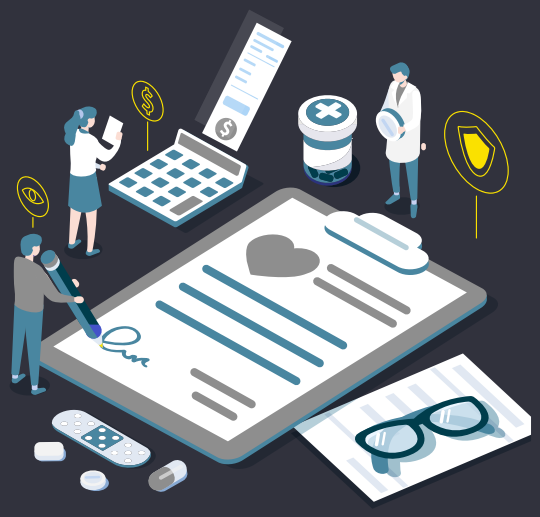
Machado Meyer

mar/2025

JUDICIALIZATION OF MEDICINES IN THE BRAZILIAN SUPREME COURT

EVERYTHING YOU NEED TO KNOW



In September 2024, the Federal Supreme Court (STF) ruled on two leading cases involving the supply of medicines in the Brazilian Public Health System (SUS). In both cases, the understanding established by the STF must be applied to all similar lawsuits.

The rulings are restricted to disputes involving medicines (including advanced therapies) regularized with the Brazilian Health Sanitary Agency (Anvisa), but not incorporated into the SUS by the National Commission for the Incorporation of Technologies (Conitec). Medical device, orthoses, prostheses and special materials (OPMEs) or therapeutic proceedings are not encompassed by the two decisions.

TOPIC 1234 (RE 1,366,243)

Subject: analyzed the Federal Government's standing and jurisdiction in claims involving access to medicines with a valid marketing authorization issued by Anvisa, but not incorporated into the SUS by Conitec. The lawsuit was originated due to a drug access request filed against the state of Santa Catarina, which, in turn, requested that it should be sent to the Federal Court and include the Federal Government for purposes of joint liability.

Rapporteur: Justice Gilmar Mendes.

Summary: the Supreme Court partially ratified three agreements executed between the Attorney General's Office (AGU), the Ministry of Health, and federative entities. The agreements define factors related to the jurisdiction and establish criteria for inter federative reimbursement in claims related to medicines not incorporated by Conitec. A binding precedent was published on September 20, while the judgment was published on October 10, 2024.

6 motions for clarification were filed, but only the Federal Government's appeal was partially granted to determine that the effects of the decision involving the topic of jurisdiction also applies to medicines already incorporated by Conitec.

TOPIC 6 (RE 566,471)

Subject: discussed the duty of the Government to provide high-cost medicines to patients with serious diseases and lacking financial conditions to support it. It also analyzed whether the Government has a duty to provide medicines registered with Anvisa, but not incorporated by the SUS, regardless of its cost.

Rapporteur: Justice André Mendonça – in succession to Justice Marco Aurélio Mello (retired).

Summary: Cumulative criteria have been established for the analysis of judicial requests involving the supply of medicines not incorporated into the SUS.

A binding precedent was published on October 3rd, while the judgment was published on November 28, 2024.

Ruling of the motions for clarification filed by the Federal Public Defender's Office, the Brazilian Association of Mucoviscidosis and the Public Defender's Office of the State of Rio de Janeiro are still pending.

WHY ARE THESES TRIALS IMPORTANT?

The two lawsuits refer to repetitive appeals. This means that once the Supreme Court's understanding is established, it must be applied to all similar lawsuits – future or already in progress in the Judiciary (subject to the adjustment of their effects). In both cases, binding precedents were approved and must be observed by all public entities.

THE VERDICTS SET FORTH:

- ☑ In which cases the Government must pay for high-cost medicines and/or medicines not incorporated into the SUS; and
- ☑ Which entity (federal, state, municipality) should bear these costs.

PRECEDENT SET BY TOPIC 1234

The STF partially approved agreements that deal with aspects to be considered in judicial claims related to medicines not incorporated into the SUS:

> A judicial agreement involves the Federal Government, the Brazilian states, Anvisa, Conitec, and the National Health Council (CNS); and

> Two agreements were signed between the Ministry of Health, the National Council of Health Secretaries (Conass), and the National Council of Municipal Health Secretaries (Conasems).

Among the items ratified by the justices, the following stand out:

1. JURISDICTION

The Federal Court has the jurisdiction to judge claims relating to medicines that have not been incorporated into the SUS. To do so, these medicines must be registered with Anvisa and their annual price – according to the maximum government sales price (PMVG) defined by the Brazilian Drug Market Regulation Chamber (CMED) – must be equal to or greater than 210 minimum wages (approximately BRL 295,000).

2. DEFINITION OF "NON-INCORPORATED MEDICINES"

- ☑ Are not included in public policies of the SUS;
- ☑ Are mentioned in official clinical protocols for other purposes;
- ☑ Have no valid marketing authorization issued by Anvisa; or
- ☑ Are off-label medicines without an official clinical protocol (those used outside the conditions provided for in the package leaflet) or are not part of the SUS' lists of the basic component.

3. COST SHARING

- The cost of non-incorporated medicines will be shared between the public entities.
- For medicines with annual cost between 7 and 210 minimum wages (approximately BRL 10 thousand and BRL 295,000, lawsuits will remain in the state courts. As a rule, the Federal Government must reimburse 65% of the expenses resulting from convictions by states and municipalities within 90 days.
- For lawsuits filed until June 10, 2024, and involving non-incorporated oncological medicines, reimbursement by the Federal Government will be of 80%, should the cost exceed seven minimum wages (approximately BRL 10,000).
- For medicines with annual cost of less than seven minimum wages, the state involved in the case must bear the cost.

4. NATIONAL PLATAFORM

The federative entities (states, municipalities, and the Federal District) will create a national platform to unify information on administrative and judicial demands involving access to medicines. The platform will be integrated with medical prescriptions and must be able to identify the entity responsible for the supply and cost. It should also enable patients to monitor their own lawsuit.

5. JUDICIARY ROLE

When assessing requests regarding non-incorporated medicines, the Judiciary must analyze the Conitec's decision (or omission) pertaining to the non-incorporation of the product and the negative administrative decision.

6. INCORPORATED MEDICINES

Will follow a specific administrative and judicial flow, including concerning the judicial jurisdiction and the form of reimbursement between the entities, when applicable.

BINDING PRECEDENT NO. 60

The administrative request and analysis concerning access to medicines in the public health system, the lawsuit and its developments (administrative and jurisdictional), must comply with the terms of the inter-federative agreements (and their flows) approved by the Federal Supreme Court, in collaborative judicial governance, according to Topic 1234 (RE 1,366,243).

MODULATION OF EFFECTS

Regarding jurisdiction, the effects of Topic 1234 will apply to lawsuits filed after the publication of the ruling (September 19, 2024), including regarding medicines already incorporated into the SUS.

PRECEDENT SET BY TOPIC 6

In 2020, the STF's plenary had already decided that the Federal Government would only be required to supply high-cost and/or non-incorporated medicines in exceptional cases.

On September 13, Justices Luís Roberto Barroso and Gilmar Mendes established the thesis (followed by the other Justices, with additions) that, as a rule, the absence of a medicine on the SUS dispensing lists prevents it from being supplied under a court decision, regardless of cost.

The effects of the ruling were not modulated.

Exceptionally, the judicial concession of a non-incorporated medicine may occur when the following requirements are cumulatively met:

- Existence of an administrative refusal to supply the medicine;
- Illegality in Conitec's decision to not incorporate the medicine, absence of a request for incorporation, or delay in its assessment;
- Unfeasibility of replacing the medicine with another one existent in Conitec's clinical protocols and therapeutic guidelines;
- Proof of the medicine's efficacy, accuracy, effectiveness, and safety, necessarily supported by randomized clinical trials and systematic review or meta-analysis;
- Clinical indispensability of the treatment, proven by a well-founded medical report, including a Clinical indispensability of the treatment; and
- The patient's financial inability to bear the cost of the medicine.

BINDING PRECEDENT NO. 61
The judicial granting of medicine registered with Anvisa, but not incorporated into the dispensing lists of the SUS must comply with the opinions established in Topic 6 (RE 566,471).

OPEN ITEMS

Pending judgment of the motions for clarification filed against the decision issued in RE 566,471 (Topic 6).

Ongoing development of the unified national platform for judicialization of medicines, including with regard to regulatory and data protection impacts of sharing sensitive personal health data. The prototype of the system, which was due to be presented by December 2024, has had its deadline extended and is currently being tested.

Need for evaluation of platform integration in situations where electronic medical prescriptions are not yet allowed by the health regulations in force.

Impacts to medicines already incorporated into the SUS, but with no DDT or PCDT approved by Conitec.

Impacts to lawsuits involving medicines already incorporated, but not yet supplied by the SUS.

Impacts to oncology medicines in the context of the ongoing arrangements under the New National Cancer Policy.

WORTH FOLLOWING UP

Judicial Review No. 7.265: filed with the STF to discuss the constitutionality of Law 14,454/22, which established criteria for coverage of health exams or treatments that are not included in the list of procedures and events in supplementary health.

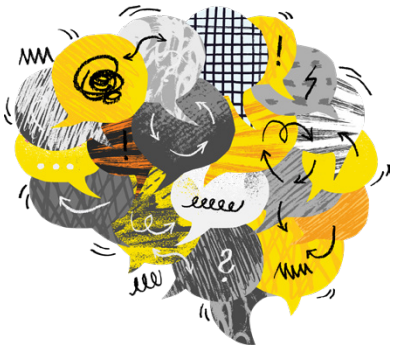
Lawsuit 5037147-80.2023.4.03.6100/JFSP: discusses the legality of ANS Technical Note 3/23, which establishes that advanced therapy medicines are not subject to the general rules for drug incorporation by the ANS.

Complementary Bill 149/2024: discusses the requirements for supplying medicines that have not been incorporated into SUS normative acts or registered with Anvisa and for recognizing the solidarity criteria of federal entities in promoting the right to health.

Complementary Bill 168/2024: discusses requirements for granting medicines not incorporated into the SUS.

COUNT ON **MACHADO MEYER**

Several federal and state courts are applying the new STF rulings to grant, deny or suspend the supply of medicines. Our expertise in Life Sciences and Healthcare uniquely positions us to assist pharmaceutical, biotechnology and advanced therapy companies in evaluating strategies and alternatives involving applications for registration and incorporation of drugs into the SUS and supplementary healthcare, considering the developments arising from Topics 1234 and 6, as well as other judicial precedents.



GET IN TOUCH

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