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Supply of Medicines by the State: main jurisprudences of the Superior Courts in Brazil

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ABSTRACT: *Health, a fundamental social right provided for in the Federal Constitution of 1988, is part of a larger context of social protection of the State oriented towards the organization of governmental public functions for the promotion, protection and recovery of the health of individuals and the community. Judicialization, represented by the pursuit of the Judiciary to implement a fundamental right, happens when there is inertia and/or ineffectiveness of access to public policies aimed at the health of the individual, among them, the policy of access to medicines. The general objective of the research was to analyze the judicialization regarding the supply of medicines by the State and to identify the main judicial demands judged by the Superior Courts in Brazil (STF and STJ) between the years 2018 and 2022 regarding this theme. The methodology used was the bibliographic and documentary research of the judgments handed down by the STF and STJ in that time frame. Therefore, in view of the results, it is concluded that the superior courts have a fundamental role in the standardization of jurisprudential understandings regarding demands as sensitive as the realization of the fundamental right to health, more specifically, access to medicines by citizens.*

KEYWORDS: *supply, medicine, state.*

I. INTRODUCTION

According to art. 196 of the Brazilian Federal Constitution of 1988, "health is everyone's right and the duty of the State, guaranteed through social policies and reduction of the risk of disease and other health disorders and universal and equal access to actions and services for its promotion, protection and recovery". Even before the aforementioned article, the right to health is "enshrined" in art. 6º, *caput*, in the scope of fundamental social rights [1].

The implementation of social rights essentially takes place through public policies, in which Bucci (2006) [2] clarifies that the characteristic note of public policy is that it is an action program and that the ideal of a public policy is to result in the achievement of social objectives (measurable) proposed; get specific results in a certain period of time.

In this sense, public policies in the health area, implemented through a set of regulations, must include benefits in the pharmaceutical field, considering that access to medicines is essential for the right to health to be fully ensured [3].

The possibility of public policies being submitted to judicial control derives from the broad constitutional guarantee expressed in art. 5º, XXXV, of the Federal Constitution of 1988 (FC/88): "The law will not exclude injury or threat to the right from the appreciation of the Judiciary". Thus, the lack, omission or inefficiency of the performance of the Public Power in the supply of medicine is subject to the action of the Judiciary Power.

In this sense, Barroso (2012) [4]clarifies that this phenomenon of judicialization means that some issues of wide political or social repercussion are being decided by Judiciary, with the redemocratization of the country, with the promulgation of the Constitution of 1988, which strengthened and expanded the Judiciary, with the democratic environment reviving citizenship, reflecting on the search for judicial protection of rights.

The constitutionalization of the right to health as a social right (art. 6º of the Federal Constitution of 1988) and a duty of the State brought the legal concept of health to the level of joint and several liability of the entities of the federation (art. 23, II), which they must build public policies that promote the comprehensive care of the needs of the population (art. 198, *caput*, II)[1]. Despite the advances in public policies for pharmaceutical assistance, in Brazil, difficulties are identified in the population's access to the necessary medicines, which implies damage to comprehensive health care, with the Judiciary Power being the alternative sought by the population for access to medicines.

Between 2008 and 2017, the number of lawsuits related to health increased by 130%, as revealed by the research Judicialization of Health in Brazil: Profile of demands, causes and proposed solutions [5]. This study, prepared by the Teaching and Research Institute (Insper) for the National Council of Justice (CNJ), also demonstrated that more than 71% of decisions within the scope of the second judicial instance were in processes related to the demand for supply of medication.

In addition, data from the 2019 Justice in Numbers report by the National Council of Justice indicate that there were more than 544,000 lawsuits in progress by the end of 2018 in the Brazilian Judiciary on the subject of Supply of Medicines (SUS) [6]. In addition, the concession of the supply of medicines through judicial decisions burdens the budgets of federal entities too much, impacting the balance initially foreseen in the budget. As an example, federal and state spending increased by 1,300% between 2008 and 2015, jumping from approximately R$70 million in 2008 to approximately R$1 billion in 2015 [7].

Thus, in view of the growing number of lawsuits based on the supply of medicines by the Government and the impacts of this phenomenon, analyzing the recent demands for the supply of medicines by the State within the scope of the superior courts in Brazil (STF and STJ) is necessary to understand this phenomenon of the judicialization of public health policy, at this point of social importance, which is access to medicines by the population.

II. METHODOLOGY

This study uses a qualitative descriptive method using judgments of the Federal Supreme Court (STF) and the Superior Court of Justice (STJ) about concession of the supply of medicines by State in Brazil. The source of research data comes from an search that was carried out on judgments of the Federal Supreme Court (STF) and the Superior Court of Justice (STJ), which were judged between the years 2018 and 2022, using as keywords the terms “supply”, “medicine” and “state” in the Jurisprudence search section available on the websites of the STF (https://jurisprudencia.stf.jus.br/pages/search) and the STJ (https:// scon.stj.jus.br/SCON/).

Thus, the main judgments of the last five years of the STF and STJ that deal with the supply of medicines by the State were analyzed, identifying the nature of the judicial demands and the criteria used for the judicial concession of the supply of medicines by the State.

III. RESULTS

Considering the methodological research criteria for STF and STJ jurisprudence, through the search with the keywords “supply”, “medicine” and “state”, 189 STF judgments and 360 STJ judgments were found as a search result, judged between the years 2018 and 2022.

After analyzing the content of the menus and the entire content of the said judgments, it is possible to filter by the thematic relevance with the study and thus identify the natures and criteria used for the judicial concession of the supply of medicines by the State from the point of view of the Brazilian Superior Courts.

IV. DISCUSSION

4.1 State's duty to supply medicines not registered by National Health Surveillance Agency (ANVISA)

The "Superior Court of Citizenship" (STJ), in mid-November 2018, established the legal thesis based on Repetitive Theme 990 (REsp 1726563) that health plan operators are not obliged to provide medicines not registered by ANVISA. This thesis corroborated the understanding of the Supreme Constitutional Court on the indispensability of registration by ANVISA as a necessary condition to certify the safety and benefit of the medicine, being the first condition for the Unified Health System to consider the incorporation of a medicine in its official lists (STA nº 175 AgR), in addition to the recommendation of the CNJ and statements nº 6 and 26, both of the "I Health Law Journey", which had the following terms: "The judicial determination of supply of medicines must avoid medicines not yet registered with ANVISA, or in the experimental phase, subject to the exceptions expressly provided for by law"; and, "It is lawful to exclude coverage of imported product, technology and medicine that is not nationalized, as well as experimental clinical or surgical treatment".

The Federal Supreme Court (STF) looked more closely at the issue in the following year, 2019, and in mid-May of that year established the general repercussion thesis (RE 657718 - Theme 500) with the following terms:

> I - The State cannot be obliged to supply experimental drugs; II - Failure to register with ANVISA prevents, as a general rule, the supply of medication by court order; III - It is possible, exceptionally, the judicial concession of medicine without sanitary registration, in case of unreasonable delay by ANVISA in appraising the request (period longer than that provided for in Law No. application for registration of the drug in Brazil (except in the case of orphan drugs for rare and ultra-rare diseases); (ii) the existence of registration of the drug in renowned regulatory agencies abroad; and (iii) the lack of a registered therapeutic substitute in Brazil; IV - Lawsuits that demand the supply of drugs not registered with ANVISA must necessarily be filed with the Federal Government [8].

Thus, as a general rule, the State cannot be obliged to supply medicines not registered with the National Health Surveillance Agency (ANVISA) by court decision. Registration with ANVISA constitutes protection for public health, attesting to the efficacy, safety and quality of drugs marketed in the country, in addition to ensuring proper price control. In the case of experimental drugs, i.e., without scientific proof of efficacy and safety, and still in the research and testing phase, there is no hypothesis in which the Judiciary can force the State to supply them. This, of course, does not interfere with the dispensation of these drugs within the scope of clinical trials, expanded access or compassionate use programs, always under the terms of applicable regulations. In the case of drugs with proven efficacy and safety and tests concluded, but still not registered with ANVISA, their supply by court decision is absolutely exceptional and can only occur in one case: ANVISA's unreasonable delay in appreciating the request (longer period than provided for in Law nº. 13.411/2016). Even in this case, however, there will need to be proof of the cumulative fulfillment of the three requirements listed in the thesis.

4.2 Joint liability of Federal Entities

The first constitutional provision in the section reserved for dealing with the right to health is the command (art. 196) that outlines the obligation of the entire State to guarantee the right to health. For this reason, all federal entities have a constitutional duty to ensure the "promotion, protection and recovery" of the

health of Brazilian citizens, in an equal and universal manner. The preface constitutional order, therefore, rejects the argument of the absence of responsibility of any of the entities, whatever the stage of implementation of the right to health[1].

In addition, the constitutional indication of common competence in health care and assistance provided for in art. 23, II, of Federal Constitution of 1988 (FC/88), undoubtedly requires the participation of all entities, but without overlapping attributions between them.

In the words of the Minister of the Supreme Court, Dias Toffoli, the understanding of each of the concepts defined by the constituent harmonizes perfectly with the decision issued in the records of STA nº 175 AgR - in which, in summary, it appears that:

> i) the obligation to guarantee health is common to all entities and the corresponding system is unique (in this precise sense, responsibility is joint and several); ii) the system is formed by a service network, which presupposes an organization by collaboration, and not by superimposition; iii) the service network must be close to the citizen, be municipalized (and, therefore, more accessible to him), without ceasing to be regional (the health regions must be able to meet local needs to guarantee the integrality of actions and health services); iv) there must be a hierarchy of services, according to their degree of complexity (the more complex the service, the greater the possibility that it will be removed from the local entity and directed to the entity most affected by technical specialization - states and, sequentially, the Union) [9].

Therefore, the Federal Supreme Court established in May 2019 the following thesis of general repercussion (Theme 793):

> The entities of the federation, as a result of common competence, are jointly and severally responsible for service demands in the health area, and in view of the constitutional criteria of decentralization and hierarchization, it is incumbent upon the judicial authority to direct compliance according to the rules for the allocation of competences and determine reimbursement to whom bore the financial burden [9].

The jurisprudence of the Supreme Court understands that adequate medical treatment for the needy is part of the list of duties of the State, since it is the joint and several responsibility of the federated entities, and the passive pole of the claim may be composed of any of them, separately or jointly. In addition, in order to optimize compensation between federal entities, it is incumbent upon the judicial authority, in view of the constitutional criteria of decentralization and hierarchization, to direct, on a case-by-case basis, compliance in accordance with the rules of division of competences and to determine compensation to those who supported the financial burden.

Finally, regarding the supply of drugs not included in public policies, actions that demand the supply of drugs not registered with ANVISA must necessarily be proposed in the face of the Union, since the Ministry of Health has competence for the incorporation, exclusion or alteration of new drugs, products, procedures, as well as constitution or alteration of clinical protocol or therapeutic guideline[10].

4.3 The state's duty to supply medicines which, although it is not registered with ANVISA, has its importation authorized by the Health Surveillance Agency

The paradigm judgment ofRE nº 657.718 (Theme 500), although it discussed the supply of medication without registration with ANVISA, since there was no consideration of drugs or substances that, although not registered with ANVISA, have the approval of the health agency to import and own consumption, under certain circumstances.

In this sense, the Supreme Court addressed the issue and established the following thesis of general repercussion for Theme 1161:

> It is up to the State to provide, in exceptional terms, a medicine that, although not registered with ANVISA, has its importation authorized by the health surveillance agency, provided that the patient's economic incapacity, the clinical indispensability of the treatment, and the impossibility of replacement are proven by another similar one contained in the official medication dispensing lists and therapeutic intervention protocols of the SUS [11].

In the words of the rapporteur of the referred paradigm in RE nº 1165959 (Theme 1161), Minister Marco Aurélio:

> As a general rule, the absence of registration prevents the supply of medication by virtue of a court decision, with the exceptions being the import and marketing authorizations implemented by the Agency itself, "with the aim of providing the Brazilian population with safe and quality products based on substances derived from Cannabis". It is necessary to do so. A different conclusion implies subjecting the citizen's survival to a strictly formal act - ANVISA's decision regarding registration. The greater, individualized need of a person affected by a serious illness must prevail. The patient should not – and cannot – remain on the wane. With permission from ANVISA and in the case of exceptional importation for its own, individual use, the State must make the acquisition feasible [11].

In short, it is up to the State to pay for the medicine, although it is not registered with ANVISA, once it authorizes, individually, the importation.

4.4 Performance of the Public Prosecutor's Office

The Federal Constitution of 1988 gave the Public Prosecutor's Office broad and unique institutional contours, intensifying its regime of guarantees and attributions. The constituent legislator transformed the Public Ministry into a true defender of society and citizenship, whether in the criminal sphere, through the exclusive ownership of public criminal action, or in the civil sphere, through the civil inquiry and public civil action[12].

In the constitutional framework, art. 129 of FC/88 provides for the institutional functions of the Public Prosecutor's Office, among which: promoting civil inquiry and public civil action, for the protection of public and social assets, the environment and other diffuse and collective interests (item III); and exercise other functions conferred upon it, provided that they are compatible with its purpose (item IX). Furthermore, art. 127 of the FC/88 states that the Public Prosecutor's Office is responsible for defending unavailable social and individual interests, among which it is understood that the right to health is included[1].

The performance of the Public Prosecutor's Office in defense of meta-individual rights and interests, and also of unavailable rights and interests, made instrumentally viable through adequate procedural means (the public civil action, in this case), which allows it to invoke the State's judicial protection with the with the aim of ensuring that public authorities respect, in favor of citizenship, services of public relevance (art. 129, II, FC/88),

as health actions and services are constitutionally qualified (art. 197, FC/88), it is fully legitimized as a result of the institutional condition of "defender of the people" that is conferred on "Parquet" by the Constitution of the Republic[1].

In this sense, the Supreme Court established an understanding based on general repercussion (Theme 262) that "The Public Prosecution Service is a legitimate party to file a public civil action aimed at providing medication to people with a certain disease"[13].

The "Citizenship Court", in the same vein as the "Constitutional Court", signed a legal thesis (Repetitive Theme 766) which instructs that:

> The Public Prosecutor's Office is a legitimate party to claim medical treatment or the delivery of medicines in the health demands proposed against federal entities, even when dealing with claims containing individual beneficiaries, because it refers to unavailable individual rights, in the form of art. 1º of Law nº. 8.625/1993 (National Organic Law of the Public Prosecutor's Office) [14].

4.5 Supply of medicines not incorporated in regulations of the United Health System - SUS

With regard to the supply of medicines not incorporated in normative acts of the Unified Health System - SUS, the "Superior Court of Citizenship" (STJ), in the context of Repetitive Theme 106 (Resp nº 1657156), established a legal thesis in the following terms:

> The granting of medicines not incorporated in normative acts of the SUS requires the cumulative presence of the following requirements: i) Proof, by means of a substantiated and detailed medical report issued by the doctor who assists the patient, of the indispensability or necessity of the medicine, as well as the ineffectiveness , for the treatment of the disease, of drugs supplied by the SUS; ii) financial inability to pay the cost of the prescribed medication; iii) existence of registration of the drug at ANVISA, observing the uses authorized by the agency [15].

In modulating the effects of the previous thesis, the STJ understood that:

> It is possible to supply medicines not incorporated in normative acts of the Unified Health System - SUS through clinical protocols, when the indispensability of the prescribed treatment is proven, in processes initiated before 5/4/2018 [15].

In addition, according to STJ jurisprudence, the choice of medication is the responsibility of a qualified physician who is knowledgeable about the patient's clinical condition, and may be either a private professional or a public health professional. What is essential is proof of medical necessity and economic hyposufficiency [16].

V. CONCLUSION

This article aimed to present the results referring to the research carried out with the purpose of identifying the main lawsuits judged by the Superior Courts in Brazil(STF and STJ) between the years 2018 and 2022 regarding the supply of medicines by the State.

As a result of the search, the themes of greater incidence and relevance dealt with by the higher courts were found referring to the State's Duty to provide medicines not registered by ANVISA; Joint and several liability of federated entities; State duty to supply medicine that, although not registered with ANVISA, has its

importation authorized by the health surveillance agency; Performance of the Public Prosecutor's Office and Provision of medicines not incorporated in normative acts of the Unified Health System - SUS.

Superior courts play a fundamental role in standardizing jurisprudential understandings regarding demands as sensitive as the realization of the fundamental right to health. As for access to medicines by citizens, there is, therefore, a great challenge for this right to health to be implemented, through public policies, as guaranteed by FC/88, as a right of all and a duty of the State.

Thus, it is hoped that this article can contribute to expanding academic and professional knowledge about the subject studied, in addition to expanding discussions on the reasons that lead to the growing judicialization for the effectiveness of the supply of medicines and on the role of state institutions both in the context of governmental as well as the judiciary and legislature to solve this problem.

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