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This is an informative newsletter produced by the **Lifesciences and Healthcare** practice of TozziniFreire Advogados.

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Supreme Court Reaches Judgement on the State's Obligation to Provide Medications Not Included in SUS List

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

The discussions focused on deciding **(i)** whether the State must supply medications not listed in SUS in cases of patients' economic weakness; and **(ii)** whether lawsuits with such request must be filed against the Government and prosecuted in Federal Court.

Regarding the obligation to supply medications, the STF Full Bench understood that, as a rule, the Judiciary Branch cannot determine the supply of medications not included in SUS list, regardless of their cost.

However, exceptionally, the Judiciary Branch may determine that such medications be supplied when the plaintiff demonstrates, cumulatively:

- The denial of supply through administrative means
- The illegality of the National Commission for the Incorporation of Technologies in the Unified Health System (CONITEC)'s act of not incorporating the medication, the absence of an incorporation request, or the delay in its analysis
- The lack of sufficient resources to cover the medication's cost
- That the medication cannot be replaced by another one included in SUS list
- That using the medication is essential for treatment; and
- That the medication's efficacy, accuracy, effectiveness, and safety are proven based on evidence-based medicine, and that this is scientifically supported (randomized clinical trials and systematic reviews or meta-analysis).

As for standing to be sued and jurisdiction for judgment, the STF Full Bench established two hypotheses:

i. Actions will be prosecuted in Federal Court, with treatment costs covered by the Government, when:

The annual costs of the requested treatment are equal to or greater than 210 (two hundred and ten) minimum wages.

ii. Actions will be prosecuted in State Courts, with treatment costs shared among federative units of Brazil, when:

The annual unit cost of the medication

ranges between 7 (seven) and 210 (two hundred and ten) minimum wages.

In this case, in the event of payments required from states and municipalities, 65% (sixty-five percent) of the expenses arising from treatments will be the Government's responsibility. The Government's share will be 80% (eighty percent) if the requested medications are oncological.

It is important to highlight that although the Judiciary Branch may determine that medications not included in SUS list be supplied in the aforementioned cases, such medications must be duly registered and regular before the National Health Surveillance Agency (ANVISA), except in exceptional cases (as previously decided under Topic No. 500 of the STF)[1].

During the judgment of Topic No. 500, the STF had decided that, as a general rule, court decisions cannot determine the supply of medications that are not registered before ANVISA. However, the STF accepted this possibility in exceptional cases of ANVISA's unreasonable delay in analyzing the application for registration. For this hypothesis to occur:

a. There must be an application for registration of the medication in Brazil (except in cases of orphan drugs for rare and ultra-rare diseases);

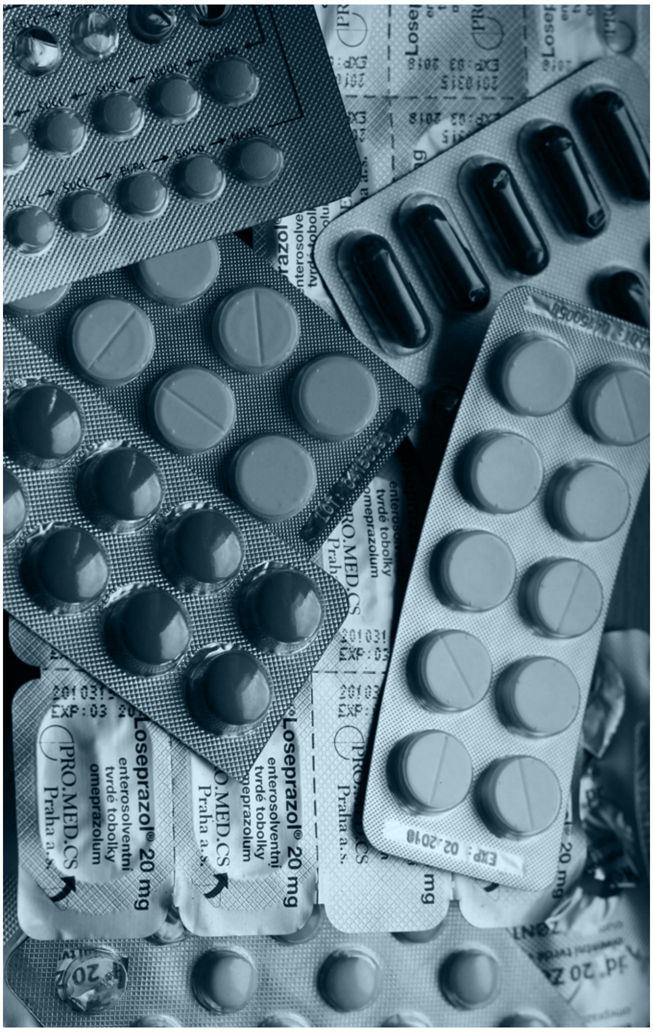
b. The medication must be registered with reputable foreign regulatory agencies; and

c. There can be no therapeutic substitute registered in Brazil.

Regarding the numbers, according to information released by the STF, in 2020, 347,000 (three hundred and forty-seven thousand) health-related lawsuits were filed. By 2024, this number reached 600,000 (six hundred thousand), considering the time data were released (10/17/2024).[2]

1 Available at: https://portal.stf.jus.br/jurisprudenciaRepercussao/verAndamentoProcesso.asp?incidente=4143144&numeroProcesso=657718&classeProcesso=RE&numeroTema=500. Access on Oct. 22, 2024.

2 Information available at: https://noticias.stf.jus.br/postsnoticias/stf-celebra-conclusao-de-julgamento-sobre-fornecimento-de-medicamentos-de-alto-custo/. Access on Oct. 21, 2024.



ANVISA Opens New Public Inquiry on the Execution of Agreements for the Regularization of Medications

The Board of ANVISA (Dicol) approved the launch of Public Inquiry No. 1,282/2024, which proposes criteria and procedures for the execution of agreements for registration, post-registration, and authorization for the temporary emergency use of medications.

If approved at the end of the regulatory process, the new rules should facilitate the procedures for registration, post-registration, and authorization for the temporary emergency use of medications before ANVISA.

The manufacture and sale of medications in Brazil depend on ANVISA's approval. To this end, medications must have been technically analyzed to certify their quality, safety, and efficacy.

Under the current rules, applications for medication registration are denied if the interested company fails to present all legally required documentation, in case of impossibility.

According to the proposal, ANVISA may enter into an agreement with the requesting company when there is data attesting to the safety and efficacy of the medication to be submitted for registration, post-registration, or authorization for temporary emergency use, even if there are regulatory requirements yet to be met.

In this scenario, the company undertakes to provide the pending documentation after the registration is granted or post-registration modification is allowed by ANVISA. The legally required documents must be submitted according to a schedule pre-established in the agreement.

ANVISA's regulatory process had previously been under public inquiry. However, the Board (Dicol) approved the launch of a new inquiry due to modifications made to the regulatory text.[3]

These changes aimed to align the proposal with the provisions of the Act for the Introduction of Brazilian Law (LINDB) and Decree No. 9,830/2019, which contain rules regarding the execution of agreements by the Federal Government.

The deadline for submitting contributions to Public Inquiry No. 1,282/2024 is November 13, 2024. Submissions can be made through Participa + Brasil website (link).

3 Proposal in Public Inquiry. Avaliable at: https://antigo.anvisa.gov.br/documents/10181/5506254/CONSULTA+P%C3%9ABLICA+N%C2%BA+1282+GGBIO.pdf/65571112-661e-40ec-936d-d271f11b6273. Access on Oct. 18, 2024.

ANS Launches Public Inquiry on Regulatory Sandbox

Brazil's National Agency of Supplementary Health (ANS) has opened Public Inquiry No. 138/2024 for contributions to be submitted on the proposal for Regulatory Resolution (RN) that outlines the rules for the establishment and functioning of an experimental regulatory environment (or regulatory sandbox) within the Agency.

The regulatory sandbox aims to provide a controlled environment that allows for the development of new products, services, or regulatory solutions.

In this environment, innovations can be tested with reduced time and costs. The results obtained may lead to regulatory adjustments in order to increase the efficiency of the applicable regulation, making it more suitable for the specificities and needs of the sector.

With this tool, ANS may authorize companies to test new solutions related to supplementary health through requests for proposals, which will include selection criteria, deadlines, eligibility rules, etc.

To join the program, companies must demonstrate technical and financial capacity to develop intended activities in the experimental environment, as well as comply with the requirements outlined in the proposal, such as periodically submitting information, maintaining regulatory compliance, etc.

Once participants are admitted into the program, the Sandbox Committee must monitor their activities, according to a specific admission agreement. The Committee may require access to relevant information and cooperation from participants, who must comply with the applicable regulatory requirements set forth in the proposal.

The deadline for submitting contributions to Public Inquiry No. 138/2024 is November 22, 2024. Submissions can be made through ANS website (link).

ANVISA Consolidates Rules on Ownership/ Responsibility Transfers Due to Corporate or Commercial Transactions

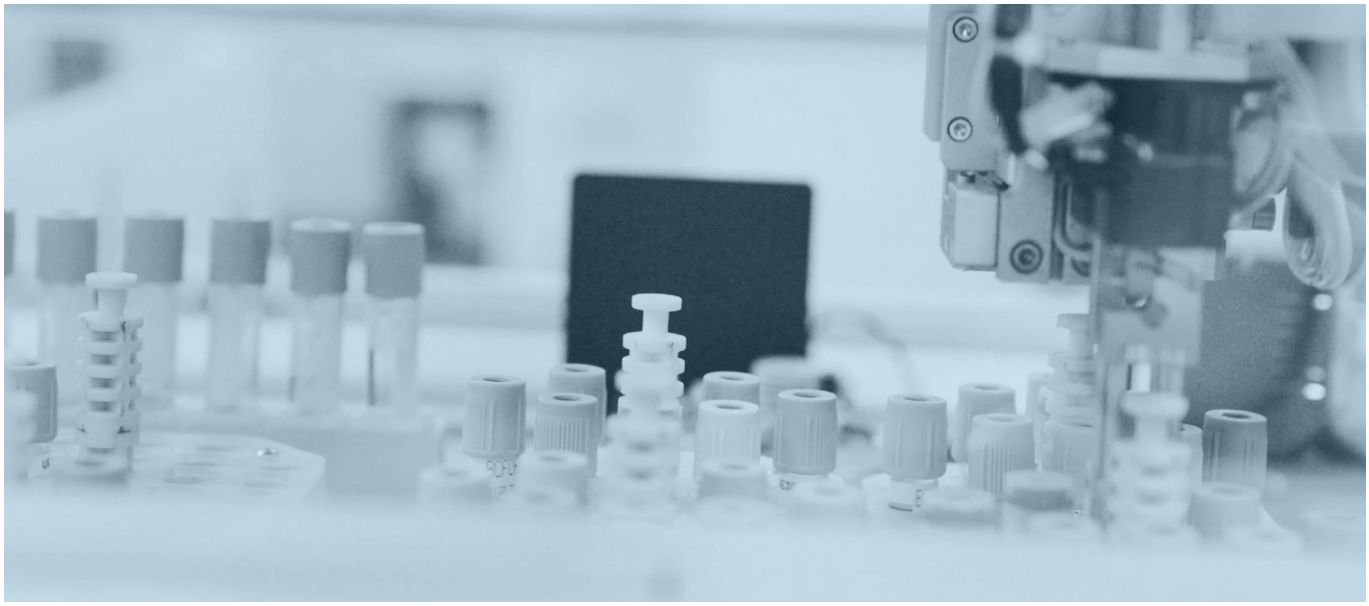
The Board of ANVISA (Dicol) approved the consolidation of rules on the transfer of ownership of product registrations subject to health surveillance and on the transfer of responsibility for clinical trials and updates of registration data related to the operation and certification of companies, resulting from corporate or commercial transactions.

This consolidation resulted in the publication of Board Resolution (RDC) ANVISA No. 903/2024, which establishes the procedures to be followed in the respective transfers and updates.

The new Resolution introduced formal changes to the existing rules, but without substantive alterations.[4] The norm resulted from ANVISA's actions to enhance the regulation under its jurisdiction, in accordance with Decree No. 12,002/2024, which establishes guidelines for the preparation, drafting, amendment, and consolidation of regulatory acts.

It is important to note that the procedures for transferring sanitary registration require mutual collaboration and activities between the new and former companies, respecting the deadlines of the applicable norm and based on the assumption that the technical conditions of the products will not change. RDC ANVISA No. 903/2024 came into effect on September 9, 2024.

4 Opinion No. 368/2024/SEI/DIRETOR-PRESIDENTE/ANVISA. Avaliable 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. Access on Oct. 21, 2024.



ANVISA Consolidates Rules Related to the Regulation of Cosmetic Products

ANVISA Dicol approved the consolidation of norms concerning personal hygiene products, cosmetics, and perfumes, as well as cosmetic products for straightening or curling hair.

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

As this is a consolidation, in line with the provisions of Decree No. 12,002/2024, the mentioned norms do not significantly alter the existing regulation. Thus, the changes arising from the new Resolution are formal.[5]

The rules established by the Resolutions provide mechanisms to ensure the quality, safety, and efficacy of the products marketed by the regulated sector to consumers.

In this context, the publication of RDC ANVISA No. 906/2024 is particularly relevant in the current landscape, considering the actions and measures adopted by ANVISA in response to reports of adverse events resulting from the use of hair ointments, such as temporary blindness and eye irritation, especially during previous Carnival holidays.

Both norms came into effect on September 23, 2024.

5 Opinion No. 405/2024/SEI/DIRETOR-PRESIDENTE/ANVISA. Avaliable 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. Access on Oct. 17, 2024.

ANVISA Also Consolidates Rules Applicable to Pharmaceutical Equivalence Centers

The Board of ANVISA (Dicol) also approved the consolidation of rules applicable to Pharmaceutical Equivalence Centers related to requests or renewals of accreditation, post-accreditation modifications, outsourcing of trials, suspensions, and cancellations, under RDC ANVISA No. 927/2024.

Pharmaceutical Equivalence Centers are responsible for conducting physicochemical, microbiological, or biological trials on generic medications. Such trials are essential to verify the correspondence between the safety and efficacy of these products relative to reference medications.

As with the consolidations mentioned in the texts above, ANVISA has not significantly changed the content of the existing rules. Thus, the consolidation brought only formal changes resulting from ANVISA's improvement in the current regulation, in line with Decree No. 12,002/2024.[6]

RDC ANVISA No. 927/2024 contains the minimum requirements to be observed both in the regularization of Pharmaceutical Equivalence Centers and in the conduction of technical trials.

The accreditation of Pharmaceutical Equivalence Centers is valid for 2 (two) years and must be renewed after this period. The renewal request must occur between 9 (nine) and 6 (six) months prior to the expiration of the accreditation.

Regarding the conduction of equivalence trails, the norm provides for the possibility of outsourcing them to other centers, as long as the relevant rules are observed, such as establishing the duties and responsibilities of those involved, as well as registering the data of outsourced trials with the Information System on Pharmaceutical Equivalence and Bioequivalence Studies (SINEB).

Failure to comply with the applicable rules may result in the suspension or even the cancellation of the Pharmaceutical Equivalence Centers.

RDC ANVISA No. 927/2024 came into effect on September 24, 2024. ANVISA is expected to establish provisions regarding Good Practices in Pharmaceutical Equivalence in the future.

6 Opinion 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. Access on Oct. 18, 2024.

ANVISA Consolidates Rules Related to Activities in Health Services

In the past month, ANVISA has also published five Resolutions aimed at consolidating the norms applicable to health services.

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

RDC ANVISA No. 916/2024: Establishes Good Practices for the Use of Parenteral Solutions in health services.

- The norm is applicable to all health establishments that use parenteral solutions and contains the minimum requirements for the use of such products in health services.
- Its provisions include organizational and infrastructure conditions; rules on procedures involving the acquisition, storage, distribution, preparation, and administration of parenteral solutions, etc.

RDC ANVISA No. 917/2024: Addresses the operation of home care services.

- All home care services that provide home assistance and/or home hospitalization must comply with the requirements set forth by this Resolution.
- The norm contains operational rules for such services, including the process to be followed for patient admission and discharge, elements of the home care plan with guidelines for the work of professionals involved, infrastructure requirements, etc.

RDC ANVISA No. 918/2024: Addresses the operation of Human Milk Banks.

- The Resolution establishes sanitary requirements for the organization and operation of Human Milk Banks and Human Milk Collection Points. It applies to all health services engaged in activities related to such establishments.
- In addition to the operating license, Milk Banks must be associated with hospitals that provide maternal and/or child assistance, while Collection Points must be technically linked to Milk Banks.
- The norm also addresses general infrastructure conditions, biosafety procedures, donor selection procedures, collection procedures, etc.

RDC ANVISA No. 919/2024: Addresses the planning, timeline, development, evaluation, and approval of Water Treatment and Distribution Systems for Hemodialysis in the National Health Surveillance System.

- The norm is applicable to all establishments providing dialysis services for patients with chronic kidney failure. Such establishments must ensure that the water used in

procedures meets the specified standards.

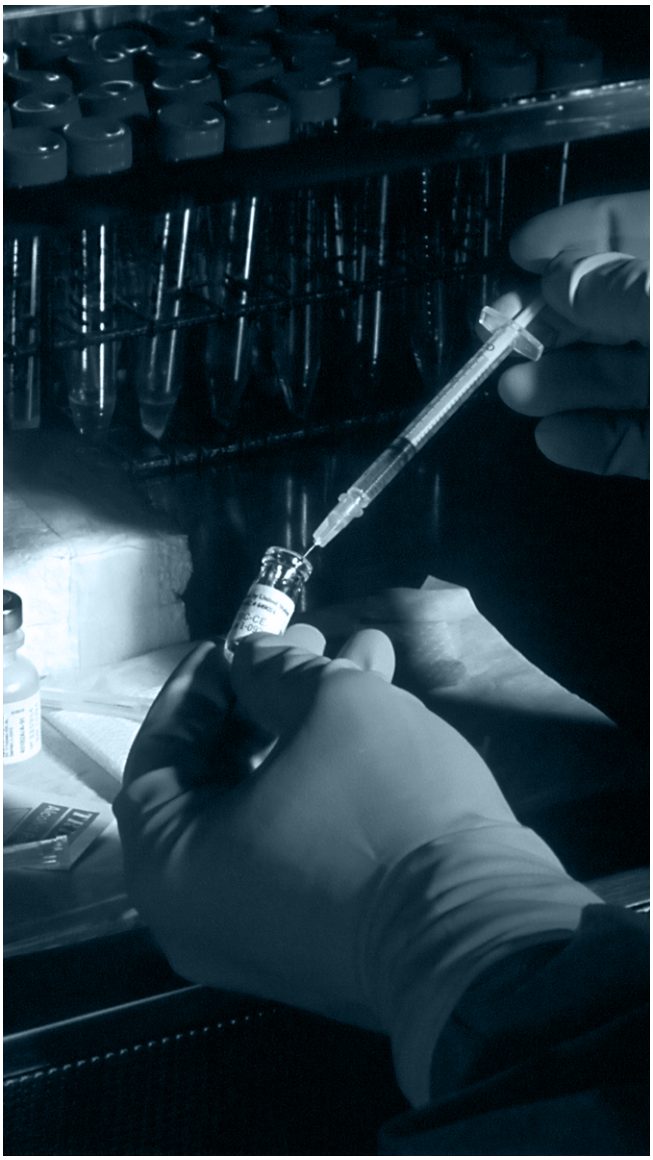
- The Resolution establishes infrastructure requirements to be met, duly represented in a basic architectural project, which must include the water treatment/ distribution systems.
- This project must consider the standards recommended by device manufacturers, along with other requirements related to maintenance, components used in the water transport system, etc.

RDC ANVISA No. 920/2024: Addresses the operation of Obstetric and Neonatal Care Services.

- The Resolution applies to health services operating in the country that engage in obstetric and neonatal activities, whether independent or part of hospitals. It also includes services related to teaching and research.
- The norm outlines operational, infrastructure, and technical responsibility requirements, among others, aimed at ensuring the safety and quality of the services provided.
- Furthermore, as it promotes humanization in health care, the Resolution explicitly lists the rights of users of the services, such as the presence of a companion of the woman's choice during admission, labor, postpartum, etc., the adoption of rooming-in from birth, and a comfortable waiting environment, among others.

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

The norms came into effect on September 26, 2024. RDC ANVISA No. 920/2024, originally published on this date, was republished on October 4, 2024.



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