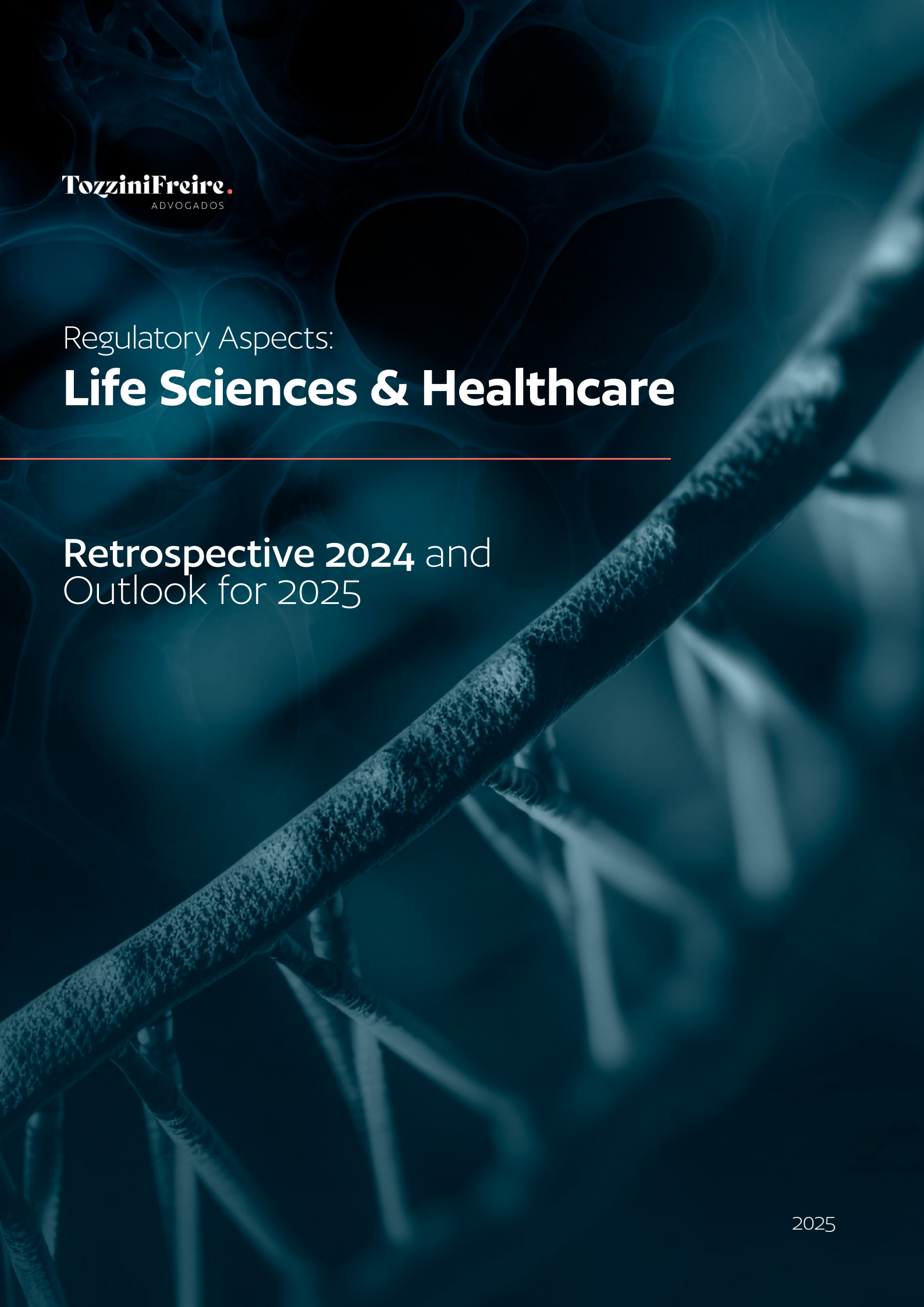

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Regulatory Aspects:

Life Sciences & Healthcare

Retrospective 2024 and Outlook for 2025

2025

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Retrospective 2024 and Outlook for 2025

Regulatory Aspects: Life Sciences & Healthcare

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Life Sciences & Healthcare Practice of TozziniFreire Advogados

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In 2024, the Brazilian National Health Surveillance Agency (Anvisa) – an agency linked to the Ministry of Health that coordinates the National Health Surveillance System (SNVS) – celebrated its 25th anniversary.

Through the regulation and oversight of matters related to health surveillance, Anvisa has enabled the introduction of measures, standards, and principles aimed at effectively protecting public health since its establishment in the late 20th century.

Since then, Anvisa's actions, as well as those of other agencies responsible for regulating and overseeing health and population well-being – such as the Brazilian National Supplementary Health Agency (ANS) and the Ministry of Agriculture, Livestock and Food Supply (Mapa) – have been essential for strengthening the quality, safety, and efficacy of products and services available to the Brazilian population.

The year of 2024 was marked by significant developments in the legal and regulatory realms regarding important issues for regulated sectors in areas such as food, cosmetics, medical devices, agricultural inputs, pharmaceuticals, health plans, etc., in addition to procedural issues inherent to the authorities' activities and prerogatives related to health surveillance.

Marco Aurélio Torronteguy

This e-book was prepared by the Life Sciences & Healthcare practice of TozziniFreire Advogados to provide insights into what to expect for 2025, as well as considerations related to the most important topics discussed in 2024 within the main agencies of the sector.

The text you will read below is based on a compilation of newsletters published by our team in 2024, with relevant additions to help you navigate the regulatory environment in 2025. Enjoy!

LIST OF ABBREVIATIONS

ADHD	Attention Deficit Hyperactivity Disorder
ADI	Direct Action of Unconstitutionality
AE	Special Authorization
AFE	Authorization for Company Operation
Anvisa	Brazilian National Health Surveillance Agency
AREE	Equivalent Foreign Regulatory Authorities
ASNVS	Advisory of the National Health Surveillance System
CBPF	Good Manufacturing Practices Certificate
CD	Deliberative Committee
CEIS	Economic-Industrial Complex of Health
CEP	Research Ethics Committee
CFF	Federal Pharmacy Council
CFM	Federal Council of Medicine
CFMV	Federal Veterinary Medicine Council
CID	International Disease Code
CMED	Market Regulation Chamber of Medicines
CNAE	National Classification of Economic Activities
CNS	National Health Council
CONEP	National Research Ethics Commission
Conitec	National Commission for the Incorporation of Technologies in the Unified Health System
CPF	National Register of Natural Person (Brazilian Individual Taxpayer Registration)
CTA	Technical Evaluation Commission
DOU	Brazil Federal Register
DEF	Electronic Devices for Smoking
DIPOA	Inspection Department of Animal Origin Products

EMA	European Medicines Agency
Embrapa	Brazilian Agricultural Research Corporation
EP	Private Entities
FDA	U.S. Food and Drug Administration
Geceis	Executive Group of the Economic-Industrial Complex of Health
GGPAF	General Management of Ports, Airports, Borders, and Customs Facilities
GGREC	General Management of Resources
GRAS	Generally Recognized as Safe
Ibama	Brazilian Institute of Environment and Renewable Natural Resources
ICH	International Council for Harmonization of Technical Requirements for Human Use Pharmaceuticals
ICT	Scientific, Technological and Innovation Institution
IFA	Active Pharmaceutical Ingredient
IFDC	International Fertilizer Development Center
IP	Public Institution
IVD	In Vitro Diagnostic Devices
LINDB	Law of Introduction to the Brazilian Rules
LMR	Maximum Residue Limits
LMT	Maximum Tolerated Limits
Mapa	Ministry of Agriculture, Livestock and Food Supply
MDSAP	Medical Device Single Audit Program
MHLW	Japan Ministry of Health, Labour and Welfare
MHRA	Medicines and Healthcare Products Regulatory Agency
OEA	Authorized Economic Operator
OMC	World Trade Organization
PAC	Growth Acceleration Program

PDIL	Local Development and Innovation Program
PDP	Partnership for Productive Development
PIC/S	Pharmaceutical Inspection Co-operation Scheme
PL	Legislative Bill
PNF	Brazilian National Fertilizer Plan
RDC	Collegiate Board Resolution
Renaciat	Brazilian National Network of Information and Toxicological Assistance Centers
REX	Exclusive Registration for Export
RFB	Brazil Internal Revenue Service
RN	Normative Resolution
SaMD	Software as a Medical Device
SDA	Secretariat of Agricultural Defense
SECTICS	Secretariat of Science, Technology, Innovation and the Economic-Industrial Complex of Health
SEI	Electronic Information System
SINEB	Information System on Pharmaceutical Equivalence Studies and Bioequivalence
SMS	Short Message Service
SNCM	Brazilian National System for the Control of Medicines
SNCR	Brazilian National System for the Control of Prescriptions
SNVS	Brazilian National Health Surveillance System
STF	Brazilian Federal Supreme Court
SUS	Unified Health System
TCAC	Commitment Term for Conduct Adjustment
TDAH	Transtorno do Déficit de Atenção com Hiperatividade
TGA	Australia Therapeutic Goods Administration
TPS	Public Consultation for Subsidies
UDI	Unique Device Identification

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REGULATORY ENHANCEMENT

OPINION: 2024, A YEAR OF REVIEW AND IMPROVEMENT OF IMPORTANT ANVISA REGULATIONS

Victor Hugo Callejon Avallone[1]

From the perspective of health regulation, the year of 2024 also represented an important period of revisions by Anvisa of significant regulations for health surveillance and the regulated sector, despite the Anvisa's well-known challenges regarding its staffing shortages. Many of the changes also stem from the guidelines of Decree No. 12,002/2024, which establishes a clear process for the review and consolidation of normative acts.

For example, the Agency amended the classic Anvisa RDC No. 16/2014, which addresses the criteria for AFE (Authorization for Company Operation) and AE (Special Authorization) for companies. This amendment was made through Anvisa RDC No. 860/2024 (which amended RDCs No. 275/2019 and No. 222/2006), which, for instance, made several registration changes immediate that previously required Anvisa's approval to be implemented. Furthermore, the revision of the regulation clarified the exemption from the AFE requirement for a headquarters that does not engage in activities subject to AFE for companies that perform activities with medical devices in their branches.

In 2024, Anvisa also approved the new regulatory framework for clinical research involving drugs, through Anvisa RDC No. 945/2024 (which revoked Anvisa RDC No. 9/2015) and Anvisa IN No. 338/2024, which will come into effect on January 1, 2025. To this end, Anvisa recognized that modernization regulatory strategies is crucial for consolidating a robust innovation ecosystem in Brazil, capable of meeting public health needs and driving technological development[2].

In addition to this, as a consequence of Decree No. 12,002, Anvisa also revised several norms regarding health services, through Anvisa RDC No. 916/2014 (good practices in parenteral solutions), No. 917/2014 (home care), No. 918/2024

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2 For an overview of the new regulation applicable to clinical research for drug development, see: TORRONTEGUY, M.A.A. Life Sciences & Healthcare Newsletter – 11th Edition of 2024, p. 9. Available at: https://tozzinifreire.com.br/en/boletins/boletim-ciencias-da-vida-e-saudeedicao-11-2024. Accessed on: December 23, 2024.

(human milk banks), No. 919/2024 (water for hemodialysis), and No. 920/2024 (obstetric and neonatal care services). Although these new norms do not change the substance of the previous regulations, they have been adapted to the format required by the Decree[3].

The same occurred with the Anvisa rules involving the transfer of sanitary registration due to corporate and commercial operations. The new Anvisa RDC No. 903/2024 did not formally change the rules of the previous regulation (Anvisa RDC No. 102/2016) but is already adapted to the new Decree. The situation is similar for the rules concerning personal hygiene products, cosmetics, and perfumes, now consolidated in Anvisa RDCs No. 906/2024 and No. 907/2024[4] .

All these revisions, among others, represent a maturation of health regulation, coming 25 years after Anvisa's establishment. It is now much easier to identify, interpret, and monitor regulatory changes from the Agency. Additionally, the fact that Anvisa no longer restarts the numbering of Resolutions every year prevents various confusions between norms (as occurred during the time when RDC No. 16/2013 on Good Manufacturing Practices and No. 16/2014 on AFE and AE coexisted and were equally important for the medical product industry).

In this spirit, Anvisa has also recently made available a new tool for accessing regulations, the AnvisaLegis portal, which allows access to consolidated regulatory norms and includes several other important sections, such as thematic libraries, guides, regulatory impact analyses, access to Agency acts in the DOU (Brazil Federal Register), etc.[5]. Updates to the Regulatory Agenda (the list of topics and their progress) also provide greater visibility of the Agency's forthcoming innovations.

Considering all these developments, 2024 highlighted a result of the continuous maturation of health regulation. Considering the future challenges (such as reliance and self-inspection trends, as well as technological innovations arising from artificial intelligence), this evolution is very welcome and desired at this moment.

3 For an overview of the new regulations applicable to healthcare services, see: TORRONTEGUY, M.A.A. Life Sciences & Healthcare Newsletter – 9th Edition of 2024, pp. 10-11. Available at: https://tozzinifreire.com.br/en/boletins/boletim-ciencias-da-vida-e-saudeedicao-9-2024. Accessed on: December 23, 2024.

4 Ibid., pp. 7-8.

5 Regarding the functionalities of AnvisaLegis, see: TORRONTEGUY, M.A.A. Life Sciences & Healthcare Newsletter – 11th Edition of 2024, p. 8. Available at: https://tozzinifreire.com.br/en/boletins/boletim-ciencias-da-vida-e-saudeedicao-11-2024. Accessed on: December 23, 2024.

OPINION: STRENGTHENING REGULATORY TRUST PRACTICES AT ANVISA

Amarildo Gabriel Filho[6]

In recent years, Anvisa has sought to increase the efficiency of its analyses through the practice of regulatory trust (or reliance). This technique consists on using analyses and approvals from certain international regulatory authorities to support the decision-making of the Brazilian Agency, aiming to confer greater efficiency to the conduct of its analyses.

The importance of reliance became evident during the Covid-19 pandemic, when access to medications for the treatment of the disease proved imperative[7].

Among the measures adopted by Anvisa, the temporary and emergency use of reports from foreign regulatory authorities for granting CBPF (Certificate of Good Manufacturing Practice) for the regularization of products intended for the treatment of Covid-19 was allowed, in accordance with Anvisa RDC No. 346/2020 (currently revoked).

The significance of regulatory trust measures was reaffirmed during the Public Health Emergency of International Concern due to the increase in MPOX cases.

In view of the countermeasures demanded by this scenario, Anvisa allowed, at that time, the waiver of requirements for the temporary and exceptional importation of medications and vaccines for the prevention or treatment of the disease.

As a condition for the exemption, Anvisa required that the use of the products had been approved by at least one of the authorities listed in Anvisa RDC No. 747/2022 (currently revoked), such as the FDA, EMA, MHRA, Health Canada, among others[8].

Currently, the general guidelines for the use of reliance by Anvisa are established by Anvisa RDC No. 741/2022. This regulation provides for the possibility of adopting optimized criteria in conducting activities related to products subject

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7 Regarding access to medicines and the measures adopted during the Covid-19 pandemic, see: AVALLONE, V.H.C. Licenciamento compulsório de medicamentos e exportação para países em situação de necessidade [Compulsory licensing of medicines and export to countries in need]. Master's Thesis, p. 194. Available at: https://www.teses.usp.br/teses/disponiveis/2/2135/tde-27092022-114952/pt-br.php. Accessed on: December 23, 2024.

8 Regarding the conditions for waiving sanitary requirements applicable during the Public Health Emergency of International Concern resulting from MPOX, see: TORRONTEGUY, M.A.A. Life Sciences & Healthcare Newsletter – 1st Edition of 2024, p. 2. Available at: https://tozzinifreire.com.br/boletins/boletim-ciencias-da-vida-e-saudeedicao-1-2024. Accessed on: December 23, 2024.

to health regulation, among which authorization, registration, qualification, accreditation, certification, inspection, among other activities, are highlighted.

While Anvisa RDC No. 741/2022 establishes general criteria for the practice of reliance, Anvisa has created specific regulations on the subject for each regulatory category under its jurisdiction (e.g., Anvisa IN No. 290/2024 – regarding medical devices; Anvisa IN No. 292/2024 – regarding medicines and CBPF; and Anvisa IN No. 338/2024 – regarding clinical research).

There is no doubt that international regulatory cooperation has proven to be a matter of great relevance for Anvisa. This year, Brazil engaged in negotiations with Chile to encourage trade in cosmetic products. Through this agreement, the aim is to increase regulatory convergence between both nations, which should reduce complexity and potential obstacles to the commercialization of cosmetics between parties from both countries[9] .

I believe that the trend of increasing reliance practices by Anvisa will continue in 2025. The benefits of optimizing the Agency's analyses extend to all involved: to Anvisa itself, which will conduct its activities in accordance with the principle of efficiency in Public Administration; to the regulated sector, whose requests will be analyzed more swiftly; and, especially, to the Brazilian population, due to the consequent strengthening of the right to health resulting from access to quality products brought to market safely and more rapidly.

ANVISA UPDATES THE REGULATORY AGENDA 2024-2025 WITH THE INCLUSION OF EIGHT NEW TOPICS

At the 21st Public Ordinary Meeting (ROP) of 2024, held on November 27, 2024, the Collegiate Board of Anvisa approved a recent version of the Regulatory Agenda 2024-2025, published through Anvisa Ordinance No. 1,514/2024.

The Agenda aims to indicate topics for better planning of regulatory changes, with the purpose of bringing more predictability and transparency to the regulatory process.

This is a mandatory instrument for regulatory agencies since 2019, with express provision in Law No. 13,848/2019 (Law of Regulatory Agencies).

9 Regarding the negotiations between Brazil and Chile, see: TORRONTEGUY, M.A.A. Life Sciences & Healthcare Newsletter – 7th Edition of 2024, p. 4. Available at: https://tozzinifreire.com.br/en/boletins/boletim-ciencias-da-vida-e-saudeedicao-7-2024. Accessed on: December 23, 2024

It is worth mentioning that the Agenda is designed to be revised as necessary. The 2024-2025 Agenda was initially created with 172 topics. With the update, 8 topics were added, and another 9 were removed, resulting in an updated list of 171 topics.

The included topics are as follows:

- Topic 1.24 - Review of the regulation that creates Renaciat (Review of Anvisa RDC No. 19/2005).
- Topic 1.25 - Procedures for the classification of border products.
- Topic 3.35 - Regulation of the extrapolation of MRLs (Maximum Residue Limits) for active pharmaceutical ingredients between animal species.
- Topic 3.36 - Review of the positive list of monomers, other initiating substances, and polymers authorized for use in plastic materials.
- Topic 5.6 - Review of the Brazilian Pharmacopoeia collegiates and their Internal Regulations (Review of Anvisa RDC No. 467/2021).
- Topic 8.46 - Update on clinical research of advanced therapy products, due to the publication of Law No. 14,874/2024 (Review of Anvisa RDC No. 506/2021).
- Topic 11.12 - Availability of the Anvisa UDI (Unique Device Identification) database, as determined by paragraph 3 of article 15 of Anvisa RDC No. 591/2021.
- Topic 12.7 - Requirements for the regularization of biological agents (macroscopic organisms) for vector and pathogen control in urban environments.

On the other hand, some excluded topics pertain to internal matters at Anvisa, such as (a) installment of debts (1.7); (b) master plan for continuing education of the SNVS (National Health Surveillance System) (9.4); and (c) contingency plans (9.5).

Despite these exclusions, some removed topics are of greater relevance, such as the topic regarding (d) antimicrobial action on clothing, surfaces, and objects (12.3); and (e) agrochemicals used for professional gardening in urban centers (2.10).

The complete list of excluded and included topics, along with their respective justifications, is available on Anvisa's page regarding the update of the Regulatory Agenda 2024-2025[10].

10 Regarding the topic, see: National Health Surveillance Agency - Anvisa aprova atualização da Agenda Regulatória 2024-2025 [Anvisa approves the update of the Regulatory Agenda 2024-2025]. Available at: https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2024/anvisa-aprova-atualizacao-da-agenda-regulatoria-2024-2025. Accessed on: December 23, 2024

ANVISA RECEIVES CONTRIBUTIONS ON PROPOSED REGULATION FOR STANDARDIZING RISKS OF ECONOMIC ACTIVITIES SUBJECT TO HEALTH SURVEILLANCE

Through Public Consultation No. 1,249/2024 approved by the Collegiate Board on April 30, 2024, Anvisa received contributions from society and the regulated sector regarding a proposed RDC involving the identification and classification of risk levels for economic activities subject to health surveillance.

The aim of the new RDC is to review and consolidate the following normative acts:

- Anvisa RDC No. 49/2013 (Provides for the regularization for the exercise of health-related activities by individual micro-entrepreneurs, rural family enterprises, and solidarity economic enterprises);
- Anvisa RDC No. 153/2017 (Regulates the Classification of Risk Levels for economic activities subject to health surveillance for licensing purposes);
- Anvisa RDC No. 418/2020 (Amends RDC No. 153/2017, which regulates the classification of risk levels for economic activities subject to health surveillance for licensing purposes, and provides other provisions); and
- IN No. 66/2020 (Establishes the list of CNAE (National Classification of Economic Activities) of economic activities subject to health surveillance by risk level and dependent on information for health licensing purposes, as provided in the sole paragraph of article 6 of RDC No. 153/2017).

The proposed new normative act aims to "serve as a model for categorizing and classifying the sanitary actions and practices carried out in pre- and post-market activities in establishments and services of health interest, considering the requirements for monitoring, control, and risk management to health of products and services offered to the population of a territory"[11].

To standardize the risks of economic activities subject to health surveillance, the ASNVS (Brazilian National Health Surveillance Agency) proposed the following identification and classification[12]:

11 Regarding the topic, see: Brazilian National Health Surveillance Agency - VOTE No. 100/2024/SEI/DIRE3/ANVISA. Available at: https://antigo.anvisa.gov.br/documents/10181/6585013/SEI_ANVISA+-+2891067+-+Voto.pdf/7bb04425-e012-44a9-a3d5-cd051ea1caaf. Accessed on: December 23, 2024.

12 *Ibidem*.

Risk I – Low: “economic activities whose supply of products and services to the population has a low likelihood of failures, technical complaints, or causing adverse events to health and the environment.”

Risk II – Medium: “economic activities whose supply of products and services to the population has a possibility of failures, technical complaints, or causing temporary or reversible health events or harms, with adequate treatment, as well as to the environment.”

Risk III – High: “economic activities whose supply of products and services to the population has a high likelihood of failures, technical complaints, or causing events or harms with risks to health and the environment.”

After completing the analysis of the proposals received, it is expected that the Collegiate Board will deliberate on the approval of the proposed RDC regarding the standardization of risks.

ANVISA CONSOLIDATES RULES ON TRANSFERS OF OWNERSHIP/RESPONSIBILITY RESULTING FROM CORPORATE OR COMMERCIAL OPERATIONS

The Collegiate Board of Anvisa approved the consolidation of the rules for transferring ownership of product registrations subject to health surveillance, as well as the transfer of responsibility for clinical trials and updates of registration data related to the operation and certification of companies, resulting from corporate or commercial operations.

This consolidation resulted in the Anvisa Resolution No. 903/2024 publication, which establishes the procedures to be followed in the respective transfers and updates.

The new Resolution brought formal changes to the rules in force, but without substantive alterations[13]. The regulation is a result of Anvisa’s actions to improve regulation under its authority, in accordance with Decree No. 12,002/2024, which establishes guidelines for the preparation, drafting, amendment, and consolidation of normative acts.

It is worth mentioning that the procedures fortransferring sanitary registration require collaboration and carrying out mutual activities between the successor

13 Regarding the topic, see: Brazilian National Health Surveillance Agency - VOTE No. 368/2024/SEI/PRESIDENT/ANVISA. Available at: https://www.gov.br/anvisa/pt-br/composicao/diretoria-colegiada/reunioes-da-diretoria/votos/2024/rop-16.2024/2-4-a-2-7.pdf/view. Accessed on: December 23, 2024

and predecessor companies, in compliance with the deadlines set out in the applicable regulation and based on the premise that the technical conditions of the products will not be altered.

Anvisa Resolution No. 903/2024 came into effect on September 9, 2024.

ANVISA CONSOLIDATES RULES REGARDING ACTIVITIES IN HEALTH SERVICES

In September, Anvisa published five RDCs aimed at consolidating the rules applicable to health services.

The regulations address parenteral solutions, home care services, human milk banks, treatment/distribution of water for hemodialysis, as well as neonatal and obstetric services.

- **Anvisa Resolution No. 916/2024:** Provides guidelines for Good Practices in the Use of Parenteral Solutions in health services.

The regulation is applicable to all health establishments that use parenteral solutions and contains the minimum requirements for the use of such products in health services.

Among its provisions, there are organizational and infrastructure conditions; rules regarding procedures involving the acquisition, storage, distribution, preparation, and administration of parenteral solutions, etc.

- **Anvisa Resolution No. 917/2024:** Regulates the operation of services providing home care.

All home care services that offer home assistance and/or home hospitalization must comply with the requirements established by this Resolution.

The regulation contains operating rules for such services, such as the process to be followed for the admission and discharge of patients, the elements of the home care plan with guidelines for the actions of the professionals involved, infrastructure requirements, etc.

- **Anvisa Resolution No. 918/2024:** Regulates the operation of Human Milk Banks.

The Resolution establishes the sanitary requirements for the organization and operation of Human Milk Banks and Human Milk Collection Points. It applies to all health services that carry out activities related to such establishments.

In addition to the operating license, Banks must be linked to hospitals providing maternal and/or child assistance, while Collection Points must be technically linked to Banks.

The regulation also addresses the general infrastructure conditions, procedures related to biosafety, donor selection procedures, collection procedures, etc.

- **Anvisa Resolution No. 919/2024:** Regulates planning, programming, preparation, evaluation, and approval of the Water Treatment and Distribution Systems for Hemodialysis within the Brazilian National Health Surveillance System (SNVS).

The regulation is applicable to all establishments offering dialysis services for patients with chronic kidney failure. Such establishments must ensure that the water used in the procedures has the specified requirements.

The Resolution establishes infrastructure requirements to be met and represented in a basic architectural project, which must encompass the water treatment/distribution systems.

The project must consider the standards recommended by the manufacturers of the devices, as well as other requirements related to maintenance, components used in the water transport system, etc.

- **Anvisa Resolution No. 920/2024:** Regulates the operation of Obstetric and Neonatal Care Services.

The Resolution is applicable to health services operating in the country that engage in obstetric and neonatal activities, whether independent or part of hospitals. It also encompasses services related to teaching and research.

The regulation outlines operational, infrastructure, and technical responsibility requirements, among others, aimed at ensuring the safety and quality of services provided.

Additionally, as it promotes health humanization actions, the Resolution explicitly lists the rights of services users, such as the presence of a companion of the woman's free choice during reception, labor, postpartum, etc., the adoption of shared accommodation from birth, a comfortable waiting environment, among others.

Just like in other cases of consolidating regulations for products/services subject to health surveillance, this work results from Anvisa's efforts to enhance current regulation, in line with the provisions of Decree No. 12,002/2024.

The regulations came into effect on September 26, 2024. Anvisa Resolution No. 920/2024, originally published on this date, was republished on October 4, 2024.

ANVISA OPENS DOORS FOR THE VETERINARY PRESCRIPTION OF CANNABIS PRODUCTS, AS WELL AS THE REGULATION OF THESE PRODUCTS BY MAPA

Anvisa approved a measure to allow the prescription of cannabis-based veterinary products by veterinarians, as well as enabling the regulation of such products by Mapa.

To this end, Anvisa published on November 7, 2024 the Resolution No. 936/2024 to update Ordinance SVS/MS No. 344/1998, which contains provisions on the registration and dispensing of products subject to special control.

Cannabis products constitute a regulatory category created by Anvisa in 2019 through Resolution No. 327/2019. This allowed, at that time, the regulation of products for human use (under the sanitary authorization regime) that had not yet met the necessary technical and regulatory requirements to be classified as medicines (regulated under the sanitary registration regime)[14].

The current measure addresses a demand from the CFMV (Federal Council of Veterinary Medicine). Considering that, until then, there was no regulatory framework authorizing the prescription of products by veterinarians, these professionals were at risk of penalties if they prescribed such products. In a statement, the CFMV said that "with the new regulation, professionals will be able to use cannabis safely and legally, without the risk of penalties"[15].

With the new rules:

- Mapa, responsible for the regulation of veterinary products, is now able to regulate cannabis products for commercial purposes in Brazil; and
- Licensed veterinarians can now prescribe cannabis medications (registered with Anvisa); cannabis products (authorized by Anvisa); and animal-only products regulated by Mapa[16].

14 Regarding the topic, see: RIBEIRO, A.; KESTENER, B.M.A.C.; SILVA, B.M.; PARISE, C. et al. Direito da Cannabis: perspectiva Life Sciences [Cannabis Law: A Life Sciences Perspective]. Organizers: JAMBOR, D.G; and FÜRST, H. Belo Horizonte: Editora Casa do Direito, 2023.

15 Regarding the topic, see: Regional Council of Veterinary Medicine of the State of Paraíba - Uso da Cannabis na Medicina Veterinária é aprovado pela Anvisa [Use of Cannabis in Veterinary Medicine is approved by Anvisa]. Available at: https://www.crmvpb.org.br/uso-da-cannabis-na-medicina-veterinaria-e-aprovado-pela-anvisa/. Accessed on: December 23, 2024.

16 Regarding the topic, see: Brazilian National Health Surveillance Agency - Produtos à base de Cannabis poderão ser regularizados para uso em animais [Cannabis-based products may be regularized for use in animals]. Available at: https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2024/produtos-a-base-de-cannabis-poderao-ser-regularizados-para-uso-em-animais. Accessed on: December 23, 2024.

As these are products subject to special control, veterinary prescriptions must occur by means of a special prescription to be kept at pharmacies. Anvisa Resolution No. 936/2024 came into effect on December 2, 2024.

NEW PUBLIC CONSULTATION ON ADMINISTRATIVE SANCTIONING PROCESSES WITHIN ANVISA

At the end of 2024, Anvisa opened Public Consultation No. 1,297/2024 to receive contributions regarding the proposal of a new RDC on sanitary administrative processes within the Agency.

Considering the publication date of this e-book, the Public Consultation is still open, and contributions can be submitted until February 3, 2025.

If approved, the new RDC will complement Laws No. 6,437/1977 (which constitutes infractions of federal sanitary legislation and establishes the respective sanctions) and No. 9,784/1999 (which regulates the administrative process within the Federal Public Administration) and Anvisa Resolution No. 266/2019 (which addresses the procedures related to the filing of administrative appeals against Anvisa's decisions).

The proposal aims to provide greater legal security in procedural matters: the draft clarifies interpretations of Anvisa that are already known, as well as providing definitions for essential terms to health surveillance actions and the sanitary administrative process.

Below are the main points of the proposal:

Processes will become public, as a rule, after the first-instance decision (art. 26):

The proposal states: "After the issuance of the first-instance decision, the PAS (sanitary administrative processes) will be public, except for data protected by legal or infra-legal acts."

Currently, the sanitary administrative case records are inaccessible to those who do not have a direct interest in the case.

Concept of responsive oversight (art. 2, XI, and arts. 3 to 12):

Defined as "a regulatory approach based on a criteria that guide the health authority in the proportional and efficient selection of administrative measures, considering the health risk associated with the infraction, the compliance history of the regulated entity, and the need to prevent or mitigate risks to public health more swiftly."

This principle relates to notions of sanitary notification and now allows for TCAC (Commitment Term for Conduct Adjustment) and dual visits explicitly mentioned by the proposal, which bring a less punitive and more guiding approach to health oversight, in line with the Agency's reliance notions and actions.

Express provision of penalties for infractions and the possibility of *reformatio in pejus* (art. 24, § 2):

It is now proposed to clarify in a specific regulation that "The limits of fines established in Laws No. 6,437, of August 20, 1977, and No. 9,294, of July 15, 1996, will be applied per infraction and not per sanitary administrative process," as well as the possibility of increasing the sanction in the context of appeal (*reformatio in pejus*).

It was already known that Anvisa had this interpretation (that *reformatio in pejus* is possible and that the penalty is for each infraction), but now the Agency aims to clarify this more explicitly.

This is a prerogative already enabled by Law No. 9,784/1999 and recognized by the Brazilian Federal Supreme Court, considering its understanding that the principle of non-*reformatio in pejus* does not apply to sanitary administrative processes.

Acts and protocols via the SEI System (art. 19, art. 28, and art. 77):

Provision that acts in the case records must be carried out electronically (SEI-Anvisa), including the filing of defenses, appeals, as well as the communication of infraction records and administrative decisions.

Defense and appeal deadlines (art. 18 and art. 27):

The deadlines for filing defenses and administrative appeals will also be clearer. The regulation maintains the current deadline of 15 days for filing administrative defenses, as provided in Law No. 6,437/1977. However, it diverges from the law by establishing a 20-day deadline for filing administrative appeals in the Appellate Court.

This should eliminate any uncertainties regarding the deadline for filing appeals before GGREC (General Coordination for Sanitary Surveillance), but Anvisa has already adopted the 20-day deadline provided by Anvisa Resolution No. 266/2019 (theoretically not applicable to sanctioning processes).

Thus, the regulation should provide greater legal certainty regarding the deadlines considered by Anvisa, which, in practice, would be as follows:

Document	Deadline (counted from the company's notification)
Defense	15 days
Appeal to GGREC	20 days
Appeal to the Collegiate Board	20 days

Criteria for applying penalties (art. 24, art. 38, and arts. 51 and 52):

Definition of criteria involving factors such as the economic capacity of the fined party, their history, and the mitigating and aggravating circumstances, including establishing a table for the base amounts of fines applicable based on the size of the fined entity and the nature of the infraction under analysis.

By detailing such criteria, already provided for by Law No. 6,437/1977, the new regulation aims to give greater clarity and transparency regarding the aspects considered by the adjudicating authority during the determination of the penalties to be applied.

ESTABLISHMENT OF ANVISA REGULATORY SANDBOX

Through TPS No. 9/2024 opened on August 12, 2024, Anvisa received public contributions regarding the Partial Report of the Regulatory Impact Analysis to establish the Regulatory Sandbox model (or Experimental Regulatory Environment)[17].

The Regulatory Sandbox is a mechanism in which companies can test innovative products and services in a controlled and safe manner before they become available on the market.

According to TPS, the proposal is that the process be supervised and allow the temporary suspension of current regulations, within an experimental environment that, in theory, would prevent the testing or regulation of innovations.

17 Regarding the topic, see: Brazilian National Health Surveillance Agency - Anvisa recebe contribuições sobre proposta de modelo de Sandbox Regulatório [Anvisa receives contributions on the proposed Regulatory Sandbox model]. Available at: https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2024/anvisa-recebe-contribuicoes-sobre-proposta-de-modelo-de-sandbox-regulatorio. Accessed on: December 23, 2024.

With this, Anvisa seeks to provide a safe and effective regulatory approach for innovative products and services, in situations where current regulations could prevent their testing and regulation.

The creation of experimental regulatory environments is provided by Complementary Law No. 182/2021, and such mechanisms are already used by other agencies in Brazil (e.g., Mapa).

It is expected that the contributions received by Anvisa will support the study of the Regulatory Impact Analysis to implement the Regulatory Sandbox model in response to the needs of the sector and society.

ANVISA ESTABLISHES THE ANVISALEGIS SYSTEM

In early December 2024, Anvisa officially implemented the AnvisaLegis system. The system consolidates the regulatory norms of the Agency, as well as all publications related to the regulatory process, such as openings of regulatory processes, public consultations, regulatory impact analysis reports, guides, etc.

The implementation of the system arose from the need to comply with the requirements of Decree No. 12,002/2024 (which defines the rules for the preparation, drafting, amendment, and consolidation of normative acts), which contains provisions on the standard for the disclosure of normative acts.

The AnvisaLegis system provides a series of tools to facilitate access to the Agency's regulatory information. Currently, the system is divided into the following sections:

i. Anvisa Regulatory Norms: "Presents the normative acts published by Anvisa, such as Collegiate Board Resolutions (RDCs), Normative Instructions (IN), Ordinances, among other acts";

ii. Thematic Libraries: "Presents the set of regulatory norms grouped by the thematic areas of Anvisa's activities, with options to consult the complete document in PDF or by specific subjects";

iii. Guides: "Presents the Guides published by Anvisa with recommendations on best practices for procedures, routines, and methods deemed appropriate for complying with technical requirements";

iv. Social Participation: "Presents Public Consultations, Hearings, Public Calls for Contributions, among other forms of society's participation in Anvisa's regulatory proposals";

v. Opening of Processes: "Presents the documents that mark and define the initial conditions of a regulatory process";

vi. Regulatory Impact Analysis: "Gathers the Regulatory Impact Analysis Reports produced by Anvisa, distributed by year or by macro-themes";

vii. Regulatory Results Evaluation: "Gathers the Regulatory Results Evaluation Reports produced by Anvisa";

viii. General Acts of Anvisa: "Makes available the normative and non-normative acts issued by the Agency, classified according to type"; and

ix. Anvisa DOU Extract: "Provides, between 5 and 8 hours of the same day, all Anvisa Acts published in the DOU (Brazil Federal Register)".

The system is already accessible through the Anvisa portal[18].

18 Regarding the topic, see: Brazilian National Health Surveillance Agency – AnvisaLegis. Available at: https://anvisalegis.datalegis.net/action/ActionDatalegis.php?acao=apresentacao&cod_menu=9434&cod_modulo=310. Accessed on: December 23, 2024.

RELIANCE AND INTERNATIONAL RELATIONS

ANVISA JOINS THE BRAZILIAN AUTHORIZED ECONOMIC OPERATOR (OEA) PROGRAM

On March 14, 2024, RFB (Brazil Internal Revenue Service) and Anvisa published RFB/Anvisa Joint Ordinance No. 400/2024 to address Anvisa's participation in the Brazilian OEA Program.

The OEA Program is a tool provided for in the WTO's Framework for Global Trade Security and Facilitation, which had already been utilized for products outside the scope of Anvisa.

The purpose is to certify operators in the international supply chain as low-risk strategic partners. To do so, operators must comply with the requirements and criteria established in the OEA Program, which allows them to benefit from advantages offered by the Brazilian Customs.

Anvisa's participation in the Program occurs through the implementation of the Integrated OEA-Anvisa Program, a complementary module of the OEA Program. Importers of products subject to regulation in the National Health Surveillance System (SNVS) that meet the admissibility requirements are eligible for certification.

The certifications granted are classified based on different product categories, each with its own admissibility requirements as set forth in Anvisa Resolution No. 845/2024. The categories are (i) food; (ii) medical devices; (iii) medicines; (iv) cosmetics, personal hygiene products, and perfumes; (v) sanitizers. Anvisa Resolution No. 845/2024 came into effect on May 26, 2024.

Certified operators under the Integrated OEA-Anvisa Program have priority in the analysis of import processes and cargo inspections, among other benefits. To continue enjoying these advantages, operators must adhere to the necessary requirements for maintaining certification, which will be monitored by Anvisa.

Participation in the Integrated OEA-Anvisa Program is voluntary. The General Coordination for International Affairs (GGPAF) is responsible for granting and canceling the certification.

ANVISA PUBLISHES REGULATION TO ESTABLISH AN OPTIMIZED PROCEDURE FOR THE ANALYSIS AND DECISION OF MEDICAL DEVICE REGISTRATION PETITIONS

During the 4th ROP (Regulatory Oversight Panel) of 2024, Anvisa's Collegiate Board unanimously approved Normative Instruction No. 290/2024, which involves reliance mechanisms related to the registration of medical devices.

The regulation is aligned with Anvisa Resolution No. 741/2022, which addresses the general admissibility criteria for analyses conducted by Recognized Regulatory Authorities (AREE) for adopting an optimized analysis and decision procedure. Specifically, Normative Instruction No. 290/2024 establishes the optimized procedure for analysis and decisions on medical device petitions.

The instruction applies to medical devices subject to the registration procedure, meaning those classified as high (Class III) or maximum (Class IV) sanitary risk. Medical devices classified as lower risk (Classes I and II), which are subject to the notification procedure, are not covered by this regulation.

The registration request via the optimized procedure must be submitted by the interested company. The applicant must provide, among other documents, proof of registration or authorization from an AREE referring to the essentially identical medical device intended for registration with Anvisa, including information on usage indications, manufacturer, etc.

Anvisa is not obliged to follow the optimized procedure in all cases, as, upon analysis of the documentation issued by the AREE, Anvisa may opt for the ordinary analysis procedure. In this case, Anvisa must inform the company of its decision.

According to Normative Instruction No. 290/2024, for the purposes of adopting the optimized procedure, Anvisa currently recognizes four foreign authorities as AREE: (i) TGA (Therapeutic Goods Administration); (ii) Health Canada; (iii) FDA (Food and Drug Administration); and (iv) MHLW (Ministry of Health, Labour and Welfare).

Normative Instruction No. 290/2024 came into effect on June 3, 2024.

ANVISA PUBLISHES IN THAT REGULATES THE OPTIMIZED CBPF PROCEDURE BY INSPECTION OF FOREIGN AUTHORITIES

On May 3, 2024, Anvisa's Collegiate Board published IN (Normative Instruction) No. 292/2024, which regulates Anvisa Resolution No. 741/2022 and establishes the optimized analysis procedure for granting the CBPF (Certificate of Good Manufacturing Practices), as well as specific criteria and procedures for defining Recognized Regulatory Authorities (AREEs).

According to the IN, the optimized procedure is based on the evaluation of inspection reports and all supporting documentation issued by the AREEs for granting the CBPF to foreign manufacturers of active pharmaceutical ingredients, cannabis products for medicinal purposes, medicines, and biological products. This procedure is optional.

The rigor of analysis and the steps of the optimized procedure may vary depending on the level of regulatory trust of the AREE responsible for health regulation in the country wherethe manufacturer is domiciled, and may be classified as: partial, full, and mutual recognition.

For an entity to be recognized by Anvisa as an AREE for the purposes of the optimized procedure, the entity must meet the following requirements: (i) be a regulatory authority; (ii) be a member of PIC/S (Pharmaceutical Inspection Cooperation Scheme); or (iii) be a member of ICH (International Council for Harmonization).

The rules established by Normative Instruction No. 292/2024 came into effect on June 3, 2024.

ANVISA AND HEALTH CANADA SIGN CONFIDENTIALITY AGREEMENT

Anvisa and the Regulatory Operations and Enforcement Branch of Health Canada signed a confidentiality agreement at the end of April 2024.

The agreement aims to create a framework in which Anvisa and the Canadian authority share non-public information regarding the safety, efficacy, quality, supply, and availability of medicines, radiopharmaceuticals, biological products, active pharmaceutical ingredients, medical devices, foods, among others. The agreement does not encompass information about blood, cells, plasma, tissues, and human organs.

The shared information may cover issues related to licensing, clinical trials, labeling, laboratory activities, monitoring and analysis of adverse reactions, compliance enforcement, policy development and guidance, unauthorized or pending products, among others.

According to the agreement, the shared information may be used by the authorities solely for the purpose of performing their functions related to the mentioned products, as well as for the protection and promotion of public health.

Anvisa and the Canadian authority had already established instruments regarding consumer safety and the regulation of medicines and foods. The new agreement and the exchange of information are expected to strengthen the relationship between the organizations and facilitate the establishment of possible reliance mechanisms. The agreement came into effect on April 29, 2024.

AGREEMENT BETWEEN BRAZIL AND CHILE TO FACILITATE COSMETIC TRADE BETWEEN THE COUNTRIES

Brazil and Chile have finalized negotiations for an agreement aimed at fostering trade in cosmetic products. The negotiations between the countries had been ongoing for more than three years.

The agreement aims to stimulate regulatory convergence between the countries, and its objectives include reducing technical barriers to trade, making regulations simple and clear, ensuring product safety, among others[19].

From a regulatory perspective, the commitments made by the countries in the agreement involve defining cosmetics, reducing prior sanitary requirements, establishing harmonization of rules regarding labeling and good manufacturing practices, etc[20].

The agreement will constitute an important initiative for the national cosmetics market. According to the Ministry of Development, Industry, Commerce, and Services, approximately 80% of Brazilian exports of cosmetics, hygiene products,

19 Regarding the topic, see: Brazilian National Health Surveillance Agency - Anvisa e Chile fecham acordo de facilitação de comércio para setor de cosméticos [Anvisa and Chile reach trade facilitation agreement for the cosmetics sector]. Available at: https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2024/anvisa-e-chile-fecham-acordo-de-facilitacao-de-comercio-para-setor-de-cosmeticos. Accessed on: December 23, 2024.

20 *Ibidem*.

and perfumes are destined for Latin America, with Chile being the second-largest destination, representing 16% of exports[21].

International cooperation involving products subject to health regulation has intensified in recent years. In this regard, Anvisa has increasingly expanded the adoption of regulatory trust practices to facilitate the regularization of products in Brazil.

MAPA AND IFDC FORM PARTNERSHIP TO STIMULATE INNOVATION AND SUSTAINABILITY IN THE FERTILIZER SECTOR

At the end of October 2024, the Mapa (Ministry of Agriculture, Livestock and Food Supply) and the IFDC (International Fertilizer Development Center) signed a Memorandum of Understanding to promote innovation and sustainability in the fertilizer sector.

The partnership involves Embrapa (Brazilian Agricultural Research Corporation), Mapa, Petrobras, and Brazilian universities. The goal is to explore technologies that increase fertilizer efficiency and promote sustainable agricultural practices. The cooperation is also expected to strengthen the Brazilian PNF (National Fertilizer Plan) by reducing foreign dependency in the sector.

Founded in 1974 and operating in over 100 countries, the IFDC is an international reference in solutions for food security and environmental impact reduction.

In a statement, Deputy Executive Secretary Cleber Soares stated that "the partnership with IFDC is an essential step to strengthen innovation in fertilizers and drive Brazilian agriculture sustainably. This advancement reinforces our commitment to food security and reducing external dependency, placing Brazil at the forefront of modern and sustainable agricultural practices."[22]

Meetings included discussions with players in the fertilizer sector from India, visits to IFDC laboratories and facilities, as well as discussions on possible measures to enhance fertilizer efficiency.

21 Regarding the topic, see: Ministry of Development, Industry, Commerce, and Services - Acordo facilita comércio de cosméticos entre Brasil e Chile [Agreement facilitates cosmetics trade between Brazil and Chile]. Available at: https://www.gov.br/mdic/pt-br/assuntos/noticias/2024/agosto/acordo-facilita-comercio-de-cosmeticos-entre-brasil-e-chile. Accessed on: December 23, 2024.

22 Regarding the topic, see: Ministry of Agriculture, Livestock and Food Supply - Mapa e Embrapa firmam parceria com IFDC nos EUA para fortalecer inovação em fertilizantes [Mapa and Embrapa establish partnership with IFDC in the USA to strengthen innovation in fertilizers]. Available at: https://www.gov.br/agricultura/pt-br/assuntos/noticias/mapa-e-embrapa-firmam-parceria-com-ifdc-nos-eua-para-fortalecer-inovacao-em-fertilizantes. Accessed on: December 23, 2024.

PARTNERSHIP PROGRAM FOR PRODUCTIVE DEVELOPMENT, LOCAL DEVELOPMENT AND INNOVATION PROGRAM, AND HEALTH ECONOMIC-INDUSTRIAL COMPLEX

OPINION: HEALTH INVESTMENTS IN THE CONTEXT OF PDPS

Marco Aurélio Antas Torronteguy[23]

As is well known[24], there is an enormous potential for public-private collaboration in the health sector, aimed at strengthening the health industrial complex in the country, particularly through technology transfer. It is unrealistic to think that the Public Administration could produce all the necessary medicines and medical devices to supply the SUS (Unified Health System). It is no coincidence that the Federal Constitution guarantees private initiative a role in the health market, including in the SUS.

In this context, how can law contribute to efficient public-private arrangements? The answer may lie in two areas. At the first level, law fulfills its role by designing collaboration models that include possibilities beyond the PDPS

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24 CASTRO, J.A.D.; TORRONTEGUY, M.A.A. De que política industrial de saúde precisamos? [What kind of health industrial policy do we need?] In: JOTA Saúde. Available at: https://www.jota.info/artigos/de-que-politica-industrial-de-saude-precisamos. Accessed on: December 23, 2024.

(Partnerships for Productive Development)[25] [26]. At the second level, it structures complex contractual arrangements involving public institutions of excellence, national private initiative, and foreign multinational companies that own health technologies strategic to national health security.

Regarding the private contracts necessary for this type of investment in health, it is important to establish clear rules on several aspects, among which the following can be highlighted:

a. Clear contractual definitions that allow not only the definition of legal concepts but also a clear delineation of the scope of obligations assumed, including their temporal and territorial scope;

b. Clarity regarding the technical assistance to be provided by the technology transferor, as well as the conditions and premises to be fulfilled by the technology recipient, considering each stage of the contract execution;

c. Governance of the execution of the agreement, so that technical and regulatory decision-making follows pre-established criteria – for example, through a steering committee created for this purpose. Special attention should be given to the decision-making rule in case of an impasse between the parties;

d. Payment amounts, cost-sharing between the parties, as well as outcome indicators to be measured;

e. Detailed rules on know-how, intellectual property rights involved, as well as confidentiality to be observed;

f. Relevant technical annexes related, for example, to the products involved, technical documentation, services to be provided, timelines, quality agreements, pharmacovigilance, etc.

Moreover, it is expected that technology transfer will indeed contribute to the sustainability of the SUS. After all, the prices of new health technologies are high, considering the development costs of these technologies.

Considering this, some contractual arrangements are beginning to test different payment modalities. One of the major challenges of health investments is to include performance-based payment criteria, so that payments are not made

25 For an overview of the applicable regulations for PDPs, see: TORRONTEGUY, M.A.A. Life Sciences & Healthcare Newsletter – Special Edition 1st Semester of 2024, pp. 32-40. Available at: https://tozzinifreire.com.br/boletins/boletim-ciencias-da-vida-e-saudeedicao-especial-1-semestre-de-2024. Accessed on: December 23, 2024.

26 See also: CASTRO, J.A.D.; TORRONTEGUY, M.A.A.; AVALLONE, V.H.C. TozziniFreire Podcast: New PAC and the Health Sector. Available at: https://www.youtube.com/watch?v=V4SCeKUXH3o. Accessed on: December 23, 2024.

solely for delivered products or provided services, but depend, in part, on results achieved in specific cases. In this context, risk-sharing agreements have been discussed for several years.

In practice, such agreements still face challenges related, for example, to indicators, how to measure results, impacts from the perspective of clinical research and data protection, and occurrences that may happen without relation to the technology used (i.e., possible biases in measuring the results of using the technology). Despite these challenges, the search for innovative solutions appears to be vital for health access in the coming years.

Given all this, it can be said that investments in health involving technology transfer have a dual complexity: regulatory and contractual.

Technology transfer projects are strategic for national security, for the sustainability of the SUS, and for the realization of the constitutional right to health for all Brazilians. Given the complexity of the applicable regulation and contracts, careful legal design is essential when advising the companies involved.

On June 21, 2024, the Ministry of Health published two ordinances with new guidelines applicable within the scope of the National Strategy for the Development of the Health Economic-Industrial Complex regarding the Partnerships for Productive Development and Local Development and Innovation programs.

PDP

Through GM/MS Ordinance No. 4,472/2024, the Ministry of Health introduced new regulations applicable to the PDP Program.

The Ordinance came into effect on the date of its publication, and its effects will apply to existing partnerships that were previously subject to earlier regulations, respecting the obligations and agreements made between the parties, in accordance with Articles 4 and 6.

Among the new features brought by the Ordinance, we highlight the following: i. the definition of requirements for products and services to be eligible for PDP; ii. the need for evaluation of the PDP proposal by the Health Economic-Industrial Complex, in addition to the Ministry of Health; iii. the possibility of ICTs participation; iv. the definition of timelines for each phase of the PDP process; and v. the definition of sanctions applicable by the Ministry of Health due to total or partial non-compliance with the Commitment Agreement.

Moreover, it is worth noting that the new regulation allows for the submission of PDP proposals for medical devices[27]. Considering its importance for the national public health system concerning the treatment, monitoring, and diagnosis of medical conditions, among other aforementioned applications, the production of medical devices is essential, and the possibility of submitting PDP proposals for projects involving such products constitutes an important action for health promotion.

Stages

The procedure for establishing PDPs is divided into 4 stages, pursuant to GM/MS Ordinance No. 4,472/2024, Annex, Article 6, I – IV, sole paragraph.

The first stage (project proposal) begins with the submission of a project proposal by the Public Institution or by the ICT, proceeds with a joint analysis by the Ministry of Health, CTA – a collegiate body aimed at analyzing and evaluating the PDPs – and the Deliberative Committee, and ends with the publication of the results or the summary of the Commitment Agreement.

The second stage (PDP projects) involves the preparation phase for the execution of technology transfer between partners, as well as training and completion of product development to absorb the scientific and technological knowledge involved in the partnership. This stage concludes with the publication of the instrument formalizing the first acquisition of the product.

The third stage (PDP), in turn, is the moment when the technology transfer will actually occur, along with its internalization, national production, and supply of the product subject to the PDPs by the responsible institutions (IP/ICT).

In the fourth stage (verification of technology internalization), finally, the completion of the transfer and absorption of the technology subject to the PDPs is verified, with the publication of the summary of the resolution term for technology internalization.

27 The regulation of medical devices in Brazil is governed by Anvisa concerning risk classification, notification and registration regimes, labeling requirements, safety and performance, etc. According to the current regulation, medical devices are any devices intended for the performance of activities related to the diagnosis, prevention, monitoring, treatment, or alleviation of diseases, injuries, or deficiencies; investigation, replacement, alteration of anatomy or of a physiological or pathological process or state; support or maintenance of life; control or assistance in conception; or provision of information through in vitro examination of samples derived from the human body, including organ and tissue donations. Regarding the topic, see: Brazilian National Health Surveillance Agency - Anvisa RDC No. 751/2022, art. 4, X, "a"-"f".

Institutional Responsibilities – IP/ICT and Private Entities

The establishment of a PDP involves the participation of the following institutions: the Ministry of Health, Anvisa, IP/ICT, and EP.

The explicit inclusion of the possibility of participation by IP/ICTs and EPs is one of the new features brought by GM/MS Ordinance No. 4,472/2024.

Each of these institutions has pre-established responsibilities defined by the Ordinance. We highlight the responsibilities outlined for IPs/ICTs and EPs as follows:

IP/ICT:

These are bodies or entities of the Public Administration (Direct or Indirect) that act in proposing and executing the PDPs.

Their main responsibilities, when submitting proposals and fulfilling the stages of the PDP, include: i. demonstrating production capacity for executing the PDP project; ii. conducting risk management and feasibility studies of the project; iii. participating in technical visits to the partner EPs, both national and international, together with the Ministry of Health; iv. celebrating a Commitment Agreement alongside the Ministry of Health and other PDP partners; v. entering into agreements, contracts, or other legal instruments with project partners; vi. submitting a registration dossier and post-registration changes for the product subject to the PDP to Anvisa; vii. requesting prioritization of analysis before Anvisa; viii. forwarding a copy of the registration request protocol to the Ministry of Health; ix. ensuring the internalization of technological competencies, according to the established productive arrangement; and x. monitoring the entire technological and regulatory-sanitary cycle.

EP:

These are legal entities of private national or international law that act in receiving and transferring technology in the same PDP project, according to the established productive arrangement.

The responsibilities instituted in the PDP process include, among others: i. participating in the preparation of the PDP project proposal in compliance with applicable requirements; ii. demonstrating production capacity for the product and the necessary human, financial, and budgetary resources for executing the PDP project; iii. proving ownership of the necessary intellectual property for the PDP project or having legitimate rights for its use; iv. celebrating the Commitment Agreement alongside the Ministry of Health and the IP/ICT; v. entering into agreements, contracts, or other legal instruments with project partners; vi. ensuring, within their responsibility, the internalization of national production

of the active pharmaceutical ingredient (API) and, when applicable, the internalization of national production of the technological device associated with the pharmaceutical form or the critical technological component, according to the degree of verticalization foreseen in the approved Executive Project; vii. ensuring technology transfer and effective compliance with the technical-regulatory schedule under their responsibility; viii. sharing the development of the product subject to the PDP with the IP; ix. receiving technical visits from teams of the Ministry of Health and public partners (IP/ICT); x. periodically informing the IP/ICT of the activities executed, ongoing, and planned, including intellectual property data; and xi. notifying the Ministry of Health and other PDP partners of the discontinuation of the manufacture or commercialization of the product at least 360 days in advance.

Monitoring and Evaluation

The Ordinance introduced mechanisms to verify compliance with the PDPs. Therefore, each PDP must be continuously monitored, from the project to the internalization of technology, according to GM/MS Ordinance No. 4,472/2024.

Technical monitoring is conducted by the technical area of SECTICS and includes activities such as registration, post-registration, Good Manufacturing Practices (CBPF), the technical process of technology transfer and absorption, and the development of institutional capabilities; analysis of follow-up reports; etc.

PDP partners are subject to notification by SECTICS if it is found that the partnership has failed to observe the applicable requirements and guidelines (e.g., actions planned in the approved project not executed, proposed or required adjustments not carried out, lack of active participation in the development, transfer, and absorption of technology and national public production of the product subject to the PDP, among other situations).

Sanctions

Ordinance No. 4,472/2024 establishes that non-compliance with obligations subjects PDP partners to administrative and judicial measures, including sanctions provided for by law and in the signed contracts, except for cases of force majeure or fortuitous events.

Sanctions resulting from total or partial non-compliance with the signed commitment agreement may include warnings, fines, and/or temporary suspension from participation in new PDPs.

The penalty of a fine is calculated according to contractual provisions, with a minimum value of 0.5% and a maximum of 30% of the contract value, with the possibility of conversion into compensatory measures.

In cases of temporary suspension of participation in new PDPs, the suspension will last until the regularization of the situation that led to the suspension.

The imposition of sanctions allows interested parties to file an administrative appeal, in accordance with Law No. 9,784/1999.

PDIL

The PDIL, in turn, was regulated by GM/MS Ordinance No. 4,473/2024. The Program aims to expand access to health through funding actions related to innovation and local development, stimulate production within the Health Economic-Industrial Complex based on sustainability, and promote the training of scientific, technological, and innovation institutions.

Like the Ordinance for PDPs, GM/MS Ordinance No. 4,473/2024 also came into effect on the date of its publication.

Existing partnerships for local development to supply products to the SUS through innovative solutions can adapt to the PDIL structure until June 2025.

Implementation

The establishment of the PDIL can occur through agreements, decentralized execution terms, technological orders, public contracts for innovative solutions, technology compensation agreements, or similar instruments.

These instruments must contain measures aimed at developing local innovation projects, characterized as plans aimed at implementing measures that result in improvements to products, services, or processes.

PDIL Proposal

IPs, ICTs, or non-profit EPs may submit PDIL proposals to SECTICS, in accordance with GM/MS Ordinance No. 4,473/2024.

The preparation of the project proposal must consider health challenges and productive and technological solutions for the SUS, as outlined in the Matrix of Productive and Technological Challenges in Health, established by GM/MS Ordinance No. 2,261/2023.

Its object consists of the technology to be developed, related to the products or platforms contained in the aforementioned matrix. The information presented through the proposals, according to GM/MS Ordinance No. 4,473/2024, is protected under industrial and commercial confidentiality.

The receipt and preliminary analysis of the PDIL proposal is assigned to SECTICS. The evaluation of the proposal's merits must consider the adequacy of the execution timeline, the technological and productive capacity of the proponent and partners, the availability of qualified human resources for project execution, the innovative nature, and benefits to the health system, among others.

Products resulting from the PDIL proposal may be prioritized during the registration and incorporation analysis stages within the SUS before the competent authorities.

Monitoring

To verify compliance with the obligations inherent to the PDIL projects, the Department of the Health Economic-Industrial Complex for the SUS must conduct the monitoring and evaluation of the results of projects related to technology development, the regulatory stage to be fulfilled before the competent authorities, the local product capacity of the technology, and the incorporation of the technology into the SUS.

Administrative Resources

In case of an unfavorable result regarding the selection of the PDIL project proposal, GM/MS Ordinance No. 4,473/2024 establishes that an administrative appeal may be filed against the evaluation results of PDIL project proposals before the Minister of Health.

SECTICS must conduct the appeal's instruction for admissibility judgment, which, if observed, will result in forwarding the appeal to the Technical Evaluation Commission for merit analysis.

In the case of a favorable decision by the Minister of Health, the result of the administrative appeal and the list of approved projects will be published in the Brazil Federal Register (DOU) and on the Ministry of Health's website within 30 calendar days from the date of the decision. This period may be extended by an equal amount of time.

GECEIS ANNOUNCES SUBSTANTIAL INVESTMENT FOR SUPPLY PRODUCTION WITHIN SUS

Geceis has announced a record investment aimed at boosting domestic production of strategic supplies for the SUS. The investment is part of the new PAC and totals R$ 4.2 billion.

From the 322 projects received by the Ministry of Health, 175 correspond to the PDIL and 147 to the PDPs.

Both programs are part of the National Strategy for the Development of the Health Economic-Industrial Complex, which aims to strengthen the national industry to produce essential supplies to promote universal access to health.

The approved proposals aim to strengthen the production of essential supplies to meet the main health demands of the Brazilian population, as well as to reduce national dependence on imports.

The products include advanced therapies for the SUS, vaccines, serums, medications for neglected diseases/populations, oncological products, immunosuppressants, monoclonal antibodies, radiopharmaceuticals, active pharmaceutical ingredients, medical devices, among others.

The investment is substantial and is expected to foster the national industry of the mentioned products. The goal is for national production to reach an average of 70% compared to the percentage of imported products. By 2027, estimated investments of R$ 8.9 billion are projected under the new PAC.

Figures released by the Ministry of Health highlight the potential impacts of the measure. Currently, over 90% of the raw materials used in Brazil to produce active pharmaceutical ingredients are of foreign origin. For medical devices, national production can meet 50% of the demand. For medications and vaccines, the amount is around 60%[28].

28 Regarding the topic, see: Ministry of Health - Governo Federal destina R$ 4,2 bilhões para alavancar indústria da saúde e atender necessidades do SUS [Federal Government allocates R$ 4.2 billion to boost the health industry and meet the needs of SUS]. Available at: https://www.gov.br/saude/pt-br/assuntos/noticias/2024/outubro/governo-federal-destina-4-2-bilhoes-para-alavancar-industria-da-saude-e-atender-necessidades-do-sus. Accessed on: December 23, 2024.

MEDICATIONS

REGULATION OF TRACEABILITY AND DIGITAL PACKAGE INSERTS

In 2022, Law No. 14,338/2022 was enacted, amending Law No. 11,903/2009 to provide for the digital package insert for medications, as well as a traceability and control system for medications within the national territory.

The former SNCM, established by Law No. 11,903/2009 and pending implementation since then, was replaced by the electronic package insert, consequently instituting control through a "medication identification system, employing technologies for capturing, storing, and electronically transmitting data," as stated in the new wording of Article 3 of Law No. 11,903/2009.

According to the new law, the holder of the medication registration must create a distribution map via an electronic system that allows the identification of the quantities sold and distributed for each batch and the identification of the recipients of the shipments, which must contain at least: (i) batch number of the medications; (ii) batch manufacturing date; and (iii) batch expiration date.

The possibility of having more than one distributor in the distribution chain is maintained, provided that the origin of the product is legitimate. The information contained in the electronic package insert and distribution map must be observed.

The provisions of Law No. 14,338/2022 created the need for regulation to enable the effective implementation of the digital package insert in medications.

Considering this, after conducting a regulatory process and analyzing contributions from society on the subject, Anvisa published Anvisa RDC No. 885/2024, which came into effect on September 10, 2024. The regulation establishes guidelines for the establishment of a pilot project with transitional rules for the phased implementation of the digital package insert.

As it is a pilot project, Anvisa RDC No. 885/2024 is a temporary regulation with a determined validity period (until December 31, 2026). During this period, it is expected to collect information that will support the ongoing Regulatory Impact Analysis at Anvisa[29].

29 Regarding the topic, see: Brazilian National Health Surveillance Agency - VOTE No. 166/2024/SEI/DIRE3/ANVISA. Available at: https://www.gov.br/anvisa/pt-br/composicao/diretoria-colegiada/reunioes-da-diretoria/votos/2024/rop-12.2024/2-5.pdf/view. Accessed on: December 23, 2024.

The regulation allows the exemption of printed package inserts in medication packaging but establishes that the registration holder must ensure the availability of the physical package insert when requested by the healthcare establishment, the prescribing professional, or the patient.

The use of the digital package insert is a significant step towards modernizing Brazilian healthcare through technological innovation. In this first phase, the implementation of the digital package insert has been permitted only for medications:

a. in free sample packaging;

b. destined for healthcare establishments (excluding pharmacies);

c. with government allocation containing distinctive elements from the Ministry of Health on the packaging; and

d. exempt from prescription, packaged in multiple units.

For the implementation of the digital package insert, the secondary packaging of the medications must contain a QR code or an equivalent digital mechanism. This mechanism should direct the patient to a repository of information that contains the package insert and other medication information.

After data collection from this first stage of the phased implementation of the digital package insert for the aforementioned categories of medications, it is expected that Anvisa will establish definitive regulation on the subject.

ANVISA'S PILOT PROJECT WILL INVOLVE STARTUPS TO STRENGTHEN DRUG DEVELOPMENT

Anvisa has approved a pilot project involving startups for the regulatory evaluation of medications of interest in health services in Brazil.

The project is aligned with the National Strategy for the Development of the Health Economic-Industrial Complex, established by Decree No. 11,715/2023, which aims to find solutions that strengthen the SUS and expand access to health.

The project, published through Joint Call Notice No. 1/2024, is based on promoting knowledge and fulfilling regulatory requirements regarding innovations in the development of medications.

The focus of the project is directed towards meeting the medical demands of the population by accelerating the development of medications primarily intended for use in the public system. To this end, Anvisa selected three startups for

this pilot project: one developing an herbal medication, one developing a new synthetic medication, and one developing a biological product[30].

Among the requirements for participation in the project, the involved startups had to be national and properly registered with Anvisa, with an adequate team and infrastructure. Additionally, Anvisa assessed whether the candidate medications represent innovative technology; whether they are in the development phase; and whether they have greater potential for treating or preventing debilitating, irreversible, and life-threatening diseases or for neglected diseases compared to existing alternatives.

During the project's progress, the selected startups will receive regulatory guidance and support so that, from the initial stages of drug development, applicable sanitary requirements are observed.

In this collaborative environment, Anvisa will have the opportunity to learn about any gaps and difficulties related to sanitary regulation that startups may encounter.

ANVISA ALTERS RULES RELATED TO THE PROCEDURES FOR GRANTING AFE AND AE FOR PHARMACIES

On May 8, 2024, Anvisa published Anvisa RDC No. 860/2024, which modifies the rules regarding the AFE (Authorization for the Functioning of Establishments) and AE (Authorization for Operation) applicable to pharmacies and drugstores, as outlined in Anvisa RDCs No. 16/2014 and No. 275/2019, and consequently the petitions required by Anvisa RDC No. 222/2006.

Among the changes brought by the new regulation, the following alterations are especially noteworthy: (i) immediate implementation for changes in technical responsibility and legal representation; (ii) alteration of the list of documents that must comprise the dossier registration; and (iii) inclusion of establishments, companies, or activities exempt from AFE.

30 Regarding the topic, see: Brazilian National Health Surveillance Agency - Anvisa divulga projetos de startups selecionados para receber orientação regulatória na inovação de medicamentos [Anvisa announces selected startup projects to receive regulatory guidance in the innovation of medicines]. Available at: https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2024/anvisa-divulga-projetos-de-startups-selecionados-para-receber-orientacao-regulatoria-na-inovacao-de-medicamentos. Accessed on: December 23, 2024.

The changes in Anvisa RDC No. 860/2024 aim to automate requests and minimize requirements in the processes of granting and amending AFE. The regulation came into effect on the date of its publication[31].

ANVISA ESTABLISHES SNCR

On May 27, 2024, Anvisa published Anvisa RDC No. 873/2024, which establishes the SNCR (National Control System for Prescriptions). The use of the platform, which was previously optional, became mandatory as of January 1, 2025.

The regulation provides that prescription control, for the purposes of the SNCR, will be carried out through an online platform to be available by Anvisa to local health surveillance authorities. This platform will provide the numbering that must be used in prescription notifications by prescribers.

It is important to highlight that the platform will not issue electronic prescriptions but will only provide the aforementioned numbering to enhance control and traceability over prescriptions and their respective numbering, thus preventing fraud or forgery of prescriptions.

The replacement of printed prescription books, issued until January 1, 2025, will be gradual, allowing these books to be delivered by the competent authority for up two years after their issuance.

At this stage, the implementation of the SNCR does not bring changes to the procedures for requesting numbering or prescription notification books by prescribers.

Therefore, the procedures already established in SVS/MS Ordinances No. 344/1998 and No. 6/1999, as well as the complementary guidelines defined by local Health Surveillance authorities, remain in place.

The SNCR came into effect on July 18, 2024.

31 Regarding the topic, see: Brazilian National Health Surveillance Agency - VOTE No. 40/2024/SEI/DIRE2/ANVISA. Available at: https://www.gov.br/anvisa/pt-br/composicao/diretoria-colegiada/reunioes-da-diretoria/votos/2024/rop-7.2024/2-11.pdf. Accessed on: December 23, 2024.

ANVISA APPROVES NEW REGULATION ON THE REGISTRATION OF BIOSIMILAR MEDICINES

On May 29, 2024, Anvisa RDC No. 875/2024 was published in the Brazil Federal Register (DOU), which addresses the registration of biosimilars. The new regulation complements Anvisa RDC No. 55/2010, which provides for the registration of biological products.

The purpose of the new RDC is to simplify the development process for biosimilars by safely relaxing the requirements demanded for the registration of biological products.

The regulation introduces the new concept of biosimilar medication. According to Article 2 of Anvisa RDC No. 875/2024, a biosimilar is "(...) a biological medication that is highly similar to a biological medication already registered with Anvisa (comparative biological product), whose similarity in terms of quality, biological activity, safety, and efficacy has been established based on an appropriate comparability assessment."

In addition, according to Anvisa, one of the new features of Anvisa RDC No. 875/2024 is the possibility of using a reference comparative medication acquired in international territory in situations of unavailability[32].

Nonetheless, the necessary technical requirements must be observed[33], such as the registration of the medication by a Regulatory Authority for Health Registration (AREE) recognized by Anvisa.

The new Resolution came into effect on June 17, 2024.

ANVISA APPROVES NEW REGULATIONS REGARDING THE LEGAL FRAMEWORK FOR MEDICINAL GASES

On May 21, 2024, and May 22, 2024, regulations were published that update the regulatory framework for medicinal gases: Anvisa RDC No. 870/2024 and IN No. 301/2024.

32 Regarding the topic, see: Brazilian National Health Surveillance Agency - Anvisa aprova novo regulamento para registro de medicamentos biossimilares [Anvisa approves new regulation for the registration of biosimilar medicines]. Available at: https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2024/anvisa-aprova-novo-regulamento-para-registro-de-medicamentos-biossimilares. Accessed on: December 23, 2024.

33 *Ibidem.*

Anvisa RDC No. 870/2024 establishes the minimum requirements for the notification, registration, and post-registration changes of medicinal gases classified as medications. It is worth noting that this RDC does not apply to health gases that do not qualify as medications or to medicinal gases produced using oxygen concentrator systems in healthcare services or homes for personal use.

Under the new regulation, existing rules applicable to medications in general are relevant for the following topics related to medicinal gases: Clinical Study, Stability Studies, Package Insert, Registration Revalidation and Expiration Dates, and Pharmacovigilance.

Complementarily, IN No. 301/2024 establishes the list of medicinal gases classified as medications subject to notification. The gases included in this list are: (i) Medicinal Air and Synthetic Medicinal Air; (ii) Medicinal Carbon Dioxide; (iii) Medicinal Nitrogen; (iv) Medicinal Oxygen; (v) Medicinal Nitrous Oxide; (vi) Medicinal Oxygen 50% + Medicinal Nitrous Oxide 50%; (vii) Medicinal Helium; and (viii) Medicinal Helium 79% + Medicinal Oxygen 21%.

The IN also covers the indications, contraindications, precautions, adverse reactions, drug interactions, and production line for each listed gas.

Both regulations came into effect on July 1, 2024, with a compliance period until July 1, 2026.

CFF REGULATES PHARMACISTS' DUTIES REGARDING ARTIFICIAL INTELLIGENCE AND DIGITAL HEALTH

On August 6, 2024, the CFF (Federal Pharmacy Council) published CFF Resolution No. 10/2024 to regulate the duties of pharmacists in the realm of digital health and the use of artificial intelligence.

According to the CFF, the advent of this regulation stems from the new paradigms resulting from advances in information technology and the implications of such advances on health products and services.

Through this regulation, the CFF established the duties and competencies of pharmacists related to the development and use of digital health products and services for health promotion.

CFF Resolution No. 10/2024 defined such products and services broadly: it encompassed the concept of SaMD (Software as a Medical Device) — a category regulated by Anvisa — and went beyond that, including various other items, some

of which are innovative, such as "Digital Therapeutics (DTx), Digital Medicines or Digiceuticals."

In practice, "Digital Therapeutics (DTx), Digital Medicines, or Digiceuticals" seem to be classified under the regulatory category of SaMD, meaning they are considered medical devices rather than medications in the strict sense.

The regulation came into effect on the date of its publication, and its full text is available on the CFF portal[34].

STF CONCLUDES JUDGMENT ON THE STATE'S OBLIGATION TO PROVIDE NOT LISTED MEDICATIONS IN SUS

The STF (Brazilian Federal Supreme Court) concluded the judgment of extraordinary appeals with general repercussion regarding the provision of medications not included in the SUS (Unified Health System) list (Topics No. 6 and No. 1,234).

The discussions focused on determining (i) whether the State has the obligation to provide medications not included in the SUS list in cases of patient vulnerability; and (ii) whether lawsuits regarding this request must be filed against the Union and processed in Federal Court.

On the Obligation to Provide Medications

The STF Plenary understood that, as a rule, the Judiciary cannot mandate the provision of medications outside the SUS list, regardless of their cost.

However, exceptionally, the Judiciary may determine that such medications be provided in cases where the petitioner cumulatively proves:

- The denial of provision through administrative means;
- The illegality of the act of non-incorporation of the medication by Conitec, the absence of an incorporation request, or delays in its consideration;
- The lack of sufficient resources to cover the cost of the medication;
- That the medication cannot be substituted by another included in the SUS's list;
- That the use of the medication is essential for treatment; and

34 Regarding the topic, see: Federal Pharmacy Council - CFF Resolution No. 10/2024. Available at: https://documentos.cff.org.br/sei/publicacoes/controlador_publicacoes.php?acao=publicacao_visualizar&id_documento=262741&id_orgao_publicacao=0. Accessed on: December 23, 2024.

- That the efficacy, accuracy, effectiveness, and safety of the medication are scientifically proven based on evidence-based medicine (randomized clinical trials and systematic reviews or meta-analyses).

Passive Legitimacy and Jurisdiction for Judgment

The STF Plenary established two hypotheses:

i. Actions should be processed in Federal Court, with treatment costs covered by the Union, when:

   The annual costs of the requested treatment are equal to or greater than 210 minimum wages.

ii. Actions should be processed in the State Court, with treatment costs divided among the federal entities, when:

   The unit annual cost of the medication is between 7 and 210 minimum wages.

   In this case, in the event of convictions against states and municipalities, 65% of the expenses arising from treatments will be the responsibility of the Union. The Union's percentage will be 80% if the requested medications are oncological.

It is important to note that, although the Judiciary may determine the provision of medications outside the SUS's list in the aforementioned cases, such medications must be duly regulated by Anvisa, except in exceptional cases (as previously decided in Topic No. 500 of the STF[35]).

During the judgment of Topic No. 500, the STF had decided that, as a rule, court decisions cannot mandate the provision of medications without registration at Anvisa. However, the STF admitted such possibilities in exceptional cases of unreasonable delays by Anvisa in analyzing the registration request. For this to occur:

- There must be a registration request regarding the medication in Brazil (except for orphan drugs for rare and ultra-rare diseases);
- The medication must be registered with reputable foreign regulatory agencies; and
- There cannot be a therapeutic substitute registered in Brazil.

35 Regarding the topic, see: Brazilian Federal Supreme Court - Tema 500: Dever do Estado de fornecer medicamento não registrado pela Anvisa [Theme 500: Duty of the State to provide drugs not registered by Anvisa]. Available at: https://portal.stf.jus.br/jurisprudenciaRepercussao/verAndamentoProcesso.asp?incidente=4143144&numeroProcesso=657718&classeProcesso=RE&numeroTema=500. Accessed on: December 23, 2024.

On the Numbers

According to information released by the STF, in 2020, 347,000 health-related lawsuits were filed. By 2024, this number reached 600,000, considering the date of the data release (October 17, 2024)[36].

ANVISA RECEIVES CONTRIBUTIONS ON THE SIGNING OF COMMITMENT TERMS FOR THE REGULARIZATION OF MEDICATIONS

Anvisa receives contributions on the signing of commitments terms for the regularization of medications.

Through Public Consultation No. 1,282/2024, approved by the Collegiate Board, Anvisa received contributions from the regulated sector and society regarding the proposed criteria and procedures for the celebration of commitment terms for medicines registration, post-registration, and temporary emergency use authorization.

If the draft proposal is approved after Anvisa's analysis of the contributions, the new rules may facilitate the procedures for medicines registration, post-registration, and temporary emergency use authorization before Anvisa.

The medicines manufacture and commercialization in Brazil depend on the granting of registration by Anvisa. For this, the medicines must have been technically analyzed to certify their quality, safety, and efficacy.

Under current rules, requests for registration of medicines are denied if the interested company fails to present all legally required documentation in cases of impossibility.

According to the proposal, Anvisa may enter a commitment term with the requesting company when there is data demonstrating the safety and efficacy of the medicine to be submitted for registration, post-registration, or temporary emergency use authorization, even if there are regulatory requirements to be met.

In this scenario, the company would assume the obligation to present the pending documentation after the granting of registration or post-registration modification

36 Regarding the topic, see: Brazilian Federal Supreme Court - STF celebra conclusão de julgamento sobre fornecimento de medicamentos de alto custo [STF celebrates the conclusion of the judgment on the provision of high-cost medications]. Available at: https://noticias.stf.jus.br/postsnoticias/stf-celebra-conclusao-de-julgamento-sobre-fornecimento-de-medicamentos-de-alto-custo/. Accessed on: December 23, 2024.

permission by Anvisa. The submission of legally required documents would occur according to a pre-established schedule in the agreement.

The proposal aligns with the provisions of the LINDB (Law of Introduction to the Brazilian Rules) and Decree No. 9,830/2019, which contain rules about entering into commitment terms by public administration[37].

After completing the analysis of the contributions received, it is expected that the Collegiate Board of Anvisa will present a proposal for RDC (Resolution of the Collegiate Board) to regulate the implementation of the possibility of entering into commitment terms for the regularization of medicines.

ANVISA CONSOLIDATES RULES APPLICABLE TO PHARMACEUTICAL EQUIVALENCE CENTERS

The Collegiate Board of Anvisa approved the consolidation of rules applicable to Pharmaceutical Equivalence Centers related to requests or renewals of accreditation, post-accreditation modifications, outsourcing of testing, suspensions, and cancellations, under Anvisa RDC No. 927/2024.

Pharmaceutical Equivalence Centers are responsible for conducting physico-chemical, microbiological, or biological tests on generic medicines. Such tests are essential to verify the correspondence between the safety and efficacy of these products compared to reference medicines.

Similar to previous consolidations reported, Anvisa did not materially alter the content of the existing rules. Thus, the consolidation only brought formal changes resulting from Anvisa's improvement in current regulation, as per Decree No. 12,002/2024[38].

Anvisa RDC No. 927/2024 contains the minimum requirements to be observed both in the regularization of Equivalence Centers and in the conduct of technical testing.

37 Regarding the topic, see: Brazilian National Health Surveillance Agency - Public Consultation No. 1,282/2024. Available at: https://anvisalegis.datalegis.net/action/ActionDatalegis.php?acao=abrirTextoAto&link=S&tipo=CPB&numeroAto=00001282&seqAto=222&valorAno=2024&orgao=ANVISA/MS&cod_modulo=630&cod_menu=9898. Accessed on: December 23, 2024.

38 Regarding the topic, see: Brazilian National Health Surveillance Agency - Vote No. 195/2024/SEI/DIRE2/ANVISA. Available at: https://www.gov.br/anvisa/pt-br/composicao/diretoria-colegiada/reunioes-da-diretoria/votos/2024/rop-17.2024/2-17-e-2-18.pdf/view. Accessed on: December 23, 2024.

The accreditation of Equivalence Centers is valid for two years and must be renewed after this period. The request for renewal must occur between nine and six months prior to the expiration of the accreditation.

Regarding the conduct of equivalence tests, the regulation provides for the possibility of outsourcing to other centers, provided that the rules are observed, such as establishing the duties and responsibilities of those involved, as well as registering the data from outsourced tests with SINEB (National System for the Management of Health Surveillance Data).

Non-compliance with the applicable rules may lead to the suspension or even cancellation of the Pharmaceutical Equivalence Centers.

Anvisa RDC No. 927/2024 came into effect on September 24, 2024. It is expected that Anvisa will establish provisions regarding Good Practices for Pharmaceutical Equivalence in the future.

ANVISA COMMENTS AND TAKES ACTIONS RELATED TO SUBCUTANEOUS HORMONAL IMPLANTS

Anvisa has recently made statements regarding "beauty microchips," subcutaneous hormonal implants compounded in pharmacies and implanted in clinics, having adopted restrictive measures concerning their prescription and marketing—some measures revoked and others still in effect.

In 2023, the CFM (Brazilian Federal Council of Medicine) had already published CFM Resolution No. 2,333/2023, which contraindicates the use of hormonal therapies with androgenic steroids and anabolic substances for aesthetic purposes, muscle gain, and improvement of athletic performance.

On October 18, 2024, Anvisa published Anvisa Resolution RE No. 3,915/2024, determining the suspension of the marketing, compounding, advertising, and use of hormonal implants in general compounded by compounding pharmacies, due to "evidence provided by the Brazilian Federation of Gynecology and Obstetrics Associations regarding complications related to the safety of compounded hormonal implants[39]."

39 Regarding the topic, see: Brazil Federal Register - Anvisa Resolution RE No. 3,915/2024. Available at: https://www.in.gov.br/en/web/dou/-/resolucao-re-n-3.915-de-18-de-outubro-de-2024-591127718. Accessed on: December 23, 2024.

This resolution was revoked on November 22, 2024, by Anvisa Resolution RE No. 4,353/2024[40]. More specifically, the act:

i. Suspended the marketing, compounding, and use of compounded hormonal implants based on anabolic steroids or androgenic hormones for aesthetic purposes, muscle gain, and improvement of athletic performance by compounding pharmacies; and

ii. Suspended the advertising of compounded hormonal implants in general, by compounding pharmacies and by any individuals/legal entities or media outlets that market or publicize the products.

Anvisa Resolution RE No. 4,353/2024, which remains in effect, also stated that it does not apply to products duly regulated by Anvisa.

On November 26, 2024, Anvisa published Order No. 163/2024[41]. Among other measures, it was determined that:

- Only hormonal implants containing active pharmaceutical ingredients (API) that have already been evaluated for efficacy and safety by Anvisa may be compounded;
- The prescription of compounding hormonal implants based on anabolic steroids or androgenic hormones must be done through a Special Control Prescription, in accordance with Ordinance No. 344/1998, and must include the corresponding CID (International Classification of Diseases) for the clinical condition being treated—therefore, it will not be permitted for aesthetic, sports, or muscle gain purposes; and
- Patients, prescribers, and pharmacies must sign a Term of Responsibility/Clarification according to the model included in the aforementioned Order.

Additionally, the Order removed the suspensive effect of any administrative appeals filed against Anvisa Resolution RE No. 4,353/2024, given the imminent risk to health.

Anvisa intends to conduct a Technical Panel on the subject, which should provide even more clarifications. For companies impacted by the Agency's decision, beyond legal arguments, technical support is essential. This discussion is expected to continue developing in 2025.

40 Regarding the topic, see: Brazil Federal Register - Anvisa Resolution RE No. 4,353/2024. Available at: https://www.in.gov.br/web/dou/-/resolucao-re-n-4.353-de-21-de-novembro-de-2024-597098013. Accessed on: December 23, 2024

41 Regarding the topic, see: Brazil Federal Register - Order No. 163/2024. Available at: https://www.in.gov.br/web/dou/-/despacho-n-163-de-25-de-novembro-de-2024-597938106. Accessed on: December 23, 2024.

CMED ESTABLISHES NEW FORM FOR SUBMITTING COMPLAINTS REGARDING THE PHARMACEUTICAL MARKET

After granting an adjustment period to society, the CMED (Market Regulation Chamber of Medicines) has made the new electronic form for submitting complaints regarding potential violations in the pharmaceutical market the only official channel for such submissions.

According to SCMED, the new complaint submission format is part of CMED's measures to strengthen market surveillance of medicines in Brazil.

In this regard, the tool aims to ensure greater transparency, as well as to enhance the tracking, delivery, and receipt of documents compared to previous communication methods used by interested parties.

SCMED also points out that the standardization in receiving responses resulting from the use of the form should, in fact, reduce the response time to citizens.

This measure may reflect a possible tightening of oversight in the pharmaceutical market by CMED. The form for submitting complaints about possible irregularities in the sale of medicines is available on the SCMED portal[42].

EXPECTATION FOR UPDATING RULES ON REMOTE DISPENSING OF MEDICINES

Law No. 5,991/1973, which regulates the Sanitary Control of the Trade of Drugs, Medicines, Pharmaceutical Inputs, and Related Products, completed 51 years in December 2024.[43]

The provisions of Law No. 5,991/1973 were complemented by Anvisa RDC No. 44/2009 regarding the dispensing and marketing of products and the provision of pharmaceutical services in pharmacies and drugstores.

42 Regarding the topic, see: Regulatory Chamber of the Pharmaceutical Market – Complaints. Available at: https://www.gov.br/anvisa/pt-br/assuntos/medicamentos/cmed/denuncias. Accessed on: December 23, 2024.

43 Regarding the topic, see: Migalhas - 51 anos da lei 5.991/73: Recapitulação e mudanças [51 years of Law 5,991/73: Recap and Changes]. TORRONTEGUY, M.A.A; AVALLONE, V.H.C; SOARES, G.B.S. Available at: https://www.migalhas.com.br/depeso/421604/51-anos-da-lei-5-991-73-recapitulacao-e-mudancas. Accessed on: December 23, 2024.

Despite this, the regulations on the subject are outdated, especially concerning the emergence of new technologies, such as new delivery services and marketplaces —none of which existed at the time of the creation of Anvisa RDC No. 44/2009.

In this sense, it is expected that the regulatory framework established by Law No. 5,991/1973 will be updated so that the regulation adapts to the current scenario. The proposed update is part of Topic No. 1.2 of Anvisa's regulatory agenda for 2024-2025.

Thus, there is an expectation for the revocation of Section V, Subsection I, of Anvisa RDC No. 44/2009, which addresses remote requests for the dispensing of medicines, as well as the publication of a specific regulatory instrument to govern the subject.

Considering the publication date of this eBook, the process is currently in the Regulatory Impact Analysis stage, which is expected to conclude in the second quarter of 2025.

It is anticipated that the discussion will advance in 2025 with the drafting of the new regulation, which will be submitted to a public consultation process before being approved by Anvisa's Collegiate Board.

MEDICAL DEVICES

EXTENSION OF CBPF VALIDITY PERIOD IN THE CONTEXT OF THE SINGLE AUDIT PROGRAM FOR MEDICAL DEVICES

After analyzing the contributions received via public consultation regarding the extension of the validity period of CBPF (Certificate of Good Manufacturing Practices) for manufacturers of medical devices granted through MDSAP (Medical Device Single Audit Program), the Collegiate Board of Anvisa approved the proposal to amend Anvisa RDC No. 497/2021, which provides for the administrative procedures for granting CBPF and Certification of Good Distribution and/or Storage Practices.

As a result, Anvisa published Anvisa RDC No. 850/2024, which extended the validity of the CBPF for companies participating in MDSAP from two to four years.

The validity of the CBPF is contingent upon the manufacturer's continued participation in the program throughout the entire period. Furthermore, the provisions of Anvisa RDC No. 850/2024 also apply to certification processes submitted to Anvisa prior to the resolution's entry into force without a published decision in the DOU (Brazil Federal Register).

Anvisa justified the intended change based on the reduction of regulatory costs for companies and the increased adherence to MDSAP, which consequently decreases "the number of national and international inspections carried out by SNVS (National Health Surveillance System), allowing Anvisa and SNVS to direct their resources to higher-risk actions"[44].

The changes came into effect on April 1, 2024.

44 Regarding the topic, see: Brazilian National Health Surveillance Agency - Public Consultation No. 1208 of October 16, 2023. Available at: https://anvisalegis.datalegis.net/action/ActionDatalegis.php?acao=abrirTextoAto&link=S&tipo=CPB&numeroAto=00001208&seqAto=222&valorAno=2023&orgao=ANVISA/MS&cod_modulo=630&cod_menu=9373. Accessed on: December 23, 2024.

NEW REGULATION PUBLISHED ON ESSENTIAL SAFETY AND PERFORMANCE REQUIREMENTS APPLICABLE TO MEDICAL DEVICES AND IVD

The Collegiate Board of Anvisa published Anvisa RDC No. 848/2024, which addresses the essential safety and performance requirements applicable to medical devices and IVDs (In Vitro Diagnostics).

Through the new regulation, Anvisa defined the essential principles applicable to medical devices and IVDs concerning safety and performance. The principles are generally applicable to all medical devices and IVDs. Depending on the device, some of the principles contained in the regulation may not be applicable, in which case justifications for their exclusion must be provided.

It is expected that medical devices and IVDs will be designed to be increasingly safe and effective, as per the principles outlined in the regulation. Likewise, the products must be manufactured and used in accordance with the design so that their characteristics are maintained[45].

The defined principles address, for example, clinical evaluations; chemical, physical, and biological properties; sterilization and microbial contamination; interoperability and compatibility in cases of operation together between different devices; protection against mechanical risks, such as vibrations and noise, thermal and electrical risks; labeling and instructions for use; among others.

The resolution came into effect on September 4, 2024.

LEGAL FRAMEWORK FOR GAMES SANCTIONED WITH PROVISION FOR THERAPEUTIC USE OF GAMES

The Presidency of the Republic has sanctioned Law No. 13,852/2024, which creates the legal framework for the electronic gaming industry. The regulation contains provisions regarding the manufacturing, importation, commercialization, development, and commercial use of games.

One of the highlights of the regulation concerning the use of electronic games has significant implications for health. The Legal Framework for Games expressly states that electronic games can be used for therapeutic purposes.

45 Regarding the topic, see: Brazilian National Health Surveillance Agency - VOTE No. 32/2024/SEI/DIRE3/ANVISA. Available at: https://www.gov.br/anvisa/pt-br/composicao/diretoria-colegiada/reunioes-da-diretoria/votos/2024/rop-2.2024/2-9.pdf. Accessed on: December 23, 2024.

This legislative provision is highly relevant for the sector, as the development of games intended to meet therapeutic goals is already a reality.

In the United States, for example, the game EndeavorRx®, used for the treatment of ADHD, has received FDA approval.

EndeavorRx® is intended for children and adolescents, and its use must be prescribed by a healthcare professional. The game should be considered as part of a therapeutic program and is not intended to be used as an independent therapy or as a substitute for medication[46].

It is important to highlight that once an electronic game is developed, marketed, and used for therapeutic purposes, it is classified as a medical device. This category of products is regulated by Anvisa (National Health Surveillance Agency).

Prior regulatory approval of medical devices by Anvisa is mandatory before the product is available on the market, in accordance with Law No. 6,360/1976, Anvisa RDC No. 751/2022, and Anvisa RDC No. 657/2022. The regulation of these products is of paramount importance, as it allows for the establishment of a chain of accountability for the product.

For electronic games to be classified as medical devices and thus subject to applicable regulation, they must be software intended for medical purposes, such as prevention, diagnosis, treatment, rehabilitation, etc.

The Legal Framework for Games came into effect on May 6, 2024.

ANVISA INCLUDES THE CATEGORY OF MEDICAL DEVICES IN THE E-NOTIVISA SYSTEM

Starting in August 2024, citizens have been able to report issues related to medical devices directly to the responsible companies through the e-Notivisa system. Until then, it was only possible to submit problems involving hygiene products, cosmetics, and sanitizers to the system.

The e-Notivisa system was created to replace the current Notivisa system for reporting problems and technical complaints involving products regulated by Anvisa. It is expected that other product categories will be included in the system in the future.

46 Regarding the topic, see: EndeavorRx - The only doctor-prescribed video game treatment for kids with ADHD. Available at: https://www.endeavorrx.com/. Accessed on: December 23, 2024.

The new tool aims to facilitate communication between citizens and the responsible companies, which will be able to respond and/or request additional information about the notification. The information sent to the companies is limited to what is necessary for conducting the investigation, so sensitive data of the notifier (e.g., name and CPF) will not be disclosed unless the citizen chooses to do so.

The new system aims to overcome limitations of its predecessor, such as difficulties in system integration. e-Notivisa changes the way information is managed through the use of tools such as data science and artificial intelligence. Thus, the system relates information about adverse events and can identify patterns through analyses conducted by artificial intelligence.

Any errors found in the system can be reported through Anvisa's communication channel "Fale Conosco" (Contact Us)[47].

ANVISA PUBLISHES LIST OF COMPANIES AUTHORIZED TO MANUFACTURE/IMPORT CUSTOM MEDICAL DEVICES

On October 29, 2024, Anvisa published the list of companies that received authorization to manufacture or import custom medical devices. The list of authorized companies can be found in Anvisa Resolution RE No. 3,971/2024[48].

Custom medical devices are part of the category of personalized medical devices, whose regulation is currently governed by Anvisa RDC No. 925/2024. This regulation establishes guidelines regarding manufacturing, marketing, importation, and exposure to use such products.

Personalized medical devices are intended for a specific individual and are divided into three categories according to Anvisa RDC No. 925/2024:

- **Custom Medical Devices:** These are exclusively designed to meet the anatomical and physiological conditions of a specific individual. They are medical devices manufactured specifically according to the prescription of a healthcare professional, who provides specific design characteristics. In this category, the responsibility for the device rests with the healthcare

47 Regarding the topic, see: Brazilian National Health Surveillance Agency – Contact Us. Available at: https://www.gov.br/anvisa/pt-br/canais_atendimento/formulario-eletronico. Accessed on: December 23, 2024.

48 Regarding the topic, see: Brazil Federal Register– Anvisa Resolution RE No. 3,971/2024. Available at: https://www.in.gov.br/en/web/dou/-/resolucao-re-n-3.971-de-24-de-outubro-de-2024-592797799. Accessed on: December 23, 2024.

professional, although the design may be developed in conjunction with the manufacturer.

- **Patient-Specific Medical Devices:** These are tailored to the anatomy of the patient through sizing techniques based on references or anatomical features verified through imaging exams. These are medical devices produced in batches through processes that can be validated and reproduced. Unlike the previous category, the responsibility rests with the manufacturer, even if development occurs in collaboration with the healthcare professional.
- **Adaptable Medical Devices:** These are adjusted, fitted, assembled, or molded according to the specific anatomical and physiological characteristics of the patient before use, in accordance with the manufacturer's instructions at the point of care. Such medical devices are mass-produced.

Regarding the regulatory framework, patient-specific medical devices and adaptable medical devices must be registered with Anvisa. Therefore, they are subject to the requirements inherent to their respective regulatory framework as outlined in Anvisa RDC No. 751/2024.

Custom medical devices, on the other hand, are exempt from registration. The sanitary control of such devices is conducted prior to market introduction through authorization for manufacturing/importation and notification of manufacturing/importation. The procedures and requirements are described in Anvisa RDC No. 925/2024.

Anvisa Resolution RE No. 3,971/2024, which includes the list of companies authorized to manufacture/import custom medical devices, came into effect on the date of its publication.

SCIENTIFIC RESEARCH

REGULATION ON THE USE OF DATABASES IN SCIENTIFIC RESEARCH APPROVED BY CNS

The CNS (National Health Council) established guidelines for the use of databases for scientific research involving human subjects. The rules are outlined in CNS Resolution No. 738/2024, approved during an Ordinary Meeting held on January 31 and February 1, 2024.

According to the new regulation, those involved in the creation and use of the databases have the duty to act with responsibility and integrity during data processing.

In this regard, researchers, sponsors, and institutions involved in the research must conduct themselves in a manner that minimizes the risk of violating the fundamental rights of data subjects. To this end, among the duties assigned to those responsible for the databases, the regulation requires the adoption of measures to ensure the safety and confidentiality of the information.

Whenever possible, personal data should be anonymized. If this is not the case, or if the data are collected with the identification of the data subject, participants in research databases must be guaranteed rights of access, rectification, or updating of their personal information, including a means to request the removal of their information from the database.

In case of damages caused to participants due to misuse, security failures, or breaches of data confidentiality, data subjects are entitled to seek compensation.

Naturally, the new regulation should be interpreted in conjunction with the current clinical research rules in Brazil, including, but not limited to, CNS Resolution No. 466/2012 and the regulations of Anvisa concerning clinical research for the development of new drugs and health products, when applicable.

FEDERAL LAW ON CLINICAL RESEARCH IN BRAZIL PUBLISHED

After nine years of deliberation, in May 2024, the bill on clinical research was sanctioned, resulting in Law No. 14,874/2024, which also establishes the National System of Ethics in Research with Human Beings.

Until then, there was no legal framework on the subject, as regulation was under the responsibility of CNS Resolution No. 466/2012. The new law encompasses all research involving human subjects, which must meet applicable ethical and scientific requirements.

One of the highlights of the law relates to post-study provision. There was a veto of item VI of Article 33 of the proposed text before presidential sanction, which established a five-year timeframe for post-study provision, counted from the commercial availability of the experimental drug in the country.

According to the justification for the veto, the interruption of treatment provision would violate the rights of research participants, as well as the conduct of ethical research based on the principles of dignity, beneficence, and justice.

As a result, the conditions for interrupting post-study provision are now limited to those provided in the other items of Article 33 of the law, such as the availability of the experimental treatment in the public health network; the occurrence of an adverse reaction that impedes the continuation of the experimental treatment, as determined by the researcher; among others.

It is important to note that post-study provision must occur whenever the experimental treatment is deemed by the researcher as the best therapy for the participant's clinical condition and presents a more favorable risk/benefit ratio compared to other available treatments.

Additionally, the provision concerning the research contract is worth highlighting, as it was previously an atypical contract due to the lack of legal provision.

With the new law, the contract is now defined as a written agreement between two or more parties involved, signed and dated, which establishes any provisions regarding delegation, distribution of tasks, as well as obligations regarding the conduct of the research and, if applicable, financial aspects, allowing the use of the protocol as the basis for the agreement.

Law No. 14,874/2024 came into effect on August 27, 2024. The regulatory framework on clinical research was subsequently approved by Anvisa (to be discussed next).

ANVISA APPROVES REGULATORY FRAMEWORK FOR CLINICAL RESEARCH RULES

The Collegiate Board of Anvisa has updated the regulation of clinical research in Brazil. The new rules are outlined in Anvisa RDC No. 945/2024 and Anvisa IN No. 338/2024.

Considering the importance of clinical research for the effective demonstration of the safety and efficacy of new medications, the new rules aim to reduce bureaucracy and facilitate clinical development without compromising applicable technical standards.

The decision occurred during the 23rd ROP (Ordinary Meeting), where the Collegiate Board recognized that the modernization of regulatory strategies is crucial to consolidating a robust innovation ecosystem in Brazil, capable of meeting public health needs and driving technological development.

The new regulation includes detailed guidelines and procedures, as well as a list of equivalent foreign authorities that can be used to optimize analyses, as defined in Anvisa IN (Normative Instruction) No. 338/2024.

Regarding this point, the optimization of analyses using equivalent foreign authorities has become common within Anvisa, as explored in the previous section, and published earlier[49].

Among the innovations in the regulation, it is noteworthy (i) the possibility of early importation, which allows the import of medications before dossier approval, thereby reducing the time between authorization and the start of the clinical study; (ii) precise definitions regarding risk category criteria, study phases, and technical requirements; (iii) alignment with international standards; among others.

The new rules introduced by Anvisa RDC No. 945/2024 and Anvisa IN No. 338/2024 will come into effect on January 1, 2025.

49 Regarding the topic, see: TORRONTEGUY, M.A.A. Life Sciences & Healthcare Newsletter – Editions 2, 4, 5, and 6. Available at: https://tozzinifreire.com.br/publicacoes. Accessed on: December 23, 2024.

FOOD

REGULATORY FRAMEWORK FOR NEW FOODS AND NEW INGREDIENTS COMES INTO EFFECT

On March 16, 2024, Anvisa RDC No. 839/2023 came into effect, which provides for the safety evaluation and authorization for the use of new foods and new ingredients.

During the development of the new regulation by Anvisa, there were discussions about potentially altering the safety assessment model for such products. Models were considered where experts are convened to work with Anvisa on an *ad hoc* basis or even the adoption of the American approach based on GRAS (Generally Recognized as Safe) status, where the manufacturer/importer is responsible for the safety of the products they sell (in the case of GRAS, prior analysis by the regulatory agency is unnecessary).

Nonetheless, Anvisa decided to maintain the previously adopted model, in which the Agency analyzes 100% of cases and authorizes new foods and new ingredients before their manufacture or sale in Brazil.

Anvisa RDC No. 839/2023 defines new foods and new ingredients as "foods and food ingredients that have no history of safe consumption in Brazil obtained from plants, animals, minerals, microorganisms, fungi, algae, or synthesized...".

The illustrative list provided by the regulation includes foods and ingredients with a new or intentionally modified molecular structure, subjected to production processes not usually applied in food production, composed of nanomaterials obtained through engineering, etc.

To confirm if a particular product is considered a new food or ingredient, the industry can submit a prior consultation to Anvisa by means of a petition protocol with a specific subject code. The result of the analysis will be communicated to the petitioner and published on Anvisa's website.

The safety analysis of the products must be requested from Anvisa through a specific petition, complying with the technical requirements established by Anvisa RDC No. 839/2023.

If the request is granted, Anvisa will send the interested party an electronic letter with the corresponding opinion in its entirety and a proposal for a public version.

The interested party will have 60 days to indicate to Anvisa the existence of confidential or secret information in the public version of the opinion.

If the request is denied, in addition to the analysis opinion sent privately, Anvisa will publish a Resolution (RE) in the DOU (Brazil Federal Register). The interested party will have 30 days to indicate to Anvisa the existence of confidential or secret information in the public version of the opinion.

Anvisa will publish a public version of the safety evaluation opinion for new foods and new ingredients on its portal. The absence of a response from the petitioner within the aforementioned deadlines will imply consent to the proposed public version of the opinion. Nevertheless, it is up to Anvisa to make the final decision about the content of the public version of the opinion, and Anvisa must notify the petitioner in the event of a disagreement between the parties.

New foods and new ingredients will be authorized after the approval of the public opinion and publication in the DOU of the updates to the lists contained in the relevant regulations, depending on their classification.

ANVISA APPROVES OPENING OF ADMINISTRATIVE PROCESS FOR LABEL WARNING REQUIREMENT ON PRODUCTS CONTAINING TARTRAZINE

During the 2nd ROP (Ordinary Meeting) of 2024, held on March 6, 2024, the Collegiate Board of Anvisa approved the opening of an administrative process for amending Anvisa RDC No. 727/2022, which pertains to the general labeling of foods, in order to create a requirement for a warning label on products containing tartrazine.

This initiative was in response to a final judicial decision rendered in Civil Action No. 00088401.22.2005.4.03.6100, filed by the Federal Public Ministry against Anvisa[50].

It was determined that Anvisa must publish a regulation requiring the declaration of the following warning on the labels of foods containing tartrazine: "This product contains the yellow dye tartrazine, which may cause allergic reactions, including bronchial asthma, especially in individuals allergic to acetylsalicylic acid.[51]"

50 Regarding the topic, see: Brazilian National Health Surveillance Agency - Vote No. 36/2024/SEI/DIRE2/ANVISA, Item 2.4. Available at: https://www.gov.br/anvisa/pt-br/composicao/diretoria-colegiada/reunioes-da-diretoria/votos/2024/rop-2.2024/2-4.pdf/view. Accessed on: December 23, 2024.

51 *Ibidem*

Pursuant to Anvisa RDC No. 727/2022, food labels containing tartrazine are already required to state the full name of the substance in the ingredient list.

It is worth mentioning that, from 2002 to 2005, it was mandatory for labels to include a similar warning, as stipulated by Anvisa RE No. 148/2002: "This product contains the dye TARTRAZINE, which may cause allergic reactions in sensitive individuals."

According to Vote No. 36/2024/SEI/DIRE2/ANVISA, "(...) the regulatory approach adopted by Anvisa for the authorization of the use of tartrazine in foods is based on its safety and is supported by scientific evidence, aligned with international guidelines, providing clear information to consumers about its presence in foods.[52]"

Due to the short timeframe for compliance with the decision — 30 days from notification — Anvisa has already approved exemptions from Regulatory Impact Analysis and Public Consultation to address the urgency of the situation, as well as exemption from Regulatory Outcome Evaluation[53].

Despite this, the process to amend Anvisa RDC No. 727/2022 is still underway within Anvisa. The topic is expected to remain under discussion in 2025.

NEW SPECIFIC RULES FOR HALAL AND KOSHER PRODUCTS (RELIGIOUS PURPOSES) FROM ANIMAL SLAUGHTER

The Ministry of Agriculture (Mapa) approved the procedures for requesting, assessing, granting, and revoking exceptional authorization for the slaughter and processing of animal products in accordance with religious precepts.

The exceptional authorization, provided for in Mapa Ordinance No. 676/2024, consists of the permission to waive compliance with rules contained in regulations that are incompatible with the religious precepts indicated in the request for the slaughter and processing of animal products.

The flexibility regarding compliance with certain requirements of Mapa, when requested, aims to produce meat in accordance with religious precepts. Thus, the granting of exceptional authorization will exempt the adherence to some traditionally established regulatory rules.

During the request, establishments must present the religious precepts involved, the reasons justifying the request for exemption from compliance with specific rules,

52 *Ibidem*
53 *Ibidem*

a declaration from the corresponding religious authority indicating the necessity to comply with religious precepts that conflict with the rules provided in specific regulations, among other requirements.

It is important to emphasize that this flexibility does not exempt establishments from complying with all other regulations, which must be followed, such as the standards required for product safety.

The significance of the regulation is underscored when considering the intention to intensify the export of Brazilian meat to Asian countries with Muslim (Halal) and Jewish (Kosher) religions. The Ordinance is in line with international practices and positions Brazil in a more competitive stance in these markets, where there is great concern over the religious origin of products.

Thus, the initiative by Mapa not only aims to ensure the safety of these products but is also beneficial from the perspective of international trade. Mapa Ordinance No. 676/2024 was published in the DOU (Brazil Federal Register) on April 19, 2024, and the rules came into effect on May 2, 2024.

ANVISA RECEIVES CONTRIBUTIONS FOR UPDATING MAXIMUM TOLERABLE LIMITS OF CONTAMINANTS IN FOODS

Through Public Consultation No. 1,289/2024, the Collegiate Board of Anvisa received contributions from society and the regulated sector aimed at updating the lists of Maximum Tolerable Limits (MTL) of contaminants in foods.

The regulation of MTL in foods is currently determined by Anvisa RDC No. 722/2022. These limits are currently set forth by Anvisa IN No. 160/2022.

Anvisa IN No. 160/2022 contains the MTL for metals (arsenic, cadmium, lead, copper, chromium, mercury, and tin), mycotoxins (toxic secondary metabolites derived from certain fungi[54]), and other contaminants in foods.

According to the Collegiate Board, the updates seek to align the regulation with the recommendations of the Codex Alimentarius, which is a collection of

54 Regarding the topic, see: Federal University of Santa Maria – O que são micotoxinas? [What are mycotoxins?]. Available at: https://www.lamic.ufsm.br/site/pt/micotoxinas/o-que-sao-micotoxinas. Accessed on: December 23, 2024.

internationally recognized standards, guidelines, and codes of practice that contribute to the safety and quality of food products[55].

The proposed changes include:

- Reduction of MTL for lead in cereal-based foods for infants (from 0.05 mg/kg to 0.02 mg/kg) and in transitional foods for infants and young children (from 0.15 mg/kg to 0.02 mg/kg);
- Increase of MTL for fumonisins (B1 + B2) in corn flour, cream of corn, cornmeal, flakes, hominy, and little hominy (from 1,500 mcg/kg to 2,000 mcg/kg);
- Insertion of MTL for fumonisins (B1 + B2) in raw corn (4,000 mcg/kg);
- Insertion of MTL for hydrogen cyanide in cassava flour (10 mg/kg);
- Insertion of MTL for monochloro-propanediol (3-MCPD) in liquid condiments containing acid-hydrolyzed vegetable proteins (0.40 mg/kg) – except naturally fermented soy sauce; and
- Insertion of MTL for melamine in (i) general foods, except infant formulas (2.5 mg/kg); (ii) formulas for infants, transitional formulas, and formulas for young children marketed in powdered form (1.0 mg/kg); and (iii) formulas for infants, transitional formulas, and formulas for young children marketed in liquid form (0.20 mg/kg).

The Collegiate Board of Anvisa clarified that the proposed MTL for contaminants in foods harmonized or negotiated within the framework of Mercosur are not part of this proposal[56].

The topic is expected to remain under discussion in 2025.

55 Regarding the topic, see: Codex Alimentarius. Available at: https://www.fao.org/fao-who-codexalimentarius/about-codex/en/#c453333. Accessed on: December 23, 2024.

56 Regarding the topic, see: Brazilian National Health Surveillance Agency – VOTE No. 236/2024/SEI/DIRE2/ANVISA. Available at: https://anvisalegis.datalegis.net/action/ActionDatalegis.php?acao=abrirTextoAto&link=S&tipo=VTO&numeroAto=00000236&seqAto=ROP&valorAno=2024&orgao=DIRE2/ANVISA/MS&codTipo=&desItem=&desItemFim=&cod_modulo=630&cod_menu=9373. Accessed on: December 23, 2024.

ANVISA CREATES REPOSITORY COMPILING FULLY RECOGNIZED CLAIMS IN FOODS

Anvisa has made available a public panel featuring 109 fully recognized claims that can be included on labels without prior analysis by Anvisa[57].

The tool includes ready-made claims related to 27 nutrients and allows for their interactive selection, facilitating the analysis and identification by the regulated sector of the requirements that must be met for their use on labels.

This measure is supported by TECHNICAL NOTE No. 64/2024/SEI/COPAR/GGALI/DIRE2/ANVISA, which details the motivation behind the initiative: although Anvisa Resolution No. 18/1999 states that for nutrients with functions fully recognized by the scientific community, no demonstration of efficacy or prior analysis is required for their inclusion in labeling, the regulation does not list the functions or the criteria for their definition/identification[58].

Informal guidelines and other measures were adopted by Anvisa over the years to address this gap. However, there was some legal uncertainty that, according to Anvisa, hindered the execution of post-market surveillance actions, "potentially amplifying unfair competition situations, complicating decision-making regarding regularization procedures, and increasing the likelihood of information asymmetry and misleading situations for consumers.[59]"

In 2018, Anvisa IN No. 28/2018 provided a list of authorized claims for dietary supplements, associated with specific requirements. However, this regulation applies only to this specific category of foods.

The new measure facilitates the identification of claims permitted by Anvisa for general foods—except for products intended for infants and young children, in line with Anvisa RDC Nos. 43, 44, and 45/2011, as highlighted in the tool.

Anvisa recommends not altering the standard phrases listed, "except to combine claims of the same nutrient into a single statement or to combine claims describing the same effects of different nutrients[60].

57 Regarding the topic, see: Brazilian National Health Surveillance Agency – Fully Recognized Claims. Available at: https://app.powerbi.com/view?r=eyJrIjoiZGExYTY5ZjMtYmE2My00ND-g0LTkwNGQtZWFlYzFhNzQ4OThlIiwidCI6ImI2N2FmMjNmLWMzZjMtNGQzNS04MGM3LWI3MDg1Z-jVlZGQ4MSJ9. Accessed on: December 23, 2024.

58 Regarding the topic, see: Brazilian National Health Surveillance Agency – TECHNICAL NOTE No. 64/2024/SEI/COPAR/GGALI/DIRE2/ANVISA. Available at: https://www.gov.br/anvisa/pt-br/centraisdeconteudo/publicacoes/alimentos/manuais-guias-e-orientacoes/sei_3029382_nota_tecnica_64.pdf. Accessed on: December 23, 2024.

59 *Ibidem*

60 *Ibidem*

COSMETICS

EVOLUTION OF THE HAIR POMADE CASE

In 2022, during the Carnival festivities, Anvisa identified reports of adverse effects allegedly arising from the use of hair styling products known as hair pomades.

In response, Anvisa began implementing preventive measures, including precautionary bans and suspensions on the marketing, distribution, manufacturing, advertising, and use of hair pomades due to reported cases of poisoning.

Preventive measures against unregulated hair pomades were also adopted. Additionally, cancellations of ongoing regularization processes for hair pomades by Anvisa were published in the DOU (Brazil Federal Register).

Among other measures, Anvisa held a technical meeting with companies manufacturing hair pomades to provide information regarding investigations into the causes of the reported adverse effects.

On September 15, 2023, Anvisa RDC No. 814/2023 came into effect, which addresses the temporary conditions for the regularization, marketing, and use of hair pomades. Guidance in the form of Questions and Answers regarding the RDC was also available to facilitate public access to the new regulation.

Considering the temporary nature of Anvisa RDC No. 814/2023, further measures from Anvisa regarding the regulation of this topic are still anticipated.

ANVISA ESTABLISHES NEW GUIDELINES RELATED TO GOOD PRACTICES IN COSMETOVIGILANCE

On August 28, 2024, Anvisa published Anvisa RDC No. 894/2024, which outlines Good Practices in Cosmetovigilance for the cosmetic products sector. The regulation will come into effect on August 28, 2025, and will revoke Anvisa RDC No. 332/2005 (the current regulation on cosmetovigilance).

Cosmetovigilance refers to the post-market surveillance and monitoring of cosmetic products. The practice includes identification, notification, evaluation, investigation, monitoring, communication, and prevention of adverse reactions resulting from the use of cosmetic products, as defined in Article 2, XIII of Anvisa RDC No. 894/2024.

The monitoring and surveillance of cosmetic products aims to prevent adverse health events. The existence of risk, even if of varying intensity, is inherent to any regulated product. In this sense, cosmetics are no exception—evidenced by the reports of over 10,000 cases of adverse events related to the use of hair pomades in 2023, which even led to the creation of the new regulation[61].

The update of the regulation arose from the need to establish obligations beyond those previously outlined in Anvisa RDC No. 332/2005. This prior regulation required companies in the regulated sector to implement their own cosmetovigilance systems to analyze occurrences reported by consumers. Accordingly, these entities must maintain a system to record these occurrences and notify Anvisa and the health authorities of the other Mercosur countries involved.

However, the previous regulation contained only three articles and did not provide clear rules regarding requirements for: monitoring of products; conducting the cosmetovigilance system established by companies; timelines for addressing occurrences reported by consumers; designating a qualified professional responsible for cosmetovigilance actions; among others.

With the revocation of Anvisa RDC No. 332/2005, the new regulation aims to address these regulatory gaps to increase the quality of cosmetic products on the market and provide greater predictability and legal certainty to the regulated sector.

Anvisa is expected to publish an inspection manual on cosmetovigilance soon, complementing Anvisa RDC No. 894/2024[62].

61 Sobre o tema, confira: Agência Nacional de Vigilância Sanitária - Voto nº 148/2024/SEI/DIRE2/ANVISA. Disponível em: https://www.gov.br/anvisa/pt-br/composicao/diretoria-colegiada/reunioes-da-diretoria/votos/2024/rop-15.2024/2-5.pdf. Acesso em: 23/12/2024.

62 Sobre o tema, confira: Agência Nacional de Vigilância Sanitária - Anvisa publica novas regras para monitoramento pós-mercado de cosméticos. Disponível em: https://www.gov.br/anvisa/pt-br/ assuntos/noticias-anvisa/2024/anvisa-publica-novas-regras-para-monitoramento-pos-mercado-de-cosmeticos. Acesso em: 23/12/2024.

ANVISA CONSOLIDATES RULES REGARDING THE REGULATION OF COSMETIC PRODUCTS

The Collegiate Board of Anvisa has approved the consolidation of norms related to personal hygiene products, cosmetics, and perfumes, as well as cosmetic products for straightening or curling hair.

This consolidation resulted in the publication of Anvisa RDC No. 906/2024 and No. 907/2024. These regulations address the technical requirements and classification rules for such products, in addition to provisions regarding labeling/packaging, regularization procedures, among others.

As this is a consolidation aligned with the provisions of Decree No. 12,002/2024, these regulations do not change the substance of the existing regulations. Thus, the changes resulting from the consolidation are formal in nature[63].

The rules established by these regulations provide mechanisms to ensure the quality, safety, and efficacy of products placed on the market by the regulated sector to consumers.

In this context, the publication of Anvisa RDC No. 906/2024 is particularly relevant, considering the actions and measures taken by Anvisa in response to reports of adverse events resulting from the use of hair pomades, such as temporary blindness and eye irritation, especially during Carnival holidays in previous years, as mentioned above.

Both regulations came into effect on September 23, 2024.

63 Regarding the topic, see: Brazilian National Health Surveillance Agency - VOTE No. 405/2024/SEI/DIRECTOR-PRESIDENT/ANVISA. Available at: https://www.gov.br/anvisa/pt-br/composicao/diretoria-colegiada/reunioes-da-diretoria/votos/2024/rop-17.2024/2-21-a-2-23.pdf/view. Accessed on: December 23, 2024.

SANITIZERS

ANVISA PUBLISHES REGULATION FOR PAINTS AND VARNISHES WITH SANITIZING ACTION

On March 8, 2024, Anvisa RDC No. 847/2024 was published, which establishes the technical requirements for the regularization of real estate paints and varnishes with sanitizing action. The regulation came into effect on April 1, 2024.

This topic has been under discussion for over 10 years: in 2011, Anvisa began receiving requests for authorization to market paints claiming antibacterial, antifungal, repellent, or insecticidal action, even if the product was not fully regulated[64].

Since then, Anvisa has approved certain products after toxicological and efficacy evaluations, but through a distinct procedure from that adopted for sanitizers in general. To establish a specific formal procedure, the regulation of paints with sanitizing effects was inserted into the Regulatory Agenda 2017-2020 and was developed starting in 2019[65].

The new Anvisa RDC No. 847/2024 includes several relevant definitions and applies to real estate paints and varnishes with antimicrobial sanitizing action (disinfectant or sanitizer) or pest control sanitizing action (insecticide or repellent), available for free sale and restricted sale to specialized companies.

These products have been classified as sanitizing products of risk level 2. Therefore, they are subject to sanitary registration in accordance with Anvisa RDC No. 59/2010 and must have their residual efficacy proven. The necessary documents for registration are listed in the regulation, including the data required for the evaluation of new active ingredients.

Thus, the requirements and prohibitions related to the composition, indication, labeling, packaging, and presentation of paints and varnishes with sanitizing action are detailed in Anvisa RDC No. 847/2024.

64 Regarding the topic, see: Brazilian National Health Surveillance Agency - VOTE No. 102/2024/SEI/DIRECTOR-PRESIDENT/ANVISA. Available at: https://www.gov.br/anvisa/pt-br/composicao/diretoria-colegiada/reunioes-da-diretoria/votos/2024/rop-2.2024/2-3.pdf/view. Accessed on: December 23, 2024

65 *Ibidem*

SMOKING PRODUCTS

ANVISA MAINTAINS PROHIBITIONS REGARDING ELECTRONIC CIGARETTES (DEF)

The Collegiate Board of Anvisa has upheld the prohibition on the manufacture, importation, marketing, distribution, storage, transport, and advertising of electronic cigarettes (DEF).

The maintenance of the prohibition was unanimously approved during the 6th Regulatory Oversight Meeting held on April 19, 2024, resulting in the publication of Anvisa RDC No. 855/2024.

The prohibition on the importation, marketing, and advertising of DEF had already been regulated since the publication of Anvisa RDC No. 46/2009. Based on the precautionary principle and the absence of scientific data demonstrating the efficacy and safety of DEF, this regulation prohibited the commercialization, importation, and advertising of these devices—especially those claiming to replace conventional smoking-agent products or to treat smoking addiction.

The decision followed the understanding presented in the Regulatory Impact Analysis Report from July 2022, which recommended maintaining the prohibition of DEF and implementing measures against the marketing of such devices.

Anvisa's directors determined that these devices lack scientific studies and solid evidence regarding their long-term health impacts. There is also no evidence of benefits related to harm reduction or cessation of smoking-agent product consumption.

Furthermore, it was considered that there is a substantial risk of exposing young people and adolescents to smoking practices, given the levels of DEF use among children and adolescents in countries where such devices are permitted.

Although individual use of DEF has not been prohibited (except for the prohibition of using smoking-agent products in enclosed places, as provided by law), the ban includes the entry of DEF into national territory through any form of importation, including personal luggage of travelers.

Anvisa RDC No. 855/2024 came into effect on May 2, 2024, and revoked Anvisa RDC No. 46/2009. Non-compliance with its provisions will result in a health infraction, without prejudice to reporting the matter to the competent authorities for civil and/or criminal measures.

ANVISA APPROVES NORMATIVE INSTRUCTIONS FOR ESTABLISHING WARNINGS ON DISPLAYS AND PACKAGING OF SMOKING-AGENT PRODUCTS

On November 1, 2024, Anvisa published Anvisa IN No. 331/2024 and Anvisa IN No. 332/2024, which contain new health warnings and messages to be used on displays, showcases, and packaging of tobacco-derived smoking-agent products.

As determined by the Collegiate Board, these regulations aim to establish guidelines for effectively disseminating clear information to raise consumer awareness about the inherent risks of consuming smoking-agent products.

The messages and warnings established by the normative instructions contain text and visual elements aimed at discouraging tobacco use.

These measures are supported by Law No. 9,294/1996, which states that such products must contain warnings about the harmful effects of their use. This Law explicitly prohibits the advertising of smoking-agent products within the national territory.

The messages and warnings regarding the harms of tobacco are periodically updated. The latest modifications occurred through the publication of Anvisa IN No. 271/2023 and Anvisa IN No. 272/2023.

The guidelines to be followed by companies regarding the layout, design, and content of the warnings are listed in the normative instructions, including the minimum percentage area of the graphic set for the warnings, the texts, and their respective formatting, among others.

The new rules came into effect on November 1, 2024, and revoked the previous regulations addressing this matter.

HEALTH ETHICS AND CFM REGULATION

OPINION: TRENDS IN HEALTH CONFLICTS OF INTEREST

Giovana Bruna Salerno Soares[66]

For a few years now, we have noticed the maturation of authorities and the market concerning potential conflicts of interest involving the industry/distributors of regulated products and health professionals.

The topic is addressed in ethical norms applicable to health professionals, in internal codes of clients and associations to which they belong, each with its particular robustness, based on the role of each agent in the supply chain of products and the inherent health risks associated with them, which can vary depending on the regulatory category they fall into.

At the same time, solutions have emerged in the market aimed at meeting the multifaceted needs of consumers in the health field, often proposing interactions and interconnections between the spheres of products and health services.

From a regulatory perspective, since the end of 2016, the state of Minas Gerais has been applying Law No. 22,440/2016, regulated by Decree No. 47,334/2017. The regulations require companies in the health sector to provide information related to donations or benefits granted to health professionals, such as gifts, airfare, registration for congresses or conventions, funding for research, among others. Reporting must be done by companies annually, and the data is available to the general public.

More recently, CFM Resolution No. 2,386/2024 – which will come into effect in March 2025 – requires physicians to inform CFM if they have ties to pharmaceutical industries, health-related supplies, and medical equipment or intermediaries selling these products, in addition to declaring any potential conflicts of interest in their presentations regarding medicine.

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This initiative innovates by intending to provide, through its own CFM platform, data related to potential conflicts of interest at the national level, based on information provided by health professionals. The notion of ties introduced by the regulation includes the provision of habitual or occasional services, participation in research, in lectures, etc., which must be reported within 60 days of the occurrence (or its commencement).

Such measures, which affect both companies and health professionals, provide greater transparency to the end consumer of regulated products, as well as encourage fruitful contributions between the industry/distributors and health professionals. I believe that in 2025 this topic will remain prominent.

NEW CFM RULES ON MEDICAL ADVERTISING COME INTO EFFECT

The CFM has presented the New Medical Advertising Manual, aiming to clarify the provisions of CFM Resolution No. 2,336/2023 (which addresses this issue). The Resolution was published in September 2023 and will come into effect on March 11, 2024.

The Resolution and the Manual contain guidelines on the use of communication vehicles, such as social media, for advertising and promotion purposes, including descriptions of the limitations and requirements to be observed by physicians when publicizing their work.

Based on the new rules, physicians are allowed to promote their work in communication vehicles within the limits imposed by the regulations, being able to share informational or academic content, promote health and well-being, present their work environment, organize educational groups for laypersons (such as for pregnancy cases aimed at promoting guidance related to pregnancy), among others.

Regarding the limitations of medical advertising, publications containing clickbait content (such as praising and prioritizing their performance or sharing information that could cause collective insecurity) are prohibited, as well as those that may characterize unfair competition, contain false information, or advertise medications, equipment, food, or any other products.

In the organization of educational groups for laypersons, conducting consultations, teaching acts exclusive to the physician, or offering information that contains diagnostic judgments, etc., is expressly prohibited.

For medical advertising purposes, the regulation allows the use of patient images but also imposes restrictions. To avoid being classified as clickbait content or self-promotion, any use of patient images must necessarily have an exclusively educational character.

In this regard, any "before and after" disclosures, for example, must include information such as indications, developments, or any complications. Furthermore, any manipulation of images is prohibited. Sharing images of procedures that allow for patient identification is also forbidden.

The complete New Medical Advertising Manual can be accessed on the CFM website[67].

CFM PUBLISHES REGULATION ON DISCLOSURE OF PHYSICIANS' TIES TO INDUSTRY

On September 2, 2024, the CFM published Resolution No. 2,386/2024 to standardize the procedures and rules for physicians to declare their ties to the pharmaceutical industry, health-related supplies, and medical devices.

The regulation will come into effect on March 1, 2025, and requires physicians with ties to these industries to inform the name of the company they are associated with, as well as to notify when such ties are terminated.

According to the regulation, a tie will be characterized when: (i) the physician is formally contracted to perform work related to the industry companies; (ii) the physician provides occasional and/or paid services; (iii) the physician conducts or participates in research (for the development of medications, materials, products, or equipment for medical use); (iv) the physician is invited or hired for advertising purposes for remuneration; (v) the physician participates in Conitec and in deliberative councils understood by the regulation as similar, such as those in ANS and Anvisa; and (vi) the physician acts as a speaker.

On the other hand, physicians are exempt from the obligation to inform when receiving (i) earnings and dividends from shares or participation in companies; (ii) free samples and/or products under the legislation; and (iii) benefits received from scientific societies and medical entities.

67 Regarding the topic, see: Federal Council of Medicine – Novo Manual da Publicidade Médica é lançado durante o ENCM 2024 [New Medical Advertising Manual launched during ENCM 2024]. Available at: https://portal.cfm.org.br/noticias/novo-manual-da-publicidade-medica-foi-lancado-durante-o-i-encm-2024. Accessed on: December 23, 2024.

The regulation emphasizes that it is completely prohibited for physicians to receive benefits related to products not registered with Anvisa, except for those that already have research protocols approved by the CEP/CONEP system.

The information regarding ties must be provided on a dedicated page of the Regional Medical Councils where the physicians have an active registration, within 60 days after receiving the benefit. Furthermore, the regulation stipulates that physicians must also declare any conflicts of interest when participating in interviews, debates, or any type of presentation about medicine, both to lay audiences and at medical events.

Physicians who fail to comply with this obligation will be liable to penalties and procedures established by the CFM and the Regional Councils. The CFM's jurisdiction does not extend to holding the industry accountable, but the new regulation is expected to impact interactions between professionals and industries from now on.

AGRICULTURAL VIGILANCE

POTENTIAL CONFLICT BETWEEN THE LEGAL FRAMEWORK FOR AGRICULTURAL PESTICIDES AND THE PRE-EXISTING REGULATORY FRAMEWORK APPLICABLE TO AGROCHEMICALS

Since December 28, 2023, Law No. 14,785/2023 has been in force, which establishes the new Legal Framework for Agricultural Pesticides[68].

The Law introduced new guidelines and rules for the registration, manufacturing, export, import, distribution, and other activities related to agrochemicals, environmental control products, their technical products, and related items. However, the Law mentioned did not formally revoke the existing regulatory standards that were applicable during its enactment.

The regulation on this topic – until then in effect – includes Decree No. 4,074/2002 (regulatory decree), in addition to various exclusive norms from the Ministry of Agriculture (Mapa) and other joint norms involving Anvisa and Ibama, which together form the Brazilian regulatory framework for agricultural pesticides[69].

Considering that such norms have not been formally revoked, conflicts may arise between the new criteria defined in the Law and the regulatory practice stemming from the pre-existing regulations.

For example, the Law exempts the registration with Mapa for the manufacturing of agrochemicals intended solely for export, requiring only the submission of a "production notification for export" containing information about the product, the quantities to be exported, and its destination.

However, both Decree No. 4,074/2002 and Joint Normative Instruction No. 1/2006 still stipulate the need for a specific registration for this export (REX), defining specific procedures and criteria for it, which were not incorporated in the new Law.

Notwithstanding this, the new Law is hierarchically superior to the norms that have not yet been formally revoked. This issue may be discussed in 2025 by Mapa.

68 Regarding the topic, see: TORRONTEGUY, M.A.A. Life Sciences & Healthcare Newsletter – 1st Edition of 2024, p. 13. Available at: https://tozzinifreire.com.br/boletins/boletim-ciencias-da-vida-e-saudeedicao-1-2024. Accessed on: December 23, 2024.

69 Regarding the topic, see: Ministry of Agriculture, Livestock and Food Supply – Legislation. Available at: https://www.gov.br/agricultura/pt-br/assuntos/insumos-agropecuarios/insumos-agricolas/agrotoxicos/legislacao. Accessed on: December 23, 2024.

LAW REGULATING BIO-INPUTS IN BRAZIL COMES INTO EFFECT

Law No. 15,070/2024 addresses the production, importation, exportation, registration, commercialization, use, inspection, supervision, research, experimentation, packaging, labeling, advertising, transportation, storage, fees, provision of services, waste and packaging disposal, and incentives to produce bio-inputs for agricultural, livestock, aquaculture, and forestry use, including production for personal use.

The regulation applies to all bio-inputs used in agriculture, as well as to all cultivation systems, including conventional, organic, and agroecological systems. The Law also provides financial mechanisms to encourage research, development, production, use, and commercialization of bio-inputs.

The established definition for "bio-inputs" includes products, processes, and technologies of plant, animal, or microbial origin for use in agricultural products, in aquatic production systems, or in planted forests, which impact animals, plants, microorganisms, soil, and derived substances that interact with the products and processes in question. The regulation includes many other definitions applicable to the sector.

According to the Law, the products (bio-inputs and inoculants of bio-inputs) and the establishments responsible for their manufacturing, importation, exportation, and commerce are subject to registration with Mapa – except, for example, for products and establishments related to personal, non-commercial use, which are outlined in a specific and detailed chapter of the regulation.

A future regulation – to be published within 360 days of the publication of the law – will be responsible for defining the classification, specifications, minimum parameters applicable to bio-inputs, the simplified registration procedure for bio-inputs similar to those already registered, any other exemptions from registration for low-risk products and specific establishments, and bio-inputs that cannot be manufactured for personal use, etc.

The Law stipulates that the sale or use of bio-inputs with low toxicity and ecotoxicity is exempt from agronomic prescriptions, as is the use of bio-inputs for personal use. The determination regarding the need for a technical person responsible for the production of bio-inputs for personal use is assigned to Mapa.

The regulation also clarifies that Law No. 14,515/2022, concerning self-control programs, procedures related to public acts of release of establishments and products, administrative supervision processes, etc., is also applicable to bio-inputs.

Under Law No. 15,070/2024, manufacturers of already registered products must adjust the corresponding labels within 12 months from the publication of the regulatory norm. It is also intended that the remaining stocks of bio-inputs be depleted, unless otherwise determined by Mapa.

Finally, the Law guarantees the continuity of the production of bio-inputs for personal use until the regulation on the topic and good practice standards are published. After these are published, users must comply within 12 months.

Law No. 15,070/2024 entered into force on December 24, 2024.

REGULATION OF THE MAPA SELF-CONTROL LAW PUBLISHED

On August 1, 2024, Decree No. 12,126/2024 was published to regulate self-control programs for the sector regulated by agricultural defense.

The Decree also regulates the Compliance Incentive Program in Agricultural Defense for sectors involving animal-derived products, both edible and non-edible, as well as products intended for animal feed. Furthermore, the Decree contains provisions regarding risk-based inspection and supervision procedures in agricultural defense.

Self-control consists on a program aimed at promoting compliance with the regulatory requirements in the productive processes of the regulated sector. These requirements seek to ensure the quality and safety of products from sector agents who conduct internal monitoring through self-control.

In this sense, the regulation of the Self-Control Law seeks to optimize the actions of monitoring the quality of products intended for the market.

Under the new regulation, self-control programs conducted by private sector agents must observe a series of mandatory requirements listed in the clauses of Article 4.

In this regard, the programs must (i) include records of the entire production process that are systematized and auditable; (ii) provide for the recall of batches in case of identified non-conformities in agricultural products that pose potential risks to consumers, animal health, or plant health; (iii) describe self-correction procedures; and (iv) apply good practices throughout the production chain.

It is expected that Mapa will also establish specific regulations regarding self-control for each productive sector, as well as the procedures and frequency for official verification, considering risk assessments, as provided in Article 5 of Decree No. 12,126/2024.

REGULATION ON INSPECTION AND SUPERVISION OF ANIMAL FEED PRODUCTS PUBLISHED

On May 29, 2024, Decree No. 12,031/2024 was published, regulating inspection and supervision procedures related to animal feed products.

The new regulation brings criteria and definitions regarding the registration of establishments and products, as well as rules applicable to the manufacturing, import/export, labeling, and transportation of animal feed products, among others.

The Decree also stipulates that establishments engaged in activities related to animal feed must have self-control programs (this is an innovation for companies generally regulated by Mapa, as defined in Law No. 14,515/2022), which will include:

- Systematized and auditable records of the production process, from the sourcing and receipt of raw materials, ingredients, and inputs to the dispatch of the resulting product;
- Provisions for the recall of batches when deficiencies or non-conformities in the product are identified that may pose risks to consumer safety or animal health;
- A description of self-correction procedures.

It is important to note that any violation of the new rules applicable to animal feed products will subject the violator to the following penalties, applicable according to the severity of the action or omission: (i) warning; (ii) fine; (iii) condemnation of the product; (iv) suspension of registration, enrollment, or accreditation; (v) revocation of registration, enrollment, or accreditation; or (vi) revocation of the professional's qualification to provide services related to agricultural defense.

The Decree came into force on July 8, 2024, and the period for establishments to comply with the new rules will end on July 9, 2025.

HEALTH PLANS AND ANS

ANS DISCUSSION ON THE INCORPORATION OF TECHNOLOGIES APPROVED BY CONITEC

On February 26, 2024, the Collegiate Board of ANS deliberated on the incorporation of technologies approved by Conitec into the list of procedures and health events that must be covered by health operators, in accordance with Law No. 9,656/1998 and ANS RN No. 465/2021.

The Collegiate Board decided to incorporate the medication beta-galactosidase for the treatment of classic Fabry disease in patients aged eight years or older into the ANS list. Other treatments that were discussed but not incorporated include (i) the tetravalent vaccine TAK-003 (dengue), (ii) icatibant acetate (hereditary angioedema type 1 and 2 for hospital use), (iii) the human plasma-derived C1 esterase inhibitor (hereditary angioedema type 1 and 2), and (iv) ustekinumab (moderate to severe Crohn's disease).

The Collegiate Board did not incorporate the tetravalent vaccine TAK-003 into the list. Regarding the other treatments, the Collegiate Board concluded that they were already covered by the list, making their inclusion unnecessary.

The discussion relates to the amendment of Law No. 9,656/1998 by Law No. 14,454/2022: since then, in the case of a prescribed treatment or procedure not included in the list, coverage must be authorized by the health plan operator, provided that, among other conditions, there are recommendations from Conitec.

In practice, in cases where there is no express mention of a specific treatment in the list of ANS RN No. 465/2021, it is common to have discussions regarding the obligation of operators to provide such treatment, which should be analyzed in light of the specific case.

STF CONFIRMS EXCLUSIVE COMPETENCE OF THE UNION IN MATTERS OF HEALTH PLANS AND INSURANCE – ADI NO. 7552

On August 9, 2024, in the scope of ADI No. 7552, the STF Plenary decided on the unconstitutionality of AL State Law No. 8,880/2023, which mandated health plans to cover exams prescribed by nutrition professionals.

As stated in the opinion of the reporting minister, Luiz Fux, the declared unconstitutional norm pertains to matters of exclusive competence of the Union. This issue had already been deliberated by the STF in ADI No. 7376, reported by Minister Gilmar Mendes, which reached a similar conclusion regarding the unconstitutionality of similar legislation from the state of Rio Grande do Norte.

According to Article 22, I and VII, of the Federal Constitution, it is the exclusive competence of the Union to legislate on civil rights and insurance policies, among other topics. Furthermore, ANS has the authority to establish coverage parameters in health care, as provided in Article 4, V, of Law No. 9,961/2000, among other responsibilities.

In this sense, any rule and/or obligation related to health plans can only be established through Federal Law.

The referred decision is individually applicable to the case analyzed but may eventually be used alongside ADI No. 7376 as a precedent for the judgment of any future similar actions.

ANS TEMPORARILY SUSPENDS RULES SET TO TAKE EFFECT REGARDING HEALTH PLAN DEFAULT

The Collegiate Board of ANS decided to temporarily suspend the effectiveness of ANS RN No. 593/2023, retroactively from December 1, 2024, to February 1, 2025. The regulation was scheduled to take effect on December 1, 2024, and the suspension decision was published in the Brazil Federal Register (DOU) on December 2, 2024[70]. Thus, the provisions of the regulation are expected to take effect on February 1, 2025.

70 Regarding the topic, see: Brazil Federal Register - Decision of December 2, 2024. Available at: https://www.in.gov.br/en/web/dou/-/decisao-de-2-de-dezembro-de-2024-599191105. Accessed on: December 23, 2024.

The regulation addresses notifications for default to individuals who have contracted private health care plans. This means it applies to individuals or family health plan contractors, individual entrepreneurs contracting collective corporate plans, or beneficiaries who pay the collective plan premium directly to the operator.

The regulation provides for the exclusion of the beneficiary or unilateral termination if there are at least two unpaid premiums, whether consecutive or not.

ANS RN No. 593/2023 also outlines the means of notification due to default, which are (a) email with digital certificate or read confirmation; (b) text message via SMS or encrypted messaging application; (c) recorded telephone call (either personal or via an automated response system) with data confirmation by the interlocutor; (d) registered letter with acknowledgment of receipt.

Contracts established prior to the start of the new regulation's effectiveness must be amended to include all the notification means set forth in ANS RN No. 593/2023.

ANS RECEIVES CONTRIBUTIONS TO THE IMPLEMENTATION OF REGULATORY SANDBOX

Through Public Consultation No. 138/2024, ANS received contributions from society and the regulated sector regarding the proposed RN that sets forth the rules for the establishment and functioning of a regulatory sandbox within the Agency.

Based on the proposed RN under discussion, ANS aims to implement a controlled environment that allows for the development of new products, services, or regulatory solutions.

In this environment, innovations related to supplementary health can be tested with reduced time and costs. The results obtained may lead to regulatory adjustments to enhance the efficiency of the applicable regulation, adapting it to the particularities and needs of the sector.

Through this tool, ANS may authorize companies to test new solutions in supplementary health through a public notice that will contain selection criteria, deadlines, eligibility rules, etc.

To participate in the program, a company must demonstrate technical and financial capacity to develop the intended activities in the experimental environment, as well as comply with the requirements set forth in the proposal, such as

submitting periodic information and maintaining the regularity of the fiscal and technical management regime, among others.

Once admitted into the program, the Sandbox Commission will monitor the activities of the participants, according to a specific admission term. The Commission may require access to relevant information and cooperation from the participants, who must comply with the applicable regulatory requirements outlined in the regulatory proposal.

The topic is expected to continue being discussed in 2025.

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