TozziniFreire.

Life Sciences and Healthcare

Newsletter

5th Edition | 2025

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

INDEX

Click at the topic of your interest and browse through the content

Ministry of Health Issues Ordinance for Compliance with Court Decisions on Medication Provision[1]

On August 15, 2025, the Ministry of Health published Ordinance GM/MS No. 7,676, which establishes new administrative procedures for complying with individual court decisions related to the provision of medications. This measure aims to standardize and expedite compliance with judicial orders, respecting the guidelines set by the Federal Supreme Court (STF in Portuguese), especially in General Repercussion Topics No. 6[2] and No. 1234[3].

Compliance with court decisions may occur in two ways: **(i)** directly providing the medication to the beneficiary or **(ii)** deposit in court. In the first case, the Department of Management of Judicial Demands in Health (DGDJS in Portuguese) will assess whether the medication is available and any potential impacts on SUS (Brazil's Unified Health System) network. If the medication is incorporated, the purchase will be centralized with a delivery deadline of up to 20 days. Deposit in court will be made upon express authorization from the judge, allowing the beneficiary to acquire the medication independently while the Government carries out national or international purchases.

The ordinance defines the responsibilities of the various agencies involved in the process. The DGDJS will be responsible for the overall coordination of court demands. The Technical Secretariats of the Ministry of Health will authorize expenditures and provide medications incorporated into SUS. The Logistics Department will handle the procurement and storage of medications, while the National Health Fund will verify the legality of deposits in court and the expenses incurred by the Federal Government.

The ordinance also establishes criteria for the acquisition of medications not incorporated into SUS and not registered at Anvisa (National Health Surveillance Agency). In these cases, the DGDJS must follow the principles of the new Public Procurement Law (Law No. 14,133/2021), and the purchase of unregistered medications will only be permitted with express authorization from Anvisa, in accordance with RDC No. 203[4]. The amount for deposit in court will be calculated based on the maximum price allowed for sale to the government, adjusted according to the ICMS (State Goods and Services Tax) of the state where the patient is located, or estimated through market research when there is no official price.

1 Available at: https://www.in.gov.br/web/dou/-/portaria-gm/ms-n-7.676-de-14-de-agosto-de-2025-648596106

2 Available at: https://www.stf.jus.br/arquivo/cms/noticiaNoticiaStf/anexo/RE566.471_tema6_infosociedade_LCFSP.pdf

3 Available at: https://www.stf.jus.br/arquivo/cms/noticiaNoticiaStf/anexo/RE1.366.243_tema1234_infosociedade_LCFSP.pdf

4 Available at: https://www.in.gov.br/web/dou/-/resolucao-rdc-n-203-de-26-de-dezembro-de-2017-31718795

Law No. 15,183 Prohibiting Animal Testing for Cosmetics is Enacted[5]

Enacted on July 30, 2025, Law No. 15,183 represents a milestone in Brazil by prohibiting the use of live vertebrate animals in testing personal hygiene products, cosmetics, and perfumes, as well as their ingredients. The law amends Laws No. 11,794/2008 and No. 6,360/1976, explicitly banning tests aimed at evaluating the safety, efficacy, or toxicity of these products.

In addition to the prohibition on testing, data obtained through animal experiments conducted after the law's entry into force cannot be used for commercial purposes. Products whose safety has been demonstrated based on such data cannot be labeled as "cruelty-free" or "not tested on animals." Therefore, the sale of products tested before the law was enacted is still allowed but is subject to labeling restrictions.

Health authorities will have up to two years to regulate the procedures related to the new law. This includes quickly recognizing alternative methods, overseeing the use of animal testing data, and publishing biennial reports detailing requests for documented evidence from companies.

Failure to comply with the new rules will be considered a health violation, subject to the penalties provided for in current legislation. It is important to note that the new law does not apply to the development and approval of medications, which continue to be governed by Law No. 6,360/1976. The legislation also excludes insect repellents from this category and prioritizes the use of internationally recognized and validated alternative methods.

5 Available at: https://www.in.gov.br/web/dou/-/lei-n-15.183-de-30-de-julho-de-2025-645253736

Chamber Approves Bill No. 2583/2020 and Establishes the National Health Strategy within the Economic-Industrial Health Complex[6]

The House of Representatives approved Bill No. 2583/2020, which establishes the National Health Strategy within the Economic-Industrial Health Complex. The proposal, which will now be analyzed in the Federal Senate, will be reviewed by the relevant committees before possible voting in the Floor and sanction by the President of the Republic.

The project aims to structure a national policy focused on strengthening the country's productive and technological capacity in the health sector, primarily by reducing dependence on other countries and increasing national autonomy. To this end, it proposes incentives for the Brazilian industry that develops and manufactures Strategic Products for Health (PES in Portuguese), a category that includes medications, medical devices, active pharmaceutical ingredients (APIs), technological and informational solutions, among other items considered essential for health security, the sustainability of SUS, and responses to public health emergencies.

The proposal also establishes criteria for the recognition of Strategic Companies for Health (EES in Portuguese), which must be accredited by the Ministry of Health. To obtain this status, companies must have an industrial structure focused on the production of PES, a proven history of work in research, development, and innovation, and the capacity to expand national production. Additionally, they must have as purpose under their constitutional documents activities related to manufacturing, scientific and technological research, and the creation of industrial parks aimed at strategic health planning.

The project also provides for partnership instruments between the public and private sectors, such as Partnerships for Productive Development, Local Development and Innovation Programs, and Technological Orders in the Health Sector, which aim to promote innovation and accelerate national production of critical technologies.

As an incentive, the EES will have priority in the analysis of regulatory processes related to these strategic products, such as registrations and marketing authorizations, as well as facilitated access to credit lines through BNDES (Brazilian Development Bank), strengthening the business environment and competitiveness across the national industry.

6 Available at: https://agenciabrasil.ebc.com.br/saude/noticia/2025-07/camara-aprova-projeto-que-cria-estrategia-nacional-de-saude

Appointment of New Directors at ANVISA and ANS

In August and September 2025, the appointments of new members to the boards of the National Health Surveillance Agency (Anvisa) and the Brazilian Regulatory Agency for Private Health Insurance and Plans (ANS) were officially announced following approval by the Federal Senate. These changes represent a renewal in the decision-making structures of the two agencies, directly impacting the regulation policies in the health sector.

At ANS, Wadih Damous took office as the president, while Lenise Secchin was appointed as the Director of Standards and Product Qualification[7]. The inauguration was marked by speeches highlighting the importance of collaboration between the private health insurance sector and the Unified Health System (SUS).

At Anvisa, Leandro Pinheiro Safatle was appointed as president, joined by Daniela Marreco Cerqueira and Thiago Lopes Cardoso Campos as new directors[8]. The composition of the collegiate board was defined in an extraordinary meeting shortly after the inauguration, with the new members assuming strategic responsibilities in areas such as the regulation of medicines, food, and healthcare services. The appointments reinforce institutional continuity and technical capacity of the agency to face regulatory challenges in the country.

7 Available at: https://www.gov.br/saude/pt-br/assuntos/noticias/2025/setembro/ministro-da-saude-empossa-novos-diretores-da-ans-e-reforca-integracao-entre-sus-e-saude-suplementar

8 Available at: https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2025/novos-diretores-da-anvisa-sao-nomeados

STF Discusses Advertising of Food and Medicines in Public Hearing on ADI No. 7,788[9]

On August 26, the Federal Supreme Court held a public hearing within the level of Direct Action for the Declaration of Unconstitutionality No. 7,788, with Cristiano Zanin as judge-rapporteur. The hearing brought together experts, civil society entities, and representatives of the regulated sector to discuss the limits of the National Health Surveillance Agency's (Anvisa) authority in regulating the advertising of ultra-processed foods and medicines.

The action was brought by the Brazilian Association of Radio and Television Broadcasters (ABERT), which questions Anvisa's resolutions issued in 2009 and 2010. According to the entity, the regulations disproportionately restrict commercial advertising, going beyond the agency's regulatory authority, with Anvisa taking on a responsibility that falls on the National Congress. ABERT also argues that the rules affect economic freedom and freedom of expression in advertising communication.

During the hearing, public health experts defended that advertising regulation is a legitimate tool to protect fundamental rights, such as health and adequate nutrition. They emphasized that advertising directly influences the consumption of products that are harmful to health and that Anvisa follows the Constitution by adopting measures for sanitary prevention and information.

The debate highlighted the conflict between two constitutional values: on one side, the protection of collective health and of consumers; on the other, the freedom of commercial expression and the free exercise of economic activity. The Federal Supreme Court now must decide whether Anvisa's resolutions remain valid or should be deemed unconstitutional, a decision that will directly impact advertising regulation in the country. The judgment has not yet been concluded.

9 Available at: https://www.conjur.com.br/2025-set-10/entre-a-promocao-e-a-protecao-a-publicidade-de-alimentos-na-adi-7-788-df/

Anvisa Restricts Compounding of GLP-1 Pens[10]

On August 25, 2025, Anvisa published Technical Note No. 200/2025, providing new guidelines on the imports and compounding of active pharmaceutical ingredients (APIs) that are GLP-1 agonists, such as semaglutide, liraglutide, and tirzepatide, found in medications such as Ozempic, Saxenda, and Mounjaro.

The regulation distinguishes biotechnological and synthetic APIs, allowing the compounding of synthetic ingredients corresponding to those present in medications registered in Brazil, also obtained synthetically.

Biotechnological APIs can only be imported and compounded if they come from the same manufacturer of the product registered with Anvisa. For example, synthetic semaglutide cannot be compounded because the currently registered medication uses an API obtained biotechnologically. To compound biotechnological semaglutide, this must be supplied by the manufacturer that provides that API to the manufacturer of the medication registered with Anvisa.

The Technical Note also establishes that compounding pharmacies cannot directly import APIs, as this activity is restricted to authorized companies. It is proposed that the imports of APIs be conducted through the customs Yellow Channel, with the release of batches subject to a Custody Instrument and minimum quality control tests. Anvisa emphasizes that the efficacy and safety data of biotechnological APIs cannot be extrapolated among manufacturers due to the complexity of production processes.

This measure results from Anvisa inspections that identified health risks involving compounded injectables with unapproved APIs, in excessive doses, among other situations. In response, the Agency has intensified oversight of importers, distributors, and pharmacies. The goal is to ensure the quality, effectiveness, and traceability of compounded medications and ingredients, protecting public health.

10 Available at: https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2025/anvisa-esclarece-e-determina-regras-para-manipulacao-de-canetas-de-glp-1/SEI_3775484_Nota_Tecnica_2002.pdf

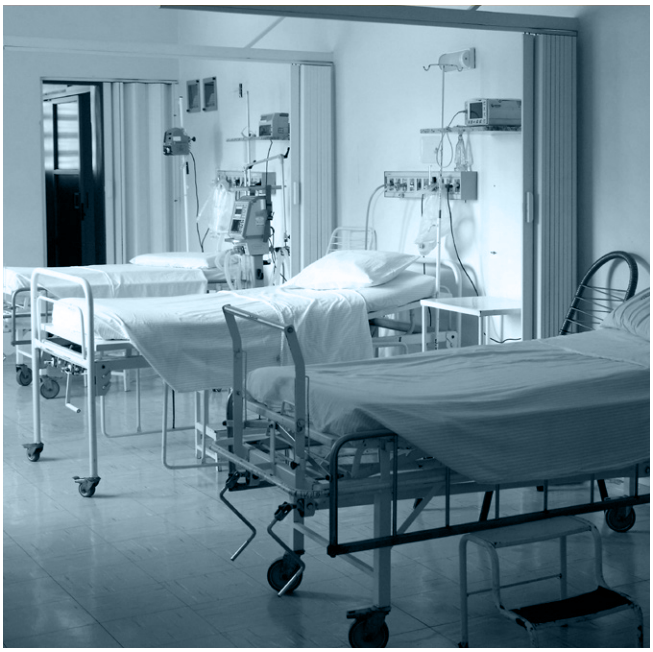
STF Establishes Criteria for Treatments Outside ANS Coverage List[11]

The Federal Supreme Court (STF) has established criteria for health plans to be required to cover treatments not included in the list of the Brazilian Regulatory Agency for Private Health Insurance and Plans (ANS). This decision occurred during the judgment of Direct Action for the Declaration Unconstitutionality No. 7,265, in which the Court deemed Law No. 14,454/2022 constitutional; such law allows for coverage of procedures not listed by ANS. The understanding was reached by a majority vote, with a score of 7 to 4.

According to the STF, the ANS list is not open for discussion, meaning it serves as a mandatory reference. However, exceptions are allowed as long as cumulative and objective requirements are met. Requirements include: medical or dental prescription from a qualified professional, the absence of an effective alternative already covered in the list, and scientific proof of the efficacy and safety of the treatment. Additionally, the procedure must be registered with Anvisa and cannot be pending review in the process of updating the list.

The decision also established that the patient or interested party bears the burden of proving the need for coverage outside the list, demonstrating that there was a prior request to the health plan and a negative response, or that the operator remained silent or took an unjustifiable amount of time to respond. The judge analyzing the case must consult technical bodies, such as the Technical Support Center of the Judiciary Branch, and presentation of a medical prescription will not suffice.

With the new criteria, the STF seeks to provide greater legal security to claims involving health plan coverage, reducing the likelihood of decisions based solely on individual medical reports. At the same time, the decision ensures that patients in exceptional situations still have access to effective treatments not explicitly covered in ANS list.



11 Available at: https://www.jota.info/saude/stf-define-criterios-mais-rigidos-para-tratamentos-fora-do-rol-da-ans

Senate Committee Approves Bill on Selling Medications in Supermarkets[12]

On September 17, 2025, the Senate's Social Affairs Committee (CAS in Portuguese) approved, in a definitive manner, a substitute for Bill No. 2,158/2023, which authorizes the sale of medications in drugstores located inside supermarkets. The text will follow to the House of Representatives for analysis, unless a request for voting on the Floor is made.

The substitute bill presented by the rapporteur, Senator Humberto Costa, modified the original proposal to ensure greater sanitary control. Instead of allowing medications on supermarket shelves, the new text requires that dispensing occur in physical drugstores, in a separate area, in compliance with Anvisa regulations, and with a pharmacist present during all hours of operation.

For medications subject to special control, the substitute bill stipulates that sales may only occur after payment or that they be transported from the counter to the register in tamper-proof and sealed packaging. The text also prohibits sales at counters or shelves outside the drugstore area and limits digital channels to logistics and delivery functions, as long as sanitary requirements are met.

The technical justification from the rapporteur highlights risks associated with self-medication, dosage errors, inadequate treatment duration, and double therapies, particularly due to the absence of professional guidance. It was also noted that there could be a potential impact on local small drugstores, as expanding medication sales into common supermarket spaces might reduce demand.

After the approval from CAS, the project is now pending analysis from the House of Representatives.

12 Available at: https://www12.senado.leg.br/noticias/materias/2025/09/17/remedio-podera-ser-vendido-em-supermercados-aprova-cas

Ordinance GM/MS No. 8,041 Establishes the National Policy on Donation and Transplants[13]

Ordinance GM/MS No. 8,041, dated September 25, 2025, published in the Federal Register, introduced the establishment of the National Policy on Donation and Transplants and the definition of a new Technical Regulation for the National Transplant System (SNT in Portuguese).

With the new ordinance, two chapters were incorporated: **(i)** national policy and **(ii)** technical regulation of the SNT. The proposal seeks to modernize legislation, provide greater clarity regarding institutional responsibilities, and ensure uniformity of procedures across the country when it comes to obtaining and transplanting organs, tissues, and cells.

The act also revokes previous regulations, such as Ordinance No. 2,600/2009, and establishes transitional measures for adjusting to the services. Operational matters include updating SIGA, the computerized system responsible for managing waiting lists, which must be aligned with the new rules within a period of up to 180 days.

Another innovation brought in by the ordinance is the emphasis on strengthening the network of specialized care, with provisions for greater integration of healthcare services, transplant teams, as well as notification, organ obtainment, and distribution centers. The regulation also reinforces the need for ongoing awareness and health education campaigns aimed at increasing the number of donors and reducing waiting times for transplantation in Brazil.

13 Available at: https://www.in.gov.br/web/dou/-/portaria-gm/ms-n-8.041-de-25-de-setembro-de-2025-*-658713632

Ordinance SDA/MAPA No. 1,364 Regulates Farming Inspection and Procedures for Entering into TAC[14]

Ordinance SDA/MAPA No. 1,364, published on September 8, 2025, establishes new rules for the administrative processes of farming inspection and defines procedures for entering into a Conduct Adjustment Agreement (TAC) within the Farming Defense Secretariat of MAPA (Ministry of Agriculture, Livestock and Food Supply).

Among the main changes, procedural deadlines are now counted in calendar days, excluding the initial day and including the due date, and are automatically extended to the following business day when they coincide with holidays or weekends. Document submission may preferably be conducted electronically, but can also be done in person or via postal service, as indicated in the records. Notifications to the notified party may occur electronically, provided that acknowledgment is certified, by correspondence with acknowledgment of receipt, or, in special cases, by public notice.

As for the flow of the farming inspection administrative process, the ordinance organizes five stages: 1) initiation; 2) instruction; 3) judgment in different instances; 4) execution of the sanction; and 5) conclusion.

The regulation also establishes priority in the judgment of processes that run the risk of being time-barred, appeals involving the suspension or revocation of registration, listing, or accreditation, and situations involving precautionary measures such as seizure or suspension of activities until a final decision is made.

As for the TAC, the ordinance provides that if the final penalty is suspension or revocation of registration, listing, or accreditation, the notified party will have a deadline to request the conversion of that penalty into a substitute fine and propose a TAC. The document must contain clear obligations, defined deadlines, control measures, and sanctions in the event of non-compliance.

14 Available at: Portaria SDA/MAPA nº 1.364, de 8 de setembro de 2025

ANS Public Inquiry: Discussion on the Implementation of the Pricing and Adjustment Policy for Health Plans[15]

Since 2024, ANS has been conducting a debate on the Pricing and Adjustment Policy for Health Plans. The aim is to review the adjustment rules for both individual and family plans as well as collective plans, and to discuss greater transparency in contractual clauses and the economic-financial balance of operators.

The regulatory process began with Public Inquiry No. 145 in December 2024, opened for inputs on four major topics: adjustment of collective plans, financial mechanisms for regulation, digital sales of plans, and technical review of individual adjustments. Concurrently, Public Inquiry No. 147 addressed issues related to copayments and deductibles, while Public Inquiry No. 151 discussed measures for transparency, contractual standardization, and communication with beneficiaries.

Discussions were fruitful at public hearings but there was also some resistance. Operators claimed risks to the sustainability of the sector, while consumer advocacy groups called for greater protection for users. The courts even suspended Public Inquiry No. 145 due to a lack of regulatory impact analysis, leading ANS to launch Public Inquiry No. 159 in July 2025, focused on the most sensitive matters: adjustments for collective plans and the revision of criteria applicable to individual/family plans.

During this period, the agency also set a ceiling of 6.06% for adjustments of individual plans between May 2025 and April 2026, protecting approximately 8.6 million beneficiaries. Collective plans remain without a ceiling but are under regulatory evaluation. The proposals under discussion include: standardization of adjustment clauses, demand for greater transparency, creation of risk pools, definition of minimum loss ratios, and the possibility of exceptional adjustments in cases of financial imbalance.

Inputs to the public inquiries are still being analyzed by ANS.

15 Available at: https://componentes-portal.ans.gov.br/link/ConsultasPublicas

Anvisa Launches International Public Inquiry on Pharmaceutical Quality System

Anvisa has announced the opening of an international public inquiry on the proposal to revise Chapter 1 of the European Union's Good Manufacturing Practices, which addresses the Pharmaceutical Quality System. The inquiry will be available until December 3, 2025, and aims to align Brazilian quality requirements with the latest international guidelines, reinforcing safety and control throughout the country.

The proposal emphasizes the need for greater integration between risk management and technical knowledge. The new text also highlights the importance of early identification of potential risks in manufacturing to prevent shortages and promote a proactive, evidence-based quality culture.

Other relevant points include guidelines on product quality review, data grouping methods, and criteria for evaluating small production batches. According to the Agency, these changes aim to strengthen monitoring processes and improve the efficiency of pharmaceutical production.

Inputs to the inquiry should be submitted via the EU Survey platform for individual interested parties. Companies linked to representative sector entities need to send their suggestions through these associations, which will consolidate comments before submitting them to the European Commission. The documents under inquiry and participation forms are available on the websites of the European Commission, PIC/S, and the EU Survey platform itself[16].

Anvisa emphasized the importance of the Brazilian sector participation to ensure that national specificities are considered in this international harmonization process.

16 Available at: https://health.ec.europa.eu/consultations/stakeholders-consultation-eudralex-volume-4-good-manufacturing-practice-guidelines-chapter-1_en

Partner responsible for the newsletter

Victor Hugo Callejon Avallone