saúde
EM DEBATE

REVIEW

Definitions of high-cost medicines present in Brazilian scientific and academic literature on health judicialization

Medicamentos de Alto Custo: definições presentes na produção científica e acadêmica brasileira sobre judicialização em saúde

Rosângela Caetano[1], Ione Ayala Gualandi de Oliveira[1], Lívia Mattos[2], Patrícia Krauze[3], Claudia Garcia Serpa Osorio-de-Castro[3]

DOI: 10.1590/2358-289820251449329I

ABSTRACT The study aimed to single out definitions and interpretations regarding high-cost medicines in the scientific and academic literature on health litigation. A scoping review followed the methodology proposed by the Joanna Briggs Institute. MEDLINE, EMBASE, LILACS, Web of Science and Scopus, and the Digital Library of Dissertations and Theses were searched for empirical studies on litigation for access to medicines that included high-cost drugs, published or presented between 2005 and 2022. A total of 62 scientific papers and 66 dissertations and theses were selected. Explicit definitions of high-cost medicines were scarce, presented in just 19.1% of papers and 15.2% of the academic output. Among the most available core themes were those related to high unit or overall treatment cost of medicines, resulting from chronic conditions, and generating financial impact on household budgets. Other patterns of meaning that emerged were: 'new' medicines without marketing approval in the country, medicines absent from funding lists, drugs for genetic or rare diseases, or those with specificities regarding procurement or dispensing. Conceptual imprecision in the field of high-cost drugs hinders a clear viewpoint of the importance of this group of medicines in the scenario of health litigation in Brazil.

KEYWORDS Pharmaceutical preparations. Health judicialization. Technology, high cost. Pharmaceutical services. Review.

RESUMO *O estudo objetivou identificar as definições e compreensões existentes sobre Medicamentos de Alto Custo (MAC) na produção científica e acadêmica brasileira relacionada à judicialização de medicamentos. A revisão de escopo seguiu a metodologia proposta pelo Joanna Briggs Institute. As bases bibliográficas Medline, Embase, Lilacs, Web of Science e Scopus, e a Biblioteca Digital de Teses e Dissertações foram pesquisadas em busca de estudos empíricos relacionados à judicialização de medicamentos que incluíssem MAC, publicadas ou defendidas no período de 2005-2022. Foram incluídos 62 artigos científicos e 66 dissertações e teses. Definições explícitas de MAC foram muito pouco frequentes nos estudos incluídos e estavam presentes em apenas 19,1% dos artigos e 15,2% dos produtos acadêmicos. Núcleos de significado mais presentes estavam relacionados ao alto custo unitário do medicamento ou medicamentos com valor total de tratamento elevado, decorrentes da cronicidade da doença, produzindo impacto financeiro no orçamento familiar. Outras relações de sentido foram: medicamentos 'novos', sem registro sanitário no País, fora das listas de financiamento, com foco em doenças raras e genéticas ou com especificidades relativas à sua aquisição e dispensação. A imprecisão conceitual identificada dificulta uma visão mais clara da importância desse grupo no cenário da judicialização de medicamentos no Brasil.*

PALAVRAS-CHAVE *Preparações farmacêuticas. Judicialização em saúde. Tecnologia de alto custo. Assistência farmacêutica. Revisão.*

[1] Universidade do Estado do Rio de Janeiro (Uerj), Instituto de Medicina Social (IMS) – Rio de Janeiro (RJ), Brasil. *caetano.r@gmail.com*

[2] Universidade Federal do Estado do Rio de Janeiro (Unirio), Hospital Universitário Gaffrée e Guinle (HUGG) – Rio de Janeiro (RJ), Brasil.

[3] Fundação Oswaldo Cruz (Fiocruz), Escola Nacional de Saúde Pública Sergio Arouca (Ensp) – Rio de Janeiro (RJ), Brasil.

Introduction

Throughout the world, medicines are a growing concern of health system managers because their costs are an important – and rapidly rising – component of health care expenditures[1,2]. That upward trend is likely to intensify, as the pharmaceutical industry has been shifting its focus from research and production of synthetic small molecules to the launch of specialized pharmaceutical products, many of which are bio-based, which are often used by a few individuals, have high prices, and are marketed by a small number of distributors[3].

Medicines are also one of the main drivers of health judicialization in Brazil[4], especially for public entities. Expenditures on lawsuits rose from 4.0% to 7.4% of the Ministry of Health's total expenditure on medicines between 2012 and 2018[5]. Those expenses achieved the amount of R$ 1.78 billion in 2021[6]. Also, as for states and municipalities, lawsuits for medicines have grown in number and value, part of them being related to high-cost medicines (HCM)[7,8].

In none of the reviews addressing the main characteristics associated with the judicialization of medicines in the country one finds a specific focus on HCM, although often being part of the litigated products[9-12]. Even when the term 'high cost' is mentioned, it lacks a uniform and precise definition[13].

Libanore[14] undertook a comprehensive literature search to examine the concept of HCM in the Brazilian Unified Health System (SUS). Only 24 papers out of 249 addressed those medicines as a central concern. No formal definition was found, although frequent use of the terms 'exceptional' and 'specialized' as synonyms for 'high cost' was identified.

Various countries denote HCMs differently. They are often defined indirectly due to their patent status, time to marketing, and direct costs associated with their use. Brazil, however, does not adopt any financial parameters to define high-cost or high-priced medicines, even though the Specialized Component of Pharmaceutical Services (CEAF) provides outpatient medicines at a higher average price in SUS[15].

That conceptual imprecision hinders a clearer view of that group's importance in the scenario of medicine judicialization in Brazil regarding its representativeness and the process' specific characteristics. Thus, the research objective was to examine the definitions and understandings of HCM present in the national scientific and academic literature related to judicialization in the government sphere so as to contribute to the conceptualization of that category of medicines.

Material and methods

This study is part of a broader scoping review carried out to map and systematize the literature on lawsuits involving HCM in Brazil, aiming to understand their importance and special characteristics[16].

Scoping reviews help to identify the current state of understanding and to summarize existing knowledge and informational gaps related to a specific theme, defining them in a practice-and-policy setting[17]. They also allow the mapping of definitions and conceptual limits of a topic, as well as a discussion on its characteristics relating to nature, resources, and volume[18].

The guiding principle of the review was to find any definition – explicitly provided or even subjectively referred to – of what HCM would mean in scientific and academic studies on lawsuits for access to medicines in Brazil and what those definitions or understandings stated.

The review followed the methodology proposed by the Joanna Briggs Institute[19], and reporting was guided by the Preferred Reporting Items for Systematic Reviews and Meta-Analysis for Scoping Reviews checklist (PRISMA-ScR)[20]. The review protocol was registered before its inception on the Open Science Framework platform[21] and subsequently published[16].

The mnemonic P (Population) – C (Concept) – C (Context) was applied to guide the search throughout the literature and the inclusion and exclusion criteria, where 'Population' corresponded to scientific and academic studies that have as their object the judicialization of medicines in Brazil, while 'Context' related to HCM judicialization. 'Concept' involved the characteristics of HCM lawsuits, whether recorded in the National Health Surveillance Agency (ANVISA), but having a public entity as a defendant, i.e., the Federal Government, a state or a municipality.

Two sets of data were examined: i) scientific papers published in indexed journals, and ii) Theses and Dissertations (T&D) produced by *stricto sensu* graduate programs of Brazilian Higher Education Institutions (IESs).

Identification of relevant studies

The search for scientific papers opted for the bibliographic reference databases MEDLINE (via PubMed), EMBASE (via CAPES Journals), LILACS (via Virtual Health Library-BVS), Scopus (via CAPES Journals), and Web of Science (via CAPES Journals). Search strategies were built collaboratively and iteratively by the reviewers, with the support of a librarian. Health descriptors (MeSH Terms, DeCS, and Emtree) were considered whenever available, as titles and abstracts containing specific terms related to health judicialization, medicine judicialization, and Brazil, combined with the Boolean operators AND or OR, according to each electronic database. Detailed search strategies used in each database were lodged and are available on the Open Science Framework[22] open data platform.

The searches were conducted from November 1 to 15, 2022, with no limits on the language of publication, with 2005 as an initial time filter, a period from which publications related to medicine judicialization in the country intensified. Alerts for new publications were inscribed in the MEDLINE and EMBASE databases and followed up every two weeks until the completion of the synthesis.

The search and inclusion of dissertations and theses considered that judicialization in health and medicines is a frequent concern of academic products in our country, the findings do not always result in publications in national or foreign journals[23,24].

The Brazilian Digital Library of Dissertations and Theses (BDTD) was used, which integrates the existing information systems in 144 Brazilian IESs, allowing for their recording and publication utilizing electronic media. The searches were carried out between January 9 and 12, 2023, with retrieval from the BDTD website and use of advanced search[25], of generic terms such as 'health judicialization', 'lawsuits' and 'medicine judicialization', for 2005 onwards. On January 17, 2023, an additional specific search in the institutional repository Arca of the Oswaldo Cruz Foundation (FIOCRUZ) was carried out through its electronic link[26], given its late joining to the BDTD.

Search results from different databases were exported to the EndNote® reference manager, and duplicates were eliminated.

Selection of relevant studies for review

The selection of papers and academic products followed standardized procedures, being carried out in two phases: a) screening based on the reading of titles and abstracts, and b) selection derived from the examination of full texts. Bibliographic references and academic products whose title and abstract left doubts about their relevance and adequacy to the object of the review had their full text retrieved and examined. Two researchers performed both phases independently, with divergences being resolved by a third senior reviewer (RC or CGSOC).

To guide and record the selection processes, standardized electronic forms were prepared – specific for each document type and phase – in Google Forms, feeding a database exported to Excel® spreadsheet format. Each form carried

a manual that drove data collection and recording by researchers, aiming to reduce bias and standardize the process. Specific training was carried out, and the forms were the object of three pre-tests using random study samples.

Given the already recognized lack of an unambiguous concept that would help the selection of studies focusing on HCM, an operational definition was elaborated including criteria usually related to that group of medicines (*box 1*).

Box 1. Elements comprising the operational definition of high-cost medicine adopted in the scoping review

1	Medicines with high financial costs for the public health system or families and individuals
2	Medicine with high global cost for treating diseases with great social impact or high mortality
3	Medicine of more complex administration, requiring monitoring to follow the patient's evolution or very specific conditions for its use
4	New entrant products, under patent or monopoly
5	Medicine belonging to the Specialized Component of Pharmaceutical Services from 2009 onwards or to the former Exceptional Dispensing Component before 2009
6	Medicines not pertaining to Brazilian SUS pharmaceutical services financing lists
7	Medicine without sanitary licensing in Brazil

Source: Prepared by the authors.

SUS – Brazilian Unified Health System.

The selection of relevant studies considered the inclusion and exclusion criteria presented in *box 2*.

Box 2. Eligibility criteria adopted in the selection of relevant studies for the scoping review

Criteria	Detailing
Inclusion	• original works of any study design, but necessarily empirical, bringing data on the judicialization of high-cost medicines, following the operational definition adopted, and having the Union, states and municipalities as defendants. • works focused on health judicialization bringing data on lawsuits for high-cost medicines, in a separate and detailed way so to allow their extraction.
Exclusion	• abstracts, letters, comments, reports, conference proceedings and literature reviews • studies restricted only to the discussion of legal arguments, without additional empirical data • studies whose defendant was exclusively different from the Union, states and municipalities, such as health insurance plans and operators or 'mixed' defendants, but without bringing separate data regarding public entities that could be extracted • studies published in languages other than English, Spanish and Portuguese • papers identified in the bibliographic research that duplicated academic products available in dissertations and thesis databases, since those tend to bring additional information due to not being limited in size • impossibility of access to the full text in the bibliographic and theses and dissertations databases, making it impossible to assess whether it meets the eligibility criteria defined for the research.

Source: Prepared by the authors.

Data retrieval

Retrieval also involved pairs of independent reviewers, with the resolution of divergences in charge of a third senior reviewer (RC or CGSOC). Standardized electronic forms were also created and specified by type of product, consisting of open and closed questions and carrying a structure that followed the review guiding questions. The forms, also developed on the Google Forms platform, feed the Excel® databases used for the qualitative and quantitative syntheses. The drafting of instructions and three training sessions were held before the beginning of data collection.

The variables were related to: i) study identification data, such as title, author, date, year of publication or defense exam date of a dissertation or thesis; publication journal, in the case of published papers; and, in the case of T&D, the IES, type of academic product, i.e., academic master's degree, professional master's degree or doctorate; and area and sub-area of knowledge, using the information available on September 5, 2023 on the website of the Coordination for the Improvement of Higher Level Personnel (CAPES)[27]; and ii) general characteristics of the study, such as objective, scope, locus, period, sample size, government entity involved as defendant, list of judicialized medicines, and values involved in HCM judicialization.

As for the specific object of this research, a record was made of whether the academic product or paper carried i) any HCM definition from the authors; ii) compiled definitions, literally transcribed, and informing the page of the original; and iii) aspect(s) of the HCM operational definition created by the research group, which was/were met by the study, so that it could be accepted into the review.

The methodological quality of the accepted studies was not evaluated, given the purpose of the review and the fact that no restrictions had been imposed on the accepted study designs.

Analysis and synthesis of the results

Results were analyzed qualitatively and quantitatively in terms of absolute and relative frequencies and, in the case of open questions, utilizing the synthesis of thematic content categories. The description was further enhanced by figures and diagrams, which helped to summarize the findings.

Prior approval by the Research Ethics Committee was waivered since papers published in indexed journals and academic products with unrestricted access were used as sources of information.

Results and analysis

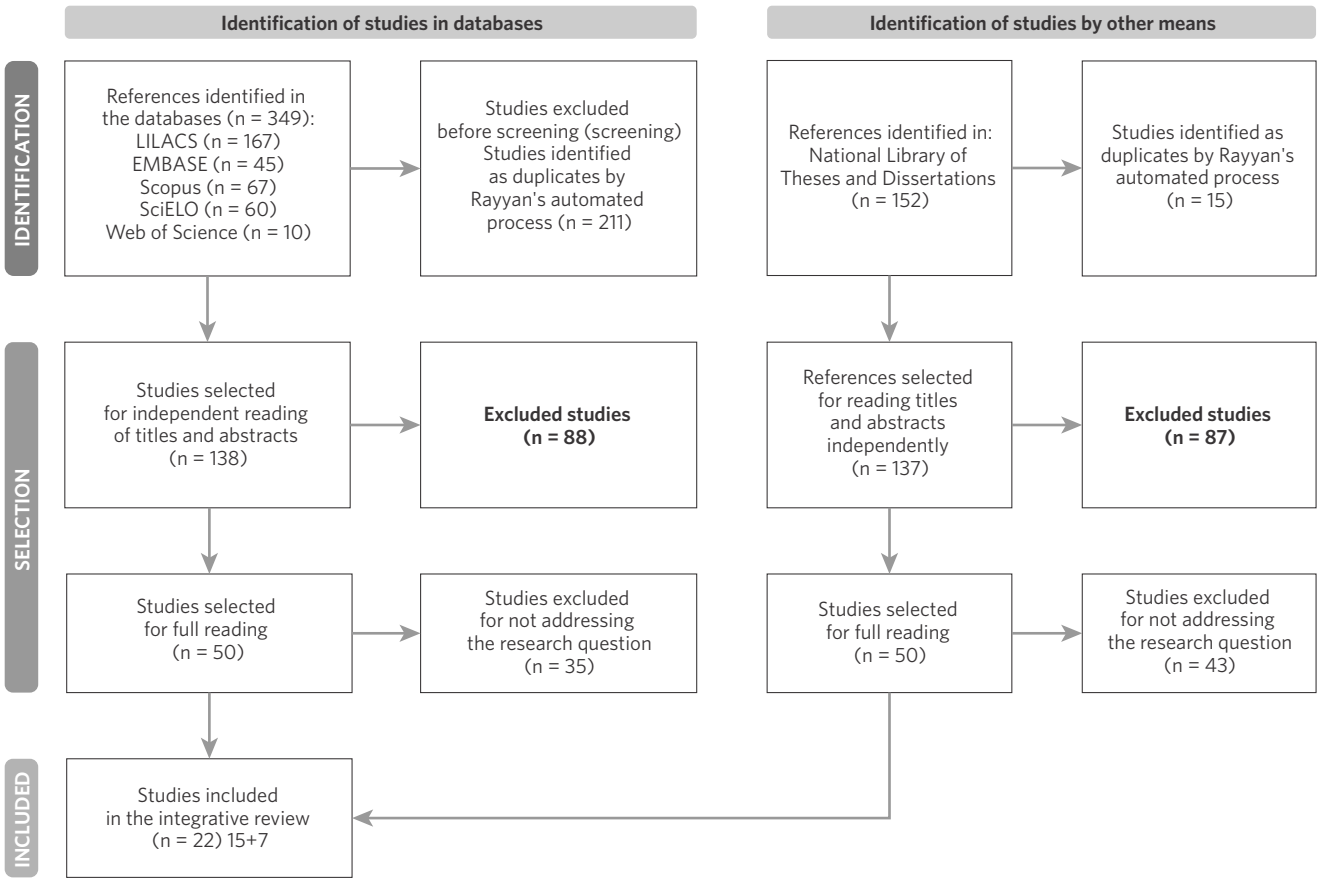
Initially, 1,709 scientific papers and 653 theses and dissertations were identified from the search. The search for cross-references and the monitoring of monthly alerts lodged in MEDLINE and EMBASE allowed the identification of six more papers, none of which were accepted. Two theses could not be retrieved, even after repeated contacts by e-mail with the authors and IESs.

The percentage of overall agreement among the reviewers in phase I of the scientific paper selection was 93.1%, and 92.7% for theses and dissertations. In the selection from full texts, the agreement was 90% and 89%, respectively.

At the end, 62 papers published in indexed journals and 66 T&D were accepted into the review. The complete reference lists is listed in the Open Science Framework open data repository[28].

The flowchart summarizing the selection results is depicted in *figure 1*.

Figure 1. Flowchart of studies accepted into the scoping review



Source: Prepared by the authors based on Page et al.[29].

Arca – FIOCRUZ institutional repository; D&T – Dissertations and Theses; MAC – High-cost medicines.

Notes: a – D&T arising from cross-reference search; b – Paper or D&T excluded on reading the title and abstract; c – D&T not found in IES database and not retrieved by other means; d – D&T retrieved, but only partial content (partially blocked).

General characteristics of accepted papers, dissertations and theses

Table 1 summarizes the characteristics of papers and academic products accepted into the review that help to contextualize the scope of the production on HCM judicialization in Brazil during the research period.

Table 1. Main characteristics of studies on judicialization involving high-cost medicines accepted into the scoping review, as for type of scientific production, 2005-2022

	Papers		D&T	
Characteristics	**No.**	**%**	**No.**	**%**
Journal				
Revista de Saúde Pública	11	17.7	NA	NA
Cadernos de Saúde Pública	6	9.7	NA	NA
Revista de Direito Sanitário	5	8.1	NA	NA

Table 1. Main characteristics of studies on judicialization involving high-cost medicines accepted into the scoping review, as for type of scientific production, 2005-2022

	Papers		D&T	
Characteristics	**No.**	**%**	**No.**	**%**
Ciência e Saúde Coletiva	5	8.1	NA	NA
Cadernos Ibero-Americanos de Direito Sanitário	5	8.1	NA	NA
Saúde e Sociedade	2	3.2	NA	NA
Jornal Brasileiro de Economia da Saúde	2	3.2	NA	NA
Health and Human Rights	2	3.2	NA	NA
Revista Einstein	2	3.2	NA	NA
BMC Public Health	2	3.2	NA	NA
Others[a]	20	32.3	NA	NA
Academic Product				
Master's Thesis	NA	NA	57	86.4
Professional master's Degree	NA	NA	18	27.3
Academic master's degree	NA	NA	39	59.1
Doctoral thesis	NA	NA	9	13.6
Knowledge area and sub-area of academic product				
Health Sciences	NA	NA	46	69.7
Nursing	NA	NA	2	3.0
Pharmacy	NA	NA	8	12.1
Medicine I	NA	NA	1	1.5
Medicine II	NA	NA	4	6.1
Collective Health	NA	NA	31	47.0
Life Sciences	NA	NA	1	1.5
Humanities	NA	NA	1	1.5
Applied Social Sciences	NA	NA	14	21.2
Interdisciplinary	NA	NA	4	6.1
Higher education institution for the defense of academic product				
University of São Paulo	NA	NA	9	13.6
Oswaldo Cruz Foundation [b]	NA	NA	8	12.1
Federal University of Minas Gerais	NA	NA	6	9.1
Federal University of Juiz de Fora	NA	NA	4	6.1
University of Brasilia	NA	NA	4	6.1
Federal University of Rio Grande do Norte	NA	NA	3	4.6
Getúlio Vargas Foundation	NA	NA	2	3.0
State University of Ceará	NA	NA	2	3.0
State University of Londrina	NA	NA	2	3.0
State University of Paraíba	NA	NA	2	3.0
State University of Rio de Janeiro	NA	NA	2	3.0
Federal University of Bahia	NA	NA	2	3.0
Federal University of Ceará	NA	NA	2	3.0
Federal University of Pernambuco	NA	NA	2	3.0
Federal University of Rio Grande do Sul	NA	NA	2	3.0

Table 1. Main characteristics of studies on judicialization involving high-cost medicines accepted into the scoping review, as for type of scientific production, 2005-2022

	Papers		D&T	
Characteristics	**No.**	**%**	**No.**	**%**
Federal University of Santa Catarina	NA	NA	2	3.0
Federal University of Santa Maria	NA	NA	2	3.0
Other IES [c]	NA	NA	10	15.2
Year of paper publication or dissertation uphold				
2005-2009	3	4.8	5	7.6
2010-2013	21	33.9	17	25.8
2014-2017	16	25.8	24	36.4
2018 onwards	22	35.5	20	30.3
Government entity as defendant				
Union	6	9.7	1	1.5
State	27	43.6	24	36.4
Municipality	8	12.9	1	1.5
State and Union	3	4.8	0	0.0
State and Municipality	11	17.7	16	24.2
Union. State and Municipality	7	11.3	24	36.4
Region				
North	2	3.2	2	3.0
Northeast	9	14.5	17	25.8
South	15	24.2	13	19.7
Southeast	25	40.3	30	45.5
Midwest	6	9.7	3	4.6
Brazil (unspecified)	5	8.1	1	1.5

Source: Prepared by the authors.

Notes: [a] Journals containing only one published paper accepted into the review; [b] Fiocruz here includes all campuses distributed in the country, containing units that offer stricto sensu postgraduate courses in the North, Northeast, Southeast and South regions; [c] IES carrying only one academic product accepted into the review.

The 62 accepted papers were published in 20 national (66.6%) and 10 international journals, totaling 50 papers (80.6%) in Brazilian journals and 12 (19.4%) in foreign publications. Five journals, all national ones, accounted for 51.6% of the papers. Also, 66 academic products were accepted, most of which were master's theses. Regarding the major areas of knowledge specified by the National Council for Scientific and Technological Development (CNPq), T&D from health sciences and applied social sciences prevailed (21.2%). In terms of sub-areas, those T&D concluded in public health stand out.

The predominance of master's theses is possibly related to the distribution of graduate programs in Brazil. As to CAPES data, of the 7,127 existing stricto sensu graduate courses in 2022, distributed among 4,492 programs recognized by the Ministry of Education (MEC), 64.2% concerned master's degrees, most (52.1%) of which academic ones[27].

Still, the concentration of products related to HCM judicialization in the Health field does

not seem directly related to the distribution of graduate courses in the country. In 2022, the Health field corresponded to 16.2% of the total number of graduate courses licensed by CAPES; 39.3% of the courses belonged to Medicine I, II, and III sub-areas, 11.9% were part of the public health sub-area and 9.6% of the pharmacy sub-area[27]. Specificities of the theme, with a strong focus on the profile of lawsuits for medicines and their relation to the National Policy on Pharmaceutical Services, are possible explanatory factors for the predominance of academic productions in the sub-areas of public health and pharmacy. On the other hand, journals that concentrate on the publication of papers on HCM judicialization are those of collective health, which traditionally addresses the interface among health policies, planning and management, and human rights[30].

Academic products were concluded in 27 different IESs, of which six are responsible for 51.2% of T&D alone. That group of IESs offers collective health programs containing lines of research related to judicialization.

Similar proportions of published scientific papers (61.3%) and defended T&D (66.7%) were presented from 2014 onwards. The National Commission for the Incorporation of Technologies in SUS (CONITEC) was installed at the end of 2011 through Law No. 12,40131, when important pressures for new medicine incorporations already existed. Decree No. 7,508, also from 2011, regulated the SUS supply of medicines[32]. The perception was that creating a continuous incorporation process would stimulate judicialization, ceding to pressures of adoption of high-cost products by the health system, which indeed happened[33]. That increase in judicialization may have generated greater interest in studying the topic.

In subsequent years, other factors such as budget constraints (2016 and 2017), economic austerity, growing demand for medicines for rare diseases, especially after the publication of the National Policy for Comprehensive Care for People with Rare Diseases in January 2014 and the SARS-CoV-2 pandemic, from March 2020 onwards may have also boosted studies on HCM judicialization[34].

States were the main passive pole of HCM judicialization in papers and T&D, either alone (43.5% and 36.4%, respectively) or with municipalities (17.7% and 24.2%). Municipalities accounted for 11.3% and the Federal Government 36.4%. This greater participation of the states had already been identified in some reviews on the judicialization of medicines in the country[35,36]. Reasons for this relevant participation could be the high cost of part of the requested medicines and the fact that a large part of T&D relied on State Health Secretariats (SES) as data sources. The significant volume of judicialization against the states led to Extraordinary Appeal No. 855,178 of the Federal Supreme Court (STF). The 2019 ruling determined cooperation among federative entities in health-related demands regardless of public policies for financing and dispensing medicines[37].

More recently, on September 16, 2024, STF settled the Súmula Vinculante (binding summary in literal translation) No. 60, based on Extraordinary Appeal No. 1,366,243, stating that the Federal Court is entitled to judge lawsuits for medicines licensed by Anvisa but not incorporated into SUS, of value equal to or greater than 210 minimum wages. That means that the largest HCM share will be allocated to the Federal Government.

The Southeast (40.3%) and South (24.2%) regions predominated as loci of the papers accepted into this research. As for T&D, the highest proportion of works originated in the Southeast (45.5%), followed by the Northeast region (25.8%). Those percentages are probably related to the IES distribution mentioned above.

Definitions and understandings associated with 'HCM' by authors of selected studies

Explicit definitions carrying some original content of what the term HCM could signify appeared very infrequently in the studies

accepted into the review, i.e., in only twelve papers[39-50] (19.4%) and ten academic products[51-60] (15.2%).

Although containing empirical data on HCM, 41 papers and 31 T&D did not bring any definition or association with the concept, even when the studies provided data on costs or expenses and the judicialization involved medicines that clearly had a high unit price[46,48,61-72].

In fact, high cost was often the motivation for choosing to focus on case studies, restricted to one or few medicines of very high cost and significant financial impact on government spending, such as eculizumab, ipilimumab, lenalidomide, galsulfase, idursulfase, laronidase, and insulin analogues, among others[43,44,73-79]. Even so, the works did not contain original definitions or greater specificity.

The most frequent core meaning in the definitions related to the high unit cost of the medicine or to medicines that, regardless of the cost or despite the low unit price, carried a high total cost of treatment due to the chronicity of the disease, impacting on the family budget[55,57,80]. Less frequently, meaningful relations to new health technologies, many of which were not market approved in Brazil came to light; medicines outside the Clinical Protocols and Therapeutic Guidelines (PCDT) or for off-label use, in clinical indications other than the ones approved by Anvisa; 'high complexity' treatments or treatments addressed to rare and genetic diseases; or, still, specificities related to acquisition and dispensing[43,49,57,81]. Some examples of these different meanings are listed in the text fragments provided below:

> High-cost medicines are among those that most provoke the sense of justice due to their unitary or aggregate financial impact but also because, in general, they reflect new health technologies, some of which are without market approval or assessment in the country[57](45).

> High-cost items are requested for their financial impact on the family budget, but technologies not available in the Brazilian market are also requested[55](37).

> [...] Medicines regarded as high cost are those carrying high added value or, due to the chronicity of the treatment, become excessively expensive to be acquired by the population[60](30-31).

Some authors explicitly mention the HCM burden for families and the collectivity from empirical estimates.

> One can note that the cost of medicine corresponds to a high percentage of the population's income. For example, in 2011, tiotropium bromide represented 44.9% of the minimum wage. That result causes individual spending on medicine to significantly impact salaried patients' finances. Even more so if they are predominantly elderly, retired, or social security recipients[50](6).

> However, certain medicines are not provided by SUS on a regular basis. In response, some users sue the government for their provision. This fact is particularly important in the case of high-cost medicines, causing the treatment of a single individual to be extremely expensive, the reason why the Federal Government is usually sued[44](1090).

It is noteworthy that several of the studies providing some HCM definition clearly explained that those medicines were part of the list of products offered by the Exceptional Dispensing Medicines Component (CMDE) and, later, by CEAF, given precisely some of the mentioned characteristics[82-88].

> Although originally known as high-cost medicines, the list of exceptional medicines includes, in addition to high unit cost items (infliximab, goserelin), median unit cost medicines, but for which continued use ends up consuming a significant volume of resources (risperidone and olanzapine) [...][89](27).

> That [Exceptional] Component is a Pharmaceutical Services Policy strategy aiming to make available within SUS medicines for the treatment of diseases that meet the criteria: a) rare or low-prevalence disease that requires the use of a medicine of high unit value or that, in case of chronic or prolonged use, becomes a high-cost treatment; and b) prevalent disease requiring high-cost medicine or that, in case of chronic or prolonged use, becomes a high-cost treatment [...][53](32).

> The CEAF, previously called exceptional dispensing medicines or high-cost medicines [...], is a strategy for access to medicines within SUS, characterized by the search for the guarantee of medicine treatment comprehensiveness at the outpatient level, for which lines of care are defined in the PCDTs published by the Ministry of Health [...][565](74).

Only one-third of the accepted publications expanded the understanding of high cost to cover special issues outside operational definitions. Some works mention that technological innovations and recent entrance into the market can be considered high cost promoters[41,43,49,68], alongside medicines without therapeutic protocols or guidelines[68,90,91].

> In the latter case [request for medicines outside SUS lists], numerous are the situations, among which the request for medicines not classified as essential by society or government entities , i.e., those characterized as technological innovations, most recently market approved in the country, not available, or generated by practices that disagree with clinical protocols defined by SUS, and requirements driven by treatments not covered by private health plans [...][68](412).

The papers and T&D contain some specific classes associated with high cost, such as biologics[60,85,92,93], antineoplastic medicines[40,48,49,70,94-102], and medicines for rare diseases[43,73,81].

In addition, original issues, truly high-cost promoters, were mentioned: restricted clinical indication; few sources of provision; new medicines recently offered in the market and under patent; and medicines without market approval in the country, forcing their importation[72,83,103-108].

> Distribution monopolies control prices, which tend to be higher than those practiced in competitive markets. It is not always possible to avoid distribution monopolies, particularly in the case of medicines that are often monopolized because of their patents' protection or, in the specific case of mucopolysaccharidosis (MPS), due to their condition of orphan medicines[43](479).

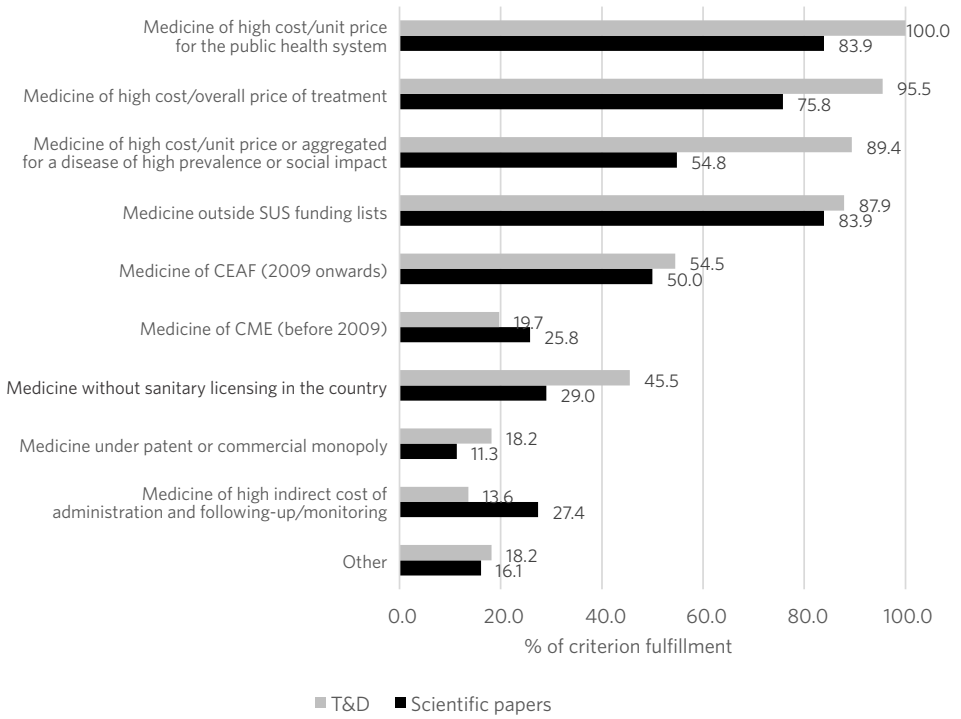
> There is no consensus on the definition of high-cost medication. However, some conceptual approximations have been made using qualitative indicators like medicines with high health risks and quantitative indicators like regulating the cost of treatment. Others still use it as a synonym for highly complex and costly medicines, with precise use conditions and expensive medicines from limited sources[108](3).

Understandings associated with 'HCM' that fit within the adopted operational definition

The selection of products for acceptance into the scoping review started with an operational definition, which originated on criteria usually associated with the so-called HCM, present in publications or in Brazilian and international government documents. The reviewers' assessment of whether one or more of those operational definition criteria fit considered listed medicines and other non-textual elements, i.e., tables, charts, graphs, or their direct citations as part of the studies' results. The fulfillment of each criterion in scientific papers and T&D, shown in *figure 2*, reveals that the high unit cost of the medicine for

the health system and patients and the high aggregate cost of the treatment were the most frequent criteria. High-cost diseases of high occurrence or social impact, such as cancer, and medicines not appearing in SUS official lists of medicines – National List of Essential Medicines (Rename) and state and municipal lists of essential medicines – made up of other prevalent criteria.

Figure 2. Level of criteria fulfillment (%) for high-cost medicine according to the research operational definition in papers and theses and dissertations accepted for the review, 2005-2022



Source: Prepared by the authors.

CME – Component of Exceptional Medicines; CEAF – Specialized Component of Pharmaceutical Services; SUS – Brazilian Unified Health System.

Although high unit cost is the criterion most frequently related to HCM, it is noteworthy that no measures were found referring to fractions of the minimum wage or others related to specific monetary values to qualify HCM. Financial or monetary parameters that help clarify that definition could not be identified in the researched literature, not even in works on administration or accounting sciences.

The same gap regarding financial or monetary values is present in government documents. Ordinance MS/GM No. 3,916, dated October 30, 1998, which created the National Drug Policy, mentions 'high cost' without specifying its meaning[109]. On the other hand, Ordinance GM/MS No. 2,577 of October 27, 2006, which created the Exceptional Dispensing Medicines Component – often called High-Cost Medicines Program – attempted to define what was meant by such medicines within SUS, even though this definition led to various interpretations precisely due to the lack of parameters[110]:

> [...] SUS medicines for the treatment of health problems [are] included in the following criteria: a) 'rare or of low prevalence disease with indication for the use of a medicine of high unit cost or that, in case of chronic or prolonged use, is a high-cost treatment; and b) prevalent disease demanding the use of a medicine of high unit cost or that, in case of chronic or prolonged use, is a high-cost treatment', provided that: b.1) there is treatment provided for the disease at the primary care level, to which the patient was intolerant, refractory or evolved to a more severe clinical condition, or b.2) the diagnosis or definition of therapeutic practice for the disease be included in specialized care[111](39-40). [emphasis added].

Although both criteria consider the high cost of medicines as the main axis for the definitions, no value thresholds are defined nor for whom those costs would have a substantial impact, since:

> Contingent on SUS users' economic conditions, cost possibilities are as varied as possible, i.e., what is a high cost for one may not be for another user of the System[111](42-43).

Ordinance GM/MS No. 204, of January 29, 2007, also does not add clarification[112], despite regulating the financing and transfer of federal resources for health actions and services in the form of financing blocks, and among them pharmaceutical services.

Concluding, Ordinance GM/MS No. 2,981, of November 26, 2009[113], which approved the Specialized Component of Pharmaceutical Services in replacement for the former Exceptional Dispensing Medicines Component, was itself replaced by Ordinance GM/MS No. 1,554, of July 3, 2013. The latter provided for the rules on CEAF financing and execution, defining that the 'most expensive' medicines would be financed by the Federal Government, responsible for groups 1A and 1B. The states would finance Group 2 and the purchase and delivery of Group 1B[114]. Innasmuch, those measures represent an important rupture, prevailing the understanding "that SUS was not offering medicines in an exceptional way to users, but rather by means of a properly structured public policy"[115](26-27).

Still on this topic, it is relevant to mention the document issued by the Pan American Health Organization entitled 'Access to high-cost medicines in the Americas: situation, challenges and perspectives', published in 2009[13]. Although it states that HCM does not have a standard definition, some characteristics of those pharmaceutical products are listed:

> [...] in most cases, those are medicines for diseases of great social impact or causing serious risk of death (HIV/AIDS, oncological diseases, etc.), or used by a very small population (orphan medicines, rare diseases), for which acquisition means a great burden to be financed by the public health system or by families and individuals[13](10).

Other common expressions also associated with that kind of medicine are highly complex medicines, usually related to complex and costly administration procedures; and medicines from limited sources, emphasizing exclusivity as one of the universal causes of high cost[13].

Study limitations

The review aimed to achieve the greatest possible representativeness of production on the subject, aggregating scientific papers, theses and dissertations, searching in five different bibliographic databases and thesis libraries. Although attempts have been made to develop comprehensive search criteria, some relevant studies may have been lost due to the lack of a specific descriptor for HCM and because adherence to BDTD by IESs is voluntary and scattered over time, generating potential shortfall of academic products.

Regardless of defined and pre-established criteria for selection, registration, and retrieval,

the rigorous method cannot overcome the limitations and informational gaps of original works that may occur when using literature data that escape research governability.

The review respected the categories of medicines indicated as 'off the lists' and those marked as Pharmaceutical Services components reported by authors of papers and T&D. Verification of that information on a case-by-case basis proved impractical, given the impossibility of identifying, in many studies, the lists in force at the various levels of government in the periods covering the original studies. Those lists involved not only Rename but also state and municipal lists, as well as the so-called Special Components, a way many states offer their own lists, which are not included in the Ministry of Health's programs.

Final comments

Despite the impossibility of retrieving a precise conceptualization of HCM, this review made clear definitions and understandings based on a double strategy: (i) the search for original definitions by authors involved in the production of studies on the judicialization of medicines and (ii) the adherence of those authors to pre-defined operational definitions existing in the literature.

Most studies do not bring any definition. And, even when existent, its character is diffuse, without adding new connections to what is already known. Most of the time, no explicit mention of the concept of the high cost was made, not even when the title referred to 'high cost' or 'cost.' What prevails in the studies is common sense, which guided the very construction of the operational definition grounded on characteristics that work as a proxy for high cost, such as therapies of great price for individual or family budgets or health system financing, even without clear values as to how much the 'high' corresponds to. For a middle- to low-income family, almost all continuous-use medicines can be 'high-cost'. That perception reflects the Brazilian reality, where the families finance the largest expenditures on medicines, not the State.

Other deductions were related to management, such as medicines not pertaining to SUS official lists and medicines belonging to components of pharmaceutical services. Regulatory aspects, such as market approval or patent protection, are mentioned much less. That suggests that high cost is understood as the accumulated cost at the end of the process of making the medicine available to the population. However, it is generated by characteristics of research and development, as well as by regulatory characteristics, and these are basically absent from the authors' imagination, leading to believe that the understanding of high cost happens late, taking into account the pharmaceutical services cycle. In turn, the distorted perception signifies that strategies to deal with high costs end up focusing primarily on discussing or encouraging inclusion in official lists, for which possibilities of addressing the issue are limited per se.

In conclusion, this review also indirectly revealed that the HCM definition is linked to the temporal pace of public financing and provision policies and to the inexorability of the therapeutic transition we experience, a product of the power of innovation in which high cost is almost entirely associated with federal government provision due to the financial shortcomings of users or of subnational entities.

Collaborators

Caetano R (0000-0003-1480-2453)* and Osorio-de-Castro CGS (0000-0003-4875-7216)* contributed to the conception and design of the research; data collection, analysis and interpretation; writing; relevant critical review of the intellectual content; and final approval of the manuscript. Oliveira IAG (0000-0002-4920-4843)*, Mattos L

(0000-0002-5396-2663)*, and Krauze P (0000-0002-9554-4451)* contributed to data analysis and interpretation; writing and final approval of the manuscript. The authors are responsible for ensuring the accuracy and completeness of any part of this work.

References

1. Parker-Lue S, Santoro M, Koski G. The ethics and economics of pharmaceutical pricing. Annu Rev Pharmacol Toxicol. 2015;55:191-206. DOI: https://doi.org/10.1146/annurev-pharmtox-010814-124649

2. Holle M, Wolff T, Herant M. Trends in the concentration and distribution of health care expenditures in the US, 2001-2018. JAMA Netw Open. 2021;4(9):e2125179. DOI: https://doi.org/10.1001/jamanetworkopen.2021.25179

3. Hirsch BR, Balu S, Schulman KA. The impact of specialty pharmaceuticals as drivers of health care costs. Health Aff (Millwood). 2014;33(10):1714-20. DOI: https://doi.org/10.1377/hlthaff.2014.0558

4. Lopes LMN, Coelho TL, Diniz SD, et al. Integralidade e universalidade da assistência farmacêutica em tempos de judicialização da saúde. Saúde Soc. 2019;28(2):124-131. DOI: https://doi.org/10.1590/S0104-12902019180642

5. Instituto de Pesquisas Econômicas Aplicadas. Direito à saúde no Brasil: seus contornos, judicialização e a necessidade da macrojustiça [Internet]. Texto para discussão nº 2547. Brasília, DF: Ipea; 2020 [acesso em 2023 set 20]. Disponível em: http://repositorio.ipea.gov.br/bitstream/11058/9714/1/TD_2547.pdf

6. Instituto de Estudos Socioeconômicos. Orçamento temático de acesso a medicamentos (OTMED) 2021 [Internet]. [local desconhecido]: Inesc; 2022 [acesso em 2023 out 1]. Disponível em: https://www.inesc.org.br/wp-content/uploads/2022/11/OTMED_PT-3.pdf

7. Peçanha LO, Simas L, Luiza VL. Judicialização de medicamentos no estado do Rio de Janeiro: evolução de 2010 a 2017. Saúde debate. 2019;43(esp4):61-70. DOI: https://doi.org/10.1590/0103-11042019S406

8. Albert CE. Análise sobre a judicialização da saúde nos municípios. Rev Técnica CNM [Internet]. 2016 [acesso em 2023 set 21];151-175. Disponível em: https://www.cnm.org.br/storage/biblioteca/Revista%20T%C3%A9cnica%20(2016).pdf

9. Gomes VS, Amador TA. Studies published in indexed journals on lawsuits for medicines in Brazil: a systematic review. Cad Saúde Pública. 2015;31(3):451-462. DOI: https://doi.org/10.1590/0102-311x00219113

10. Catanheide ID, Lisboa ES, Souza LEPF. Características da judicialização do acesso a medicamentos no Brasil: uma revisão sistemática. Physis. 2016;26(4):1335-1356. DOI: https://doi.org/10.1590/S0103-73312016000400014

11. Ribas MC, Pedroso B. Judicialização de medicamentos: uma revisão sistemática da literatura no Brasil entre os anos de 2015 e 2019. Rev Bras Pesq Saúde. 2020;22(3):145-155. DOI: https://doi.org/10.47456/rbps.v22i3.32533

12. Freitas BC, Fonseca EP, Queluz DP. A judicialização da saúde nos sistemas público e privado de saúde: uma revisão sistemática. Interface (Botucatu). 2020;24(e190345):1-17. DOI: https://doi.org/10.1590/Interface.190345

*Orcid (Open Researcher and Contributor ID).

13. Organização Pan-Americana da Saúde. O acesso aos medicamentos de alto custo nas Américas: contexto, desafios e perspectivas [Internet]. Brasília, DF: OPAS/Ministério da Saúde; 2009 [acesso em 2023 set 20]. Disponível em: https://bvsms.saude.gov.br/bvs/publicacoes/acesso_medicamentos_alto_custo_americas.pdf

14. Libanore AC. Medicamentos de alto custo segundo a perspectiva do SUS [dissertação]. São Paulo: Faculdade de Ciências Farmacêuticas da Universidade de São Paulo; 2020. 113 p.

15. Rover MRM, Faraco EB, Vargas-Peláez CM, et al. Acesso a medicamentos de alto preço: desigualdades na organização e resultados entre estados brasileiros. Ciênc saúde coletiva. 2021;26(11):5499-5508. DOI: https://doi.org/10.1590/1413-812320212611.27402020

16. Caetano R, Oliveira IAG, Mattos LT, et al. Analysis of right-to-health litigation involving high-cost medicines in Brazil: a scoping review protocol. Res Soc Dev. 2022;11(15):e550111537584.

17. Anderson S, Allen P, Peckham S, et al. Asking the right questions: scoping studies in the commissioning of research on the organisation and delivery of health services. Health Res Policy Syst. 2008;6:7. DOI: https://doi.org/10.1186/1478-4505-6-7

18. Colquhoun HL, Levac D, O'Brien KK, et al. Scoping reviews: time for clarity in definition, methods, and reporting. J Clin Epidemiol. 2014;67(12):1291-1294. DOI: https://doi.org/10.1016/j.jclinepi.2014.03.013

19. Aromataris E, Munn Z, Editores. JBI Manual for Evidence Synthesis. JBI; 2020. DOI: https://doi.org/10.46658/JBIMES-20-01

20. Tricco AC, Lillie E, Zarin W, et al. PRISMA extension for scoping reviews (PRISMA-ScR): checklist and explanation. Ann Intern Med. 2018;169(7):467-473. DOI: https://doi.org/10.7326/m18-0850

21. Mattos LT. Protocolo de revisão de escopo sobre demandas judiciais de medicamentos de alto custo no Brasil [Internet]. Open Science Framework (OSF); 2024 [acesso em 2024 out 23]. Disponível em: https://osf.io/udfme/

22. Mattos LT. Revisão de escopo sobre demandas judiciais de medicamentos de alto custo no Brasil: estratégias de busca utilizadas na revisão [Internet]. Open Science Framework (OSF); 2024 [acesso em 2024 out 23]. Disponível em: https://osf.io/gvsfy/

23. Oliveira MRM, Delduque MC, Sousa MF, et al. Judicialização da saúde: para onde caminham as produções científicas? Saúde debate. 2015;39(105):525-535. DOI: https://doi.org/10.1590/0103-110420151050002019

24. Ribeiro KD, Vidal JP. Uma análise da produção acadêmica sobre a evolução do fenômeno da judicialização da saúde no Brasil. Cad Ibero Am Direito Sanit. 2018;7(2):239-261.

25. Biblioteca Digital Brasileira de Teses e Dissertações. Busca avançada. BDTD [Internet]; 2024 [acesso em 2023 jan 12]. Disponível em: https://bdtd.ibict.br/vufind/Search/Advanced

26. Fundação Oswaldo Cruz. Repositório ARCA. Consulta a dissertações e teses. Fiocruz [Internet]; 2024 [acesso em 2023 jan 17]. Disponível em: https://www.arca.fiocruz.br/discover

27. Fundação Coordenação de Aperfeiçoamento de Pessoal de Nível Superior (BR). Painel de dados do Observatório da Pós-Graduação. Capes [Internet]; 2022 [acesso em 2022 out 1]. Disponível em: https://sucupira-v2.capes.gov.br/painel

28. Mattos LT. Revisão de escopo sobre demandas judiciais de medicamentos de alto custo no Brasil: lista de artigos, dissertações e teses incluídas na revisão [Internet]. Open Science Framework (OSF); 2024 [acesso em 2024 out 23]. Disponível em: https://osf.io/5g3ht/

29. Page MJ, McKenzie JE, Bossuyt PM, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ. 2021;372:n71. DOI: https://doi.org/10.1136/bmj.n71

30. Nunes ED, Ferreto LE, Oliveira ALO, et al. O campo da Saúde Coletiva na perspectiva das disciplinas. Ciênc saúde coletiva. 2010;15:1917-1922. DOI: https://doi.org/10.1590/S1413-81232010000400007

31. Presidência da República (BR). Lei nº 12.401, de 28 de abril de 2011. Altera a Lei nº 8.080, de 19 de setembro de 1990, para dispor sobre a assistência terapêutica e a incorporação de tecnologia em saúde no âmbito do Sistema Único de Saúde – SUS. Diário Oficial da União [Internet], Brasília, DF. 2011 abr 29 [acesso em 2024 out 20]; Seção 1:1. Disponível em: https://www.planalto.gov.br/ccivil_03/_ato2011-2014/2011/lei/l12401.htm

32. Presidência da República (BR). Decreto nº 7.508, de 28 de junho de 2011. Regulamenta a Lei nº 8.080, de 19 de setembro de 1990, para dispor sobre a organização do Sistema Único de Saúde – SUS, o planejamento da saúde, a assistência à saúde e a articulação interfederativa, e dá outras providências. Diário Oficial da União [Internet], Brasília, DF. 2011 jun 29 [acesso em 2024 out 20]; Seção 1:1. Disponível em: https://legis.senado.leg.br/norma/412353#

33. Santos-Pinto CDB, Ventura M, Pepe VLE, et al. Novos delineamentos da assistência farmacêutica frente à regulamentação da Lei Orgânica da Saúde. Cad Saúde Pública. 2013;29(6):1056-1058. DOI: https://doi.org/10.1590/S0102-311X2013000600002

34. Pedrosa KA, Sena DBC, Pinto JR, et al. Need to reconfigurate SUS financing in the face of austerity: a narrative review. Res Soc Dev. 2022;11(5):e8711527785. DOI: https://doi.org/10.33448/rsd-v11i5.27785

35. Batistella PMF, Ferrari RP, Girotto E, et al. Judicialização na saúde em município de grande porte. Rev Min Enferm. 2019;23(e-1244):1-7. DOI: https://doi.org/10.5935/1415-2762.20190092

36. Trindade MCN, Peres KC, Souza MN, et al. Acciones judiciales que exigen tecnologías en salud en Brasil: una revisión sistemática de métodos mixtos. Cad Ibero Am Direito Sanit. 2022;11(1):64-83. DOI: https://doi.org/10.17566/ciads.v11i1.904

37. Supremo Tribunal Federal (BR). Recurso Extraordinário 855.178. Tribunal Regional Federal da 5ª Região. Tema 793. Recurso extraordinário em que se discute, à luz dos arts. 2º e 198 da Constituição Federal, a existência, ou não, de responsabilidade solidária entre os entes federados pela promoção dos atos necessários à concretização do direito à saúde, tais como o fornecimento de medicamentos e o custeio de tratamento médico adequado aos necessitados [Internet]. Brasília, DF: STF; 2020 abr 16 [acesso em 2024 out 20]. Disponível em: https://portal.stf.jus.br/jurisprudenciaRepercussao/verAndamentoProcesso.asp?incidente=4678356&numeroProcesso=855178&classeProcesso=RE&numeroTema=793

38. Supremo Tribunal Federal (BR). Recurso Extraordinário 1.366.243. Recurso Extraordinário com Repercussão Geral. Tema 1.234. Recurso extraordinário em que se discute, à luz dos artigos 23, II, 109, I, 196, 197 e 198, I, da Constituição Federal, a obrigatoriedade de a União constar do polo passivo de lide que verse sobre a obtenção de medicamento ou tratamento não incorporado nas políticas públicas do SUS, embora registrado pela Anvisa [Internet]. Brasília, DF: STF; 2024 out 11 [acesso em 2024 out 20]. Disponível em: https://portal.stf.jus.br/jurisprudenciaRepercussao/verAndamentoProcesso.asp?incidente=6335939&numeroProcesso=1366243&classeProcesso=RE&numeroTema=1234

39. Vieira FS, Zucchi P. Distorções causadas pelas ações judiciais à política de medicamentos no Brasil. Rev Saúde Pública. 2007;41(2):1-8. DOI: https://doi.org/10.1590/S0034-89102007000200007

40. Chieffi AL, Barata RB. Judicialização da política pública de assistência farmacêutica e equidade. Cad Saúde Pública. 2009;25(8):1839-1849. DOI: https://doi.org/10.1590/S0102-311X2009000800020

41. Chieffi AL, Barata RC. Ações judiciais: estratégia da indústria farmacêutica para introdução de novos medicamentos. Rev Saúde Pública. 2010;44(3):421-429. DOI: https://doi.org/10.1590/S0034-89102010000300005

42. Biehl J, Amon JJ, Socal MP, et al. Between the court and the clinic: lawsuits for medicines and the right to health in Brazil. Health Hum Rights. 2012;14(1):36-52.

43. Diniz D, Medeiros M, Schwartz IVD. Consequências da judicialização das políticas de saúde: custos de medicamentos para as mucopolissacaridoses. Cad Saúde Pública. 2012;28(3):479-489. DOI: https://doi.org/10.1590/S0102-311X2012000300008

44. Medeiros M, Diniz D, Schwartz IVD. A tese da judicialização da saúde pelas elites: os medicamentos para mucopolissacaridose. Ciênc saúde coletiva. 2013;18(4):1089-1098. DOI: https://doi.org/10.1590/S1413-81232013000400022

45. Biehl J, Socal MP, Amon JJ. The judicialization of health and the quest for state accountability: evidence from 1,262 lawsuits for access to medicines in southern Brazil. Health Hum Rights. 2016;18(1):209-20.

46. Silva EM, Almeida KC, Pessôa GSC. Análise do gasto com judicialização de medicamentos no Distrito Federal. Cad Ibero Am Direito Sanit. 2017;6(1):112-126.

47. Nisihara RM, Possebom AC, Borges LMC, et al. Judicial demand of medications through the federal justice of the state of Paraná. Einstein (São Paulo). 2017;15(1):85-91. DOI: https://doi.org/10.1590/S1679--45082017GS3792

48. Barreto AAM, Guedes DM, Rocha Filho JA. A judicialização da saúde no estado de Pernambuco: os antineoplásicos novamente no topo? R Dir Sanit. 2019;20(1):202-222. DOI: https://doi.org/10.11606/issn.2316-9044.v20i1p202-222

49. Oliveira DB, Silva RAM, Paula EA, et al. A judicialização de medicamentos imunoterápicos sem registro na Anvisa: o caso do Estado de São Paulo. Cad Ibero Am Direito Sanit. 2019;8(3):27-47.

50. Szpak R, Strapasson GC, Böger B, et al. Legal demands of the tiotropium bromide for treatment of chronic obstructive pulmonary disease and their financial impact for the State of Paraná, Brazil. Einstein. 2020;18(eGS4442):1-7. DOI: https://doi.org/10.31744/einstein_journal/2020GS4442

51. Pereira JR. Análise das demandas judiciais solicitando medicamentos encaminhados à diretoria de assistência farmacêutica da secretaria de estado da saúde de Santa Catarina nos anos de 2003 e 2004 [dissertação]. Florianópolis: Universidade Federal de Santa Catarina; 2006. 132 p.

52. Sant'ana JMB. Essencialidade e assistência farmacêutica: um estudo exploratório das demandas judiciais individuais para acesso a medicamentos no estado do Rio de Janeiro [dissertação]. Rio de Janeiro: Escola Nacional de Saúde Pública Sergio Arouca, Fundação Oswaldo Cruz; 2009. 93 p.

53. Pereira JG. Demandas judiciais de medicamentos no estado do Paraná: aplicação de indicadores de avaliação e monitoramento e qualidade de vida relacionada à saúde dos usuários [tese]. Rio de Janeiro: Escola Nacional de Saúde Pública Sergio Arouca, Fundação Oswaldo Cruz; 2013. 161 p.

54. Mapelli Junior R. Judicialização da saúde e políticas públicas: assistência farmacêutica, integralidade e regime jurídico-constitucional do SUS [tese]. São Paulo: Universidade de São Paulo; 2015. 390 p.

55. Rodrigues-Pinto PC. Custos médicos diretos dos tratamentos para diabetes mellitus solicitados por via judicial no município de Juiz de Fora, Minas Gerais [dissertação]. Juiz de Fora: Universidade Federal de Juiz de Fora; 2016. 97 p.

56. Souza TG. A judicialização residual da saúde e sua relação com o desempenho dos serviços públicos de saúde e a efetividade do direito à saúde em dois municípios do estado do Rio de Janeiro [dissertação]. Rio de Janeiro: Escola Nacional de Saúde Pública Sergio Arouca, Fundação Oswaldo Cruz; 2018. 192 p.

57. Franco GSM. Acesso a medicamentos: um estudo sobre a judicialização e o fornecimento de medicamentos [dissertação]. Porto Alegre: Universidade Federal do Rio Grande do Sul; 2019. 123 p.

58. Silva A. Perfil da judicialização de medicamentos na área de abrangência de uma regional de saúde do norte do Paraná [dissertação]. Londrina: Universidade Estadual de Londrina; 2019. 74 p.

59. Loreto DR. A judicialização do acesso a medicamentos no âmbito de uma coordenadoria regional de saúde do Rio Grande do Sul [dissertação]. Santa Maria: Universidade Federal de Santa Maria; 2020. 58 p.

60. Oliveira P. Judicialização por medicamentos do componente especializado da assistência farmacêutica no estado de Minas Gerais [dissertação]. Belo Horizonte: Universidade Federal de Minas Gerais; 2021. 115 p.

61. Karnikowski MGO, Silva KM, Salgado FXC, et al. Aspectos farmacoeconômicos das ações judiciais impetradas à secretaria de estado de saúde do Distrito Federal. Brasília Med. 2012;49(3):170-179.

62. Leitão LCA. Análise das demandas judiciais para aquisição de medicamentos no estado da Paraíba [dissertação]. Campina Grande: Universidade Estadual da Paraíba; 2012. 72 p.

63. Marçal KKS. A judicialização da assistência farmacêutica: o caso Pernambuco em 2009 e 2010 [dissertação]. Recife: Centro de Pesquisas Aggeu Magalhães, Fundação Oswaldo Cruz; 2012. 125 p.

64. Mello AF. Medicamentos 'sub judice' no sistema único de saúde do município de Tubarão – SC: uma abordagem econômica [dissertação]. Tubarão: Universidade do Sul de Santa Catarina; 2012. 68 p.

65. Conti MA. Avaliação das demandas judiciais por acesso a medicamentos no Distrito Federal [dissertação]. Brasília, DF: Universidade de Brasília; 2013. 101 p.

66. Reinheimer IC. Medicamentos judicializados na região central do estado do Rio Grande do Sul [dissertação]. Santa Maria: Universidade Federal de Santa Maria; 2014. 69 p.

67. Nunes RP. Judicialização no âmbito do sistema único de saúde: um estudo descritivo sobre o custo das ações judiciais na saúde pública do município de Juiz de Fora [dissertação]. Juiz de Fora: Universidade Federal de Juiz de Fora; 2016. 95 p.

68. Mello AF, Soares LS, Areda CA, et al. Uma abordagem econômica de processos judiciais de medicamentos impetrados contra um município do sul do Brasil. J Bras Econ Saúde. 2016;8(1):39-46. DOI: https://doi.org/10.21115/JBES.v8.n1.p39-46

69. Moraes VMS. Análise dos gastos com ações judiciais na secretaria de saúde do estado de Pernambuco no ano de 2014 [dissertação]. Recife: Universidade Federal de Pernambuco; 2016. 53 p.

70. Ribeiro FO, Ribeiro GAS, Willenshofer I. A judicialização de medicamentos oncológicos no estado de São Paulo [dissertação]. São Paulo: Fundação Getúlio Vargas; 2017. 103 p.

71. Pinheiro PNQ, Garcia JVM, Cardoso ETC, et al. Farmacoeconomia: gastos com análogos de insulina adquiridos por meio de judicialização em um município do estado do Pará, Brasil, no ano de 2016. J Bras Econ Saúde. 2019;11(1):42-8. DOI: https://doi.org/10.21115/JBES.v11.n1.p42-8

72. Coelho TL, Lopes LMN, Campos Neto OH, et al. A propriedade intelectual na judicialização da assistência farmacêutica: uma demanda estrutural em defesa do sistema único de saúde. Saúde Soc. 2021;30(1):1-14. DOI: https://doi.org/10.1590/S0104-12902021190781

73. Sartori Jr D, Leivas PGC, Schwartz IVD, et al. Judicialização do acesso ao tratamento de doenças genéticas raras: a doença de Fabry no Rio Grande do Sul, Brasil. Ciênc saúde coletiva. 2012;17(10):2717-2128. DOI: https://doi.org/10.1590/S1413-81232012001000020

74. Lima JA. Perfil dos usuários de insulinas análogas nas regiões sul e nordeste nos anos de 2010 a 2012: a responsabilidade do sistema único de saúde e a judicialização [dissertação]. Brasília, DF: Universidade de Brasília; 2014. 138 p.

75. Lisboa ES. Acesso ao tratamento da diabetes na Bahia: por que se recorre ao judiciário? [dissertação]. Salvador (BA): Universidade Federal da Bahia; 2015. 78 p.

76. Alves GAC. Custo do tratamento hospitalar de melanoma maligno em Pernambuco: uma análise da judicialização do ipilimumabe a partir de demandas junto aos tribunais de Pernambuco [dissertação]. Recife: Universidade Federal de Pernambuco; 2016. 59 p.

77. Mendonça TS, Silva ES, Pereira ML, et al. Use of more expensive insulin despite guidelines in Brazil. Diabetes Metab Syndr. 2020;14(2):155-157. DOI: https://doi.org/10.1016/j.dsx.2020.02.005

78. Dias GAA. Judicialização da saúde: análise dos processos judiciais do medicamento lenalidomida impetrados contra a secretaria de saúde do estado de São Paulo para tratamento de mieloma múltiplo [dissertação]. São Paulo: Universidade de São Paulo; 2021. 121 p.

79. Cardoso JV. Judicialization of orphan drugs in Brazil: the justiciability of a politically unpalatable issue. Int J Const Law. 2021;19(4):1322-1350. DOI: https://doi.org/10.1093/icon/moab130

80. Oliveira RTG, Agostinho GLPL, Granja R, et al. Socioeconomic impact of high-cost drugs in Brazilian dermatology: legal and financial aspects, and impact on clinical practice. An Bras Dermatol. 2021;96(2):200-209. DOI: https://doi.org/10.1016/j.abd.2020.08.010

81. Ramos KA, Ferreira ASD. Análise da demanda de medicamentos para uso off label por meio de ações judiciais na secretaria de estado de saúde de Minas. Rev Direito Sanit. 2013;14(1):98-121. DOI: https://doi.org/10.11606/issn.2316-9044.v14i1p98-121

82. Machado MAA. Acesso a medicamentos via poder judiciário no estado de Minas Gerais [dissertação]. Belo Horizonte (MG): Universidade Federal de Minas Gerais; 2010. 131 p.

83. Macedo RCR. Judicialização da assistência farmacêutica em Minas Gerais: uma análise da correlação entre proteção aos direitos de propriedade intelectual e o perfil das demandas por medicamentos atendidas pela secretaria de estado de saúde no ano de 2010 [dissertação]. Belo Horizonte: Universidade Federal de Minas Gerais; 2012. 121 p.

84. Barreira SCF. Direito à saúde e judicialização de medicamentos: a experiência de Niterói [dissertação]. Rio de Janeiro (RJ): Universidade do Estado do Rio de Janeiro; 2012. 145 p.

85. Campos Neto OH. As ações judiciais por anticorpos monoclonais em Minas Gerais, 1999-2009: médicos, advogados e indústria farmacêutica [dissertação]. Belo Horizonte: Universidade Federal de Minas Gerais; 2012. 81 p.

86. Silva RSA. Análise da judicialização da assistência farmacêutica no Rio Grande do Sul: a coletividade no banco dos réus: uma avaliação da 7ª coordenadoria regional de saúde [dissertação]. Porto Alegre: Universidade Federal do Rio Grande do Sul; 2014. 90 p.

87. Aires CCNF. Perfil das demandas judiciais para o fornecimento de medicamentos no município de Rio Largo-AL [dissertação]. Maceió: Universidade Federal de Alagoas; 2016. 79 p.

88. Cardoso GGP. Judicialização de medicamentos na microrregião de saúde de Pirapora-MG [dissertação]. Belo Horizonte: Universidade Federal de Minas Gerais; 2021. 114 p.

89. Barcelos PC. Perfil de demandas judiciais de medicamentos da secretaria de estado da saúde do Espírito Santo: um estudo exploratório [dissertação]. Rio de Janeiro: Universidade do Estado do Rio de Janeiro; 2010. 170 p.

90. Campos Neto OH, Acúrcio FA, Machado MA, et al. Médicos, advogados e indústria farmacêutica na judicialização da saúde em Minas Gerais, Brasil. Rev Saude Publica. 2012;46(5):784-790. DOI: https://doi.org/10.1590/S0034-89102012000500004

91. Barbosa PB, Machado Alves SC. A judicialização de medicamentos no estado da Bahia: os números no período de 2014 a 2017. Cad Ibero Am Direito Sanit. 2019;8(4):45-65.

92. Lopes LC, Silveira MSN, Camargo IA, et al. Biological drugs for the treatment of psoriasis in a public health system. Rev Saúde Pública. 2014;48(4):651-661. DOI: https://doi.org/10.1590/S0034-8910.2014048005109

93. Souza KAO. A influência das ações judiciais na incorporação de medicamentos biológicos ao Sistema Único de Saúde [tese]. Salvador: Universidade Federal da Bahia; 2017. 136 p.

94. Lopes LC, Barberato-Filho S, Costa AC, et al. Uso racional de medicamentos antineoplásicos e ações judiciais no Estado de São Paulo. Rev Saúde Pública. 2010;44(4):620-8. DOI: https://doi.org/10.1590/S0034-89102010000400005

95. Souza IP, Bellato R, Araújo LFS, et al. Direito à saúde no tribunal de justiça: demanda por medicações em oncologia. Rev Rene. 2012;13(4):919-28.

96. Honorato S. Judicialização da política de assistência farmacêutica: discussão sobre as causas de pedir no Distrito Federal [dissertação]. Brasília, DF: Universidade de Brasília; 2014. 100 p.

97. Ramos KA. Solicitações judiciais de medicamentos para tratamento de câncer, Minas Gerais, 1999-2009: estudo descritivo [dissertação]. Belo Horizonte: Universidade Federal de Minas Gerais; 2014. 88 p.

98. Galvão MFSM. Causas da judicialização e suas consequências para implementação da política oncológica no Rio Grande do Norte [tese]. Natal: Universidade Federal do Rio Grande do Norte; 2017. 227 p.

99. Vidal TJ, Moraes EL, Retto MPF, et al. Demandas judiciais por medicamentos antineoplásicos: a ponta de um iceberg. Ciênc saúde coletiva. 2017;22(8):2539-2548. DOI: https://doi.org/10.1590/1413-81232017228.07982017

100. Brito SA. Judicialização por medicamentos antineoplásicos para o tratamento de câncer de mama no estado de Pernambuco [dissertação]. Recife: Fundação Oswaldo Cruz; 2020. 93 p.

101. Oliveira FHC, Lorena SJE, Cruz GMA, et al. Profile of judicialization in access to antineoplastic drugs and their costs: a cross-sectional, descriptive study based on a set of all lawsuits filed between 2016 and 2018 in a state in the Northeast Region of Brazil. BMC Public Health. 2022;22(1):1824. DOI: https://doi.org/10.1186/s12889-022-14199-1

102. Vieira FFM, Vidal TJ, Silva MJS, et al. Efeitos da judicialização de medicamentos antineoplásicos nos serviços farmacêuticos em oncologia. Cad Ibero Am Direito Sanit. 2022;11(1):163-182.

103. Alberto MF. Análise das características da Judicialização da Saúde no Estado de São Paulo [dissertação]. Araraquara: Universidade Estadual Paulista; 2012. 116 p.

104. Nunes CFO. Judicialização do direito à saúde no estado do Ceará, Brasil: cenários e desafios [dissertação]. Fortaleza: Universidade Federal do Ceará; 2014. 222 p.

105. Torrieri RT. O fenômeno da judicialização de medicamentos na divisão regional de saúde de Ribeirão Preto/SP [dissertação]. Ribeirão Preto: Universidade de São Paulo; 2017. 131 p.

106. Cirico PF. Análise dos resultados do programa Acessa SUS na judicialização de medicamentos na grande São Paulo – SP [dissertação]. São Paulo (SP): Universidade Nove de Julho; 2019. 115 p.

107. Laffin NHF. Determinantes da judicialização de medicamentos: evidências para as políticas públicas de dispensação [tese]. Ribeirão Preto: Universidade de São Paulo; 2019. 108 p.

108. Salha LA, Reis FC, Gonçalves RM, et al. Judicialization of health: profile of demands for oncological medicines in a state in the central region of Brazil. Int J Equity Health. 2022;21(112):1-15. DOI: https://doi.org/10.1186/s12939-022-01704-6

109. Ministério da Saúde (BR), Gabinete do Ministro. Portaria nº 3.916, de 30 de outubro de 1998. Aprova a Política Nacional de Medicamentos. Diário Oficial da União, Brasília, DF. 1998 nov 10; Edição 215-E; Seção I:18.

110. Ministério da Saúde (BR). Portaria nº 2.577, de 27 de outubro de 2006. Aprova o Componente de Medica-

mentos de Dispensação Excepcional. Diário Oficial da União, Brasília, DF. 2006 nov 13; Seção I:44-64.

111. Ministério da Saúde (BR). Da excepcionalidade às linhas de cuidado: o Componente Especializado da Assistência Farmacêutica [Internet]. Brasília, DF: Ministério da Saúde; 2010 [acesso em 2023 out 2]. Disponível em: https://bvsms.saude.gov.br/bvs/publicacoes/excepcionalidade_linhas_cuidado_ceaf.pdf

112. Ministério da Saúde (BR), Gabinete do Ministro. Portaria nº 204, de 29 de janeiro de 2007. Regulamenta o financiamento e a transferência dos recursos federais para as ações e os serviços de saúde, na forma de blocos de financiamento, com o respectivo monitoramento e controle. Diário Oficial da União, Brasília, DF. 2007 jan 31; Seção I:44-51.

113. Ministério da Saúde (BR), Gabinete do Ministro. Portaria nº 2.981, de 26 de novembro de 2009. Aprova o Componente Especializado da Assistência Farmacêutica. Diário Oficial da União, Brasília, DF. 2009 nov 30; Seção I:725-771.

114. Ministério da Saúde (BR). Portaria nº 1.554, de 30 de julho de 2013. Dispõe sobre as regras de financiamento e execução do componente especializado da assistência farmacêutica no âmbito do Sistema Único de Saúde. Diário Oficial da União, Brasília, DF. 2013 jul 31; Seção I:146.

115. Ministério da Saúde (BR). Componente Especializado da Assistência Farmacêutica: inovação para a garantia do acesso a medicamentos no SUS [Internet]. Brasília, DF: Ministério da Saúde; 2014 [acesso em 2022 ago 26]. Disponível em: https://www.gov.br/saude/pt-br/assuntos/assistencia-farmaceutica-no-sus/sistema-horus/modulo-especializado/arquivos/2020/livro-2-componente-especializado-da-assist-ncia-farmac-utica-inova-o-para-a-garantia-do-acesso-a-medicamentos-no-sus.pdf

Received on 03/02/2024
Approved on 11/07/2024
Conflict of interests: non-existent
Financial support: The study is part of a larger research entitled 'Analysis of lawsuits for medicines against the Federal Government and mapping of strategies for out-of-court resolution of conflicts with medicines', developed and funded by FIOCRUZ (Decentralized Execution Term (Ministry of Health/FIOCRUZ) No. 01/2022)

Editor in charge: Elda Coelho de Azevedo Bussinguer