



## Commentary on Health Case Law and Legislation


### Constitutional claim and the assimilation of recent Supreme Court jurisprudence regarding Topics No. 6 and 1234

Reclamação constitucional e a assimilação da jurisprudência recente do STF em relação aos Temas nº 6 e 1234

Reclamación constitucional y la asimilación de la jurisprudencia reciente del Supremo Tribunal sobre los Temas nº 6 y 1234

#### Iara Veloso Oliveira Figueiredo<sup>1</sup>

Instituto René Rachou, Belo Horizonte, MG.

 <https://orcid.org/0000-0002-0927-859X>

✉ [iaravof@gmail.com](mailto:iaravof@gmail.com)

#### Mônica Silva Monteiro de Castro<sup>2</sup>

Instituto René Rachou, Belo Horizonte, MG.

 <https://orcid.org/0000-0003-2461-3699>

✉ [monica.castro@fiocruz.br](mailto:monica.castro@fiocruz.br)

#### Rômulo Paes-Sousa<sup>3</sup>

Instituto René Rachou, Belo Horizonte, MG.

 <https://orcid.org/0000-0002-3384-6657>

✉ [romulo.paes@fiocruz.br](mailto:romulo.paes@fiocruz.br)

### Abstract

The judicialization of public health consists of resorting to the Judiciary to obtain actions, services, medications, and health technologies from the Unified Health System (SUS), a right guaranteed by the 1988 Federal Constitution. In this scenario, the Supreme Federal Court (STF), as guardian of the Constitution, plays a central role in standardizing the interpretation of the right to health through its jurisprudence. In 2024, the STF ruled on Topics 6 and 1234, which redefined the parameters for the judicial granting of medications by the SUS. Topic 6 established rigorous cumulative criteria, requiring proof of the efficacy and safety of the medication based on Evidence-Based Medicine, the non-existence of an incorporated therapeutic alternative, and the financial incapacity of the plaintiff. Theme 1234, in turn, regulated the judicial competence and passive legitimacy of federative entities, in addition to linking judicial provision to the Maximum Price for Sale to the Government (PMVG). These understandings were consolidated in Binding Precedents 60 and 61, whose non-compliance authorizes the filing of a Constitutional Claim with the STF, an instrument intended to preserve the authority of the Court's decisions. However, recent decisions, such as Constitutional Claim No. 87,745/RJ, highlight difficulties in assimilating the new parameters. The study points out that the Constitutional Claim has consolidated itself as a relevant mechanism for the process of assimilating

<sup>1</sup> PhD in Public Health, Instituto René Rachou, Belo Horizonte, MG, Brazil. Researcher, Instituto René Rachou, Belo Horizonte, MG, Brazil.

<sup>2</sup> PhD in Public Health, Fundação Oswaldo Cruz, Rio de Janeiro, RJ, Brazil. Researcher, Instituto René Rachou, Belo Horizonte, MG, Brazil.

<sup>3</sup> PhD in Environmental Epidemiology, London School of Hygiene and Tropical Medicine, London, England. Senior Researcher, Instituto René Rachou, Belo Horizonte, MG, Brazil.



the recent jurisprudence of the STF, revealing interpretative tensions and the need for greater decisional harmonization to ensure legal certainty, equity, and sustainability to the SUS.

**Keywords:** Judicialization of health; Right to Health; Jurisprudence.

### Resumo

A judicialização da saúde pública consiste no acionamento do Poder Judiciário para obtenção de ações, serviços, medicamentos e tecnologias em saúde junto ao Sistema Único de Saúde (SUS), direito assegurado pela Constituição Federal de 1988. Nesse cenário, o Supremo Tribunal Federal (STF), como guardião da Constituição, exerce papel central na uniformização da interpretação do direito à saúde por meio de sua jurisprudência. Em 2024, o STF julgou os Temas No. 6 e 1234, que redefiniram os parâmetros para a concessão judicial de medicamentos pelo SUS. O Tema No.6 estabeleceu critérios cumulativos rigorosos, exigindo a comprovação da eficácia e segurança do medicamento com base na Medicina Baseada em Evidências, a inexistência de alternativa terapêutica incorporada e a incapacidade financeira do autor da ação. O Tema No. 1234, por sua vez, disciplinou a competência judicial e a legitimidade passiva dos entes federativos, além de vincular o fornecimento judicial ao Preço Máximo de Venda ao Governo (PMVG). Esses entendimentos foram consolidados nas Súmulas Vinculantes No. 60 e 61, cujo descumprimento autoriza a propositura de reclamação constitucional ao STF, instrumento destinado à preservação da autoridade das decisões da Corte. Contudo, decisões recentes, como a Reclamação Constitucional No. 87.745/RJ, evidenciam dificuldades na assimilação dos novos parâmetros. O estudo aponta que a reclamação constitucional tem se consolidado como mecanismo relevante para o processo de assimilação da jurisprudência recente do STF, revelando tensões interpretativas e a necessidade de maior harmonização decisória para assegurar segurança jurídica, equidade e sustentabilidade ao SUS.

**Palavras-chave:** Judicialização da saúde; Direito à Saúde; Jurisprudência.

### Resumen

La judicialización de la salud pública consiste en recurrir al Poder Judicial para obtener acciones, servicios, medicamentos y tecnologías sanitarias del Sistema Único de Salud (SUS), un derecho garantizado por la Constitución Federal de 1988. En este escenario, el Supremo Tribunal Federal (STF), como garante de la Constitución, desempeña un papel central en la estandarización de la interpretación del derecho a la salud a través de su jurisprudencia. En 2024, el STF se pronunció sobre los Temas 6 y 1234, que redefinieron los parámetros para la concesión judicial de medicamentos por parte del SUS. El Tema 6 estableció criterios acumulativos rigurosos, que exigen la prueba de la eficacia y seguridad del medicamento con base en la Medicina Basada en la Evidencia, la inexistencia de una alternativa terapéutica incorporada y la incapacidad financiera del demandante. El Tema 1234, a su vez, reguló la competencia judicial y la legitimidad pasiva de las entidades federativas, además de vincular la provisión judicial al Precio Máximo de Venta al Gobierno (PMVG). Estos entendimientos se consolidaron en los Precedentes Vinculantes 60 y 61, cuyo incumplimiento autoriza la presentación de una Demanda Constitucional ante el STF, instrumento destinado a preservar la autoridad de las decisiones del Tribunal. Sin embargo, decisiones recientes, como la Demanda Constitucional n.º 87.745/RJ, ponen de manifiesto dificultades para asimilar los nuevos parámetros. El estudio señala que la Demanda Constitucional se ha consolidado como un mecanismo relevante para el proceso de asimilación de la jurisprudencia reciente del STF, lo que revela tensiones interpretativas y la necesidad de una mayor armonización de decisiones para garantizar la seguridad jurídica, la equidad y la sostenibilidad del SUS.

**Palabras clave:** Judicialización de la salud; Derecho a la salud; Jurisprudencia.

The judicialization of public health is the phenomenon by which individuals resort to the Judiciary with requests to obtain, through the Unified Health System (SUS), access to health actions, services, medications, treatments, or technologies<sup>(1)</sup>. The 1988 Federal Constitution (CF/88) provides for the right to health in its article 198, and also provides in article 5, item XXXV, that the Judiciary is the only institutional instance with competence to judge conflicts<sup>(2)</sup>. The Supreme Federal Court (STF), in turn, is the guardian of the Constitution and the highest body of the Brazilian Judiciary, acting as the last instance of constitutional review and interpretation. It plays an important role in standardizing understandings on various subjects through its jurisprudence<sup>(2)</sup>.

The recent jurisprudence of the STF on the judicialization of health, made explicit through Topics No. 6 and 1234, judged at the end of 2024, dealt with the specific judicialization of medications against the SUS and significantly impacted the judicialization of health in Brazil<sup>(3)</sup>. Topic No. 6<sup>(4)</sup> standardized cumulative criteria for the provision, by judicial decision, of medication registered with the National Health Surveillance Agency (ANVISA), but not included in the SUS dispensing lists, that is, non-standardized, regardless of its cost. For these non-incorporated medications, it is up to the plaintiff to prove, based on Evidence-Based Medicine (EBM), the safety and efficacy of the drug, as well as the non-existence of a therapeutic substitute already incorporated, and the non-existence of an available therapeutic alternative, with a mere medical prescription or report without the backing of high-level scientific evidence not being sufficient. Topic No. 1234<sup>(5)</sup>, in turn, brought passive legitimacy (who should be sued, whether the Union, State, or Municipality) and judicial competence (Federal or State Justice) for lawsuits requesting these same non-standardized medications. Furthermore, it linked the judicial provision of medications to the ceiling of the Maximum Sale Price to the Government (PMVG), set by the Chamber of Medication Market Regulation (CMED).

These topics brought significant changes in the way of interpreting the constitutional right to health, seeking to make the judicialization of medication requests more rational and to strengthen a model of judicial governance based on cooperation between institutions in the legal and health fields<sup>(6)</sup>.

The judgment of Topics No. 6 and 1234 resulted in the issuance of Binding Precedents 60<sup>(7)</sup> and 61<sup>(8)</sup>, which define mandatory criteria for judicial requests for medications against the SUS. If the binding precedents are breached, it is appropriate to file a Constitutional Claim (RC) directly with the STF. The RC instrument has the role of preserving the competence of superior courts, which are the STF and the Superior Court of Justice (STJ), and the authority of their decisions, and it should be used when a judicial or administrative act violates a binding decision or usurps the court's competence, by breaching, for example, a Binding Precedent, thus functioning as a remedy to ensure the uniformity and effectiveness of constitutional justice.

Minas Gerais (MG) is one of the states that presents the highest volume of health lawsuits<sup>(9)</sup>, being the second most populous state in the country and one of the most heterogeneous states in terms of socioeconomic conditions, distribution of public services, and epidemiological profile<sup>(10)</sup>, and therefore very representative and relevant as a thermometer of health judicialization. According to preliminary surveys conducted by the State Health Secretariat of Minas Gerais (SES-MG) and presented at the meeting of the State Health Committee of the TJMG, on 12/05/2025, considering only lawsuits against MG, from 2024 to 2025 there was a 29% reduction in the granting of injunctions and 34% in successful sentences, and for medications and diets these reductions were respectively 55% and 53%. This same analysis showed that MG ranks third in the number of new health lawsuits with health requests from plaintiffs against SES-MG, with a 37% increase in the number of lawsuits and an

astonishing 550% increase in the committed amounts between 2019 and 2024, and in this last year, health judicialization consumed 9% of the state's entire health budget<sup>(11)</sup>.

These preliminary data demonstrate the need to evaluate the impact of Topics No. 6<sup>(4)</sup> and 1234<sup>(5)</sup>: whether SES/MG is spending more, but in a more assertive way; whether the six cumulative requirements set out by Topic No. 6 are being properly considered; and whether the division of competence among the entities is being complied with by judicial decisions and whether lawsuits with requests other than medications are growing or not. Theoretically, the recent jurisprudence of the STF was a containment barrier for the phenomenon related to medications. It is expected that, after the assimilation period of the recent STF jurisprudence, decisions will be more qualified.

On November 25, 2025, STF Minister Cristiano Zanin judged the RC 87745/Rio de Janeiro – RJ<sup>(12)</sup>. In this decision, the reporting minister understood that Topics No. 6 and 1234 do not apply to supplies in general, and in the specific case, to a special milk intended for children with cow's milk protein allergy. He considered the claim well-founded, since, in fact, as it is not a medication, the application of Topics No. 6 and 1234 (STF Binding Precedents No. 60 and 61)<sup>(4,5,7,8)</sup> would be improper. He also noted that the merit of this RC does not imply automatic recognition by the STF of the right pleaded by the plaintiff in the first and second instances. In the case, the decision only set aside the improper application of Topics No. 6 and 1234 and judged the claim to be founded, based on art. 992 of the 2015 Civil Procedure Code (CPC/2015)<sup>(13)</sup> and art. 161, single paragraph, of the STF Internal Regulation<sup>(14)</sup>, quashing the challenged decision and determining that another be issued, without the improper application of STF Topics No. 6 and 1234.

The judgment of this claim, which once again reinforced that Precedents No. 60 and 61 apply only to cases of medication judicialization, suggests the need to harmonize STF precedents, which is a system that was reinforced by the CPC/2015 with the aim of consolidating and standardizing its own jurisprudence to ensure legal certainty, equality, and predictability of decisions throughout the Brazilian judicial system<sup>(15)</sup>. Furthermore, the example brought by RC 87745/RJ indicates the need to improve or expand the scope of application of the criteria established in the decisions of Topics No. 6 and 1234, since health supplies, including food items, as well as orthoses, prostheses, and special materials (OPME), despite not being medications, require evaluation by Evidence-Based Medicine (EBM) and Budgetary Impact Assessment (BIA), in order to guide the decisions of judges and magistrates.

It is possible that the massive financial burden of medication judicialization caused health supplies and OPME to be put aside initially, considering that the budgetary burden of these items may be falling on states and municipalities, now that the competences of the entities in judicialization are better established. The STF jurisprudence reinforced the co-responsibility between the Union, States, and Municipalities, organizing the execution of pharmaceutical assistance in a more balanced way and bringing greater predictability to judicial and budgetary decisions within the scope of medications<sup>(3)</sup>.

As we are in the assimilation period of Topics No. 6 and 1234, the RC can be considered a good instrument for this process, as it sheds light on the reality of how Topics No. 6 and 1234 have been applied and interpreted by judges and magistrates. In the year 2025, the General Advocacy of the State of Minas Gerais (AGE/MG) filed 22 RCs pointing out flaws in the judgment of lawsuits out of harmony with the precepts of Precedents No. 60 and 61. The main topics of these RCs were cases of decisions contrary to the recommendations of the National Commission for the Incorporation of Technologies (CONITEC) in the SUS, decisions in non-conformity with the Maximum Sale Price to the Government

(PMVG), conflict of judicial competence, absence of the requirements of Topic No. 6, and insufficiency of medical prescription (cases of approval in which only the medical prescription was considered sufficient)<sup>(11)</sup>.

STJ Topic No. 106 is applied to cases prior to September 19, 2024 (time governs the act). From then on, Topics No. 6 and 1234 must be applied. However, in practice, there is a lack of assimilation of the new parameters with STJ Topic No. 106<sup>(16)</sup>, for example, still applied to cases after September 19, 2024. In this context, the concept of overcoming (overruling) a more recent topic over an older one is essential for the observance of precedents, and STF Topic No. 6 represents a significant change in relation to Topic No. 106<sup>(4)</sup> which discussed the mandatory provision of medications not incorporated by the SUS. When comparing the two topics, it is noted that STF Topic No. 6 establishes more rigorous and complex criteria, by requiring, among other points, prior administrative denial and the demonstration of qualified scientific evidence, requirements that were not expressly provided for in Topic No. 106. The common point between the two refers to the need to prove the patient's financial incapacity<sup>(17)</sup>.

But what happens to the other health benefits, apart from medications, which also represent an important financial burden for public managers? At the moment, STF Topic No. 793 is applied to all other health benefits<sup>(18)</sup> with the exception of medications. It provides that entities of the federation are jointly and severally liable in health demands, and that it is up to the judicial authority to direct compliance according to the rules for sharing responsibilities and to determine compensation to whoever bore the financial burden. Thus, decisions on health requests except medications remain subject to various interpretations made by the Judiciary, for example, regarding the way in which the right of recourse will be implemented and the mandatory nature of the Union appearing as a defendant in the lawsuit. There are decisions that determine that the Union's reimbursement occurs in the same process, others with the summoning of the Union, while others state that the reimbursement must happen in an autonomous process. Meanwhile, states and municipalities bear unexpected costs and await reimbursement.

The reimbursement process between federative entities had been suspended since 2017, awaiting decisions from the Supreme Federal Court (STF). In December 2024, the Ministry of Health Ordinance GM/MS No. 6,212/2024 established rules for the interfederative reimbursement of judicialized medications<sup>(19)</sup>. However, it treats reimbursement on an individualized basis. Thus, for entities to receive the amount owed by the Union, they must make the request case by case, generating slow and individual procedures. As a result, states and municipalities continue to have difficulties in obtaining the funds spent.

The most recent debate on health judicialization has focused almost exclusively on the provision of medications, while demands related to orthoses, prostheses, special materials, and supplies, including food compounds, end up being neglected. This gap has a direct impact, especially on municipalities, which have less financial capacity. Even in the current context, in which the competences of the federative entities have come to be more clearly delimited, it is observed that the municipality continues to be included in a joint and several manner in lawsuits in which, in light of the new parameters, it should not appear as responsible,.

Lawsuits requesting other health supplies, unlike medication lawsuits, do not require the plaintiff to prove their request with high-level scientific evidence, which can generate distortions of requests granted based solely on a medical prescription, opening space for the prescription of experimental

treatments, for conflicts of interest in the doctor-industry relationship, and for the distortions generated by the pricing mechanisms of health technologies<sup>(20)</sup>.

A major advancement is perceived in the Judiciary's treatment related to issues involving health judicialization, through the holding of public hearings on the subject, the creation of Technical Advisory Nuclei (NAT-JUS), and the standardization of judgments, aiming to contribute to a more equitable use of public health resources. However, this action mostly affects individual health lawsuits, filed by people who had access to the judiciary due to financial privileges or literacy about their rights. There is still a long way to go, in the sense of creating knowledge and jurisprudence that guides judges, magistrates, and their teams in the judgment of health lawsuits.

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