Latest News on Anvisa's Regulatory Processes

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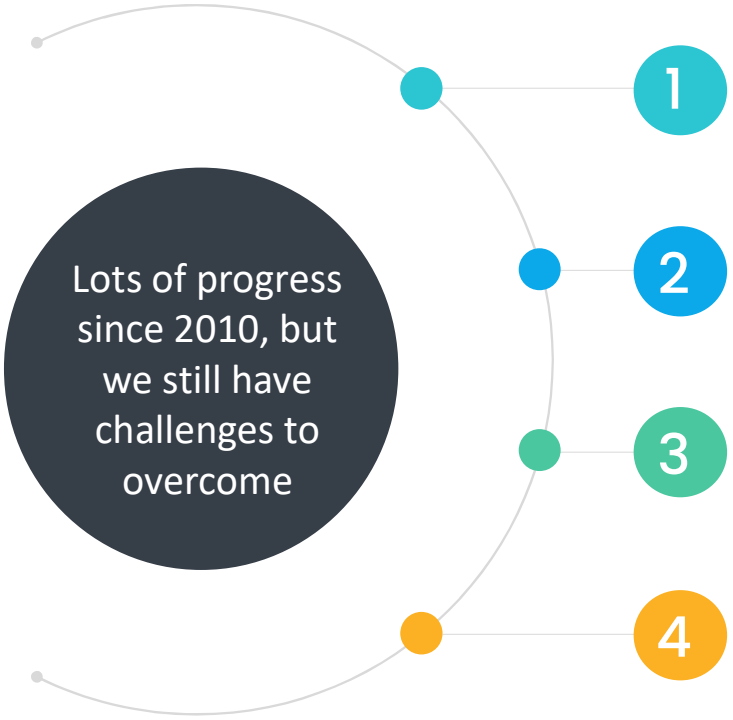
Where we are - Biosimilars

WHO Survey (2019 – 2020) Identifies Global Regulatory Challenges for Biosimilars*



Unavailability or insufficient reference products in particular countries

Limited access to information on the reference biologic, financial constraints due to the price of the reference biologic, and difficulty of obtaining reference biologic samples to assess comparability.

Lack of resources

Especially human resources and building capacity is “a lengthy process.

Problems with the quality of some biosimilars

In some countries, there are biosimilar products on the market that were approved before the establishment of a regulatory framework for approving biosimilars.

Difficulties with interchangeability and naming of biosimilars

Regulator role would be to inform physicians and patients, and not to have the final word on interchangeability.

There is still no consensus among countries on the naming and labeling of biosimilars

*Kang HN, Thorpe R, Knezevic I, et al. Regulatory challenges with biosimilars: an update from 20 countries. Ann N Y Acad Sci. Published online November 21, 2020. doi:10.1111/nyas.14522

How can we resolve these challenges?

WHO Survey (2019 – 2020) Identifies Global Regulatory Challenges for Biosimilars*

It will require cooperation between regulatory authorities in different countries

Avoiding unnecessary duplication of studies by accepting foreign-licensed and sourced reference products.

Relying on approvals from other regulatory authorities or using joint review to facilitate approval of biosimilars

Exchanging information on biologics with other regulatory authorities

Reassessing products approved before the biosimilar regulatory framework was in place and establishing regulatory oversight for pharmacovigilance.

*Kang HN, Thorpe R, Knezevic I, et al. Regulatory challenges with biosimilars: an update from 20 countries. Ann N Y Acad Sci. Published online November 21, 2020. doi:10.1111/nyas.14522

Biosimilar landscape in Brazil

Updated information until July 2022

Approvals

46

Infliximab (4)
Filgrastim (3)
Pegfilgrastim (2)
Glargine Insulin (3)
Human insulin (1)
Isophane Insulin (1)
Etanercept (5)
Trastuzumab (6)
Bevacizumab (3)
Adalimumab (5)
Rituximab (6)
Enoxaparin (5)
Somatropin (2)

Rejections

13

Pegfilgrastim (1)
Filgrastim (1)
Recombinant factor VIII (1)
Isophane Insulin (1)
Human Insulin (1)
Epoetin alfa (1)
Glargine Insulin (2)
Teriparide (1)
Rituximab (1)
Beta interferon (1)
Recombinant factor VII (1)
Eculizumab (1)

Withdrawls /Canceled

6

Human insulins (NPH, regular, 30/70) (4)
Etanercept (2)

Under Review

7

Human insulin (1)
Isophane Insulin (1)
Follitropin alfa (1)
Teriparide(1)
Adalimumab (1)
Bevacizumab (1)
Pegfilgrastim (1)

Waiting for Review

11

Eculizumab (1)
Bevacizumab (4)
Adalimumab (1)
Enoxaparin (2)
Ranibizumab (1)
Glargine Insulin (1)
Aspart Insulin (1)

ANVISA – TRANSPARENCY

RELATED INFORMATION AVAILABLE AT ANVISA'S WEBSITE

Authorized drugs
https://consultas.anvisa.gov.br/#/bulario/

Public assessment reports
https://consultas.anvisa.gov.br/#/pareceres/

Product's prescribing information
https://consultas.anvisa.gov.br/#/bulario/

Authorized Clinical trials
https://www.gov.br/anvisa/pt-br/assuntos/medicamentos/pesquisaclinica/ensaios-autorizados

Anvisa's legislation
http://antigo.anvisa.gov.br/legislacao#/

Biosimilar landscape in Brazil

Regulatory Convergence

Regulatory Convergence is a major value of Anvisa

WHO – World Health Organization

ICMRA - International Coalition of Medicines Regulatory Authorities (ICMRA)

ICH - International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use

PIC/S - Pharmaceutical Inspection Co-operation Scheme

IPRP - International Pharmaceutical Regulators Programme

International Cooperation

ANVISA AND RELIANCE

45 days for comments

Several dissociated initiatives, with limited outcomes

Medicines,
Medical Devices
Food
Pharmacopeia ...

RDC 741 de 10/08/22

Provides **general criteria** for the admissibility of analysis carried out by an Equivalent Foreign Regulatory Authority through an optimized analysis procedure.

Public Consultation Nº 1.108 18/08/22

Provides **specific criteria** for an optimized analysis procedure of **medicines, biologic products, active pharmaceutical ingredients** based on reliance procedures.

ANVISA AND RELIANCE

Public Consultation nº 1.108 18/08/22

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Provides **specific criteria** for an optimized analysis procedure of **medicines, biologic products, active pharmaceutical ingredients** based on reliance procedures.

45 days for comments

The propose is to fully assess studies, data and documents prepared to meet specific conditions for products to be commercialized in Brazil and benefit from equivalent assessments already carried out by trusted regulators.

GOALS:

To strengthen regulatory capacities

To make better use of limited resources

To avoid duplication of efforts

To promote expedite access to medicines

To increase convergence practices among regulators

By expediting assessment of products having reliance as a tool, it is expected to dedicate enough human resources to also expedite the assessment of products that are developed aiming to be approved first in Brazil.

ANVISA AND RELIANCE

Public Consultation nº 1.108 18/08/22

AREE

Equivalent Foreign Regulatory Authority - AREE: foreign regulatory authority or international entity that has regulatory practices aligned with those of Anvisa.

Documents

All documents required by current regulation should be submitted to Anvisa in addition to assessment reports from AREE.

Modalities A, B or C

Modality A – approved by AREE in less then 1 year;
Modality B – approved by AREE at any time;
Modality C – lower risk products approved by AREE (specific guide yet to be developed)

Shorter Time

Once the submitted dossier is considered eligible, Anvisa will conclude the assessment in 150 days (registration) or 90 days (post-registration change/alteration)

ANVISA AND RELIANCE

Public Consultation nº 1.108 18/08/22

AREE

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To be considered Equivalent to Anvisa (AREE), a Regulatory Authority must:

I - carry out pre- and post-market regulatory activities, in a manner consistent with those adopted by Anvisa;

II - have a transparent regulatory system, guided by good regulatory practices, with measures that prevent conflicts of interest;

III - adopt international standards and norms equivalent to those currently adopted by Anvisa applicable to API, medicines and biological products and their active substances, those established by the International Council for Harmonization of Technical Requirements for Medicines for Human Use (ICH) and the Organization World Health Organization (WHO);

IV - has established a formal and practical structure of technical cooperation with Anvisa, supported by a Memorandum of Understanding, or equivalent document, that allows the exchange of confidential information;

V – can interact in English, Spanish or Portuguese; and

VI - is not prevented from submitting, or allowing them to be submitted, the necessary documents and reports required by this resolution

ANVISA AND RELIANCE

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AREE

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The Public Consultation already lists some AREE that are considered to be equivalent, but others may be included, if established criteria are fulfilled

I - European Medicines Agency EMA (centralized analysis processes), applicable to medicines and biological products;

II - Health Canada, applicable to medicines and biological products;

III - World Health Organization - WHO, applicable to API and medicines;

IV - European Directorate for the Quality of Medicines & HealthCare - EDQM, applicable for API;

V - Swiss Agency for Therapeutic Products - Swissmedic, applicable to medicines;

VI - Medicines and Healthcare products Regulatory Agency – MHRA, United Kingdom: applicable to medicines and biological products;

VII - US Food and Drug Administration - FDA: applicable to medicines and biological products.

ANVISA AND RELIANCE

Public Consultation nº 1.108 18/08/22

Documents

All documents required by current regulation should be submitted to Anvisa in addition to assessment reports from AREE.

The documentation of the AREE submitted to support the request for regularization of a drug, API or biological product and active substances with Anvisa by the optimized analysis procedure must:

I – contain updated data and information that ensure that the drug or biological product has essential characteristics identical to those approved by the AREE, including its quality aspects;

II - have been prepared in accordance with standards consistent with those used by Anvisa, in order to ensure that it has the same scope;

III - be sufficient to identify the level of quality of the drug, API or biological product and active substances;

IV - be submitted in its complete form, without any information relevant to Anvisa's evaluation being redacted or excluded;

V - not be subject to any restriction of use by Anvisa;

VI - allow concluding that the manufacturing process evaluated by AREE is equivalent to what is being submitted to Anvisa.

*If any difference between the product approved at the AREE and the one submitted in Anvisa must be justified and will be assessed by Anvisa to evaluate its applicability to go under the optimized analysis procedure.

ANVISA AND RELIANCE

Public Consultation nº 1.108 18/08/22

SOVEREIGNTY

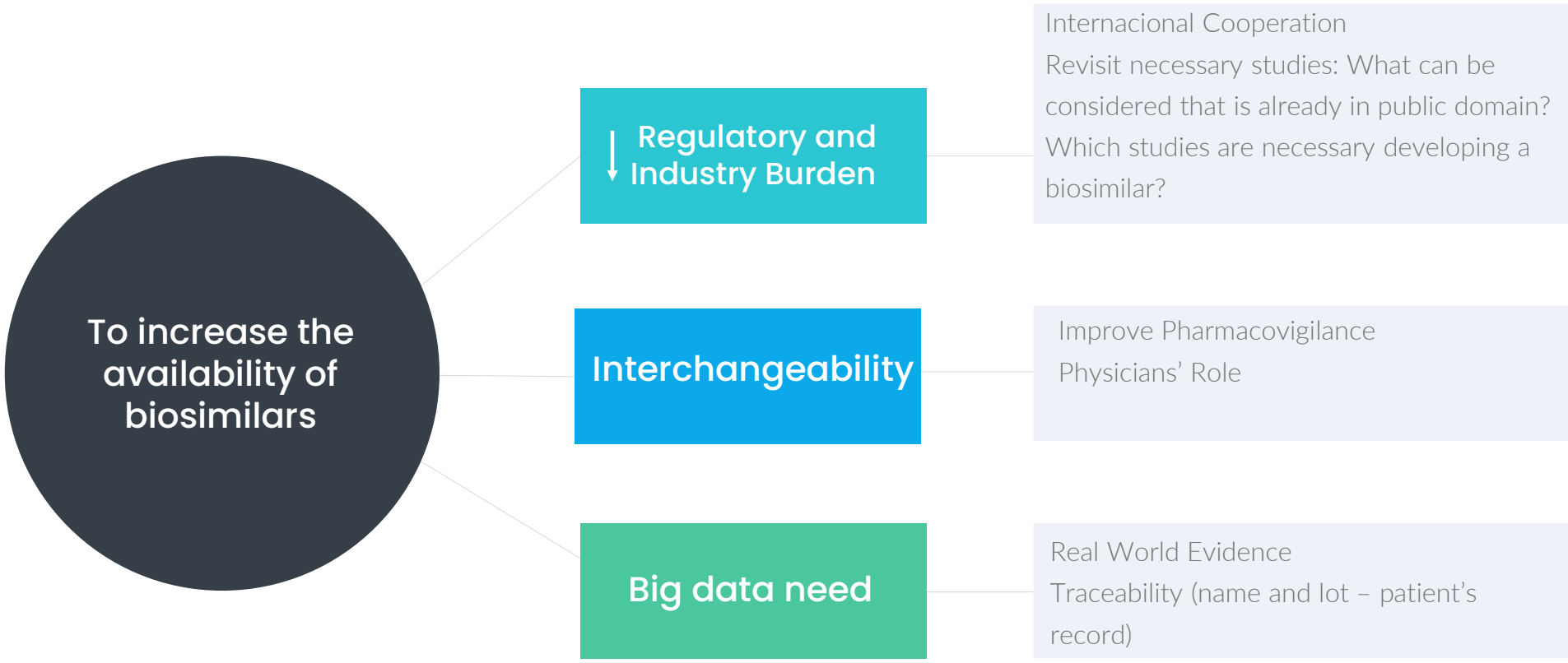
Decisions on regularization requests submitted under the optimized analysis procedure is the exclusive responsibility of Anvisa and is not necessarily linked to the decisions and conditions approved by the AREE.

ANVISA AND BIOSIMILARS

PUBLIC NOTICE (Edital de Chamamento) ON BIOSIMILARS
To be published soon

Anvisa will release in the next days a Call Notice to discuss main difficulties and possible solutions for the registration of biosimilars in Brazil.

The way forward



THANK YOU

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