



## Review

## Right to health, essential medicines, and lawsuits for access to medicines – A scoping study



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## ABSTRACT

Despite countries' efforts to ensure access to essential medicines, some people do not have their needs met, and often resort to the Judiciary to get access to the medicines they need. This phenomenon, known as "judicialization of access to medicines", has aroused the academia's interest in law, health and social fields. In this context, this scoping study investigates, through qualitative thematic analysis, the approach to judicialization of access to medicines (normative or social) and its possible impacts (positive or negative) described in articles published in scientific journals indexed in the main health databases prior to July 2012. 65 of 384 papers met the inclusion criteria of focusing on lawsuits for access to medicines or judicialization of access to medicines as a phenomenon; empiric studies, review articles or theoretical discussions, written in English, Portuguese or Spanish; most of them were about Brazil, Colombia and England. Results show that judicialization is a complex phenomenon that involves technical-scientific, legal and social aspects. The judicialization impacts mentioned have changed over time. In the late 1990s and early 2000s the emphasis of positive impacts predominated both on the normative and social approaches, having as main reference the movements that claimed from the States the guarantee of access to HIV/AIDS treatment. In the mid-2000s, however, there was an emphasis of the negative effects of judicial intervention, when lawsuits for access to medicines became a problem in some countries. Few studies used the social approach to judicialization. For this reason, there is not enough information about whether lawsuits for access to medicines are related to a real recognition of the right to health as an exercise of citizenship. Such aspects need to be further studied.

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### 1. Introduction

Medicines are products involved in two contexts of society: health and market. In the health context, medicines are considered social goods, whose purpose is to prevent and solve health problems (Tobar and Sánchez, 2005). In the international sphere, access to essential medicines (as defined by the World Health Organization) is part of the Right to Health (Committee on Economic, Social and Cultural Rights CESCR, (2000)).

To fulfill the commitments agreed in international treaties on the Right to Health, the states have established public health policies and specific strategies to ensure access, financing and rational

use of medicines and health services through health systems (Lobato and Giovanella, 2008). However, despite the adopted measures, governments still face difficulties like reduced levels of coverage and financial fragility of the health systems, and general problems of access to essential health services and medicines by a large part of the population (Fondo Nacional de Recursos FNR, (2010)).

In the market context, medicines are considered products aimed at generating profit. In fact, the pharmaceutical industry plays an important role in the scientific development, which generates great added value, and makes this industry a strategic sector for the economy (Tobar and Sánchez, 2005). Furthermore, conforming to the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), medicines are considered patentable innovations (World Trade Organization, 1995).

As a consequence, since the last two decades there has been a rapid onset of new medicines, which are usually costly because of the patent protection, but these do not always have an

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additional therapeutic value (Prescrire, 2011). However, the use of these products is promoted by the pharmaceutical industry through marketing to prescribers and patients (Vacca et al., 2011), and this might create a pressure on the health system aimed at the incorporation of its products (Glassman et al., 2012). So, access and funding of high-cost medicines in health systems are current issues in public policy discussions due to both economic and public health impacts (Pan American Health Organization, 2010).

In this framework, when patients feel that their health demands are not satisfied by the health system, they increasingly often have recourse to the courts to gain access to treatment (Reveiz et al., 2013). This phenomenon, called “judicialization of access to medicines”, became relevant and controversial owing to the different interests and stakeholders involved.

This paper aims, by means of a scoping study (Levac et al., 2010), to analyze the approach to judicialization of access to medicines and its possible impacts described in articles published in scientific journals indexed in the main health databases.

## 2. Methodology

The search was conducted using the databases Scopus, Pubmed, Scielo and Lilacs. The keywords combinations used are shown in Table 1. Additionally, manual search was conducted using the Pubmed tool “related articles”. Only papers published prior to July 2012 were considered.

Two independent reviewers selected the papers according to the following inclusion criteria: focus on lawsuits for access to medicines or judicialization of access to medicines as a phenomenon; empiric studies, review articles or theoretical discussions, written in English, Portuguese or Spanish. Genres such as monographs, dissertations or theses, and articles about other kinds of right-to-health related lawsuits like medical malpractice, euthanasia and abortion, or about access to medicines by other ways rather than lawsuits, were excluded. No limit was established on studied countries.

Descriptive analysis considered publication data, the studied country, the journal thematic area, authors' fields of expertise and kinds of institutions. The journals were classified according to the All Science Journal Classification (ASJC) available in the SCOPUS database; the fields of expertise were obtained by consulting information from the articles, the Lattes Platform (for Brazilian researchers), and institutional websites. Institutions were

categorized as academic (universities), health (hospitals and clinics), government agencies (Ministries, health department.), or others.

In the thematic analysis (Bardin, 1977; Minayo, 1993), the approaches to judicialization and type of impacts categories were created after a brief reading of the articles, identifying explicit definitions of judicialization of access to medicines and the impacts mentioned by the authors. These categories were applied in the exploration and analysis phases of this study.

This is a review of published papers and, for this reason, an ethics committee evaluation was not necessary. However, the studies that included data about patients getting medicines by means of lawsuits were analyzed to make sure they had ethics committee approval.

## 3. Results

The selection of articles is shown in Fig 1.

Most of the articles were published between 2009 and 2011. The most frequently studied countries were Brazil ( $n = 44$ ; 68%), Colombia ( $n = 6$ ; 9%) and England ( $n = 4$ ; 6%) (Fig 2).

The included articles were published in 31 journals. According to ASCJ, 17 (54.8%) journals were classified in the Health Sciences category, 7 (22.6%) in the Social Sciences category, and 7 (22.6%) in both categories. Following the same classification, 35 articles (53.8%) were published in Health Sciences journals, 11 (17%) in Social Sciences journals, and 19 (29.2%) in journals of both categories.

A total of 116 authors were involved in the 65 articles. Their fields of expertise are public health (49; 42.2%), law and political sciences (30; 25.9%), pharmacy (21; 18.1%), medicine (19; 16.4%), and others (10; 8.6%) (biological sciences, social work, sociology and anthropology).

Among the 61 institutions identified, there were 41 (67.2%) academic institutions, 12 (19.7%) government entities, 6 (9.8%) health institutions, 3 (4.9%) international organizations, and others (law firms, NGOs and nonprofit organizations).

### 3.1. Thematic analysis

Seven articles had their own definition of judicialization. Five described the phenomenon as an increase in judicial decisions that determine the medications dispensing through health systems (Romero, 2010; Biehl et al., 2012; Biehl and Petryna, 2011; Andrade et al., 2008; Cubillos et al., 2012). Borges and Ugá (2010) defined judicialization as “the involvement of the judiciary in the political sphere”, and for Leite et al. (2009), judicialization is the exercise by the Judiciary of attitudes of the Executive such as decisions about health resources allocation.

For Ventura et al. (2010), judicialization goes beyond legal components and management of health services, it expresses “legitimate claims and actions of citizens and institutions for safeguarding and promoting the citizenship rights widely affirmed in international and national laws”.

Five articles had theoretical framework supporting a definition for judicialization (Borges and Ugá, 2009; Machado, 2008; Marques, 2008; Asensi, 2010; Abramovich and Pautassi, 2009). The cited authors were Tate and Vallinder (1995), and Vianna (2002).

Tate and Vallinder (1995) considered that “judicialization of politics” is an expression that indicates expansion of judicial power in the decision-making process in contemporary democracies. Judicialization from without, the more common form, represents the control expansion of the Judiciary on Executive and Legislative powers' issues. Judicialization is based on the mechanisms of

**Table 1**  
Search strategy and syntax by database.

Data base	Keywords
PUBMED	(“Human Rights”[Mesh] OR “human rights”) AND (“Drugs, Essential”[Mesh] OR “essential medicines”) AND (“legislation and jurisprudence”[subheading] OR “Judicial Role”[Mesh] OR “Patient Advocacy”[Mesh] OR lawsuits)
SCOPUS	“Right to Health” AND “essential medicines” AND (judicial OR lawsuits)//Articles or reviews//All fields “Right to Health” AND “drug” AND lawsuits//All fields “Right to Health” AND Drugs//Articles or reviews//Title, abstract, keywords “Right to health” AND “essential medicines”//Articles or reviews//All fields
SCIELO	“Direito à saúde” AND Medicamentos “Derecho a la salud” AND Medicamentos Right to health AND (essential medicines OR drugs)
LILACS	“Direito à saúde” AND Medicamentos “Right to health” AND (drugs OR “Essential medicines”) “Derecho a la salud” AND (“Medicamentos esenciales” OR Medicamentos)

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