23 de set/2024

JUDICIALIZATION OF MEDICINES IN THE BARAZILIAN SUPREME COURT

EVERYTHING YOU NEED TO KNOW

In September, the Federal Supreme Court (STF) resumed the trial of two leading cases involving the supply of medicines. In both cases, the understanding established by the STF must be applied to all similar lawsuits.

The trials are restricted to disputes involving medicines (including advanced therapies) not incorporated by the Brazilian National Commission for the Incorporation of Technologies in the National Public Health System (Conitec). That is, they do not comprise lawsuits involving access to medical device or equipment, Orthotics, Prosthetics and Special Materials (OPSM), or therapeutic procedures.

TOPIC 1.234 (RE 1.366.243)

Subject: analyzes the Federal Government's standing and jurisdiction in claims involving access to medicines duly regularized with the Brazilian National Health Surveillance Agency (Anvisa), but not incorporated into the Brazilian National Public Health System (SUS). The lawsuit originated due to a drug access request filed against the state of Santa Catarina, which, in turn, requested that the lawsuit should be sent to the Federal Court and include the Federal Government for purposes of joint liability.

Rapporteur: Justice Gilmar Mendes

Status: on September 13 of this year, 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 of the Federal Court and establish criteria for inter federative reimbursement in claims related to medicines not incorporated by Conitec.

Motions for clarification filed on September 23.

TOPIC 6 (RE 566.471)

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

Rapporteur: during a virtual session held between September 6 and 13 of this year, justices Luís Roberto Barroso and Gilmar Mendes proposed to fix cumulative criteria to be met in lawsuits involving access to medicines not incorporated into the SUS.

The proposal was followed by the other justices, including Justice Nunes Marques, after a request for review (concluded on September 20, 2024).

Motions for clarification are still applicable.

WHY ARE THESE 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, the approval of a binding precedent was also proposed, subject to the support of 2/3 of the STF (i.e., eight ministers). Once approved and published, the binding precedent must be observed by all public entities, including the Judiciary and the Public Administration.

THE VERDICT OF THESE ACTIONS BY THE STF SETS FORTH:

- ☑ in which cases the State 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

On September 13 of this year, 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 had the participation of the Union, the federated entities, the Brazilian National Health Surveillance Agency (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 Justice has jurisdiction to judge claims related to medicines not incorporated into the SUS by Conitec, whenever the medicine has a valid marketing authorization with Anvisa and the annual price – according to the maximum sales price to the government (PMVG) defined by the Brazilian Drug Market Regulation Chamber (CMED) – is equal to or greater than 210 minimum wages (approximately R$ 295 thousand).

2. **DEFINITION OF "NON-INCORPORATED MEDICINES". They are those who:**

   - ☑ Are not included in public policies of the SUS;
   - ☑ Are provided for in official clinical protocols, but for other purposes;
   - ☑ Have no valid marketing authorization issued by Anvisa; or
   - ☑ Are off-label drugs without an official clinical protocol or not part of lists of the basic component.

3. **COST SHARING.**
   Costs involving non-incorporated medicines will be shared among the federative entities as follows:

   - For drugs with annual unit cost between 7 and 210 minimum wages (approximately R$ 10 thousand and R$ 295 thousand), lawsuits will remain in the **state courts**. As a general 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 dealing with **non-incorporated oncological medicines**, the percentage of reimbursement by the Federal Government will be 80%, should the cost exceeds seven minimum wages (approximately R$ 10 thousand).
   - For drugs with annual cost of less than seven minimum wages, the state in question must bear the cost.

4. **NATIONAL PLATFORM.**
   The federative entities (states, municipalities, and the Federal District) will create a national platform to combine information on administrative and judicial demands involving access to medicines. The platform will be integrated with the medical prescriptions issued by the doctor in charge and must identify the entity responsible for the supply and costing. It should also enable the monitoring of judicial decisions by the patients themselves.

5. **JUDICIARY ROLE.**
When assessing access requests regarding non-incorporated medicines, the Judiciary will have to analyze the decision (or omission) of Conitec on the non-incorporation of the product and the administrative refusal.

6. **INCORPORATED MEDICINES.**
Will follow a specific administrative and judicial flow, including concerning the judicial jurisdiction to assess the demands and the form of reimbursement between the entities, when applicable.

BINDING PRECEDENT NO. 60
The administrative request and analysis of medicine access in the public health network, the judicialization of the case, as well as its developments (administrative and jurisdictional), must comply with the terms of the 3 approved inter-federative agreements (and their flows) by the Federal Supreme Court, in collaborative judicial governance, under Topic 1234 of the RE 1,366,243.

PRECEDENT SET BY TOPIC 6

In 2020, the STF had already decided that the State would only be required to provide high-cost drugs and/or drugs not incorporated by the SUS in exceptional cases.

On September 13, Justices Luís Roberto Barroso and Gilmar Mendes established a thesis (accompanied by the other justices, with complements) that, as a general rule, the absence of a medicine in the SUS dispensing lists prevents access by judicial decision, regardless of the cost.

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

- Refusal to supply the medicine on an administrative level;
- Illegality on Conitec's deliberative act on the non-incorporation of the drug, absence of a request for incorporation or delay in its assessment, considering the deadlines and criteria provided for in the Brazilian laws (Law 8.080/90 and Decree 7.646/11);
- Whenever substitution of the medicine by another one provided for in Conitec's clinical protocols and therapeutic guidelines is not feasible;
- Proof of the efficacy, accuracy, effectiveness, and safety of the drug, which must be supported by randomized clinical trials and systematic review or meta-analysis;
- Clinical indispensability of the treatment, proven by a substantiated medical report, which also describes treatments already performed; and
- Patient's financial lack of ability to bear the cost of the drug.

OPEN ITEMS

Possibility of opposing motion for clarification under Topic 1.234 and Topic 6 until October of this year, to correct material error or deal with omissions, obscurities, or contradictions in the decisions.

The drafting and approval of the binding precedents related to the two topics are pending.

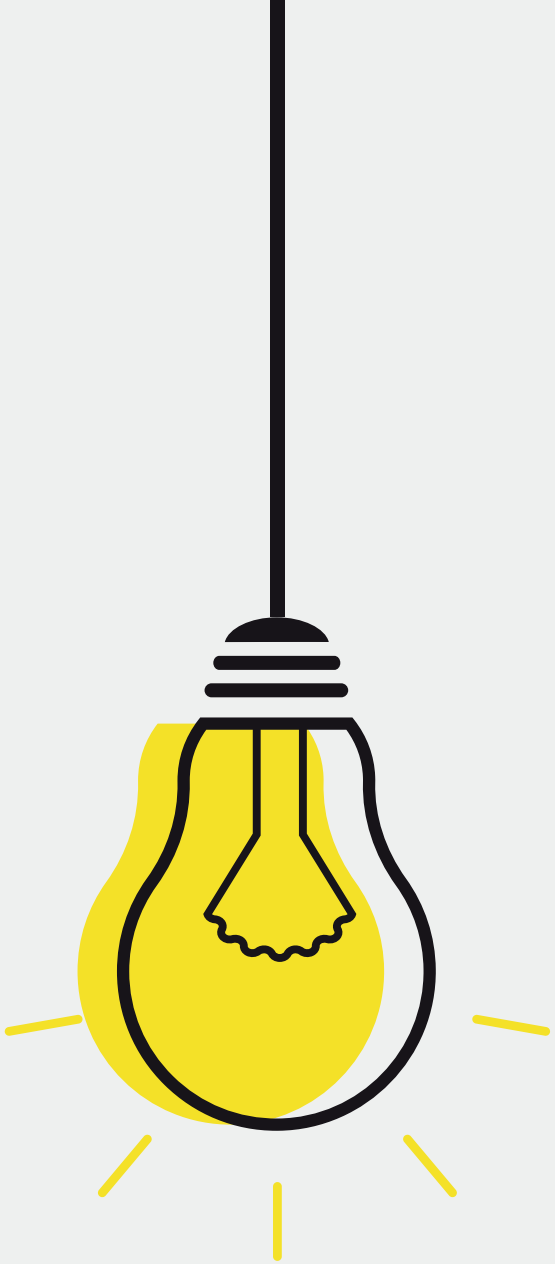
Adequacy of the National High Court of Brazil (STJ)'s precedents with the thesis established in Topic 1.234 by the STF.

development of a unified national platform for judicialized medicines will require an analysis of data protection impacts arising from sensitive personal data sharing of patients. A prototype of the system should be presented by December this year.

Need for evaluation of platform integration in situations where electronic prescription of the drug is not yet allowed by the health regulations in force (color prescription drugs).

Extent of impacts for lawsuits involving access to medicines for rare diseases..

Impacts applicable to actions involving medicines already incorporated, but not yet supplied in the SUS.



WORTH FOLLOWING UP

Direct Action of Unconstitutionality 7.265, filed with the Supreme Court 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 by the National Agency for Supplementary Health Services (ANS).

Lawsuit 5037147-80.2023.4.03.6100/JFSP, which 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 No. 149/2024, which intends to establish requirements for federated entities to provide medicines not incorporated in SUS normative acts or not registered with Anvisa and joint liability of federated entities for the promotion of the right to health.

GET IN TOUCH

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