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Public health work is an honour â?? we see its impact in peopleâ??s lives every day

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Dr. Rodrigues Mota brings two decades of leadership experience within ANVISA, the Brazilian Health Regulatory Authority, where he has held multiple senior positions and now serves as a key architect of the organisationâ??s strategic transformation. His tenure spans critical periods of regulatory modernisation, digital transformation, and international collaboration, positioning him as an authoritative voice on the evolving dynamics of pharmaceutical regulation in Latin Americaâ??s largest market.

ANVISA has recently unveiled its strategic plan for 2024-2027. Could you elaborate on the principal objectives of this framework and its anticipated impact on Brazilâ??s public health infrastructure?

I appreciate the opportunity to articulate ANVISAâ??s strategic vision and our commitment to advancing both Brazilian and global public health outcomes. Our strategic planning represents a comprehensive approach aligned with internationally recognised best management practices, developed through extensive collaboration across all organisational divisions under the coordination of our Planning Assistance Office, which reports directly to the Presidentâ??s Office.

The framework encompasses seven strategic objectives, each carrying equal strategic importance. The primary objective focuses on ensuring safe access to essential health products and services for our population. We are committed to contributing to the domestic development of promising health

technologies, while simultaneously building capabilities to anticipate and respond effectively to health crises and public health emergencies.

Our internal management objectives include empowering citizens with information to make informed health choices, achieving recognition as an international reference for health authority, promoting the effective utilisation of data, and developing human capital to address future challenges. These strategic imperatives align with ANVISAâ??s priority to expedite registration processes for essential health products, particularly those addressing rare diseases or serving unmet clinical needs, while providing transparent information to empower informed decision-making across our society.

Central to our strategic vision is achieving recognition as a World Health Organisation-listed authority (WLA). This designation will generate significant benefits for our domestic industry by elevating quality standards and ensuring our population has access to internationally recognised safe, effective, and high-quality products.

Regarding the WHO ML4 status application, what is the current progress of this initiative?

We are currently engaged in an internal audit and consultancy process, supported by the Pan American Health Organization (PAHO). Following the WHOâ??s preliminary evaluation, we are now in a compliance assessment phase, addressing the requirements and recommendations identified during this evaluation. Upon completion of this action plan, we anticipate conducting the final phaseâ??on-site WHO auditor visitsâ??by late 2025 or early 2026. It is important to note that we already maintain ML4 status through PAHO and serve as a National Regulatory Authority of Regional Reference (NRAr) for PAHO/WHO.

Digital transformation represents a critical modernisation imperative across regulatory agencies. How is ANVISA positioning itself within this technological evolution?

Digital transformation represents an inevitable evolutionâ??regulatory agencies must either embrace this advancement or risk obsolescence. ANVISA has established itself as a leader in digital service provision domestically, initiating this transformation in 2019 and achieving near-complete digitisation of our service portfolio. Currently, our processes operate on a fully digital infrastructure, with all incoming and outgoing documentation processed through digital platforms.

We have advanced beyond basic digitisation to implement artificial intelligence solutions that are currently undergoing large-scale testing. One notable application involves AI-powered evaluation of company authorisation processes, transforming individualised analysis into optimised, AI-enhanced assessments. This innovation delivers substantial efficiency gains while maintaining analytical rigour.

Additionally, we are piloting AI applications for post-registration medication analysis in partnership with the Brazilian Agency for Industrial Development. These initiatives provide valuable insights into regulatory applications of AI while preserving our technical expertise and commitment to safety and efficacy analysis.

Our *Inova-Visa* project, developed in partnership with Albert Einstein Hospital in SÃ£o Paulo, aims to enhance innovation within the sanitary regulation environment. This initiative implements open innovation strategies and strengthens our capacity to address novel, complex, and unexpected challenges, facilitating the development and internalisation of innovative products in Brazil.

This preparation is crucial because innovation invariably precedes regulation. However, regulatory frameworks must not impede innovation. We must accelerate regulatory processes to ensure optimal population access to breakthrough innovations.

Latin America has emerged as a significant clinical trials destination. Brazil recently enacted legislation to enhance clinical trial regulatory efficiency. Could you discuss these regulatory changes and their anticipated impact on approval rates and sponsor engagement?

Modernising our clinical research regulatory framework remains essential to ensure the Brazilian populationâ??s access to clinical research across all phases. In 2024, our National Congress approved legislation subsequently sanctioned by the Presidency, establishing a new regulatory framework for clinical trials in Brazil.

This legislation provides enhanced predictability in timelines and approvals while clarifying sponsor responsibilities and participant rights and obligations. We await an imminent presidential decree providing comprehensive regulatory details, which will establish operational parameters for the National Ethics System in Researchâ??an innovative consolidation of stakeholders introduced by this legislation.

The framework establishes specific timelines for various approval entities: research ethics committees receive 30 working days for file analysis, while ANVISA has 90 days to complete evaluations. Notably, if ANVISA does not complete the analysis within the prescribed timeframe, sponsors may commence research upon receiving ethical authority approval.

ANVISA has implemented complementary regulations through Resolution 945 of 2024, which adopts risk-based analysis optimisation strategies and incorporates assessments from equivalent regulatory authorities, supporting regulatory convergence initiatives and reliance.

These regulations position Brazil to attract additional clinical research, particularly Phase I and II studies. While Phase III research maintains reasonable volumes, we anticipate improvement across all phases. Brazil is establishing a regulatory environment that provides fertile and secure conditions for sponsor investment in clinical research implementation.

What do you identify as the primary challenges and opportunities for clinical research growth throughout Latin America?

Beyond regulatory convergence among core regional agenciesâ??including those in Argentina, Chile, Mexico, Colombia, and Peruâ??we require harmonisation that elevates standards to global best practices. This cannot be an exclusively Latin American regulatory harmonisation; rather, it must eliminate barriers, reduce regulatory complexity, and simplify material importation challenges for studies.

Latin America possesses populations with exceptional clinical research potential, featuring diverse genetic profiles and access to treatment-naÃ¯ve patient populations with various conditions. Regulatory harmonisation and process simplification will generate increased corporate interest in conducting regional clinical research.

Brazil specifically offers compelling advantages: a population exceeding 200 million, substantial GDP, and a robust pharmaceutical industry equipped with world-class capabilities. These factors

position Brazil as a catalyst for attracting clinical studies regionally. Furthermore, Brazilian agency participation in international harmonisation forumsâ??including ICH, PIC/S, WHO, and ICMRAâ??strengthens our global integration.

Innovative drug access remains a universal regulatory challenge. How does ANVISA balance the imperative for rapid access to innovative therapies against maintaining rigorous safety and efficacy standards?

We face structural challenges common to regulatory agencies globally: insufficient staffing relative to increasing demand. The Brazilian government is addressing this through agency expansion, whether through personnel augmentation or, as previously discussed, enhanced analytical tools.

Beyond product registration, we must ensure registered medications reach the populationâ??a significant challenge. Recent data from the Regulatory Chamber of the Drug Market (CAMED), whose executive secretariat ANVISA leads, indicates that nearly half of the registered drugs are never subsequently marketed. This represents our primary access challenge: ensuring regulated products achieve effective Brazilian market penetration.

We maintain clear prioritisation regulations to accelerate product analysis through two primary frameworks. Resolution 204 establishes criteria and procedures for priority categorisation of medicines and clinical research. Priority categories include medications for public health emergencies, situations lacking therapeutic alternatives, products providing significant patient improvements, new pharmaceuticals, vaccines and sera incorporated into national immunisation programs, and the first three generic drug applications following reference product registration eligibility.

This resolution is currently undergoing updates, with anticipated publication in the second half of this year to reflect the contemporary regulatory environment.

Additionally, we participate in collaborative evaluation projects, notably the FDAâ??s ORBIS oncology initiative, conducting joint evaluations for cancer treatments while maintaining independent agency decision-making authority. Since 2020, ANVISA has participated in this project, approving over 40 applications collaboratively. We have similar experience with vaccine protocol analysis during the pandemic in conjunction with the WHO.

These joint analyses provide significant time and efficiency gains for regulators while maintaining thorough evaluation standards and preserving individual agency decision-making authority.

Regarding biological and biosimilar products, what developments do you observe in Brazil, and how do you anticipate their impact on domestic access?

Biological and advanced therapy products represent significant regulatory challenges addressed through specialised agency structuring. These products typically target rare or unmet clinical needs and carry substantial costs, requiring particular attention given Brazilâ??s operation of the worldâ??s largest universal public health system.

Products approved by ANVISA undergo Ministry of Health evaluation for public health service incorporation, heightening our decision-making responsibility. We maintain transparent regulations on biological and biosimilar products, currently updating our foundational 2010 resolution.

Resolution 875 of 2024 has delivered significant advances by updating technical requirements for biosimilar registration through comparability study development. This regulation incorporates internationally accepted practices, addressing regulatory gaps from the 2010 framework. We anticipate this update will substantially increase biosimilar registrations nationally, expanding drug supply and aligning with federal policies promoting national production and access to high-complexity medications.

This represents a complex system where regulatory agencies must align with broader public health policies, coordinating with the Ministry of Health as Brazilâ??s primary public health authority.

As a regional reference authority, how does ANVISA leverage this position to exercise leadership and support regulatory capacity development across Latin America?

We maintain active participation in all Latin American agency forums, meetings, and initiatives. Recently, I participated in Chilean meetings with presidents of the National Regulatory Authorities of Regional Reference (NRAr), including observer agencies.

We recognise our responsibility, alongside regional organisations, to lead cooperation processes throughout Latin America while maintaining alignment with international harmonisation. We cannot develop Latin America-specific regulations that risk technological isolation from major innovations.

ANVISAâ??s participation in international forums allows us to encourage and provide technical support to neighbouring regulatory agencies in their efforts to meet the necessary requirements for joining internationally recognised forums, such as PIC/S and ICH. We facilitate knowledge transfer by hosting international conferences and meetings in Brazil, inviting regional agency representatives to participate and access internationally recognised forums, thereby elevating continental health regulation standards.

How do you envision public-private partnerships evolving to accelerate innovation while ensuring equitable access to emerging health technologies?

Our Productive Development Partnerships (PDPs) represent an established Brazilian model with both successful and unsuccessful precedents. The Ministry of Health has reformulated this policy over the past two years, clarifying objectives and technology transfer intentions through partnerships between marketing authorisation holders and manufacturing companies, whether public laboratories or domestic private companies.

The pandemic demonstrated that, despite globalisation, we require infrastructure to meet internal needs during crises. While recognising we cannot achieve complete self-sufficiency, we must develop sufficient technological capacity to rapidly expand production of essential medicines or needed products during emergencies.

ANVISA actively participates in the committee managing these PDPs, enabling us to monitor technology development from inception, facilitating analysis of plant certifications, packaging or production line approvals, and future registration or post-approval variations for domestic production.

After two decades with ANVISA across multiple positions, what motivates your daily leadership, and what represents the most valuable learning from your public health service career?

There exists a uniquely Brazilian product called cachaÃ§a, which is notably addictive. We often say that public health and health surveillance are similarly addictive. Working in public health is not a sacrificeâ??it is a field where we witness direct application of our work within families and communities.

When someone receives a vaccination at a health centre in Brazil, I have the assurance that I contributed somehow to ensuring that the product safely reached that individual, whether a niece, daughter, spouse, or any citizen. This creates motivation rather than sacrifice, because public health work represents an honourable addiction that those of us in this field embrace willingly.

What message would you like to convey to our international readership?

Regulatory agencies must increasingly exchange information, promote innovation, and invest in structural initiatives, such as what I envision as a Regional School of Regulation for experience sharing and capacity building. Mature agencies have a key role in supporting developing agencies to strengthen regional capacities and enabling the adoption of reliance practices among agencies in the Americas.

This approach enables data and information sharing through memoranda of understanding for restricted information exchange between agencies. By fostering regulatory trust among authorities in the Americas, we can strengthen collaboration and make more effective use of reliance to streamline assessments and decisions while maintaining individual agency sovereignty.

This process must be aligned with international best practices and harmonisation efforts, while also addressing specific public health policies and requirements for each country.

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