, such as those in Central Africa.

Applying Flexibility to African Markets

In African markets, this competence is particularly evident, as they represent one of the most heterogeneous and dynamic contexts for healthcare exports.

Rather than a single market, Africa is a complex mosaic of regulatory systems, economic conditions, and healthcare infrastructures.

Exporters are therefore required to develop tailored approaches, combining regulatory expertise, cultural sensitivity, and collaboration with local partners to seize long-term opportunities.

In this scenario, access to healthcare markets is intricately linked to registration with national authorities. Countries such as Egypt, Morocco, Algeria, South Africa, Nigeria, and Ethiopia have developed increasingly structured regulatory frameworks, while others are still evolving.

The registration process is typically managed by local importers but requires manufacturers to provide comprehensive and adaptable technical documentation. Devices such as electrosurgical units or infusion pumps, generally classified as Class IIb, require more complex approval processes compared to Class I devices, such as gauze.

Across the African continent, regulatory flexibility translates into the ability to adapt to heterogeneous requirements: documentation in local or official languages (such as French in West Africa or Arabic in North Africa), specific formats for manuals and technical dossiers, and requests for additional documentation that may arise even months later.

Registration timelines vary significantly between structured markets, such as South Africa or Morocco, and more uncertain and fragmented contexts. This requires constant coordination between manufacturers, regulatory teams, and local distributors, as well as the ability to respond quickly throughout the authorization process.

Beyond regulation, cultural factors also play a decisive role. Business relationships are built progressively, with trust and personal presence often preceding negotiation. In countries such as Nigeria, Ghana, or Kenya, relationship continuity is valued more than quick results.

The commercial model also requires flexibility. Finan-

cial constraints, currency volatility, and limited access to credit frequently lead to requests for adapted payment terms. Letters of credit are common in Algeria, Ghana, and South Africa, while CAD (Cash Against Documents) remains widespread in Morocco, Egypt, and Tunisia.

Finally, logistics represents an additional layer of complexity. Shipments often require supplementary documentation, compliance with specific procedures, and, in some cases, the use of digital customs platforms such as CargoX in Egypt. This is combined with dedicated labeling requirements and stricter controls during import phases.

In more remote or infrastructurally complex contexts, the ability to adapt logistics models becomes crucial to ensure operational continuity and supply chain reliability.

Understanding Africa's Healthcare Landscape

The African continent is one of the most heterogeneous areas in the global healthcare landscape. Rather than a single market, it is a set of deeply different regulatory and infrastructural systems.

An important reference for understanding healthcare dynamics in the continent is the Abuja Declaration of 2001, through which African Union member states committed to allocating at least 15% of public expenditure to healthcare. Initially aimed at combating HIV/AIDS, tuberculosis, and malaria, the initiative later evolved toward strengthening national healthcare systems.

Although the target has not yet been fully achieved, the declaration remains a benchmark for the evolution of African healthcare systems, helping to strengthen public investment and attract international funding.

For European exporters of medical devices, these dynamics—between healthcare policies, demographic growth, and regulatory evolution—are key elements in identifying high-potential areas. In some markets, however, access is not achieved exclusively through direct commercial channels, but also through programs funded by international organizations and NGOs, often via international tenders.

North Africa: Structured Markets with Strong Import Demand

North African countries represent some of the most established healthcare markets on the continent, characterized by more structured regulatory systems and a strong dependence on imported medical technologies.

Egypt, with over 100 million inhabitants, shows growing demand for advanced healthcare technologies. The introduction of digital systems for customs and document management, such as the CargoX platform, has made the preparatory phase of shipments more stringent. Elements such as the commercial invoice, packing list, certificate of origin, and the ACID number are now central to customs clearance processes.

Morocco stands out for its stability and business openness, supported by investments in healthcare infrastructure and private sector growth. Knowledge of French is often an advantage in business relations.

Algeria, on the other hand, presents a more complex environment, with cumbersome import procedures and variable timelines. In this scenario, local distributors often play a decisive role in managing administrative processes and relations with public institutions.

Overall, North Africa requires rigorous management of export documentation and structured use of payment instruments.

East Africa: Rapidly Growing Healthcare Systems

East Africa is one of the most dynamic regions on the continent in terms of healthcare development and investment attraction.

Kenya represents an expanding regional hub, with Nairobi hosting a growing private healthcare system and increasing demand for advanced medical technologies from neighboring countries. Each year in September, the WHX Nairobi trade fair (formerly Medic East Africa) brings together around 7,500 visitors.

Uganda, although smaller in size, is progressively strengthening its healthcare system thanks to international programs and multilateral investments, with growing demand for diagnostic and medical devices. It is often served by divisions of companies headquartered in Kenya.

West Africa: Large Markets with Strong Growth Potential

West Africa represents one of the most promising areas of the continent, driven by demographic growth and expanding healthcare systems.

Nigeria, with approximately 240 million inhabitants, is one of the most significant markets for imported medical devices. Despite regulatory and logistical complexities, demand remains high, especially in the private sector, also supported by international events such as the WHX Lagos trade fair, which attracts around 8,000 industry professionals every year.

Ghana stands out for its relative stability and healthcare system growth, supported by public investments and private sector development. There are numerous opportunities offered by turnkey projects often coordinated by foreign investors.

Ivory Coast is also experiencing significant evolution, accompanied by new investments in healthcare infrastructure.

Emerging and Niche Markets

Some African markets, although smaller in size, offer targeted opportunities for companies oriented toward long-term strategies.

Mali and Burkina Faso have healthcare systems heavily dependent on international aid and imports, where collaboration with organizations and local distributors is often the key to market access.

Madagascar, on the other hand, combines geographic isolation with strong dependence on imported healthcare technologies, creating niche opportunities for specialized operators.

Southern Africa: A More Mature Market

South Africa represents the most mature healthcare market on the continent, thanks to an advanced regulatory framework and a well-established private sector. The latter provides services with standards close to European ones and is mainly used by the insured population (around 20%).

For many companies, the country serves both as a direct market and as a distribution hub for the entire southern region, extending to Zambia, Mozambique, and Zimbabwe through local import networks.

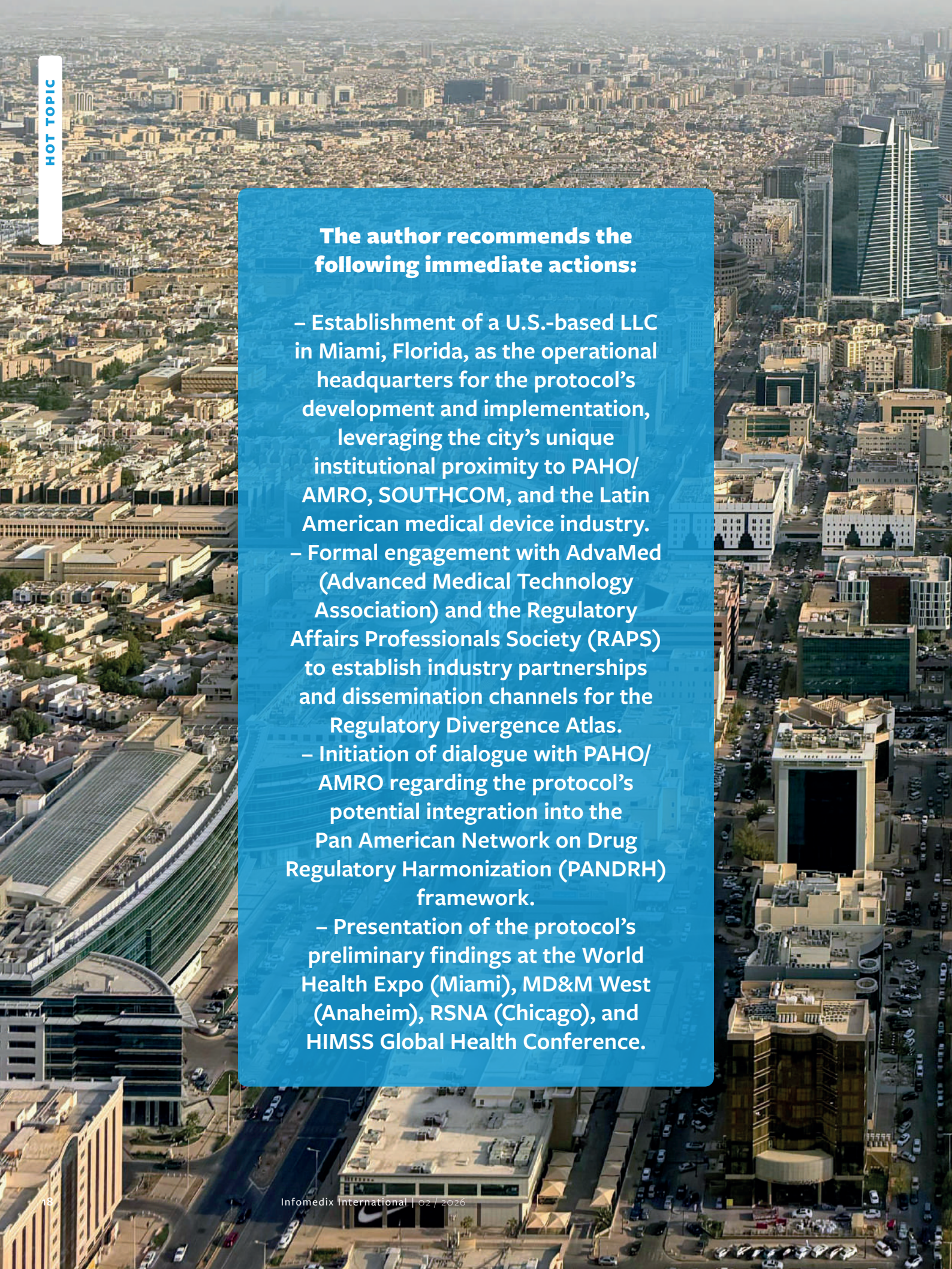
Each year, the WHX Johannesburg trade fair takes place, attracting over 10,000 visitors and more than 600 exhibitors.

Strategic Considerations for Exporters

Entering African markets requires a structured, but above all flexible, strategy. The selection of reliable local partners, knowledge of regulatory requirements, and the ability to adapt processes and documentation remain decisive factors.

In a context characterized by strong fragmentation and dynamism, flexibility is no longer simply a competitive advantage—it is a core component of international operations.

Companies that successfully integrate it systematically into their processes will be best positioned to turn the complexity of African markets into concrete opportunities for sustainable growth.



The author recommends the following immediate actions:

– Establishment of a U.S.-based LLC in Miami, Florida, as the operational headquarters for the protocol's development and implementation, leveraging the city's unique institutional proximity to PAHO/AMRO, SOUTHCOM, and the Latin American medical device industry.
– Formal engagement with AdvaMed (Advanced Medical Technology Association) and the Regulatory Affairs Professionals Society (RAPS) to establish industry partnerships and dissemination channels for the Regulatory Divergence Atlas.
– Initiation of dialogue with PAHO/AMRO regarding the protocol's potential integration into the Pan American Network on Drug Regulatory Harmonization (PANDRH) framework.
– Presentation of the protocol's preliminary findings at the World Health Expo (Miami), MD&M West (Anaheim), RSNA (Chicago), and HIMSS Global Health Conference.

Bilateral Regulatory Harmonization Protocol:

Bridging the FDA and Latin American Regulatory Frameworks for Medical Device Market Access

The regulatory fragmentation between the U.S. Food and Drug Administration (FDA) and the five principal Latin American health regulatory authorities — INVIMA (Colombia), ANVISA (Brazil), ARCSA (Ecuador), ANMAT (Argentina), and COFEPRIS (Mexico) — constitutes a critical structural barrier to the timely flow of medical technology across the Americas. This paper proposes a bilateral regulatory harmonization protocol designed to reduce approval timelines, eliminate duplicative certification requirements, and establish a convergence framework anchored in FDA standards. Drawing on over 13 years of direct operational experience in medical device import/export and a landmark 2014 regulatory precedent before INVIMA — in which FDA-aligned international nomenclature standards were successfully invoked to establish a novel device classification category in Colombia — the author presents a structured methodology applicable to all five jurisdictions. The protocol addresses a documented $2.1 billion annual loss to the U.S. medical device industry attributable to regulatory fragmentation, while simultaneously improving access to life-saving diagnostic and therapeutic technologies across a Latin American market projected to grow from $45.37 billion in 2024 to $75.30 billion in 2033.

6′
Reading time

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1. INTRODUCTION

The global medical device industry operates within a complex and heterogeneous regulatory landscape. While the United States Food and Drug Administration (FDA) has established one of the world's most rigorous and widely recognized regulatory frameworks for medical devices, the five principal Latin American regulatory authorities — INVIMA (Colombia), ANVISA (Brazil), ARCSA (Ecuador), ANMAT (Argentina), and COFEPRIS (Mexico) — each maintain independent, structurally divergent approval pathways that create substantial barriers to cross-border market access.

The consequences of this fragmentation are measurable and severe. U.S. manufacturers face average approval timelines of 18 to 36 months per Latin American market, redundant technical dossier requirements, duplicative safety testing, and inconsistent device classification standards. The cumulative economic impact on the U.S. medical device sector has been estimated at $2.1 billion in annual losses attributable to re-certification costs and market entry delays (SelectUSA, 2024). Simultaneously, Latin American healthcare systems bear the cost of delayed access to medical innovations that could improve diagnostic accuracy, reduce surgical morbidity, and address the growing burden of non-communicable diseases — including cardiovascular disease, cancer, and diabetes, which are projected to cause 81% of deaths in Latin America by 2030 (Population Reference Bureau, 2023).

This white paper proposes a structured Bilateral Regulatory Harmonization Protocol (BRHP) that takes FDA approval as the primary reference standard and establishes a convergence methodology applicable to the five identified Latin American jurisdictions. The protocol is grounded in direct regulatory practice, including a documented precedent before INVIMA in 2014 in which the author successfully applied FDA-aligned international standards to establish a new device classification category in Colombia — a case that serves as the methodological foundation for the broader framework proposed herein.

2. BACKGROUND AND PROBLEM STATEMENT

2.1 The Latin American Medical Device Market

Latin America represents one of the most significant growth opportunities for U.S. medical device exporters. The regional market was valued at $45.37 billion in 2024 and is projected to reach $75.30 billion by 2033, representing a compound annual growth rate (CAGR) of 5.79% (www.marketdataforecast.com, 2024). Brazil alone constitutes the largest medical device import market in the region, with total imports reaching $9.33 billion in 2024 — an 18% year-over-year increase — and the United States maintaining its position as the single largest supplier with a 20.64% market share and $1.93 billion in exports (UN Comtrade, 2025; www.pureglobal.com, 2025).

In 2023, the United States was the world's largest exporter of medical instruments, with $34.8 billion in total exports (www.towardshealthcare.com, 2025). Despite this dominant position, regulatory fragmentation across Latin American jurisdictions significantly constrains the U.S. sector's ability to capitalize on regional demand growth.

2.2 Regulatory Fragmentation as a Structural Barrier

Each of the five principal Latin American regulatory authorities operates under a distinct legal framework, device classification system, technical dossier structure, and approval timeline:

- INVIMA (Colombia): Governed by Decree 4725/2005. Devices classified in four risk categories (I, IIA, IIB, III). Approval timelines for Class IIB devices historically range from 18 to 36 months. Requires Spanish-language technical documentation, independent risk analysis per ISO 14971, and clinical evidence of safety and efficacy.
- ANVISA (Brazil): Governed by RDC 185/2001 and subsequent resolutions. Maintains an independent classification system with four risk classes. Brazil requires localized labeling, Portuguese-language documentation, and mandatory registration renewal every five years. Total approval timeline averages 24 months for Class III devices.
- ARCSA (Ecuador): Governed by Agreement No. 00004521. Classification system partially aligned with PAHO/WHO recommendations but diverges significantly from FDA risk classification criteria, creating uncertainty for U.S. exporters.
- ANMAT (Argentina): Governed by Decree 9763/64 and subsequent resolutions. Requires a local technical director, Spanish-language labeling, and Argentine-specific clinical validation data for high-risk devices.
- COFEPRIS (Mexico): Governed by NOM standards and the General Health Law. Mexico benefits from partial supply chain integration with U.S. manufacturers through maquiladora operations, but maintains an independent approval pathway for market authorization that does not recognize FDA clearance as sufficient for domestic commercialization.

The cumulative effect of these divergent frameworks is a system in which a device approved by the FDA — arguably the world's most stringent regulatory authority — must nonetheless undergo independent, duplicative evaluation in each Latin American jurisdiction before it can be legally commercialized. This structural inefficiency imposes disproportionate costs on small and medium-sized U.S. manufacturers and delays patient access to innovative technologies by years.

2.3 The COVID-19 Precedent

The COVID-19 pandemic provided the most dramatic and consequential demonstration of the human cost of regulatory fragmentation in the Americas. As demand for respiratory support equipment, diagnostic imaging systems, and personal protective equipment surged globally in early 2020, Latin American health authorities faced the impossible task of rapidly approving devices that had already received FDA Emergency Use Authorization — but whose domestic registration processes remained subject to standard multi-year timelines. The resulting delays in the availability of ventilators, portable X-ray units, and critical care supplies contributed directly to preventable mortality across the region. This experience establishes an irrefutable public health rationale for the harmonization protocol proposed in this paper.

3. FOUNDATIONAL CASE STUDY: INVIMA 2014 REGULATORY PRECEDENT

The methodological foundation of the proposed harmonization protocol is grounded in a regulatory precedent established in Colombia in 2014. In November 2013, the author initiated, on behalf of TRADE AND S.A.S. — as legal representative Claudio Molinari — a petition before INVIMA for a Marketing Authorization (Permiso de Comercialización) for X-ray tube assemblies and protective housings manufactured by IAE Industria Applicazioni Elettroniche S.p.A. (Italy), classified as Class IIB Controlled Technology Biomedical Equipment.

INVIMA's initial technical review (Auto No. 2014002047, March 14, 2014) concluded that X-ray tubes and housings, when considered independently of the complete radiological system, did not meet the definition of a medical device under Article 2 of Decree 4725/2005, and therefore could not be granted independent marketing authorization. This position reflected a structural gap between the Colombian regulatory framework and the internationally accepted classification of these components as autonomous biomedical devices.

To contest this determination, the author invoked the

classification authority of the ECRI Institute (Emergency Care Research Institute, USA) — the not-for-profit organization responsible for developing and maintaining the Universal Medical Device Nomenclature System (UMDNS), an internationally standardized device nomenclature adopted by regulatory agencies, healthcare systems, and government bodies worldwide, including the U.S. Department of Defense. The ECRI UMDNS assigns code 16604 to X-ray tubes, formally classifying them as independent biomedical equipment. Additionally, the technical submission demonstrated that the X-ray tube, by converting high-voltage electrical energy into ionizing radiation, constitutes an Active Medical Device under Article 2 of Decree 4725/2005 — independent of any associated radiological system.

INVIMA accepted the argument in its entirety. Resolution No. 2014027135 (August 22, 2014) granted Marketing Authorization No. INVIMA 2014EBC-0011808, valid for ten years, classifying Carcasas y Tubos de Rayos X — IAE as Class IIB Biomedical Support Equipment for diagnostic imaging. TRADE AND S.A.S. became the only company in the Colombian market to hold marketing authorization for X-ray tube assemblies as independent medical devices — establishing a regulatory category that did not previously exist in Colombian law.

This precedent demonstrates the core methodology of the proposed harmonization protocol: the systematic application of FDA-aligned international nomenclature standards (ECRI UMDNS, ISO 14971, IEC 60601 series) as a regulatory convergence bridge between the FDA framework and Latin American approval authorities. What was achieved individually for one product category in one jurisdiction in 2014 can be systematized, scaled, and applied across five jurisdictions and multiple device categories through a structured bilateral protocol.

4. PROPOSED BILATERAL REGULATORY HARMONIZATION PROTOCOL (BRHP)

4.1 Conceptual Framework

The Bilateral Regulatory Harmonization Protocol (BRHP) is structured around three operational pillars: (1) Comparative Regulatory Mapping, (2) Convergence Methodology, and (3) Digital Interoperability Infrastructure. Together, these pillars create a systematic pathway through which FDA device clearance can serve as the evidentiary foundation for accelerated market authorization across INVIMA, ANVISA, ARCSA, ANMAT, and COFEPRIS.

4.2 Pillar I — Comparative Regulatory Mapping

The first operational pillar involves the systematic mapping of divergences between the FDA's device classification system (21 CFR Parts 860-892) and the classification frameworks of the five Latin American authorities. This mapping exercise, to be conducted using Natural Language Processing (NLP) algorithms applied to the regulatory corpora of each jurisdiction, will identify:

- Device categories for which FDA classification directly corresponds to Latin American risk categories — enabling immediate equivalence recognition.
- Device categories where partial correspondence exists — enabling streamlined supplementary documentation requirements.
- Device categories where structural divergence requires targeted harmonization — representing the highest-complexity cases for the protocol.

The output of this mapping exercise will be a publicly available Regulatory Divergence Atlas — a comprehensive reference document for U.S. manufacturers seeking Latin American market access — updated annually to reflect regulatory changes in all six jurisdictions.

4.3 Pillar II — Convergence Methodology

The second pillar establishes a standardized technical dossier structure that satisfies the core documentation requirements of all five Latin American authorities simultaneously, while anchoring evidentiary standards to FDA-cleared submissions. The convergence dossier will include:

- FDA 510(k) clearance or PMA approval as the primary safety and efficacy evidence base.
- ECRI UMDNS classification as the international device nomenclature reference.
- ISO 14971 risk analysis as the harmonized risk management standard.
- IEC 60601 series compliance as the harmonized electrical safety standard.
- Multilingual technical translation (English, Spanish, Portuguese) of all core documentation.
- Jurisdiction-specific supplementary modules addressing labeling, clinical validation, and local representative requirements.

4.4 Pillar III — Digital Interoperability Infrastructure

The third pillar involves the development of a regional digital platform for regulatory data exchange, built on FHIR (Fast Healthcare Interoperability Resources) and HL7 standards, with blockchain-based traceability to ensure the integrity and provenance of all shared regulatory documentation. This infrastructure will enable real-time exchange of approval status, safety alerts, and technical updates between the FDA and Latin American authorities — reducing approval timelines and eliminating redundant document submission requirements.

5. PROJECTED IMPACT

5.1 Economic Impact on the United States

The U.S. medical device industry employs over 420,000 Americans and generated $34.8 billion in medical instrument exports in 2023 (SelectUSA, 2024; www.towardshealthcare.com, 2025). The elimination of duplicative certification requirements across five Latin American jurisdictions is projected to recover a significant portion of the estimated $2.1 billion in annual losses currently attributable to regulatory fragmentation, while accelerating U.S. manufacturers' access to a market growing at 5.79% annually.

5.2 Public Health Impact in Latin America

Over 50 million people in Latin America live with diabetes as of 2023, and non-communicable diseases are projected to account for 81% of regional mortality by 2030 (PAHO, 2023). Accelerated access to FDA-approved diagnostic and therapeutic devices — including imaging systems, cardiac monitors, surgical robotics, and in vitro diagnostics — will directly improve clinical outcomes for millions of patients who currently experience multi-year delays between device innovation and clinical availability.

5.3 Strategic Positioning of the United States

The implementation of the BRHP from U.S. territory, anchored in FDA standards, positions the United States as the global reference center for medical device regulatory governance in the Western Hemisphere. This strategic positioning strengthens bilateral health diplomacy, reinforces U.S. influence within multilateral health forums including the Pan American Health Organization (PAHO/AMRO), and creates a replicable model for regulatory harmonization applicable to other high-growth markets in Africa, Southeast Asia, and the Middle East.

6. CONCLUSIONS AND RECOMMENDATIONS

The regulatory fragmentation between FDA standards and Latin American medical device approval frameworks represents a structural inefficiency with documented costs to U.S. economic competitiveness, Latin American public health outcomes, and the broader mission of equitable access to medical technology. The Bilateral Regulatory Harmonization Protocol proposed in this paper offers a systematic, evidence-based solution grounded in direct regulatory practice and validated by a landmark 2014 precedent before INVIMA.

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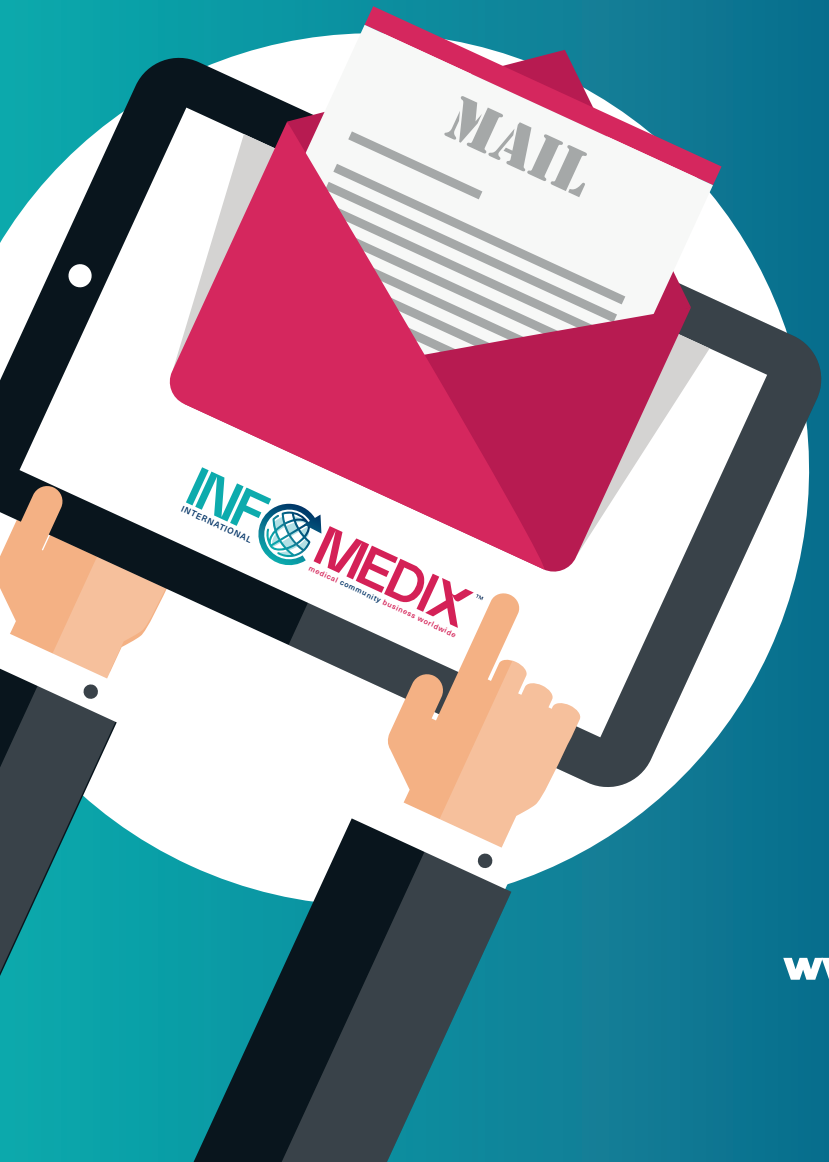

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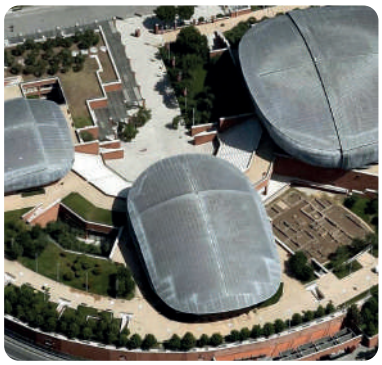

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Joint WHO, Gavi, and UNICEF press release for World Immunization Week

Guinea-Bissau renews commitment to vaccines and sustainable co-financing to protect every child

As Guinea-Bissau joins the global community to mark World Immunization Week (24–30 April 2026) under the theme "For every generation, vaccines work", the World Health Organization (WHO), UNICEF, and GAVI, the Vaccine Alliance, are calling for renewed commitment to vaccination and sustainable financing to protect children, families, and communities, particularly the most vulnerable and zero-dose children who have yet to receive a single vaccine.

Vaccines remain one of the most effective and cost-effective public health interventions, protecting people of all ages against life-threatening diseases. Immunization has saved millions of lives over the past five decades and continues to protect children from diseases such as measles, polio, tetanus, diphtheria and malaria.

In Guinea-Bissau, vaccines are a cornerstone of primary health care and child survival, contributing significantly to reductions in under-five mortality, from 174 in 2000 to 69 deaths per 1,000 live births in 2023. However, declines in immunization routine coverage highlight the need to urgently reach children who are missed by the system. [IK1]

It estimated that around 14,000 children have not received a first dose of the DTP1 vaccine by the age of 6 weeks, when the first dose is scheduled according to the national immunization calendar. These children are referred to as "zero-dose" children, and DTP1 coverage is widely used as a proxy indicator to assess access to immunization services.

While efforts such as the Big Catch-Up initiative have helped identify and reach a significant proportion of these children, drop-out between the first and third doses remains a major challenge. By the time children reach 14 weeks of age, when the third dose (DTP3) should be completed, only 68% of children were fully vaccinated in 2025. This situation is compounded by delays in domestic financing for vaccines, and barriers to access in remote communities, continue to affect vaccination coverage.

"Vaccines are a public good and a shared responsibility," said Dr. Walter Kazadi Mulombo, WHO's Special Representative to Guinea Bissau. "Sustained political commitment and financing are essential to ensure that every child, everywhere, is protected from vaccine-preventable diseases, while strengthening health and protection across generations."

A key pillar of Guinea-Bissau's immunization programme is the GAVI co-financing policy, which supports countries to gradually increase their own financial contributions to vaccines as part of a transition towards long-term sustainability. Ensuring timely fulfilment of these co-financing commitments is critical to avoid stockouts and sustain routine immunization services.

This approach has enabled the country to expand protection for children while laying the foundation for sustainable immunization financing.

"Through co-financing, countries like Guinea-Bissau are not only receiving support, but also building the foundations for self-reliant immunization systems," said Mr. Marius Keller, the Gavi Liaison Officer for Guinea-Bissau.

During World Immunization Week 2026, WHO, UNICEF and GAVI call on:

- Government of Guinea-Bissau to protect and increase domestic investment in immunization,
- Partners and donors to continue supporting vaccine access and system strengthening, and
- Health workers and community actors to actively identify and reach zero-dose children, and
- Communities to seek accurate information and ensure children receive all recommended vaccines on time.

"Every missed vaccine is a missed opportunity to protect a child," said Dr. Inoussa Kabore, UNICEF's Representative in Guinea-Bissau. "By investing in vaccines and strengthening co-financing, Guinea-Bissau is investing in the health, development and future of its children."

Together, sustained investment, strong partnerships and community trust can ensure that vaccines continue to work – for every child, in every generation.

Source:
https://www.unicef.org/guineabissau/press-releases/joint-who-gavi-and-unicef-press-release-world-immunization-week

World Immunization Week is celebrated every year in the last week of April and aims to promote the use of vaccines to protect people of all ages against disease.

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Gavi helps vaccinate nearly half the world's children against deadly and debilitating diseases and supports countries through a co-financing model to ensure long-term sustainability of immunization programmes.

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