



Judicialization of drugs for the treatment of hepatitis C in the state of Rio Grande do Sul, Brazil

Judicialização de medicamentos para tratamento da hepatite C no estado do Rio Grande do Sul, Brasil

Bonnia Acosta Vinholes¹, Alice Hirdes², Letícia Thomast Jabnke Botton³

¹Programa de Pós-graduação Mestrado em Promoção da Saúde, Universidade Luterana do Brasil (ULBRA), Canoas (RS), Brasil;

²Programa de Pós-graduação Mestrado em Promoção da Saúde, Universidade Luterana do Brasil (ULBRA), Canoas (RS), Brasil;

³Programa de Pós-graduação Mestrado em Promoção da Saúde, Universidade Luterana do Brasil (ULBRA), Canoas (RS), Brasil.

*Corresponding author: Bonnia Acosta Vinholes – E-mail: bonnia@gmail.com

ABSTRACT

This article aimed to identify the reasons that led people to seek the Judiciary Power to obtain medication for the treatment of hepatitis C. This was a quantitative cross-sectional descriptive study of 235 judgments and monocratic decisions rendered by the Court of Justice of the state of Rio Grande do Sul between 2010 and 2020. The main reason why people turn to the judiciary to obtain medication for the treatment of hepatitis C was low-income, followed by non-compliance with the requirements of the Clinical Protocol and Therapeutic Guidelines for Hepatitis C and Coinfections, lack of predictability in having the medication in the public list, zero stock, and required medication without registration with ANVISA. The results also pointed out that health judicialization is not a phenomenon restricted to low-income; the most required drugs are Ribavirina, Interferon, Sofosbuvir, and Daclatasvir; the percentage of judicial concession of medicines was 93.6%. In conclusion, there is a need to reassess the Clinical Protocol and Therapeutic Guidelines for Hepatitis C and Coinfections, the National Plan for Viral Hepatitis, and the Plan for the Elimination of Hepatitis C.

Keywords: Health judicialization. Public Policy. Pharmaceutical Care. Hepatitis C. Health Systems.

RESUMO

O artigo tem por objetivo identificar quais motivos levaram as pessoas a buscarem o Poder Judiciário, a fim de obter medicamentos para tratamento da hepatite C. Trata-se de um estudo descritivo transversal, de natureza quantitativa, no qual foram analisados 235 acórdãos e decisões monocráticas proferidas pelo Tribunal de Justiça do Estado do Rio Grande do Sul entre os anos de 2010 e 2020. Os resultados evidenciam que o principal motivo pelo qual as pessoas recorrem ao Judiciário para tratamento da hepatite C é a insuficiência de renda, seguido pelo não atendimento aos requisitos do Protocolo Clínico e Diretrizes Terapêuticas para Hepatite C e Coinfecções, a ausência de previsão em lista pública de medicamentos, o estoque zerado e medicamento requerido sem registro na ANVISA. Os resultados também apontaram que a judicialização da saúde não é um fenômeno adstrito às pessoas de baixa renda; os medicamentos mais requeridos são a Ribavirina, o Interferon, o Sofosbuvir e o Daclatasvir; o percentual de concessão judicial de medicamentos é de 93,6%. Conclui-se que há necessidade de reavaliação do Protocolo Clínico e Diretrizes Terapêuticas para Hepatite C e Coinfecções, do Plano Nacional de Hepatites Virais e do Plano para Eliminação da Hepatite C.

Palavras-chave: Judicialização da saúde. Política pública. Assistência farmacêutica. Hepatite C. Sistemas de Saúde.

Received in August 15, 2022

Accepted in March 03, 2023

INTRODUCTION

Data from the World Health Organization (WHO) indicate that there are, in the world, around 71 million people infected with the hepatitis C virus. Also, in 2016, around 399,000 people died as a result of hepatitis C, especially cirrhosis and liver cancer¹. In Brazil, figures from the Ministry of Health, released at the end of July 2020, indicate that 22,474 cases of hepatitis C were registered, and in the same year, the aforementioned government agency restructured the model of acquisition, programming, and distribution of medicines for viral hepatitis. The same epidemiological bulletin indicated that the South region had the highest number of cases of hepatitis C, 23.9 per 100,000 inhabitants, with Porto Alegre being the Brazilian capital with the highest rate, 84.4 cases every 100,000 inhabitants².

Because it is a public health problem, due to the high percentages of chronicity of the disease, evolutionary potential, virological diversity, forms of transmission, and diagnostic and therapeutic complexity, hepatitis C is a disease that demands specific health policies³. In Brazil, the Ministry of Health and state secretariats have implemented actions in the field of prevention, such as the National Program for the Prevention and Control of Viral Hepatitis⁴, and also of control, detection, and treatment, such as the Clinical Protocols and Therapeutic Guidelines (PCDTs). Among the items covered by the PCDT for hepatitis C and coinfections are the criteria for diagnosis, treatment, care for patient safety, clinical control mechanisms, and means for monitoring and verifying therapeutic results by health professionals and managers⁵. Although the Unified Health System is based on the principles of social justice, equality, and universal access, public policies are often not sufficient or fail to implement the right to health.

Health, according to Article 196 of the Federal Constitution, is a right of all and a duty of

the State, ensured through social and economic policies aimed at reducing the risk of diseases and also equal access to actions and services for its promotion, protection, and recovery⁶. The right to health makes the State responsible not only for the prevention, treatment, and control of diseases but also for the creation and implementation of policies that, in addition to guaranteeing access to health in its broadest sense, should enable individuals to have greater control over conditions that affect their health⁷.

In this context, the failure to implement public policies has caused the Judiciary Power to be called upon to intervene and oblige federal entities to meet the right to health⁸. This interference of the Judiciary Power in the creation and implementation of public policies related to that right is called judicialization of health. The result of this new paradigm is a growing number of individual lawsuits that claim everything from hospital beds to other forms of health-related provision, which have proven to be the fastest way to enforce the right⁹.

Among the public policies impacted by judicialization is pharmaceutical assistance, which presents several challenges in terms of its design, operation, updating of lists of medicines distributed by the SUS, transparency of clinical protocols, absence of appeal instances, speed in decisions, articulation with other spheres of inspection and registration^{10,11}. Judicialization is a product generated by the fragility of the system, which not only guarantees the realization of a social right but also raises the need to evaluate existing public policies and create new ways to ensure rights, as the courts are overloaded¹².

The general objective of the present study was to investigate the reasons people appealed to the Judiciary to request the State to supply medicines for the treatment of hepatitis C, given the existence of specific public policies and the Plan for the Elimination of Hepatitis C by the year 2030. Among the specific objectives are: (i) to identify the medications most required in

court; (ii) to verify whether the cause of claim of the lawsuit indicates gaps in the pharmaceutical assistance policy and/or Clinical Protocol and Therapeutic Guidelines; (iii) to estimate the percentage of success of the demands that deal with the supply of medicines; and (iv) find out if the judicialization of health is a phenomenon restricted to low-income people.

METHOD

This was a quantitative cross-sectional descriptive study of judgments and monocratic

decisions rendered by the Court of Justice of the state of Rio Grande do Sul, in legal proceedings that seek the supply of medicines for the treatment of hepatitis C, in the period from 2010 to 2020.

In order to obtain the decisions that were the object of analysis, a search was first carried out in the jurisprudence research system available on the website of the Court of Justice of the state of Rio Grande do Sul¹³, in which the descriptors ‘medication’ and ‘hepatitis C’, in addition to the Boolean operator ‘and’ (illustration 1), which resulted in 770 decisions that contained the descriptors used in its menu (illustration 2):

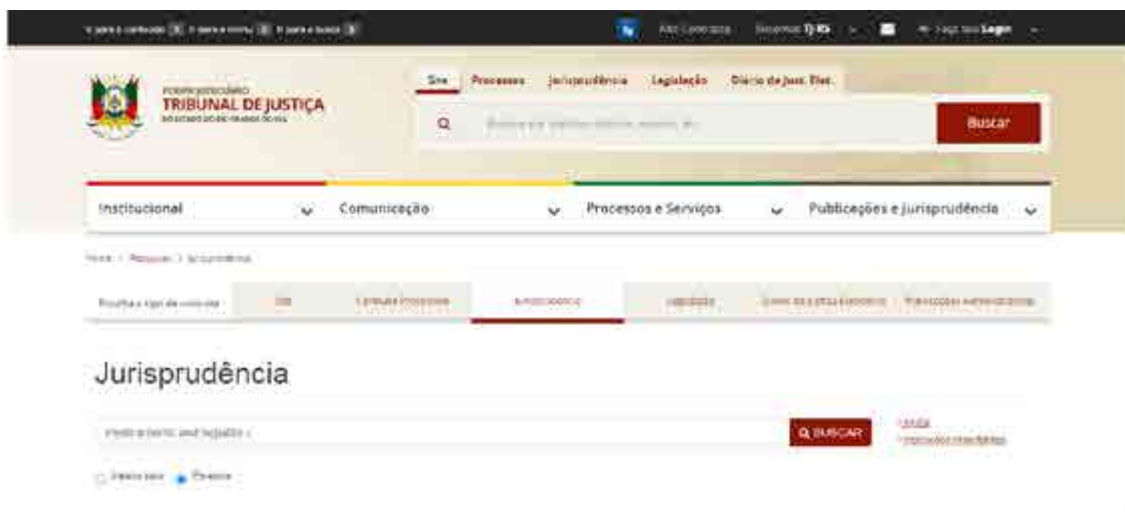


Figure 1. Busca de jurisprudência
Source: Rio Grande do Sul (2015)¹³.

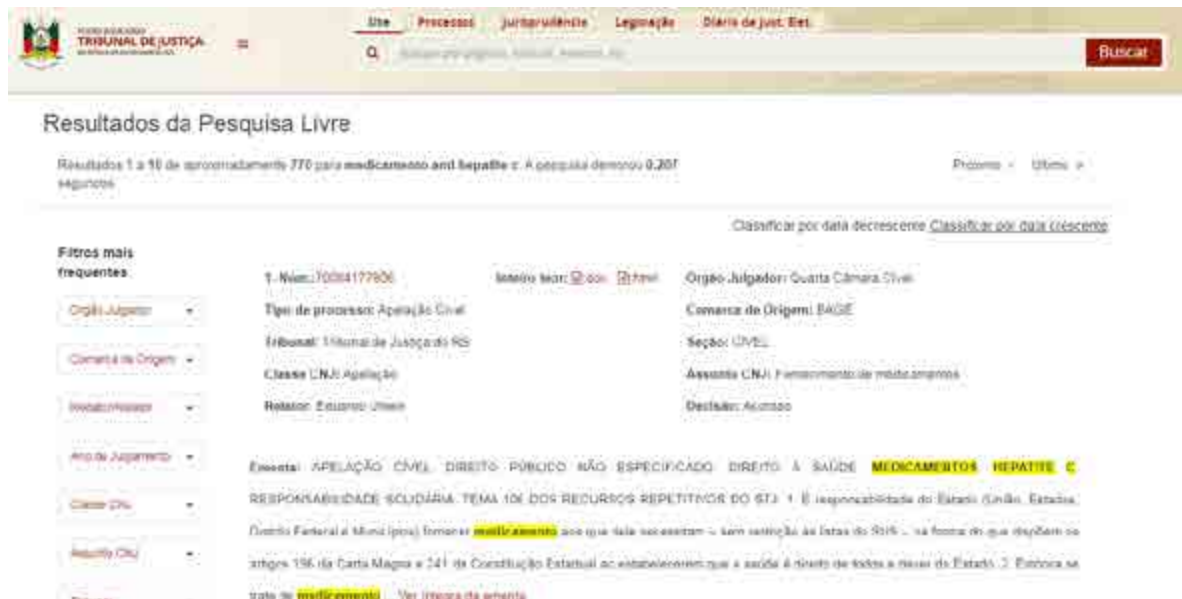


Figure 2. Resultado da pesquisa livre
Source: Rio Grande do Sul (2015)¹³.

As the Court’s search system presents all the decisions containing the descriptors used in the menu, without going into the merits, a second filter was applied, through the individualized analysis of the results, which led to the exclusion of decisions of cases that dealt with exemption taxes, civil liability, private health plans, life insurance, criminal law, accountability, accident and illness assistance, leaving 299 decisions eligible for the study.

Once the decisions suitable for the study were cataloged, they were submitted to the application of an instrument developed by the author specifically for the study, consisting of open and closed questions. Data were collected by three lawyers aligned for that purpose, considering as an inclusion criterion those decisions in which the state of Rio Grande do Sul appeared as a defendant, and exclusion criteria: (i) decisions whose content dealt with strictly procedural issues such as costs, blocking of amounts, fees, annulments, and suspension, (ii) public civil actions, (iii) lawsuits in which the plaintiff has withdrawn, and (iv) decisions on the motion for clarification. Also, decisions issued in the context of an interlocutory appeal were discarded, when the decision of the appeal was already included in

the database, as well as judgments with different numbers, but related to the same process, in order to avoid a double analysis. In the end, 235 decisions were evaluated, whose data are part of the results of the present study.

The variables researched were: the sex of the plaintiff, the district of origin, the type of sponsorship of the lawsuit, whether there was a request for free legal assistance or free justice, the amount of prescribed drugs, the name(s) of the required medication(s), the duration of the treatment, the reason for filing the lawsuit (cause of claim), the existence or not of an administrative request and whether the medication was granted in court.

Consolidated data were organized in a Microsoft Office Excel spreadsheet and analyzed using descriptive statistics (absolute and relative frequency), obtained with the help of IBM® SPSS Statistics for Windows, Version 22.0 software.

According to Article 1, sole paragraph, item II, of the Resolution of the National Health Council 510, of April 7, 2016, this research was not submitted to the Research Ethics Committee since we used data obtained from the website of the Court of Justice of the state of Rio Grande do Sul, which can be accessed by any citizen.

RESULTS AND DISCUSSION

Of the decisions analyzed, 54.9% were related to lawsuits filed by males and 45.1% by females. The result obtained is in line with the

information obtained from the Ministry of Health website¹⁴, which indicates that, in the period from 2010 to 2020, the number of men infected with hepatitis C was higher than women (see Table 1).

Table 1. Hepatitis C cases and detection rate (per 100,000 population) by sex and year of notification, 2010-2020

| Hepatitis C | Total | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | 2020 |
|----------------------|--------|------|------|------|-------|-------|-------|-------|-------|-------|-------|-------|
| Men | 19,524 | 858 | 823 | 796 | 1.023 | 1.339 | 2.860 | 2.827 | 2.579 | 2.608 | 2.471 | 1.340 |
| Rate (male gender) | - | 16.5 | 15.8 | 15.2 | 19.0 | 24.7 | 52.6 | 51.7 | 47.0 | 47.3 | 44.6 | 24.1 |
| Women | 15,627 | 700 | 651 | 704 | 856 | 1.020 | 2.322 | 2.260 | 1.977 | 2.175 | 2.023 | 939 |
| Rate (female gender) | - | 12.8 | 11.8 | 12.7 | 15.1 | 17.9 | 40.5 | 39.2 | 34.1 | 37.4 | 34.6 | 16.0 |

Source: Brasil (2020)¹⁴.

(1) Data up to 31 dec 2020; (2) Preliminary data for the last 5 years.

With regard to the district of origin, 74.5% lawsuits came from cities in the interior of the state of Rio Grande do Sul. In this regard, according to the Epidemiological Bulletin of Viral Hepatitis, in 2019, Porto Alegre was the Brazilian capital with the highest detection rate of hepatitis C, with 84.4 cases per 100,000 inhabitants². This data not only indicates that most lawsuits come from cities other than the capital Porto Alegre, but also raises a series of questions that, due to the limitations of the present study, cannot be answered. More in-depth studies on related issues, such as, for example, if access to medicines is easier for residents of the capital, or if physicians from cities other than the capital have a greater tendency to prescribe medicines that are not available at the public health network, or even if the number of appeals filed against decisions issued by judges from cities other than the capital is greater than the number of appeals against decisions originating in the capital, are relevant to broaden the understanding of the studied phenomenon and the result found.

Regarding the variable “type of sponsorship of the lawsuit”, the results are analyzed together with those related to the variable “request for free legal assistance or

free justice” once they aim to verify whether judicialization is a phenomenon restricted to people with low income.

One of the existing hypotheses regarding the judicialization of health is that it is an elitist phenomenon^{9,15,16,17}. This proposition had already been rejected, in the context of Rio Grande do Sul, by a study that analyzed 1,262 court cases from the year 2008, which verified that more than half of lawsuits were sponsored by the Public Defender’s Office and 91% plaintiffs obtained some type of gratuity benefit¹⁸. In this area, the results obtained validate the 2008 study, as will be explained below.

The research data show that 97.9% plaintiffs received some kind of benefit, whether free legal assistance or free justice. Still, 56.6% plaintiffs were represented by a private lawyer, 43% by the state Public Defender’s Office, and 0.4% on their behalf.

Importantly, the Public Defender of the state of RS only acts in the defense of people considered to be financially hyposufficient, that is, those who prove a monthly income equal to or less than three national minimum wages, considering the total gross earnings of the family, and who do not own movable or immovable

property, in addition to other economically measurable assets, worth more than 300 national minimum wages¹⁹. Thus, about the authors who were assisted by the Public Defender's Office of the State, there is no doubt that they are financially hyposufficient individuals since the agency only serves people with a family income equal to or less than three minimum wages. However, with regard to most of the plaintiffs, represented, according to data, by a private lawyer, there is no way to say that they are low-income people, but only subjects who do not have the conditions to bear the costs arising from a lawsuit without prejudice to their livelihood and that of their family.

Added to the above, the data obtained in the present study show that insufficient income is the cause of claims in 79.6% of the analyzed decisions. However, this point must be seen with caution since the medications proposed in court have a high value, even more so considering the use of double or triple therapies and the duration of treatment, as will be shown below.

Thus, based on the concept of low-income family used by the Federal Government, for the single registration (CadÚnico), which

is the sum of the salaries of all members of the family in the amount of up to BRL 3,135.00²⁰ and also that of financial hyposufficiency adopted by the Public Defender's Office of the State¹⁹ it is not possible to state that judicialization is restricted to low-income people.

Regarding the quantity of required medications, the results indicated that 71.5% decisions approved two drugs, 19.6% three drugs or more, and 8.9% only one drug. On the topic, the average of 2.1 drugs granted per lawsuit is in accordance with the Clinical Protocol and Therapeutic Guidelines, whose most related treatments combine two or more drugs⁵.

Thus, although 235 decisions were analyzed, 495 required drugs were identified, about the total number of decisions analyzed, the most requested was Ribavirin, followed by Interferon, Sofosbuvir, and Daclatasvir (see Table 2). To identify the proposed drugs, the name as granted in the decision was used, which could be the active ingredient or the commercial name. In addition, in some cases, there was also a request to grant medication to treat other diseases, which was disregarded.

Table 2. Medications requested

(Continua)

| Medications requested | Number of requests | Percentage considering the number of requests (%) | Percentage considering the number of decisions (%) |
|------------------------|--------------------|---|--|
| Peginterferon alfa | 7 | 1.4 | 3.0 |
| Baluferon 2B | 1 | 0.2 | 0.4 |
| Boceprevir | 13 | 2.6 | 5.5 |
| Interferon | 118 | 23.8 | 50.2 |
| Ribavirin | 162 | 32.7 | 68.9 |
| Sofobuvir | 83 | 16.8 | 35.3 |
| Telaprevir | 7 | 1.4 | 3.0 |
| Velpatasvir/Sofosbuvir | 1 | 0.2 | 0.4 |
| Victrelis | 4 | 0.8 | 1.7 |
| Viekira Pak | 8 | 1.6 | 3.4 |

(Conclusão)

| Medications requested | Number of requests | Percentage considering the number of requests (%) | Percentage considering the number of decisions (%) |
|-----------------------|--------------------|---|--|
| Virazole | 4 | 0.8 | 1.7 |
| Daclatasvir | 63 | 12.7 | 26.8 |
| Ledispavir/Sofosbuvir | 1 | 0.2 | 0.4 |
| Pegasys | 7 | 1.4 | 3.0 |
| Peginterferon | 7 | 1.4 | 3.0 |
| Simeprevir | 9 | 1.8 | 3.8 |
| Total | 495 | 100 | 210.60 |

Source: Research data.

Of the 16 medicines listed in the decisions, five of them are found in the State List of Essential Medicines (RESME) (Interferon, Ribavirin, Sofosbuvir, Velpatasvir/Sofosbuvir, and Ledispavir/Sofosbuvir) and six in the National List of Essential Medicines (RENAME). Also, Victrelis, Virazole, and Pegasys are trade names for Boceprevir, Ribavirin, and Alfapeginterferon, which are already on the list of requested drugs.

Importantly, Peginterferon Alfa, Daclatasvir, Ribavirin, Simeprevir, and Sofosbuvir are drugs centrally acquired by the Ministry of Health, as they are part of Group 1A (drugs for the treatment of diseases covered in the Specialized Component of Pharmaceutical Assistance - CEAF). In this way, the State depends on the Union to acquire and ship the aforementioned medicines, being responsible for receiving, storing, and distributing them to health regions and municipalities²¹. Such facts lead to the belief that the judicialization, in the present case, results, even if partially, from an ommissive posture of the Executive Power of the Union, insofar as part of the claimed medicines are in the list of those offered by the Unified Health System (SUS) and that it is its exclusive responsibility to acquire and send medicines to other entities of the federation.

The data collected also indicate that the medications listed in RESME do not fully coincide with those provided for in RENAME and PCDT, which is a mistake, considering that this is

reviewed every two years and updated according to scientific evidence^{5,22,23}. The consolidated data in the present study can serve to provoke an evaluation of the existing public policies, including the current pharmaceutical assistance and medicines contained in the public lists, since the expansion of access to treatment, prevention, and diagnosis, constitute the general objective of the Plan for the Elimination of Hepatitis C in Brazil⁵. In this sense, reference should be made to the state of São Paulo, which, in addition to adopting the guidelines contained in the Ministry of Health protocol, added other therapeutic options according to the peculiarities of its health system²⁴.

Of the 235 decisions studied, 305 claims for judicially requesting medication for the treatment of hepatitis C were extracted, which corresponds to an average of 1.29 claims per lawsuit. Still, the reason that most led people to seek the Judiciary Power to obtain access to medicines was insufficient income, found in 79.6% decisions, either alone or combined with another motive. The economic variable had already been identified as the most alleged reason in the initial petitions to justify going to the judiciary to resolve health conflicts, in a study that analyzed the judicialization of health in the municipality of Manaus²⁵ and also in the state of Bahia²⁶.

As the second cause of claim, non-compliance with PCDT requirements, with 23.4%.

Table 3. Causes of claim

| Cause of claim | Number of requests | Percentage considering the number of requests (%) | Percentage considering the number of decisions (%) |
|--|--------------------|---|--|
| Delay in delivery | 3 | 1.0 | 1.3 |
| Zero stock | 12 | 3.9 | 5.1 |
| Ongoing lawsuit | 1 | 0.3 | 0.4 |
| Income insufficiency | 187 | 61.3 | 79.6 |
| Experimental medication or medication not registered with ANVISA | 5 | 1.6 | 2.1 |
| Not on public medication list | 14 | 4.6 | 6.0 |
| Does not meet PCDT requirements | 55 | 18.0 | 23.4 |
| Not informed | 26 | 8.5 | 11.1 |
| Administrative request without response | 2 | 0.7 | 0.9 |
| Total | 305 | 100 | 129.80 |

Source: Research data.

The fact that insufficient income tops the ranking of causes of claim is not surprising, given that drugs for the treatment of hepatitis C are expensive. In a study carried out at the Municipal Outpatient Clinic for Viral Hepatitis in the municipality of São José do Rio Preto, estimates indicate that the value of double therapy using Peginterferon + Ribavirin is BRL 15,131.52, while the triple therapy Peginterferon + Ribavirin + Telaprevir has a value of BRL 49,290.52 and BRL 51,979.34, in the case of therapy with Peginterferon + Ribavirin + Boceprevir²⁷. Corroborating the above, data from the Ministry of Health indicate that treatment with Sofosbuvir + Ribavirin, for a period of 12 weeks, costs the government BRL 18,047.04, whereas with the combination is Sofosbuvir + Daclatasvir, the value rises to BRL 24,240.00 and if it is Sofosbuvir + Simeprevir the value is even higher BRL 25,200.00²⁸. The duration also has an impact on the total cost of the treatment, as 31.9% decisions granted the postulated medications on an ongoing basis, which is also a factor that contributes to the impossibility of acquiring the

treatment by the plaintiff.

On the other hand, non-compliance with the requirements of the PCDT, as a second motivation for filing lawsuits, draws attention. Of the 305 causes of claim detected, denial appeared 55 times, which is equivalent to 18%. The PCDTs are SUS documents that establish criteria for diagnosis, and treatment, including medications, dosages, recommended technologies, care for patient safety, clinical control mechanisms, and means for monitoring and verifying therapeutic results by health professionals and managers⁵. PCDT for hepatitis includes drug therapies that vary according to the genotype and severity of the disease. Thus, when the individual seeks pharmaceutical assistance, to check the necessary medications dispensed, they must prove, through documents and exams, the indication of treatment, according to the PCDT.

The variable under discussion demonstrated that success in obtaining the medicine, through the administrative route, is conditioned to fulfilling the requirements established by the PCDT, which analyzes the case,

in a way, generalized. Despite the existence of a general clinical protocol used by public health management bodies, an assessment that considers the individual's clinical history and the treatment suggested by the physician accompanying the case are necessary since they have greater knowledge than the health professional responsible for the dispensation, which is limited to evaluating a series of documents and checking their adequacy or not to the PCDT. This does not imply disqualifying PCDT, but recognizing that it is not absolute and that other treatments and drugs can also be effective for the treatment of the pathology, which meets one of the objectives of the Plan for the Elimination of Hepatitis C in Brazil, which is to expand access to treatment.

The administrative request, despite having occurred in 43.8% cases whose decisions are now analyzed, is not a requirement for the judicial granting of the drug, given the principles of inalienable access to justice and the dignity of the human person, in addition to the right to health, all guaranteed by the Federal Constitution⁶.

According to the classical legal doctrine, the principle of the dignity of the human person is understood as the intrinsic and unique quality of each individual to have due respect before the state entity and before society, being the holder of rights and social responsibilities in which people are assured of any degrading situation, guaranteeing the existential minimum for the individual to live with dignity²⁹. Thus, it is possible to affirm that the right to health, by constitutional provision, is a fundamental social right, whose fullness should be untouchable, in respect for the principle of human dignity, but which is constantly being violated, due to medical and hospital circumstances to which human beings have been subjected³⁰.

Data also show that 1% causes of claims are related to the delay in supplying the medicine through the administrative route and 3.9% due to the lack of stock. Once again, the results reflect

an omissive behavior by the Union, since it is its exclusive competence to acquire and send medicines to the other entities of the federation. Evidently, the responsibility of the State cannot be excluded, which must also be prepared to serve the population, sharing this burden with the Union and the Municipalities. The lack of administrative response also emerged as a cause of claim, corresponding to 0.7% causes of claim found. Such data may indicate that there is a gap in the administrative procedure for dispensing medications, which may be due to a failure in the flow or even the human factor. In this sense, a study that evaluated the dispensing of medicines for hepatitis C in four pharmacies with specialized components of the Health Department of São Paulo identified that the clinical exams requested for analysis of the case varied from pharmacy to pharmacy, and there was also a pharmacy that did dispense based only on medical prescription³¹, which indicates that the system is not free from mistakes.

In addition to showing that part of the medicines legally requested was on the list of therapies provided by the PCDT, the results also showed the lack of predictability of the drug on the public list as a cause of claim, with a 4.6% incidence. The denial of the supply of medication on this basis does not have the power to exempt the State from the obligation imposed by the Federal Constitution, which is that of health care. This is undoubtedly one of the reasons why the PCDT and the medication lists must follow the evolution of science, leaving the State to search for treatment alternatives that are effective, safe and that cause a smaller financial impact on the treasury.

Other results such as the existence of ongoing lawsuits (0.3%) and drugs not registered with ANVISA (1.6%) also appear as a cause of claim. With regard to the first, considering that it refers to a single case, there is no need for further consideration, given its irrelevance compared to other causes of claim. Regarding the second, it is

pertinent to mention that the Federal Supreme Court understands that the State cannot be obliged to supply medicines without registration with ANVISA, with some exceptions³². This bias in health judicialization was recently judged by the Supreme Court, pacifying the discussion about the possibility or not of supplying medicines without registration with ANVISA by the state. Considering that in the present study, decisions from the period from 2010 to 2020 were analyzed, the referred cause of claim may be linked to the lawsuits proposed before the STF pronouncement on the subject.

The causes of claim identified suggest the occurrence of failures in the public policy of state pharmaceutical assistance, insofar as there is a delay in responding to administrative requests, discrepancies between the lists of essential medicines of the state (RESME) and of the Union (RENAME), in addition to the lack of measures that reflect regional peculiarities, since judicialization is a social and political phenomenon. In addition, the lack of medication in sufficient amounts indicates an omissive behavior by the Union, responsible for the acquisition and distribution of medications to other federal entities, and also by the State, which shares responsibility and must take the necessary measures so that the demand for medication is met. Still, the adoption of the PCDT as the only criterion for granting or not the medications can mean that sick people with cure potential are denied treatment since they simply do not meet the pre-established requirements and that, with due caution, cannot be taken as absolute.

Finally, the data collected show that 93.6% evaluated decisions granted the required medication(s) or ratified the concession decision issued by the judge of the original instance. Past studies already indicated that the percentage of success of demands that seek the concession, not only of medicines but of inputs and treatments related to health is high^{9,26,33,34}. From a legal point of view, the issue does not require further

digressions, since the outcome, whether favorable or not, results from the application of the law and the defense elements of each of the parties. Still, studies show that judges tend to grant the author's request based on the fundamental nature of the right to health^{35,36}.

CONCLUSION

The main reason why people seek the judiciary power to obtain medicines for the treatment of hepatitis C is low income, followed by non-compliance with the requirements of the Clinical Protocol and Therapeutic Guidelines for Hepatitis C and Coinfections (PCDT), lack of predictability in having the medication in the public list, zero stock, and required medication without registration with ANVISA

Thus, the identified causes of claim suggest gaps in the pharmaceutical public policy, omissive conduct by the Union, responsible for the acquisition and distribution of medicines to States and Municipalities, and that the adoption of the PCDT as the only criterion for the concession or not of medicines by the State, can make people who are sick and have the potential to be cured denied treatment. The analysis as performed ends up being, in a way, discriminatory, because although the SUS is based on public funding and universal coverage of health actions, only those people who meet the pre-established requirements are benefited.

The research also pointed out that Ribavirin, Interferon, Sofosbuvir, and Daclatasvir are the most legally required drugs for the treatment of hepatitis C. Some of the postulated medications are on the public lists of drugs and are provided for in the PCDT, which indicates a failure in the pharmaceutical assistance policy. The topic remains uncontroversial of the omissive conduct of the State that does not provide drugs in sufficient amounts to meet the existing demand, which in no way collaborates with health

promotion, prevention, assistance, and the plan to eliminate hepatitis C by the year 2030.

It is not possible to say that health judicialization is a phenomenon restricted to low-income people, because despite the data showing that 97.9% plaintiffs received some kind of benefit, whether free legal assistance or free justice, only 43% met the concept of low-income family used by the Federal Government, for the single registration - CadÚnico and financial hyposufficiency adopted by the Public Defender's Office of the State of RS.

The results indicate that 93.6% of the evaluated decisions granted the required medicine(s) or ratified the granting decision issued by the judge of the original instance. In this scenario, although the Federal Constitution of 1988 established that the right to health will be ensured through public policies, the realization of the right to health through the judicial process is the legitimate alternative for citizens to have their right ensured in the face of inefficient public management and a fragile political system.

In this sense, the need to analyze in more depth the characteristics of the phenomenon of judicialization is undeniable. Thus, further studies should be conducted to investigate whether access to medicines is easier for residents of the capital, whether physicians from cities other than the capital have a greater tendency to prescribe medicines not available at the public health network, or even if the number of appeals against decisions issued by judges from cities other than the capital is greater than appeals against decisions originating in the capital city. Another important point to be investigated is why the acquisition and availability of medicines by the Union occur below the demand. These are some relevant developments for future research to broaden the understanding of the topic.

PRACTICAL APPLICATIONS

The present study investigated the reasons why people turned to the Judiciary Power

to demand that the State supply medicines for the treatment of hepatitis C, given the number of people who have the disease, despite the existence of specific public policies and the Plan for the Elimination of Hepatitis C by the year 2030. However, the data obtained indicate the need to reassess the Clinical Protocol and Therapeutic Guidelines for Hepatitis C and Coinfections, the National Plan for Viral Hepatitis and the Plan for Elimination of Hepatitis C, and also the existence of possible failures in the medicine dispensing system. Further studies on the causes of health judicialization and its characteristics are relevant to complement the scenario and provide a greater understanding of the phenomenon.

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