Legal and technical basis of the sentences of the Special Courts of the Public Treasury of Rio de Janeiro (RJ), 2012-2018

Bases jurídicas e técnicas das sentenças dos Juizados Especiais Fazendários do Rio de Janeiro (RJ), 2012-2018

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ABSTRACT The paper analyzes the factual and legal reasons and sentences issued by the Special Courts of the Public Treasury of the city of Rio de Janeiro (2012-2018). It was sought to know how decisions on medication requests are made, seeking legal arguments, opinions from the Court's Technical Support Center (TSC), and scientific evidence. A total of 19.773 processes were retrieved and a 500 processes simple random sample was selected, being 290 about drugs. In 94.1% of the cases, the decision was based on medical report, followed by the medical prescription; and, although TSC consultation is mandatory, the technical opinion was used only in 22.2%. Of 221 judgments on merits, 94.6% were based on article 196 of the Federal Constitution; 85.5% in jurisprudence of the higher courts; and 62.5% rejected theses of the Public Treasury from the reservation of the possible and principle of budgetary legality. Most requested drugs treated endocrine-metabolic diseases (insulin, ranibizumab), kidney diseases (cinacalcet), obstetric complications (enoxaparin), immune and inflammatory diseases (adalimumab). Only 32% had scientifically based drug recommendation, 14% 'not recommended', and 54% 'recommended without a scientific basis'. It is concluded that the technical opinion is little used, but when present, it does not explain scientific evidence, since, only in obstetric causes, 100% of the recommendations were scientifically based.

KEYWORDS Health's judicialization. Pharmaceutical services. Evidence-based medicine. Unified Health System. Drug utilization.

RESUMO *O trabalho analisa razões fáticas e jurídicas das decisões e sentenças prolatadas pelos Juizados Especiais da Fazenda Pública do município do Rio de Janeiro (2012-2018). Buscou-se conhecer como são tomadas as decisões sobre pedidos de medicamentos, perquirindo argumentos jurídicos, pareceres do Núcleo de Apoio Técnico do Tribunal (NAT) e evidências científicas. Foram recuperados 19.773 processos e realizada amostragem aleatória simples para seleção de 500 processos, dos quais 290 foram de medicamentos. Em 94,1% dos processos, usou-se apenas o laudo médico na decisão, seguido da prescrição médica; e, embora a consulta ao NAT seja obrigatória, o parecer técnico somente foi usado em 22,2%. De 221 sentenças de mérito, 94,6% basearam-se no art. 196 da Constituição Federal; 85,5%, em jurisprudência dos tribunais superiores; e 62,5%, afastadas teses da Fazenda Pública da reserva do possível e princípio da legalidade orçamentária. Medicamentos mais solicitados tratavam doenças endócrino-metabólicas (insulina, ranibizumabe), doenças renais (cinacalcete), complicações obstétricas (enoxaparina), doenças imunológicas e inflamatórias (adalimumabe). Apenas 32% dos pareceres recomendavam o medicamento com base científica, 14% 'não recomendado' e 54% 'recomendado sem base científica'. Conclui-se que o parecer técnico é pouco usado, mas quando presente, não explicita evidência científica, visto que, apenas nas causas obstétricas, 100% das recomendações tiveram base científica.*

PALAVRAS-CHAVE *Judicialização da saúde. Assistência farmacêutica. Medicina baseada em evidências. Sistema Único de Saúde. Uso de medicamentos.*

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Introduction

Health is a human right recognized in the Brazilian Federal Constitution (FC)[1], which is materialized in public health policies. It is up to the State to act in the prevention of diseases and in the promotion and recovery of citizen health. In order to guide health care, there are protocols and guidelines for clinical management based on scientific research that must be observed, both to rationalize the use of public resources and to enable the adoption of effective and safe treatments.

The FC of 1988[1] elevated health to the condition of fundamental social right. In its own chapter on the social order, article 193 envisages health as one of the goals of the State, as well as the primacy of labor, welfare and social justice. The configuration of social welfare State is embodied in the determinations provided for in articles 194, 195 and 196, and a social assistance and social security model was formulated along the lines of social security. With the enactment of Law nº 8.080/90[2], the Unified Health System (SUS) was legally born, based on the idea of health as a right of all and the duty of the State, and the principles of equality (which the doctrine understands to be equity) and comprehensiveness in health care. Thus, the FC of 1988[1], enshrined within the Brazilian legal order, the human right to universal health.

In the Court of Justice of the State of Rio de Janeiro (TJRJ), there are numerous requests: i) for medicines used routinely in certain clinical conditions that should be provided free of charge and regularly by SUS, but are not – such as immunosuppressants prescribed to transplant patients; ii) exceptional medicines and proposed treatments, but not yet part of Clinical Protocols and Therapeutic Guidelines (PCDT) or that have been incorporated by SUS.

It is well known that, in court action related to the supply of the requested medicine, decisions often taken without technical bases or scientific evidence capable of answering not only questions of efficacy but also bioethics – principle of nonmaleficence – have provided an excessive increase of demands aiming at guaranteeing the citizen's care in SUS, despite the insufficient budget allocation for the universalization of care. Such measures become unforeseen expenses, favoring a greater mismatch between the public budget and the provision of services, generating a vicious cycle. In addition, it has been built, in recent decades, a jurisprudence that, in the legal discussion involving comprehensiveness and equity, disregards the budgetary limits according to constitutional principles imposed on the public administrator.

Thus, the decision of the judges would have as premise that the performance of the Judicial Branch is limited by constitutional and legal parameters, which properly regulate and discipline the judicial protection of the right to health and technical parameters such as evidence of effectiveness and safety of judged interventions. However, in night shifts, for example, the magistrates, pressured by the urgency referred to in the medical report, make decisions on the provision of inputs requested with impacts on the public budget of federative entities.

It is worth reflecting that regarding the judicialization of the right to health, its constitutional, legal and ethical scope, it is convenient to consider alongside the constitutional principles of the SUS and the budgetary principles, scientific, technical and ethical parameters. Thus, this study aims to: i) describe the reasons for judicialization; (ii) identify the legal and technical reasons (within the scope of Special Courts of the Public Treasury of the capital of Rio de Janeiro) used for the granting of medicines; (iii) identify the most commonly required diseases and medicines for treatment; and iv) to evaluate whether the decisions and judgments are based on the technical scientific advice of the Technical Advisory Council (NAT).

Methodology

This is a descriptive study of secondary data from the TJRJ records which evaluates

the profile of decisions and judgments that granted or not the requests for anticipation of protection to supply medicines in face of the Public Treasury of the state of Rio de Janeiro or municipality of Rio de Janeiro from July 1, 2012 to May 31, 2018, at the Special Courts of the Public Treasury in the District of Capital. The reason for judicialization, the main clinical syndromes and medications required were analyzed, indicating if there are problems such as irregular supply, request for non-incorporated medicines, off-label use or others. The records of the processes of the TJRJ are entirely electronic and were analyzed individually, online, in the period between 18 January and 20 February 2019.

It was assessed whether there was consultation with the NAT before the decision granting the anticipation of guardianship, observing the frequency of decisions favorably granted to the applicant, as well as the document most used as the basis of the decision and whether the scientific recommendation was observed in the opinion of the NAT.

The analysis of decisions was also carried out, verifying whether or not the granting of the request for anticipation of protection and judgment for the supply of the medicine were given on legal grounds and based on scientific reasons (scientific evidence of effectiveness/efficacy) of the requested medicine. The recommendation made in the NAT opinion regarding the required medicine as for the existence of scientific evidence for use in the author's disease was observed. Data were extracted from the TJRJ database for the period mentioned above, in claims related to Pharmaceutical Assistance (PA), specifically in Special Courts of the Public Treasury, located in the District of the Capital of the State of Rio de Janeiro. The cases were classified according to standardized codes by the National Council of Justice (CNJ): 10069: Hospital-Medical Treatment and/or Provision of Medicines, 10892: Medicine/Treatment/Surgery of Unproven Effectiveness, 11884: Provision of Medicines, 30323: Provision Medicines – Disabled – Launch, 11884; Deige (required for old processes), 30434: Provision of Supplies, 10856: Prescription by Physician not linked to SUS, 30431: Non-Standardized Medicines by SUS, 30431: Non-Standardized Medicines by SUS, 30432: Medicines – Other, 30433: Unregistered Medicine at the National Health Surveillance Agency (Anvisa), 30435: Milk Supply, 30436: Diaper Supply, 30437: Medical and Hospital Equipment, 30438: Provision of Supplies – and Others; 30459: Medicines and Other Health Supplies – Special Courts.

As a way of enabling and optimizing the research, only records from the electronic process database were chosen, due to the possibility of full access to the records and documents, allowing the analysis of the reasons for the decision. In the case of restricted access public data, the use of the information for academic purposes was required and authorized by the TJRJ. The names of the perpetrators, judges, promoters, defenders and prosecutors who acted in the proceedings were not identified. Cases that were processed in secrecy were excluded.

Although technical, Opinions of the NAT often did not refer to the existence or not of scientific evidence. However, they indicated when the medicine had no health record in Anvisa[3], whether or not it was incorporated into the SUS, whether it was indicated for the applicant's disease according to the label, whether the request was for use outside the SUS PCDT, whether there was medication or PCDT provided by SUS, as well as if the part was already registered in the competent sector, if the attending physician informed the previous use of PCDT without success. In general, with the exception of cases of evident off-label use or lack of registration with Anvisa, the Opinion of the NAT pointed out the above elements without making a value judgment about the existence of scientific evidence, although, in some cases, it indicated that current medical practice has not yet incorporated the claimed medicine into clinical protocols.

In analyzing the opinions of the NAT, it was sought to classify the conclusion of recommendation or not according to the existence and intended use of the PCDT of the SUS, which, in our understanding, would characterize the scientific evidence of medicine efficacy, a necessary reason to incorporation.

The project was submitted to the Research Ethics Committee of the Sergio Arouca National School of Public Health after the qualification exam and was exempted from analysis by the Committee, according to Opinion 14/2018.

Results

For this study, data were initially extracted from the proceedings of the period studied, found in the three Special Courts of the Public Treasury, located in the District of the Capital of the State of Rio de Janeiro, which, due to their legal disposition, should consider less complex issues that do not need to be addressed, however, the opinion of the NAT is required by the Court of Justice. A total of 19,773 processes were recovered from 2012 to 2018. Then, the simple random sampling technique selected 500 processes. After individual analysis, 290 cases were selected regarding the request for medicines, specifying the disease and the prescription drugs that were the subject of the lawsuit. Thus our sample had the following distribution per year: 2012=1 (0.3%), 2013=26 (9.0%), 2014=71 (24.5%), 2015=53 (18.3%), 2016=61 (21.0%), 2017=59 (20.3%) and 2018=19 (6.6%).

In some cases, more than one medicine was required, which is why the number does not equal the number of cases analyzed. Most of the requests or medicines – 56.3% – in legal proceedings at the Special Courts of the Public Treasury (Jefaz) are due to their non-inclusion in the SUS list, which harms other patients with the same disease and without ease of treatment access to the judiciary and who could benefit from collective action with a view to incorporating the medicine through the SUS. A significant proportion – 22.5% – of the cases referred to medicines that, although incorporated, did not have the administrative dispensation granted because the prescribing physician requested their use outside the PCDT of the SUS. There were 27 applications of incorporated medicines, due to the lack of public network – 8.4% –, indicating management problems, possibly due to the crisis that hit the state of Rio de Janeiro *(table 1)*.

Table 1. Reasons for the judicialization of medicines from Jefaz/RJ, 2012-2018

Order	N	%
Medicine not incorporated into the SUS list	180	56.3
Incorporated medicine, but needs use outside PCDT	72	22.5
Medicine without registration with Anvisa	5	1.6
Medicine incorporated into the list, but lacking	27	8.4
Medicine not incorporated and off-label use according to package insert	6	1.9
Medicine incorporated into SUS, but does not integrate list due to the short time of incorporation	25	7.8
Medicine incorporated without association required by the part	5	1.6
Total requests for medicines	320	100.0

Source: Own elaboration.

The result obtained in relation to the technical justification of the preliminary decision and the sentence (which may use more than one plea) mirrors that already mentioned in other studies, indicating that, when substantiating the sentence and the decision that anticipates the protection, the magistrate, in 94.1% of the time, uses the medical report as the main justification for his/her decision, followed by the medical record (prescription); and, although consultation with NAT is mandatory, technical advice is only used as a basis in 22.2% of cases *(table 2)*.

Table 2. Technical basis for assessing the merits and types of sentences issued in Jefaz/RJ, 2012-2018

Basis	N	%
Proof of illness (medical report)	208	94.1
Need for medicine (prescription)	154	69.7
Opinion of the NAT	49	22.2
Need to prove prior care and administrative refusal to supply the medicine	1	0.5
Total of sentences on the merit	221	-
Sentences without merit	49	-
Not sentenced	20	-
Total	290	-

Source: Own elaboration.

Table 2 shows that of the 290 cases studied, 49 were extinguished without merit, either due to the inertia of the author who did not proceed or due to the requirement to waive the case, representing 16.9% of the total.

As already pointed out, the classification is made by the applicant using codes standardized by the CNJ. As in the vast majority of actions the author is sponsored by the public defender, the institution is responsible for the classification.

It should also be clarified that, frequently, asking for anticipatory protection refers only to the claimed medicine, while the final application includes a standard final claim:

> [...] judgment on the merits of the claim, with the defendants condemned to supply the claimed medicines, or other medicines, equipment and apparatus that the plaintiff may need in the course of the treatment, in the prescribed amounts, in monthly and continuous indefinite installments[4].

This is possibly why the most commonly used classification is "medicines and other health supplies"[4].

Even in the most simplified environment of the Courts, decisions and judgments need to be substantiated at the risk of being null and void. The sentences have several legal and technical basis, most commonly, used together. We studied the basis used by the magistrates to grant the request. Of the 221 merit sentences, 94.6% referred to article 196 of CF[1]; 85.5% of the decision was based on jurisprudence of the higher courts on the subject (TJRJ/STJ/STF); in 62.5%, the theses of the Public Treasury were removed from the possible reserve and principle of budgetary legality; 56.6% referred to the Precedent 65 of the TJRJ; in 40.7%, to article 198 of the FC; 34.4% of decisions were made based on the understanding of the obligation of federative entities to supply medication even outside the SUS[2]

list. The economic hyposufficiency of the part was the basis in 23.1% of the cases *(table 3)*.

It was found that 14.2% of the decisions that anticipated the protection required to grant the medicine used as argument only the need of the author and the presentation of medical evidence for the request, without presenting legal basis. The technical basis for early protection decisions were 98.1%, totaling 255 cases. Regarding the classification or nature of the technical basis of the judgments of merit in the Jefaz/RJ (2012-2018), 94.1% made use of the medical report to prove the disease, 69.7% made use of the claim of need for the medicine attested by prescription, 22.2% (49 cases) were based on the opinion of the NAT. In one case, on the basis of 'need to prove prior care', there was an administrative refusal to supply the medicine.

Table 3. Classification of the most used legal basis in the Jefaz/RJ sentences (2012-2018)

Basis	N	%
1 - Article 6 of the Federal Constitution: right to health	33	14.9
2 - Article 23, II of the Federal Constitution: solidarity between federal entities	71	32.1
4 - Article 196 of the Federal Constitution: health is the right of everyone and duty of the State.	209	94.6
5 - Article 198 of the Federal Constitution: SUS	90	40.7
7 - Precedent 65 TJRJ	125	56.6
8 - Precedent 180 TJRJ	60	27.1
9 - Article 3 of the Federal Constitution: social welfare	58	26.2
10 - Law nº 8.080/90	48	21.7
11 - The part is financial hyposufficient	51	23.1
12 - Article 5 of the Federal Constitution – right to life	34	15.4
13 - Article 6 of Law nº 8.080/90: Comprehensive and Pharmaceutical Therapeutic Assistance of SUS	188	85.1
14 - Law nº 12.153/09: Provides for the Special Courts of the Public Treasury within the states, FD.	1	0.5
15 - Obligation of federative entities to supply medication even outside the SUS list	76	34.4
16 - It removes the theses of the Public Treasury from the possible reserve and principle of budgetary legality.	144	65.2
17 - RE 855178 RG, Rep.: Minister Luiz Fux, Joint liability of the federated entities. General repercussion recognized. Reaffirmation of jurisprudence	4	1.8
18 - Resp. 1.657.156/RJ STJ. Judged by the general repercussion regime, Thesis nº 106 of the STJ	11	5.0
19 - Jurisprudence of the Superior Courts on the subject (TJRJ/STJ/STF)	189	85.5
Total of sentences on the merit	221	-

Source: Own elaboration.

Of the 290 cases studied, 49 were extinguished without merit either by inertia of the plaintiff (26), who did not, for some reason, proceed with the fact, or for having requested the withdrawal of the case (5), representing more than 10% of total achievements. Only in one case there was a sentence pointing out that the author did not prove to have made previous use of the PCDT of SUS.

In general, the objections or non-concessions of the anticipated tutelage by the Public Treasury are standardized and claim, in summary, the following items: 1) that the required medicine is not part of the SUS or public entity dispensation list (National List of Essential Medicines – Rename, State List of Medicines – Resme, Municipal List of Essential Medicines – Remume); 2) that the author requires the use of the medicine outside the PCDT of the SUS or registration with Anvisa; 3) that the required medicine does not exist in the Brazilian market (imported and not registered with Anvisa).

In our study, diseases were classified into large groups: endocrine-metabolic (23.5%); kidney diseases and complications (16.9%); immunological and inflammatory (14.8%) neuropsychiatric (12.4%); the genetic ones (2.4%); obstetric diseases and complications (4.1%); the neoplasms (3.1%); respiratory diseases (3.8%) and ophthalmologic diseases (7.2%); lymphohematopoietic and thromboembolic (2.1%) and others (9.7%). We also observed that judicialization occurs predominantly in relation to more specifically chronic diseases, type I and II diabetes mellitus, chronic renal failure, Alzheimer's disease, Crohn's disease, schizophrenia, psoriasis, epilepsy, among others.

The most required medicines in Judgment in Jefaz/RJ (2012-2018) were compatible with the disease profile. Among the processes analyzed, there were 14 requests for sodium enoxaparin, 13 with private report and 1 with public report, and 3 patients who presented both private and public report. The most requested medications were for the treatment of endocrine-metabolic diseases (insulin, ranibizumab), renal diseases and complications (cinacalcet), obstetric diseases and complications (enoxaparin), immune and inflammatory diseases (adalimumab), and neuropsychiatric disorders *(table 4)*.

Despite the opinion of the NAT prior to the consideration of the preliminary injunction being mandatory in the TJRJ, according to Normative Act TJRJ 05/2012, we could observe that the decisions are not based on scientific evidence of efficacy of the claimed medicine, since only 93 (32.1 %) of the opinions recommended the medicine with explicit scientific basis, and 197 (67.9%) did not recommend or recommended without referring to the scientific basis: opinion 'not recommended', 41 (14.1%); and 'recommended without scientific basis', 156 (53.8%).

Table 4. Medicines required at Jefaz/RJ (2012-2018) in relation to group of diseases

Group of diseases	INS	CCA	ADM	RBZ	ENX	Other	Total
	N	N	N	N	N	N	N
Endocrine-metabolic diseases	29	0	0	22	0	17	68
Kidney diseases and complications	0	31	0	0	0	18	49
Immune and inflammatory diseases	0	0	6	0	0	37	43
Neuropsychiatric Diseases	0	0	0	0	1	35	36
Genetic diseases	0	0	0	0	1	6	7
Diseases and obstetric complications	0	0	0	0	12	0	12

Table 4. (cont.)

Neoplasms	0	0	0	0	0	9	9
Respiratory diseases	0	0	0	0	0	11	11
Eye diseases	0	0	0	9	0	12	21
Lymphohematopoietic and thromboembolic diseases	0	0	0	0	0	6	6
Other	0	0	0	0	0	28	28
Total	29	31	6	31	14	179	290

INS – Insulin, CCA – Cinacalcet, ADM – Adalimumab, RBZ – Ranibizumab and ENX – Enoxaparin.

It is observed that most of the opinions that recommends the medicine without scientific basis does so on the basis that the patient has already made use of alternatives provided by SUS, such as NPH and regular insulin in the case of diabetes mellitus, for example. We have already mentioned that the NAT opinion always tells you whether the medicine is indicated for the applicant's disease, then whether or not it is incorporated into the SUS and other relevant elements. Most NAT opinions recommending the medicine without reference to scientific evidence are, among the processes studied, in the group of endocrine-metabolic diseases – 69.1%; followed by the group of neuropsychiatric diseases – 66.7%; eye diseases – 66.7%; respiratory diseases – 63.6%; kidney disease and complications – 53.1%; immune and inflammatory diseases – 44.12%. In the group 'obstetric diseases and complications', the recommendation was based on evidence in 100% of cases. In the group of neoplasms, the percentage was 66.7% *(table 5)*.

Table 5. Classification of the NAT recommendation regarding groups of diseases in processes of the Jefaz/RJ (2012-2018)

Group of diseases	What does the opinion of NAT say?							
	NOT recommended		Recommended with NO basis		Recommended WITH basis		Total	
	N	%	N	%	N	%	N	%
Endocrine-metabolic diseases	8	11.8	47	69.1	13	19.1	68	100.0
Kidney diseases and complications	0	0.0	26	53.1	23	46.9	49	100.0
Immune and inflammatory diseases	11	25.6	19	44.2	13	30.2	43	100.0
Neuropsychiatric diseases	3	8.3	24	66.7	9	25.0	36	100.0
Genetic diseases	3	42.9	1	14.3	3	42.9	7	100.0
Diseases and obstetric complications	0	0.0	0	0.0	12	100.0	12	100.0
Neoplasms	1	11.1	2	22.2	6	66.7	9	100.0
Respiratory diseases	2	18.2	7	63.6	2	18.2	11	100.0
Eye diseases	6	28.6	14	66.7	1	4.8	21	100.0
Lymphohematopoietic and thromboembolic diseases	1	16.7	3	50.0	2	33.3	6	100.0
Other	6	21.4	13	46.4	9	32.1	28	100.0
Total	41	14.1	156	53.8	93	32.1	290	100.0

Discussions

The decisions and judgments analyzed indicate that medicine applications are granted, most of the time, without analyzing the NAT recommendation regarding the scientific evidence of the medicine. This pattern of jurisdictional decision, without prior appreciation of the technical elements involved, is frequently criticized in the specialized literature, affecting the PA cycle and the public budget in the health area.

In judicial practice, the granting of an injunction is a rule; and the necessary and sufficient proof that the perpetrator needs the required medication is the prescription of a physician since, for judges, it is up to the physician to point out the patient's needs[5]. The point that seems to be the most important in the decisions is the indication of the medicine for the disease, even though there is no evidence that the author has previously made use of the medicines provided by SUS[2].

Regarding the technical basis for the preliminary decision and the sentence, this study corroborates the findings of other studies, indicating that, when substantiating the sentence and the decision that anticipates the protection, the magistrate, in most cases, uses the medical report as the main justification for his/her decision, followed by the prescription. Although consultation with the NAT was mandatory, the technical advice was used as the basis in only 22.2% of cases, a result similar to that found in the review by Catanheide et al.[3] on lawsuits from 2011 to 2014 when they found that, in more than 90% of the cases, the only additional document to the prescription of the medicine attached in the process was the medical report.

The results obtained have confirmed that most of the claims (56.3%) for medicine in judgment at Jefaz are due to its non-inclusion in the SUS[2] list. All orders were made in individual actions; and, considering that other patients have the same disease and greater difficulty in accessing the judiciary, we believe that a larger number of patients could benefit from collective action that could lead to the incorporation of the medicine into SUS[2]. With reference to the individual judicialization of chronic diseases to obtain non-incorporated medicines to the detriment of collective actions, D'Espindula[6] points out that patients with chronic diseases, in general, fill suits individually to obtain their medicines. The author also refers to the strong influence of the pharmaceutical industry on the medical class and the little knowledge about various aspects of medicines dispensed by the PA of the SUS. This lack of knowledge may be one of the causes of the significant percentage of 22.5% of medicines that, although incorporated, did not have the administrative dispensation granted because the prescribing physician requested their use outside the PCDT of the SUS. As an example, medicine orders such as enoxaparin sodium (Clexane or Versa) in different dosages, a drug that, according to the PCDT of the SUS, could only be dispensed with during hospitalizations or in clinical care, excluding the outpatient use required by part. There were also requests for incorporated medicines made due to THEIR lack in the public network (8.4%), indicating problems in the management of PA or budget in recent years, especially due to the crisis that hit the state of Rio de Janeiro.

For Travassos et al.[7], the dilemma is similar to that posed to judges, in the sense of the clash between the individual right of the applicant to a treatment or medication and the needs of the entire population. Thus, for the magistrate, it would be a mistake to consider the non-provision of a service to an individual as an application of the right to health, considering that the laws emphasize the individual right to health, leading to the question of how to evaluate an individual's right to health in relation to the other. Or furthermore, there is a conflict of rights, considering that almost all lawsuits in the health area are individual and that the rejection could

lead to irreversible compromise or even the sacrifice of essential goods, such as life, integrity and the dignity of the human person.

As for the significant number of private reports, we believe it could indicate that the part requested the medicine for use outside the SUS network, which would corroborate the observation by Medeiros et al.[8], who claim that there is a 'mixed public' able to afford consultations and eventual exams in the private network, but that uses the SUS to obtain higher cost medicines, affecting the distributive justice of the health system. Applications for sodium enoxaparin, for example, were entirely made by private physician reports.

The most requested medicines were initially not incorporated into Rename[9]. In the public system, for example, only regular and NPH insulins are offered. Long-acting analogue insulins (glargine, detemir and degludec) were submitted for review by the National Commission for incorporation of Health Technologies into SUS[10] (Conitec) on December 6, 2018, recommending the non-incorporation of said technology into the SUS for the treatment of type I diabetes mellitus. The fast-acting analog insulin (aspart, lispro and glulisine) were incorporated into SUS in February 2017, which may indicate pressure from the pharmaceutical industry to incorporate the technology, since, in September 2016, Conitec[10] opposed the merger, recommending that the matter be sent for public consultation.

Cinacalcet hydrochloride (Mimpara), indicated for the treatment of hyperparathyroidism secondary to kidney disease in patients on dialysis and refractory to conventional therapy, was evaluated by Conitec[10] and, on October 15, 2015, recommended for incorporation into Rename[9]. Many requests were due to the non-availability of the medicine after incorporation, with delay in availability by the public network.

Conitec[10], on May 9, 2018, recommended the incorporation into the SUS of adalimumab as a first line of biological treatment after failure of standard therapy and secuquinumab as a second line of biological treatment after adalimumab failure to treat moderate to severe psoriasis, already being incorporated for treatment of other syndromes such as rheumatoid arthritis, since June 2012.

Ranibizumab was evaluated by Conitec[10] in October 2015, concluding that it was effective and safe, but was similar in efficacy and safety to bevacizumab, which had the recommended incorporation due to its cost-effectiveness in the treatment of diabetic macular edema. As the medicine is listed in Rename[9] for treatment of other diseases, the requirements characterized its use outside the PCDT, with information from the NAT opinions in 2018 that Conitec would carry out another evaluation.

Although the higher courts and the CNJ are already pointing towards greater weighting and more qualified evaluation of health claims, observing standardized and more scientifically rigorous requirements by magistrates, at least since 2010 with Recommendation nº 31 of the CNJ[11], there was still strong resistance from magistrates to more closely analyze the Opinion of the NAT and to request greater technical support to render the decision, at least before the judgment of the 2018 theme 106 of the STJ.

It should be noted that although Statement nº 5 of the National Health Council of Justice of the CNJ states that the processing of actions requiring medicines not registered by Anvisa[3], off label and experimental[12] should be avoided, that statement was repealed on 18 March 2019.

In the State capital, following the establishment of the Health Dispute Resolution Chamber (CRLS) in 2014, many medicine applications were granted without the intervention of the judiciary. However, drug requests outside the PCDT of the SUS, or not yet incorporated, still require a judicial order to obtain it.

There is no denying the strong pressure to incorporate new technologies and medicines into the SUS, and that one of the instruments has been judicialization, which could perhaps be minimized with greater discussion and

transparency about the deliberations of public health policies, including reforming the curriculum of medical careers so that they pay attention to the functioning of the SUS, which should be the privileged system. Most magistrates and medical professionals seem to be unaware of the collective purpose of SUS.

The TJRJ and CNJ have made efforts to reduce the judicialization of health by establishing prior administrative mechanisms such as the CRLS in health and by promoting public hearings on the topic.

With the financial crisis that has hit the Country, a new perspective should open to the theme in order to question whether the part has demonstrated the inadequacy of existing PCDT, given that a large number of judicial actions are of medicines for chronic diseases, whose use will be indefinite, with no information about previous use of PCDT of the SUS, demonstrating that most doctors, even those in the public service, are unaware of the lists of medicines and technologies or PCDT of the SUS.

The analysis was made before the judgment of the Theme 106 of the STJ (RESP. RG 1.657.156/RJ do STJ), which will impact the decisions in the sense of greater questioning; and it is expected that the scientific evidence demonstrated will be adhered to, as well as greater rigor in the development of decisions.

Finally, it is proposed a decision flowchart based on Theme 106 of the STJ that would follow the following steps: the initial request for the medicine has a medical report based on the indispensability of the patient's use and the patient's non-adaptation of the PCDT of SUS. If so, it is appropriate to judge whether the party has the financial capacity to purchase the requested medicine. If not, it is up to decision requiring adequacy of medical report. In case of financial hyposufficiency of the part, refer to the opinion of the NAT aiming at confirming the registration of the medicine in Anvisa and the agreement between the clinical indication and the medical report. If this is the case, the claim is well founded and granted. If not, the application is dismissed as article 927, II of the CPC – Theme 106 STJ. From the judgment of the theme 106 of the STJ, one can no longer ignore the need to observe the scientific evidence of effectiveness and cost and risk/benefit relationship of the medicines claimed, and it is always necessary to prioritize the choice of the public administrator, that is, the use of the PCDT chosen by SUS based on technical and scientific criteria.

Final considerations

The judges basically ground the well-founded judgments based on the constitutional argument of article 196 of the FC, that health is the right of all and the duty of the State (94.6% of cases), and by article 6 of Law nº 8.080/90, which states the comprehensive therapeutic and pharmaceutical care of most judgments dismisses merits of public treasuries, although without further basis (65.2%), also using the jurisprudences of the TJRJ, the STJ and STF as the foundation (85.5%) of solidarity between the entities and the integrality of the right to health, in addition to the technical argument.

Collaborators

Saad EM (0000-0002-3924-6230)* and Braga J (0000-0001-5247-007X)* contributed to the conception, planning, analysis and interpretation of data. Maciel EMG (0000-0002-9095-3141)* contributed to the planning, analysis and interpretation of data, critical review and approval of the final version. ■

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