

HIGH-COST MEDICINES: PERCEPTIONS AND DEFINITIONS PRESENT IN THE BRAZILIAN SCIENTIFIC AND ACADEMIC LITERATURE ON HEALTH LITIGATION

HPR170

Authors: Caetano R¹, Oliveira IA¹, Mattos L², Krauze P², Osorio-de-Castro CGS²

¹ Instituto de Medicina Social, Universidade do Estado do Rio de Janeiro, Rio de Janeiro, Brazil; ² Sergio Arouca National School of Public Health, Oswaldo Cruz Foundation, Rio de Janeiro, Brazil

INTRODUCTION

The Brazilian Ministry of Health spent R\$1.78 billion to meet legal demands in 2021. Drugs are one of Brazil's main drivers of health litigation, and especially high-cost medicines, on which a large portion of demands are based.

However, there is no uniform or precise definition of the term 'high-cost' medicine (HCM) in the country's judicialization literature.

OBJECTIVE

The study intended to identify the existing definitions and understandings of HCM in Brazilian scientific and academic literature related to health litigation

METHOD

We conducted a scoping review following the JBI guidelines. The main question for the review was: *"Do scientific and academic studies on lawsuits for access to medicines in Brazil provide any definition, either explicitly stated or referred to subjectively, of what 'high-cost medicines' are? If so, what do these definitions and understandings assert?"*

We searched Medline, Embase, Lilacs, Web of Science and Scopus, and the Digital Library of Theses and Dissertations for empirical studies on medicines litigation that included HCM between 2005-2022. The selection of studies was based on an operational definition derived from criteria commonly found in HCM-related publications or in Brazilian and international policy documents.

Two independent reviewers conducted the selection and data extraction, with disagreements resolved by a third reviewer.

The results were analyzed according to thematic content categories.

RESULTS

We included 62 scientific articles and 66 thesis and dissertations. Similar proportions of scientific articles and theses/dissertations were published or defended from 2015 onwards, 53.2% and 53% respectively. The volume in 2012-2014 is also noteworthy: 15 articles and 23 academic products.

Explicit definitions of HCM were very infrequent (19.1% of articles and 15.2% of academic studies).

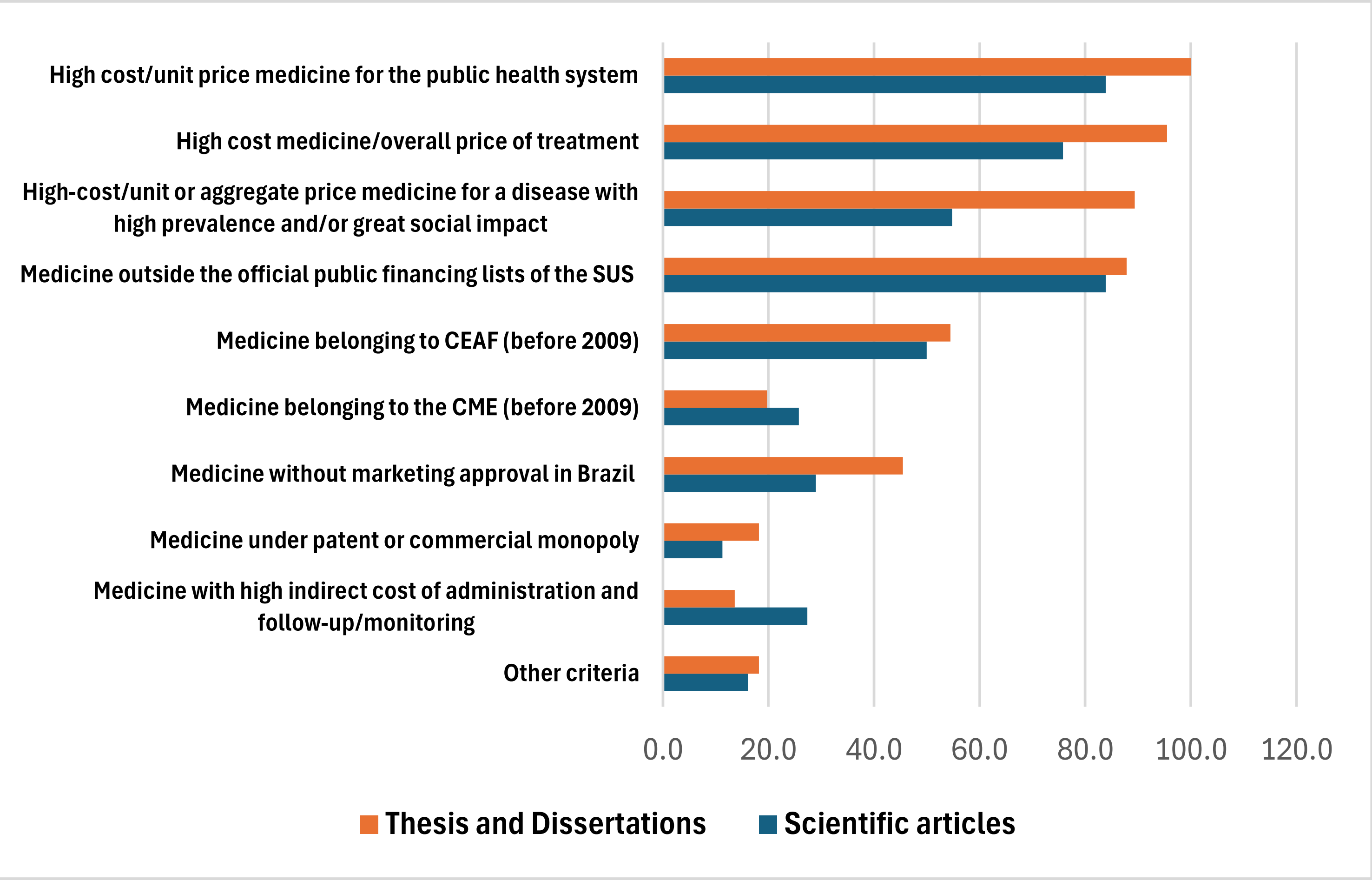
Either the high unit cost of the medicine or the high total treatment cost, due to the chronicity of the disease, producing a substantial financial impact on the family budget, represented the core meaning of the term HCM (Fig.1).

Less frequently, meaningful relationships with HCM came from very new technologies, many without marketing approval in the country, drugs absent from the MoH Clinical Protocols and Therapeutic Guidelines or those employed in off-label use, and those aimed at treating rare and genetic diseases.

Other aspects related to HCM referred to drugs outside the official public financing lists of the Brazilian Unified Health System (SUS) and to drugs belonging to the Specialized Component of Pharmaceutical Services, which provides outpatients in the SUS with medicines deemed more expensive or with substantial average prices

Specific drug classes were associated with high costs, such as biologics, orphan drugs, and antineoplastic medicines.

Figure 1. Degree of fulfillment of the criteria for high-cost medicines according to the operational definition established for the research in the articles and theses and dissertations included in the scoping review, 2005-2022



Caption: CEAF – Specialized Component of Pharmaceutical Services; CME – Exceptional Medication Component; SUS - Brazilian Unified Health System

CONCLUSIONS

It is difficult to arrive at an exact comprehensive definition of high-cost drugs, but this review clarified meanings and perceptions using a two-pronged strategy. First, it searched for original definitions from authors who have worked on studies on the legal aspects of medicines use in Brazil. Second, it examined the adherence of the studies to a pre-established operational definition present in the literature.

Brazil does not adopt any financial parameter to define high-cost medicines.

Conceptual imprecision hinders a clearer view of the importance of high-cost medicines in the judicialization of medicines in Brazil.

CONTACT INFORMATION

caetano.r@gmail.com

REFERENCES

Lopes LMN, Coelho TL, Diniz SD, et al. Integralidade e universalidade da assistência farmacêutica em tempos de judicialização da saúde. Saude soc. 2019Apr;28(2):124–31.

Instituto de Estudos Socioeconômicos. Orçamento temático de acesso a medicamentos (OTMED) 2021. 2022. IN: https://www.inesc.org.br/wp-content/uploads/2022/11/OTMED_PT-3.pdf.

Organização Pan-Americana da Saúde. O acesso aos medicamentos de alto custo nas Américas: contexto, desafios e perspectivas. 2009. IN: https://bvsms.saude.gov.br/bvs/publicacoes/acesso_medicamentos_alto_custo_americas.pdf

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