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Evaluation of drug litigation against the Campinas municipal health system from 2017 to 2021

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In Brazil, the judicialization of public health for access to medications has resulted in significant challenges to the management of public policies, especially at the municipal level. To evaluate the profile of drug litigations against the Campinas municipal health system from 2017 to 2021, this study analyzed the characteristics of litigants, medicine dispensation, and the timing of court decisions. A quantitative, analytical, and comparative cross-sectional study was conducted using data on the dispensation of 506 types of medications and 493 court cases. The analysis included sociodemographic, procedural, medical-sanitary, and pharmaceutical assistance management variables. The time of court decisions was assessed using the Kruskal–Wallis test complemented by the Dunn test. The plaintiffs were predominantly adults, females, and self-declared students, and some cases involved nonresidents. Most of the lawsuits were represented by private lawyers, gratuitousness of justice and with decisions favorable to the plaintiff. However, only 43% of the patients obtained a preliminary injunction or early tutelage. The median time needed for a court decision from the date of case filing was 12 days until the granting of a preliminary injunction or early tutelage and 6.5 months until a judgment or dismissal without a decision on the merits. Approximately 32.4% of the medications dispensed by the judicial pharmacy already belonged to the list of the Brazil's Unified Health System in 2020; 46.3% were prescribed by their generic name; 75.5% had therapeutic equivalents, and 94.9% had marketing authorization from the Brazilian National Health Surveillance Agency. Judicialization in Campinas is an alternative way of accessing medications, but it is time-consuming and benefits only a small portion of the population (0.068%). The characteristics of the plaintiffs and judicialized medicines highlight the need to review health policies to promote equitable and efficient access to essential treatments for the population.

Keywords Right to health, Unified Health System, Judicialization of access to medicines

Abbreviations

Anvisa	Agência Nacional de Vigilância Sanitária (National Health Surveillance Agency)
ATC	Anatomical Therapeutic Chemical
CBAF	Componente Básico da Assistência Farmacêutica (Basic Component of Pharmaceutical Assistance)
CBO	Classificação Brasileira de Ocupações (Brazilian Classification of Occupations)
CEAF	Componente Especializado da Assistência Farmacêutica (Specialized Component of Pharmaceutical Assistance)
CESAF	Componente Estratégico da Assistência Farmacêutica (Strategic Component of Pharmaceutical Assistance)
Fiocruz	Fundação Oswaldo Cruz (Oswaldo Cruz Foundation)
Fiocruz's Manual	Fiocruz's Manual of Indicators for Evaluating and Monitoring Judicial Demands for Medicines
JP	Judicial Pharmacy
PA	Pharmaceutical Assistance
PCDT	Clinical Protocols and Therapeutic Guidelines

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PMC	Prefeitura Municipal de Campinas (Municipal City Hall of Campinas)
RMC	Região Metropolitana de Campinas (Campinas Metropolitan Region)
Remume	Relação Municipal de Medicamentos Essenciais (Municipal List of Essential Medicines)
Rename	Relação Municipal de Medicamentos Essenciais (Municipal List of Essential Medicines)
SES/SP	Secretaria Estadual de Saúde do Estado de São Paulo (São Paulo State Health Department)
SMS/ Campinas	Secretaria Municipal de Saúde de Campinas (Campinas Municipal Health Department)
SUS	Sistema Único de Saúde (Unified Health System)
TJSP	Tribunal de Justiça do Estado de São Paulo (Court of Justice of the State of São Paulo)

The judicialization of health is the practice of seeking judicial intervention to guarantee access to health-related goods and services. This is quite common in low- and middle-income countries, including nations in Central America, South America, India, Nigeria, and South Africa, where the right to health is guaranteed constitutionally or by international treaties such as the United Nations' International Covenant on Economic, Social and Cultural Rights^{1,2}.

In Brazil, a significant milestone in securing the right to health through judicialization was the fight for free distribution of antiretroviral drugs in the 1990s for individuals with the human immunodeficiency virus (HIV) and acquired immune deficiency syndrome (AIDS), based on the right to health³⁻⁵. This effort resulted in the formulation of public health policies and laws that expanded access to essential medicines and treatments through the *Sistema Único de Saúde* (SUS, Unified Health System)⁶.

The *Política Nacional de Medicamentos* (PNM, National Medicines Policy)⁷ structures pharmaceutical assistance (PA) in Brazil through the SUS into three segments comprising (1) a basic component (*Componente Básico da Assistência Farmacêutica* [CBAF]) aimed at primary care, (2) a strategic component (*Componente Estratégico da Assistência Farmacêutica* [CESAF]) focused on endemic diseases; and (3) a specialized component (*Componente Especializado da Assistência Farmacêutica* [CEAF]) for chronic and rare diseases. Furthermore, the policy establishes financial guidelines for each SUS component, considering the economic capacity of each government sphere. Medicines incorporated into the SUS are distributed among these components and published in the *Relação Nacional de Medicamentos Essenciais* (Rename, National List of Essential Medicines) biannually. The government sphere responsible for financing and delivering for each medicine to users has already been established in this document. This organizational structure aims to ensure economic sustainability among all spheres of the SUS government.

Judicialization is a multifaceted phenomenon with unique characteristics in each region⁸. The positive or negative effects of this form of access to medicines on universal public health systems vary over time and according to the perspective of the parties involved. Lawsuits in this context have largely been motivated by the pressure from the pharmaceutical industry for access to the public market, excessive bureaucracy in public processes, restrictions on access to standardized essential medications in public lists, especially from CEAF; inadequate structure of health departments and dispensing units; dehumanized patient care; and ineffective management of human and financial resources⁹⁻¹².

In 2020, the *Prefeitura Municipal de Campinas* (PMC, Municipal City Hall of Campinas) allocated approximately R\$10.5 million—about 28% of the PA budget—to comply with court decisions, benefited only 0.056% of the population¹³. This highlights the imminent need for public officials to carefully analyze the demands for which they are defendants and the profile of the claimants. Such analysis can inform the formulation and structuring of proposals, goals, indicators, and actions in the city's municipal health plan to mitigate the detrimental effects of judicialization, which include a high financial impact, disorganization of the SUS and public finances, exacerbation of disparities in healthcare access, and the irrational use of medicines¹⁴.

Given this context and the growing expenditure of the *Secretaria Municipal de Saúde de Campinas* (SMS/ Campinas, Campinas Municipal Health Department) on medicines required by court decisions, this study assessed the profile of the judicialization of access to medicines in Campinas from 2017 to 2021 by considering the litigants' sociodemographic characteristics, procedural aspects of the lawsuits, medical-sanitary characteristics, and political-administrative characteristics (PA management). We also estimated the time required to issue decisions granting preliminary injunctions or early tutelage, sentences, or the conclusion through the extinction of the judicial process (i.e., dismissed without resolution of the merit).

Method

Study design

A quantitative, analytical, and comparative cross-sectional approach was employed to examine the data collected from the judicial pharmacy (JP) of the SMS/Campinas and the *Tribunal de Justiça do Estado de São Paulo* (TJSP, Court of Justice of the State of São Paulo), Campinas Forum. The *Fundação Oswaldo Cruz* (Fiocruz, Oswaldo Cruz Foundation) Manual of Indicators for Evaluating and Monitoring Judicial Demands for Medicines (hereinafter, Fiocruz's Manual)¹⁵ was used to select the indicators. To guarantee the quality and consistency of research, we followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines¹⁶.

Study site

This study was carried out in Campinas, a city in the state of São Paulo with an estimated population of 1.3 million, making it the 3rd most populous city in the state and 14th in Brazil¹⁷. As the hub of the *Região Metropolitana de Campinas* (RMC, Campinas Metropolitan Region), composed of 20 municipalities, the city of Campinas serves as a reference for the provision of healthcare services at various levels of complexity to more than 3.3 million inhabitants. The municipality is the full manager of the healthcare system and adopts the organizational model of the SUS's Family Health Strategy to guide primary care in addressing the health needs of the population¹⁸.

Study population

We assessed the medicine outflows recorded in the JP database under the management of the Departmental Supply Coordination of the SMS/Campinas and information from the TJSP, Campinas Forum, specifically lawsuits that had the PMC as the defendant in the period 2017–2021. Careful application of the exclusion criteria eliminated court cases and JP dispensations unrelated to the medicines, as well as lawsuits filed with the TJSP, Campinas Forum in which the PMC was not a defendant.

Variables

Twelve of the thirty indicators from Fiocruz's Manual¹⁵ were selected and are highlighted below with an asterisk (*). We also used nine other indicators. The variables were organized into four dimensions, described below.

1. **Sociodemographic characteristics of the plaintiffs** refer to the proportions of the population by sex, age group*, occupation*, and domicile*.
2. **Procedural characteristics of the lawsuits** refer to the proportions of (a) lawsuits by plaintiff's representation*; (b) lawsuits with the gratuity of justice; (c) lawsuits granting preliminary injunctions or early tutelage*, including the average and median* time for this decision (in days) and the situational description of the judicial cases for the medication (judgment rendered, ongoing process, dismissals without resolution of the merit); and (d) judgments in favor of the plaintiff*, including the average and median time elapsed until sentencing or dismissal without resolution of the merit (in months).
3. **Medical–sanitary characteristics of the medicines** refer to the proportions of medicines in therapeutic groups (1st ATC level), medicines prescribed by generic name*, requested medications in the current essential medication lists (with the same active ingredient, pharmaceutical form, and dosage), required medications that have therapeutic equivalent (similar or generic) on the Brazilian market (according to the *Agência Nacional de Vigilância Sanitária* [Anvisa, National Health Surveillance Agency] website), and new medicines prescribed by trade name.
4. **Political–administrative characteristics (PA management)** refer to the proportions of medications by regulatory category at the Anvisa, medications registered with the Anvisa*, and medications by component of the PA financing block*.

Data sources/measurement

The procedural information of the lawsuits and plaintiffs' sociodemographic information (occupation and domicile) were obtained through the Access to Information Law of the TJSP, Campinas Forum. Information on medical–sanitary, political–administrative, and sociodemographic characteristics (gender and age) was based on the information contained in the database of items being dispensed by the JP of the SMS/Campinas.

To complement this information, official websites of the Ministry of Health, Anvisa, *Câmara de Regulação do Mercado de Medicamentos* (CMED, Medicines Market Regulation Chamber), World Health Organization Collaborating Center for Drug Statistics Methodology's Anatomical Therapeutic Chemical (ATC) Classification System, *Secretaria Estadual de Saúde do Estado de São Paulo* (SES/SP, São Paulo State Health Department)—PA, and SMS/Campinas—PA were consulted.

The data were systematized in a semi-structured electronic instrument using the Microsoft Excel 2013 program for processing and statistical analysis. The spreadsheets contained rows representing each lawsuit or item being dispensed by the JP, and columns containing the variables of interest.

Bias

To avoid possible sources of bias, errors and duplications in the database were corrected. Variables were categorized and technical terms were standardized. In addition, any discrepant values we detected were removed, and missing data were obtained from the official websites of public agencies to complement the use of semi-structured electronic instruments.

Sample size

The sample for this study comprised all drug lawsuits filed against the PMC and all records of the supply of drugs intended for plaintiffs who obtained the benefit of a preliminary injunction, early tutelage, or a favorable sentence, including those who were attended to during the study period and whose judicial decisions were rendered before 2017.

Statistical methods

The descriptive analysis of the data was carried out in collaboration with the biostatistics service of the School of Medical Sciences of the Universidade Estadual de Campinas. Frequency tables were drawn for the categorical variables, while position and dispersion measures were calculated for the continuous variables, thus providing a basis for data analysis.

To compare continuous measurements among three or more groups, both the mean and median times were calculated using the Kruskal–Wallis test, supplemented, where necessary, by the Dunn test. The significance level adopted for all statistical tests was 5%. The statistical programs used in this study were the R Core Team (2020), version 9.4 of the SAS System for Windows, and version 7.2.5.0 of the Epi Info™ Team (2021).

Ethical issues

The Research Ethics Committee of the Universidade Estadual de Campinas approved this study (CAAE: 55551921.6.0000.5404). The requirement for informed consent was waived by Research Ethics Committee of the Universidade Estadual de Campinas because only anonymized retrospective data were obtained from databases. All methods were performed in accordance with the relevant guidelines and regulations.

Results

From 2017 to 2021, the JP of SMS/Campinas registered 41,209 dispensations of PA-related items. A total of 18,587 items were excluded, of which 12,149 (29.5%) were medical hospital materials; 3,772 (9.1%) were insulin infusion pump systems; 2,636 (6.4%) were food and supplements; and 30 (0.1%) were medicines not regulated by the Anvisa. The sample included 22,622 (54.9%) dispensations across 506 pharmaceutical presentations (322 active substances, single drugs or combinations) intended for the care of 770 litigants (0.68% of the population of Campinas). The analysis also included the following 493 lawsuits over the years studied: 140 (2017), 109 (2018), 129 (2019), 52 (2020), and 63 (2021).

An analysis of sociodemographic characteristics revealed that the litigants were mainly adults (20–59 years, 43.1%), older persons (≥ 60 years, 27.6%), and females (52.3%). The majority declared themselves to be students (28.6%), retired/pensioners (25.0%), and with no formal income (24.1%). Some litigants against the PMC (2.2%) were not residents of Campinas but came from cities in the RMC region or São Paulo (Table 1).

The majority of the procedural characteristics (Table 2) included representation by private lawyers (69.8%) and gratuitousness of justice (84.4%). Injunctions or early tutelage were granted to 43.0% of the patients. Of the patients analyzed, 383 (77.7%) had already been sentenced. Furthermore, 81.7% of the judgments were favorable to the plaintiff's request, with 74.9% being fully favorable, guaranteeing the plaintiff's right to all the requested items. No class actions were identified.

Sociodemographic variables	Frequency (n)	%
Proportion of the population by gender (n=770)		
Female	403	52.3
Male	367	47.7
Proportion of the population by age group (n=770)		
< 1 year	0	0.0
01–04 years	18	2.3
05–09 years	43	5.6
10–14 years	64	8.3
15–19 years	65	8.4
20–29 years	101	13.1
30–39 years	86	11.2
40–49 years	74	9.6
50–59 years	71	9.2
60–69 years	83	10.8
70–79 years	70	9.1
≥ 80 years	59	7.7
Unknown	36	4.7
Proportion of the population by occupation (n=493)		
Student	141	28.6
Retiree/Pensioner	123	25.0
Occupation included in the CBO	98	19.9
Unemployed	69	14.0
Homemaker	39	7.9
No occupation included in the CBO	11	2.2
Unknown	12	2.4
Proportion of the population by the municipality of the litigant's domicile (n=493)		
Campinas	482	97.8
Others	11	2.2

Table 1. Sociodemographic characteristics of the plaintiffs for medicines in Campinas, São Paulo, Brazil; 2017–2021. *Source:* Authors' own elaboration based on the research data. *Variables (gender and age group):* Judicial Pharmacy Review (12/31/2021). *Variables (occupation and domicile):* São Paulo State Court of Justice (categorized). *Categorization:* Adults (20–59 years); Older person (≥ 60 years); *Population without formal income* (unemployed, homemaker, and other occupations not included in CBO). *CBO:* Classificação Brasileira de Ocupações (Brazilian Classification of Occupations).

Procedural variables of the judicial proceedings	Frequency (n)	%
Proportion of lawsuits by plaintiff's representation (n=493)		
Private lawyer	344	69.8
Public defender's office/Public prosecutor's office	149	30.2
Proportion of lawsuits with the gratuity of justice (n=493)		
Yes	416	84.4
No	77	15.6
Proportion of lawsuits granting preliminary injunctions or early tutelage (n=493)		
Yes (totally)	193	39.2
Yes (in part)	19	3.8
No	281	57.0
Time for preliminary injunction or early tutelage decision at the first instance (in days; n=212)		
0–30	163	76.9
31–90	33	15.6
>90	16	7.5
Situational description of the judicial cases for medication (n=493)		
Sentence rendered	383	77.7
Ongoing process	50	10.1
Process dismissed without resolution for various reasons	60	12.2
Proportion of judgments in favor of the plaintiff (n=383)		
Completely favorable sentence	287	74.9
Partially favorable sentence	26	6.8
Unfavorable sentence	70	18.3
Time elapsed until the sentence or dismissal of the case (in months; n=383)		
0–6	173	45.2
>6–12	105	27.4
>12–24	75	19.6
>24	30	7.8

Table 2. Procedural characteristics of the lawsuits for medicines in Campinas, São Paulo, Brazil; 2017–2021. *Source:* Authors' own elaboration based on the research data.

The median time elapsed between the date of case distribution and the granting of an injunction or preliminary injunction, in the period between 2017 and 2021, was 12 days (23.1% of these cases lasted over 30 days). The Kruskal–Wallis test results showed a significant difference ($p < 0.001$) between time (in days) and the year of the judicial decision. Dunn's post hoc test identified a significant increase ($p < 0.05$) in the median time in the periods 2017–2019, 2017–2020, 2017–2021, 2018–2020, 2018–2021, and 2019–2021 (Table 3).

Additionally, the median time between the date of case distribution and judgment or dismissal without resolution of merits was 6.5 months (54.8% of these cases lasted more than six months). The Kruskal–Wallis test results also showed a significant difference ($p < 0.001$) between time (in months) and the year of the judicial decision. Dunn's post hoc test identified a significant reduction ($p < 0.05$) in the median time in the periods 2017–2018, 2017–2019, and 2017–2020, indicating a faster analysis of lawsuits. However, even with a reduction in the number of new lawsuits, a significant increase in time was found in 2021 compared with the years 2018–2020 (Table 3).

The analysis of the medical–sanitary characteristics showed that the most requested medicines were related to the nervous system (21.7%), alimentary tract and metabolism (21.3%), cardiovascular system (16.8%), and anti-neoplastics and immunomodulators (11.9%). In addition, 1.4% of the items requested as medicines did not have an active substance recognized in the ATC classification. The requests for medicines were predominantly made by the trade name (53.8%). The frequency of prescribing a new medicine by the trade name was 78.8% (Table 4).

Regarding the medicines made available by the SUS, the number of medicines incorporated into Rename increased from 136 (26.9%) in 2017 to 164 (32.4%) in 2020—a 20.6% increase. This occurred exclusively within the CEAf. Of the 164 medicines included in Rename in 2020, 78 (15.4%) were part of the official list of medicines of the CEAf, the supply of which is the responsibility of the SES/SP, and 58 (10.5%) were from the *Relação Municipal de Medicamentos Essenciais* (Remume, Municipal List of Essential Medicines) of Campinas, which is made available by the PMC in the basic health units (Table 4).

In the political–administrative management of PA (Table 5), 34.6% of the medicines purchased were reference medicines, 34.6% were generics, and 12.6% were biologicals, totaling 82.1% of the purchases. Additionally, except for 30 items exempt from registration, 15 compounded formulations, and 6 imports, all had Anvisa's marketing authorization. The most requested PA component was the CEAf, which varied from 49.3% in 2017 to 57.9% in 2020 (Table 5).

Variable	Year of filing (start of the process)						p value*
	2017	2018	2019	2020	2021	2017–2021	
A. Time elapsed between the date of filing and the date of granting a preliminary injunction (in days; n=212)							
Mean (Standard deviation)	52.07 (197.40)	38.41 (142.11)	34.92 (69.58)	26.68 (29.41)	28.00 (35.72)	36.31 (113.22)	<0.001
Median (1st–3rd quartile)	1.00 (1.00–6.50)	6.50 (1.00–21.25)	10.00 (2.00–27.00)	15.00 (10.25–32.25)	20.00 (13.00–31.00)	12.00 (1.00–27.25)	
Minimum–Maximum (valid n)	0.00–1.047.00 (28)	0.00–1.088.00 (64)	0.00–321.00 (65)	0.00–122.00 (22)	3.00–210.00 (33)	0.00–1.088.00 (212)	
Quantitative variable	Period	p value	Period	p value	Period	p value	
A.1. Dunn's post hoc analysis for the time elapsed between the date of filing and the date of granting a preliminary injunction by year							
Time elapsed between the date of filing and the date of granting a preliminary injunction (in days)	2017–2018	0.0848	2018–2019	0.1420	2019–2021	0.0091	
	2017–2019	0.0135	2018–2020	0.0185	2020–2021	0.2585	
	2017–2020	0.0019	2018–2021	0.0006			
	2017–2021	<0.001	2019–2020	0.0927			
Variable	Year of filing (start of the process)						p value*
	2017	2018	2019	2020	2021	2017–2021	
B. Time elapsed between the date of filing and the date of sentencing or dismissal of the case (in months; n=443)							
Mean (Standard deviation)	14.24 (12.35)	8.00 (6.78)	7.28 (5.70)	6.23 (2.62)	12.02 (9.33)	10.00 (9.24)	<0.001
Median (1st–3rd quartile)	12.08 (4.90–18.65)	5.50 (3.72–10.00)	5.63 (3.77–8.33)	6.03 (4.47–6.83)	8.68 (6.18–13.70)	6.53 (4.27–12.60)	
Minimum–Maximum (valid n)	1.27–58.67 (134)	1.40–41.03 (107)	0.37–29.80 (121)	2.33–14.90 (33)	3.00–38.77 (48)	0.37–58.67 (443)	
Quantitative variable	Period	p value	Period	p value	Period	p value	
B.1. Dunn's post hoc analysis for the time between the date of filing and the date of sentencing or dismissal of the case in the first instance by year							
Time between the date of filing and the date of the sentence or dismissal of the case in the first instance in months	2017–2018	<0.001	2018–2019	0.3188	2019–2021	0.0001	
	2017–2019	<0.001	2018–2020	0.3915	2020–2021	0.0027	
	2017–2020	0.0003	2018–2021	0.0005			
	2017–2021	0.4177	2019–2020	0.4844			

Table 3. Comparison of the time elapsed between the date of filing and the dates of granting a preliminary injunction or early tutelage, and sentencing or dismissal of the case in the first instance by year in Campinas, São Paulo, Brazil; 2017–2021. *Kruskal–Wallis test Significant results are in bold. Source: Authors' own elaboration based on the research data.

Discussion

Lawsuits in Campinas have proven to be an effective means of gaining access to various health items, including those that are not part of the PA provided by SUS, with the most requested item being medication.

The analysis of sociodemographic characteristics showed that most claimants were women, adults, or older person; this reflects the population profile of the municipality identified in the 2022 demographic census¹⁷ of the city. Costa et al.¹⁹, in a previous study conducted in Campinas, found that the use of medicines was predominant among women older than 40 years, which corroborates our findings. In general, healthcare service organizations offer more health services to women, with specific programs available to them at all life stages, such as prenatal care and prevention of cervical and breast cancer. This contributes to the predominance of women in the access to healthcare services, early diagnosis, prescriptions, and new healthcare technologies.

The economic situation of litigants is often a central issue in discussions about the equitable distribution of public resources, particularly regarding granting individual needs, funded by the government. Despite the lack of information on the litigants' income in this study, it is important to consider the socioeconomic reality of the population of Campinas. Data from the 2022 demographic census¹⁷ also revealed that the average salary of formal workers in the municipality of Campinas is 3.8 times the minimum wage (approximately 30.2% earn up to half the minimum wage). The employment rate was only 38.8%¹⁷.

This study revealed a lower incidence of employed individuals filing lawsuits, suggesting that those who file the most lawsuits are those with lower incomes. This result corroborates the finding of Biehl et al.²⁰ that 53% of litigants had incomes below the national minimum wage. Additionally, as highlighted by Oliveira and Noronha²¹, having a high income does not necessarily mean that people can afford medical treatment, as the high cost of medications can sometimes exceed an individual's or family's financial capacity. Furthermore, according to Kozan and Magalhães²², for some individuals, litigation is the only viable means of obtaining the necessary treatment, effectively enabling them to assert their right to health and social justice. Most importantly, the comprehensive care provided by the SUS is universal²³ and covers all citizens, regardless of their income.

Campinas serves as a gateway for individuals seeking health care but live in neighboring municipalities. This phenomenon explains the identification of lawsuits for nonresidents. However, this implies that Campinas assumes another municipality's responsibility and costs to comply with the court's decision, which diverts resources away from health actions and services planned for the population of Campinas based on local epidemiological data.

The representation of plaintiffs by private lawyers and a high percentage of gratuitousness of justice represented the procedural characteristics of the lawsuits. By correlating these findings with the information available from the demographic census¹⁷ on the employment and income rates of Campinas, we can infer that the legal

Medical-sanitary variables	Frequency (n)	%
Proportion of medicines by therapeutic group (1st ATC level; n = 506)		
N—Nervous system	110	21.7
A—Alimentary tract and metabolism	108	21.3
C—Cardiovascular system	85	16.8
L—Antineoplastic and immunomodulating agents	60	11.9
B—Blood and blood-forming organs	25	4.9
S—Sensory organs	19	3.8
P—Systemic hormonal preparations	18	3.6
R—Respiratory system	18	3.6
Others	56	11.2
Not classified in the ATC classification system	7	1.4
Proportion of medicines prescribed by generic name (n = 506)		
No	272	53.8
Yes	234	46.2
Proportion of requested medications included in the current essential medication of the SUS lists (n = 506)*		
Rename 2017	136	26.9
Rename 2018	137	27.1
Rename 2020	164	32.4
CEAF—SES/SP (accessed on May 14, 2022)	78	15.4
Remume—Campinas (1st edition; December 2020)	58	10.5
Proportion of required medications with a therapeutic equivalent (similar or generic) on the Brazilian market (n = 506)		
Yes	382	75.5
No	124	24.5
Ratio of new medicines prescribed by trade name (n = 118)		
New medicine prescribed by brand name	93	78.8
New medicine prescribed by generic name	25	21.2

Table 4. Medical and sanitary characteristics of the medicines judicialized in Campinas, São Paulo, Brazil; 2017–2021. *Source:* Authors' own elaboration based on the research data. ATC: Anatomical Therapeutic Chemical; CEAF: Componente Especializado da Assistência Farmacêutica (Specialized Component of Pharmaceutical Assistance); *Remume*: Relação Municipal de Medicamentos (Municipal List of Essential Medicines); *Rename*: Relação Nacional de Medicamentos Essenciais (National List of Essential Medicines); SES/SP: Secretaria Estadual de Saúde do Estado de São Paulo (São Paulo State Health Department); SUS: Sistema Único de Saúde (Unified Health System). * The total does not add up to 506 because the same medication can appear on different SUS lists.

costs for plaintiffs may be lower than the costs of prolonged treatment with drugs not provided by the SUS, which are costly. The literature^{24,25} also suggests that, in some cases, legal costs are covered by pharmaceutical laboratories, associations, or nongovernmental organizations that provide free private legal representation to citizens.

Several decisions favored the plaintiffs' claims in legal actions. One reason is that in health-related lawsuits, the judge's decision is often predominantly based on the medical prescription, which is considered sufficient to support the sentence^{26–30}. Thus, judges tend to rule in favor of the plaintiff based on limited evidence²⁶, disregarding recommendations and technical opinions from bodies such as the National Committee for Health Technology Incorporation (CONITEC)²⁹ and the Health Technology Assessment Centers (NATS)²⁸.

The manifestation of public administration contesting the claimant's request is also part of the judicial process. In the PMC, the body responsible for the municipality's defense is the Office of Specialized Legal Advisory of the Department of Justice³¹, which refutes the request based on the technical opinions issued by doctors and pharmacists from the Municipal Health Department and the current health legislation. However, the results of the present study show that judges predominantly rule in favor of the litigants' requests for medications not included in the municipal SUS list (CBAF). This highlights the judiciary's interference in health management.

The National Council of Justice (CNJ) has played an important role in establishing the criteria for regulating the process, mainly through recommendations, resolutions, public hearings, and forums, aiming to train judges on the various aspects and challenges of health-related demands. In 2018, the Technical Support Center for the Judiciary (NAT-Jus), comprising health professionals, was created to provide technical opinions on the demanded health technologies and assist the courts with medical- and health-related concepts³². However, a recent study found that in 94.1% of the cases, the medical report was the main basis for the decision, with technical opinions from NATS used in only 22.2% of the cases²⁸. Similarly, 68% of the decisions regarding treatments not covered by the health system and 45% of the decisions on treatments without Anvisa approval were based solely on the medical prescription²⁹.

Particularly in the context of the judicialization of cancer treatments, the literature reveals a complex triad comprising the vulnerability and propensity of patients to initiate legal proceedings in search of treatment³³,

Pharmaceutical assistance management variables	Frequency (n)	%
Proportion of medications by regulatory category at the Anvisa (n = 506)		
Reference	175	34.6
Generic	175	34.6
Biological	65	12.9
Similar	25	4.9
Specific	23	4.6
Food	19	3.8
Compounded	15	3.0
Uncategorized (imported)	6	1.2
Phytotherapics	3	0.6
Proportion of medications registered with the Anvisa (n = 506)		
Yes	467	92.3
No	06	1.2
Exempt from registration	33	6.5
Proportion of medications by component of the PA financing block of the SUS		
Rename 2017 (n = 136)		
CEAF	67	49.3
CBAF	61	44.9
CESAF	4	2.9
CBAF/CEAF	3	2.2
CBAF/CESAF	1	0.7
Rename 2018 (n = 137)		
CEAF	68	49.6
CBAF	61	44.5
CESAF	4	2.9
CBAF/CEAF	3	2.2
CBAF/CESAF	1	0.7
Rename 2020 (n = 164)		
CEAF	95	57.9
CBAF	61	37.2
CESAF	4	2.4
CBAF/CEAF	3	1.8
CBAF/CESAF	1	0.6

Table 5. Political-administrative characteristics (PA management) of lawsuits for medicines in Campinas, São Paulo, Brazil; 2017–2021. *Source:* Authors' own elaboration based on the research data. *PA:* Pharmaceutical Assistance; *Anvisa:* Agência Nacional de Vigilância Sanitária (National Health Surveillance Agency); *CBAF:* Componente Básico da Assistência Farmacêutica (Basic Component of Pharmaceutical Assistance); *CEAF:* Componente Especializado da Assistência Farmacêutica (Specialized Component of Pharmaceutical Assistance); *CESAF:* Componente Estratégico da Assistência Farmacêutica (Strategic Component of Pharmaceutical Assistance); *Rename:* Relação Nacional de Medicamentos Essenciais (Rename – National List of Essential Medicines); *SUS:* Sistema Único de Saúde (Unified Health System).

the interest of the pharmaceutical industry in developing medicines with greater financial returns¹⁰, and the inclination of the judiciary in legal actions to favor patients seeking cancer treatment³³.

The waiting time for litigants seeking access to medication through legal actions is crucial to ensure treatment starts properly. In this study, a quarter of the litigants experienced delays of more than 30 days in obtaining injunctions or early tutelage, a benefit granted to less than half of them. Most judgments took more than six months to be finalized, indicating critical delays, especially for cancer and other serious illnesses. The judicial determination for public administration to provide medication to the litigant does not guarantee immediate access, and the time required for public administration to comply with the legal formalities for the acquisition of non-standardized medicines in the SUS must also be considered. Therefore, the long waiting times faced by citizens highlights that, although the judicial route ensures therapeutic care, it is not free from implications, whether clinical and/or physical^{34–36}, psycho emotional³⁷, or financial³³.

The most requested medications were those used to treat neurological disorders and chronic degenerative diseases. These conditions are associated with several factors, including aging, lifestyle, environment, work, injuries, autoimmune diseases, and genetic predispositions. In this study, medications such as nintedanib and pirfenidone (for idiopathic pulmonary fibrosis), ibrutinib (for chronic lymphocytic leukemia), omalizumab (for persistent allergic asthma), ranibizumab (for macular degeneration and diabetic retinopathy), abiraterone

(for prostate cancer), immunoglobulins (for chronic inflammatory polyradiculoneuropathy demyelinating), ustekinumab (for psoriasis and psoriatic arthritis), and insulin analogs (for diabetes mellitus) were the judicialized medications that incurred the highest costs for the municipality, due to the high clinical complexity of the treated diseases and the individual cost of these medications.

Treatments for these conditions often require the continuous use of medications for extended periods, highlighting the long-term impact that a single legal demand causes on the public administration budget.

It is important to emphasize that mere access to medication does not guarantee the realization of the right to health. Comprehensive health care is achieved only through pharmacotherapeutic monitoring of the litigant to assess effectiveness, monitor serious adverse effects, and adjust dosage as needed. However, a study showed that in 78% of judicial decisions, periodic reassessment of medication provision based on medical reports and updated prescriptions was not required by the judiciary³⁰.

Medicines belonging to the CEAf were the most litigated, which corroborates findings from studies conducted in other municipalities^{38–40}. According to the organizational structure of the SUS, CEAf medications, owing to their high individual cost and dispensation linked to the Clinical Protocols and Therapeutic Guidelines (PCDTs), are funded and distributed by the State and the Ministry of Health⁴¹. The municipality is responsible for the purchase and dispensation of CBAf medications, which have tripartite funding. Therefore, when the judiciary assigns an obligation to provide medication to a municipality that is the responsibility of the State or Union, it imposes an additional burden on the municipality⁴² because the medications requested through the judicial pathway are not accounted for in financial planning.

The judicialization of medications already incorporated into the SUS aims to correct administrative failures in the provision of these technologies and defend the exercise of the rights recognized and guaranteed in health policies⁴³. This practice is often justified by gaps in PA management; the freezing of minimum health investments; poor management of limited financial resources; and shortages because of insufficient planning, inadequate logistics, or delays in procurement processes^{8,14,44}.

Mello et al.²⁷ have identified three main reasons for the judicialization of medicines within the CEAf: inadequate knowledge of the access flow by prescribers and patients, patient difficulties in meeting CEAf requirements, such as the periodic submission of monitoring exams, and the absence of the litigant's clinical indication in the PCDT.

These factors urgently need to be reagreed upon between different spheres of government and the judicial system. This would impact clinical aspects related to the timely treatment of the plaintiff's health problems and the prioritization of essential medicines already included in the Ministry of Health's PCDTs, which would allow immediate access through administrative channels.

We also observed the prevalence of requests for medications by their brand names, which was in disagreement with Federal Law No. 9797/1999⁴⁵ that mandates the use of generic names for acquisitions and medical prescriptions within the SUS. In the private health sector, doctors have the autonomy to prescribe their preferred medication. However, prescribing by brand name forces the state manager to purchase products from a specific manufacturer, contrary to public procurement legislation and in violation of the principle of economic efficiency. According to Oliveira and Noronha²¹, people often seek legal intervention to obtain a specific brand, even when equally safe and effective alternatives are available for free within the SUS, thereby increasing access inequalities and raising ethical questions about judicialization. The judiciary's adoption of the generic drug policy⁴⁵ in judicial decisions, that is, allowing public administration to provide medications by their generic names, would promote equality in meeting demands regardless of the prescription's origin.

This study also revealed a correlation between a certain medication being new and being prescribed with a specific brand. This practice has multiple implications, including increased healthcare costs, favoring specific pharmaceutical industries, reduced competitiveness in the generic market, challenges in substituting therapeutic equivalents, and influencing patients' expectations regarding the benefits of innovative treatments^{22,26,46–48}. However, only a few drugs registered as new represent therapeutic innovations with clinical benefits superior to those of current drugs^{48,49}.

Finally, we highlight the impasse imposed on public administration when the court order is to supply imported medicines. The acquisition request overrides Executive Branch legislation⁵⁰, which prohibits the dispensing of medicines that do not have Anvisa's marketing authorization at all SUS management levels.

Some strategies to fill the gaps leading litigants to see judicial intervention as the most effective way of guaranteeing access to medicines in the municipality include adopting strategies for monitoring and evaluating lawsuits to recognize the real needs of the local population; discussing problems with inter-federative commissions and the municipal health council; disseminating information to the community, health professionals, and other interested parties about the municipality's PA policy; and accessing primary care, specialized, and oncological medicines.

Some limitations of this study include the complexity of accessing justice profiles, which are influenced by the socioeconomic, cultural, and health context of each plaintiff, and the lack of information in the JP database regarding the amount of time the public administration needs to deliver the medications required by plaintiffs in lawsuits after the court order has been granted.

Conclusions

The judicialization of medicines in Campinas represents an alternative way to access medications, but it brings significant challenges pertaining to prolonged wait times, whereas the benefits are only limited to a portion of the population that turns to the judiciary. Access to non-standardized treatments in the SUS, especially oncological and immunobiological medications, highlights the urgent need to review health policies to promote more

equitable and efficient access to essential treatments for the population, with particular attention to medications provided by CEAF aimed at reducing their judicialization.

The complexity and implications of judicialization in public health management require a comprehensive approach that considers current health legislation and the need for extensive cooperation among federative entities and the judiciary, aiming to find more effective solutions for the benefit of the community. When proposing health actions and policies, it is crucial to consider the clinical, healthcare-related, emotional, and financial aspects faced by litigants when accessing medications through judicialization, and to seek measures that ensure fair, adequate, and timely access.

Data availability

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

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Author contributions

S.C.P.O. participated in the conceptualization, analyzed and interpreted the data, prepared de tables 1–5, and was the major contributor to writing the main manuscript. PM provided supervision and conducted a relevant critical review of the manuscript. MBV participated in the conceptualization, interpreted the data, provided supervision, and conducted a relevant critical review of the manuscript. M.B. conducted a relevant critical review of the manuscript. All authors read and approved the final manuscript.

Competing interests

The authors declare no competing interests.

Additional information

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