"ENABLING THE USE OF REGULATORY RELIANCE IN THE AMERICAS".

The role of NRAr in the advancement of reliance: Lessons learned

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BRAZILIAN PHARMACEUTICAL MARKET – ANVISA 2021

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Brazilian Pharmaceutical Market

↑13,6%

(compared to 2020)

8° in revenue

Biggest market in Latin America

54° position in the world innovation ranking

(Global Innovation Index 2022)

349 pharmaceutical companies

118 (33,81%) International origin

231 (66,19%) national origin

Multinational: 40,73% (revenue) and 19,54% (units sold)

National: 59,27% (revenue) and 80,46% (units sold)

*Retail

Insufficient Human Resources

1.146 extra employees are needed

(69% of the current amount)

Direct Impact in queue waiting time

ANVISA

Sources: Perfil da Indústria Farmacêutica e Aspectos Relevantes do Setor https://sindusfarma.org.br/uploads/files/229d-gerson-almeida/Publicacoes_PPTs/PERFIL_IND_FARMACEUTICA_22_PORT.pdf Guia 2022 Interfarma. Disponível em https://www.interfarma.org.br/wp-content/uploads/2022/08/Guia-Interfarma-2022.pdf; https://progenericos.org.br/genericos/mercado/ https://www.wipo.int/edocs/pubdocs/en/wipo-pub-2000-2022-section1-en-gii-2022-at-a-glance-global-innovation-index-2022-15th-edition.pdf; ANVISA

ENGAGEMENT IN INTERNATIONAL INITIATIVES AS A STRATEGY FOR REGULATORY STRENGTHENING

Increased the quality of medicines consumed in the country

Increased the competitiveness of national medicines

Increased Anvisa's efficiency

2010

Organização Pan-Americana da Saúde

NRAr Level IV

Anvisa was recognized as National Regulatory Authority of Regional Reference (NRAr) – Level IV. Positive impacts nationally and internationally.

2012

ICMRA

International Coalition of Medicines Regulatory Authorities

Co-Founder of ICMRA

International Coalition of Medicines Regulatory Authorities.

Heads of Agencies discuss strategic issues of the pharmaceutical field.

2015

APIs Equivalence

European Union recognized as equivalent the control of Active Pharmaceutical Ingredients (APIs) carried out in Brazil.

It simplified APIs exportation to the EU.

2016

ICH Member

Regulatory Convergence of Anvisa's regulatory framework with the main international guidelines.

2020

Pharmaceutical Inspection Coperation

Harmonization of the regulatory framework for drug and API inspection. Information sharing initiatives and reliance discussions among members.

2020

Orbis Project

Simultaneous submission and review of oncology products among international partners.

FDA's coordination. TGA, ANVISA, HC, MoH Israel, HSA, Swissmedic and MHRA.

2021

Programme to rationalize international GMP inspections of APIs manufacturers

Cooperation and mutual trust between regulators to allow more AFI manufacturers to be monitored, while also reducing unnecessary duplication of effort.

2024?

GBT - WHO listed authority

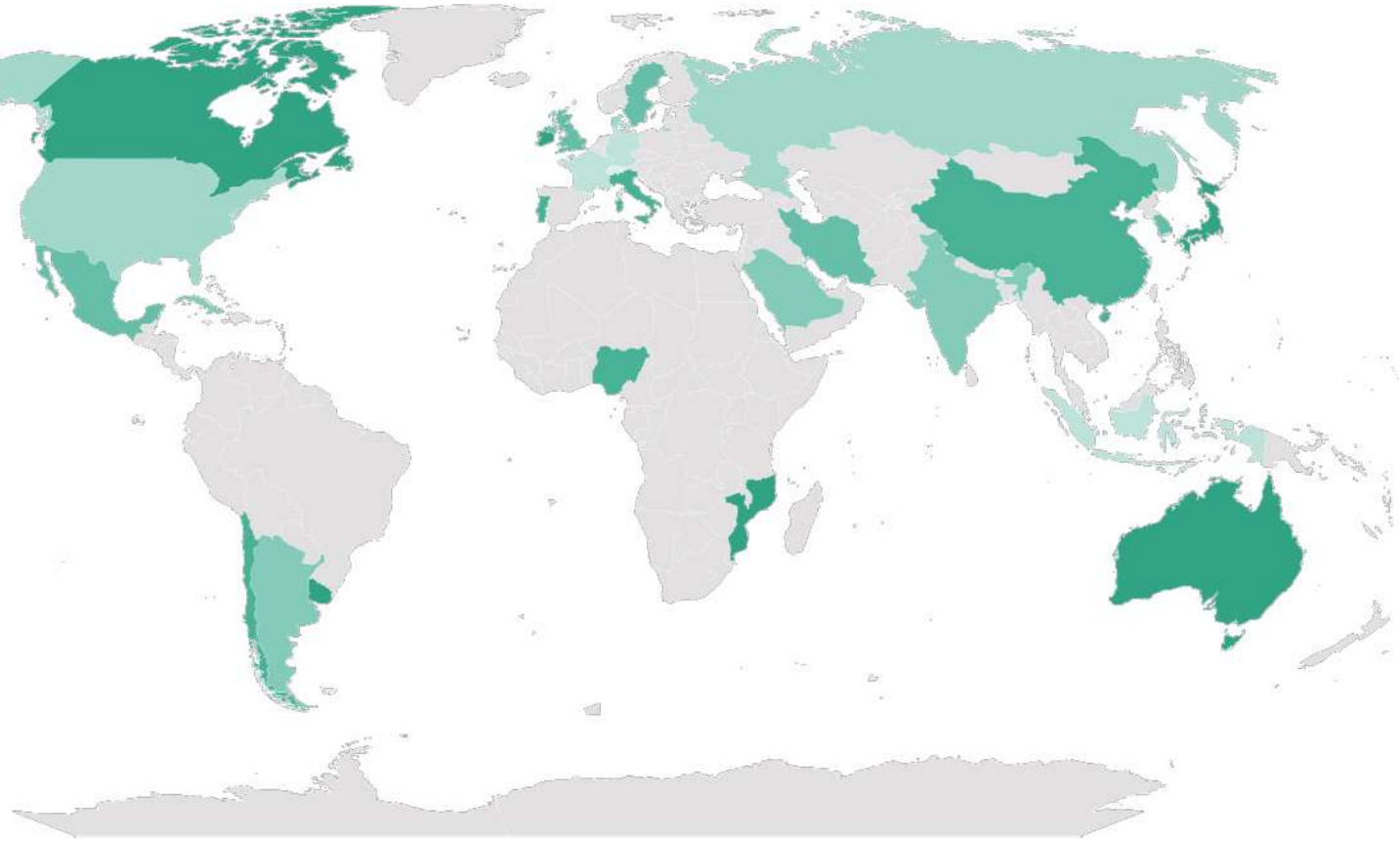
As a mechanism of strengthening it`s regulatory capacity, Anvisa intends to be assessed by WHO, probably in 2024.

MOUs WITH FOREIGN REGULATORS AND INTERNATIONAL ENTITIES

Exchange of Information and Confidentiality Commitment

In addition to foreign regulators of countries indicated on the map, Anvisa maintains agreements with:

WHO
PAHO
EUROPEAN UNION
(EDQM, EMA and DG SANTÉ)



RELIANCE AS A NATURAL PATHWAY

AT LEAST, IN THEORY

Understanding and

Engaging

Regulatory Equivalence

Confidence Building

ANVISA AND RELIANCE: OUR JOURNEY

Law changes were made

Previous internal debate – The change was not mandatory, but helped to pave the way

Different Regulatory Proposition

were made by different units:

Synthetic Drugs
Biological Drugs
Inspections

Very different results

Internal Staff Resistance

Adopting a reliance approach would mean:
. Loss of sovereignty?

. Agency weakening at long term?

. Some Heads of Offices were missing internal guidance on the topic.

National Manufactures Resistance

Adopting a reliance approach would mean:

Favoring medicines from international industries?

Discouragement of manufacturing intended for national market?

Low adhesion of multinationals

Rules were not ideal:

Significant administrative burden

Difficult in obtaining full reports from reference regulators

Lack of clear benefits related to time approval

ANVISA AND RELIANCE: OUR JOURNEY

Adoption of a transversal policy/guidance for Reliance by Anvisa

Resolution **RDC 741/2022**: general criteria for the admissibility of analysis carried out by Equivalent Foreign Regulatory Authority.

Specific proposition for medicines

Public Consultation 1.108/22:

Modalities and criteria for optimized analysis procedure, in which evaluations conducted by Equivalent Foreign Regulatory Authority (AREE) are used to support dossiers assessment for registration and post-registration of drugs and biological products, and letter of adequacy of active pharmaceutical ingredient (CADIFA)

Key Points

Equivalent Foreign Regulatory Authority (AREE)

Sameness of product means that two products have identical essential characteristics.

Lifecycle approach: similarity of the drug or biological product from initial approval to discontinuation.

Submission of **complete** dossiers + AREE reports.

Predictability of the Review Time

150 90 days

ANVISA AND RELIANCE:
LESSONS LEARNED, SO FAR

Sameness and Lifecycle approach would benefit from broader global discussions

Industry and regulators should discuss objectively differences and sameness of products destined to different markets. This information should me clear and available for regulators from the submission.

Balance between different strategies to address all submissions

There is no intention to privilege medicines according to the origin. The goal is to make medicines (Q.S.E.) available to the population as quickly as possible. Reliance pathway is one of them, but other strategies were/are adopt to reach the objective.

Close interaction between regulators and industry

Reliance pathways will only work if its rules are feasible, have concrete benefits and pharmaceutical industry plays an active role on discussions, improvement and submissions under reliance pathways.

Transparency is key

Access to information is fundamental for reliance approaches. Reports available at regulators websites is gold. Public reports X Complete reports discussions. Enhance Anvisa's own transparence mechanisms, as well as regional mechanisms.

Close Interaction

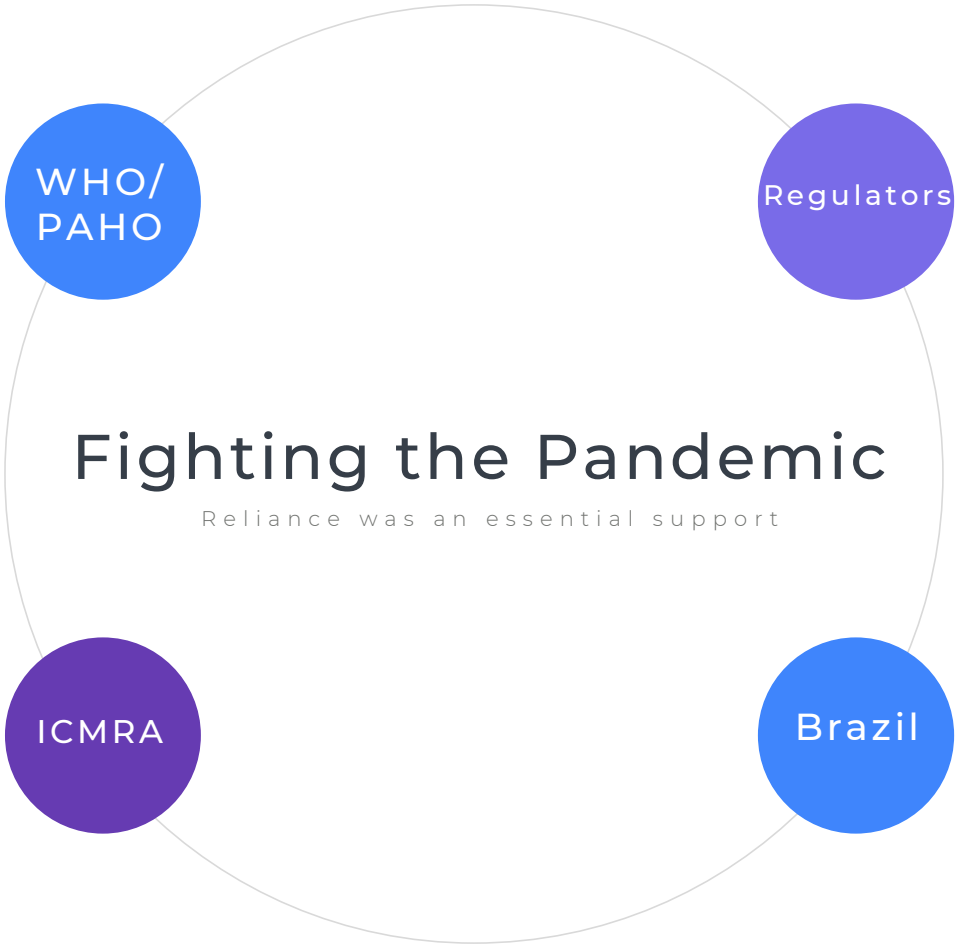
Participation in the assessment of vaccines dossiers.

Request of bilateral meetings.

Request of reports under MoU.

Rapid discussion and exchange of information

Timely discussion and access to information, challenges and solution among regulators and WHO played an extremely important role.



Foreign Regulatory Authority

Followed daily updates at websites.

Public Assessment Reports.

Bilateral Meetings and formal consultations.

National Actions

Benefiting from all information obtained international, in addition to Anvisa's own assessment, contributed to assemble the puzzle and draw strategies that fit the Country need. (e.g Monitoring studies)

Thank you