CHARACTERISTICS OF HIGH-COST MEDICINES IN THE CONTEXT OF HEALTH JUDICIALIZATION IN BRAZIL: A SCOPING REVIEW

HPR121

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INTRODUCTION

Brazil is the sixth most populous country in the world and placed among the eight largest pharmaceutical consumer markets. The cost of medicines is a significant burden for families.

Comprehensive therapeutic care, including pharmaceutical services, is a constitutional right guaranteed to all citizens, being part of the list of services provided by the Brazilian Unified Health System (SUS).

Despite this, health litigation, especially for high-cost medicines, has increased over the years, with the Brazilian Health Ministry (MOH) spending around BR$1.78 billion on legal claims for medicines in 2021.

There is substantial research on litigation for access to medicines in Brazil, but more focus is needed on high-cost medicines.

OBJECTIVE

The study investigated the profile and representativeness of high-cost medicines (HCM) among the drugs cited in the Brazilian scientific and academic literature on health judicialization, describing their main characteristics, from 2005 to 2022.

METHOD

A scoping review of articles, dissertations, and theses containing information on the judicialization of HCM in Brazil, with public government entities as defendants. The review followed the JBI guidelines.

The guiding question of the review was: “In national scientific and academic studies on lawsuits for access to medicines, is it possible to infer any information about the participation of HCM and specific characteristics regarding the judicialization of high-cost medicines?”

We scanned the bibliographic databases MEDLINE, EMBASE, LILACS, SCOPUS, Web of Science, and the Brazilian Digital Library of Theses and Dissertations.

The lack of a consensual definition for HCM in Brazil required the creation of an operational definition for the selection of studies, composed of different criteria based on national and international literature.

Two researchers performed selection and data extraction independently, with disagreements resolved by a third reviewer.

RESULTS

A total of 1,709 original papers and 653 thesis and dissertations were identified. After selection, 62 articles and 66 academic studies were included.

More than 60% of studies were published or defended from 2014 onwards, especially after 2018. Most had been developed in the South and Southeastern regions of the country, focusing on medicines in general, including HCM.

The Brazilian states were the main defendants involved, alone or jointly with other government entities (federal and municipal).

The high cost/unit price for the public health system was the single most frequently cited criterion, from all criteria making up the operational definition.

A high proportion of HCMs outside the official SUS public financing lists was identified among the demanded medicines. This subset mainly included medicines from the Specialized Component of Pharmaceutical Services, which lists products with higher unit or treatment costs, requested for indications other than those recommended in the MoH Clinical Protocols and Therapeutic Guidelines, or for off-label use (according to the marketing approval indications).

The HCMs recurrently mentioned in 30% or more of the studies were: short- and long-acting insulin analogues; adalimumab; bevacizumab; tiotropium bromide; quetiapine hemifumarate; infliximab; methylphenidate; ranibizumab; rituximab and trastuzumab.

Mention of values involved in HCM litigation was mostly absent from studies.

Table 1 – Main characteristics of studies involving high-cost drugs included in the scoping review, according to type of scientific publication, 2005-2022

Characteristics	Articles		Theses and Dissertations	
	N.	%	N.	%
Year of publication				
2005-2009	3	0.05	5	0.08
2010-2013	21	0.34	17	0.26
2014-2017	16	0.26	24	0.36
2018 onwards	22	0.35	20	0.30
Government entities (defendants)				
Federal government	6	0.10	1	0.02
Brazilian states	27	0.44	24	0.36
Municipalities	8	0.13	1	0.02
Federal government and States	3	0.05	0	-
States and Municipalities	11	0.18	16	0.24
Federal government, States and Municipalities	7	0.11	24	0.36
Region / Brazilian State				
North	2	0.03	2	0.03
Northeast	9	0.15	17	0.26
Bahia	2	0.03	1	0.02
Pernambuco	2	0.03	4	0.06
Ceará	2	0.03	4	0.06
Rio Grande do Norte	2	0.03	3	0.05
Other states in the Northeast	1	0.00	5	0.08
South	15	0.24	13	0.02
Paraná	5	0.08	4	0.06
Santa Catarina	5	0.08	3	0.05
Rio Grande do Sul	5	0.08	6	0.09
Southeast	25	0.40	30	0.45
São Paulo	11	0.18	13	0.20
Minas Gerais	8	0.13	10	0.15
Rio de Janeiro	6	0.10	6	0.09
Espírito Santo	0	-	1	0.02
Midwest	6	0.10	3	0.05
Brazil (no region specified)	5	0.08	1	0.02
Study Analysis Unit				
Lawsuits	51	0.82	58	0.88
Court decisions	2	0.03	3	0.05
Patients	2	0.03	2	0.03
Medicines	6	0.10	3	0.05
NATS-Jus Technical Notes	1	0.02	0	-
Scope of the study				
Health Judicialization with HCM among the items subject to judicialization	3	0.05	16	0.24
Medicines Judicialization with HMC among other medicines	41	0.66	41	0.62
Case study of a high-cost drug or therapeutic class	18	0.29	9	0.14
Mention of judicialization values with HCM				
Yes	27	0.44	27	0.41
No	35	0.56	39	0.59

Table 2 – High-cost medicines explicitly cited in 25% or more of the papers included in the scoping review, by type of scientific publication, 2005-2022

High-cost medicines	No. studies mentioning the drug	% of total
Scientific articles (n= 62, 123 different HCMs)		
rituximab	28	0.45
insulin glargine	26	0.42
bevacizumab	19	0.31
insulin aspart	18	0.29
temozolomide	18	0.29
teriparatide	18	0.29
infliximab	16	0.26
tiotropium bromide	**16**	**0.26**
Theses and dissertations (n=66, 124 different HCMs)		
rituximab	41	0.62
insulin glargine	38	0.58
insulin lispro	33	0.50
bevacizumab	28	0.42
ranibizumab	28	0.42
trastuzumab	28	0.42
tiotropium bromide	26	0.39
adalimumab	23	0.35
quetiapine hemifumarate	23	0.35
insulin aspart	23	0.35
infliximab	21	0.32
methylphenidate	20	0.30
cetuximab	19	0.29
insulin detemir	19	0.29
sorafenib	19	0.29
etanercept	18	0.27
sunitinib malate	18	0.27
mycophenolate mofetil	18	0.27
teriparatide	17	0.26

CONCLUSIONS

Conceptual elements of HCM stood out, such as the association of high costs with individual expenditures and treatments that exceed families' ability to pay, and the high and growing cost for public entities, exerting pressure on public management to seek inclusion in official medicines lists.

However, the lack of a recognized definition of the term, and the heterogeneity in existing mentions of HCM in the literature prevented a precise accrual of their percent participation in litigation in Brazil or their overall contribution in terms of expenditures.

Nonetheless, the review allowed us to obtain a different perspective on these medicines in the context of the national ‘phenomenon’ of litigation for access to medicines. It may contribute to reorienting public policies and the sustainability of the SUS.

CONTACT INFORMATION

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