Claudia Marcela Vargas-Peláez

# JUDICIALIZATION OF ACCESS TO MEDICINES AND PHARMACEUTICAL POLICIES IN LATIN AMERICAN COUNTRIES

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**POR**

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“Poderia se alegar, naturalmente, que é este um critério inumano porque certos indivíduos seriam privados de assistência ou de conforto quando a cura é impossível.

Mas em realidade, ¿o que é mais inumano? ¿atender a uns poucos privilegiados com todo tipo de placebos caros e deixar à grande maioria da população mundial desprovida dos cuidados mais essenciais, ou velar por uma distribuição mais equitativa da assistência essencial?

És evidente que, una vez mais, se trata de um dilema cuja solução deve buscar-se não no cenário técnico senão no cenário social”

(Halfdan Mahler, 1977)

## RESUMO

Atualmente, o financiamento e o acesso a medicamentos nos sistemas de saúde são temas relevantes nas discussões de políticas públicas. Apesar dos esforços dos países para garantir o acesso aos medicamentos sem comprometer a sustentabilidade dos sistemas de saúde, nem todas as pessoas conseguem ter suas necessidades atendidas. Como resultado, as pessoas entram com ações judiciais reivindicando a defesa do seu direito à saúde para obterem acesso aos medicamentos. Este fenômeno, conhecido como "judicialização do acesso a medicamentos" ou "litígio para acesso a medicamentos" tem se tornado uma via alternativa aos mecanismos estabelecidos pelo sistema de saúde. A fragmentação dos sistemas de saúde tem sido apontada como um dos fatores que mais contribuem para a ocorrência de judicialização do acesso a medicamentos. No entanto, a extensão do fenômeno varia entre os países, independente da forma de organização dos sistemas de saúde. Nesse contexto, este estudo visou analisar a judicialização do acesso aos medicamentos e as políticas farmacêuticas na Argentina, no Brasil, no Chile e na Colômbia. Esta pesquisa adotou uma abordagem qualitativa e foi desenvolvida em duas partes. A primeira parte compreende o desenvolvimento do referencial teórico para a análise comparativa. O *scoping study* mostrou que a judicialização é um fenômeno complexo que envolve aspectos técnico-científicos, legais e sociais. Porém, grande parte dos artigos revisados utilizava uma abordagem normativa focada nos aspectos técnicos do fenômeno, evidenciando a necessidade de estudos adicionais utilizando a abordagem social da judicialização. Este estudo também evidenciou a forma como as características das ações judiciais e da judicialização tem mudado ao longo do tempo: de um carácter coletivo, no caso do tratamento do HIV, para um carácter individual, no caso dos novos medicamentos. O modelo teórico foi proposto com base nos resultados do *scoping study* e considerando a definição de medicamentos como necessidades em saúde. O modelo teórico inclui os elementos (*stakeholders* e políticas) que influenciam a percepção dos medicamentos como necessidades em saúde em três níveis: internacional, nacional e demanda local (*demand-side*) e que, em consequência, modulam a ocorrência de judicialização do acesso a medicamentos. A segunda parte compreende a análise comparativa, a qual foi desenvolvida por meio de uma revisão integrativa da literatura, e a realização de entrevistas semiestruturadas com representantes dos *stakeholders* envolvidos na judicialização do acesso a medicamentos na Argentina, no Brasil, no Chile e na Colômbia. A comparação das

políticas farmacêuticas, que incluiu também os Países Baixos, evidenciou que, nos últimos quinze anos, todos os países estudados tomaram medidas visando melhorar o acesso a medicamentos para a população. Durante esse período, o foco das medidas mudou dos medicamentos essenciais para os medicamentos de alto custo, os quais significam uma importante carga econômica para os sistemas de saúde. Apesar dos esforços dos países, o acesso equitativo aos medicamentos continua sendo uma meta a ser alcançada, mesmo em países desenvolvidos como os Países Baixos. Os resultados mostram que a fragmentação do sistema de saúde em diferentes aspectos (organização, financiamento, regulação) tem um papel relevante na geração de barreiras ao acesso aos medicamentos. A análise *cross-country* das causas e consequências da judicialização do acesso a medicamentos demonstrou que, nos quarto países latino-americanos estudados, o litígio para acesso aos medicamentos resulta principalmente das limitações dos sistemas de saúde na garantia do acesso aos medicamentos cobertos; e também pela influência das práticas de marketing da indústria farmacêutica. Os resultados mostraram, ainda, que as políticas de controle de preços de medicamentos, de proteção de propriedade intelectual e de desenvolvimento científico em saúde também são fatores que influenciam a judicialização nos níveis nacional e internacional. As consequências da judicialização foram mencionadas apenas nos níveis nacional e de demanda local. No nível nacional, a atualização das listas e a definição de protocolos clínicos foram as consequências mais mencionadas. O financiamento de medicamentos de alto custo sem evidência de eficácia e segurança foi considerado uma consequência negativa. Outras consequências mencionadas foram a sobrecarga do Judiciário. No nível demanda local, a reafirmação do papel dos pacientes como consumidores de serviços de saúde foi apontada também como uma consequência negativa. Por fim, a análise comparativa das respostas dos países à judicialização mostrou que, apenas no Brasil e na Colômbia, as medidas focadas na incorporação de novas tecnologias nos sistemas de saúde foram em resposta ao fenômeno. Nesses dois países, as medidas do Executivo e do Legislativo foram precedidas de intervenções dos altos tribunais. Apesar das diferenças nas intervenções do Judiciário – uma audiência pública no Brasil e uma ordem judicial na Colômbia –, as medidas do Executivo e o Legislativo foram similares: o estabelecimento de agências de Avaliação de Tecnologias em Saúde, a incorporação de novas tecnologias na cobertura dos sistemas de saúde e mudanças nas estratégias de financiamento dos medicamentos. A percepção comum sobre os

resultados dessas medidas é que elas não foram suficientes para reduzir a judicialização do acesso a medicamentos. Em conclusão, a judicialização do acesso a medicamentos é um fenômeno complexo que envolve os interesses de diferentes stakeholders e as relações entre eles. Essas características destacam a relevância de se realizar estudos adicionais sobre o fenômeno sob uma perspectiva social. Além disso, as estratégias focadas na incorporação de novas tecnologias têm se mostrado insuficientes para controlar a judicialização do acesso aos medicamentos. Portanto, é urgente o desenho de estratégias inovadoras que tenham como alvo pontos críticos identificados neste estudo, tais como as relações entre a indústria farmacêutica e outros *stakeholders* (prescritores, gestores, tomadores de decisão, e pacientes); o controle de preços de medicamentos e o desenvolvimento científico.

**Palavras-chave**: Direito à saúde. Acesso a medicamentos. Ações judiciais. Políticas Farmacêuticas. Argentina. Brasil. Chile. Colômbia.

## ABSTRACT

Currently, the financing and access to medicines in health systems are relevant issues in what concerns discussions on public policies in certain countries. Despite the countries' efforts to guarantee access to medicines without compromising the health systems' sustainability, some people do not have their needs met, and often resort to the Judiciary claiming the defence of their Right to Health to get access to the medicines they need. This phenomenon, known as "judicialization of access to medicines" or "litigation for access to medicines", has become an alternative pathway to the mechanism established by the health system to ensure access to medicines. The health system's fragmentation has been described as the main addressing factor of judicialization for access to medicines. However, the extension of the phenomenon varies across countries regardless of the health systems' organization. In this context, this study aimed to analyse judicialization of access to medicines and pharmaceutical policies in Argentina, Brazil, Chile and Colombia. The study adopted a qualitative approach and was carried out in two parts. In the first part, the theoretical framework was developed for the comparative analysis. The scoping study showed that judicialization is a complex phenomenon that involves technical-scientific, legal and social aspects. However, most of the papers reviewed had a normative approach focused on the technical aspects of the phenomenon. Thus, it evidenced the need for further research on judicialization from a social perspective. This study also demonstrated how the characteristics of both lawsuits and judicialization have changed over time: from a collective approach in the case of HIV treatment to an individual approach in the case of new medicines. A theoretical model was proposed based on the results of the scoping study and taking into consideration the definition of medicines as a health need. The theoretical model comprised the elements (stakeholders and policies) that influence the perception of medicines as a health need at three levels (international, national and demand-side), therefore modulating the occurrence of litigation. In the second part the comparative analysis was carried out by means of an integrative literature review and semi-structured interviews with representatives of the stakeholders involved in judicialization of access to medicines in Argentina, Brazil, Chile and Colombia. The comparison among the pharmaceutical policies, which also included The Netherlands, evidenced that in the last fifteen years the studied countries have taken measures to improve the access to medicines for the population. During this time, the measures' focus has

changed from essential medicines to new and expensive medicines, which means an important financial burden for the health systems. Despite the countries efforts, equitable access to medicines is still a goal to be achieved, even in developed countries as The Netherlands. The results showed that the health system's fragmentation at different levels (organization, financing, regulation) significantly contributes to the creation of barriers to the access to medicines. The cross-country analysis of the causes and consequences of judicialization showed that, in the four Latin American countries, it results mainly from the health systems' limitations in ensuring access to the covered medicines; and also from the influence of the pharmaceutical marketing. The results evidenced that policies on medicines price control, on intellectual property protection, and on health scientific development are also addressing factors of litigation at the international and national levels. The consequences of judicialization were mentioned only at the national and demand-side levels. At the national level, the updating of the medicines list and the establishment of clinical guidelines were the most mentioned consequences. The financing of expensive medicines without evidence of efficacy and safety was considered a negative consequence. Other consequences mentioned included the overcharge of the Judiciary. At the demand-side level, the assertion of the patients' role as consumers of healthcare services was also noted as a negative consequence. Finally, the comparative analysis of the responses to judicialization of access to medicines showed that, only in Brazil and Colombia, the measures focussed on the incorporation of new technologies in the health resulted from the judicialization phenomenon. In both cases, the Judiciary's high instance interventions preceded the Executive and Legislature measures. Despite the differences between the Judiciary's interventions – a public hearing in Brazil and a judicial order in Colombia –, the Executive and Legislature measures were similar: the establishment of a Health Technology Assessment agency, the incorporation of new technologies in the health systems' coverage, and changes in the financing strategies. The common perception about the results of these measures was the fact that they were not sufficient to decrease litigation for access to medicines. In conclusion, litigation for access to medicines is a complex phenomenon that involves the stakeholders' interests and the relationships established among them. These characteristics highlight the relevance of carrying out further research on the phenomenon from a social perspective. Furthermore, the strategies focused on the incorporation of new technologies have been insufficient to control litigation for access to medicines. Thus,

innovative strategies focused on critical points such as the relationships between the pharmaceutical industry and other stakeholders (prescribers, managers, policy-makers, patients), medicines price control and scientific development should be urgently implemented.

**Keywords**: Right to health. Access to medicines. Lawsuits. Pharmaceutical Policies. Argentina. Brazil. Chile. Colombia.

# LIST OF FIGURES

Figure 1-1 – Flow diagram of articles included in the review. .....49
Figure 1-2 - Articles published by year and by studied country .....50
Figure 2-1 Theoretical model adopted as framework for the thematic analysis.71
Figure 2-2 Conflict in the definition of 'need' in judicialization of access to medicines.....81
Figure 3-1 Health System Organization and Access to medicines pathways in Argentina .....98
Figure 3-2 Health System Organization and Access to medicines pathways in Colombia .....103
Figure 3-3 Health System Organization and Access to medicines pathways in Brazil .....107
Figure 3-4 Health System Organization and Access to medicines pathways in Chile .....112
Figure 3-5 Health System Organization and Access to medicines pathways in The Netherlands.....116

# LIST OF TABLES

Table 1-1 – Search strategy and syntax by database .....47
Table 1-2 – Thematic analysis categories .....52
Table 3-1 Number of interviewed respondents .....89
Table 3-2 Specific questions per country. .....91
Table 3-3 General information about the studied countries. .....92
Table 4-1 - Right to health and pathways to resort the Judiciary for protecting it in Argentina, Brazil, Chile and Colombia .....124
Table 5-1 Measures taken by the Judiciary branch in Brazil and Colombia in response to judicialization of access to medicines .....161
Table 5-2 Measures taken by the Executive and Legislative branches in Brazil and Colombia in response to judicialization of access to medicines .....166

## LIST OF BOXES

Box 4-1. Examples of the categories at International level.....129
Box 4-2. Examples of causes related to the category right to health in the Political Constitution .....130
Box 4-3. Examples of consequences related to the category right to health in the Political Constitution .....131
Box 4-4. Examples of causes related to the category health system hardware 132
Box 4-5. Examples of consequences related to the category health system hardware .....134
Box 4-6. Examples of causes related to the category health system software .138
Box 4-7. Examples of consequences related to the category health system software .....140
Box 4-8. Examples of the category Pharmaceutical marketing .....141
Box 4-9. Examples of the category National policies for science and technology development, intellectual property protection and medicines prices control ...142
Box 4-10. Examples of causes related to the category Judiciary Power .....145
Box 4-11. Examples of consequences related to the category Judiciary Power .....146
Box 4-12. Examples of the category Medicines as health needs .....147
Box 4-13. Examples of causes related to the category Demand side level .....148
Box 4-14. Examples of consequences related to the category Demand side level .....149

## LIST OF ABBREVIATIONS AND ACRONYMS

AIDS – Acquired Immune Deficiency Syndrome
ANMAT – Administración Nacional de Medicamentos Alimentos y Tecnologías en salud, Argentinan Medicines Regulatory Agency
APE – Administración de Programas Especiales, Argentinian Special Programs Administration
ASJC – All Science Journal Classification
AUGE – Acceso Universal con Garantías Explícitas (Plan), Chilean Universal Access with Explicit Guarantees (Plan)
CAC – Cuenta de alto costo, Colombian National Account of High Cost
CAEC - Cobertura Adicional para Enfermedades Catastróficas, Chilean Coverage for Catastrophic Diseases
CAPS – Centros de Atención Primaria en Salud, Argentinean Primary Care Centres
CAS – Complex Adaptive Systems
CBAF – Componente Básico da Assistência Farmacêutica, Brazilian Basic Component of Pharmaceutical Assistance
CEAF – Componente Especializado da Assistência Farmacêutica, Brazilian Specialized Component of Pharmaceutical Assistance
CEPSH – Comitê de Ética de Pesquisa com Seres Humanos, Research with Human Beings Ethics Committee
CEsAF – Componente Estratégico da Assistência Farmacêutica, Brazilian Strategic Component of Pharmaceutical Assistance
CESCR – Committee on Economic, Social and Cultural Rights
CMDE – Componente de Medicamentos de Dispensação Excepcional, Brazilian Exceptional Dispensation Medicines Component
COFESA – Consejo Federal de Salud, Federal Health Council
CONITEC – Comissão Nacional de Incorporação de Tecnologias no Sistema Único de Saúde-SUS, Brazilian National Committee for Health Technology Assessment
COP – Colombian Pesos
CTC – Comité Técnico Científico, Colombian Technical-Scientific Committee
CVZ – College voor Zorgverzekeringen, Dutch Healthcare Insurance Board
ECLAC – Economic Commission for Latin America and the Caribbean
EMA – European Medicines Agency
EPS – Empresas Promotoras de Salud, Colombian Health Promoting Entities
FDA – Food and Drug Administration

FNR – Fondo Nacional de Recursos, Uruguaian National Fund of Resources
FONASA – Fondo Nacional de Salud, Chilean public health insurer
FOSYGA – Fondo de Solidaridad y Garantía, Colombian Solidarity and Guarantee Fund
FSR – Fondo Solidario de Redistribución, Argentinean Solidarity Redistribution Fund
GDP – Gross Domestic Product
GES – Garantías Explícitas en Salud, Chilean Explicit Health Guarantees
GVS – Geneesmiddelen Vergoedings Systeem, Dutch medicine reimbursement system
HDI – Human Development Index
HIV – Human Immunodeficiency Virus
HTA – Health Technology Assessment
ICESCR – International Covenant on Economic, Social and Cultural Rights
ICH – International Conference on Harmonization
IETS – Instituto de Evaluación de Tecnologías en Salud, Colombian Health Technology Assessment Agency
IMS – Institute for Healthcare Informatics
INN – International Non-proprietary Name
INSSJyP – Instituto Nacional de Servicios Sociales para Jubilados y Pensionados, National Institute of Social Services for Retirees and Pensioners
ISAPRES – Instituciones de Salud Previsional. Chilean private health insurance companies
LMIC – Low and Middle Income Countries
MAI – Modalidad de Atención Institucional, Chilean Institutional Attention Modality
MLE – Modalidad de Libre Elección, Chilean Free Choice Modality
NGO – Non-Governmental Organization
NZa – Nederlandse Zorgautoriteit, Dutch Healthcare Authority
OS – Obra Social, Argentinean insurer of the social security sub-sector
OTC – Over-the-counter medicines
PACBI – Prestaciones de Alto Costo y Baja Incidencia, Argentinean Benefits of high cost and low incidence
PAHO – Pan-American Health Organization
PAMI – Programa de Atención médica Integral, Integral Medical Care Plan

PCDT – Protocolo Clínico e Diretrizes Terapêuticas, Brazilian Official Clinical Guidelines
PMO – Programa médico obligatorio, Argentinean Mandatory Medical Plan
PNM – Política Nacional de Medicamentos, Brazilian National Medicines Policy
POS – Plan Obligatorio de Salud, Colombian Compulsory Health Plan
POS-S - Plan Obligatorio de Salud del Régimen Subsidiado, Colombian Compulsory Health Plan for subsidized regime
PPP – Public-Private Partnership
PPP – Purchasing Power Parity Value
R&D – Research and Development
RENAME – Relação Nacional de Medicamentos Essenciais, Brazilian National List of Essential Medicines
SGSSS – Sistema General de Seguridad Social en Salud, Colombian General System of Social Security in Health
SNSS – Sistema Nacional de Servicios de Salud, Chilean National Health Services System
SSS – Superintendencia de Servicios de Salud, Argentinean Superintendence of Healthcare Services
STF – Supremo Tribunal Federal, Brazilian Supreme Court
SUR – Sistema Único de Reintegros, Argentinian Unified System of Refund
SUS – Sistema Único de Saúde, Brazilian Unified Health System
THE – Total Health Expenditure
TRIPS – Agreement on Trade Related Aspects of Intellectual Property Rights
UHC – Universal Health Coverage
UN – United Nations
UNDP – United Nations Development Programme
USD – United States Dollar
VWS – Ministerie van Volksgezondheid, Welzijn en Sport, Dutch Minister of Healthcare, Welfare and Sports
WHA – World Health Assembly
WHO – World Health Organization
WTO – World Trade Organization
ZiN – Zorginstituut Nederland, Dutch National Healthcare Institute Netherlands
Zvw – Zorgverzekeringswet, Dutch Health insurance Act

**CONTENTS**

**INTRODUCTION ..... 37**

**PART I: STATE OF THE ART IN JUDICIALIZATION OF ACCESS TO MEDICINES AND THEORETICAL FRAMEWORK ..... 43**

**1. CHAPTER 1 – RIGHT TO HEALTH, ESSENTIAL MEDICINES, AND LAWSUITS FOR ACCESS TO MEDICINES: A SCOPING STUDY. ..... 45**

1.1. ABSTRACT ..... 45
1.2. INTRODUCTION ..... 46
1.3. METHODOLOGY ..... 47
1.4. RESULTS ..... 48
*1.4.1. Thematic Analysis ..... 51*
*1.4.2. Normative Approach of Judicialization ..... 53*
*1.4.3. Social Approach of Judicialization ..... 58*
1.5. DISCUSSION ..... 60

**2. CHAPTER 2 – TOWARDS A THEORETICAL MODEL FOR JUDICIALIZATION OF ACCESS TO MEDICINES ..... 65**

2.1. ABSTRACT ..... 65
2.2. INTRODUCTION ..... 66
2.3. MEDICINES AS HEALTH NEEDS ..... 67
2.4. THEORETICAL MODEL ..... 69
*2.4.1 International level ..... 70*
*2.4.2 National level ..... 76*
*2.4.3 Demand-side level: Citizens and consumers ..... 79*
*2.4.4 Judicialization of access to medicines: Conflict in defining health needs? ..... 80*
*2.4.5 The Consequences of Judicialization: Feedback Loop ..... 82*
2.5 DISCUSSION AND CONCLUSIONS ..... 83

**PART II: JUDICIALIZATION OF ACCESS TO MEDICINES AND PHARMACEUTICAL POLICIES: CROSS-COUNTRY ANALYSIS. ..... 85**

**3 CHAPTER 3 – ACCESSIBILITY TO MEDICINES IN FOUR LATIN AMERICAN COUNTRIES AND THE NETHERLANDS: A COMPARATIVE STUDY ..... 87**

3.1. INTRODUCTION ..... 87
3.2. METHODOLOGY ..... 88
*3.2.1. Integrative Literature Review ..... 88*
*3.2.2. Semi-structured interviews ..... 88*
3.3. RESULTS ..... 90
*3.3.1. Argentina ..... 90*
*3.3.2. Colombia ..... 99*
*3.3.3. Brazil ..... 102*
*3.3.4. Chile ..... 108*
*3.3.5. The Netherlands ..... 113*
3.4. DISCUSSION ..... 115
*3.4.1. Population coverage ..... 117*
*3.4.2. Technology coverage ..... 117*
*3.4.3. Costs coverage ..... 120*
3.5. CONCLUSION ..... 122

**4 CHAPTER 4 – JUDICIALIZATION OF ACCESS TO MEDICINES IN FOUR LATIN AMERICAN COUNTRIES: A COMPARATIVE ANALYSIS 123**

4.1 INTRODUCTION ..... 123
4.2 METHODOLOGY ..... 127
4.3 RESULTS ..... 128
*4.3.1 International level ..... 128*
*4.3.2 National level ..... 130*
*4.3.3 Medicines as health needs ..... 147*
*4.3.4 The demand side level ..... 147*
4.4 DISCUSSION ..... 150
4.5 LIMITATIONS ..... 154
4.6 CONCLUSION ..... 154

**5 CHAPTER 5 – RESPONSES TO JUDICIALIZATION OF ACCESS TO MEDICINES IN LATIN AMERICA: THE CASES OF BRAZIL AND COLOMBIA ..... 157**
5.1. INTRODUCTION ..... 157
5.2. METHODOLOGY ..... 157
5.3. RESULTS ..... 158
*5.4.1 Measures taken by the Judiciary branch in Colombia and Brazil ..... 159*
*5.4.2 Measures taken by the Executive branch in Brazil and Colombia ..... 164*
5.4. DISCUSSION ..... 171

**FINAL CONSIDERATION ..... 175**

**REFERENCES ..... 179**

**ANNEXES ..... 211**

**ANNEX A – HEALTH SYSTEM ORGANIZATION: ARGENTINA, COLOMBIA, BRAZIL, CHILE AND THE NETHERLANDS ..... 213**

**1. THE ARGENTINIAN HEALTH SYSTEM ..... 213**
1.1. PUBLIC SECTOR: ..... 213
1.2. SOCIAL INSURANCE SECTOR: ..... 214
1.3. PRIVATE SUBSECTOR: ..... 215

**2. THE COLOMBIAN HEALTH SYSTEM ..... 215**
2.1. CONTRIBUTORY AND SUBSIDIZED REGIMES: ..... 216
2.2. SPECIAL REGIMES ..... 217
2.3. POOR UNINSURED POPULATION ..... 217
2.4. PRIVATE SECTOR: ..... 217

**3. THE BRAZILIAN HEALTH SYSTEM ..... 218**
3.1. PUBLIC SECTOR ..... 218
3.2. PRIVATE SECTOR ..... 219

**4. THE CHILEAN HEALTH SYSTEM ..... 219**
4.1. PUBLIC SECTOR ..... 220
4.2. PRIVATE SECTOR ..... 220
4.3. ARMED FORCES ..... 220

**5. THE DUTCH HEALTH SYSTEM ..... 221**
5.1. COMPULSORY SOCIAL HEALTH INSURANCE..... 221
5.2. VOLUNTARY HEALTH INSURANCE..... 223

**ANNEX B – SPEECHES FRAGMENTS IN ORIGINAL LANGUAGE CITED IN CHAPTER 4 ..... 225**

# INTRODUCTION

***Why study judicialization of access to medicines and pharmaceutical policies in Latin American countries?***

Access to essential medicines has been recognized as part of the right to health (CESCR COMMITTEE ON ECONOMIC, SOCIAL AND CULTURAL RIGHTS, 2000) as well as a relevant component of the Universal Health Coverage (UHC), for different reasons. Firstly, essential medicines are useful to resolve health problems guaranteeing efficacy, safety and efficient use of financial resources (WHO WORLD HEALTH ORGANIZATION, 2015a). Secondly, essential medicines represent an important share of the countries' healthcare budget and it is expected that prices of new technologies become higher (WAGNER; QUICK; ROSS-DEGNAN, 2014).

In the last two decades, Latin American countries reformed their health systems aiming to increase the health coverage. This includes ensuring equitable access to essential health services and medicines (ATUN et al., 2015). At the same time, the health systems also cope with pressure for incorporating new and expensive medicines; and rarely real novelties (PRESCRIRE EDITORIAL STAFF, 2015). Funding and access to medicines in health systems are relevant issues in global discussions on public policies, which most recently included the guarantee access to more expensive medicines, , without compromising the health systems' sustainability (HOGERZEIL, 2004; PAN-AMERICAN HEALTH ORGANIZATION, 2010). However, in some regions, this goal is still a challenge because of reduced levels of coverage and financial fragility of the health systems (FONDO NACIONAL DE RECURSOS, 2010).

In this context, litigation has become an alternative pathway for access to medicines in the Latin American region (REVEIZ et al., 2013; YAMIN; GLOPPEN, 2011). Some authors have suggested the occurrence of judicialization of access to medicines is more probable in fragmented health systems (FONDO NACIONAL DE RECURSOS, 2010). However, all health systems currently face the challenge of ensuring access to medicines (SANCHEZ-SERRANO, 2014), and the extension of the phenomenon varies regardless of the health system organization (unified or fragmented) (BURGIN, 2014; REVEIZ et al., 2013).

The effects of judicial intervention for guaranteeing the right to health, particularly access to medicines, generate controversy. On one hand, the Judiciary can disregard the regulations established to guarantee rational use of the medicines, specially of the more expensive ones (TANAKA, 2008). Additionally, litigation can press for the incorporation of new medicines even without enough evidence of effectiveness and safety (SANT'ANA et al., 2011a; VIEIRA et al., 2010). On the other hand, lawsuits can show gaps in the public policies and then protect the right to health from the Executive and Legislative branches' omissions (ASENSI, 2010; MACHADO-ALBA; TORRES-RODRÍGUEZ; VALLEJOS-NARVÁEZ, 2011). In this sense, lawsuits for access to medicines can be considered as a modulator of the health policies design.

The proliferation of judicialization for access to medicines in Latin America justifies carrying out a cross-country analysis of public policies that aim to ensure access and financing of medicines, the development of litigation for access to medicines and the responses that countries have implemented against this phenomenon.

Within this framework, the Brazilian research group *Pharmaceutical Policies and Services* of the Federal University of Santa Catarina in partnership with researchers from Colombia, Chile and Argentina proposed the present study.

**Objectives:**

The study aims to analyse judicialization of access to medicines and pharmaceutical policies in Brazil, Colombia, Argentina and Chile.

The specific objectives established for this study were:

1. To analyse 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. To develop a theoretical model for analysing the causes and consequences of judicialization of access to medicines, taking into account the social, political, and economic elements that modulate the role of medicines as health needs.

3. To review the historical development of strategies for access to medicines in Argentina, Brazil, Chile and Colombia in the period 2000-2014 and compare them with measures taken in The Netherlands.
4. To conduct a comparative analysis of the causes and consequences of judicialization of access to medicines from the perspective of the stakeholders involved in the phenomenon in Argentina, Brazil, Chile and Colombia.
5. To characterize and compare the States' responses to lawsuits related to access to medicines, especially those focused on extending the list of medicines covered by the health systems.

The thesis is presented in two parts:

The first part, consisted of two chapters, encompasses the theoretical framework of the study, presenting the state of the art in judicialization of access to medicines. Chapter 1 presents a scoping study that analyses the approaches to the phenomenon (normative and social) and its possible impacts (positive or negative), described in articles published in scientific journals. This manuscript was published in the *Social Science and Medicine* journal in October 2014 (VARGAS-PELÁEZ et al., 2014). Chapter 2 presents the development of the theoretical model proposed for analysing judicialization of access to medicines. It also constitutes a paper that was submitted to the *Social Science and Medicine* journal.

The second part comprises the comparative cross-country analysis of public policies for access to medicines and judicialization of access to medicines. This analysis involved literature review, documental analysis, and interviews with representatives of stakeholders involved with judicialization. Since the data collected were source of information for three different analyses, chapters 3 through 5 constitute this section. For a better understanding, the methodology used for the literature review and for conducting the interviews is detailed in chapter 3; and cited in chapter 4 and 5, in which only the analysis methodology is described.

Chapter 3 presents the comparative analysis of the health systems and the strategies to ensure access to medicines in Brazil, Argentina, Chile and Colombia. This chapter includes a comparison with the Dutch health system, which was made possible by a doctoral internship in The

Netherlands that aim to learn the methodology used by the WHO Collaborating Centre for Pharmaceutical Policy & Regulation, Utrecht University (The Netherlands) for carrying out comparative analysis of pharmaceutical policies. The analysis included a historical approach to the reforms between 2000 and 2014. It also constitutes a paper that will be submitted to the *International Journal of Health Economics and Management*.

Chapter 4 analyses the causes and consequences of judicialization of access to medicines in Argentina, Brazil, Chile and Colombia with a qualitative approach and using the theoretical model presented in Chapter 2. The results will be submitted as a paper to the *Health Policy and Planning* journal.

To precede in the comparative analysis of judicialization of access to medicines, the Chapter 5 presents the comparative analysis of the States' responses to the phenomenon, related to access to medicines, especially those focused on extending the list of medicines covered by the health systems. The results will be submitted to the *Journal of Health Organization and Management*.

Finally, we present the general discussion of the study and suggestions for future research related to judicialization of access to medicines.

This doctoral dissertation is part of the research project *Public Policies and Judicialization of Access to Medicines* (Call No. 41/2013 MCTI / CNPq / CT-Health / MS / SCTIE / Decit - National Network for Research on Health Policies: Knowledge Production for Recognition of the Universal Right to Health, Line 3 - Monitoring and analysis of decisions and regulations related to health; and the Universal Call 14/2013) involving researchers from the group *Pharmaceutical Policies and Services* of the Federal University of Santa Catarina, Fundación IFARMA (Colombia), Faculty of Pharmacy of Universidad Nacional de Colombia, Universidad Arcis (Chile), and an independent researcher from Argentina.

The PhD student received financial support from the Departamento Administrativo de Ciencia, Tecnología e Innovación, Colciencias from Colombia in the form of a doctoral scholarship abroad, Call No. 529/2011 and performed a doctoral internship in the

Netherlands by Dr Aukje Mantel-Teewesse from the Utrecht Institute for Pharmaceutical Sciences, WHO Collaborating Centre for Pharmaceutical Policy & Regulation, Utrecht University (The Netherlands).

This research project was assessed and approved by the Research with Human Beings Ethics Committee (CEPSH by its name in Portuguese) of the Federal University of Santa Catarina under Report No. 712.031/2014.

# PART I:

# STATE OF THE ART IN JUDICIALIZATION OF ACCESS TO MEDICINES AND THEORETICAL FRAMEWORK

# 1. CHAPTER 1 – Right to health, essential medicines, and lawsuits for access to medicines: A scoping study[1].

## 1.1. 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. **Keywords:** Right to health, access to medicines, essential medicines, lawsuits, Latin America, Europe, South Africa, North America

[1] VARGAS-PELÁEZ, C. M. et al. Right to health, essential medicines, and lawsuits for access to medicines – A scoping study. **Social Science & Medicine**, v. 121, p. 48–55, nov. 2014.

## 1.2. 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; SANCHEZ, 2005). In the international sphere, access to essential medicines (as defined by the World Health Organization) is part of the Right to Health (CESCR COMMITTEE ON ECONOMIC, SOCIAL AND CULTURAL RIGHTS, 2000).

To fulfil 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; 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, 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; SANCHEZ, 2005). Furthermore, conforming to the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), medicines are considered patentable innovations (WTO 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 additional therapeutic value (PRESCRIRE EDITORIAL STAFF, 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; COLQUHOUN; O’BRIEN, 2010), to analyse 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.

## 1.3. METHODOLOGY

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

Table 1-1 – 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<br>"Right to Health" AND "drug" AND lawsuits//All fields<br>"Right to Health" AND Drugs// Articles or reviews//Title, abstract, keywords<br>"Right to health" AND "essential medicines"//Articles or reviews//All fields |
| SCIELO | “Direito à saúde" AND Medicamentos<br>“Derecho a la salud” AND Medicamentos<br>Right to health AND (essential medicines OR drugs) |
| LILACS | "Direito à saúde" AND Medicamentos<br>"Right to health" AND (drugs OR "Essential medicines")<br>"Derecho a la salud" AND ("Medicamentos esenciales" OR Medicamentos) |

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.

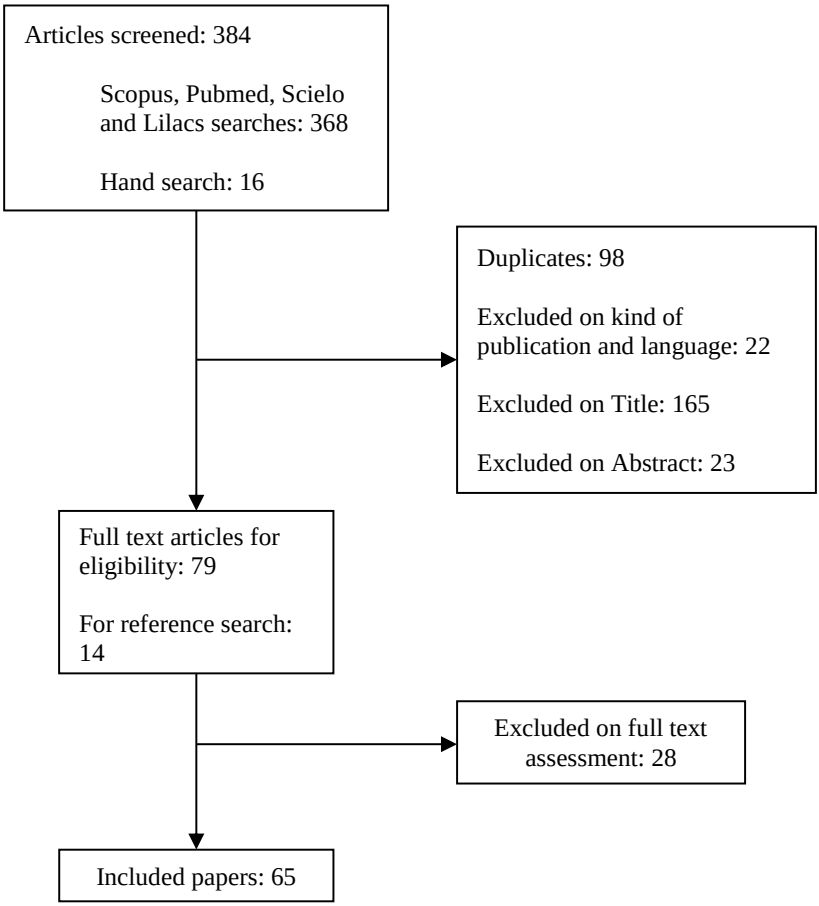
In the thematic analysis (BARDIN, 1977; MINAYO, 1993), the approaches to judicialization and type of impacts categories were created after a brief reading of the articles, identifying explicit definitions of judicialization of access to medicines and the impacts mentioned by the authors. These categories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

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

## 1.4. RESULTS

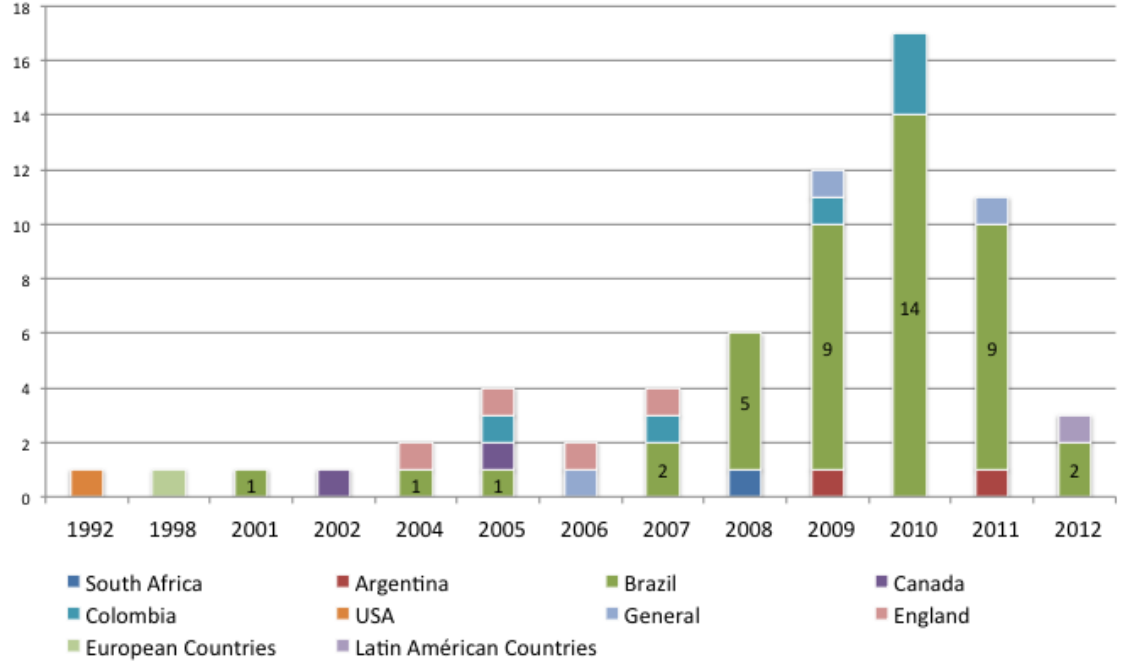
The selection of articles is shown in Figure 1-1.

Figure 1-1 – Flow diagram of articles included in the review.




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%) (Figure 1-2).

Figure 1-2 - Articles published by year and by studied country




Source: Authors. The data of 2012 included only papers indexed in the database on 31st of July.

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 non-profit organizations).

### 1.4.1. 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 (ANDRADE et al., 2008; BIEHL et al., 2012; BIEHL; PETRYNA, 2011; CUBILLOS et al., 2012; ROMERO, 2010). 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 (ABRAMOVICH; PAUTASSI; FURIO, 2008; ASENSI, 2010; BORGES; UGÁ, 2009; MACHADO, 2008; MARQUES, 2008). 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 *checks and balances* between the powers to maintain State equilibrium and it is characterized by the positioning of the judicial above legislative and administrative spheres in order to control the action of the Legislature and protect the society against abuse of the Executive (TATE; VALLINDER, 1995).

For Vianna (2002), judicialization is a citizens' reply, when the State fails to meet their needs by representative democracy means, being the judiciary the last option to claim their rights. This can also be interpreted as the expansion from political citizenship conception to social citizenship conception.

Based on such premises, according to the approach to judicialization and the highlighted phenomenon impacts, four categories were defined for the thematic analysis (Table 1-2). The predominant approach was normative-negative (51; 78.5%), followed by normative-positive (23; 35.4%); and the social approach, negative (16; 24.6%) or positive (4; 6.2%), was less considered.

Table 1-2 – Thematic analysis categories

| **Impacts** | **Approaches** | |
|---|---|---|
| | *Normative:* Judicialization is the interference of Judicial Power on the Executive Power. | *Social:* judicialization understood as a form of citizen participation |
| *Positive* | Judicialization protects the Right to Health from policy gaps or omissions of the Executive. | Legitimate exercise of citizenship, particularly by minorities and vulnerable groups |
| *Negative* | Judicialization does not recognize public policies established by the Executive, and can deepen the existing inequality for access to healthcare. | The lawsuits do not mean that people are empowered, and it can contribute to reinforce the "state paternalism". |

### 1.4.2. Normative Approach of Judicialization

#### 1.4.2.1. Positive Impacts

The articles with this approach argued that judicial intervention is a useful mechanism for promoting the right to health and for pushing governments to fulfil their constitutional obligations and those agreed in international treaties (HOGERZEIL et al., 2006). Moreover, judicialization may evidence the limitations of health policies and the need to update the Health Systems' programs and clinical guidelines (ASENSI, 2010; MACHADO-ALBA; TORRES-RODRÍGUEZ; VALLEJOS-NARVÁEZ, 2011).

Some examples are low-prevalence diseases (BAPTISTA; MACHADO; DE-LIMA, 2009; MACEDO; LOPES; BARBERATO-FILHO, 2011; SANT'ANA et al., 2011b; VIEIRA; ZUCCHI, 2009) or in the event of non-supply of a drug not covered by the health system, although it is necessary to ensure the patient's health (COSTA, 2004). So, under this approach, judicialization is positive if it follows criteria, and represents a real advance in terms of enforcement of fundamental rights (DALLARI, 2010; VALLE; CAMARGO, 2011).

In this approach, the most cited case was the extension of benefits in health systems for HIV diagnosis and treatment, highlighting experiences from India (MEIER; YAMIN, 2011), Argentina (BERGALLO, 2010), Brazil (BIEHL et al., 2012; MACHADO, 2008), Colombia (YAMIN; PARRA-VERA, 2009) and South Africa (FORMAN, 2008), countries where the courts played a major role in requiring the Executive to create and execute policies to ensure the right to health of the HIV+ population.

In Latin America, courts have assumed an increasing role in human rights interpretation and protection, in some cases forcing the Executive to redefine public policy priorities. The courts understand that when administrative inefficiency or the prioritization process of health systems fails to guarantee the right to health, judicial intervention is justified (CUBILLOS et al., 2012).

Argentinean (ABRAMOVICH; PAUTASSI; FURIO, 2008; BERGALLO, 2010) and Colombian authors (VÉLEZ, 2005; VÉLEZ-ARANGO et al., 2007; YAMIN; PARRA-VERA, 2009, 2010) also

emphasize the role of the Judiciary in two situations: omissions of private companies responsible for managing health services, and Executive omissions in the regulation of these companies. In the latter case, the Judiciary recognizes the accountability of the State to guarantee the right to health to the population, even if implementation is delegated to private actors (CUBILLOS et al., 2012; GAURI; BRINKS, 2007).

Brazilian authors Oliveira (2001) and Costa (2004) find positive the intervention of the Judiciary because it protects the constitutional right to health and life from financial constraints imposed by the Executive through infra-constitutional regulations like budget laws.

In South Africa, the courts have been reluctant to decide individual cases that may affect most of the population. Jurisprudence in this country is based on "*Ubutu*", where the collective benefit predominates over the individual benefit. Also, the Constitutional Court has demonstrated the potential of social justice of an enforceable right to health, when it responds to urgent needs affecting a significant segment of the South African population such as guarantee of access to HIV treatment (FORMAN, 2008).

#### 1.4.2.2. Negative Impacts

In general, the authors in favour of this approach emphasize that the use of the Judiciary as a route for medicines and/or access to healthcare services results mainly in negative impacts, because judicialization neglects the public policies established by the Executive and the Legislature (MACHADO, 2008), and because nothing guarantees that policies generated by the accumulation of lawsuits are better than or equal to those resulting from a legislative process (MANFREDI; MAIONI, 2002).

Judicialization induces distortions in the implementation of such policies (MACHADO-ALBA; TORRES-RODRÍGUEZ; VALLEJOS-NARVÁEZ, 2011; MARQUES, 2008), especially when medicines not covered by the health system are supplied (HOGERZEIL et al., 2006; LEITE et al., 2009; SANT'ANA et al., 2011b). These distortions can compromise the health systems sustainability (GONTIJO, 2010; HOGERZEIL et al., 2006; YAMIN; PARRA-VERA, 2010) owing to forced relocation and not-efficient use of limited resources (CUBILLOS

et al., 2012). This happens because the system is obligated to bear higher costs caused by loss of negotiating power in front of drug providers (DINIZ; MEDEIROS; SCHWARTZ, 2012; VIEIRA, 2008), high-cost of patented medications, or the impossibility of performing programmed purchases (DINIZ; MEDEIROS; SCHWARTZ, 2012; MACHADO, 2008; PEPE et al., 2010a).

Different authors considered that the courts have a limited role in improving equity and operation of health systems because their decisions widen the existing gaps and inequalities in the access to health services (ABRAMOVICH; PAUTASSI; FURIO, 2008; ANDRADE et al., 2008; FLOOD, 2005; GLOPPEN, 2008; MARQUES; DALLARI, 2007; MCHALE, 2006; VALLE; CAMARGO, 2011; YAMIN; PARRA-VERA, 2010).

These regressive effects stemmed from public resources deviation without government planning (GLOPPEN, 2008; MARQUES, 2008; MEIER; YAMIN, 2011; MESSEDER; OSORIO-DE-CASTRO; LUIZA, 2005; TANAKA, 2008; VENTURA et al., 2010; VIEIRA; ZUCCHI, 2009). As a result, the implementation of broad population coverage programs is compromised (CHIEFFI; BARATA, 2009, 2010; ROMERO, 2010) and the health system is able to meet only non-priority demands from population sectors with more economic resources and more possibility of accessing legal resources (ABRAMOVICH; PAUTASSI; FURIO, 2008; BERGALLO, 2010; BORGES; UGÁ, 2010; CHIEFFI; BARATA, 2009; CUBILLOS et al., 2012; FERRAZ, 2009, 2010; FERRAZ; VIEIRA, 2009; PEREIRA et al., 2010; VIEIRA et al., 2010; YAMIN; PARRA-VERA, 2010).

For Bergallo (2010), the courts order the supply of treatments without considering budget constraints nor effectiveness, quality or availability in the country; moreover, they do not consider political and management deficiencies as causes of the lawsuit. Thus, in some cases, judicial intervention puts the plaintiff at risk rather than ensuring his/her right to health because the prescription is not always appropriate to the patient's needs (BORGES; UGÁ, 2010), and judges disregard the rational use of medicines and possible damages arising from misuse (DINIZ; MEDEIROS; SCHWARTZ, 2012; PEPE et al., 2010b).

Particularly, studies about Brazil have shown that sometimes the evidence of drug efficacy and safety for the requested indication is

limited (DINIZ; MEDEIROS; SCHWARTZ, 2012), especially in cases of off-label indications or unregistered medicines in the country (CUBILLOS et al., 2012; FIGUEIREDO; PEPE; OSORIO-DE-CASTRO, 2010; TANAKA, 2008).The courts do not consider these aspects in the legal decision-making.

Borges and Ugá (2009), Gloppen (2008), Romero (2010) and Anderson (1992) argue that the negative effects of judicialization result from judges' limited technical expertise and their lack of understanding of the drugs selection process in the health system. Another judges' limitation is the narrow focus with which decisions are made, since they only consider specific cases, subordinating the collective to individual needs through implementation of public policies.

Other Judiciary's limitations mentioned are: the difficulties faced by the courts to decide on goods provided by the State with public funds; the institutional inertia of the Judiciary since it acts only when triggered (BORGES; UGÁ, 2009); variability of judgments for similar cases (ANDERSON, 1992); the tendency of the courts to make law for the best or worst case but not for the modal case (MANFREDI; MAIONI, 2002); inadequate interpretation of the right to health by judges (FERRAZ, 2010); and non-recognition, by judges, of other interests rather than those of patients with drug coverage (SANT'ANA et al., 2011a; VIEIRA et al., 2010).

Brazilian authors highlighted two possible conceptions that judges have about the right to health: an individual and absolutist conception that considers health as a constitutional right which cannot be limited by infra-constitutional norms (as regulations that define the budget or the health system organization) or by economic restrictions (BIEHL; PETRYNA, 2011; FERRAZ, 2010); and a reduced conception that considers the right to health as a simple delivery of medication, disregarding the importance of comprehensive healthcare (DINIZ; MEDEIROS; SCHWARTZ, 2012; GONTIJO, 2010; PEPE et al., 2010a).

Pharmaceutical industry appears as another actor interested in providing medicines through the courts (SANT'ANA et al., 2011a; VIEIRA et al., 2010). Some studies found a possible link between the increase of lawsuits requesting and inclusion of medicines in the official lists of the Brazilian health system (CHIEFFI; BARATA, 2010;

FIGUEIREDO; PEPE; OSORIO-DE-CASTRO, 2010; MESSEDER; OSORIO-DE-CASTRO; LUIZA, 2005; PEPE et al., 2010a). Consequently, the health system ends up satisfying the pharmaceutical market needs, including in its lists recent drugs that meet the needs of a small group of people but do not offer a real therapeutic contribution to the needs of the collectivity (BAPTISTA; MACHADO; DE-LIMA, 2009; LOPES et al., 2010; SANT'ANA et al., 2011b).

At this point, there are ethical conflicts mainly related to the great budgetary burden over public funding caused by the requested drugs in relation to their effectiveness (cost-effectiveness) versus the treatment supply for minorities affected by serious and rare diseases (BOY et al., 2011).

Articles from European countries noticed that judges themselves are aware of the limitations of their intervention and the negative impacts it could have on the community, so there is some resistance from the courts to intervene in matters relating to the allocation of resources in the health system (SYRETT, 2004) even though people frequently recur to this route (FOSTER, 2007).

In England, the legal challenges regarding the allocation of resources are seen by the Judiciary under the logic of reasonableness and fairness – judges recognizing the legitimacy of rationalizing financial resources, advising policymakers to bring special attention to the impacts of decisions made over individual patients (NEWDICK, 2005). Actually, judges intervene only in those cases where they consider that the proportionality principle has been infringed, the rights compromised, or when the Executive decisions are irrational (FOSTER, 2007).

According to Den-Exter and Hermans (1998), in some European countries judges, in order to make a decision, consider the principles of medical need, urgency and no possibility of delay; however judges do interpret such principles in a relative basis, once they recognize the limited availability of resources. Some example of lawsuits of this kind are Nitecki v. Poland (Application No. 65653/01) and BGE 136 V 395 et sqq.; 9C_334/2010 (KESSELRING, 2011).

### 1.4.3. Social Approach of Judicialization

1.4.3.1. Positive Impacts

For some authors, judicialization is an effective way for people to claim their right to health, a legitimate exercise of citizenship (MACHADO et al., 2011), and a way to demand overcoming of the gaps between what is stipulated in public policy and what has been implemented (GLOPPEN, 2008).

In the Brazilian (BIEHL; PETRYNA, 2011; BORGES; UGÁ, 2010; MARQUES, 2008; VENTURA et al., 2010) and Colombian contexts (MOLINA MARÍN et al., 2010; RODRÍGUEZ-TEJADA; MOLINA MARÍN; JIMÉNEZ, 2010; VÉLEZ-ARANGO et al., 2007), the authors emphasized that the increased lawsuits for access to positive health benefits are associated with greater community awareness of their rights, and recognition of the Judiciary as a means to demand them, particularly regarding access to medicines or services covered by the health system. Moreover, this trend would mean the identification of the Judiciary as a political arena in response to failures of traditional institutional channels of social control and popular participation.

Furthermore, these authors consider that this phenomenon empowers individuals and NGOs to claim rights in the courts as a means of pressure for the system to ensure medicines supply (MEIER; YAMIN, 2011). They also point out that the NGOs' support to this social mobilization allows visualization of the problems related to access to medicines because these NGOs get support from the community and the media interest (HOGERZEIL et al., 2006). Experiences from Chile, Costa Rica (CUBILLOS et al., 2012), Brazil (MACHADO, 2008), Argentina (BERGALLO, 2010) and South Africa (FORMAN, 2008) were emphasized because, in these countries, litigations brought before the courts by organized groups of patients unquestionably contributed to the adoption of laws that guaranteed access to antiretroviral treatment.

Other aspects described in this approach were the positive effects that judicial intervention brings to minorities (e.g. rare diseases) (BOY et al., 2011) and vulnerable groups (e.g. women and the elderly) (CUBILLOS et al., 2012; VÉLEZ-ARANGO et al., 2007) who usually have less power in the traditional political sphere, thus preventing the

"tyranny of the majority" (BOY et al., 2011). In the case of health plans in Brazil, Alves, Bahia and Barroso (2009) and Lopes, Lopes-Filho, Gubolino, Mattos, and Marin-Neto (2009) pointed out that the courts have also been converted into an important space for claiming consumer rights.

#### 1.4.3.2. Negative Impacts

Only Brazilian authors present the negative perception of the social point of view of judicialization. For them, the use of the courts as a way of access to medicines and health services does not mean by itself that the people consider that they are exercising their citizenship and that health is a right.

For Leite and Mafra (2010), the access by way of the courts is not necessarily an outcome of the patient empowerment; on the contrary, according to their study, the general perception of the lawsuits beneficiaries was that they were receiving a favour from someone who served in the public sphere (aldermen, physicians, staff, etc.). Therefore, the authors concluded that the use of lawsuits has a strong tendency to "strengthen the relations of dependence and user perception of powerlessness."

In this sense, according to Borges and Ugá (2009) quoting from Vianna (2002), the invasion of politics by claiming rights, even if in the name of equality, would negatively lead to 'passive enjoyment of rights', and state paternalism, reducing the citizens to the status of individuals-customers of a providential state.

In the case of access to medicines, Machado et al. (2011) argued that judicialization causes health to become a commodity disputed by all citizens, rather than a right guaranteed to the entire population.

Finally, Da-Silva and Terrazas (2008) also emphasized that NGOs' support and participation in the preparation of legal actions cannot be considered as a process of legitimate social participation. These organizations finance the attorney and the entire judicial process, so patients do not have a real link with the NGO. These authors also noted that this situation might indicate the influence of the pharmaceutical industry in funding these NGOs.

## 1.5. DISCUSSION

A concentration of publications in Brazil was also observed in other studies (EMMERICK et al., 2013). This concentration may be related to three aspects: the fact that judicialization of access to medicines has become a problem of large magnitude in Brazil if compared with other countries (HOGERZEIL et al., 2006); the proximity of the Brazilian academia to the designing and implementation of the Unified Health System (PAIM et al., 2011); and the increasing investment in public health research in Brazil (VICTORA et al., 2011). So, the large number of publications during the period of 2009-2011 may be due to greater investment in research with resources provided by the Ministry of Health in the period of 2005-2009 (BRAZIL, 2013).

The public health expertise of most of the studied authors and the predominance of health sciences journals may be related to the databases consulted, and may justify the greater frequency of normative approaches to judicialization, and the emphasis on the health systems managers' view. The above demonstrates the predominance of a technical view of the phenomenon, while the social aspects are less considered in the analyses.

The thematic analysis results allowed observing that the judicialization impacts regarded as positive or negative have changed over time. Thus, 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 treatment for HIV/AIDS, by means of both individual and collective lawsuits.

Some particular features of HIV/AIDS cases include: high prevalence and incidence of the disease, becoming a public health priority; availability of drugs of proven efficacy but under patent protection and high prices (EIMER; LÜTZ, 2010); social mobilization including patient organizations and other civil organizations like "Doctors Without Borders" (FORD, 2004); and the recourse to the courts both to press governments to provide treatments, and to challenge the protection of drug patents in order to instigate the production of generic drugs that would guarantee access to treatment for the HIV+ population (FORMAN, 2008). This can be considered an example

where social mobilization claimed the guarantee of a human right by lawsuits, and as a result collective interests prevailed over the interests of the market.

The emphasis on the negative effects of judicial intervention began in the mid-2000s, when there was an "explosion" in the number of lawsuits for access to medication in some countries like Brazil and Colombia (HOGERZEIL et al., 2006). In this period, the characteristics of the claims changed. Individual lawsuits predominated, requesting three kinds of drugs: (a) medicines included in the health systems list; (b) new drugs indicated for diseases that had therapeutic option of recognized efficacy included in the health systems list, and (c) new drugs indicated for diseases that did not have therapeutic option in the health systems list. Furthermore, lawsuits that challenge the protection of drug patents are absent, and there is some evidence of the close relationship between pharmaceutical industries and patient groups (PEREHUDOFF; ALVES, 2010). The latter aspect particularly compromises the legitimacy of the social mobilization and its role in pursuing the right to health.

According to CESCR (2000) "[t]he right to health is not to be understood as a right to be *healthy*..." but this right contains both freedoms and entitlements, which include "…the right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health". Thus, the right to health must be understood as both an individual and a collective right.

Nevertheless, the thematic analysis results show that judicial interpretations of the right to health are different in Europe and Latin America. European judges tend to prioritize common wealth over individual rights (DEN EXTER; HERMANS, 1998), but in Latin American countries judicial decisions are usually favourable to individual lawsuits, without considering the impacts on the health system and the rest of the population. This variation may be a consequence of differences between law systems (common law vs. civil law); disposition of the courts to become involved in these matters (GAURI; BRINKS, 2007); and the health system legitimacy related with its good or poor performance (BELMARTINO, 2002; HERNÁNDEZ, 2002).

On the other hand, the implementation of the right to health has as background the project of modernity. According to Santos (2008), the project of modernity, based on two pillars – regulation and emancipation –, had unbalanced development within capitalism. As a consequence, there was a strengthening of the regulation pillar over the emancipation pillar. Also, within the pillars there were imbalances between their principles, in the case of the regulation pillar, market prevails over the State and the Community, while in the emancipation pillar, science prevails over morality, ethics and arts, generating a close relationship between the market and scientific development in the modern society (SANTOS, 2008).

Medical-industrial complex is an example of this context and its effects on society. The development of scientific knowledge based mainly on positivism (biomedicine) led to a reduced conception of health, which considers only biological and individual causes of diseases, ignoring the important effect of social and environmental factors on the population's health (TESSER; LUZ, 2002). Moreover, this is accompanied by the phenomenon known as "medicalization of life" which can be understood in at least two ways: (a) the concealment of usually conflicting aspects of social relationships by their transformation into "health problems", and (b) the expropriation of the ability to care for people in general, making them dependent on the care given by doctors (CAMARGO JR, 2007). Thus, according to Illich (1975), the individual as a "consumer of care medicine is powerless to heal or cure their peers", reducing people's right-to-health perception down to right to access to health services and medicines.

At the same time, the subordination of scientific development to market interests resulted in the denominated crisis of innovation of pharmaceutical industry. This crisis has caused two effects. First, the neglect of diseases which affect major portions of the population, but who cannot afford to bear the costs of the treatment. Second, the entrance to the market of new drugs that often do not have enough evidence to guarantee the safety of people's health, nor represent significant advances to justify their high costs (ERVITI-LÓPEZ, 2011). Given this situation, the South Centre and the WHO have presented the proposal of a new model for funding research and drug development where these activities are separated from priorities imposed by the market (VELASQUEZ, 2012).

Furthermore, for the pharmaceutical industry it is more profitable now to focus on the research of rare diseases considering the marketing monopolies resulting from the patent protection of orphan drugs (HYRY et al., 2013). Rare diseases frequently affect specific "items" of the body (genes, enzymes, etc.), which can be treated with medicines of biotechnological origin (monoclonal antibodies, etc.). The lack of transparency about the real costs of research and development of these products, however, cause the prices to be charged so high that only governments have the capacity to pay them (LIGHT; LEXCHIN, 2012).

In conclusion, judicialization is a complex phenomenon that involves technical-scientific, legal and social aspects. This phenomenon might be a result of different factors such as health system deficiencies, pharmaceutical industry interests and/or citizen empowerment. The studied papers analysed judicialization using mainly a normative approach (judicialization as interference of the Judicial Power in the Executive Power), and the regressive effects of judicialization on health systems were the most frequently cited impacts. Few studies used the social approach to judicialization (as a form of citizen participation). 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. These aspects need to be further studied.

Some limitations of this study are the bias that can be induced by the large amount of papers from Brazil; and the exclusion of other types of publications, since many studies in Latin America about judicialization of access to medicines are not published in indexed journals but as official documents and academic theses or dissertations (REVEIZ et al., 2013). Finally, although the framework for the definition of judicialization approaches (normative or social) is from authors of the law area, this analysis considers mainly the perspective from healthcare professionals.

# 2. CHAPTER 2 – Towards a theoretical model for judicialization of access to medicines[2]

## 2.1. ABSTRACT

Although ensuring access to high-priced medicines is a challenge that all health systems currently face, not all the countries face the judicialization for access to medicines phenomenon. Health systems' fragmentation has been appointed as one of the main causes, but since the judicialization occurs in health systems with different integration levels, other factors must be taken into account to analyse this phenomenon. A theoretical model is proposed for analysing the causes and consequences of judicialization of access to medicines, taking into account the social, political, and economic elements that modulate the role of medicines as health needs. The theoretical model considers elements (stakeholders, policies) that modulate the perception of medicines as health needs from two perspectives –health and market– in three levels: international, national and demand-side. Since the different perceptions created about medicines as a health need (according to Bradshaw's categories) do not always coincide, sometimes the patients do not get access to the medicines they perceive as a need. In this scenario, individuals could seek the judiciary system. If it is sensible to patients' complains, litigation becomes an alternative pathway towards access to medicines, which could affect the elements included in the model (feedback loop). Our theoretical model considers a broader view of this phenomenon and its effects emphasising how power structures, interests, interdependencies, values and principles of the stakeholders could influence the perception of medicines as health needs and the occurrence of litigation for access to medicines, according to each particular context.

[2] VARGAS-PELÁEZ, C. M. et al. Towards a theoretical model for judicialization of access to medicines. **Social Science & Medicine**, Submitted .

## 2.2. INTRODUCTION

Health rights litigation is a global phenomenon that is on the rise. Globally courts are demanded to act to protect and fulfil the right to health. However, frequency and characteristics of lawsuits vary across the countries. In the Latin American region, for instance, court cases related to access to medicines are frequent (YAMIN; GLOPPEN, 2011) and have become a challenge for public health policies in some countries (BURGIN, 2014; HOGERZEIL et al., 2006; REVEIZ et al., 2013)

Health system fragmentation and health systems' difficulties to guarantee access to medicines, especially new medicines, have been appointed as one of the main driving factors behind the rise of judicialization (FONDO NACIONAL DE RECURSOS, 2010). However, this phenomenon is frequent in countries with unified (Brazil, Costa Rica) or fragmented (Colombia, Argentina) health systems (BURGIN, 2014; REVEIZ et al., 2013). Furthermore, though all health systems currently face the challenge of ensuring access to high-cost medicines (SANCHEZ-SERRANO, 2014), they do not necessarily face the judicialization phenomenon or is less intense (e.g. United Kingdom or Chile) (BURGIN, 2014; FOSTER, 2007). This means that judicialization of access to medicines not only involves technical and scientific aspects at national level but also political and social factors (VARGAS-PELÁEZ et al., 2014).

Medicines are considered as health needs, and their valuation can vary depending on the actors involved (users, prescribers, managers, etc.) (SOARES, 2013). Differences materialize in the incorporation of certain technologies over others, and lawsuits for access to medicines uncovered by the health system. In this way, the judiciary as a guarantor of the right to health could obtain an active role in the recognition of medicines as health needs and could become a modulator of public policies for access to medicines.

This paper aims to present a theoretical model for analysing the causes and consequences of judicialization of access to medicines, taking into account the social, political, and economic elements that modulate the role of medicines as health needs. This theoretical model will be used for the comparative analysis of the causes and

consequences of juidicialization of access to medicines in Argentina, Brazil, Chile and Colombia.

## 2.3. MEDICINES AS HEALTH NEEDS

Literature presents different approaches to health needs definition, and many theoretical essays and empirical studies have sought to characterize this construct. However, given its complexity, the results are highly variable and even today there is no uniformity in the concept of need, both in ontological and epistemological terms, and neither in the most appropriate indicators for the measurement of health needs (ACHESON, 1978; BUTTER, 1967; DONABEDIAN, 1974; JEFFERS; BOGNANNO; BARTLETT, 1971). The theoretical model was constructed based on the definitions of 'needs' proposed by Max-Neef *et al*. (1998), Willard (1982) and Bradshaw (1972).

Max-Neef *et al.* (1998) argue that it is necessary to differentiate actual needs from satisfiers of these needs. Fundamental human needs are finite, few and classifiable; they are the same in all cultures and in all historical periods; what changes, both over time and through cultures, is the way or the means by which these needs are satisfied. Then, each economic, social and political system adopts different ways for satisfying the same fundamental human needs.

Satisfiers are not the available economic goods. "While a satisfier is in an ultimate sense the way in which a need is expressed, goods are in a strict sense the means by which individuals will empower the satisfiers to meet their needs". So, in other words, health systems are satisfiers of the need for protection (MAX-NEEF; ELIZALDE; HOPENHAYN, 1998), and medicines are goods that allow increasing or decreasing the health systems' efficiency.

In the same sense, Willard (1982) argues that human needs are not facts (properties, states, processes, relations) about people, but values. Needs are goal-oriented and goals are things people value. For this reason, disagreements about what people need are disagreements in attitude toward, and emotional attachment to, things variously considered to be valuable.

Both of these conceptions ("needs as facts" and "goods as needs") are related with how industrial capitalism has organized the

goods' production and consumption, making the goods an end (MAX-NEEF; ELIZALDE; HOPENHAYN, 1998). Industrial capitalism has also created a close relationship between science and market (SANTOS, 2008), which influences on how health needs are understood. The hegemonic scientific development based on the positivist paradigm results in the predominance of a reductionist view of health focused on the biological and individual causes of disease (TESSER; LUZ, 2002). Moreover, scientific progress can lead the professional to be more concerned about the techniques and procedures than with the patient's health, arising "a moral flavour as follows: If medical science and technology can do it, then people need it" (WILLARD, 1982).

At the same time, the market turns the individual into a healthcare consumer that is not able to heal or cure their peers (ILLICH, 1975), making individuals dependent on the medical-industrial complex to resolve their health problems. Medicines use is increasing by the continuous and unlimited valuation of medicines as needs, and then patients demand unlimited availability of these products in the health systems.

Nevertheless, health systems must meet the need for individual and collective protection. Limited resources determine choices according to some values (i.e. cost-effectiveness) to achieve the highest level of efficiency. Patients consider these choices not always legitimate, leading to lawsuits. Judges also consider certain values to make their decisions and recognize (or not) a medicine as a health need (i.e. constitutional provisions on right to health).

Bradshaw's (1972) "Taxonomy of social need" is useful for understanding the different value assessments about medicines. Bradshaw classified social needs, which included health needs, as *normative* (corresponding to a professional standard definition of need), *felt* (corresponding to the individual desire), *expressed* (also called demand, corresponding to the felt need turned into action) and *comparative* (corresponding to a deficit of a population when compared to other similar characteristics).

In the case of access to medicines, the *normative need* corresponds to the decision-making of *experts* to define the medicines covered by the health system. The *felt need* is the need perceived by the user after getting a medical prescription. The *expressed* need (or

demand) is determined by the *felt need* and health services accessibility, that is, the services' structural characteristics that enable the user to access them. Finally, the *comparative need* corresponds, in practice, to the health system capacity of responding equitably to people's needs (SOARES, 2013).

## 2.4. THEORETICAL MODEL

In order to consider a comprehensive view of access to medicines, the analysis of the health systems as Complex Adaptive Systems (CAS) was used as a basis for the theoretical model, because it reflect the complex dynamic of health systems, including the influence of both external (e.g. historical background) and internal factors (e.g. relationships established among the stakeholders) and how the outputs of a process within the system could feed back as an input into the same system. (PAINA; PETERS, 2012).

The theoretical model (Figure 2-1) considers elements (stakeholders, policies) that modulate the perception of medicines as health needs from two perspectives –health and market–at three levels: international, national and demand-side (individuals, households and communities) (BIGDELI et al., 2013). The different perceptions created about medicines as a health need (according to Bradshaw's categories) do not always coincide, and as result of this "conflict", the patients do not get access to the medicines they perceive as a need. In this scenario, individuals could seek the judiciary system. If it is sensible to patients' complains, litigation becomes an alternative pathway towards access to medicines, which could affect the elements included in the model (feedback loop) (PAINA; PETERS, 2012).

The international level considers the recognition of the Right to Health in the Human Rights treaties, the World Health Organization (WHO)'s definition of essential medicines, the Innovation Model and the intellectual property protection treaty (TRIPS) and Multinational Pharmaceutical Industry.

The national level includes the constitutional definition of right to health, the health system model and its components ('*software'* and *'hardware'*, according to (SHEIKH et al., 2011)) and the national pharmaceutical industry. This level also considers the national policies related to intellectual property protection, science and technology

development and medicines price control. Moreover, due to their direct impact on the perception of medicines as needs, the pharmaceutical marketing practices were taken into account. All these elements could be influenced by the pharmaceutical policy.

The third level, the demand-side level, comprises individuals, households and communities. People relate to the health system as citizens demanding their right to access to medicines and as healthcare consumers. Additionally, the organization of patient support networks aiming to overcome difficulties in access to medicines is also incorporated (OLMEN et al., 2012).

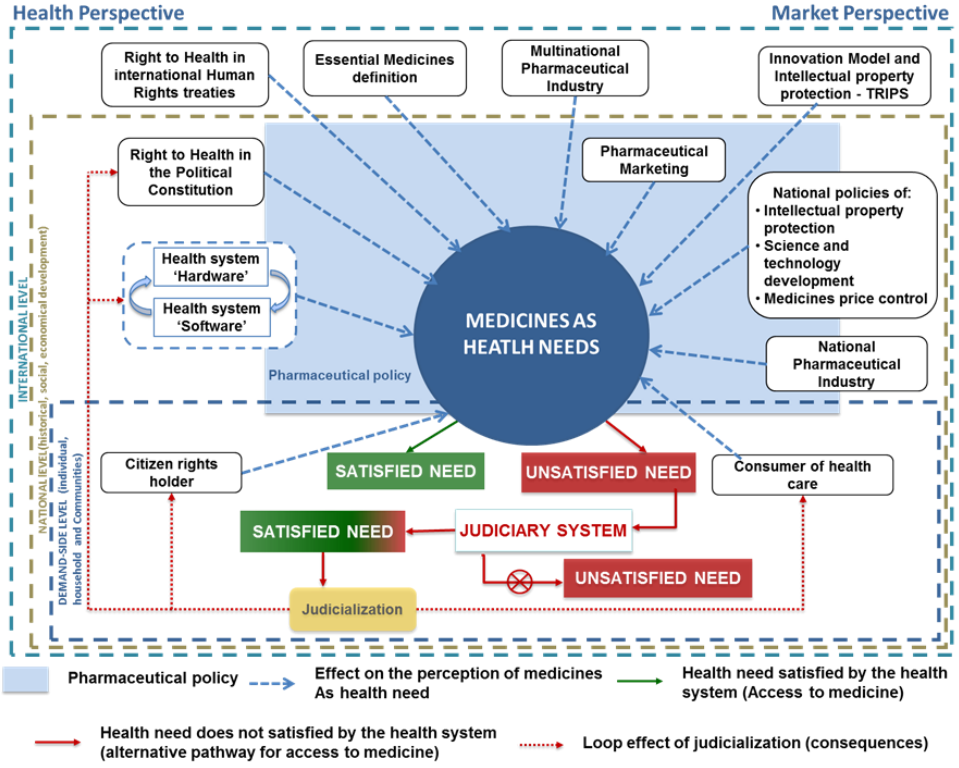
Finally, the model shows the ways in which the judicialization phenomenon, if it happens, could influence the national level (e.g. inclusion of new medicines in the health system coverage) and the demand-side context (e.g. reaffirmation of the individual as a healthcare consumer).

### 2.4.1 International level

#### 2.4.1.1 Health as a Human Right

Health is recognized as a Human Right in different international treaties (HOGERZEIL et al., 2006). The International Covenant on Economic, Social and Cultural Rights–ICESCR (UNITED NATIONS, 1966) recognizes “the right of everyone to the enjoyment of the highest attainable standard of physical and mental health”. To achieve this goal the States must: (a) ensure access to essential medicines, according to the WHO’s definition; (b) “give sufficient recognition to the Right to Health in their national political and legal systems”; and (c) adopt legislation or take measures for controlling healthcare market actors (providers of goods and services, insurers, etc.) to ensure equitable access to health care and health services. However, this does not mean that the right to health is limited to the right of access to health services (CESCR COMMITTEE ON ECONOMIC, SOCIAL AND CULTURAL RIGHTS, 2000).

Figure 2-1 Theoretical model adopted as framework for the thematic analysis



In 2005, the World Health Organization (WHO) Member States committed to achieve Universal Health Coverage (UHC), ensuring access to health services for all people and protecting them of financial hardship paying (WHO WORLD HEALTH ORGANIZATION, 2010). For this, the countries must "ensure that health-financing systems include a method for prepayment of financial contributions for health care, with a view to sharing risk among the population and avoiding catastrophic health-care expenditure and impoverishment of individuals as a result of seeking care" (WHA WORLD HEALTH ASSEMBLY, 2005). More recently, in 2012, the United Nations (UN) General Assembly adopted a resolution on affordable universal healthcare, recognizing UHC as a priority of the post-Millennium Development Goal. In all these discussions, access to medicines has been considered a critical component of UHC (GOROKHOVICH; CHALKIDOU; SHANKAR, 2013).

Although the UHC initiative aims to fill the current gaps in the health systems coverage around the world, these commitments must be treated with caution, as there is evidence of the influence that medical-industrial complex stakeholders (i.e. pharmaceutical industry) have on multilateral organisms' recommendations (COHEN; CARTER, 2010). Indeed, the UHC commitments are interesting for industrial medical complex as an opportunity for expanding the market for their products with the guarantee that the states are responsible for the healthcare payment and have resources available in the risk pooling funds.

#### 2.4.1.1 Definition of essential medicines

In 1977, the WHO published for the first time the definition of essential medicines. The concept has changed over time, incorporating prioritization criteria and availability conditions. The current definition states that essential medicines are those that satisfy the priority health care needs of the population, which must be selected considering criteria of prevalence of the disease, evidence of efficacy and safety and comparative cost-effectiveness. In addition, essential medicines must always be available in adequate amounts, in appropriate dosage forms, with assured quality and at prices the individual and the community can afford (WHO WORLD HEALTH ORGANIZATION, 2015a).

Nowadays, discussions about essential medicines have grown especially regarding the high price of new medicines. On the one hand,

even when new therapeutic alternatives meet the criteria to be considered essential, their affordability is compromised because they are priced, in some cases, at over ten times the gross domestic product (GDP) per capita of Low and Middle Income Countries (LMIC) (GOROKHOVICH; CHALKIDOU; SHANKAR, 2013). Some examples are sofosbuvir and daclatasvir for hepatitis C treatment and trastuzumab for breast cancer treatment, recently included in the WHO essential medicines list (WHO WORLD HEALTH ORGANIZATION, 2015b).

On the other hand, the emergence of high-priced medicines for the treatment of rare diseases, that cannot be considered essential medicines according to the WHO definition, rises the discussion on how to guarantee the right to health for people diagnosed with such diseases without compromising the health system's sustainability (STOLK; WILLEMEN; LEUFKENS, 2006).

#### 2.4.1.2 Pharmaceutical Industry and pharmaceutical marketing practices

The pharmaceutical industry is an economic strategic sector because of its huge profit margin (almost 20% in 2013, surpassing the banking and the oil industries) (ANDERSON, 2014), and for its research and development (R&D) activities and generation of new knowledge, that create high added value (TOBAR; SANCHEZ, 2005).

The pharmaceutical industry has a large lobby capacity and influence on decision-making concerning both health and trade policies, even in developed countries (SANCHEZ-SERRANO, 2014). For example, the pharmaceutical industry payments correspond to 50% or more of the total funding of regulatory agencies such as the European Medicines Agency (EMA) or the Food and Drug Administration (FDA). In this context, it is noted that the review time for new patentable medicines was significantly reduced, and alternatives of fast-track approval requiring less data about efficacy and safety have been created for medicines indicated for "serious" or "life-threatening" conditions (WILLIAMS; MARTIN; GABE, 2011).

The pharmaceutical industry also lobbies for harmonization of regulatory frameworks across countries (i.e. International Conference on Harmonization – ICH) in order to open new markets in emerging

economies and to outsource some aspects of medicine development, including clinical trials, which are cheaper in developing countries (WILLIAMS; MARTIN; GABE, 2011).

Pharmaceutical marketing practices have become more aggressive over time targeting physicians and, with raising frequency, the public. The creation of unhealthy reliance on and over-use of medicines have been questioned at different levels, from governmental spheres (HOUSE OF COMMONS, 2005) to academic discussions (ABRAHAM, 2010; MOYNIHAN; HENRY, 2006).

The marketing strategies of the pharmaceutical industry include the redefinition or reconfiguration of health problems as having a pharmaceutical solution (disease mongering); the use of medicines for non-medical (enhancement) purposes; and the creation of new social identities and mobilisation of patient or consumer groups around medicines (MOYNIHAN; HENRY, 2006; WILLIAMS; MARTIN; GABE, 2011). Other strategies are medicines innovation and colonization of health futures, creating the expectation that with tools like pharmacogenetics or pharmacogenomics, "personalized medicine" will possibly resolve all the health problems, notwithstanding the limitation that the biotechnological approach to the medicines development has shown (FERNALD et al., 2013; HOPKINS et al., 2007)

#### 2.4.1.3 The TRIPS agreement, innovation model, and medicines prices

The agreement of the World Trade Organization (WTO) on Trade-Related Aspects of Intellectual Property Rights (TRIPS) recognizes medicines as patentable products. The patent protection must be available for at least 20 years from the date of application and granted as long the product meets the requisites of novelty, inventive step and utility (WTO WORLD TRADE ORGANIZATION, 1995). The patent guarantees monopoly to the manufacturer who can set the prices, usually high, to the medicines in order to recoup investments in R&D activities (SANCHEZ-SERRANO, 2014).

This is the reason why pharmaceutical companies have great interest in policy-making of intellectual property rights protection at international and national levels, especially in the implementation of the

TRIPS agreement (TOBAR; SANCHEZ, 2005). Among the concerns are the relaxation of the patentability criteria to achieve protection for *me-too* medicines; and the monopoly period extension to delay the entry of generic drugs, and the resulting prices reduction (ROSSI, 2006).

Although the pharmaceutical industry's sales depend on its ability to innovate, in recent decades the industry has devoted more efforts for developing *me-too* medicines, which is easier and involves less financial risk, than truly innovative medicines development (SANCHEZ-SERRANO, 2014). This tendency appeared first in chemically synthesized medicines, and has recently been observed in biotechnological medicines (HOPKINS et al., 2007).

Despite the aim of this protection system is to stimulate innovation (WHO 2006), this model does not necessarily translate into significant therapeutic advances. Actually, it is estimated that 70% of the medicines available on the global pharmaceutical market are duplicates, non-essential and minor variations of the parent drug (PAN-AMERICAN HEALTH ORGANIZATION, 2010). Moreover, some of the new drugs have produced additional health risks as a result of adverse events leading to commercialization suspension, like COX-2 inhibitors (INSTITUTO CATALÁN DE FARMACOLOGÍA, 2005).

Recently, concerns about the fact that this system has resulted in abuses in the definition of exorbitant prices of medicines that offer little benefit to patients have risen (SANCHEZ-SERRANO, 2014). While pharmaceutical industries justify high prices as a result of high investments in R&D activities, this argument has been questioned, because evidence indicates that the expenses for marketing activities are higher than those for R&D activities (MORGAN et al., 2011). Some authors argue that firms set the new drugs' prices in the early stages of the development process. As in the case of luxury goods, the more devastating the disease is and more unique and effective the medicine is, the greater price it has, regardless of the development cost (SANCHEZ-SERRANO, 2014).

Other signs of the crisis in the innovation model are the poor development of therapeutic alternatives aimed at solving the public health needs of developing countries (VELASQUEZ, 2012), and the null impact of patents on local capacity for scientific and technological development in these countries (WHO WORLD HEALTH

ORGANIZATION, 2006). As a result, although pharmaceutical spending has considerably increased in recent years, this has not translated into better health outcomes of the population (SANCHEZ-SERRANO, 2014).

### 2.4.2 National level

#### 2.4.2.1 Right to Health in the National Constitution

Considering the obligations set out in the International Covenants on Human Rights, social justice values, equity and efficiency interpretations (VARGAS; VÁZQUEZ; JANÉ, 2002), the historical background and development model adopted (MEJÍA-ORTEGA; FRANCO-GIRALDO, 2007), each State defines in its political Constitution the type of citizenship that will be recognized and the way in which the social question will be inserted in public policies (FLEURY; MOLINA, 2002). These aspects will determine if the social rights, including the Right to Health, will be recognized as fundamental rights, that is, the state's role in the fulfilment of these rights (PEREHUDOFF; LAING; HOGERZEIL, 2010). National Constitutions define if social rights would or would not be claimed through the courts, and if these claims would be through specific judicial ways (HOGERZEIL et al., 2006; YAMIN; GLOPPEN, 2011).

In states where liberal culture predominates, social policies tend to be residualist: the state action, in the form of social assistance, aims mostly at the social needs of those who are unable to seek solutions in the market resulting in *inverted citizenship*. In states where conservative culture predominates, social policies on social protection are based on rights and duties related to the occupational status, in the form of social insurance, corresponding to *regulated citizenship*. Finally, in the social democratization of capitalism, state intervention aims to correct distributive social inequities and has as scope all the individuals, resulting in *universal citizenship* (FLEURY; MOLINA, 2002).

#### 2.4.2.2 Health System Model

Each country establishes the health system model based on the assumptions set out in the Political Constitution as well as the values of each society (FLEURY; MOLINA, 2002). Health systems are social constructions whose design and performance involves confrontations

and negotiations among different stakeholders, such as state bureaucracy, healthcare professionals, trade unions, political parties, and the industrial medical complex (LABRA, 1999).

Thus, although the health system *hardware* (finance, medical products, information systems, levels and types of human resources, forms of service delivery, and governance understood as organizational structures and legislation) has been defined, this does not guarantee that the population will have access to health services. The health system *software,* that is, ideas, interests, values, affinities and power relationships between the health system stakeholders also influence its performance, since not all the stakeholders have as main goal to improve the health of the population (SHEIKH et al., 2011).

In the same sense, the availability of a list of essential medicines that the health system must supply does not ensure that such medicines will be accessible. Actually, some barriers for the access to medicines related to the health systems performance, like weak governance, fragmentation of the healthcare networks, and health sector pluralism have been identified (BIGDELI et al., 2013).

#### 2.4.2.3 Judiciary system

The Judiciary system has become an alternative way for access to medicines in some countries; however, the level of intervention of the courts in issues related to access to medicines depends on their characteristics. The judiciary system organization (hierarchy of the tribunals, level of decentralization) determines its accessibility. On the other hand, some factors like the law system (civil or common law), the perception about the health system performance, and the perception of the physician's authority as professional capacitated to decide about the best treatment for a specific patient could influence the judges' willingness to accept and grant lawsuits for access to medicines (GAURI; BRINKS, 2007; YAMIN; GLOPPEN, 2011).

#### 2.4.2.4 Generic Medicines: National Patents Policies and regulation harmonization

Each country, based on the TRIPS agreement, defines in its territory the regulations relating to the protection of Intellectual property. The agreement allows some flexibility for countries to decide

whether they recognize the patentability of medicines, and for second uses of medicines already available on the market (WHO WORLD HEALTH ORGANIZATION, 2006). In the Doha Declaration of 2001, the WTO recognized the negative impact that the patent protection had on public health, and highlighted the TRIPS agreement flexibilities (i.e. compulsory licensing) that countries can use if facing serious health problems (WTO WORLD TRADE ORGANIZATION, 2001). Nevertheless, pharmaceutical companies lobby in Free Trade Agreements negotiations to limit the applicability of TRIPS flexibilities and demand application of the requirements contemplated in the TRIPS-Plus agreement (i.e. exclusivity of test data) (CORREA, 2006; GOLDMAN; LOVE, 2015).

Other strategies to delay the entry of generic products are the lobby for the harmonization of the regulation related to bioequivalence and bioavailability for chemically synthesised medicines, and biosimilarity for biotechnological medicines (SEUBA, 2010); marketing strategies for questioning generic medicines quality (HOLGUIN, 2014) and payment to generic companies to suspend the release of generics (FEDERAL TRADE COMMISSION, 2013).

#### 2.4.2.5 National policies of scientific and technological development and National Pharmaceutical Industry

Each country, according to its development model and technical capacities, establishes national policies for scientific and technological development. These policies may include measures both to promote investments by foreign companies in the country, and to stimulate national initiatives such as the creation of public pharmaceutical industries or encouraging the creation of private pharmaceutical companies of national capital to ensure local production of generic medicines (TOBAR, 2008).

On the other hand, states can create and maintain public research institutes or allocate resources for funding research to generate technological knowledge and capacity to produce medicines, and the required materials (active pharmaceutical ingredients and excipients) aiming to reduce the country's dependence on external imports (PINHEIRO et al., 2014).

#### 2.4.2.6 Pharmaceutical policies

In order to harmonize the market and health contexts, governments define national pharmaceutical polices. These policies express and prioritize medium to long-term goals for the pharmaceutical sector, and identify the main strategies for attaining them. They provide a framework within which the activities of the pharmaceutical sector can be coordinated. They cover both the public and the private sectors, and involve all the main actors in the pharmaceutical field (WHO WORLD HEALTH ORGANIZATION, 2001).

Pharmaceutical policies are transversal, considering both market aspects (local production of medicines, production of generic medicines etc.) and sanitary aspects (regulations related to sanitary registration, quality assessment etc.). Many also include the promotion of International Non-proprietary Name (INN) prescribing, strategies for selecting medicines covered by the health system, price regulation policies and orientation of science and technology policies to meet the health needs of the population (TOBAR; SANCHEZ, 2005).

### 2.4.3 Demand-side level: Citizens and consumers

In the relationship between users and the health system, users can be considered as citizens demanding their right of access to health services and medicines, and as consumers of health care (FRENK, 2010). In both cases, the health services accessibility (e.g. organization, geographical distribution), and enabling factors (e.g. socio-economic status, perception about the system and the right to health) influence the possibility of getting access to medicines (SOARES, 2013).

Despite the demand for health services and medicines is usually individual, in most difficult situations people tend to organize and form support networks that facilitate overcoming barriers to access. However, some studies show that the power of patient activism and collective mobilisation have been ‘captured’ by the pharmaceutical industry by means of marketing strategies ‘to inform or to educate patients’ that highlight the “expert patient” discourse (ABRAHAM, 2010; WILLIAMS; MARTIN; GABE, 2011). Thus, patient groups have become important stakeholders in the health systems, particularly in the case of high-priced medicines, in two ways: (1) their advocacy during the process of incorporation of new medicines in the coverage of health

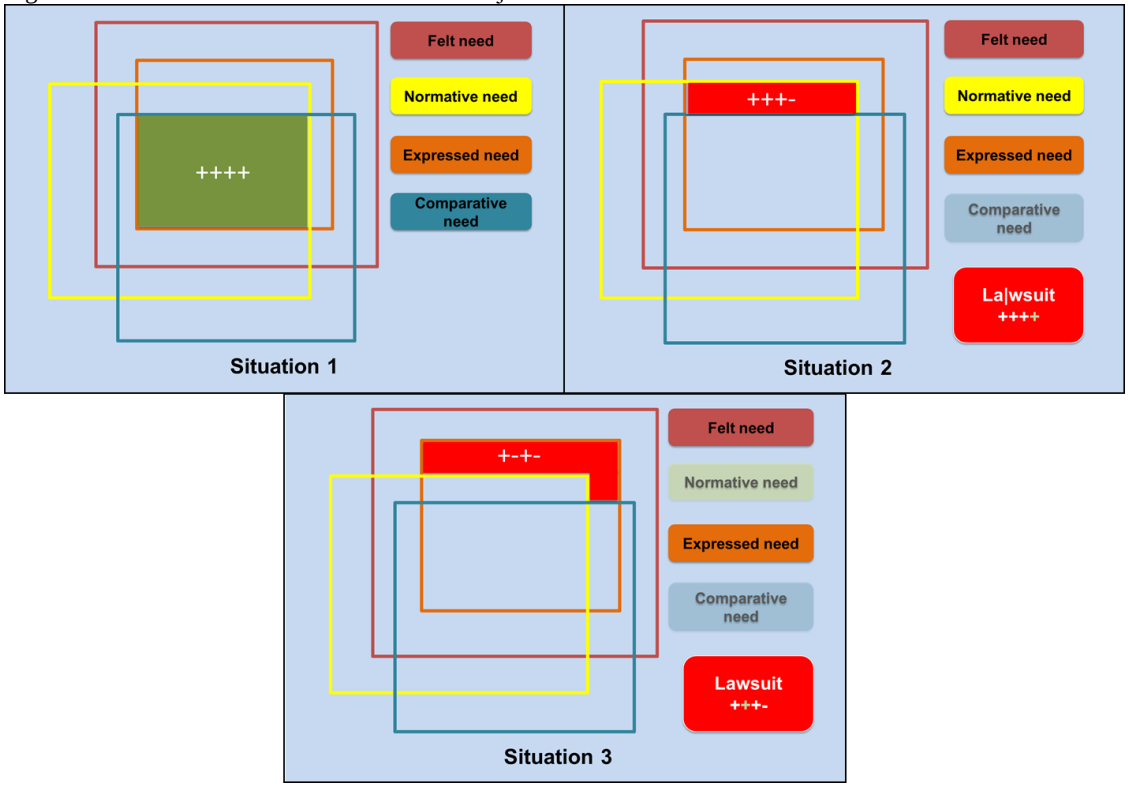
systems (PEREHUDOFF; ALVES, 2010), and (2) for the support and promotion of access to medicines through the courts (DA-SILVA; TERRAZAS, 2008).

### 2.4.4 Judicialization of access to medicines: Conflict in defining health needs?

As a consequence of the interaction among the aforementioned elements, different valuations of medicines as health needs rise in the society. Applying the Bradshaw's taxonomy, we identify three possible combinations (Figure 2-2) useful to explain the causes of judicialization of access to medicines from the definition of health needs.

*Situation 1* represents the ideal scenario: the medicine is prescribed, is covered by the health system, and is supplied to the patient. *Situation 2* represents two possible scenarios: (a) The patient do not receive a medicine covered because the health system is not able to ensure access to the medicines covered; or (b) Despite the medicine is covered, the patient or the prescriber requests a specific brand. Finally, *situation 3* also represents two scenarios: (a) The health system does not offer a therapeutic alternative that is adequate for the patient's specific situation (e.g. low prevalence diseases or when the patient does not respond to the therapies offered by the health system); or (b) The patient receives the prescription of a medicine that could be substituted by a medicine covered by the health system (e.g. me-too medicines). In both situations (2) and (3), the patient can resort to the judiciary to have his/her need met. In situation (2), the judiciary system meets the comparative need since the patient receives the medicine that all patients must receive from the health system. In situation (3), even though the judiciary makes the health system recognize the medicine as a need (normative need, positive), the comparative need is not met because the lawsuit is individual, so it does not guarantee access to that medicine for patients in similar conditions.

Figure 2-2 Conflict in the definition of 'need' in judicialization of access to medicines



### 2.4.5 The Consequences of Judicialization: Feedback Loop

If litigation becomes an effective way to get access to medicines, the proliferation of lawsuits may induce some positive and/or negative effects, depending on the lawsuits characteristics. Some of the possible effects are described below.

#### 2.4.5.1 Demand-side level

At the individual level, the positive impact of a successful lawsuit is the satisfaction of the need felt by the patient, because it ensures access to medicines. This positive result leads other patients who need the same therapy to view the courts as a means of access to medicines. This occurs through the creation of support networks and patient groups to facilitate access to medicines (DA-SILVA; TERRAZAS, 2008).

When the answer to the lawsuit responds to a healthcare gap in rights protection (situations 2a, 3a), judicialization reinforces citizenship. However, when the lawsuit serves individual desires for particular medicines at the expense of the alternatives available (situations 2b and 3b), it reinforces the patients' identity as medicines consumers rather than as citizens that aim to improve the performance of the health system aiming to achieve collective impact (BIEHL, 2013).

#### 2.4.5.2 National level

When most of the lawsuits are for situations as described in scenario 2a, judicialization has positive effects, such as regulatory changes within health systems aimed at strengthening surveillance and control of the pharmaceutical market (i.e. medicines price control) and control over the medical industrial complex actors (insurance companies, hospitals/clinics), which do not comply with their obligations to ensure access to medicines (BERGALLO, 2010; UPRIMNY; DURÁN, 2014). In addition, because of judicialization, the right to health can become a fundamental right (COLOMBIA, CORTE CONSTITUCIONAL, 2008a).

Another positive effect is the creation of strategies aiming to close public policies gaps evidenced by lawsuits resulting from situations as in scenario 3a. These measures include the equalization of medicines coverage for all the population, the creation of Health

Technology Assessment (HTA) agencies, the development of clinical guidelines, the incorporation of some of the medicines required in the lawsuits in the health system coverage, and the creation of special funds to financing high-priced medicines (FONDO NACIONAL DE RECURSOS, 2010).

However, when most of the lawsuits correspond to scenario 3b, the measures for updating the covered medicines lists meet the market needs of the pharmaceutical industry, rather than fill a health policy gap (BORGES; UGÁ, 2010; CUBILLOS et al., 2012).

As consequence of the lawsuits' rising number and economic impacts, judicialization of access to medicines brings up *pharmaceuticalization* of public health policies. Discussions about the health system performance focus on medicines accessibility, neglecting other strategies that could have a greater impact on the health outcomes of the population.

Furthermore, judicialization has a regressive effect on both the equity of the resources distribution and the definition of priorities within the health system. As most of the lawsuits are individual, and the access to the Judiciary system, similarly to the health system, depends on individual enabling factors, people with higher socio-economic resources usually have a greater possibility of access to justice (ABRAMOVICH; PAUTASSI; FURIO, 2008; BERGALLO, 2010; UPRIMNY; DURÁN, 2014).

## 2.5 DISCUSSION AND CONCLUSIONS

Medicines have become health needs in modern society because they are goods considered valuable (WILLARD, 1982). This value results from the combination of the social expectation that scientific development will resolve the health problems (WILLIAMS; MARTIN; GABE, 2011) and the economic and political interests of different health system stakeholders that rise around medicines as products.

In recent years, the discussion about the health systems performance has been colonized by pharmaceuticals (goods) despite the health system (the satisfier) may be more efficient and have broader impacts on the population's health by the implementation of other strategies (i.e. promotion and prevention activities). The analysis of

judicialization of access to medicines as a complex phenomenon brings the opportunity to discuss how the pharmaceuticals have colonized not only the health system scope but also the juridical spheres where access to medicines has been the subject of intense discussion (BRASIL, CONSELHO NACIONAL DE JUSTIÇA, 2010a; COLOMBIA, CORTE CONSTITUCIONAL, 2008a).

In this sense, our theoretical model considers a broader view of this phenomenon and its effects, overcoming the positivist view that predominates in the health system research (PAINA; PETERS, 2012) and in the judicialization of access to medicines analysis (VARGAS-PELÁEZ et al., 2014). The model emphasises how power structures, interests, interdependencies, values and principles of the stakeholders could influence the perception of medicines as health needs and the occurrence of litigation for access to medicines, according to each particular context.

By applying the Bradshaw's (1972) taxonomy of social needs, the model also allows showing the different nuances that judicialization may have according to the characteristics of court cases. For instance, the interpretation of the phenomenon as an intervention of the Judiciary that aims to protect the right to health of the individuals based on the gaps of the health system, or as a strategy of the pharmaceutical industry to ensure market for their products (BAPTISTA; MACHADO; DE-LIMA, 2009).

Due to the different characteristics and consequences that judicialization of access to medicines has had across countries, general approaches are necessary for seeking common tools to face the challenge of guaranteeing equitable access to medicines and healthcare services that improve the population's health. These approaches should consider the context of scarce resources, and ensure that the right to health be an instrument to guarantee the population's health rather than an instrument of marketing.

Finally, this model is an attempt to show that different factors and stakeholders can influence the occurrence of judicialization of access to medicines according to the context of each country. But models have limitations since they are simplified representations of reality. For this reason, this model does not intend to serve as a definitive model, and needs to be enhanced by being applied in practical cases.

# PART II:

# JUDICIALIZATION OF ACCESS TO MEDICINES AND PHARMACEUTICAL POLICIES: CROSS-COUNTRY ANALYSIS.

# 3 CHAPTER 3 – Accessibility to medicines in four Latin American countries and The Netherlands: A comparative study

## 3.1. INTRODUCTION

Universal Health Coverage (UHC) is a commitment of the World Health Organization (WHO) member states with the aim of ensuring access to health services for all people and protecting them from financial hardship. For meeting this goal, three dimensions of coverage are considered: population, health services and technologies, and costs (WHO WORLD HEALTH ORGANIZATION, 2010). The access to essential medicines is recognized as a significant UHC component for different reasons. Firstly, they are useful to resolve health problems by guaranteeing efficacy, safety and efficient use of financial resources (WHO WORLD HEALTH ORGANIZATION, 2015a). Secondly, essential medicines represent an important share of the countries' healthcare budget, and it is expected that the prices of new technologies, which are increasingly designated as essential medicines, be higher (WAGNER; QUICK; ROSS-DEGNAN, 2014). Global pharmaceutical expenditures have increased in the last years, reaching US$1.06 trillion in 2014, and it is estimated that it will reach US$1.3 trillion in 2018 (IMS INSTITUTE FOR HEALTHCARE INFORMATICS, 2014). In the region of the Americas, the average share of the total pharmaceutical expenditure within the total health expenditure was 24.1% (9.3% to 39.7%) in 2006, where 64.1% of that was funded privately (LU et al., 2011).

South American countries have established some measures in the last 15 years in order to achieve a UHC and guarantee equitable access to the medicines. However, the access to essential medicines is still a challenge and judicialization of access to medicines has emerged as an alternative way for patients to receive the medicines they need. When this phenomenon became frequent, for instance in Colombia and Brazil, changes in the policies related to the access to medicines were induced, such as the inclusion of new medicines in the health system's coverage (TOBAR et al., 2014; VARGAS-PELÁEZ et al., 2014).

In this context, this study aims to review the historical development of strategies for access to medicines in Argentina, Brazil, Chile and Colombia in the period 2000-2014 and compare them with

measures taken in The Netherlands – a country where judicialization is not as common as in the Latin American countries.

## 3.2. METHODOLOGY

An integrative literature review was carried out in order to obtain information about the measures for access to medicines taken between 2000 and 2014 and their results in the studied countries. This review was complemented with information collected by means of semi-structured interviews with the stakeholders from this countries involved in litigation for access to medicines[3].

### 3.2.1. Integrative Literature Review

The databases PubMed, Scielo, and Scopus were consulted using the keywords "public policy", "health policy", "access to drugs", "expensive drugs", "provision of medicines", "public policy analysis", "health system", "Brazil", "Colombia", "Argentina", "Chile" and "The Netherlands" in English, Portuguese and Spanish. Additionally, the WHO Pharmaceutical Sector Country Profiles Data and Reports, The Ibero-American Observatory on Health Policies and Systems, The European Observatory on Health Systems and Policies, and the Commonwealth Fund were also consulted. The information collected included the structure and organization of the health systems, the regulatory changes related to the strategies for access to medicines, and data about the results of these strategies, when they were available.

### 3.2.2. Semi-structured interviews

Semi-structured interviews were conducted with 50 key actors linked to the different stakeholders involved in the judicialization of access to medicines phenomenon (Table 3-1). The interviews were conducted in Argentina (Buenos Aires, La Plata), Brazil (Rio de Janeiro, Porto Alegre, Brasilia, and Sao Paulo), Chile (Santiago) and Colombia (Bogota), between August and December 2014.

[3] For this analysis data from the interviews were used as a complement of the literature review, but no specific technique of analysis was applied.

Table 3-1 Number of interviewed respondents

| Stakeholder | Argentina | Brazil | Chile | Colombia | Total |
|---|---|---|---|---|---|
| Executive[(a)] | 2 | 1 | 0 | 5 | 8 |
| Judiciary | 3 | 3 | 0 | 2 | 8 |
| Health system manager [(b)] (Manager) | 6 | 3 | 2 | 2 | 13 |
| Patient organization (Patient) | 1 | 1 | 1 | 2 | 5 |
| Health professional organization (Professional) | 1 | 1 | 2 | 2 | 6 |
| Other | 5[(c)] | 0 | 2[(d)] | 3[(e)] | 10 |
| Total | 18 | 9 | 7 | 16 | 50 |

Source: The authors.

(a) Executive: Ministry of Health, medicines regulatory agency, superintendence of health or healthcare services;
(b) Health system managers: State Health departments, *Obras Sociales* (OSs), *Instituciones de Salud Previsional* (ISAPREs), *Empresas Promotoras de Salud* (EPSs)
(c) NGOs, Senator's advisor, Expert in pharmaceutical marketing, Expert in public policies of health.
(d) Lawyer involved in judicial cases for access to medicines, University lecturer expert in health economics.
(e) NGOs, University lecturer expert in litigation for health right.

A key actor was defined here as an individual involved in the judicialization of access to medicines, working for the stakeholder during at least one year, who was willing to offer their expertise, their opinions and knowledge to the object of study.

The researchers from each country, who were involved in the study, helped identify key actors as potential participants. Additional respondents were identified through the snowball technique. Respondents were invited to participate in the study by means of e-mail, telephone or personally. None of them declined the invitation. All the interviews were conducted as individual face-to-face interviews and, in almost all the cases, they happened at the participants' workplace.

The interview script included two general questions: *(a)* “In your opinion, what are the possible causes of judicialization of access to medicines?” and *(b)* “In your opinion, what are the possible consequences of judicialization of access to medicines?” These results are included in chapter 4. The interview scripts also considered two specific questions about interventions of the Judiciary and the Executive to cope with litigation and to improve access to medicines (Table 3-2). These results are described in chapter 5.

All the interviews lasted from 30 to 45 minutes and were conducted by the same interviewer in Spanish or Portuguese. The interviews were audio-recorded and transcribed verbatim. To guarantee the quality of the data, all the transcriptions were sent to each participant for checking and correction. In order to maintain the participants’ confidentiality, only the country name and the represented stakeholder were informed. All participants signed informed consent before the interview.

## 3.3. RESULTS

Table 3-3 displays the demographic and economic background, administrative divisions, and health indicators of the studied countries. A full description of the health systems can be found in Annex A. The most relevant aspects of the measures taken by the studied countries to guarantee the access to medicines, between 2000 and 2014, are outlined below.

### 3.3.1. Argentina

The Argentinean health system is comprised of three subsectors. The public subsector corresponds to the public health system and the Federal Program *Incluir Salud*. The social insurance subsector corresponds to the *Obras Sociales* (OSs) and the National Institute of Social Services for Retirees and Pensioners/Integral Medical Care Plan (INSSJyP/PAMI). The private sector involves voluntary health insurance by direct payment or through the OSs (ABRUTZKY; BRAMUGLIA; GODIO, 2009; BELLÓ; BECERRIL-MONTEKIO, 2011).

Table 3-2 Specific questions per country.

| | |
|---|---|
| Argentina | In the last years, the health system has taken some actions such as implementing the Unified System Refund (SUR) which incorporated some technologies to the health insurance system and changed the management of requests for expensive medicines. In your opinion, have these measures helped to improve the access to medicines and reduce the number of lawsuits?<br><br>Has the judiciary also taken initiatives against the large number of lawsuits for access to medicines? If so, in your view, have these measures helped to improve the access to expensive medicines and reduce the number of prosecutions? |
| Brazil | In 2010, the Specialized Component of Pharmaceutical Assistance was created in the Unified Health System in which there were changes both in the list and management of the covered medicines. In your view, have these measures improved the access to medicines and reduced the number of lawsuits?<br><br>The judiciary has also taken initiatives due to the large number of lawsuits, including a public hearing of the Supreme Court in 2009 and Recommendation No. 31 of 2010. Have the suggested measures contributed to improving the access to medicines and reducing the number of lawsuits? |
| Chile | In the last years, the health system has taken some measures such as the FONASA's High-cost Medicines Program, special allowance fund and the Plan of Explicit Health Guarantees. In your opinion, have these measures helped to improve the access to medicines and reduce the number of lawsuits?<br><br>Has the judiciary also taken initiatives against the large number of lawsuits for access to medicines? If so, in your view, have these measures helped to improve the access to medicines and reduce the number of lawsuits? |
| Colombia | Because of the numerous lawsuits for access to medicines, the health system has taken measures such as incorporating some technologies to the benefits plan. In your opinion, have these measures helped to improve the access to medicines and reduce the number of lawsuits?<br><br>The judiciary has also taken initiatives due to the large number of lawsuits for access to medicines, such as Ruling T-760 of 2008. In your view, have these measures helped to improve the access to medicines and reduce the number of lawsuits? |

Table 3-3 General information about the studied countries.

| Country | Argentina | Brazil | Chile | Colombia | The Netherlands |
|---|---|---|---|---|---|
| Population (2013)[a] | 41,446,246 | 200,361,925 | 17,619,708 | 48,321,405 | 16,804,432 |
| Administrative division | 23 provinces 1 Autonomous City | 26 states, 1 federal district | 15 regions | 32 departments 1 capital district | 12 provinces |
| Life expectancy at birth (2012)[c] | 76 | 74 | 80 | 78 | 81 |
| Healthy life expectancy (2012)[c] | 67 | 64 | 70 | 67 | 71 |
| Under-5 mortality per 1,000 live births (2013)[c] | 13 | 14 | 8 | 17 | 4 |
| GDP per capita (Current USD) (2013)[a] | 14,715.2 | 11,208.1 | 15,732.3 | 7,831.2 | 50,792.5 |
| GDP per capita PPP (2013)[a] | Not Available | 15,037.5 | 21,942.2 | 12,423.9 | 46,162.1 |
| Gini index (2011)[a] | 43.6 | 53.1 | 50.8 | 54.2 | 28.9 (2010) |
| HDI Rank (2013)[b] | 0.808 | 0.744 | 0.822 | 0.711 | 0.915 |
| THE as % of GDP (2013)[d] | 7 | 10 | 8 | 7 | 13 |
| Government expenditure on health as % of THE (2013)[d] | 68 | 48 | 47 | 76 | 80 |
| Private expenditure on health as % of THE (2013)[d] | 32 | 52 | 53 | 24 | 13 |
| Government expenditure on health as % of general government expenditure (2013)[d] | 32 | 7 | 15 | 16 | 21 |
| Government expenditure on health per capita PPP (2013)[d] | 1,725 | 1,454 | 1,678 | 843 | 5,601 |

**Abbreviations:** GDP: Gross Domestic Product. HDI: Human Development Index. THE: Total Health Expenditure. PPP: purchasing power parity value.
**Sources:** (a) World Bank indicator. Retrieved from: data.worldbank.org [Accessed: 11 Jun 2015]. (b) United Nations Development Programme – Human Development Reports. Retrieved from: http://hdr.undp.org/es/content/table-1-human-development-index-and-its-components [Accessed: 11 Jun 2015]. (c) World Health Organization - Global Health Observatory (GHO) data. Retrieved from: http://www.who.int/gho/countries/en/ [Accessed: 11 Jun 2015]. (d) WHO, Global Health Expenditure Database. Retrieved from: http://apps.who.int/nha/database/Select/Indicators/en. [Accessed: 12 Jun 2015]

According to the 2010 census, 46.4% of the population had health coverage by affiliation to the *Obras Sociales* (including the INSSJyP/PAMI[4]), 10.6% had coverage by a private insurance company through the OSs (*desregulados* – *unregulated*), 5.1% had a voluntary private insurance (prepaid medicine), and 1.8% had coverage by state health programs or plans. The other 36.1% did not have health coverage by the other ways and depended on the public subsector for medical attention (ARGENTINA, INSTITUTO NACIONAL DE ESTADÍSTICA Y CENSOS - INDEC, 2012).

As a result of the huge fragmentation of the Argentinian health system the medicines coverage varies among and within the subsectors. Argentina does not have a National Health Technology Assessment (HTA) agency or health economic guidelines (AUGUSTOVSKI et al., 2012). Thus, the HTA activities are completely decentralized and the definition of the medicines covered in each health system's subsector depends on different actors: the Ministry of Health, the Provincial Health Secretary, the Superintendence of Health Services, the *Obras Sociales*, and private insurers (*Prepagas*). In addition, there is no regulation about how frequent the lists of medicines must be updated.

In the public sector, the coverage of health services and medicines varies greatly according to the development level and management capacity of the provinces. Since national regulations related to the health system are not binding in the provinces, the National Ministry of Health must negotiate with the provincial health ministries or secretaries about the implementation of the regulatory measures in the Federal Health Council (COFESA) (PROGRAMA DE LAS NACIONES UNIDAS PARA EL DESARROLLO - PNUD; ORGANIZACIÓN PANAMERICANA DE LA SALUD - OPS; COMISIÓN ECONÓMICA PARA AMÉRICA LATINA Y EL CARIBE - CEPAL, 2011).

In 2000, the *Plan Remediar* was implemented as a response to the social, economic and health crisis. This plan involved the creation of primary care centres that offer access to healthcare services and essential medicines to vulnerable populations without charges. The plan is funded

[4] National Institute of Social Services for Retirees and Pensioners/Integral Medical Care Plan

by the National government where purchasing is centralized and distribution is made directly to the pharmacies of the Primary Care Centres (CAPS) (FERNÁNDEZ PRIETO et al., 2013).

The National Ministry of Health has specific programs for funding and supplying high-price medicines, such as the Medicines Bank, which delivers cancer medicines to patients with no formal health coverage; and the HIV-AIDS Program, which also provides immunosuppressant medicines (TOBAR et al., 2012). These programs purchase medicines in a centralized way and distribute them to provincial health ministries or provincial referral services for the treatment of *catastrophic diseases*. Additionally, provincial health ministries undertake public procurements in order to complement these national programs.

The coverage of the Federal Program *Incluir Salud* includes the Medical Mandatory Program (Programa Médico Obligatorio – PMO) (*later addressed here*) and the *Benefits of High Cost and Low Incidence* (PACBI). In both provincial and central levels, the PACBI provides high-cost benefits and assists in cases whose resolution involves a high complexity that requires the coordination of different sectors of the *Incluir Salud* program. Moreover, the PACBI provides highly complex surgical services that are performed only once, biological medicines and new drugs for chronic administration. The list of covered healthcare services and medicines was defined by Resolution 1862 of 2011 (ARGENTINA, MINISTERIO DE SALUD, 2011).

The PACBI is funded by part of the per capita monthly resources that the National Medical Benefit Direction (*Dirección Nacional de Prestaciones Médicas)* transfers to the provinces. The Direction retains the PACBI's resources and reimburses the provinces only if they present the documentation proving that catastrophic diseases treatments were carried out (TOBAR et al., 2012).

In the social insurance sector, the national OSs and the INSSJyP/PAMI must provide to their beneficiaries the basic package of healthcare services and medicines, which is called Medical Mandatory Program (Programa Médico Obligatorio – PMO) and defined by the National Ministry of Health (ARGENTINA, PRESIDENCIA, 1995). In contrast, for the provincial OSs, the PMO provision is not mandatory.

Since the national constitution states autonomy to the provinces, each provincial OS defines the coverage of healthcare services and medicines for their beneficiaries (PROGRAMA DE LAS NACIONES UNIDAS PARA EL DESARROLLO - PNUD; ORGANIZACIÓN PANAMERICANA DE LA SALUD - OPS; COMISIÓN ECONÓMICA PARA AMÉRICA LATINA Y EL CARIBE - CEPAL, 2011).

Although some benefits have been incorporated into the PMO in the last years (emergency hormonal contraception, assisted fertilization and obesity treatment) (BÜRGIN, 2013), the list of medicines has not been updated systemically since 2004 (ARGENTINA, MINISTERIO DE SALUD, 2004). Furthermore, as the PMO is the minimal coverage package, each OS can include other medicines according to its economic capacity. The OSs are free to update or not their list of coverage.

In order to remedy the inequality among the national OSs and to guarantee that all of them be able to provide the PMO, the *Solidarity Redistribution Fund* (FSR) was created. The FSR is funded by the OSs through mandatory contributions that vary between 10% and 20% according to the their beneficiaries' salary range (CAVAGNERO et al., 2006). However, the INSSJyP/PAMI and provincial OSs do not contribute to this fund.

High-priced medicines have been financed with resources from FSR since 1998. Initially, the *Administración de Programas Especiales* (Administration of Special Programs – APE) was responsible for managing the resources to subsidize the coverage of high economic impact benefits for the treatment of low-incidence diseases (ARGENTINA, ADMINISTRACIÓN DE PROGRAMAS ESPECIALES, 1998). The APE therefore was a sort of reinsurance against catastrophic diseases to the national OSs (TOBAR et al., 2012).

The list of pathologies covered by the APE was established by Resolution 500/2004, comprising 42 pathologies and 20 medicines of *high economic impacts* (ARGENTINA, ADMINISTRACIÓN DE PROGRAMAS ESPECIALES, 2004). The APE originally financed these medicines by means of, subsidies to the national OSs. However as the documentation to support the subsidies was not timely submitted by the OSs, this modality was nullified in 2008. Thus, instead of subsidies the APE established a reimbursement modality for the pathologies

considered in Resolution 500/2004 and maintained the subsidy modality for "exceptional cases" (YJILIOFF, 2014).

As a consequence of the limited number of pathologies and medicines covered, the subsidies defined by way of exception increased significantly, forcing the financing of the uncovered medicines (LIFSCHITZ, 2014). Additionally, in practice, the APE destined less than half of its resources to the reimbursement of high-cost medicines and the funds were not allocated through transparent mechanisms (TOBAR et al., 2012).

In view of that, in 2012, the APE was incorporated into the Superintendence of healthcare services and substituted by the *Sistema Único de Reintegro* (Unified Reimbursement System – SUR). With this reform, other 75 pathologies and 105 medicines were included in the coverage (ARGENTINA, SUPERINTENDENCIA DE SERVICIOS DE SALUD, 2012a). Later, also in 2012, the *Sistema de Tutelaje de Tecnologías Sanitarias Emergentes* (Supervisory System for Emerging Sanitation Technologies) was created as a mechanism to include new technologies in the SUR's coverage (ARGENTINA, SUPERINTENDENCIA DE SERVICIOS DE SALUD, 2012c). With this reform, other 12 pathologies and 45 new medicines were included in the coverage (LIFSCHITZ, 2014).

In the implementation of the SUR, maximum reimbursement rates for medicines were established, and the Superintendence of Healthcare Services was in charge of developing treatment guidelines for the covered pathologies, and updating the medicines list. In 2013, a follow-up system for safety and efficacy of the medicines covered by the Supervisory System for Emerging Sanitation Technologies was created. In this system, the national OSs are responsible for collecting the data (ARGENTINA, MINISTERIO DE SALUD, 2013a).

Furthermore, some changes in the reimbursement authorization procedure were introduced. Nowadays, in order to apply for reimbursement, the national OS must submit online all the documents related with the clinic chart of the patient, the prescription, and the documents related to the medicines traceability systems in order to improve the transparency of the process (YJILIOFF, 2014). However, for some actors these measures have been more complicated.

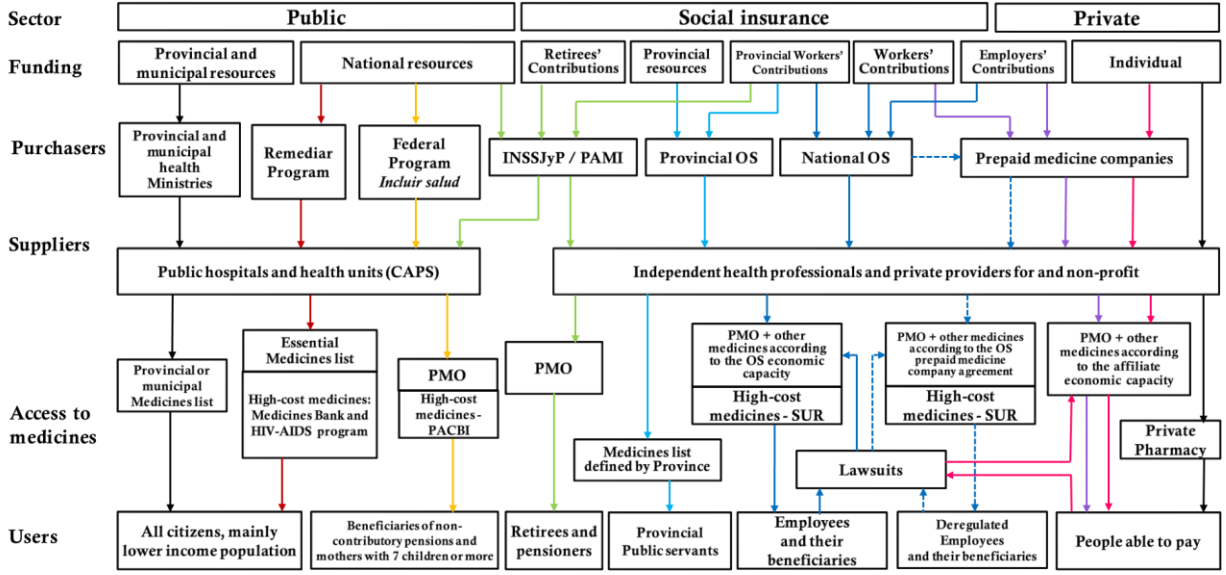
The national OSs beneficiaries have 100% coverage of high-cost medicines. In contrast, for the provincial OS beneficiaries the access to these medicines involved co-payments. For providing expensive medicines for catastrophic diseases, the provincial OS make agreements with pharmacies and drugstores (TOBAR et al., 2012).

In the private sector, the PMO coverage has been mandatory for all private insurance companies since 1996 (ARGENTINA, CONGRESO DE LA NACIÓN, 1996), but similarly to the social insurance subsector, the medicines coverage is rather variable. While for the *deregulated* affiliates the list of covered medicines varies according to the agreement made between the OS and the insurance company, for the voluntary private insurance the medicines coverage depends on the beneficiaries' affordability to pay.

Although the Superintendence of Health has been regulating the private insurance companies since 2011 (ARGENTINA, CONGRESO DE LA NACIÓN, 2011), these companies do not contribute to the FSR, and cannot apply to the SUR for reimbursement of high-cost medicines, except for *deregulated* affiliates, when the insurance company can get the reimbursement through the national OS. If a voluntary private insurance affiliate requires a high-priced medicine, which is not explicitly excluded of the policy, the company must finance it with its own resources, without possibility of reimbursement. Since 2013, a proposal about strategies for the reimbursement of medicines of high cost and for low-incidence disease treatment has been discussed (ARGENTINA, MINISTERIO DE SALUD, 2013b).

In the last years, lawsuits have become an alternative pathway to obtain access to high-cost medicines, especially in both social insurance and private sector. When a patient requires a medicine that is not included in the OS list or in the insurance policy, he/she can resort the Judiciary system. If the court decision favours the patient, the OS or the private insurance company must supply the medicine and finance it with their own resources (BÜRGIN, 2013). The strategies for access to medicines are summarized in Figure 3-1.

Figure 3-1 Health System Organization and Access to medicines pathways in Argentina




Source: Prepared by the author based on Belló and Becerril-Monteiko (2011)

### 3.3.2. Colombia

Two subsectors, the General System of Social Security in Health (SGSSS) and the private health insurance, constitute the Colombian health system. The SGSSS has three regimes: the contributory regime focused on formal workers and employees; the subsidized regime focused on the low-income population; and the special regimes focused on employees of specific economic sectors. Uncovered poor people depend on the public sector for access to healthcare services (COLOMBIA, 1993b), but access is provided only to emergency health services (COLOMBIA, 2007). In 2014, 48.01% of the population were covered by the subsidized regime, 43.56% by the contributory regime, 3.9% by special regimes; and 4.55% were uncovered (ASI VAMOS EN SALUD, 2015). In addition, the affiliates to the contributory regime can buy private health insurance (*medicina prepagada* – prepaid medical service).

All the insurers of the subsidised and contributory regimes, called Health-Promoting Enterprises (EPSs), must guarantee access to the medicines and healthcare services included in the Compulsory Health Plan (*Plan Obligatorio de Salud – POS*) with the resources per capita (UPC) that they received from the Solidarity and Guarantee Fund (FOSYGA) (GUERRERO et al., 2011). In 1993, when the health system was created, two different lists were defined. While the POS for the contributory regime considered health services and treatments at all health care complexity levels, the POS for the subsidized regime (POS-S) covered only primary healthcare and some high-cost services (i.e. some cancer treatments and treatment for chronic renal disease). As for medicines, the list specified the active, the dosage form and the concentration of the products covered. Both lists were matched in 2012 after a progressive process (COLOMBIA, COMISIÓN DE REGULACIÓN EN SALUD – CRES, 2009, 2010, 2012) ordered by the Constitutional Tribunal (COLOMBIA, CORTE CONSTITUCIONAL, 2008a).

Since the creation of the POS, the updating process was neither continuous, periodical nor with a transparent methodology (GIEDION; PANOPOULOU; GÓMEZ-FRAGA, 2009). Only in 2011, the process for updating the list of medicines came to include strategies for social participation. Additionally, the Health Technology Assessment Institute (IETS) was created and a frequency of two years for the updating

process was set (COLOMBIA, 2011). Currently, the POS covers services and medicines required at different healthcare levels, from primary care to high-cost treatments like cancer, transplantations and some biotechnological medicines (COLOMBIA, MINISTERIO DE SALUD Y PROTECCIÓN SOCIAL, 2015a).

The development of clinical practice guidelines has neither been organized nor coordinated with the process of POS updating. Only in 2011, as part of the POS updating, the medicines included in the guidelines published by the Ministry of Health were considered. However, according to the regulation, the presence of a medicine in an official guideline does not mean that this medicine is automatically covered by the POS (GIEDION et al., 2014). Although the guidelines should be a tool to guarantee rational use of medicines, their application is not mandatory to define the coverage in specific cases, especially in cases where high-cost medicines are covered only under specific indications.

In order to avoid the adverse selection of patients with high-cost or catastrophic diseases whose treatment is covered by the POS, the National Account of High Cost (*Cuenta de Alto Costo – CAC*) was created in 2007 (VARGAS-ZEA et al., 2012). The CAC is an auto-managed entity administrated by the insurers. All insurers of both subsidized and contributory regimes must report to the CAC with information about patients with catastrophic diseases. In addition, the EPSs must transfer part of the UPC resources to CAC, which is in charge of redistributing such resources following criteria based on catastrophic diseases' prevalence, incidence, cost and number of affiliates of each insurer (COLOMBIA, MINISTERIO DE LA PROTECCIÓN SOCIAL, 2007). The pathologies comprised in the CAC are chronic kidney disease and HIV/AIDS, which are followed since 2008. More recently, cancer, haemophilia, rheumatoid arthritis and rare diseases were incorporated (COLOMBIA, CUENTA DE ALTO COSTO, 2015).

If a patient requires a medicine that is not covered by the POS, his/her specific case is assessed by the insurer's technical-scientific committee (*Comité Técnico-Científico - CTC*). If the CTC considers that the medicine is needed, the insurer supplies the product and can start the process for reimbursement. The contributory regime insurers get reimbursement from the FOSYGA, while the subsidized regime insurers

get reimbursement from the Health Secretary of the Departments (COLOMBIA, 2001, 2007; COLOMBIA, CORTE CONSTITUCIONAL, 2008a).

In case the CTC considers that the prescription of that medicine is not pertinent and denies the requirement, the patient can resort the Judiciary by means of a lawsuit (*accion de tutela*) invocating the defence of his/her right to health. If the Judiciary grants the medicine, the insurer must supply it. In this scenario, the insurer can also get reimbursement, as above described. However, if the lawsuit is against an EPS-S, the judge can order reimbursement from FOSYGA; although regulation states that the reimbursement is a responsibility of the Health Secretary of the Departments (COLOMBIA, CORTE CONSTITUCIONAL, 2013).

In the case of especial regimes, each regime defines the list of healthcare services and medicines that will be covered, usually considering some therapies not included in the POS. Similar to the EPS, whether a patient requires a medicine that is not covered, it is also evaluated by the CTC of that special regime. If the request is denied, the patient can also resort to the Judiciary. In both cases, it is the special regime, with its own resources, that must pay for the medicines. They cannot ask for reimbursement from the FOSYGA.

The private sector can be divided into two parts, the private insurance (*Medicina prepagada – Prepaid medical service*) and out-of-pocket expenditure. Private insurance can only be hired by contributory regime affiliates. This kind of insurance usually provides optional benefits such as care for events not included in the POS, or different or additional conditions of hospitality and technology (COLOMBIA, 1993a). Nevertheless, the prepaid medical service usually does not cover medicines. Then, the user must access medicines by out of pocket expenditure, or in case the same company owns an EPS and a prepaid medical service, sometimes the patient is advised to request the medicine by means of a lawsuit against the EPS (UPRIMNY; DURÁN, 2014).

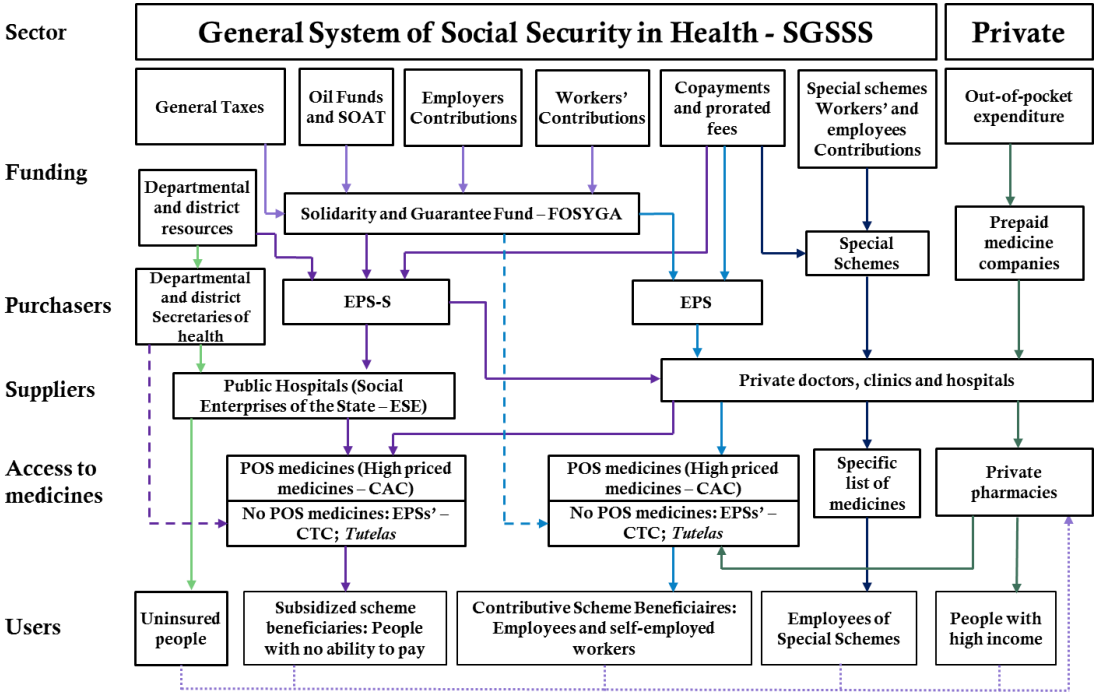
As a consequence of the pressure induced by exceptional pathways for access to medicines, since 2014 a process has taken place to change the way how the medicines covered by the health system are

described. So, the positive list (explicit inclusions) that describes the international Non-proprietary Names (INN), dosage form and strength of the medicines covered is being changed for a negative list describing only the medicines not covered by the health system (explicit exclusions). As a part of this process, the most recent updating of the POS eliminated the specification of dosage form and strength of the medicines covered. In addition, to avoid the use of exceptional pathways for access to medicines, all the medicines of some therapeutic groups were included in the POS (e.g. proton pump inhibitors) (COLOMBIA, MINISTERIO DE SALUD, 2014a).

### 3.3.3. Brazil

The health system in Brazil consists of public and private sectors. The public sector involves the Unified Health System (SUS) created by the National Constitution of 1988 whose principle was universal and equitable access to comprehensiveness healthcare (LEVINO; CARVALHO, 2011). The private sector, called supplementary health system, corresponds to insurance companies and private healthcare institutions. Although all citizens could access public services, in 2013, 72.1% of the population depended exclusively on the SUS for access to healthcare services, and 27.9% had some health insurance plan (GADELHA et al., 2015). Regarding access to medicines, in the Brazilian context the term *pharmaceutical assistance* involves the set of activities related to access to, quality and rational use of medicines for outpatient care (BRASIL, CONSELHO NACIONAL DE SAÚDE, 2004). In 1998, the pharmaceutical assistance was incorporated in the SUS for the first time (SANTOS, 2011) by means of the National Medicines Policy (PNM) (BRASIL, MINISTÉRIO DA SAÚDE, 1998). This policy, based on the principle of decentralized management, aimed to prioritize the universal access to essential medicines, to ensure the medicines' quality, efficacy and safety, and promote their rational use (KORNIS et al., 2011).

Figure 3-2 Health System Organization and Access to medicines pathways in Colombia




Source: Prepared by the author based on Guerrero et al (2011)

However, the PNM implementation occurred through isolated and disjointed programs for the provision of medicines. Consequently, while some essential medicines were included in more than one program, other medicines were uncovered. Other problems resulted from the lack of clarity in the financing regulation and the increasing number of services related to medicines supply (KORNIS et al., 2011; SANTOS, 2011).

Aiming to resolve these difficulties, the *Management Pact* established in 2006 a specific set of funds for pharmaceutical assistance within outpatient care considering three *components*: the *Basic Component* (CBAF) for financing the medicines required within Primary Healthcare; the *Strategic Component* (CESAF) focused on medicines for treatment of transmissible diseases (i.e. tuberculosis, HIV/AIDS); and the *Exceptional Dispensation Medicines Component* (CMDE) for financing high-cost medicines. This funding does not include resources for medicines for inpatient care (BRASIL, MINISTÉRIO DA SAÚDE, 2006).

Despite these measures, the barriers to access to medicines within outpatient care persisted. As a consequence, the number of lawsuits for access to medicines increased considerably (most of them from people getting healthcare by private insurance), generating budgetary limitations especially for the states (CHIEFFI; BARATA, 2009; FERRAZ, 2010). In view of this scenario, the Federal Supreme Court (STF) called a public hearing in 2009 that was attended by representatives of health managers, legal professionals, the healthcare private sector, pharmaceutical industry and civil society organizations (from users, health professionals and educational and research institutions) (GOMES et al., 2014).

The Ministry of Health applied some of the measures suggested in the public hearing, aiming to extend the coverage and improve access to medicines in the SUS. In late 2009, the *Specialized Component of Pharmaceutical Assistance* (CEAF) replaced the CMDE (BRASIL, MINISTÉRIO DA SAÚDE, 2009). As part of the CEAF implementation, new medicines for the treatment of pathologies already covered by the SUS as well as some medicines for the treatment of uncovered pathologies were included in the National List of Essential Medicines (RENAME). Other measures aiming to keep a balance in the budgetary burden of high-cost medicines among the three government

levels (municipal, state and Union), including centralized purchasing by the Ministry of Health for the most expensive medicines, and reorganization of the funding schemes (BRASIL, MINISTÉRIO DA SAÚDE, 2010).

Additionally, the National Committee for Technology Incorporation (CONITEC) was created. The CONITEC is responsible for advising the Brazilian Ministry of Health about health technologies' incorporation into or exclusion from the SUS and development of clinical guidelines. The technology assessment is carried out considering the evidence of efficacy, safety and cost-effectiveness. Aiming to maintain the transparency of the assessment process, all the technical reports are submitted for public consultation. The contributions and suggestions of the public consultation are analysed and entered into the CONITEC's final report, which is later forwarded to the Secretary of Science, Technology and Strategic Inputs of the Brazilian Ministry of Health for a final decision (INTERNATIONAL NETWORK OF AGENCIES FOR HEALTH TECHNOLOGY ASSESSMENT - INAHTA, 2015).

In order to guarantee comprehensiveness of the pharmacological treatment, clinical guidelines (PCDT) were developed or updated for each covered pathology. The PCDT states the criteria for diagnosis, the algorithm for treatment decision-making and the measures for clinical monitoring (i.e. frequency of appointments with a medical specialist or clinical tests). From the management perspective, the PCDT is a guideline about how to organize the healthcare network for the state and municipal health managers (BRASIL, MINISTÉRIO DA SAÚDE, 2010).

Notwithstanding, in some cases the PCDT criteria become a barrier to access to these medicines, because of the SUS limitations for supplying secondary care services (LIMA-DELLAMORA; CAETANO; OSORIO-DE-CASTRO, 2012; ROVER et al., 2016). Another access restriction appears when a patient requires a medicine covered by the health system but his/her characteristics do not meet the PCDT's criteria, or when the patient has a pathology that is not covered by the CEAF.

In all the aforementioned situations, patients can resort to the judiciary against the state or municipal health department, or less frequently to the Ministry of Health, claiming the protection of their

right to health (BAPTISTA; MACHADO; DE-LIMA, 2009; MACEDO; LOPES; BARBERATO-FILHO, 2011; ROVER et al., 2016).

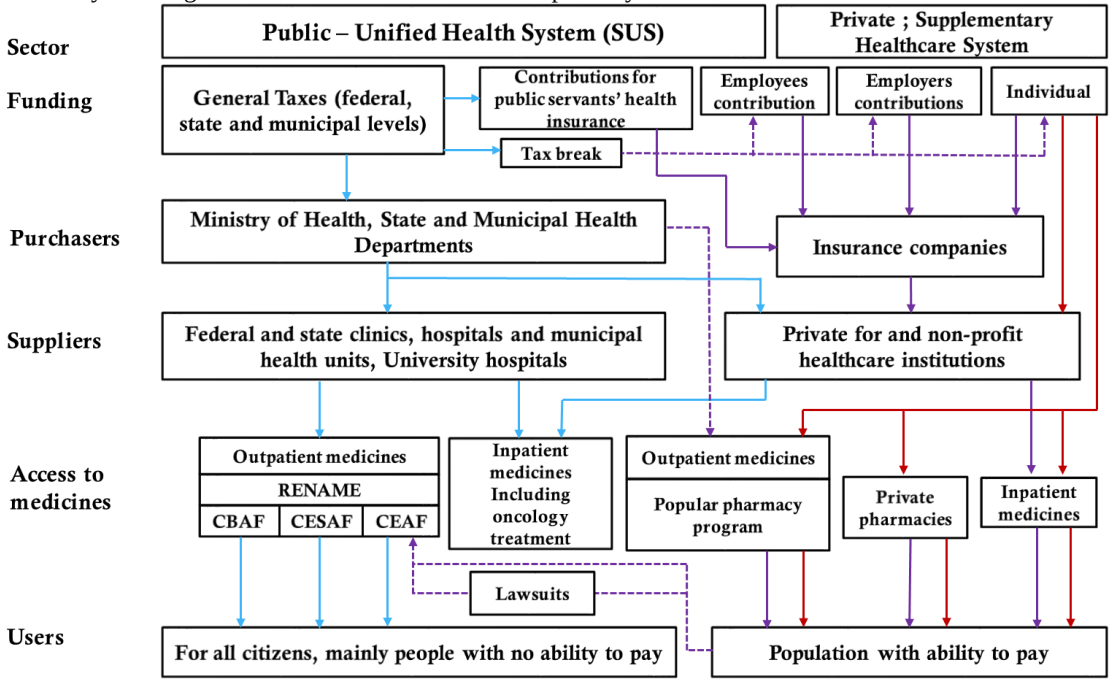
The SUS does not have specific resources to fund medicines for inpatient care (including cancer treatment). The costs of these medicines are financed via fee-for-service payments from the SUS to the hired providers, which are fixed by the Ministry of Health. Currently, the Ministry of Health is working on a new policy for funding these medicines, since the emergence and more frequent use of new high-cost oncologic medicines cannot be afforded with the current resources (BRASIL, MINISTÉRIO DA SAÚDE, 2014)

In the private insurance sector, the coverage depends on the client's ability to pay, and the benefits usually allow direct access to specialist physicians and some advantages in hospitality for inpatient care. In general, the insurance companies do not cover high-cost treatments (i.e. transplantations), that are covered by the SUS (PAIM et al., 2011).

The insurance companies usually do not cover medicines for outpatient care. In this case, the affiliates buy the medicines in private pharmacies according to their ability to pay. In order to make access to medicines for chronic conditions (i.e. hypertension or diabetes mellitus) affordable for health insurance beneficiaries, the Ministry of Health created the program *Farmácia Popular* (*Popular Pharmacy*). In this case, the Ministry of Health hire private pharmacies by which users can access these medicines by a co-payment (SANTOS-PINTO; COSTA; OSORIO-DE-CASTRO, 2011).

If a patient requires a high-cost medicine covered by the CEAF, and she or he meets the PCDT criteria, then the patient can get access to the treatment in the SUS. In contrast, if the patient does not meet the criteria, she/he can resort the judiciary against the public system and get access by public resources funding (BAPTISTA; MACHADO; DE-LIMA, 2009; MACEDO; LOPES; BARBERATO-FILHO, 2011; ROVER et al., 2016). Recently, lawsuits against insurance companies have also occurred requiring medicines or procedures to be excluded from the insurance plans. In these cases, the company pays for the treatment with its own resources (PANDOLFO; DELDUQUE; AMARAL, 2012).

Figure 3-3 Health System Organization and Access to medicines pathways in Brazil




Source: Prepared by the author based on: Becerril-Montekio, *et al*. (2011)

### 3.3.4. Chile

The Chilean health system is constituted of three subsectors. The public sector corresponds to the National Health Fund (*Fondo Nacional de Salud* - FONASA); the private sector corresponds to Health Insurance Institutions (*Instituciones de Salud Previsional* - ISAPREs); and the third subsector is the Armed Forces' health system. In 2014, 77% of the population was covered by FONASA; 17% was affiliated to the ISAPREs; and the Armed Forces' health system covered 3% (CHILE, COMISIÓN ASESORA PRESIDENCIAL, 2014). However, most of the resources are concentrated in the private sector, since the high-income population is affiliated to the ISAPREs (MONTOYA-AGUILAR, 2013).

Medicines were once supplied solely by the public health system, in accordance with the *National Formulary*, which contains a list of the medicines covered (by International Non-proprietary Name) and a monograph for each product. If the patients needed other medicines, they had to buy them in private pharmacies by out-of-pocket expenditure. Nevertheless, since 2004, with the statement of the Explicit Health Guarantees (*Garantias Explicitas en Salud* – GES), some medicines have been included in the health system' coverage. Currently, GES covers 80 pathologies (BECERRIL-MONTEKIO; REYES; MANUEL, 2011).

The Guarantees include *access* to the healthcare services and medicines defined for each pathology according to the guideline; *opportuneness* in the access to healthcare according to maximum waiting time set out in the guidelines; *financial protection* related to the aforementioned co-payments; and *quality* of the healthcare ensured by the accreditation process of healthcare institutions (CHILE, SUPERINTENDENCIA DE SALUD, 2015a). The process of choosing the covered pathologies takes into account criteria such as the health status of the population, the interventions' effectiveness and their effect on extending or improving the quality of life, and if possible, cost-effectiveness and public's preferences and priorities. Since there is not an official agency in charge of the HTA activities, the Ministry of Health commissioned the development of these studies to academic institutions, independent researchers etc. (GIEDION et al., 2014).

The GES must be guaranteed by the FONASA and the ISAPREs for all citizens. Nevertheless, access to the GES depends on some conditions. In the public sector, the FONASA offers two possible modalities for accessing healthcare services: the Institutional Attention Modality (*Modalidad de Atención Institucional - MAI*) and the Free Choice Modality (*Modalidad de Libre Elección – MLE*) (CHILE, SUPERINTENDENCIA DE SALUD, 2015b). The MAI is available for all the beneficiaries, but those with higher income (groups C and D) must pay co-payments of 10% and 20% respectively. This modality supplies the healthcare services in the National Health Services System (SNSS) (BECERRIL-MONTEKIO; REYES; MANUEL, 2011). The affiliates to the MAI can access to the GES, but the patient does not have the possibility of choosing health care facilities or a physician. Sometimes, in order to guarantee the opportunity of access to healthcare, the FONASA hires healthcare services from private hospitals (MONTOYA-AGUILAR, 2013).

In 2014, the Medicines Fund was established in order to guarantee timely access to medicines for treating hypertension, diabetes mellitus and hypercholesterolemia in the primary care of the public health sector (CHILE, MINISTERIO DE SALUD, 2015).

Regarding high-priced medicines, there are three pathways for access to these medicines in the MAI. The first one is the GES, which include some high-priced medicines for the included pathologies (e.g. biotechnological medicines for breast cancer or rheumatoid arthritis treatment) (CHILE, SUPERINTENDENCIA DE SALUD, 2015a). The second way is the *FONASA's catastrophic insurance* (also called *FONASA's program for complex healthcare service*) which covers 100% of the cost of some healthcare service such as chemotherapy or medicines for HIV infection treatment (CHILE, SUPERINTENDENCIA DE SALUD, 2015c). The third way is the *FONASA's high-cost medicines program* which also covers 100% of the treatment cost of eight different pathologies (e.g. trastuzumab for breast cancer or biotechnological medicines for rheumatoid arthritis), but this program has limited economic resources, thus only a limited number of patients has access to this coverage, usually for a short time (3 months) (CHILE, FONDO NACIONAL DE SALUD, 2015).

The MLE is available for people from groups B, C, and D. In this case, the users can choose private institutions for access to a healthcare

service, and must pay some vouchers (according to three levels) which are more expensive than the MAI's co-payments. If the patient gets medical attention by means of the MLE, the FONASA is not bound by the GES.

As for diseases not covered by the GES, patients can get access to health services and medicines by means of a regular coverage offered by the FONASA. But they can face difficulties in access, such as, longer waiting time and/or increased out-of-pocket expenditure, because such care is not supported by legal guarantees (GIEDION et al., 2014).

In the private sector, the ISAPREs offer different health plans that cannot be inferior to the healthcare services covered by the MLE of the FONASA. From 2004 on, the ISAPREs must guarantee the GES to their affiliates, charging the same price from all affiliates. In addition, the *Solidarity Compensation Fund* was created in order to pool health risks (related to the GES) among the beneficiaries of such institutions, but it comprises only the open ISAPREs (CHILE, COMISIÓN ASESORA PRESIDENCIAL, 2014). Nevertheless, similarly to the FONASA, the guarantees only apply if the patient accesses a healthcare service in a specific network defined by the insurer for the GES. If the patient wants to choose the healthcare facility or the physician, he or she does not have the right to the GES (MONTOYA-AGUILAR, 2013).

As regards catastrophic pathologies, the open ISAPREs has created the *Coverage for Catastrophic Diseases* (CAEC) since 2000, which is funded by payroll mandatory contributions (7%). The CAEC does not focus on specific pathologies, thus it could be activated in case the cost of the treatment (e.g. co-payments) jeopardizes the economic sustainability of the family. However, the coverage is limited, for instance, in the case of outpatient medicines CAEC covers only immunosuppressant or chemotherapy medicines included in programs of the Ministry of Health, and the patient must access healthcare services from a specific network defined by the ISAPRE (CHILE, SUPERINTENDENCIA DE SALUD, 2015d). The coverage of non-GES pathologies in the ISAPREs sector depends on each health plan/policy (GIEDION et al., 2014).

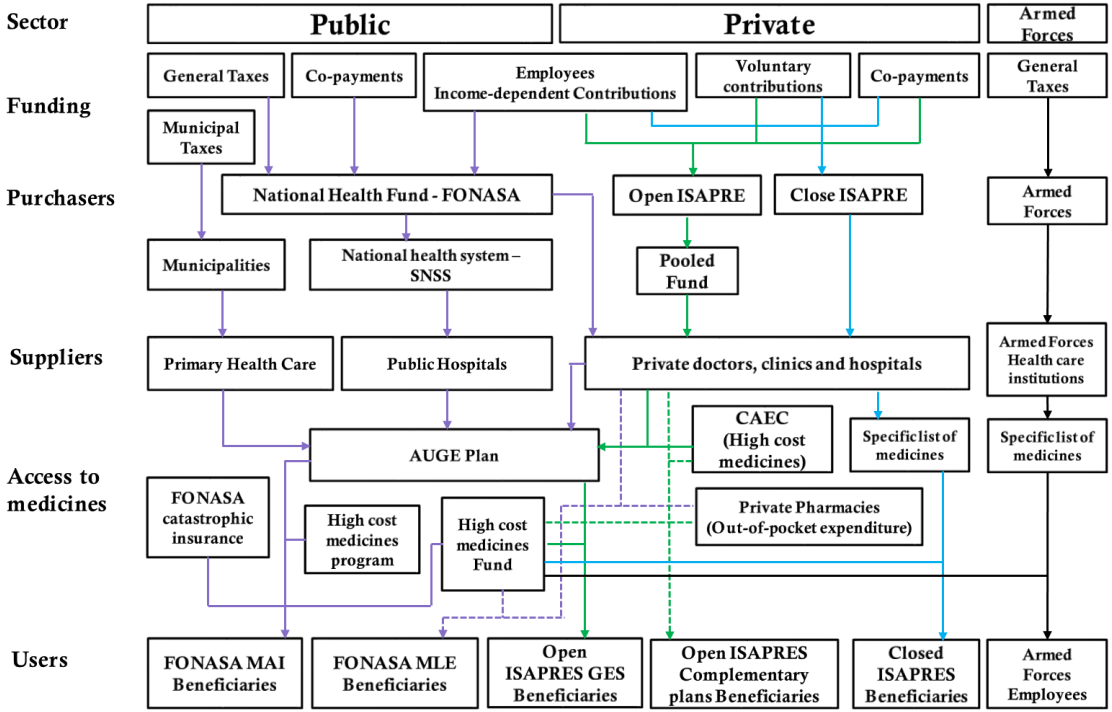
The Armed Forces' subsystem has a specific coverage of healthcare services and medicines defined by the Ministry of Defence. This subsystem does not have a reinsurance or risk equalization system

to support the coverage of catastrophic expenditures; however, there are welfare services that operate as solidarity funds (GATINI; ALVAREZ LEIVA; GONZÁLEZ ESCALONA, 2011).

In 2015, in order to guarantee universal access to high-priced medicines for all citizens, regardless of their affiliation to a health system (FONASA, ISAPREs or Armed Forces), the *High-cost Treatment Fund* was created by Law Ricarte Soto, and it is being currently implemented. Initially, as from November 2015, 11 pathologies will be covered (COOPERATIVA.CL, 2015). The Fund will be managed by FONASA. The selection of medicines will consider a social, economic and scientific prioritization process, evidence-based medicine criteria, and price (higher than a threshold fixed by the Ministry of Health and Ministry of Finances). In addition, for getting access to these medicines the patient will be referred to a specific healthcare service network defined by the Ministry of Health (CHILE, 2015).

In the case of ISAPREs' affiliates, this fund does not comprise the medicines covered by the CAEC. In fact, an ISAPRE affiliate must resort first to the CAEC, and if it does not cover the medicine, then he/she can get access to it by means of the High-cost Treatments Fund. Finally, the law also states that if a medicine covered by this Fund is incorporated in the GES in the future, the Fund will keep covering it for the people that do not have access to the GES (e.g. FONASA MLE affiliates) (CHILE, 2015). The strategies for access to medicines are summarized in Figure 3-4.

Figure 3-4 Health System Organization and Access to medicines pathways in Chile




Source: Prepared by the author based on: Becerril-Montekio *et al* (2011) and Cid, *et al.* (2013)

### 3.3.5. The Netherlands

Since the health system reform stated by the *Health insurance Act (Zvw)* in 2006, the Dutch health system has been constituted of two sectors: the compulsory social health insurance and the voluntary health insurance (SCHÄFER et al., 2010). In 2013, less than 0.2% of the Dutch population were uninsured, and most of the population (85%) had voluntary insurance (WAMMES,; JEURISSEN; WESTERT, 2015). The Armed Forces has an independent health system managed by the Ministry of Defence.

In the compulsory health insurance system, all the insurers must guarantee access to the medicines included in the national basic care package. For selecting the medicines, the Dutch health system has used the Health Technology Assessment since the early 1980s, considering the Dunning criteria (necessity, efficacy, cost-effectiveness and feasibility) (LE POLAIN et al., 2010) (NATIONAL HEALTH CARE INSTITUTE, 2015). Until April 2014, the agency responsible for the HTA activities was the Healthcare Insurance Board (CVZ), reformed into the Health Care Institute Netherlands (ZiN), which is now responsible for advising the Minister of Healthcare, Welfare and Sports (VWS) on whether to include medicines in the basic package (NATIONAL HEALTH CARE INSTITUTE, 2015; ZORGINSTITUUT NEDERLAND, 2015)

For financing of and access to medicines, there are two reimbursement schemes in the compulsory health insurance, for inpatient and outpatient medicines respectively. Outpatient medicines fall under the medicine reimbursement system (GVS). The GVS determines classification of the medicines (prescription-only or over the counter medicines – OTC), and defines the medicines' reimbursement level. The medicines in the positive reimbursement list are classified into two lists called *Annex 1A* and *Annex 1B.* In Annex 1A, therapeutic equivalent medicines are grouped into clusters of interchangeable medicines (LE POLAIN et al., 2010).

The reimbursement level is limited to a historically determined average product price of the cluster. Pharmaceuticals that are not interchangeable and have an added therapeutic value are placed on *Annex 1B.* All medicines on *Annex 1B* are fully reimbursed. Manufacturers have to submit evidence of the therapeutic value in order

to be included in Annex 1B's reimbursement list. In addition, as for Annex 1B, manufacturers have to provide evidence on cost-effectiveness and an assessment of the national budget impact. Medicines on Annex 1A and 1B can also be placed on the conditional reimbursement list (called *Annex 2*) if specific conditions apply (e.g. prior permission or specific indications) (LE POLAIN et al., 2010).

Inpatient medicines dispensed by hospitals are financed through hospital budgets based on diagnosis-related groups. However, "normal" medicines are not separately specified within these groups. The Dutch government introduced in 2002 policy regulations ("Beleidsregel dure geneesmiddelen") to relieve the financial burden of hospitals for expensive inpatient medicines. Since 2006, a "coverage with evidence development" scheme has been implemented, in which the medicines are initially admitted to the expensive medicine or expensive orphan medicine list of the Dutch Healthcare Insurance Board (NZa) only in a temporary way (LE POLAIN et al., 2010).

Hospitals receive additional funding of 80% of the costs of these medicines (100% for orphan medicines). As a condition, applicants are required to conduct outcomes research and thus have to provide evidence on appropriate medicine use ("doeltreffende toepassing") and real-world cost-effectiveness ("doelmatigheid"). After four years, a reassessment ought to be conducted in order to decide whether (or not) to continue the financial compensation for hospitals (LE POLAIN et al., 2010).

However, if as a result of the reassessment the evidence does not support the reimbursement of the medicine, the pressure of stakeholders such as the media and the organization of patients can make the decision maker decide to maintain the reimbursement. It was the case of Myozyme for Pompe disease which created a big controversy (COLLEGE VOR ZORGVERZEKERINGEN, 2012; KOUWENBERG; BIJL, 2012).

Over the counter (OTC) medicines are not covered by the insurance system and must be bought by the patients in the pharmacies. However, if the physician indicates chronic use (i.e. intended as use for 6 months or longer) on the prescription, the patient must pay the first two weeks of treatment and after this period the patient gets the

medication free of taxes and the community pharmacy will directly claim reimbursement at the insurer (SCHÄFER et al., 2010).

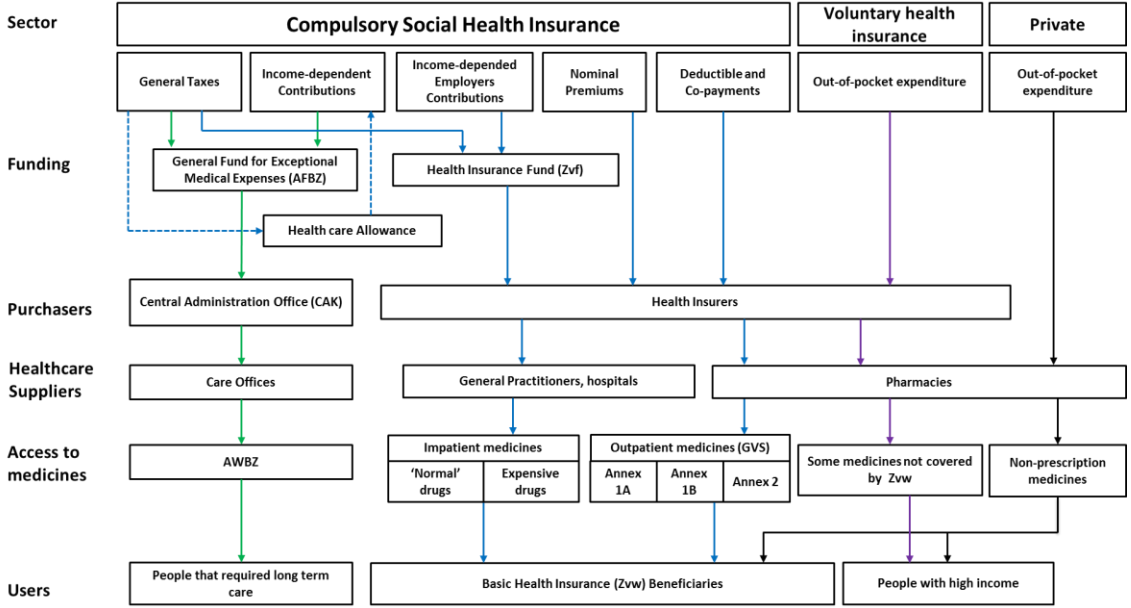
Supplementary to the compulsory social health insurance, the voluntary health insurance provides coverage of services excluded or not fully covered by the compulsory social health insurance, because these health care services are not evidence-based or are not considered medically necessary (e.g. dental care, alternative medicine, physiotherapy, spectacles and lenses, contraceptives). The complementary packages vary considerably among insurers and in addition to the aforementioned healthcare, it could include the full cost of co-payments for medicines (excess costs above the limit for equivalent drugs) (SCHÄFER et al., 2010; WAMMES,; JEURISSEN; WESTERT, 2015).

In the Netherlands, lawsuits claiming access to uncovered medicines are also filled, although they are not as frequent as in the Latin American region. Some of these judicial cases claim access to medicines for rare diseases (THE NEHERLANDS, RECHTBANK, 2014) or require specific brand medicines (THE NEHERLANDS, RECHTBANK, 2015). The strategies for access to medicines are summarized in Figure 3-5.

## 3.4. DISCUSSION

Our results showed that during the period under analysis, all the studied countries took measures aiming to extend the coverage of their health systems and access to medicines. In the Latin American countries, some of these measures were possible because of the economic growth and the increase in public health spending (PIOLA, 2015). Despite the differences in the economic resources available and the health indicators across countries, it was possible to identify common characteristics in the measures implemented. These measures are discussed below, in accordance with the three UHC dimensions.

Figure 3-5 Health System Organization and Access to medicines pathways in The Netherlands




Source: The author

### 3.4.1. Population coverage

Our results suggest that, at least in their regulations, all the studied countries offer alternatives of coverage and access to health services and medicines for the general population. Nonetheless, in all of them, the population coverage is fragmented and depends on the socioeconomic conditions of the individual, mainly related to their labour status, health status and ability to pay.

Argentina has the highest level of fragmentation, with seven different pathways to access the health system, followed by Chile where the population is stratified according to the income in the public sector and according to their ability to pay and their health status in the private sector. In Brazil, although all citizens have access to the SUS, the presence of the private health insurance creates fragmentation as regards ability to pay and health status. In Colombia, access to the health system depends mainly on the income level and labour status within the SGSSS, and the income level and health status in the case of private health insurance.

### 3.4.2. Technology coverage

The fragmentation in the population coverage results in the fragmentation of the health services and technology coverage, including pharmaceuticals, since each pathway involves a particular medicines coverage. During the timeframe analysed, some advances in reducing the medicines coverage fragmentation were observed in Colombia, Chile and the Netherlands. In these countries, the reforms aimed to reduce the differences in quality and access to health care and medicines between different health systems' subsectors: contributory and subsidised regimes in Colombia, the FONASA and the ISAPREs in Chile, and public and private insurance in the Netherlands.

One aspect that is worth remarking is that although the equalization of the POS lists in Colombia and the reorganization of the Specialized Component of the Pharmaceutical Assistance in Brazil were implemented by the Ministries of Health, in both cases the reforms were influenced by the Judiciary because of the high frequency of lawsuits for access to medicines (see chapter 5) (COLOMBIA, CORTE CONSTITUCIONAL, 2008a; GOMES et al., 2014). In contrast, the establishment of the GES in Chile and the Basic Health Insurance in the

reform of the Dutch Health system emerged from executive and legislative powers (GIEDION et al., 2014; SCHÄFER et al., 2010).

Argentina is the country that has more diversity in the list of covered medicines among and within the health system's subsectors. The PMO was an attempt to achieve equalization of the benefits for all beneficiaries statement of the PMO in the social insurance sector; but since this is a minimum coverage, and the financial capacity of the OS depends on the level of income of their affiliates, the inequality in the access to medicines remains (TOBAR et al., 2014).

During the timeframe analysed, all the countries took measures to increase the number of medicines covered by the health systems. The process for including new technologies varied across the countries, but some measures such as the adoption of the HTA's principles were common, although with different scope and development levels.

In the Netherlands, the HTA is consolidated within the health system and has been used as support for the decision making of the Ministry of Health for the last 30 years. In contrast, in the Latin American countries analysed, although the HTA principles were considered in the health systems as criteria to select the medicines, HTA agencies have been formally created only in the last years. These measures are in part consequence of the claim for transparency and efficiency in the updating process of the medicines list, from different stakeholders such as insurers, managers, patient organizations and, in the case of Colombia and Brazil, the Judiciary Power.

Another important aspect that varies among the countries is the scope of the HTA agencies. While the Dutch agency (ZiN), the Brazilian agency (CONITEC) and the Colombian agency (IETS) assess and advise about inclusion of medicines to be supplied for the entire or almost the entire population in their countries, the Argentinian agency (SUR) has a restricted scope because its decisions only bind to the national OS.

The Latin American countries have adopted clinical guidelines as a strategy to guarantee rational use of medicines, especially of the most expensive ones, and to support the organization of the healthcare service networks. Brazil and Chile are the countries that present more development in this sense, since the guidelines design is linked with the

updating process of medicines coverage. However, discrepancies between clinical guidelines requirements and the real availability of health services sometimes become a barrier to the access to medicines (GIEDION et al., 2014; ROVER et al., 2016).

A noteworthy aspect is that notwithstanding the level of development or consolidation of the HTA process, the health systems' stakeholders do not always consider as legitimate the use of the HTA criteria for decision-making about reimbursement or financing. Even though the HTA process is a technical process, the relevance of the political support for its implementation and compliance with its decision in the clinical practice has been recognized (WANNMACHER, 2006).

In the Latin American countries, the lack of legitimacy of the HTA process can be explained by concerns over the transparency and standardization of the process (ROSSI; UMBACÍA; SÁNCHEZ, 2012) and the technical capacity of the agency (YJILIOFF, 2014). Nevertheless, the controversy generated by the Myozyme assessment in the Netherlands underlines that factors such as the social expectation that scientific development will resolve all the health problems (WILLIAMS; MARTIN; GABE, 2011) and the large lobby capacity of the Big-Pharma over decision-makers, prescribers, and patients (SANCHEZ-SERRANO, 2014; WILLIAMS; MARTIN; GABE, 2011) have an important influence across countries.

Due to the lack of legitimacy of the HTA process, and the governments' weakness in the control of different actors in the health system, the use of exceptional ways to access to medicines such as alternative ways designed by the health systems (e.g. CTC in Colombia and exceptional reimbursement of the APE in Argentina) and litigation become frequent.

This fact generates pressure on the processes of prioritization and inclusion of new technologies in the health systems' coverage. So these processes end up following criteria of economic burden because of the high costs of the medicines, instead of criteria of efficacy, safety, or yet criteria of epidemiological profile and disease burden representing the health needs of the general population.

### 3.4.3. Costs coverage

Medicines affordability and financing have become relevant issues in the discussion about the organization of the health systems to ensure cost coverage and financial protection for the population, since once the cost of the new technologies has been identified as the main factor for the rising of the healthcare cost (SORENSON; DRUMMOND; BHUIYAN KHAN, 2013). This UHC dimension involves two aspects: resources available for financing the medicines (e.g. risk pool funds, public resources) and out-of-pocket expenditure (including co-payments). All the countries have created risk-pooling funds in order to redistribute the risk of high cost medicines or health services. Nevertheless, none of them has universal population coverage or includes all the medicines covered by the health system.

The Dutch Health Insurance Fund has universal population coverage, but does not cover inpatient medicines, which are covered by means of the hospitals' budgets. The Colombian CAC only covers people from the subsidised and contributory regimes, and only medicines included in the POS; in the case of medicines not covered by the POS required by the CTC or lawsuits (*tutelas*), only the contributory regime insurers get reimbursement from the FOSYGA, creating inequality as the health secretaries of the departments have fewer resources.

In the Argentinian context, as aforementioned, the SUR only covers national OSs affiliates and covers only a list of medicines defined by the Health Superintendence, and in the public sector there are specific funds for high cost medicines, but they are fragmented and cover only some specific medications. In Chile, besides the fact that the CAEC does not have a specific coverage (but explicit exclusions), this fund covers only the open ISAPREs affiliates; and in the public sector there are other specific funds for high-cost medicines and health services which have limited economic capacity, and then, limited population coverage. It is expected that some of these problems might be resolved with the implementation of Law *Ricarte Soto*, which constitutes the first intent for reducing the financing fragmentation of the Chilean health system.

The abovementioned fragmentation creates inequalities in the access to medicines and also results in financial burdens for some actors in the health system. In the Netherlands, there is inequality in the access to biotechnological medicines, including the treatment for rare diseases, because these treatments are mostly supplied within impatient care and the hospitals have autonomy to prioritize the financing of health services and medicines (NIEZEN et al., 2006). In the Colombian case, the fragmentation of the fund creates inequality in the resources distribution because the Departments have fewer resources than the FOSYGA, and the subsidised regime beneficiaries are the lowest income population.

A similar situation is observed in Argentina where the lowest income population depends on the public sector and has less coverage of medicines compared to the social insurance and private subsector (TOBAR et al., 2014). In Chile, the highest income and healthiest population is covered by the private subsector, which holds most of the resources of the overall health system (MONTOYA-AGUILAR, 2013).

In Brazil, where only the public sector covers high cost medicines for inpatient care, the creation of the CEAF in 2010 increased the resources for financing these medicines. Nonetheless, the inequality in the resources distribution and in the access to high-cost medicines still remain, because the patients with more resources have easier access to specialized care than the low-income population (BIEHL, 2013).

One aspect worth highlighting is that the implementation of specific funds to finance high-cost medicines has been accompanied by other measures, such as the maximum prices of reimbursement in Colombia (COLOMBIA, MINISTERIO DE SALUD Y PROTECCIÓN SOCIAL, 2015b), and the establishment of public-private partnerships (PPP) aiming at transferring technology for the production of high-cost medicines in Brazil (BRASIL, MINISTÉRIO DA SAÚDE, 2014). Even with the recognized adverse effects of the patent protection such as the emergence of pseudo-innovation and the neglecting of diseases prevalent in low and middle income countries, measures related to intellectual property protection were not taken (VELASQUEZ, 2012).

## 3.5. CONCLUSION

Our analysis showed that the five countries included in this study took measures aiming to improve access to medicines in the three UHC dimensions in the last fifteen years, but equitable access to medicines is still a major goal to be achieved. Similar to other studies (BOSSERT et al., 2014), fragmentation at different levels of the health systems (financing, structure, organization, regulation and control) was the most common cause of inequality in the access to medicines.

Nevertheless, the most relevant finding in our study is the change of focus of the public policies for access to medicines across the studied countries from essential medicines to high-cost medicines and its potential regressive effects, even for developed countries like the Netherlands.

# 4 CHAPTER 4 – Judicialization of access to medicines in four Latin American countries: A comparative analysis

## 4.1 INTRODUCTION

Medicines are important tools to prevent and resolve health problems; however, adequate access to medicines for all is still not achieved in many countries (BIGDELI et al., 2015). According to General Comment 14 of the Committee on Economic, Social and Cultural Rights–CESCR (2000), the states have, as a core obligation: (a) to ensure access to essential medicines, according to the WHO's definition; (b) to "give sufficient recognition to the Right to Health in their national political and legal systems"; and (c) to adopt legislation or take measures for controlling healthcare market actors (providers of goods and services, insurers, etc.) to ensure equitable access to health care and health services (CESCR COMMITTEE ON ECONOMIC, SOCIAL AND CULTURAL RIGHTS, 2000). Moreover, in 2012, the United Nations (UN) General Assembly recognized Universal Health Coverage (UHC) as a priority of the post-Millennium Development Goal, considering access to medicines as a critical component of UHC (GOROKHOVICH; CHALKIDOU; SHANKAR, 2013).

In the last years, some Latin American countries have taken measures in order to improve the access to essential medicines, and more recently such efforts have been focused on improving access to high-cost medicines (Chapter 3). At the same time, litigation for access to medicines has risen in the region, mainly in Colombia and Brazil (HOGERZEIL, 2006; YAMIN; GLOPPEN, 2011), and the magnitude of the phenomenon is growing in countries such as Argentina and Chile (BURGIN, 2014), despite the differences on the legal recognition of the right to health (Table 4-1) and health system organization among these countries (see chapter 3).

Table 4-1 - Right to health and pathways to resort the Judiciary for protecting it in Argentina, Brazil, Chile and Colombia

| Right to health | Access to medicines | Pathways to resort the Judiciary |
|---|---|---|
| **Argentina** | | |
| ***National Constitution, Article 42*** "Consumers and users of goods and services have the right to the protection of their health, safety, and economic interests".<br><br>Each province defines in its Constitution the recognition of the right to health in its territory. | ***Decree 492/95, Article 1:*** "The beneficiaries of the agents of the National Health Insurance System, covered by Article 1 of Law No. 23.660, are entitled to receive medical care benefits established in the medical care program to be approved by the Ministry of Health and Social Welfare through the secretary of health policy and health regulations. This program will call the Compulsory Medical Program (PMO) and will be mandatory for all agents set forth above".<br><br>***Law 24.754, Article 1.*** "From within 90 days of enactment of this law, companies or entities that provide prepaid medical services should cover at least in medical care plans the same "Mandatory Medical Plan (PMO) arranged to the *Obras Sociales*, as established by Law 23.660, 23.661 and 24.455, and their respective regulations.<br><br>For the public sector, each province defines its own regulations on the coverage of medicines. | *Amparo.* It can be brought only to federal, civil and commercial tribunals.<br><br>*Amparo* requires the intervention of a lawyer |

| Right to health | Access to medicines | Pathways to resort the Judiciary |
|---|---|---|
| **Brazil** | | |
| ***National Constitution, Article 196***: "Health is a right of all and a duty of the State and shall be guaranteed by means of social and economic policies aimed at reducing the risk of illness and other hazards and at the universal and equal access to actions and services for its promotion, protection and recovery." | ***Law 8080/1990, Article 6:*** "… the Unified Health System - SUS also includes in its field of action:<br>I - the execution of actions: (d) of integrated care, including pharmaceutical assistance". | Civil lawsuit<br>It can be filed in any tribunal.<br>Require the intervention of a lawyer. |
| **Chile** | | |
| ***National Constitution, Article 19 No. 9:*** "The right to health protection. The State protects free and equal access to the actions for the promotion, protection and recovery of health and rehabilitation of the individual. It will also be responsible for coordination and control of health-related actions. The prime duty of the state is to ensure the implementation of health actions, whether undertaken by public or private institutions, in the form and manner prescribed by law, which may establish compulsory contributions. Every person shall have the right to choose the health care system that wishes to join, be it state or private." | ***Law N° 19.966, Article 2:*** The General System of Guarantees shall also contain Explicit Health Guarantees concerning access, quality, financial protection and timeliness of the benefits provision associated with a prioritized set of programs, diseases or health conditions indicated by the corresponding decree. The National Health Fund (FONASA) and the Health Insurance Institutions (ISAPREs) shall mandatorily ensure such guarantees to their respective beneficiaries. | Protection resource.<br><br>It only can be brought to the Supreme Court.<br><br>Require the intervention of a lawyer. |

| Right to health | Access to medicines | Pathways to resort the Judiciary |
|---|---|---|
| **Colombia** | | |
| ***National Constitution, Article 49:*** "Health care and environmental protection are public services charged to the state. To everyone is guaranteed access to health promotion, protection and recovery. The State organizes, manages and regulates the provision of health services and environmental sanitation to residents according to the principles of efficiency, universality and solidarity." | ***Law 100/1993, Article 156***. "Basic features of the general social security health. The general social security health shall have the following characteristics: ***(d)*** All members of the general system of social security health plan will receive a comprehensive health protection, with preventive care, medical-surgical and essential drugs, which will be called mandatory health plan." | *Tutela* action<br><br>It can be brought to any tribunal.<br>Does not require the intervention of a lawyer |

The access to medicines depends on complex and dynamic relationships among the health system's stakeholders. Additionally, the health system's organization and litigation for access to medicines are determined by social and political features (VARGAS-PELÁEZ et al., 2014). In view of that, it is interesting to analyse the possible causes and consequences of litigation for access to medicines in these countries, from the stakeholders' perspective, in order to better understand the phenomenon and collect information to work towards possible solutions to promote equitable access to medicines.

This study therefore aims to conduct a comparative analysis of the causes and consequences of judicialization of access to medicines from the perspective of the stakeholders involved in the phenomenon in Argentina, Brazil, Chile and Colombia.

## 4.2 METHODOLOGY

This qualitative study was carried out based on the semi-structured interviews described in Chapter 3 (see section 3.2.2), specifically questions *(a)* "In your opinion, what are the possible causes of judicialization of access to medicines?" and *(b)* "In your opinion, what are the possible consequences of judicialization of access to medicines?" The verbatim of the selected segments of speech in the original language can be found in Annex B.

Thematic analysis was applied to the verbatim. The analysis was conducted manually by two researchers following the methodology proposed by Pope et al. (2000): familiarization with the data, identification of the thematic framework, indexation, charting and mapping and interpretation. The categories adopted for the analysis, previously discussed by the researchers in a seminar, correspond to the elements (stakeholders and policies) considered in the theoretical model proposed in Chapter 2 (Figure 2-1). In addition, the data from interviews were sorted by country and stakeholder, in order to identify similarities and differences in their perceptions on the causes and consequences of judicialization of access to medicines.

## 4.3 RESULTS

Representatives from Argentina, Brazil and Colombia considered judicialization of access to medicines as a widespread phenomenon in their respective countries, while in Chile the respondents highlighted that most of lawsuits related to the right to health are filed against the ISAPREs because of unjustified increases in the insurance premiums.

The causes and consequences of judicialization of access to medicines mentioned by the stakeholders' representatives were related to aspects from both perspectives considered in the theoretical model: health and market.

The causes of judicialization mentioned by the respondents concentrate in the categories: health system 'hardware' and 'software'; role of the Judiciary; influence of the pharmaceutical industry; and role of the users/patients. Regarding the consequences of judicialization, the categories related to the effects of the phenomenon on the health system and on the users were most frequently mentioned.

The least frequently mentioned categories, comprising both causes and consequences, were: definition of the right to health at international and national levels; the innovation model at international level; the policies related to intellectual property protection; the science and technology policies; the medicine price control policies; and the concept of health needs.

### 4.3.1 International level

At the international level, only Colombian representatives highlighted the conflict between market and human rights, and the global dominance of an economistic view of the fundamental rights, which prevent access to medicines. In addition, the interest of the pharmaceutical industry the lobby of the pharmaceutical industry for both the recognition of health as a fundamental right and the adoption of the third payer model in the national health systems, since these policies can guarantee market and financing of their new and expensive products (Box 4-1).

From the market's perspective, two factors were recognized as the main causes of judicialization of access to medicines: the emergence of expensive technologies and the pharmaceutical industry's interest for profit. For the respondents, new medicines create huge expectations about their impacts on health, although they actually do not represent an additional therapeutic value (failure of the current innovation model). The aforementioned aspects were highlighted by the majority of the stakeholders' representatives from the four countries, but to a lesser extent the Judiciary's ones (Box 4-1). Consequences were not mentioned at this level.

Box 4-1. Examples of the categories at International level

- **Right to health in the International Human Right treaties and essential medicines definition**

"We identify two opposing *doors*. One is the market philosophy and the other is the human rights philosophy itself… What happens with access to medicines is also the expression of the clash between these two philosophies... As regards these three pillars [access to medicines, health system's sustainability, and guarantee of fundamental rights], after all, the more expensive the medicines are, the more I lean towards the economy rather than the access to the right [to health]. That's basically what we've seen as a serious problem, which is not, we believe, a problem only in Colombia, but a global... worldwide trend, say, towards a purely economic principle for fundamental rights, for access to fundamental rights " (Colombia, Patient).

"… We all know that Big Pharma has been the most important lobbyist for pushing UN, WHO, everyone, to make the right to health a fundamental right in all countries, as it was clear [for pharmaceutical industry] that the people individually would not be able to buy and pay for the costs of their products, and the best thing about it was that the states have to pay for [the medicines]" (Colombia, Patient).

- **The market and the Innovation model and intellectual property protection – TRIPS**

"The first [cause] is the market issue, the market interest in the sales and revenues from the pharmaceutical industry. This is the first major reason, in my opinion" (Brazil, manager).

"I think that [judicialization] is closely related to the R&D model; and to how the pharmaceutical industry resolved the price issue very easily by means of what would be called third-party payer models. Thus, for them, it is no longer a problem that medicines may cost COP 600 million pesos or COP 700 million

pesos patient/year, because in the end it is not the patient himself that pays, but the [health] system" (Colombia, professional).

"The biggest conflict, currently, has to do with expensive medicines, obviously, by their costs, because such medicines, as it is known, are on the market without scientific evidence of effectiveness. In some cases if there are other medicines already on the market, these [new medicines] do not ensure that they are better than the ones that are maybe not so costly" (Argentina, NGO).

### 4.3.2 National level

#### 4.3.2.1 The right to health in the Political Constitution

In this category three aspects were mentioned as causes of judicialization: (a) the Constitution's broad definition of the right to health, which does not explicit limits in Argentina and Brazil; (b) the creation of judicial mechanisms to protect the right to health in Colombia; and. (c) the government decentralization where the population's health is a Provincial rather than a National Government's responsibility in Argentina (Box 4-2).

Box 4-2. Examples of causes related to the category right to health in the Political Constitution

"There are many reasons [for judicialization]. First, fundamentally, the rules we have are very broad. Constitutional norms and treaties with constitutional status… which are very broad in terms of coverage, so virtually any patient that requires any benefits, because the rights are so broad, they [the rights] somehow allow them [the patients] to ask for [the benefits]" (Argentina, Executive).

"... [The new constitution] was much more open than the previous ones from the military regime […] it was a constitution that, for the first time in Brazil's history [in 1988], included some rights. Among them, the so-called Article 196 of the Constitution that, in a very broad and general way, provided health as a citizen's right and an obligation of the state, without defining it clearly "(Brazil, manager).

"The Constitution of 1991 did two fundamental things in the country. It introduced the market in the provision of social services, public services in the country and, as a counterbalance, it guaranteed rights... it [the Constitution]

made the citizens' rights explicit, and created the *Tutela* mechanism to claim them in the case of… when it is considered that such rights have been violated" (Colombia, NGO).

Stakeholders from Argentina, Chile and Colombia mentioned consequences of judicialization relative to the national recognition of the right to health. The negative consequences included the *pharmaceuticalization* of the right to health, and the inappropriate interpretation of the right to health as an unlimited and individual right. The respondents pointed out two positive consequences. First, the visibility of the right to health as an issue relevant to the policy resulted of the media impact towards the judicial cases. Second, the generation of jurisprudence related to the right to health, which in the Colombian context resulted in the recognition of the right to health as a fundamental right (Box 4-3).

Box 4-3. Examples of consequences related to the category right to health in the Political Constitution

"But I would say that one of the most negative aspects [of judicialization] is [...] what I call [...] the pharmaceuticalization of the right to health, where it seems that everything is solved with medicines" (Colombia, University lecturer).

"The *Tutela* is [...] for the medicine that can be very expensive compared to the one available in the POS, and adds very little to life. That is, the cost-effectiveness is very low. But it is all about the person; the right [to health] is individual and not collective. So we're struggling for things of high cost, low impact on public health, and we're spending the money this way… I mean, there's a whole discussion of collective rights vs. the individual rights" (Colombia, manager).

"If [the patients] do not have money to hire a lawyer, they resort to the newspaper, to the media to denounce the situation [of lack of access to medicines]. They [the patients] do not accept to be discriminated because they are poor, because they do not have resources, since the state must resolve their problems" (Chile, lawyer).

#### 4.3.2.2 The health system

##### *4.3.2.2.1 'Hardware'*

Taking the organization of the health systems as a cause of litigation, the respondents mentioned aspects that result in the barriers to access to healthcare services timely. Such aspects include the health systems' fragmentation, the health systems' decentralization without adequate coordination, inefficiency of the health system managers, inappropriate organization of the healthcare service networks, and limited availability of human resources, particularly specialized health professionals.

The lack of a consolidated Health Technology Assessment (HTA) agency (in Colombia and Argentina) and the technical weakness of the EPSs' technical-scientific committees (Colombia) were pointed out as an important cause of judicialization of access to medicines.

Other causes were mentioned, such as the limited financial resources of the health systems to include new, expensive medicines in the coverage. In the case of Argentina, limited resources were related to the small OSs, and in Chile to the closed ISAPREs (Box 4-4).

Box 4-4. Examples of causes related to the category health system hardware

"The problem is… a more economic one, since the resources are scarce. So… the lack of protection… is a common denominator" (Argentina, Executive).

[One should consider] "which part of the problem [judicialization] is due to the EPS's inefficiency, poor service provision or deficient management; and which part is due to a structural problem related to a human resources deficit, particularly regarding specialist and subspecialist" (Colombia, manager).

"Here [in Argentina], there is a National Administration since [president] Menen's office, which is the ANMAT, National Administration of Medicines, Food and Technology, that determines, when certain standards are met, if a medicines can enter the market or not. But there is no one, no national organization, to tell if that [medicine] will be covered or not by the Social Security or the State, right? There is nothing. So, that depends on the free will, of any doctor [general or specialist] because doctors can prescribe what they want (Argentina, NGO).

The respondents from Argentina, Brazil and Colombia mentioned some negative effects of judicialization of access to medicines on the health systems' 'hardware'. First, litigation prompts the creation of additional administrative processes to meet the judicial demands. So, the health system's operating costs increase and the management becomes more complex, generating inefficiency. As a result, the timely access to healthcare and medicines by the people that do not use the judicial pathway is compromised.

Second, some lawsuits favour the public financing of medicines without evidence of efficacy, safety or cost-effectiveness. In these cases there are two possible scenarios: (a) the health system's resources focus on financing expensive medicines with poor therapeutic value versus the medicines covered by the health system; or (b) lawsuits favour the treatment of a limited number of patients (e.g. rare diseases) at the expense of the access to essential medicines for the rest of the population. According to representatives of the health professional organizations from Brazil and Colombia, both scenarios may compromise the long-term sustainability of the health systems.

In this sense, in all the studied countries, the health system managers' representatives remarked that the diversion of resources for financing the medicines covered by the health system to the financing of uncovered medicines accessed through litigation compromises their liquidity. This happens in Brazil and Chile because the managers do not receive any reimbursement for the uncovered medicines. In Argentina and Colombia, this is a result of the belated reimbursement from the SUR or the FOSYGA, respectively. Additionally, sometimes the judicial decision also causes resource diversion among the health system's subsectors, having a regressive effect mainly when the public sector must finance medicines for patients treated in the private sector (Brazilian managers' and Argentinian NGO) (Box 4-5).

Other negative impacts mentioned include the healthcare fragmentation when the lawsuit requires only the medicines but no other services needed for a comprehensive care (as stated by a Colombian patient organization's representative). A Brazilian health system managers' representative also stated difficulties in guaranteeing the quality of the products since the medicines required by lawsuits have a different logistics process with poor quality control.

Box 4-5. Examples of consequences related to the category health system hardware

"Listen, regarding [the impacts] on the *Obra Social*, sometimes the trouble is that [the judges] force you to provide a benefit; and for the *Obra Social*, obviously, it is not economically convenient because by being obliged to provide a certain part of the benefit, [the *Obra social*] ends up spending double or triple what you [the *Obra Social*] had to give... For the company, these [lawsuits] are prejudicial because the company spends twice more than what it was supposed to spend to cover the disease" (Argentina, Manager).

"[Judicialization] obviously also affect the budget, the health ministry's budget can be compromised for punctually conforming to a certain lawsuit, it puts us in a frequent constraint situation, since I have to automatically allocate resources. There are no resources for [funding medicines required by] lawsuits... It is not part of our framework to include them in the budget. So we have to suspend our budget execution to meet a specific action" (Brazil, Executive).

"From the State's point of view, judicialization, in practice, calls forth a disorganization of the service. We have a lot of difficulties in handling the volume of lawsuits here in the state... We now have a concentration of lawsuits here; and this, from the point of view of the State and municipal health secretariats, represents an unmanageable volume; we cannot respond to the volume of lawsuits that we have here. The State's structure is not scaled for that" (Brazil, manager).

"There is definitely a negative impact [of judicialization] on the financing of the [health] system, since the way people get access to the benefits not included in the benefit plan is messy, the system has the need to spend a lot of resources on therapeutic technologies, including medicines.... whose [costs] are very high and, as a consequence, the system has to allocate a great part of the resources" (Colombia, professional).

"Then everyone [filing lawsuits] generates this disorganization, and the patient is the only one losing, because the pathway we are following now including safe and effective technologies in the POS has not been followed, then the *Tutela* [judicialization] starts giving things to everyone, which, at some point, could be useful or not" (Colombia, Executive).

"There should be a state body that could supply these expensive medicines, with a budget defined as part of the fiscal budget, because ... you'll see, for a private entity, especially like us who does not seek profit.... in case we suffer one of these penalties [lawsuits] we would fall off the chair, because, as a consequence of these judgments, we would have to spend 20 million pesos (~USD 34.000)

> on a medicine, for one single person, and it is too much money for our budget, which must always tend towards a balance." (Chile, Manager).

*4.3.2.2.2 'Software'*

Representatives of the four countries highlighted two aspects related to the health systems' 'software' as causes of judicialization: (a) the weakness of the states in guaranteeing the fundamental rights of their citizens; and (b) the inertia of the states for taking measures to improve the access to medicines timely. The latter aspect was particularly remarked by the respondents in relation to the fact that the health systems' list of covered medicines is not updated on a regular basis.

The configuration of the list of covered medicines was the most mentioned contributing factor to litigation for access to medicines. According to a Colombian NGO's representative, the establishment of an explicit list of covered healthcare services and medicines does not encompass the healthcare complexity neither recognizes the right to health as a general right. As a consequence, it generates adverse selection of patients by the health system managers, which results in litigation.

In this train of thought, the Argentinian and Colombian respondents cited the *grey zones* of the list of covered services and medicines as one of the reasons for the growth of judicialization. In Colombia, according to health system managers' representatives, this happens because the list does not explicitly state if the coverage of a medicine depends on factors such as its origin (e.g. biotechnological coagulation factors). In turn, for the Executive representative, the inflexibility of the medicines list, which until 2012 included specific dosage form and strength for the covered products, also contributed to litigation.

Other causes mentioned were the differences in the medicines coverage among the health systems' subsectors. Yet within the public sector in Argentina and Brazil, there are differences in the medicines coverage among states and municipalities. Additionally, Argentinian health system managers' representatives mentioned the fact of the PMO

comprises a minimum medicines coverage rather than a maximum one contributes to litigation for access to medicines.

In the Chilean context the explicit coverage of a limited number of pathologies and the non-existence of an explicit medicines list have influenced on lawsuits filing for access to medicines (NGO's). In Argentina, litigation rises because the medicines coverage is not linked to a specific pathologies list (Executive and health Manager).

Furthermore, the use of Health Technology Assessment criteria for defining the list of covered medicines and clinical guidelines is also questioned by other stakeholders such as health professional organizations, patient organizations and the Judiciary. The accuracy of the HTA is particularly criticized because the decision-makers do not have consistent data about the real demand for the treatments (Brazil and Chile, Judiciary and patient). Additionally, the evaluation process was also considered limited because the treatment costs are considered to be more relevant than the outcomes; and the assessment usually considers only the prolongation of life as an acceptable outcome, disregarding the importance of the improvement of the patient's quality of life (Brazilian patient).

In Colombia, the lack of an administrative pathway to guarantee the access to uncovered medicines in the reform of the health system in 1993 was cited as factor that contributed to the origin of litigation in the country in 1990s, Nevertheless, the later establishment of reimbursement for uncovered medicines, without medicine prices control incites the stakeholders, such as the EPSs and healthcare services providers, to likewise promote litigation for access to medicines in the country. In the case of Argentina, the excessive bureaucracy and discretion involved in the SUR's high-cost medicines reimbursement process was cited as a contributing factor to litigation for access to medicines.

Representatives from Colombia, Chile and Argentina emphasized that privatization of healthcare facilities, introduction of market logic in the health system, and poor capacity of the state to oversee and to impose sanctions to the health system's stakeholders are among the main causes of litigation in their countries. As a result of the aforementioned factors, the organization of the health systems itself lead

the health system managers deny the provision of covered services and medicines, especially the more expensive ones, in order to earn profit.

On the other hand, especially health system managers' representatives from Argentina, Colombia and Chile mentioned that the people do not consider them as legitimate stakeholders. Thus when the health system manager denies some medicine, the people think that it is because the manager wants to make more profit, but not because the medicine is not the best option for the patient.

In Brazil, the patient organization's representative mentioned that litigation occurs because the health system managers do not want to spend the money. A Judiciary's representative added that in some cases the health system managers use litigation to favour a third party by means of corrupt practices.

The limited number of clinical guidelines defined in the health system was also mentioned as a contributing factor to the occurrence of judicialization of access to medicines (Argentina, Executive, managers; Brazil, professional and patient). The guidelines' inflexibility also favours lawsuits because it generates discrimination of some patients because of their age or clinical situation (Chile, patient).

As regards prescription practices, representatives of the physician organizations and patient organizations defended the medical autonomy. They argued that it is the prescriber who better knows the patient's clinical situation and has the information to decide the best treatment option. In this sense, the questioning about the medical prescription by the health system actually causes litigation (Patient).

On the other hand, the fact that physicians disregard the impacts of their prescription practices upon the access to medicines for the population was considered a cause of litigation (Argentina and Brazil, Executive, Professional, Manager). This point was especially remarked by Brazilian Judiciary's representatives, who recognized that in some cases lawsuits are filed by patients assisted in health facilities of the private sector expecting to get quick access to the medicines in the public sector.

Likewise, some representatives argued that litigation occurs because doctors, based on the foundation of their medical autonomy, prescribe medicines for off-label uses, unlicensed medicines, or medicines still in a research stage, and do not comply with the health system's clinical guidelines (Brazil, Argentina, Colombia, professional, Executive, managers, NGO). In addition, Argentinian Executive's and NGO's representatives and Colombian health system managers' representatives mentioned that the lack of information about medicines, financially or intellectually independent of the pharmaceutical industry, also contributes to litigation for access to medicines (Colombia, managers, Argentina, Executive (Box 4-6).

Box 4-6. Examples of causes related to the category health system software

"The second one [cause] is a perverse incentive that is generated by the creation of the EPS in Colombia. The perverse incentive, which is what kills them [EPS] and kills the way the system was designed in Colombia, is that ... [the nature] for profit of these companies implies that if they spend... if they supply fewer services [...] or spend less money, they can make more money... so there is a widespread opinion resulted from this contract model; it does not mean that EPS always does so, but whenever they deny or do not provide a service, people will believe that they are profit-oriented, that they want to make more money by denying the service" (Colombia, NGO).

"In addition, [there are] other cases of treatments in which it is not clear how the coverage is. For example, assisted fertilization is lately [...] within the compulsory medical program (PMO), but since a lot of issues were not regulated, it is not known whether these medicines, which are expensive, should be covered at 40%, 70 % or 100% [...] Then, generally, today most of the claims related to assisted reproduction have to do with medicines claims at 100%, because, of course, the *Obra Social* tries to cover 40% in the absence of regulation "(Argentina, NGO).

"We noticed that there was certain resistance right at the entrance [of the health service unit], you see? ...in the sense that the public servant did not do what they had to do. So the public defender office [...] had a view that, in order to achieve prestige, it had to resort the Judiciary, so it filed lawsuits. So ... there was a favourable movement [at the defender office] but the servant did not want to do their job. Inadequate supply ... by the municipality, the state, somehow allows some favouritism to some pharmacy owned by someone kin to the health secretary or the mayor" (Brazil, Judiciary).

> "[In the AUGE], for some pathologies the access to medicines is stratified into age ranges... In this case there are some things... for instance... [some people] within a certain age range are given the medicines and others are not ... So the access is not a standard for everyone, and there will be people who, for their age or [clinical] situation, will not have access to this program" (Chile, Patient organization).

Few consequences of judicialization of access to medicines were mentioned by Chilean representatives as this is a recent phenomenon in the country. In Argentina, Brazil and Colombia lawsuits have made some limitations of the public policies evident, and have pressured the government to make structural positive reforms. Among these reforms, they mentioned the updating of the list of covered medicines, the creation of HTA agencies, the establishment of new mechanisms of reimbursement, and better overseeing of the health system stakeholders.

On the other hand, representatives from Colombia and Brazil mentioned some negative impacts of litigation such as the inclusion of new medicines because of their high-cost instead of their impacts on the public health. Therefore, the health policies design is highly influenced by the heath needs of few patients who are able to access the Judiciary, at the expense of the rest of the population's health needs.

In all the studied countries, litigation was considered positive when lawsuits involved covered medicines that for some reason are not supplied to the patient, because it forces the health system manager to carry out their duties.

Nevertheless, the respondents recognized that when lawsuits require uncovered medicines by the health system, litigation jeopardize the health system managers' sustainability. Since the judicial decision must be fulfilled in a short time (usually 48 hours), the managers lose their bargain power with the pharmaceutical industry and/or healthcare services providers.

Furthermore, particularly in Brazil and Argentina, judges often grant injunctive relief without resolving the merits of the lawsuit, then the health system managers cannot interrupt the supply of the treatment, even if it is no longer effective.

Representatives of Colombia, Brazil and Argentina also mentioned that litigation promotes corruption, as it does not allow the proper execution of the overseeing processes. In addition, according to representatives from Colombia, litigation, rather than solving the underlying problems of the health systems, such as unequal access to health services and medicines, makes them worse and reduces the health systems' credibility and governance (Box 4-7).

Box 4-7. Examples of consequences related to the category health system software

[As a result of judicialization] "Public policy is exaggeratedly litigation-driven, and in the macro level of the health system, litigation is marginal in terms of access [...] less than 0.5% of the health actions are accessed [...] by judicial mechanisms" (Colombia, NGO).

"In the case of [medicines and services] not included in the POS (No POS), the contracting mechanisms of health services are *fee for service*, [...], nobody says anything, no one questions anything ... So, from the perspective of a healthcare provider or supplier [including the pharmaceutical industry] this is the most reasonable logic from the economic point of view, and this is covered by something called *Tutela* in Colombia". (Colombia, manager).

"In the case of benefits which are included in the Mandatory Health Program, there is no doubt that they are in charge of the *Obra Social*, [...], and if something is taken to the Judiciary, [...] it is correct [...]. If the patient is not satisfied with what the *Obra Social* provides and [the medicine] is within the Compulsory Medical program, it is quite right that [the patient] resorts to the Judiciary, because a contract was somehow broken" (Argentina, manager).

"Well, a large number of individual lawsuits causes disorganization in their system [the agents responsible for the health care organization], so they start to do something. [...] They become so bothered that they actually start to act, to change the public policy, you see? So this is a really positive aspect" (Brazil, Judiciary).

#### 4.3.2.3 Pharmaceutical marketing

The influence of the pharmaceutical industry in the occurrence of litigation was recognized in the four studied countries. The stakeholders' representatives mentioned that the pharmaceutical industry uses lawsuits as a way to pressure the health systems for financing new medicines or branded medicines.

The interviewees mentioned some pharmaceutical industry's strategies to prompt litigation for access to medicines, including the relationship with prescribers, patient organizations and lawyers; and the marketing campaigns to discredit generic medicines, which results in the requirement of specific brands both by prescribers and patients.

With regard to consequences, Argentinian and Colombian representatives remarked that the pharmaceutical industry is the stakeholder that mostly profit from litigation for access to medicines, since the financing of their products becomes guaranteed (Box 4-8).

Box 4-8. Examples of the category Pharmaceutical marketing

**Causes**

"There is evidence about [the relationship between] pharmaceutical companies and doctors, who are somewhat influenced by the industry, [the doctors] also ended up going into that thing [litigation] as they realized that the Judiciary, let's put it this way, looks favourably upon that sort of thing [litigation]" (Brazil, manager).

"But we must also see that there are vested interests behind them [patient organizations], which also led to judicialization, and yet important, right? In other words, the pharmaceutical companies are at times behind the patients and, a new medicine that has just come out... at the very next day, they [patients] are asking for it. You may think "But how can that be?" right? Of course, the pharmaceutical companies want to make up for the research costs, and want to put it [the medicine] on the market (Argentina, NGO).

The transnational [pharmaceutical] companies [...] will always push expensive drugs and will use all strategies do to so... from patient associations to the lawyers paid by such patient associations to demand the medicines. So, the transnational pharmaceutical industries are pushing the *tutela* (Colombia, NGO).

**Consequences**

"Some interesting data that we had showed how some pharmaceutical companies took advantage by concentrating some very good and extremely profitable items and reimbursements, that is, it was clear that some companies were doing very well with the reimbursements" (Colombia, NGO).

#### 4.3.2.4 National policies for science and technology development, intellectual property protection and medicines prices control

The weakness of the research and development (R&D) national policies and the lack of medicine price control were recognized as causes of litigation for access to medicines in Colombia (Patient organization and health professional organization). In contrast, the monopoly created by the patent protection was also mentioned as a possible cause of litigation in the four studied countries.

Impacts of litigation for access to medicines on these policies were mentioned in Brazil and Colombia. In Brazil, R&D policies have become interrelated with policies for access to medicines since the creation of the Specialized Component of the Pharmaceutical Assistance. In Colombia, since 2012 the Ministry of Health have established maximum prices for uncovered medicines reimbursement from the FOSYGA to the EPS (Box 4-9).

Box 4-9. Examples of the category National policies for science and technology development, intellectual property protection and medicines prices control

**Causes**

"When [innovation] is in private hands, we cannot know the value of that innovation [...] the interest in profit gets in the way of access, and somehow [...] these [developing] countries are compelled to meet the market rules, that is, to protect patents [...] which we believe is an encouragement for [carrying out research on] certain diseases [as] in the case of orphan medicines or in the case of the medicines for a few patients, because it ends up being an interesting incentive to innovate; but at the same time other public policies are not implemented so as to allocate a lot of money from the State for the same type of innovation." (Colombia, Patient).

"So, all this combined with high prices by the State which, as in the case of Colombia, did not intervene in the prices but instead was absolutely open to abuse, as this indeed caused increased spending on a group of medicines [...] a part of few biotechnological medicines and some medicines of known chemical structure [...] as consequence of all the variables that we have taken into account and because the [Colombian] state has been [...] an accomplice and has also sold the ethics of ministers, congressmen, to the industry in order to allow free prices" (Colombia, Patient).

"So, take an [oncologic] medicine that was recently licensed as an example, which is under monopoly and under patent protection, this procedure, that we [ministry of health] pay to the [health care] provider, will probably not be enough to fund this medicine and it ends up generating a lawsuit" (Brazil, Executive).

**Consequences**

"Another important issue that we have interest in this set of medicines [included in the Specialized Component of Pharmaceutical Assistance – CEAF] is a highly strategic action, which is the strengthening of the health industrial complex [...] This component [CEAF] contributes a lot to the Brazilian policy in the industrial complex of health. We are already at a stage where we are not going to the market just to buy medicines, but we are stimulating the national production through technological transfer for products of this component" (Brazil, Executive).

The important thing [...] is that the Sentence T-760 and the instrument to monitor compliance of this sentence have indeed allowed to follow the whole issue from the Judiciary, [including] the obligation of government authorities to regularly submit reports to the Court [...] has recently brought about, shall we say, and certainly for other reasons, changes in the public policy on the control of medicine prices and the need that pharmaceutical companies do not fix the prices at their discretion, but the state is the one interested in controlling this issue (Colombia, Judicial).

#### 4.3.2.5 Judiciary

In general, representatives of all stakeholders, except the patient organizations, mentioned causes of judicialization related to the Judiciary. In this sense, the respondents called attention to the judges' limited technical knowledge about medicines and their vision favouring the supply of the required medicine as always the best alternative for the patient.

Other aspects pointed out as possible causes of litigation included the judges' perception that the medical prescription is a sufficient technical support for granting access to the medicines required through lawsuits, the judges' unawareness of possible conflicts of interest in which the prescriber could be involved, and the judges' non-recognition of the health insurers' technical arguments (Professional, NGO, Manager, Judiciary; Argentina, Colombia, Brazil)..

According to Argentinian and Colombian representatives, litigation is the result of the judges' awareness of the right to health (Executive and NGO). Brazilian and Colombian representatives also attributed this to the judges' wide interpretation of the right to health, considering it as an unlimited right and that any measure aiming to limit it constitutes a violation. This perception might be a consequence of the judges' unconsciousness of the impacts of their decisions on the access to health services by the general population. (Executive, health system manager)

The aforementioned aspects were also cited by the Chilean patient organization's representative, who did not consider them as a negative aspect; in contrast to the other participants.

Particularly in Colombia, an NGO's representative remarked that litigation occurs in the country because the judges conceive that granting access to medicines by means of individual lawsuits is a progressist action and denying it is a neoliberal one.

Chilean and Brazilian representatives highlighted as a cause of litigation the non-recognition of the health system' regulation and organization by the judges in their decision-making process (health system managers, NGOs, Executive and Judiciary). However, for a Brazilian Judiciary's representative, this non-recognition is justified when the health system's regulation does not guarantee access to medicines to the population and infringes the right to health.

Other causes of judicialization of access to medicines related to the Judiciary mentioned include the easy access to the justice; and the judges' position of always favouring the patients, seen as the *weaker party* involved in the lawsuits, promotes judicialization (Argentina, Colombia and Chile; Manager, Judiciary, NGO) (Box 4-10).

Box 4-10. Examples of causes related to the category Judiciary Power

"I understand that one [the judge] sometimes does not have many elements, say, the judge understands about law, but sometimes not much about medicine. So, sometimes, we don't have enough elements to decide whether the *Amparo* is appropriate or not if it is urgent or not. According to my experience, what I do is to try to investigate on my own ... I go to Internet and try to find out whether the situation is really urgent… but, well, you would always choose, when in doubt, for granting the *Amparo* to the person" (Argentina, Judicial).

"What the Judiciary thinks is that [...] there is a doctor who asks for it [the medicine], this person who needs it [the medicine], and there is someone who denies it, that is the prepaid medical company [or *Obra Social*]. [...] Beyond any arguments that you as a financier might have, the Judiciary will rule in favour of the request and the person in need" (Argentina, manage).

"When I recourse to the court, I step over all these divisions [of the health care organization] because if they, in practice, are not working, I ignore that, you see? For, in fact, what is our main foundation? The Federal Constitution says that such responsibility lies with the Union, the State and the municipality. And if they organize themselves internally, I think it's great, as long as it [this organization] turns out fine" (Brazil, Judicial).

"The [Supreme] Court reasons out on the basis that the right to health protection itself has to provide the means to protect it [health] [...] In Chile, I would say that most of these protection resources are won, and I have seen the situation in Uruguay, and in Uruguay [...] almost 15% of the protection resources have been won, and the remaining part has been lost, the Judiciary is a little more in line with the state or insurers, however not here [in Chile] where the Judiciary is closely aligned with consumers, users, patients" (Chile, Lawyer).

[In Colombia] "there has been an issue that could be called legal mobilization, that is, recognition of the right [to health] in the Constitution [...] and judges [have] an idea of granting the right [to health] with the idea that social rights are also protectable through the courts" (Colombia, NGO).

In general, the cited impacts of judicialization of access to medicines on the Judiciary were negative. They include the additional expenses and the overcharge that compromise the Judiciary's responsiveness (Executive, managers and health professional organizations, representatives of the patient organization, Argentina, Colombia).

The loss of effectiveness of lawsuits to guarantee access to medicines, resulted of the large number of judicial cases was also cited as a negative impact of litigation in Brazil and Colombia, but with two different approaches. On one hand for a Brazilian health system managers' representative such loss results from the overcharge of the health system managers, which reduces the manager's responsiveness. On the other hand for the Colombian patient organization's representative this loss is related to the inefficient punishment of the health system managers when do not comply with court decision.

The Judiciary's representative considered as positive impacts the judicial protection of the right to health from omissions of the Executive and the Legislature, and the recognition of this fact by the population. In contrast, the health system managers' representative considered that the judicial intervention and the wide interpretation of the right to health result in abuses by the people who aim to get access to products and services, which are not considered healthcare, most of them related to the right to free development of the personality (Box 4-11).

In the Brazilian context, one of the positive impacts of judicialization was the creation of technical teams to assist in the judges' decision-making.

Box 4-11. Examples of consequences related to the category Judiciary Power

"Because this also affects [...] the Judiciary, as we, the Judiciary itself, are overwhelmed with the amount of lawsuits that we have of all kinds, right? Both civil and penal. Then all these cases that come this way will, of course, sum to those [lawsuits] that the Judiciary already has" (Argentina, professional).

"I believe that a court should not be taking this amount [of lawsuits]. This is additional work in hours/man, right? And that means that you need more people because it [the court] must respond first in 10 days, as it [the lawsuit] is [related to] health, and secondly the ones [lawsuits] that set a pre-cautionary measure [the deadline to respond] within 24 hours. This obviously implies more work charge for the Judiciary personnel, which I think no one had planned... [Moreover] no one has either foreseen that the *Tutela* is no longer respected [...] we evolved to the point that nobody complies with the *Tutela*, and the [Constitutional] Court has to pronounce against contempt for the *Tutela*"(Colombia, patient).

"The courts, although widely used, were not a guarantee of access [to medicines]. And why? Because the state was not able to account for that" (Brazil, manager).

### 4.3.3 Medicines as health needs

The conflict of the definition of need, in accordance with Bradshaw (1972), and the argument of the infinity of need, discussed by Max-Neef (1998) were found in the speech of two respondents. The lawsuits are filed because the health system does not recognize certain health needs. In turn, must be considered that health needs are unlimited, and there is a conflict because the health systems resources to meet the health needs of the population are limited (Brazil and Argentina; Patient and Professional) (Box 4-12).

Box 4-12. Examples of the category Medicines as health needs

"I believe that if it is necessary that a patient resorts to the Judiciary for a request [of a medicine], one can assume that [...] there is a refusal by the state to provide [this medicine], and this is the basics, that is, it is the denial of a need" (Brazil, patient).

"What we know today is that the resources are very limited [and] the needs are unlimited, but we cannot make the health system fall overboard" (Argentina, professional).

### 4.3.4 The demand side level

According to representatives from Argentina, Colombia, and Brazil, lawsuits for access to medicines occur because the patients nowadays have more access to information and can press the physician to get some product that he or she has seen on the Internet, for example. In this sense, some respondents remarked that most of the information currently available about healthcare products is of poor quality (Argentina, Colombia and Brazil; Executive, Managers, Professional, NGO).

For Argentinian representatives, lawsuits result from the non-use of administrative pathways offered by the health system to guarantee access to medicines in case the health system manager does not comply

with its obligations (Executive, Managers, and NGO). While Colombian representatives considered that most lawsuits for medicines included in the POS occur because the users do not know what medicines are covered by the health system (Executive, health professional organization).

In Argentina, according to a Judiciary's representative, litigation for access to medicines occurs because the citizens recognize this branch as 'the saviour', while an Executive's representative considered that lawsuits for access to medicines are filed because now the citizens are more aware of their right to health. In Colombia, respondents mentioned that the creation of patient organizations and the unwillingness to pay of the higher income population also have an important influence on litigation for access to medicines (NGO).

In Brazil, health system managers' representatives stated that one of the causes of judicialization was the organization of the civil society in 1990 to require access to HIV treatment, which at that time was expensive. In addition, they mentioned that the people are now unwilling to change their lifestyle and expect that all their health problems are resolved by medicines (Box 4-13).

Box 4-13. Examples of causes related to the category Demand side level

"Obviously, with the advancement of information that patients receive, [...] they are changing [... from] a patient who was just a common denominator, who was a passive patient and would say "Doctor, what do I have? What [medicine] do I have to take or what I can take?" to a patient that says "I have this, I have this disease, I have to take this medicine, give me the prescription" (Argentina, Executive).

"People do not strive to know what rights they have." (Colombia, Executive).

"This awareness of the right [to health] and [that] the protection of the *Tutela* works fast to effectively give access to the medicines, then it generates the idea of 'I have that right, then I can claim it', 'If they [EPS] deny it [the medicine], I will claim it'..."(Colombia, NGO).

"There is a belief in society that the Judiciary has the solutions when the other branches [Executive and Legislative] fail" (Argentina, Judiciary).

In the four countries, the respondents considered that a positive effect of litigation for access to medicines is that lawsuits defend the right to health of the population and the patient gets access to the medicines required. Nevertheless, the respondents also noted that judicialization has negative impacts when the Judiciary concedes to the patients medicines without evidence of efficacy or safety or medicines that should be used in advanced stages of the disease. In such cases, the patients are exposed to unnecessary risk to their health or the therapeutic alternatives are prematurely used up.

In all the studied countries, the respondents highlighted that litigation is an unequal solution to the barriers to access to medicines, once lawsuits have an individual scope and the access to both the health services and the justice depends on the individual's socioeconomic characteristics. Thus, judicialization of access to medicines, ends up benefiting the people with higher income and/or more empowered. They have more possibilities of creating patient organizations to claim their rights in the court. In this way, representatives emphasized that an individual who is benefited by a lawsuit jumps the queue and passes over those who must follow the administrative pathway.

In Colombia, the most relevant positive effect of judicialization of access to medicines is raising awareness of the right to health. However the representative also recognized that, due to the huge number of lawsuits, nowadays litigation is no longer an efficient pathway to obtain access to medicines and sometimes it ends up delaying the user's access to healthcare (Executive and Patient).

Finally, other negative effect of judicialization of access to medicines is the social movement fragmentation into those pro-branded medicines and pro generic medicines (Brazil and Colombia; Executive and NGO) (Box 4-14).

Box 4-14. Examples of consequences related to the category Demand side level

| |
|---|
| "I consider the improvement in the access to medicines totally positive [...] and obviously is the defence of the right [to access to medicines] of patients that actually need them [the medicines]" (Colombia, Professional). |

"It is important that patients understand they have a right [...], that most people know that there is a right and that there is a mechanism to demand it" (Colombia, Patient).

"One issue [...] about getting [access to] benefits by filing a *Amparo* is that it is not entirely fair, not only because it affects the budget for the remaining patients, but also because access to the Judiciary is just for a certain group of people who somehow gets to know about it and can get in contact with some lawyer groups or organizations, etc." (Argentina, Executive).

"But there is another problem, which is that not all people have access to a lawyer to file a protection resource, so the issue is absolutely detrimental to patients" (Chile, lawyer).

"Another issue that can create difficulty is the lack of safety for the user. So when [the judge] makes the decision to concede a particular benefit, for example, a medicine that has already been incorporated into the SUS [for indications not covered by the CEAF], this can put the user's own safety in check" (Brazil, Executive).

## 4.4 DISCUSSION

This study analyses factors that influence the occurrence and consequences of judicialization of access to medicines in Argentina, Brazil, Chile and Colombia from the perspective of the stakeholders involved in this phenomenon, using the framework proposed on chapter 2. Since this theoretical model allows a wide view of the factors involved, it is useful to conduct a cross-country analysis of this phenomenon.

The comparative analysis showed that in Brazil, Colombia and Argentina, judicialization of access to medicines is more extended than in Chile. This result coincides with the findings of previous analyses (CUBILLOS et al., 2012; HOGERZEIL et al., 2006; REVEIZ et al., 2013; YAMIN; GLOPPEN, 2011). These differences can be explained by two factors: the recent change on the axis of the Chilean Constitutional Tribunal for interpreting the right to health (JORDÁN, 2013a); and the late establishment of an explicit (or positive) list of coverage of medicines in the health system.

In the first case, while the Judiciary from Argentina, Brazil and Colombia, which in the 1990s were sensible to lawsuits of patients with HIV that claim access to antiretroviral medicines, the Chilean Courts did not concede access to these medicines. Indeed, the earliest successful court cases involving access to medicines and health services occurred only at the end of the 2000s in this country (JORDÁN, 2013b), when the Supreme tribunal moved from an "individualistic/contractual" interpretation of the right to health to a "social perspective" one, that conceptualizes health as a social right (JORDÁN, 2013a)

Similarly, in the case of the explicit medicines list, the Explicit Guarantees in Health (GES) were established in 2004 (CHILE, 2004), in comparison with the other three countries, which established explicit list in the 1990s (ARGENTINA, PRESIDENCIA, 1995; BRASIL, 1990a, p. 80; COLOMBIA, 1993b).

The analysis also showed that the aspects of the international level, recognition of the right to health in human rights treaties and the TRIPS agreement, are poor recognized by the stakeholders, with the exception of some representatives from Colombia. The disregard for the aforementioned factors, especially the second one, neglects to a certain extent the effects that the crisis of the current innovation model has on the occurrence of judicialization of access to medicines.

At the national level was observed that judicialization for access to medicines emerged in Argentina, Brazil, Chile and Colombia regardless of aspects such as the recognition of the right to health in the constitution or the proportion of population covered by the public and private sectors. In the first case, only in Brazil health was explicitly considered a fundamental right when the study was carried out (BRASIL, 1988). In the second case, in both Chile and Brazil most of population depend on the public sector for accessing healthcare services in (chapter 3).

In the four studied countries, causes in common were described such as the health systems' limitations in guaranteeing universal, equitable and timely access to health services and medicines covered by the health systems. According to our results, these limitations are related to management inefficiencies, health services networks fragmentation; stakeholders' corruption and weak state regulation capacity. This results in loss of credibility of the health system.

The respondents' speeches showed that the measures to regularly update the lists are insufficient for controlling litigation for access to medicines. Notwithstanding, the combination of the health system's lack of credibility and the expectations created by the pharmaceutical marketing about the medicine outcomes makes the discussion about the judicialization causes concentrate on the comprehensiveness of the list of covered medicines.

In fact, our results evidence that the pharmaceutical industry, by means of the marketing practices, reinforces the *"fallacy of the outdated medication list"* and challenges the HTA criteria. In this way the discussion about medicines inclusion in the health system focus on the premise of "the health system does not cover expensive medicines" rather than on the population criteria considered on the Health Technology Assessments.

On the other hand, the role of the physicians' prescription practices in the occurrence of judicialization of access to medicines was recognized in the four studied countries. Nevertheless, strategies both to counter the pharmaceutical marketing and to make transparent the relationship between the pharmaceutical industry and prescribers were not cited by the respondents. These strategies could contribute to reduce the frequency of lawsuits claiming uncovered medicines.

Furthermore, our results show that the question "why the new medicines are that expensive?" as well as the relationship among the public policies for guaranteeing access to medicines and the intellectual property protection and the science and technological development policies are aspects frequently neglected in the discussion of litigation of access to medicines.

The disregard of some sectors for these political economy features of the right to health, had been previously described in Colombia (LAMPREA, 2015), and our result suggest a similar situation in Brazil, Argentina and Chile. In addition, this neglect compromises the ability of countries to create strategies at a national and a regional level aiming to defend their health sovereignty against the pharmaceutical industry's abuses.

In the case of the Judiciary, the aforementioned aspects influence their decision making. Although the judges' desire is to promptly protect the patients' right to health, they usually do not recognize that their decisions can have adverse effects in special when uncovered medicines are grant. This comes from the fact that the health system manager has a short time to respond, and needs to use exceptional pathways for procurement, which are usually difficult to control, favouring diversion of resources and corruption.

Furthermore, the Judiciary's representatives argued that it is ethically unacceptable to *sacrifice* the individual right to health in order to protect the collective right to health. This evidenced the conflict of this view with the Executive' and health system managers' perspective that consider that what is actually unethical is to *sacrifice* the collective right to health in order to protect the individual right to health. In addition, they argued that the exposition of the patient to unsafe or unnecessary medicines, indeed, constitutes a violation of the right to health.

As regards the consequences of judicialization of access to medicines, our results coincide with the impacts reported in other studies. Particularly our study showed the impacts related to inequality induced by litigation in the distribution of the health system resources. In the present study, the respondents recognized that litigation is an unequal solution to access to medicines, because the lawsuits are individual, and access both to healthcare and justice services highly depend on the socioeconomic characteristics of the population. Moreover, it is possible to observe that those who get the access to medicines granted by the judge jump the queue and pass the people who follow official or predefined pathways of the health system.

Concerning the positive impacts of litigation, one of the most emphasized ones was the pressure that this phenomenon exerts over the health system managers to fulfil their responsibilities (VARGAS-PELÁEZ et al., 2014). Nevertheless, the respondents also highlighted other impacts such as the health system's governability loss, which can compromise the implementation of corrective measures to control litigation and to improve the health system's performance.

Following the theoretical model, a remarkable finding of our study includes the fact that only in Brazil judicialization has had impacts over R&D policies, including measures as the establishment of public-private partnerships for technology transfer in order to locally produce the medicines considered a priority for the public health system (SUS) (BRASIL, MINISTÉRIO DA SAÚDE, 2014).

In Colombia, litigation also encourages the recognition of the right to health as a fundamental right, the development of policies for controlling medicines prices, and the creation of a specific commission of the Judiciary that supervises the measures taken by the Ministry of Health to meet the commitments established by ruling T-760/2008 (UPRIMNY; DURÁN, 2014).

## 4.5 LIMITATIONS

This qualitative study does not aim to generalize its findings, but describe the perceptions of the stakeholders involved in judicialization of access to medicines. Some limitations of this study include the fact that most of the interviews were conducted only in the capital cities, with the exception of Brazil, and the fact that pharmaceutical industry's representatives were not invited to participate.

## 4.6 CONCLUSION

According to the results of this study, the causes of judicialization of access to medicines more often described by the studied countries' representatives were those related to the organization of the health system ('software' and 'hardware'). They mentioned especially issues about the definition of the list of medicines covered by the health system and the non-social legitimacy of the Executive and health system managers. The influence of the international context and the national economic and social policies on judicialization was little known. Additionally, it is possible to conclude that the Judiciary sees itself as a protector of the right to health. As so other stakeholders, especially patients and health professionals perceive it.

The analysis of judicialization of access to medicines using the theoretical model proposed in chapter 2 allowed a comprehensive view of the phenomenon. In this way, our analysis explored the influence of different factors from the health and market perspective at different

levels (international, national and demand-side), which can influence the occurrence of judicialization as well as the feedback effects that the phenomenon can bring.

Our analysis shows some similarities in the causes and consequences of litigation for access to medicines in the studied countries, despite the differences on the contexts and the possible aspects that define the extension or occurrence of this phenomenon in a specific time frame. The result suggest that this kind of analysis, applying the theoretical model adopted, creates the possibility of identifying critical points that can guide the policy making at both national and international levels to improve the performance of the health systems and control the lawsuits for access to medicines.

# 5 CHAPTER 5 – Responses to judicialization of access to medicines in Latin America: The cases of Brazil and Colombia

## 5.1. INTRODUCTION

Litigation for access to medicines has risen as an alternative pathway for patients regardless of whether or not the medicine is covered by the health system (chapter 3). The extension of litigation for access to medicines varies from country to country. In Chile, it is still incipient since most lawsuits related to the right to health result from arbitrary adjustments by health insurance premiums in the private sector. In Argentina, the phenomenon concentrate in the social security subsector, and the stakeholders recognize that the number of lawsuits is getting out of control. Meanwhile, in Brazil and Colombia, litigation for access to medicines is more intense (Chapter 4), and both countries stand out because of the impacts that the phenomenon have had over the health systems (HOGERZEIL et al., 2006; REVEIZ et al., 2013).

The comparative analysis of the causes and consequences of litigation for access to medicines in Argentina, Brazil, Chile and Colombia showed that, despite the countries' differences in their constitutional recognition of the right to health and the health system organization, there are similarities among them. Health systems' limitations to incorporate new medicines were mentioned by all interviewed stakeholders as a cause of litigation. Additionally, regressive effects of the phenomenon on equal access to healthcare and medicines especially when new and expensive medicines are required was mentioned as a consequence of litigation in all the studied countries (see chapter 4).

Within this framework, in order to proceed in the comparative analysis, this study aims to characterize and compare the States' responses to litigation for access to medicines, especially those focused on extending the list of medicines covered by the health systems.

## 5.2. METHODOLOGY

In this cross-country study, two methodologies were used. Firstly, an integrative literature review was carried out to identify the regulations related to the measures taken to guarantee access to

medicines in response to litigation, following the methodology described in Section 3.2.1.

This information was supplemented with semi-structured interviews conducted with representatives of the stakeholders involved in the phenomenon of litigation for access to medicines described in Section 3.2.2. They were asked about the impacts of the measures adopted by the Executive and Judiciary branches (see Table 3-2).

Documentary analysis was applied to the regulations identified in order to identify the assumptions of the policy-makers related to the extension of the access to medicines and the expected impacts of public policies. The results of this analysis were contrasted with the interviewees' statements.

## 5.3. RESULTS

In Argentina, the recently implemented Unified Reimbursement System (SUR) (ARGENTINA, SUPERINTENDENCIA DE SERVICIOS DE SALUD, 2012b) and the Supervisory System for Emerging Sanitation Technologies (ARGENTINA, SUPERINTENDENCIA DE SERVICIOS DE SALUD, 2012c) aim to improve the Health Technology Assessment (HTA) process and streamline the resources flow within the social security subsector for the financing of new technologies. However, according to the Argentinian stakeholders' representatives, these measures were not established in response to litigation for access to medicines, but in response to the '*Obras Sociales'* corruption detected in the reimbursement processes.

In addition, the Argentinean respondents recognized that although litigation for access to medicines is a concern for some sectors of the Judiciary and the Supreme Court has ruled some lawsuits related to access to medicines, there were not any statements from this branch about substantive issues of the phenomenon. In the respondents' opinion, there are two reasons for this. Firstly, the Argentinian Supreme Court is conservative in its statements; and secondly, in this country the Executive and the Legislature are responsible for resolving the health system problems.

Despite the aforementioned observations, the respondents noted that in order to control the phenomenon's growth the Judiciary has limited the jurisdiction over right-to-health claims to civil and commercial courts. These measures reduced the number of gateways to the Judiciary. Furthermore, according to the respondents, the Judiciary recognized its limitations in dealing with right-to-health claims and proposed the creation of specialized tribunals to meet these claims. Nevertheless, these tribunals have not been implemented yet.

In Chile the respondents observed that, although the rate of successful lawsuits for access to medicines in the Supreme Court was high, there were not any statements related to the right to health. This was in part because, according to the Constitution, the Judiciary is not responsible for creating or executing measures related to the health system.

As litigation for access to medicines is not extend in Chile as in the other analysed countries, the measures taken by the Chilean Legislature (CHILE, 2004) and Executive (CHILE, MINISTERIO DE SALUD, 2010, 2013) for the implementation and expansion of the Health Explicit Guarantees (GES) were not influenced by the phenomenon. These measures were taken in response to the health system's unequal technology coverage between public and private sectors. According to the respondents, the specific measures to extend the coverage of expensive medicines are the result of the social mobilization that has caught media attention. The best example is Law Ricarte Soto that has recently come into force and was under discussion at the time when the interviews were conducted (CHILE, 2015).

In Colombia and in Brazil public policies for expanding the list of medicines covered by health system in response to litigation for access to medicines were identified. The comparative analysis of the measures taken by the three branches (Judiciary, Executive and Legislative) in these countries is presented below.

### 5.4.1 Measures taken by the Judiciary branch in Colombia and Brazil

The Judiciary was the branch that first took measures in response to litigation for access to medicines in Colombia and Brazil. These measures came into force with little time difference between the

countries. In Colombia, ruling T-760 came into force in July 2008, and the public hearing in Brazil occurred in April 2009 (Table 5-1). However, the measures had different characteristics. In Brazil, the Supreme Court opted for a public hearing, a participatory way, in which all stakeholders could expose their perspective on the phenomenon of right-to-health judicialization and openly discuss the matter (BRASIL, SUPREMO TRIBUNAL FEDERAL, 2009); Colombia's Constitutional Court issued a court order of mandatory compliance to the Executive take corrective actions to resolve the failure in the health system that compromised the population's right to health (COLOMBIA, CORTE CONSTITUCIONAL, 2008a).

Another difference that was found between those measures is the acknowledgement of the Judiciary's role in the development of the phenomenon. So, in Brazil the National Justice Council by means of Recommendation No. 31, 2009 (BRASIL, CONSELHO NACIONAL DE JUSTIÇA, 2010a) sent order to all instances of the Judiciary to take actions to better support decisions related to the right to health. In contrast, the Constitutional Court of Colombia makes no explicit mention of recommendations for the Judiciary's members.

From the interviews in both countries, it was observed that ruling T-760 was widely known by the Colombian respondents, while both the STF public hearing and CNJ Recommendation 31/2009 were just recognized by representatives of the Ministry of Health, managers and the Judiciary in Brazil.

Regarding the impacts of these measures, similarities were found too. In both countries, the measures adopted by the Judiciary favour and/or press the Executive to take measures for:

a) Updating the list of medicines of the health systems;
b) Establish the frequency of updating;
c) Increase the transparency of the list updating process, ensuring the participation of all stakeholders, including the civil society;
d) The creation and/or restructuration of the Health Technology Assessment Agencies: National Commission for Health Technology Incorporation in the SUS – CONITEC in Brazil, and Health Technology Assessment Institute – IETS in Colombia;
e) Improve the medicine financing mechanisms.

Table 5-1 Measures taken by the Judiciary branch in Brazil and Colombia in response to judicialization of access to medicines

| Entity | Regulation | Premises |
|---|---|---|
| Federal Supreme Court (BRASIL, SUPREMO TRIBUNAL FEDERAL, 2009) | *Public Hearing No. 4 2009*<br><br>Date: 27th -29th of April and 4th-7th of May 2009 | Litigation for access to healthcare services is a complex phenomenon that involves technical, scientific, management, political, economic and legal issues.<br><br>The State is responsible for the protection of the right to health of the population<br><br>There are situations not considered by the health system and the public policies (e.g. uncovered medicines, unlicensed medicines, medical treatment aboard) in which it is not clear if the state has the obligation of financing them.<br><br>The RENAME'S updating process needs to be periodical, efficient and transparent.<br><br>Litigation may involve Unified Health System frauds. |
| National Justice Council (BRASIL, CONSELHO NACIONAL DE JUSTIÇA, 2010a) | *Recommendation No.31 2009*<br><br>Date: 30th of March 2010 | The Judiciary members are also responsible for ensuring efficiency in the solution of lawsuits by guaranteeing that their decisions are subsidized by technical information. |

| Entity | Regulation | Premises |
|---|---|---|
| Constitutional Court (COLOMBIA, CORTE CONSTITUCIONAL, 2008b) | *Ruling T-760 de 2008*<br><br>Date: 31st of July 2008 | The right to health is a fundamental right.<br><br>All people have the right to access to the same list of benefits (healthcare services and medicines) regardless of the health system regime that they are affiliated<br><br>The Executive's lack of regulation and overseeing over the health system stakeholders is the leading cause of judicialization.<br><br>The reimbursement system favours the EPS and encourages the filing of lawsuits (*tutelas*).<br><br>The POS list has not been comprehensively or periodically updated.<br><br>The flow of resources from the reimbursement system is not working, so the FOSYGA's arrears with the EPS must be paid in the short term.<br><br>This ruling must be widely disseminated. |

In the Brazilian context different strategies to provide technical support for judicial decisions were implemented as a result of Recommendation nº 31/2009. Some examples mentioned by the respondents include the Technical Support Centres (*Núcleos de Apoio Técnico - NATs*), the Health Dispute Resolution Chamber (*Câmara de Resolução de Litígios em Saúde* – CRLS) in Rio de Janeiro, the Interinstitutional Committee for Administrative Resolution of Health Demands (*Comitê Interinstitucional de Resolução Administrativa de Demandas Da Saúde – CIRADS*) in Rio Grande do Norte, and the implementation in the state of Santa Catarina of measures to evaluate the demands and file a lawsuit only after assessing the case and verifying previous treatment alternatives used and available in the SUS.

In addition, the National Justice Council created the National Judicial Forum for Health. This aim the monitoring and resolution of health care claims. Furthermore, it intends to conduct studies and proposition of concrete and regulatory measures to improve procedures, effectiveness of court proceedings and prevention of new conflicts" (BRASIL, CONSELHO NACIONAL DE JUSTIÇA, 2010b).

Nevertheless, the respondents recognized that the effects of these measures are limited. They cited as cause the little dissemination of information about them; lack of knowledge of judges and lawyer about specific aspects of the right to health; and judiciary decentralization. The judiciary decentralization resulted in huge variability in the implementation of these measures among the states. Particularly, in the view of the health system managers' representatives, these measures did not have the expected effects. For them the Judiciary did not take a stand against the broad interpretation of the right to health and its effect on the equity of the health system.

In Colombia, the respondents mentioned that ruling T-760 had positive impacts such as the recognition of the right to health as a fundamental right. Health became an important issue in the public agenda and lead to higher consciousness of the right to health in society, especially in the subsidized regime that serves the most vulnerable population. At the same time, ruling T-760/2008 allowed social cohesion by the approach of civil society groups working around the right to health, actively monitoring the Executive branch's compliance with the orders stated in the ruling.

Ruling T-760/2008 also changed the reimbursement mechanism of medicines required by lawsuits, establishing that if the medicine is supplied under a lawsuit the FOSYGA would only reimburse 50% of the value to the Health-Promoting Enterprises (EPSs). If the medicine is provided by a decision of the Scientific and Technical Committee (CTC) the EPS would receive 100% of the value.

This change makes it advantageous for EPS process the requirement of uncovered medicines through the CTC. According to the respondents, the measure facilitated access to medicines for the patients that because of their clinical situation require uncovered medicines. Nonetheless, for the respondents an undesirable effect of this decision is the reinforce of the perverse incentive that makes the EPS prefer to provide uncovered medicines instead of using the resources given to finance the POS benefits.

The respondents mentioned other undesired effects of ruling T-760. The increased number of lawsuits claiming access to medicines became more evident due to the broad dissemination of the measures in the media. Also, they pointed out that the Court's pressure to speed up the payment of pending reimbursement by the FOSYGA to the EPS favours corruption, since this order limits the ability to audit payments. Finally, the respondents mentioned that ruling T-760 does not solve the underlying problems of the health system derived from the system management, which is delegated to private companies.

Moreover, according to a NGOs' representative, ruling T-760 favours an individualist interpretation of the right to health, which in some cases limits the ability of the Ministry of Health to take collective framework measures. In other words, in order to comply with the Constitutional Court orders, the Ministry of Health must adopt very specific measures that sometimes are counterproductive to the equity of the health system.

### 5.4.2 Measures taken by the Executive and Legislative branches in Brazil and Colombia

The measures taken by the Executive and Legislature in these two countries were also close in time and had similar objectives: to adopt HTA criteria for the inclusion of new technologies in the health system

coverage; make the HTA process more efficient and transparent; expand the list of medicines supplied by the health system; streamline the flow of resources within the health system for ensuring its sustainability; and guarantee equity in the access to medicines (Table 5-2).

The Legislature also participates in the health system reforms but in different ways. In Brazil, the Legislature defined what pharmaceutical assistance means within the SUS, as a way to fill the regulatory gap in Law 8080/1990. For the Judiciary, the Law 8080/1990 put the "integrated care, including pharmaceutical" as one of the SUS actions without regulating it. In Colombia, in turn, the Legislature undertook a general reform of the health system that, among other aspects, considered the creation of the Health Technology Assessment Institute, and the extinction of the Commission of Regulation in Health (CRES) which was in charge of the POS updating process until 2012.

In Colombia, all the respondents recognized the influence of judicialization and Ruling T-760 on the creation and implementation of these public policies by the other branches. Indeed, all the subsequent regulations cite Ruling T-760/2008 in their preambles. In turn, in the Brazilian context, the influence of the Judiciary's initiative on the measures taken by the Executive and the Legislative is controversial.

As regards the impacts of these measures, the respondents' opinions were similar in Colombia and Brazil. For instance, in both countries most of the respondents considered the expansion and updating of the list of medicines a positive effect of the policy, which resulted in a decrease in the number of lawsuits for the now covered medicines.

In Colombia, the two biggest POS's updating process happened after ruling T-760 came into force. The update of 2011 incorporated some expensive medicines; and the update of 2013 eliminated the specifications of strength for solid dosage forms (tablets, capsules, etc.) and for some therapeutic groups all the 'me too' medicines were incorporated.

Table 5-2 Measures taken by the Executive and Legislative branches in Brazil and Colombia in response to judicialization of access to medicines

| Entity | Regulation | Propositions |
|---|---|---|
| **Brazil** | | |
| Ministry of Health (BRASIL, MINISTÉRIO DA SAÚDE, 2009) | Ordinance No. 2.981 of 26th of November/2009 | The Specialized Component of the Pharmaceutical Assistance aims to improve the tools and strategies for ensuring and expanding access to health services, including medicines (particularly expensive ones). |
| National Congress (BRASIL, 2011b) | Law No. 12.401 of 28th of April/2011 | The therapeutic assistance and health technology incorporation process should be defined to resolve the gap in the SUS regulation related to this issue. |
| Presidency of the Republic (BRASIL, 2011a) | Decree No. 7.508 of 28th June of 2011 | The RENAME consists of the list of medicines covered by the health system (SUS), which must be periodically updated and whose financing is negotiated and supported by the three governmental levels for a financial balance among them. |
| Presidency of the Republic (BRASIL, 2011c) | Decree No. 7.646 of 21st of December/2011. | The HTA agency performance must be improved; the HTA process must be more efficient and participative. |
| Ministry of Health (BRASIL, MINISTÉRIO DA SAÚDE, 2013) | Ordinance No. 1.554 of 30th of July/2013. | Takes into consideration that the minimum slice of the budget of the different government levels must be spent on health, and the list of medicines must be updated every two years. |

| Entity | Regulation | Propositions |
|---|---|---|
| **Colombia** | | |
| Commission of Regulation in Health – CRES (COLOMBIA, COMISIÓN DE REGULACIÓN EN SALUD – CRES, 2009) | *Agree No. 004 of 2009*<br><br>Date: 30th of September of 2009 | The benefits plan of the contributory and subsidized regimes are equalized for people between 0 and 12 years old in order to comply with the order of the Constitutional Tribunal. |
| CRES (COLOMBIA, COMISIÓN DE REGULACIÓN EN SALUD – CRES, 2010) | *Agree No. 011 of 2010*<br><br>Date: 1st of February of 2010 | The benefits plan of the contributory and subsidized regimes are equalized for people between 12 and under 18 years old in order to comply with Decision T-760/2008 of the Constitutional Tribunal. |
| National Congress (COLOMBIA, 2011) | *Law 1438 of 2011*<br><br>Date: 19th of January of 2011 | The Benefits Plan must be fully updated every two years according to the changes in the population's epidemiological profile and disease burden, availability of resources, balance and extraordinary medicines that are not explicit in the Benefits Plan.<br><br>The Health Technology Assessment Institute (IETS) must evaluate health technologies based on scientific evidence, guides and protocols on procedures, medicines and treatment according to the Benefits Plan. Its guidelines will be used as a benchmark for defining benefit plans, for technical concepts of the Scientific Committees and the Scientific and Technical Board, and for providers of health services. |
| CRES (COLOMBIA, COMISIÓN DE REGULACIÓN EN SALUD – CRES, 2011a) | *Agree No. 27 of 2011*<br><br>Date: 11th of November of 2011 | The benefits plan of the contributory and subsidized regimes are equalized for people older than 60 years old to comply with the orders of Decision T-760 of the Constitutional Tribunal. |

| Entity | Regulation | Propositions |
|---|---|---|
| CRES (COLOMBIA, COMISIÓN DE REGULACIÓN EN SALUD – CRES, 2011b) | *Agree No.29 of 2011*<br><br>Date: 28th of December of 2011 | Aiming to meet the statement of Article 25 of Law 1438/2011 (related to the public consultation for the list updating) and the orders of Decision T-760 of the Constitutional Tribunal, the new list of medicines include the suggestions from the public consultation and was considered adequate. |
| CRES (COLOMBIA, COMISIÓN DE REGULACIÓN EN SALUD – CRES, 2012) | *Agree No. 32 of 2012*<br><br>Date: 17th of May of 2012 | The benefits plan of the contributory and subsidized regimes are equalized for people between 18 and 59 years old to comply with the orders of Decision T-760 of the Constitutional Tribunal. |
| Ministry of Health (COLOMBIA, MINISTERIO DE SALUD, 2013) | *Resolution No.5521 of 2013*<br><br>Date: 27th of December of 2013 | Takes into consideration that the minimum slice of the budget of the different government levels must be spent on health, and the list of medicines must be updated every two years.<br><br>Defines, clarifies and fully updates the Mandatory Health Plan (POS).<br><br>Includes new technologies, some of them with coverage specifically to some indications only. Eliminates the concentration specification and dosage form of the covered medicines, and includes full therapeutic subgroups (proton pump inhibitors, H2-receptor agonists, calcium channel blockers, ACE inhibitors such as mono-drugs, HMG-CoA reductase inhibitors). |

In Brazil, before the decree No. 7.508/2011 came into force, there were three different lists of medicines; the National List of Essential Medicines (RENAME); the list of medicines for the treatment of HIV and sexually transmitted diseases; and the CEAF medicines list. From 2012 all list were unified and the RENAME became the list of medicines supplied by the SUS. In addition, the process of HTA of new technologies or medicines for their inclusion in the SUS was centralized in the Brazilian National Committee for Health Technology Assessment (CONITEC).

This kind of expansion of the medicines list is based on a change in the essential medicines' definition, which creates controversy. Representatives of the Executive in both countries argue that the change in the definition is positive. Their arguments include first the fact that the cost is not a reason for excluding medicines that have evidence of safety and efficacy. Second the availability of different dosage forms is good for the prescribers and the patients as it facilitates the dose adjustment for each patient and prevents the fractioning of dosage forms and wasting of resources.

Nevertheless, according to a health professional organization's representative these measures distort the concept of essential medicines because the inclusion of new medicines does not respond to the technical criteria for cost-effectiveness. On the contrary, the inclusion process responds to the pressure that the pharmaceutical industry exert by means of litigation of access to medicines. In addition, difficulties for managing a big list of items was cited as a negative effect of this update process in Colombia.

In both countries, another controversial decision is the coverage for specific indications. Some medicines, particularly the expensive ones, are provided by the health system only for clinical situations that have sufficient evidence of efficacy and safety. The indications are defined by means of compulsory clinical guidelines (Brazil) or specifications from the list (Colombia). For some respondents this ensures the rational use of medicines and economic resources (Executive, Professional, NGO).

In contrast, some respondents pointed out that this measure generates inequality in the access to medicines (Patients, Professionals). As example, they cited the case of patients who have uncovered pathologies, but that could have benefits with the medicines available in the lists for other diseases. This generates lawsuits claiming covered medicines for off-label uses. Another factor cited in the Brazilian context is the limitation of SUS in providing appointments with a specialist, which is required in the clinical protocols (Patient).

The last common aspect between these two countries was the Judiciary's representatives' unawareness and/or perception that the measures taken by the Ministries of Health are still insufficient.

Regarding the positive consequences of the CEAF implementation, the respondents mentioned the coordination of the policies for access to medicines with the policies aiming at strengthening the local industrial medical complex. The redistribution among the three government levels of the expensive medicines' financial burden was also mentioned as a positive result (Executive). Furthermore, the representatives agreed on improvement of the access to medicines in all the Brazilian states as result of the CEAF implementation. However, managers' representatives noted that the incorporation of technologies had limited effects upon the financial burden that they face as consequence of the claim for access to expensive medicines through lawsuits.

In Colombia, representatives considered the changes in the doctor's prescription practice as an adverse effect of the POS's updating (Executive and Managers). Due to the inclusion of new medicines in the list, the physicians now indicate longer treatments. This is also in part because of the unavailability of mandatory clinical guidelines. This tendency ends up increasing the health system's spending on expensive medicines.

In addition, the equalization of the POS lists was considered an advance in terms of equity in the access to medicines and health services between the subsidized and the contributory regimes. Nevertheless, the non-equalization of the Unit per Capita (UPC) of the subsidized regime compromises the financial sustainability of the EPS-S. This generates uncertainty about the real impacts of this measure on access to medicines in the subsidize regime (NGO).

Furthermore, according to these respondents, the equalization of the POS lists can also increase the number of lawsuits, as it expands the access to specialized care therefore the number of patients requiring expensive medicines. Finally, this measure also changed the profile of the lawsuits, as now the patient does not require the financing of the medicine but claims continuous and timely access to it (patient).

## 5.4. DISCUSSION

This study carried out a cross-country analysis of measures taken in response to judicialization of access to medicines. We defined health system as a complex set of stakeholders, rules, and values (SHEIKH et al., 2011). For this reason, we adopted a qualitative approach as it allows to understand how health system actors understand and experience particular services or policies, and what social and political processes, including power relations, influence them (GILSON et al., 2011).

The results show that that judicialization presents differences and similarities in the four analysed countries. In Chile, the incipient expansion of lawsuits for access to medicines can be explained because only in the last years, the Supreme Court has adopted a *progressist* interpretation of the Right to Health, recognizing its protection as an obligation of the state (JORDÁN, 2013a). In turn, in Argentina and Colombia, despite the introduction of the market logic in the health system since 1990, the Judiciary's interpretation of the right to health as a fundamental right has been frequent (BERGALLO, 2010; YAMIN; PARRA-VERA, 2010). In Brazil, the right to health had been recognized as a fundamental right in the Constitution since 1998 (BIEHL, 2013).

However, our results show that the Judiciary's high instances for taking a position and/or actions to control or understand the phenomenon vary among the studied countries, regardless of phenomenon's growth, as in the comparison between Chile and Argentina.

Furthermore, in Brazil and Colombia, where the high courts have taken actions in response to litigation for access to medicines, we also found differences in the intensity of the expansion of the Judiciary's control over the Executive and Legislative powers, or judicialization

*from without*, according to Tate and Vallinder (1995). In Brazil, the Supreme Court opted for a participative way as a first intervention (public hearing) comprising all the stakeholders. This resulted in binding measures only for the Judiciary (PRADO, 2014), while in Colombia the Constitutional Court's approach was vertical (judicial decision) whose orders focused on the Executive branch (LAMPREA, 2014).

In this sense, the Colombian Judiciary took a position above the legislative and administrative spheres because of the characteristic of the measures and the recognition obtained by the social actors, as consequence of the media dissemination of Ruling-T760. This is perhaps the reason why there is a consensus in the actors' view about the important role of the Judiciary in the health system's reform in the last ten years. In turn, in Brazil the stakeholders do not considered crucial the effects of the public hearing over the measures taken by health system in the same period.

Moreover, it is worth noting that in the Brazilian context the Judiciary recognizes its responsibility in the adequate use of the health system's resources. In Colombia conversely, the Judiciary did not recognize its role in preventing and controlling abuses by different stakeholders against the health system through litigation. This branch only pointed out the failures of the health system as a cause of the limited access to medicines.

The incorporation of medicines in the list of the health systems in Brazil and Colombia increased the number of items covered for the health care of the population. Currently the POS in the Colombia health system comprise 367 medicines and 793 dosage forms (COLOMBIA, MINISTERIO DE SALUD, 2014b). In Brazil in 2014, the RENAME comprised approximately 886 dosage forms (BRASIL, MINISTÉRIO DA SAÚDE, 2015); 194 drugs and 383 dosage forms of them were financed by the CEAF (BRASIL, MINISTÉRIO DA SAÚDE, 2014).

The controversy related to the change in the essential medicines' definition is present in both countries, although in this study only one Colombian representative expressed arguments against this change. In the literature, other sectors of the Colombian civil society have stood position in the same sense as Rossi et al. (2012). In Brazil, Figueiredo et al. (2014) considered that the new updating process do not follow the principles of HTA in a proper way. Furthermore, Santos-Pinto et

al.(2013) also disagree with the inclusion of a huge number of dosage forms, because it makes the management of the medicines logistic more difficult.

However, the essential medicines' definition of the World Health Organization has evolved, and currently new medicines can be considered essential if there is evidence of their efficacy and safety, despite their high cost (e.g. trastuzumab and sofosbuvir) following criteria such as the disease epidemiological profile and burden (WHO WORLD HEALTH ORGANIZATION, 2015b). In this train of thought, Brazil and Colombia are following similar criteria to those proposed by the WHO.

The aforementioned aspects guarantee that the health system will supply medicines for the majority of the population. Nevertheless, the health system must also guarantee alternatives for those patients that because of their particular clinical situation, the medicines useful and safe for most of the people are not adequate alternative of treatment (e.g. cases of intolerance or non-response). The adoption of a broad list gives the opportunity of individualize the therapy and adjusted it for the specific needs of the patient and guarantee the comprehensiveness of the treatment (DO NASCIMENTO JÚNIOR et al., 2015).

Furthermore, the access to medicines not only depends on technical-scientific assessment, but it is the result of a complex relationship and balance among the different health system stakeholders and the particular values of equity and justice present in a society. In this way, the decision to make a small list of medicines is not a guarantee of access to or rational use of medicines. A rigid list may lead to distortions in the market and limit the bargain capacity of the health system manager. Thus, the expansion of the medicines list in terms of dosage forms give to the health system manager the possibility of using the market forces in favour of the efficient use of the resources.

Taking into consideration a wide view about the access to medicines, it is also possible to note that the ministries of health and health system managers are not only responsible for guaranteeing the availability of the product. As the establishment of a list or clinical guidelines does not guarantee its compliance, this situation shows that the measures to control other stakeholders, such as the pharmaceutical industry and the prescribers, are necessary to guarantee the successful

and effective application of the HTA criteria in the daily routine of the health systems for ensuring the medicines' effectiveness and safety.

In this sense, some urgent measures must be taken to make relationships transparent between the pharmaceutical industry and other health system's stakeholders (policy-makers, managers, prescribers, patients, etc.) with strategies for disseminating information about the medicines independently of the pharmaceutical industry.

In both Colombia and Brazil, according to the respondents, the measures taken in response to litigation for access to medicines have resulted in some advances. However, the health systems still need to overcome challenges regarding rational use of medicines and equity in the distribution of the health system resources.

In conclusion, a wide extension of litigation for access to medicines is not enough to trigger macro interventions of the Judiciary in response to the phenomenon. Furthermore, the analysis of the experiences of Brazil and Colombia allows inferring that in order to control the phenomenon of litigation it is not sufficient to direct the attention for possible solutions towards the incorporation of new technologies in the health systems' coverage.

## Final Consideration

### *Lessons learned*

The present PhD thesis aimed to explore and compare litigation for access to medicines in Latin American countries. This phenomenon rose in Latin America in the 1990s, when the first lawsuits claiming access to antiretroviral medicines were filed. Since then, particularly from the 2000s, the phenomenon has steadily increased, catching the attention of health system's stakeholders: policy makers, health system managers, health professionals, patient organizations, the academia, and the newest health system's stakeholder: the Judiciary.

Conducting studies on this phenomenon appears to be significant taking into account that the costs of new health technologies, including medicines, have been identified as a key driver of the rising health expenditure. Within this framework, the countries need information about litigation for access to medicines in order to design strategies aiming to meet the Universal Health Coverage's goals, to guarantee equity in the access to medicines and sustainability of the health system.

Litigation for access to medicines is a complex phenomenon that involves technical-scientific, legal and social aspects. However, similar to research about health systems and access to medicines, most studies about litigation are based on the positivist paradigm and highlight only the technical and scientific aspects of the phenomenon. Additionally, academic analyses use in general the normative approach which understands litigation as the interference of the Judiciary (a non-technical body) on the Executive (a technical body) branch in the definition of health policies. In this sense, social and legal aspects of litigation are frequently neglected in the analyses.

Recently the social nature of the access to medicines has been increasingly recognized. This new approach acknowledges that the access to medicines, in addition to technical issues, depends on the interaction between the stakeholders' interests and values related to the medicines in their two roles in society: social goods and commodities.

With the aim of applying this framework to the analysis of litigation for access to medicines, this PhD thesis proposed a theoretical model based

on the definition of health needs, a topic rarely discussed in the health area. The model considers the following premises:

(a) Human needs are not facts (properties, states, processes, relations) about people, but values.

(b) Health systems are satisfiers of the human need for protection, and medicines are goods that allow increasing or decreasing the health systems' efficiency.

(c) When the definitions of medicines as a health need (according to Bradshaw's categories) do not coincide, the patient can resort to the Judiciary claiming access the medicines.

So, the theoretical model shows how the different factors and stakeholders related to the medicines influence the perceptions of the medicines as a health need, and modulate the occurrence of litigation for access to medicines. The theoretical model considers stakeholders and policies at different levels (international, national, and demand-side). This was useful to analyse the phenomenon at a local level and carry out cross-country comparisons.

The first part of the cross-country analysis evidenced that in the last fifteen years Argentina, Brazil, Chile, Colombia, and The Netherlands have taken measures aiming to improve the access to medicines in the three Universal Health Coverage dimensions. However, barriers to the access to medicines persist, despite the countries' efforts to achieve equitable access. The analysis suggests that the causes of inequity are similar among the countries, and are related to the health systems' fragmentation in different features such as financing, coverage, regulation and control. Furthermore, the results show that in all the studied countries lawsuits have become an alternative way for access to medicines, however the number of lawsuits and the involvement of the Judiciary varies across the countries.

The comparative analysis of the causes and consequences of litigation for access to medicines in Argentina, Brazil, Chile and Colombia corroborate the aforementioned findings. These causes and consequences related to health systems' 'software' and 'hardware' issues were the most frequently mentioned. Among them, the issues related to the definition of the list of covered medicines and the use of

this pathway by the pharmaceutical industry to force the inclusion of new products were especially highlighted.

Besides, the proposed theoretical model allowed a comprehensive view of the phenomenon. The results evidenced that other factors such as the non-social legitimacy of the Executive and health system managers and the disposition of the Judiciary to intervene in issues related to the right to health have also an important influence in the occurrence of litigation and its consequences. Due to the different characteristics and the consequences that litigation has had across the countries, general approaches are necessary to seek common tools to face the challenge of guaranteeing equitable access to medicines and healthcare services that improve the population's health.

In this sense, the comparison of the countries' responses to litigation for access to medicines shows that a the phenomenon's growth is not a triggering factor for macro interventions by the Judiciary branch, as in Argentina. Furthermore, the Brazilian and Colombian experiences allows inferring that in order to control the phenomenon of litigation it is not enough just to incorporate new technologies in the health systems' coverage. The respondents' experience demonstrates that the influence of other factors such as values and relationships among the stakeholders also needs to be discussed for a broader solution to the problem.

In conclusion, the complexity of the phenomenon requires comprehensive actions involving different actors in their discussions. The lawsuits can both demand the fulfilment of the health system's obligations and claim the health system's provision of new medicines whose efficacy and safety are uncertain. On the other hand, the sustainability of the health systems is essential both to guarantee the right to health and to guarantee itself the incorporation of new technologies. For this reason, it is worth remarking that in order to respond to litigation the countries need broad strategies. Such strategies should consider both measures for adequately overseeing the stakeholders in the execution of their duties and measures for regulating medicine prices and guaranteeing that intellectual property protection really generates innovations.

***Next steps***

The results of this study evidenced the complexity of litigation for access to medicines and some gaps in the literature about this issue. First, this study evidenced the necessity of conducting research under a social approach to the phenomenon as a fundamental source of information so as to achieve a comprehensive understanding of litigation for access to medicines. This type of research can be especially useful for exploring the impacts of the phenomenon at a demand-side level.

Taking into account the limited information about the profile of the lawsuits claiming access to medicines in the studied countries, except for Brazil, further research is also needed to characterize them. These studies will provide information for defining strategies to control litigation.

For the governments, the present study demonstrates the necessity to adopt a comprehensive approach to litigation, and to implement innovative strategies. Some strategies identified as potential solutions to the phenomenon include:

(a) Implementation of measures to promote a transparent relationship between the pharmaceutical industry and other stakeholders;
(b) Design of strategies to disseminate information not influenced by the pharmaceutical industry about medicines;
(c) Coordination of R&D policies and health system goals.
(d) Development of cooperation strategies between the Executive and the Judiciary in order to identify lawsuits due to failures in the health system, and lawsuits caused because of the pressure exerted by the pharmaceutical industry.
(e) Creation of courts specialized in issues related to the right to health.

## REFERENCES

ABRAHAM, J. On the prohibition of conflicts of interest in pharmaceutical regulation: precautionary limits and permissive challenges. A commentary on Sismondo (66:9, 2008, 1909-14) and O'Donovan and Lexchin. **Social Science & Medicine**, v. 70, n. 5, p. 648–651, mar. 2010.

ABRAMOVICH, V.; PAUTASSI, L.; FURIO, V. Judicial activism in the Argentine health system: Recent trends. **Health and Human Rights Journal**, v. 10, n. 2, p. 53–65, 2008.

ABRUTZKY, R.; BRAMUGLIA, C.; GODIO, C. Los sistemas de salud en los países del MERCOSUR. **Margen: revista de trabajo social y ciencias sociales**, n. 54, p. 24, 2009.

ACHESON, R. M. The definition and identification of need for health care. **Journal of Epidemiology and Community Health**, v. 32, n. 1, p. 10–15, mar. 1978.

ALVES, D. C.; BAHIA, L.; BARROSO, A. F. The role of the court system in regulating health insurance plans in Brazil. **Cadernos de Saúde Pública**, v. 25, n. 2, p. 279–290, 2009.

ANDERSON, G. F. The courts and health policy: strengths and limitations. **Health Affairs**, v. 11, n. 4, p. 95–110, 11 jan. 1992.

ANDERSON, R. Pharmaceutical industry gets high on fat profits. **BBC News**, 6 nov. 2014.

ANDRADE, E. I. G. et al. The judicialization of healthcare and the pharmaceutic care national policy in Brazil: the clinic management and the medicalization of the justice. **Rev. méd. Minas Gerais**, v. 18, n. 4,supl.4, p. S46–S50, dez. 2008.

ARGENTINA, ADMINISTRACIÓN DE PROGRAMAS ESPECIALES. **Resolución 1/98. Establécese el Programa de Cobertura de Alta Complejidad, a través del cual se financiará el pago de las prestaciones médicas, prótesis, órtesis, materia descartable y otras prácticas e insumos de alto costo.**, 20 abr. 1998. Disponível em: <http://www.infoleg.gob.ar/infolegInternet/anexos/50000-54999/50462/norma.htm>. Acesso em: 5 nov. 2015

ARGENTINA, ADMINISTRACIÓN DE PROGRAMAS ESPECIALES. **Resolución 500/2004. Establécese el nuevo Programa de Cobertura de**

**Prestaciones Médico Asistenciales, por medio del cual se otorgará apoyo financiero para el pago de determinadas prestaciones médicas, prótesis, órtesis, medicación y material descartable. Requisitos a cumplir por parte de los Agentes del Seguro de Salud.**, 27 jan. 2004. Disponível em: <http://infoleg.mecon.gov.ar/infolegInternet/anexos/90000-94999/92321/norma.htm>. Acesso em: 4 abr. 2016

ARGENTINA, CONGRESO DE LA NACIÓN. **Ley 24.754. Establécese que las empresas o entidades que presten dichos servicios deberán cubrir, como mínimo, determinadas "prestaciones obligatorias " dispuestas por las obras sociales.**, 28 nov. 1996. Disponível em: <http://infoleg.mecon.gov.ar/infolegInternet/anexos/40000-44999/41166/norma.htm>. Acesso em: 5 nov. 2015

ARGENTINA, CONGRESO DE LA NACIÓN. **Ley 26.682. Marco Regulatorio de Medicina Prepaga.**, 16 maio 2011. Disponível em: <http://www.infoleg.gov.ar/infolegInternet/anexos/180000-184999/182180/norma.htm>. Acesso em: 5 nov. 2015

ARGENTINA, INSTITUTO NACIONAL DE ESTADÍSTICA Y CENSOS - INDEC. **Censo 2010 Argentina**. 1. ed. Buenos Aires, Argentina: Instituto Nacional de Estadística y Censos, 2012. v. 2

ARGENTINA, MINISTERIO DE SALUD. **Resolución 310/2004. Modificación de la Resolución N° 201/2002, mediante la cual se aprobó el Programa Médico Obligatorio de Emergencia (PMOE) integrado por el conjunto de prestaciones básicas esenciales garantizadas por los Agentes del Seguro de Salud comprendidos en el Artículo 1° de la Ley N° 23.660.**, 4 jul. 2004. Disponível em: <http://www.infoleg.gob.ar/infolegInternet/anexos/90000-94999/94218/norma.htm>. Acesso em: 5 nov. 2015

ARGENTINA, MINISTERIO DE SALUD. **Resolución 1862/2011. Programa Federal de Salud "Incluir Salud". Funciones**, 11 ago. 2011. Disponível em: <http://www.infoleg.gov.ar/infolegInternet/anexos/185000-189999/189759/norma.htm>. Acesso em: 4 nov. 2015

ARGENTINA, MINISTERIO DE SALUD. **Resolución Nº 2206/2013. Convocase a la primera etapa de presentación de propuestas sobre fundamentos terapéuticos e informes sobre seguridad y efectividad de las tecnologías del sistema de tutelaje de tecnologías sanitarias emergentes que se detallan en el anexo I, el que se aprueba y forma parte integrante de la presente, en el marco del procedimiento de elaboración participativa de normas conforme el anexo V del Decreto Nº 1172/03-PEN.**, 27 jun. 2013a.

Disponível em: <http://www.infoleg.gob.ar/infolegInternet/anexos/215000-219999/216982/norma.htm>. Acesso em: 5 nov. 2015

ARGENTINA, MINISTERIO DE SALUD. **Resolución 2840/2013. Convocase a la presentación de propuestas por escrito sobre posibles modalidades de financiamiento, reaseguro, valores diferenciales y/o sistemas solidarios para la cobertura de las prestaciones de alto costo en el sistema de medicina prepaga, en el marco del procedimiento de elaboración participativa de normas establecido en el anexo V del Decreto N° 1172/03-PEN.**, 27 set. 2013b. Disponível em: <http://www.infoleg.gob.ar/infolegInternet/anexos/220000-224999/220697/norma.htm>. Acesso em: 5 nov. 2015

ARGENTINA, MINISTERIO DE SALUD. **Incluir Salud**. Disponível em: <http://www.msal.gob.ar/incluirsalud/index.php?option=com_content&view=article&id=385&Itemid=168>. Acesso em: 6 nov. 2015.

ARGENTINA, PRESIDENCIA. **Decreto 9/1993. Establécese que, los beneficios comprendidos en los artículos 8 y 9 de la Ley N° 23.966, tendrán libre elección de su obra social dentro de las comprendidas en los incisos a), b), c), d), y f) del artículo 1° de la citada Ley.**, 1 jul. 1993. Disponível em: <http://infoleg.mecon.gov.ar/infolegInternet/anexos/10000-14999/11554/texact.htm>. Acesso em: 6 nov. 2015

ARGENTINA, PRESIDENCIA. **Decreto 492/95. Programa Médico Obligatorio. Fusión de Obras Sociales. Reducción de Contribuciones Patronales. Trabajadores a tiempo parcial. Transformación y disolución de los Institutos de Servicios Sociales. Disposiciones Finales. Derógase el decreto N° 282/95.**, 22 set. 1995. Disponível em: <http://infoleg.mecon.gov.ar/infolegInternet/anexos/25000-29999/27540/norma.htm>. Acesso em: 5 nov. 2015

ARGENTINA, SUPERINTENDENCIA DE SERVICIOS DE SALUD. **Créase Sistema Unico de Reintegros. Normas generales. Limítase vigencia temporal de Normas —APE—.**, 21 set. 2012a. Disponível em: <http://www.infoleg.gob.ar/infolegInternet/anexos/200000-204999/202779/norma.htm>. Acesso em: 5 nov. 2015

ARGENTINA, SUPERINTENDENCIA DE SERVICIOS DE SALUD. **Resolución 1200/2012 Créase Sistema Unico de Reintegros. Normas generales. Limítase vigencia temporal de Normas —APE—**, 21 set. 2012b. Disponível em: <http://www.infoleg.gov.ar/infolegInternet/anexos/200000-204999/202779/texact.htm>. Acesso em: 16 mar. 2016

ARGENTINA, SUPERINTENDENCIA DE SERVICIOS DE SALUD. **Resolución 1561/2012. Créase el Procedimiento para Autorización de Reintegros del Sistema de Tutelaje de Tecnologías Sanitarias Emergentes.**, 30 nov. 2012c. Disponível em: <http://www.infoleg.gob.ar/infolegInternet/anexos/205000-209999/205595/norma.htm>. Acesso em: 5 nov. 2015

ASENSI, F. D. Judicialization or juridicization? Legal institutions and their strategies in health. **Physis: Revista de Saúde Coletiva**, v. 20, n. 1, p. 33–55, 2010.

ASI VAMOS EN SALUD. **Indicadores - Aseguramiento**. Disponível em: <http://www.asivamosensalud.org/inidicadores/aseguramiento/grafica.ver/15>.

ATUN, R. et al. Health-system reform and universal health coverage in Latin America. **The Lancet**, v. 385, n. 9974, p. 1230–1247, mar. 2015.

AUGUSTOVSKI, F. et al. Status Update of the Reimbursement Review Environment in the Public Sector across Four Latin American Countries. **Value in Health Regional Issues**, v. 1, n. 2, p. 223–227, dez. 2012.

BAPTISTA, T. W. DE F.; MACHADO, C. V.; DE-LIMA, L. D. State responsibility and right to health in Brazil: a balance of the Branches' actions. **Ciência & Saúde Coletiva**, n. 3, p. 829–839, 2009.

BARDIN, L. **Análise de conteúdo**. Lisboa: Edições 70, 1977.

BECERRIL-MONTEKIO, V. B.; MEDINA, G.; AQUINO, R. Sistema de salud de Brasil. **Salud Pública de México**, v. 53, p. s120–s131, jan. 2011.

BECERRIL-MONTEKIO, V.; REYES, J. DE D.; MANUEL, A. Sistema de salud de Chile. **Salud Pública de México**, v. 53, p. s132–s142, jan. 2011.

BELLÓ, M.; BECERRIL-MONTEKIO, V. M. Sistema de salud de Argentina. **Salud Pública de México**, v. 53, p. s96–s109, jan. 2011.

BELMARTINO, S. Equity issues in health care reform in Argentina. **Cadernos de Saúde Pública**, v. 18, n. 4, p. 1067–1076, 2002.

BERGALLO, P. Courts and social change: Lessons from the struggle to universalize access to HIV/AIDS treatment in Argentina. **Tex. L. Rev.**, v. 89, p. 1611, 2010.

BIEHL, J. et al. Between the court and the clinic: Lawsuits for medicines and the right to health in Brazil. **Health and Human Rights Journal**, v. 14, n. 1, p. E36-52, 2012.

BIEHL, J. The judicialization of biopolitics: Claiming the right to pharmaceuticals in Brazilian courts. **American Ethnologist**, v. 40, n. 3, p. 419–436, 2013.

BIEHL, J.; PETRYNA, A. Bodies of rights and therapeutic markets. **Social Research: An International Quarterly**, v. 78, n. 2, p. 359–386, 2011.

BIGDELI, M. et al. Access to medicines from a health system perspective. **Health Policy and Planning**, v. 28, n. 7, p. 692–704, out. 2013.

BIGDELI, M. et al. Medicines and universal health coverage: challenges and opportunities. **Journal of Pharmaceutical Policy and Practice**, v. 8, p. 8, 2015.

BORGES, D. DA C. L.; UGÁ, M. A. D. Legal suits concerning supply of medicines in the Brazilian public health system: Characteristics and limits for the judicial performance. **Revista de Direito Sanitário**, v. 10, n. 1, p. 13–38, 2009.

BORGES, D. DA C. L.; UGÁ, M. A. D. Conflicts and impasses in the judicialization of the supply of medicines: circuit court rulings on claims brought against the State of Rio de Janeiro, Brazil, in 2005. **Cad. Saúde Pública**, v. 26, n. 1, p. 59–69, 2010.

BOSSERT, T. et al. **Comparative Review of Health System Integration in Selected Countries in Latin America**. [s.l.] Inter-American Development Bank, 1 jan. 2014. Disponível em: <http://publications.iadb.org/handle/11319/6024>. Acesso em: 27 out. 2015.

BOY, R. et al. Ethical issues related to the access to orphan drugs in Brazil: the case of mucopolysaccharidosis type I. **Journal of Medical Ethics**, v. 37, n. 4, p. 233–239, 25 jan. 2011.

BRADSHAW, J. The taxonomy of social need. In: MCLACHLAN, G. (Ed.). . **Problems and Progress in Medical Care**. Oxford: Oxford University Press, 1972.

BRASIL. **Constituição da República Federativa do Brasil de 1988**, 1988. Disponível em:

<http://www.planalto.gov.br/ccivil_03/Constituicao/Constituicao.htm>. Acesso em: 2 mar. 2016

BRASIL. **Lei nº 8.080 de 19 de setembro de 1990. Dispõe sobre as condições para a promoção, proteção e recuperação da saúde, a organização e o funcionamento dos serviços correspondentes e dá outras providências.**, 19 set. 1990a. Disponível em: <http://www.planalto.gov.br/ccivil_03/leis/L8080.htm>. Acesso em: 17 mar. 2016

BRASIL. **Dispõe sobre as condições para a promoção, proteção e recuperação da saúde, a organização e o funcionamento dos serviços correspondentes e dá outras providências.**, 19 set. 1990b. Disponível em: <http://www.planalto.gov.br/ccivil_03/Leis/L8080.htm>. Acesso em: 6 nov. 2015

BRASIL. **Decreto nº 7508 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.**, 28 jul. 2011a. Disponível em: <http://www.planalto.gov.br/ccivil_03/_ato2011-2014/2011/decreto/D7508.htm>. Acesso em: 16 mar. 2016

BRASIL. **Lei 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.**, 28 nov. 2011b. Disponível em: <http://portalsaude.saude.gov.br/images/pdf/2014/janeiro/28/LEI-12401.pdf>. Acesso em: 19 fev. 2016

BRASIL. **Decreto nº 7.646 de 21 de dezembro de 2011. Dispõe sobre a Comissão Nacional de Incorporação de Tecnologias no Sistema Único de Saúde e sobre o processo administrativo para incorporação, exclusão e alteração de tecnologias em saúde pelo Sistema Único de Saúde - SUS, e dá outras providências.**, 21 dez. 2011c. Disponível em: <http://www.planalto.gov.br/ccivil_03/_Ato2011-2014/2011/Decreto/D7646.htm>. Acesso em: 20 fev. 2016

BRASIL, CONSELHO NACIONAL DE JUSTIÇA. **Recomendação n° 31 de 30 de março de 2010**. Brasilia: Conselho Nacional de Justiça, 2010a. Disponível em: <http://conselho.saude.gov.br/informativo/2010/31/reccnj_31.pdf>.

BRASIL, CONSELHO NACIONAL DE JUSTIÇA. **Resolução nº 107 de 06 de abril de 2010**, 6 abr. 2010b. Disponível em: <http://www.cnj.jus.br/busca-atos-adm>. Acesso em: 22 fev. 2016

BRASIL, CONSELHO NACIONAL DE SAÚDE. **Resolução n° 338 de 2004**, 5 jun. 2004. Disponível em: <http://repositorio.ufpe.br/handle/123456789/9696>. Acesso em: 5 nov. 2015

BRASIL, MINISTÉRIO DA SAÚDE. **Portaria n° 3.916 de 1998**, 30 out. 1998. Disponível em: <http://bvsms.saude.gov.br/bvs/saudelegis/gm/1998/prt3916_30_10_1998.html>. Acesso em: 5 nov. 2015

BRASIL, MINISTÉRIO DA SAÚDE. **Portaria nº 399 de 22 de fevereiro de 2006. Divulga o Pacto pela Saúde 2006 – Consolidação do SUS e aprova as Diretrizes Operacionais do Referido Pacto.**, 22 fev. 2006. Disponível em: <http://bvsms.saude.gov.br/bvs/saudelegis/gm/2006/prt0399_22_02_2006.html>. Acesso em: 26 mar. 2016

BRASIL, MINISTÉRIO DA SAÚDE. **Portaria nº 2.981 de 26 de novembro de 2009. Aprova o Componente Especializado da Assistência Farmacêutica**, 26 nov. 2009. Disponível em: <http://bvsms.saude.gov.br/bvs/saudelegis/gm/2009/prt2981_26_11_2009_rep.html>. Acesso em: 20 fev. 2016

BRASIL, MINISTÉRIO DA SAÚDE. **Da Excepcionalidade às Linhas de Cuidado: O Componente Especializado da Assistência Farmacêutica**. 1. ed. Brasilia: Ministério da Saúde, 2010.

BRASIL, MINISTÉRIO DA SAÚDE. **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 (SUS).**, 30 jun. 2013. Disponível em: <http://bvsms.saude.gov.br/bvs/saudelegis/gm/2013/prt1554_30_07_2013.html>. Acesso em: 20 fev. 2016

BRASIL, MINISTÉRIO DA SAÚDE. **Componente Especializado da Assistência Farmacêutica: inovação para a garantia do acesso a medicamentos no SUS**. 1. ed. Brasilia: Ministério da Saúde, 2014.

BRASIL, MINISTÉRIO DA SAÚDE. **Nota explicativa referente ao elenco da Rename 2014**, 2015. Disponível em: <http://u.saude.gov.br/images/pdf/2015/janeiro/13/Nota-explicativa-referente-ao-elenco-da-Rename-2014.pdf>. Acesso em: 6 abr. 2016

BRASIL, SUPREMO TRIBUNAL FEDERAL. **Despacho de convocação de audiência pública, de 5 de março de 2009**, 2009. Disponível em: <http://www.stf.jus.br/arquivo/cms/processoAudienciaPublicaSaude/anexo/Despacho_Convocatorio.pdf>. Acesso em: 18 fev. 2016

BRAZIL. **Investimentos em pesquisa**. Disponível em: <http://pesquisasaude.saude.gov.br/bdgdecit/index.php.>. Acesso em: 24 ago. 2013.

BÜRGIN, T. **El amparo judicial como instrumento de ampliación del PMO : El estado nacional como garante de la salud**. 1. ed. Buenos Aires, Argentina: Fundación Sanatorio Güemes, 2013.

BURGIN, T. Las enfermedades catastróficas desde una perspectiva judicial. In: **Respuestas a las enfermedades catastróficas**. 1ra. ed. Buenos Aires: Fundación CIPPEC, 2014. p. 125–154.

BUTTER, I. Health Manpower Research: A Survey. **Inquiry**, v. 4, n. 4, p. 5–41, 1967.

CAMARGO JR, K. R. DE. The pitfalls of the "positive concept of health". **Physis: Revista de Saúde Coletiva**, v. 17, n. 1, p. 63–76, abr. 2007.

CAVAGNERO, E. et al. **Health financing in Argentina: An empirical study of health care expenditure and utilization**. 1. ed. Mexico: Fundación Mexicana para la Salud, A. C., Instituto Nacional de Salud Pública, 2006.

CESCR COMMITTEE ON ECONOMIC, SOCIAL AND CULTURAL RIGHTS. **General CommentThe right to the highest attainable standard of health**, 2000. Disponível em: <http://www.unhchr.ch/tbs/doc.nsf/(symbol)/E.C.12.2000.4.En>. Acesso em: 5 nov. 2015

CHIEFFI, A. L.; BARATA, R. B. "Judicialization" of public health policy for distribution of medicines. **Cadernos de saúde pública**, v. 25, n. 8, p. 1839–1849, ago. 2009.

CHIEFFI, A. L.; BARATA, R. DE C. B. Legal suits: pharmaceutical industry strategies to introduce new drugs in the Brazilian public healthcare system. **Revista de Saúde Pública**, v. 44, n. 3, p. 421–429, 2010.

CHILE. **Ley N° 19.966 Establece un Régimen de Garantías Explícitas en Salud (AUGE)**, 25 ago. 2004. Disponível em:

<http://www.supersalud.gob.cl/normativa/571/w3-article-554.html>. Acesso em: 12 mar. 2016

CHILE. **Crea un sistema de protección financiera para diagnósticos y tratamientos de alto costo y rinde homenaje póstumo a Don Luis Ricarte Soto Gallegos**, 6 jan. 2015. Disponível em: <http://www.bcn.cl/leychile/Navegar?idNorma=1078148&idVersion=2222-02-02>. Acesso em: 5 nov. 2015

CHILE, COMISIÓN ASESORA PRESIDENCIAL. **Estudio y Propuesta de un Nuevo Marco Jurídico para el Sistema Privado de Salud**. Santiago de Chile: Ministerio de Salud, 2014. Disponível em: <http://web.minsal.cl/sites/default/files/Informe%20Final%20Comisi%C3%B3n%20Asesora%20Presidencial.pdf>. Acesso em: 5 nov. 2015.

CHILE, FONDO NACIONAL DE SALUD. **Medicamentos de Alto Costo**. Disponível em: <https://www.fonasa.cl/portal_fonasa/site/artic/20140711/pags/20140711025813.html>. Acesso em: 5 nov. 2015.

CHILE, MINISTERIO DE SALUD. **Decreto supremo n° 1, de 2010, aprueba garantías explícitas en salud del régimen general de garantías en salud**, 27 fev. 2010. Disponível em: <http://www.supersalud.gob.cl/normativa/571/articles-5768_recurso_1.pdf>. Acesso em: 12 mar. 2016

CHILE, MINISTERIO DE SALUD. **Decreto Supremo n° 4 de 2013, aprueba garantías explícitas en salud del régimen general de garantías en salud**, 5 fev. 2013. Disponível em: <http://www.supersalud.gob.cl/normativa/571/articles-8166_recurso_1.pdf>. Acesso em: 12 mar. 2016

CHILE, MINISTERIO DE SALUD. **Fondo de Farmacias**. Disponível em: <http://web.minsal.cl/fofar/>. Acesso em: 5 nov. 2015.

CHILE, SUPERINTENDENCIA DE SALUD. **Garantías Explícitas en Salud AUGE-GES - Orientación en Salud. Superintendencia de Salud. Gobierno de Chile.** Disponível em: <http://www.supersalud.gob.cl/difusion/572/w3-propertyvalue-3130.html>. Acesso em: 5 nov. 2015a.

CHILE, SUPERINTENDENCIA DE SALUD. **¿Fonasa o Isapre? - Orientación en Salud. Superintendencia de Salud. Gobierno de Chile.** Disponível em: <http://www.supersalud.gob.cl/difusion/572/w3-propertyvalue-3137.html>. Acesso em: 5 nov. 2015b.

CHILE, SUPERINTENDENCIA DE SALUD. **Seguro catastrófico - Preguntas Frecuentes. Superintendencia de Salud. Gobierno de Chile.** Disponível em: <http://www.supersalud.gob.cl/consultas/570/w3-propertyvalue-4010.html>. Acesso em: 5 nov. 2015c.

CHILE, SUPERINTENDENCIA DE SALUD. **Cobertura Adicional para Enfermedades Catastróficas (CAEC) - Preguntas Frecuentes.** Disponível em: <http://www.supersalud.gob.cl/consultas/570/w3-propertyvalue-4011.html>. Acesso em: 5 nov. 2015d.

CHILE, SUPERINTENDENCIA DE SALUD. **Isapres**. Disponível em: <http://www.supersalud.gob.cl/568/w3-article-2528.html>. Acesso em: 6 nov. 2015e.

CID, C. et al. Bases para una reforma necesaria al seguro social de salud chileno. In: **Propuestas para Chile**. Concurso Políticas Públicas. 1. ed. Santiago de Chile: Portificia Universidad Católica de Chile, 2013. p. 183–219.

COHEN, D.; CARTER, P. Conflicts of interest. WHO and the pandemic flu "conspiracies". **BMJ (Clinical research ed.)**, v. 340, p. c2912, 2010.

COLLEGE VOR ZORGVERZEKERINGEN. **CVZ: aparte financieringsvorm voor middelen bij Pompe & Fabry**. Persbericht: [s.n.]. Disponível em: <http://www.zonmw.nl/fileadmin/documenten/DO_Farmacotherapie_Dure_Weesgeneesmiddelen/persbericht-aparte-finan-pompe-fabry.pdf>. Acesso em: 3 nov. 2015.

COLOMBIA. **Por el cual se reglamenta la Ley 10 de 1990 en cuanto a la organización y funcionamiento de la medicina prepagada.**, 8 dez. 1993a. Disponível em: <https://www.minsalud.gov.co/Normatividad_Nuevo/DECRETO%201570%20DE%201993.pdf>. Acesso em: 5 nov. 2015

COLOMBIA. **Ley 100 de 1993 Por la cual se crea el sistema de seguridad social integral y se dictan otras disposiciones**, 24 dez. 1993b. Disponível em: <http://www.alcaldiabogota.gov.co/sisjur/normas/Norma1.jsp?i=5248>. Acesso em: 5 nov. 2015

COLOMBIA. **Decreto 1486 de 1994. Por el cual se reglamenta el Estatuto Orgánico del Sistema General de Seguridad Social en Salud en cuanto a la organización y funciones de la Medicina Prepagada, se modifica el Decreto 1570 de 1993 y se dictan otras disposiciones.**, 13 jul. 1994. Disponível em:

<http://www.icbf.gov.co/cargues/avance/docs/decreto_1486_1994.htm>. Acesso em: 6 nov. 2015

COLOMBIA. **Ley 715 de 2001. Por la cual se dictan normas orgánicas en materia de recursos y competencias de conformidad con los artículos 151, 288, 356 y 357 (Acto Legislativo 01 de 2001) de la Constitución Política y se dictan otras disposiciones**, 2 dez. 2001. Disponível em: <https://www.invima.gov.co/images/stories/normatividad/ley_715_2001.pdf>. Acesso em: 27 out. 2015

COLOMBIA. **Ley 1122 de 2007. Por la cual se hacen algunas modificaciones en el Sistema General de Seguridad Social en Salud y se dictan otras disposiciones.**, 9 jan. 2007. Disponível em: <http://www.alcaldiabogota.gov.co/sisjur/normas/Norma1.jsp?i=22600>. Acesso em: 27 out. 2015

COLOMBIA. **Ley 1438 de 2011. Por medio de la cual se reforma el Sistema General de Seguridad Social en Salud y se dictan otras disposiciones**, 19 jan. 2011. Disponível em: <http://www.alcaldiabogota.gov.co/sisjur/normas/Norma1.jsp?i=41355>. Acesso em: 5 nov. 2015

COLOMBIA, COMISIÓN DE REGULACIÓN EN SALUD – CRES. **Acuerdo 004 de 2009. Por el cual se da cumplimiento a la Sentencia T – 760 de 2008 de la Corte Constitucional**, 30 set. 2009. Disponível em: <https://www.minsalud.gov.co/Normatividad_Nuevo/ACUERDO%20004%20DE%202009.pdf>. Acesso em: 5 nov. 2015

COLOMBIA, COMISIÓN DE REGULACIÓN EN SALUD – CRES. **Acuerdo 011 de 2010. Por el cual se da cumplimiento al Auto número 342 de 2009 de la Honorable Corte Constitucional.**, 2 jan. 2010. Disponível em: <http://www.icbf.gov.co/cargues/avance/docs/acuerdo_cres_0011_2010.htm>. Acesso em: 5 nov. 2015

COLOMBIA, COMISIÓN DE REGULACIÓN EN SALUD – CRES. **Acuerdo 027 de 2011. Por el cual se unifican los Planes Obligatorios de Salud de los Regímenes Contributivo y Subsidiado a nivel nacional, para las personas de sesenta (60) y más años de edad y se modifica la Unidad de Pago por Capitación UPC del Régimen Subsidiado**, 11 out. 2011a. Disponível em: <http://www.icbf.gov.co/cargues/avance/docs/acuerdo_cres_0027_2011.htm>. Acesso em: 5 nov. 2015

COLOMBIA, COMISIÓN DE REGULACIÓN EN SALUD – CRES. **Acuerdo 029 de 2011. Por el cual se sustituye el Acuerdo 028 de 2011 que define,**

**aclara y actualiza integralmente el Plan Obligatorio de Salud**, 28 dez. 2011b. Disponível em: <http://www.alcaldiabogota.gov.co/sisjur/normas/Norma1.jsp?i=45257>. Acesso em: 5 nov. 2015

COLOMBIA, COMISIÓN DE REGULACIÓN EN SALUD – CRES. **Acuerdo 032 de 2012. Por el cual se unifican los Planes Obligatorios de Salud de los Regímenes Contributivo y Subsidiado a nivel nacional, para las personas de dieciocho (18) a cincuenta y nueve (59) años de edad y se define la Unidad de Pago por Capitación (UPC), del Régimen Subsidiado.**, 17 maio 2012. Disponível em: <http://www.alcaldiabogota.gov.co/sisjur/normas/Norma1.jsp?i=47532>. Acesso em: 27 out. 2015

COLOMBIA, CORTE CONSTITUCIONAL. **Sentencia T-760 de 2008**, 2008a. Disponível em: <http://www.corteconstitucional.gov.co/relatoria/2008/T-760-08.htm>. Acesso em: 7 out. 2015

COLOMBIA, CORTE CONSTITUCIONAL. **Sentencia T-760 de 2008**, 31 jul. 2008b. Disponível em: <http://www.corteconstitucional.gov.co/relatoria/2008/T-760-08.htm>. Acesso em: 21 fev. 2016

COLOMBIA, CORTE CONSTITUCIONAL. **Derecho a la Salud - Garantía iusfundamental**, 3 jul. 2013. Disponível em: <http://www.corteconstitucional.gov.co/RELATORIA/2013/T-115-13.htm>. Acesso em: 27 out. 2015

COLOMBIA, CUENTA DE ALTO COSTO. **Patologías**. Disponível em: <http://cuentadealtocosto.org/site/index.php/patologias>. Acesso em: 5 nov. 2015.

COLOMBIA, MINISTERIO DE LA PROTECCIÓN SOCIAL. **Por el cual se establecen algunas normas relacionadas con el Sistema General de Seguridad Social en Salud y se dictan otras disposiciones.**, 13 jul. 2007. Disponível em: <http://www.icbf.gov.co/cargues/avance/docs/decreto_2699_2007.htm>. Acesso em: 5 nov. 2015

COLOMBIA, MINISTERIO DE SALUD. **Resolución 5521 de 2013. Por la cual se define, aclara y actualiza integralmente el Plan Obligatorio de Salud (POS)**, 27 dez. 2013. Disponível em: <http://www.alcaldiabogota.gov.co/sisjur/normas/Norma1.jsp?i=60055#137>. Acesso em: 21 fev. 2016

COLOMBIA, MINISTERIO DE SALUD. **Resolucion 5521 de 2013 -Ajustes específicos**. [s.l: s.n.]. Disponível em: <http://pospopuli.minsalud.gov.co/LinkClick.aspx?fileticket=Rn-eaw_kr5A%3d&tabid=956&mid=1819>. Acesso em: 3 nov. 2015a.

COLOMBIA, MINISTERIO DE SALUD. **Comparación entre la 18a lista modelo de medicamentos esenciales de la OMS y la lista de medicamentos del Plan Obligatorio de salud de Colombia Resolución 5521 de 2013**. Bogotá, D.C. Colombia: Ministerio de Salud, 2014b. Disponível em: <https://www.minsalud.gov.co/salud/POS/mi-plan/Normatividad/17.%20Informe%20t%C3%A9cnico%20Medicamentos%20Esenciales%20Final.pdf>. Acesso em: 16 mar. 2016.

COLOMBIA, MINISTERIO DE SALUD. **Aseguramiento al Sistema General de Seguridad Social en Salud**Imprenta Nacional de Colombia, , 2014c. Disponível em: <http://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/VP/DOA/RL/cartillas-de-aseguramiento-al-sistema-general-de-seguridad-social-en-salud.pdf>

COLOMBIA, MINISTERIO DE SALUD Y PROTECCIÓN SOCIAL. **Copagos y cuotas moderadoras 2015**. Bogotá, D.C. Colombia: Ministerio de Salud, 2014a. Disponível em: <http://pospopuli.minsalud.gov.co/LinkClick.aspx?fileticket=NCLRrPFQfkY%3d&tabid=741&mid=1819>. Acesso em: 11 jun. 2015.

COLOMBIA, MINISTERIO DE SALUD Y PROTECCIÓN SOCIAL. Gobierno incrementa en 6,06% Unidad de pago por capitación (UPC) para 2015. **Boletín de Presna**, 19 dez. 2014b.

COLOMBIA, MINISTERIO DE SALUD Y PROTECCIÓN SOCIAL. **Plan Obligatorio de Salud**. Disponível em: <https://www.minsalud.gov.co/salud/POS/mi-plan/Paginas/Mi-Plan.aspx>. Acesso em: 27 out. 2015a.

COLOMBIA, MINISTERIO DE SALUD Y PROTECCIÓN SOCIAL. **Control de precios**. Disponível em: <https://www.minsalud.gov.co/salud/Paginas/sistema-informacion-precios-medicamentos.aspx>. Acesso em: 9 dez. 2015b.

COLOMBIA, MINISTERIO DE SALUD Y PROTECCIÓN SOCIAL. **Prestación del servicio de salud a la población pobre no asegurada y actividades no cubiertas con subsidios a la demanda**. Disponível em: <https://www.minsalud.gov.co/proteccionsocial/Financiamiento/Paginas/Sistem

a-General-de-Participaciones---Prestacion-de-servicios.aspx>. Acesso em: 6 nov. 2015c.

COLOMBIA, SUPERINTENDENCIA DE SALUD. **Afiliados Activos BDUA publicados por el Ministerio de Salud y Protección Social a Diciembre de 2014 – Régimen contributivo**. Bogotá, Colombia: Superintendencia de Salud, 2015a. Disponível em: <http://www.supersalud.gov.co/supersalud/Default.aspx?tabid=955>. Acesso em: 11 jun. 2015.

COLOMBIA, SUPERINTENDENCIA DE SALUD. **Afiliados Activos BDUA publicados por el Ministerio de Salud y Protección Social a Diciembre de 2014 – Régimen subsidiado**. Bogotá, Colombia: Superintendencia de Salud, 2015b. Disponível em: <http://www.supersalud.gov.co/supersalud/Default.aspx?tabid=956>. Acesso em: 11 jun. 2015.

COOPERATIVA.CL. Ley Ricarte Soto rige desde noviembre con 11 patologías. **Cooperativa.cl**, 28 out. 2015.

CORREA, C. **Propiedad intelectual y salud pública**. 1st. ed. Buenos Aires, Argentina: La ley, 2006.

COSTA, L. F. G. Medicine roll and the pronounced decision of superior court of justice STJ about social rights. **Revista de Direito Sanitário**, v. 5, n. 1, p. 119–135, 2004.

CUBILLOS, L. et al. Universal health coverage and litigation in Latin America. **Journal of Health Organization and Management**, v. 26, n. 3, p. 390–406, 2012.

DA-SILVA, V. A.; TERRAZAS, F. V. Claiming the right to health in Brazilian courts: The exclusion of the already excluded. **Law and Social Inquiry**, v. 36, n. 4, p. 825–853, 2008.

DALLARI, S. G. Judicial control of pharmaceutical care policy: law, science and technology. **Physis: Revista de Saúde Coletiva**, v. 20, n. 1, p. 57–75, 2010.

DEN EXTER, A.; HERMANS, B. Constitutional rights to health care: the consequences of placing limits on the right to health care in several Western and Eastern European countries. **European Journal of Health Law**, v. 5, n. 3, p. 261–289, set. 1998.

DINIZ, D.; MEDEIROS, M.; SCHWARTZ, I. V. D. Consequences of the judicialization of health policies: the cost of medicines for mucopolysaccharidosis. **Cadernos de Saúde Pública**, v. 28, n. 3, p. 479–489, 2012.

DO NASCIMENTO JÚNIOR, J. M. et al. Avanços e perspectivas da RENAME após novos marcos legais: o desafio de contribuir para um SUS único e integral. **Gestão e Saúde**, v. 6, n. 4, p. pàg–3354, 2015.

DONABEDIAN, A. **Aspects of medicalcare administration: specifying requirements for health care**. Cambridge: Harvard Univerty Press, 1974.

EIMER, T.; LÜTZ, S. Developmental states, civil society, and public health: Patent regulation for HIV/AIDS pharmaceuticals in India and Brazil. **Regulation & Governance**, v. 4, n. 2, p. 135–153, 1 jun. 2010.

EMMERICK, I. C. M. et al. Access to medicines in Latin America and the Caribbean (LAC): a scoping study. **BMJ open**, v. 3, n. 5, 2013.

ERVITI-LÓPEZ, J. Medicamentos biotecnológicos y cáncer: no es oro todo lo que reluce. **Boletín Terapéutico de Navarra**, v. 19, n. 4, p. 45–64, 2011.

FEDERAL TRADE COMMISSION. **FTC Study: In FY 2012, Branded Drug Firms Significantly Increased the Use of Potential Pay-for-Delay Settlements to Keep Generic Competitors off the Market**. Washington, D.C.: [s.n.]. Disponível em: <https://www.ftc.gov/news-events/press-releases/2013/01/ftc-study-fy-2012-branded-drug-firms-significantly-increased>. Acesso em: 7 out. 2015.

FERNALD, K. D. S. et al. The myth of the biotech revolution. **Technology and Investment**, v. 4, n. 3, p. 168–178, 2013.

FERNÁNDEZ PRIETO, A. et al. **Evaluación y Monitoreo 2013 Acceso a Medicamentos Diversas miradas. Un mismo derecho**. 1. ed. Buenos Aires, Argentina: Ministerio de Salud de la Nación. programa REMEDIAR+REDES, 2013.

FERRAZ, O. L. M. The right to health in the courts of Brazil: Worsening health inequities? **Health and Human Rights Journal**, p. 33–45, 2009.

FERRAZ, O. L. M. Harming the poor through social rights litigation: lessons from Brazil. **Texas Law Review**, v. 89, p. 1643, 2010.

FERRAZ, O. L. M.; VIEIRA, F. S. The Right to Health, Scarce Resources, and Equity: Inherent Risks in the Predominant Legal Interpretation. **Dados**, v. 52, n. 1, p. 223–51, 2009.

FIGUEIREDO, T. A.; PEPE, V. L. E.; OSORIO-DE-CASTRO, C. G. S. A sanitary focus on medicines lawsuit. **Physis: Revista de Saúde Coletiva**, v. 20, n. 1, p. 101–118, 2010.

FIGUEIREDO, T. A.; SCHRAMM, J. M. DE A.; PEPE, V. L. E. Seleção de medicamentos essenciais e a carga de doença no Brasil. **Cadernos de Saúde Pública**, v. 30, n. 11, p. 2344–2356, nov. 2014.

FLEURY, S.; MOLINA, C. G. Modelos de protección social. In: **"Diseño y gerencia de políticas y programas sociales**. [s.l.] INDES, 2002.

FLOOD, C. M. Supreme disagreement: The highest court affirms an empty right. **Canadian Medical Association Journal**, v. 173, n. 2, p. 142–143, 19 jul. 2005.

FONDO NACIONAL DE RECURSOS. **Política y gestión de la cobertura de medicamentos de alto costo. Relevamiento de la experiencia internacional y respuesta del Fondo Nacional de Recursos**. Primera ed. Montevideo: FNR, 2010.

FORD, N. Patents, Access to Medicines and the Role of Non-Governmental Organisations. **Journal of Generic Medicines: The Business Journal for the Generic Medicines Sector**, v. 1, n. 2, p. 137–145, 1 jan. 2004.

FORMAN, L. Justice and justiciability: Advancing solidarity and justice through South Africans' right to health jurisprudence. **Med. & L.**, v. 27, p. 661, 2008.

FOSTER, C. Simple rationality? The law of healthcare resource allocation in England. **Journal of Medical Ethics**, v. 33, n. 7, p. 404–407, jul. 2007.

FRENK, J. The Global Health System: Strengthening National Health Systems as the Next Step for Global Progress. **Plos Medicine**, v. 7, n. 1, p. e1000089, 2010.

GADELHA, P. et al. **Pesquisa nacional de saúde 2013: Acesso e utilização dos serviços de saúde, acidentes e violências : Brasil, grandes regiões e unidades da federação**. 1. ed. Rio de Janeiro: Instituto Brasileiro de Geografia e Estatística - IBGE, 2015.

GATINI, C.; ALVAREZ LEIVA, J.; GONZÁLEZ ESCALONA, F. **Salud en Chile 2010 - Panorama de la situación de salud y del sistema de salud en Chile**. 1. ed. Santiago de Chile: Oficina de la Representación OPS/OMS en Chile, 2011.

GAURI, V.; BRINKS, D. Rights-based approach to social and economic policy in developing countries: law, politics and impact. In: GAURI, V.; BRINKS, D. (Eds.). . **The Impact of Litigation for Claiming Economic and Social Rights**. 1. ed. Cambridge: Cambridge: University Press, 2007.

GIEDION, U. et al. **Health Benefit Plans in Latin America: A Regional Comparison**. [s.l.] Inter-American Development Bank, 2014.

GIEDION, U.; PANOPOULOU, G.; GÓMEZ-FRAGA, S. **Diseño y ajuste de los planes explícitos de beneficios: el caso de Colombia y México**: Serie Financiamiento del desarrollo. Santiago de Chile: Naciones Unidas, 2009. Disponível em: <http://repositorio.cepal.org/bitstream/handle/11362/5201/S0900746_es.pdf?sequence=1>.

GILSON, L. et al. Building the Field of Health Policy and Systems Research: Social Science Matters. **PLOS Med**, v. 8, n. 8, p. e1001079, 23 ago. 2011.

GLASSMAN, A. et al. Priority-Setting Institutions in Health: Recommendations from a Center for Global Development Working Group. **Global Heart**, Supporting Country-Led Approaches to NCD Prevention and Control. v. 7, n. 1, p. 13–34, mar. 2012.

GLOPPEN, S. Litigation as a strategy to hold governments accountable for implementing the right to health. **Health and Human Rights Journal**, p. 21–36, 2008.

GOLDMAN, A.; LOVE, J. **KEI TPP Briefing note 2015:1 Compulsory licenses on patents and the 3-step test | Knowledge Ecology International**: KEI TPP Briefing note. [s.l.] Knowledge Ecology International, 2015. Disponível em: <http://www.keionline.org/node/2231>. Acesso em: 7 out. 2015.

GOMES, D. F. et al. Judicialization of health and public hearing convened by the Supreme Court in 2009: what has changed since then? **Saúde em Debate**, v. 38, n. 100, p. 139–156, mar. 2014.

GONTIJO, G. D. Judicial interference in health rights. **Rev. méd. Minas Gerais**, v. 20, n. 4, 2010.

GOROKHOVICH, L. E.; CHALKIDOU, K.; SHANKAR, R. Improving Access to Innovative Medicines in Emerging Markets: Evidence and Diplomacy as Alternatives to the Unsustainable Status Quo. **Journal of Health Diplomacy**, v. 1, n. 1, 2013.

GUERRERO, R. et al. Sistema de salud de Colombia. **Salud Pública de México**, v. 53, p. s144–s155, jan. 2011.

HERNÁNDEZ, M. Health reform, equity, and the right to health in Colombia. **Cadernos de Saúde Pública**, v. 18, n. 4, p. 991–1001, 2002.

HOGERZEIL, H. et al. Is access to essential medicines as part of the fulfilment of the right to health enforceable through the courts? **The Lancet**, v. 368, n. 9532, p. 305–311, 2006.

HOGERZEIL, H. V. The concept of essential medicines: lessons for rich countries. **BMJ : British Medical Journal**, v. 329, n. 7475, p. 1169–1172, 13 nov. 2004.

HOGERZEIL, H. V. Essential medicines and human rights: what can they learn from each other? **Bulletin of the World Health Organization**, v. 84, n. 5, p. 371–375, 2006.

HOLGUIN, G. **La guerra contra los medicamentos genéricos: Un crimen silencioso**. 1. ed. Bogotá, D.C. Colombia: Penguin Random House Grupo Editoral SAS, 2014.

HOMEDES, N.; UGALDE, A. Neoliberal reforms in health services in Latin America: a critical view from two case studies. **Revista Panamericana de Salud Pública**, v. 17, n. 3, p. 210–220, 2005.

HOPKINS, M. M. et al. The myth of the biotech revolution: An assessment of technological, clinical and organisational change. **Research Policy**, v. 36, n. 4, p. 566–589, maio 2007.

HOUSE OF COMMONS. **The Influence of the Pharmaceutical Industry**. London, England: House of Commons, 2005. Disponível em: <http://www.publications.parliament.uk/pa/cm200405/cmselect/cmhealth/42/42.pdf>.

HYRY, H. I. et al. The legal imperative for treating rare disorders. **Orphanet Journal of Rare Diseases**, v. 8, p. 135, 2013.

ILLICH, I. **A expropriaçao da saúde: Némesis da Medicina**. 3. ed. Rio de Janeiro: Nueva Fronteira, 1975.

IMS INSTITUTE FOR HEALTHCARE INFORMATICS. **Global Outlook for Medicines Through 2018**. USA: [s.n.]. Disponível em: <http://www.imshealth.com/portal/site/imshealth/menuitem.762a961826aad98f53c753c71ad8c22a/?vgnextoid=266e05267aea9410VgnVCM10000076192ca2RCRD>. Acesso em: 16 out. 2015.

INSTITUTO CATALÁN DE FARMACOLOGÍA. La decepción de los coxibs. **Butlletí groc**, v. 18, n. 1, p. 1–4, fev. 2005.

INTERNATIONAL NETWORK OF AGENCIES FOR HEALTH TECHNOLOGY ASSESSMENT - INAHTA. **CONITEC – National Committee for Technology Incorporation**. Disponível em: <http://www.inahta.org/our-members/members/conitec/>. Acesso em: 3 nov. 2015.

JEFFERS, J. R.; BOGNANNO, M. F.; BARTLETT, J. C. On the demand versus need for medical services and the concept of "shortage". **American Journal of Public Health**, v. 61, n. 1, p. 46–63, jan. 1971.

JORDÁN, T. The change of the reference axis of the right to health's protection following the constitutional jurisprudence regarding the private health's sub-system. **Estudios constitucionales**, v. 11, n. 1, p. 333–380, 2013a.

JORDÁN, T. **Examen de la tutela jurisprudencial constitucional del derecho a la protección de la salud: El caso chileno**, 2013b.

KESSELRING, F. First fundamental decision of the Federal Supreme Court of Switzerland on cost-effectiveness in the area of human healthcare. **Eur. J. Risk Reg.**, v. 2, p. 442, 2011.

KORNIS, G. E. M. et al. Health regulation in Brazil: a brief survey of the decade from 1999 to 2008. **Physis: Revista de Saúde Coletiva**, v. 21, n. 3, p. 1077–1102, 2011.

KOUWENBERG, H.; BIJL, J. "Hoeveel mag 28 meter lopen van een Pompe-patiënt kosten?" **De Volkskrant**, 8 jan. 2012.

LABRA, M. E. Análise de políticas, modos de policy making e intermediação de interesses: uma revisão. **Physis Revista de Saúde Coletiva**, v. 9, n. 2, p. 131–166, 1999.

LAMPREA, E. Colombia's right-to-health litigation in a context of health care reform. In: FLOOD, C. M.; GROSS, A. (Eds.). . **The right to health at the public/private Divide: A global comparative study**. 1. ed. New York: Cambridge University Press, 2014. p. 131–158.

LAMPREA, E. **Derechos en la practica. Jueces litigantes y operadores de politicas de salud en Colombia**. Bogotá: Universidad De Los Andes, 2015.

LE POLAIN, M. et al. **Drug reimbursement systems: international comparison and policy recommendations**. Brussels: Belgian Health Care Knowledge Centre, 2010. Disponível em: <https://kce.fgov.be/sites/default/files/page_documents/KCE_147C_Drug_reimbursement_systems_4.pdf>.

LEITE, S. N. et al. Legal actions and administrative demands related to the guarantee of the right to drugs access in the city of Florianópolis-SC. **Revista de Direito Sanitário**, v. 10, n. 2, p. 13–28, 2009.

LEITE, S. N.; MAFRA, A. C. Que direito? Trajetórias e percepções dos usuários no processo de acesso a medicamentos por mandados judiciais em Santa Catarina. **Ciência & Saúde Coletiva**, v. 15, n. Suppl 1, p. 1665–1672, 2010.

LEVAC, D.; COLQUHOUN, H.; O'BRIEN, K. K. Scoping studies: advancing the methodology. **Implementation Science**, v. 5, p. 69, 2010.

LEVINO, A.; CARVALHO, E. F. DE. Comparative analysis of health systems on the triple border between Brazil, Colombia, and Peru. **Revista Panamericana de Salud Pública**, v. 30, n. 5, p. 490–500, nov. 2011.

LIFSCHITZ, E. ¿Cuáles son las enfermedades catastróficas? In: **Respuestas a las enfermedades catastróficas**. 1ra. ed. Buenos Aires: Fundación CIPPEC, 2014. p. 31–70.

LIGHT, D. W.; LEXCHIN, J. R. Pharmaceutical research and development: what do we get for all that money? **BMJ : British Medical Journal**, v. 345, 7 ago. 2012.

LIMA-DELLAMORA, E. DA C.; CAETANO, R.; OSORIO-DE-CASTRO, C. G. S. Dispensing specialized component medicines in areas of the State of Rio de Janeiro. **Ciência & Saúde Coletiva**, v. 17, n. 9, p. 2387–2396, set. 2012.

LLOYD-SHERLOCK, P. When social health insurance goes wrong: Lessons from Argentina and Mexico. **Social Policy and Administration**, v. 40, n. 4, p. 353–368, 2006.

LOBATO, L. DE V. C.; GIOVANELLA, L. Sistema de saúde: Origens, componentes e dinâmica. In: GIOVANELLA, L. et al. (Eds.). . **Políticas e Sistema de Saúde no Brasil**. 1ra reimpresão ed. Rio de Janeiro: Fiocruz, 2008. p. 107–140.

LOPES, L. C. et al. Rational use of anticancer drugs and patient lawsuits in the state of São Paulo, Southeastern Brazil. **Revista de Saúde Pública**, v. 44, n. 4, p. 620–628, 2010.

LOPES, M. et al. Ethical and legal conflicts in the use of drug eluting stents in Brazil. Analysis of the major controversies for the adoption of this technology in public and private health care systems in this country. **Rev Bras Cardiol Invas**, v. 17, n. 1, p. 117–132, 2009.

LU, Y. et al. **The World Medicines Situation 2011 - Medicine Expenditures**. Geneva, Switzerland: World Health Organization, 2011. Disponível em: <http://apps.who.int/medicinedocs/en/d/Js18767en/>. Acesso em: 19 out. 2015.

MACEDO, E. I. DE; LOPES, L. C.; BARBERATO-FILHO, S. A technical analysis of medicines request-related decision making in Brazilian courts. **Revista de Saúde Pública**, v. 45, n. 4, p. 706–713, 2011.

MACHADO, F. R. DE S. Contributions to the discussion of health judicialization in Brazil. **Revista de Direito Sanitário**, v. 9, n. 2, p. 73–91, 2008.

MACHADO, M. A. DE Á. et al. Judicialization of access to medicines in Minas Gerais state, Southeastern Brazil. **Revista de Saúde Pública**, v. 45, n. 3, p. 590–598, jun. 2011.

MACHADO-ALBA, J. E.; TORRES-RODRÍGUEZ, S.; VALLEJOS-NARVÁEZ, A. Effectiveness the pharmaceutical care in diabetic patients. **Colombia Medica**, v. 42, n. 1, p. 72–80, 2011.

MANFREDI, C. P.; MAIONI, A. Courts and health policy: Judicial policy making and publicly funded health care in Canada. **Journal of Health Politics, Policy and Law**, v. 27, n. 2, p. 213–240, 2002.

MARQUES, S. B. Judicialization of the right to health. **Revista de Direito Sanitário**, v. 9, n. 2, p. 65–72, 2008.

MARQUES, S. B.; DALLARI, S. G. Safeguarding of the social right to pharmaceutical assistance in the state of São Paulo, Brazil. **Rev Saúde Pública**, v. 41, n. 1, p. 1017, 2007.

MAX-NEEF, M.; ELIZALDE, A.; HOPENHAYN, M. **Desarrollo a escala humana: Conceptos, aplicaciones y algunas reflexiones**. 2nd. ed. Montevideo, Uruguay: Editorial Nordan-Comunidad, 1998.

MCHALE, J. V. Law, Patient's Rights and NHS Resource Allocation: Is Eurostar the Answer? **Health Care Analysis**, v. 14, n. 3, p. 169–183, 1 dez. 2006.

MEIER, B. M.; YAMIN, A. E. Right to health litigation and HIV/AIDS Policy. **The Journal of Law, Medicine & Ethics**, v. 39, n. s1, p. 81–84, 2011.

MEJÍA-ORTEGA, L. M.; FRANCO-GIRALDO, Á. Latin-American social protection and development models. **Revista de Salud Pública**, v. 9, n. 3, p. 471–483, 2007.

MESSEDER, A. M.; OSORIO-DE-CASTRO, C. G. S.; LUIZA, V. L. Can court injunctions guarantee access to medicines in the public sector? The experience in the State of Rio de Janeiro, Brazil. **Cadernos de Saúde Pública**, v. 21, n. 2, p. 525–534, abr. 2005.

MINAYO, M. C. DE S. **O Desafio Do Conhecimento: Pesquisa Qualitativa Em Saúde**. 2. ed. Sao Paulo: Hucitec, 1993.

MOLINA MARÍN, G. et al. Tutelage actions on health rights at the municipality of Leticia, in the Amazon River region of Colombia, 2004-2008. **Iatreia**, v. 23, n. 4, p. 335–343, dez. 2010.

MONTOYA-AGUILAR, C. **La Salud Dividida. Chile 1990-2010 Ideología, debates y decisiones acerca de la Salud: lo que dicen los documentos del período de los gobiernos de la Concertación**. 1. ed. Santiago: CEIBO, 2013.

MORGAN, S. et al. The cost of drug development: A systematic review. **Health Policy**, v. 100, n. 1, p. 4–17, abr. 2011.

MOYNIHAN, R.; HENRY, D. The Fight against Disease Mongering: Generating Knowledge for Action. **PLoS Med**, v. 3, n. 4, p. e191, 11 abr. 2006.

NATIONAL HEALTH CARE INSTITUTE. **Health Care Coverage: A well-balanced basic health care package**National Health Care Institute, , 2015. Disponível em:

<https://www.zorginstituutnederland.nl/binaries/content/documents/zinl-www/publicaties/publications-in-english/publications-in-english/publications-in-english/zinl%3Adocuments%5B4%5D/1506-health-care-coverage-a-well-balanced-basic-health-care-package/Health+Care+Coverage+%28A+well-balanced+basic+health+care+package%29.pdf>. Acesso em: 3 nov. 2015

NEWDICK, C. Accountability for Rationing-Theory into Practice. **The Journal of Law, Medicine & Ethics**, v. 33, n. 4, p. 660–668, 2005.

NIEZEN, M. G. H. et al. Inequalities in oncology care: Economic consequences of high cost drugs. **European Journal of Cancer**, v. 42, n. 17, p. 2887–2892, nov. 2006.

NORONHA, J. C.; SANTOS, I. S.; PEREIRA, T. R. Relações entre o SUS e a saúde suplementar: problemas e alternativas para o futuro do sistema universal. In: SANTOS, N. R. DOS; AMARANTE, P. D. DE C. (Eds.). . **Gestão pública e relação público privado na saúde**. Coleção Pensar em Saúde. 1. ed. Rio de Janeiro: Centro Brasileiro de Estudos de Saúde (Cebes), 2010. p. 152–179.

OLIVEIRA, E. B. DE. The Right to Health. **Revista de Direito Sanitário**, v. 2, n. 3, p. 36–58, 9 nov. 2001.

OLMEN, J. VAN et al. The Health System Dynamics Framework: The introduction of an analytical model for health system analysis and its application to two case-studies. **Health, Culture and Society**, v. 2, n. 1, p. 1–21, 23 mar. 2012.

PAIM, J. et al. The Brazilian health system: history, advances, and challenges. **The Lancet**, v. 377, n. 9779, p. 1778–1797, maio 2011.

PAINA, L.; PETERS, D. H. Understanding pathways for scaling up health services through the lens of complex adaptive systems. **Health Policy and Planning**, v. 27, n. 5, p. 365–373, 8 jan. 2012.

PAN-AMERICAN HEALTH ORGANIZATION. **Access to High-Cost Medicines in the Americas: Situation, Challenges and Perspectives.**: Technical Series - Essential Medicine, Access, and Innovation. Washington, D.C.: Pan-American Health Organization, 2010. Disponível em: <http://apps.who.int/medicinedocs/en/d/Js19112en/>. Acesso em: 7 out. 2015.

PANDOLFO, M.; DELDUQUE, M. C.; AMARAL, R. G. Aspectos jurídicos e sanitários condicionantes para o uso da via judicial no acesso aos medicamentos no Brasil. **Revista de Salud Pública**, v. 14, n. 2, p. 340–349, 2012.

PEPE, V. L. E. et al. Health litigation and new challenges in the management of pharmaceutical services. **Ciência & Saúde Coletiva**, v. 15, n. 5, p. 2405–2414, 2010a.

PEPE, V. L. E. et al. Characterization of lawsuits for the supply of "essential" medicines in the State of Rio de Janeiro, Brasil. **Cadernos de Saúde Pública**, v. 26, n. 3, p. 461–471, 2010b.

PEREHUDOFF, K.; ALVES, T. L. **Patient & Consumer Organisations at the European Medicines Agency Financial disclosure and transparency**. 1. ed. Amsterdam, Netherlands: Health Action International (HAI) Europe, 2010.

PEREHUDOFF, S. K.; LAING, R. O.; HOGERZEIL, H. V. Access to essential medicines in national constitutions. **Bulletin of the World Health Organization**, v. 88, n. 11, p. 800–800, 2010.

PEREIRA, J. R. et al. Situation of lawsuits concerning the access to medical products by the Health Department of Santa Catarina State, Brazil, during the years 2003 and 2004. **Ciência & Saúde Coletiva**, v. 15, p. 3551–3560, nov. 2010.

PINHEIRO, E. DOS S. et al. Production of antiretroviral drugs in middle- and low-income countries. **Antiviral Therapy**, v. 19, n. Suppl 3, p. 49–55, 2014.

PIOLA, S. F. et al. Gasto tributário e conflito distributivo na saúde. In: CASTRO, J. A. DE; SANTOS, C. H. M. DOS; RIBEIRO, J. A. C. (Eds.). . **Tributação e equidade no Brasil. Um registro da reflexão do IPEA no biênio 2008-2009**. 1. ed. Brasilia: Ipea, 2010. p. 351–373.

PIOLA, S. F. **Relatório Técnico de Análise da Matriz de Indicadores do Observatório Ibero-Americano de Políticas e Sistemas de Saúde (OIAPSS)**. Brasilia: Observatório Ibero-Americano de Políticas e Sistemas de Saúde, jul. 2015. Disponível em: <http://www.oiapss.org/wp-content/uploads/2015/07/Relat%C3%B3rio-T%C3%A9cnico_SERGIO-PIOLA.pdf>. Acesso em: 15 out. 2015.

POPE, C.; ZIEBLAND, S.; MAYS, N. Analysing qualitative data. **BMJ**, v. 320, n. 7227, p. 114–116, 8 jan. 2000.

PRADO, M. M. Provision of health care services and the right to health in Brazil: The long, winding and uncertain road to equality. In: FLOOD, C. M.; GROSS, A. (Eds.). . **The right to health at the public/private Divide: A global comparative study**. 1. ed. New York: Cambridge University Press, 2014. p. 319–345.

PRESCRIRE EDITORIAL STAFF. New drugs and indications in 2010: inadequate assessment; patients at risk. **Prescrire International**, v. 20, n. 115, p. 105–107, 109–110, abr. 2011.

PRESCRIRE EDITORIAL STAFF. ThThe Prescrire Awards 2014. **Prescrire International**, v. 35, n. 376, p. 85–88, fev. 2015.

PROGRAMA DE LAS NACIONES UNIDAS PARA EL DESARROLLO - PNUD; ORGANIZACIÓN PANAMERICANA DE LA SALUD - OPS; COMISIÓN ECONÓMICA PARA AMÉRICA LATINA Y EL CARIBE - CEPAL. **El sistema de salud argentino y su trayectoria de largo plazo: Logros alcanzados y desafíos futuros**Programa de las Naciones Unidas para el Desarrollo, , 2011. Disponível em: <http://www.paho.org/arg/images/Gallery/publicaciones/El%20sistema%20de%20salud%20argentino%20-%20pnud%20ops%20cepal.pdf?ua=1>. Acesso em: 30 out. 2015

REVEIZ, L. et al. [Right-to-health litigation in three Latin American countries: a systematic literature review]. **Revista Panamericana De Salud Pública = Pan American Journal of Public Health**, v. 33, n. 3, p. 213–222, mar. 2013.

RODRÍGUEZ-TEJADA, C. M.; MOLINA MARÍN, G.; JIMÉNEZ, S. A. Features of the protective actions related to health processed in Medellin, Colombia. **Investigación y Educación en Enfermería**, p. 92–100, 2010.

ROMERO, L. C. The jurisprudence of the Distrito Federal (Brazil) Court of Justice on medicaments lawsuits. **Revista de Direito Sanitário**, v. 11, n. 2, p. 11–59, 2010.

ROSSI, F. **¿Sslvamos los genéricos? Apuntes para una mejor comprensión del impacto del TLC en el acceso a los medicamentos y la Salud Pública.**Misión Salud, , 2006. Disponível em: <http://www.mision-salud.org/wp-content/uploads/2013/02/SALVAMOS-LOS-GENERICOS-F.ROSSI_.pdf>

ROSSI, F.; UMBACÍA, L. M.; SÁNCHEZ, E. **Anexo técnico: Inclusiones de medicamentos incorporados en el Plan Obligatorio de Salud (POS) – Acuerdo 029 de 2011**. Bogotá, D.C. Colombia: Fundación IFARMA, 2012. Disponível em: <http://viva.org.co/pdfs/comision_salud/documento_ifarma.pdf>. Acesso em: 4 nov. 2015.

ROVER, M. R. M. et al. Acceso a medicamentos de alto precio en Brasil: la perspectiva de médicos, farmacéuticos y usuarios. **Gaceta Sanitaria**, v. 30, n. 2, p. 110–116, fev. 2016.

SANCHEZ-SERRANO, I. **La crisis mundial de los sistemas de salud: Del laboratorio de investigaciones hasta la cama del paciente**. Traducción al español de la 1ra edición ed. Bogotá, Colombia: Elsevier, 2014.

SANT'ANA, J. M. B. et al. Essential drugs and pharmaceutical care: reflection on the access to drugs through lawsuits in Brazil. **Revista Panamericana de Salud Pública**, v. 29, n. 2, p. 138–144, 2011a.

SANT'ANA, J. M. B. et al. Rational therapeutics: health-related elements in lawsuits demanding medicines. **Revista de Saúde Pública**, v. 45, n. 4, p. 714–721, ago. 2011b.

SANTOS, B. DE S. **Pela mão de Alice. O social e o político na pos-modernidade**. 2. ed. São Paulo: Cortez, 2008.

SANTOS, R. I. DOS. **Concepções de assistência farmacêutica no contexto histórico brasileiro.** Doutorado en Farmacia—Florianópolis/SC, Brasil: Universidad Federal de Santa Catarina, 2011.

SANTOS-PINTO, C. D. B. et al. Novos delineamentos da Assistência Farmacêutica frente à regulamentação da Lei Orgânica da Saúde Essential medicines and technology incorporation following novel Brazilian Public Health. **Cad. Saúde Pública**, v. 29, n. 6, p. 1056–1058, 2013.

SANTOS-PINTO, C. D. B.; COSTA, N. DO R.; OSORIO-DE-CASTRO, C. G. S. The "Farmácia Popular do Brasil" Program and aspects of public provision of medicines in Brazil. **Ciência & Saúde Coletiva**, v. 16, n. 6, p. 2963–2973, jun. 2011.

SCHÄFER, W. et al. The Netherlands Health system review. **Health Services in Transition**, v. 12, n. 1, p. 1–228, 2010.

SEUBA, X. **La protección de la salud ante la regulación internacional de los productos farmacéuticos.** 1. ed. Barcelona: Marcial Pons, 2010.

SHEIKH, K. et al. Building the Field of Health Policy and Systems Research: Framing the Questions. **PLoS Medicine**, v. 8, n. 8, p. e1001073, 16 ago. 2011.

SOARES, L. **O acesso ao serviço de dispensação e a medicamentos: modelo teórico e elementos empíricos**. Doctorado em Farmácia—Florianópolis: Universidad Federal de Santa Catarina, 2013.

SORENSON, C.; DRUMMOND, M.; BHUIYAN KHAN, B. Medical technology as a key driver of rising health expenditure: disentangling the relationship. **ClinicoEconomics and Outcomes Research: CEOR**, v. 5, p. 223–234, 30 maio 2013.

STOLK, P.; WILLEMEN, M. J.; LEUFKENS, H. G. Rare essentials: drugs for rare diseases as essential medicines. **Bulletin of the World Health Organization**, v. 84, n. 9, p. 745–751, 2006.

SYRETT, K. Impotence or importance? Judicial review in an era of explicit NHS rationing. **The Modern Law Review**, v. 67, n. 2, p. 289–304, 2004.

TANAKA, O. Y. Juridical process of drugs prescription in the Brazilian public health system or the challenge of ensuring the constitutional right to drugs access. **Revista de Direito Sanitário**, v. 9, n. 1, p. 139–143, 2008.

TATE, N.; VALLINDER, T. (EDS.). **The Global Expansion of Judicial Power**. 1. ed. New York: NYU Press, 1995.

TESSER, C. D.; LUZ, M. T. An introduction to the contributions of contemporary epistemology to medicine. **Ciência & Saúde Coletiva**, v. 7, n. 2, p. 363–372, 2002.

THE NEHERLANDS, RECHTBANK. **ECLI:NL:HR:2014:3679, Hoge Raad, 13/04451**, 19 dez. 2014. Disponível em: <http://uitspraken.rechtspraak.nl/inziendocument?id=ECLI:NL:HR:2014:3679>. Acesso em: 9 dez. 2015

THE NEHERLANDS, RECHTBANK. **ECLI:NL:RBZWB:2015:6768, Rechtbank Zeeland-West-Brabant, 3063993-CV-EXPL-14-3979**, 28 out. 2015. Disponível em: <http://uitspraken.rechtspraak.nl/inziendocument?id=ECLI:NL:RBZWB:2015:6768>. Acesso em: 9 dez. 2015

TOBAR, F. Economía de los medicamentos genéricos en America Latina. **Revista Panamericana de Salud Publica/Pan American Journal of Public Health**, v. 23, n. 1, p. 59–67, 2008.

TOBAR, F. et al. **Un seguro nacional de enfermedades catastróficas: fundamentos para su implementación**Cippec, , 2012. Disponível em:

<http://www.cippec.org/documents/10179/51827/Un+seguro+nacional+de+enfermedades+catastroficas/7e0bf436-e50a-46a9-b524-38c90948be33>. Acesso em: 30 out. 2015

TOBAR, F. et al. **Respuestas a las enfermedades catastróficas**. 1ra. ed. Buenos Aires: Fundación CIPPEC, 2014.

TOBAR, F.; SANCHEZ, D. **El impacto de las políticas de medicamentos genéricos sobre el mercado de medicamentos en tres países del MERCOSUR**: Avances de Investigación. Montevideo: Fundación Carolina, 2005. Disponível em: <http://www.fundacioncarolina.es/wp-content/uploads/2014/07/Avance_Investigacion_12.pdf>.

UNITED NATIONS. **International Covenant on Economic, Social and Cultural Rights**, 1 mar. 1966. Disponível em: <http://www.ohchr.org/Documents/ProfessionalInterest/cescr.pdf>

UPRIMNY, R.; DURÁN, J. **Equidad y protección judicial del derecho a la salud en Colombia**. 1. ed. Santiago de Chile: United Nations, 2014.

VACCA, C. et al. Drug advertising and promotion: regulations and extent of compliance in five Latin American countries. **Revista Panamericana de Salud Pública**, v. 29, n. 2, p. 76–83, fev. 2011.

VALLE, G. H. M. DO; CAMARGO, J. M. P. The public hearing about health judicialization and its consequences in the jurisprudence of the Brazilian Federal Supreme Court. **Rev. direito sanit**, v. 11, n. 3, p. 13–31, fev. 2011.

VARGAS, I.; VÁZQUEZ, M. L.; JANÉ, E. Equidad y reformas de los sistemas de salud en Latinoamérica Equity and health systems reform in Latin America. **Cad. Saude Publica**, v. 18, n. 4, p. 927–937, 2002.

VARGAS-PELÁEZ, C. M. et al. Right to health, essential medicines, and lawsuits for access to medicines – A scoping study. **Social Science & Medicine**, v. 121, p. 48–55, nov. 2014.

VARGAS-ZEA, N. et al. Colombian Health System on its Way to Improve Allocation Efficiency—Transition from a Health Sector Reform to the Settlement of an HTA Agency. **Value in Health Regional Issues**, v. 1, n. 2, p. 218–222, dez. 2012.

VELASQUEZ, G. Rethinking The R&D Model for Pharmaceutical Products: A Binding Global Convention. **South Centre Policy Brief**, v. 8, p. 1–5, 2012.

VÉLEZ, A. L. The action tutelage: as mechanisms the protection right health an instrument of access to the health services? **Colombia Médica**, v. 36, n. 3, p. 199–208, set. 2005.

VÉLEZ-ARANGO, A. et al. Legal action as mechanisms of protection the right to health in Manizales, Colombia. **Rev Salud Pública**, v. 9, n. 2, p. 297–307, 2007.

VENTURA, M. et al. Judicialization of the right to health, access to justice and the effectiveness of the right to health. **Physis: Revista de Saúde Coletiva**, v. 20, n. 1, p. 77–100, 2010.

VIANNA, L. W. **A democracia e os três poderes no Brasil.** 1. ed. Belo Horizonte: Editora UFMG, 2002.

VICTORA, C. G. et al. Health conditions and health-policy innovations in Brazil: the way forward. **The Lancet**, v. 377, n. 9782, p. 2042–2053, jun. 2011.

VIEIRA, F. S. Right to health litigations: a discussion on the observance of the principles of Brazil's Health System. **Revista de Saúde Pública**, v. 42, n. 2, p. 365–369, 2008.

VIEIRA, F. S. et al. Pharmaceutical services and judicial decisions: proposals to improve access and rational use of medicines. **Revista de Administração em Saúde**, v. 12, p. 79–86, 2010.

VIEIRA, F. S.; ZUCCHI, P. Judicial demands and therapeutic assistance in the Brazilian Public Health System. **Revista da Associação Médica Brasileira**, v. 55, n. 6, p. 672–683, 2009.

WAGNER, A. K.; QUICK, J. D.; ROSS-DEGNAN, D. Quality use of medicines within universal health coverage: challenges and opportunities. **BMC Health Services Research**, v. 14, n. 1, p. 357, 27 ago. 2014.

WAMMES, J.; JEURISSEN, P.; WESTERT, G. The Dutch Health Care System, 2014. In: MOSSIALOS, E. et al. (Eds.). . **International Profiles Of Health Care Systems 2014**. 1. ed. New York: The Commonwealth Fund, 2015. p. 93–101.

WANNMACHER, L. Medicamentos essenciais: vantagens de trabalhar com este contexto. **OPAS. Uso Racional de Medicamentos: Temas Seleccionados**, v. 3, n. 2, p. 1–6, 2006.

WHA WORLD HEALTH ASSEMBLY. **Sustainable health financing, universal coverage and social health insurance**, 2005. Disponível em: <http://apps.who.int/iris/bitstream/10665/20383/1/WHA58_33-en.pdf?ua=1>

WHO WORLD HEALTH ORGANIZATION. **How to Develop and Implement a National Drug Policy**. 2. ed. Geneva, Switzerland: World Health Organization, 2001.

WHO WORLD HEALTH ORGANIZATION. **Public health, innovation and intellectual property rights. Report of Commission on Intellectual Property Rights, Innovation and Public Health**. Geneva, Switzerland: World Health Organization, 2006. Disponível em: <http://www.who.int/intellectualproperty/report/en/>. Acesso em: 7 out. 2015.

WHO WORLD HEALTH ORGANIZATION. **The world health report: Health systems financing: the path to universal coverage**. Geneva, Switzerland: [s.n.]. Disponível em: <http://www.who.int/whr/2010/en/>. Acesso em: 7 out. 2015.

WHO WORLD HEALTH ORGANIZATION. **WHO | Essential medicines**. Disponível em: <http://www.who.int/medicines/services/essmedicines_def/en/>. Acesso em: 7 out. 2015a.

WHO WORLD HEALTH ORGANIZATION. **WHO | WHO moves to improve access to lifesaving medicines for hepatitis C, drug-resistant TB and cancers**. Disponível em: <http://www.who.int/mediacentre/news/releases/2015/new-essential-medicines-list/en/>. Acesso em: 7 out. 2015b.

WILLARD, L. D. Needs and Medicine. **Journal of Medicine and Philosophy**, v. 7, n. 3, p. 259–274, 8 jan. 1982.

WILLIAMS, S. J.; MARTIN, P.; GABE, J. The pharmaceuticalisation of society? A framework for analysis. **Sociology of Health & Illness**, v. 33, n. 5, p. 710–725, 1 jul. 2011.

WTO WORLD TRADE ORGANIZATION. **Agreement on Trade-Related Aspects of Intellectual Property Rights**, 1995. Disponível em: <https://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm>. Acesso em: 7 out. 2015

WTO WORLD TRADE ORGANIZATION. **Declaration on the TRIPS agreement and public health**, 2001. Disponível em:

<https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm>. Acesso em: 7 out. 2015

YAMIN, A. E.; GLOPPEN, S. **Litigating Health Rights: can the courts bring more justice to health?** 1st. ed. United States of America: Harvard University Press, 2011.

YAMIN, A. E.; PARRA-VERA, O. How Do Courts Set Health Policy? The Case of the Colombian Constitutional Court. **PLoS Medicine**, v. 6, n. 2, p. e32, 2009.

YAMIN, A. E.; PARRA-VERA, O. Judicial Protection of the Right to Health in Colombia: From Social Demands to Individual Claims to Public Debates. **Hastings International and Comparative Law Review**, v. 33, p. 431, 1 jul. 2010.

YJILIOFF, R. D. Estructuras organizativas para dar respuesta a las enfermedades catastróficas. In: **Respuestas a las enfermedades catastróficas**. 1ra. ed. Buenos Aires: Fundación CIPPEC, 2014. p. 155–171.

ZORGINSTITUUT NEDERLAND. **Historie**. Disponível em: <https://www.zorginstituutnederland.nl/organisatie/historie>. Acesso em: 3 nov. 2015.

# ANNEXES

# ANNEX A – HEALTH SYSTEM ORGANIZATION: ARGENTINA, COLOMBIA, BRAZIL, CHILE AND THE NETHERLANDS

## 1. The Argentinian health system

The Argentinian health system is constituted by three subsectors. Public subsector corresponds to the public health system and the Federal Program *Incluir Salud*. Social insurance subsector correspond to *Obras sociales* (OS) and the National Institute of Social Services for Retirees and Pensioners/Integral Medical Care Plan (INSSJyP/PAMI). Private sector involves voluntary health insurance by direct payment or through the OS (ABRUTZKY; BRAMUGLIA; GODIO, 2009; BELLÓ; BECERRIL-MONTEKIO, 2011). According to the 2010 census, 46.4% of the population had health coverage by affiliation to an *Obra Social* (including PAMI), 10.6% had coverage by a private insurance company through OS (*deregulated*), 5.1% had voluntary private insurance (prepaid medicine); 1.8% had coverage for state health programs or plans. The other 36.1% did not have coverage in health for the other ways and for medical attention depend on the public subsector (ARGENTINA, INSTITUTO NACIONAL DE ESTADÍSTICA Y CENSOS - INDEC, 2012).

### 1.1. PUBLIC SECTOR:

In the public sector each of the 23 provinces and the Autonomous City of Buenos Aires are responsible for providing healthcare services in their territories. Healthcare services are provided by public hospitals and healthcare units, which are financed with national, provincial and municipal resources. National regulation related to the health system is not binding on the provinces; this is reason why the Nation must negotiate with the provincial ministries or secretaries of health the implementation of the regulatory measures in the Federal Health Council (COFESA). In addition, the Federal Program *Incluir Salud* is a Public Health Insurance system, which guarantees access to health services for mothers of seven or more children, disabled people and adults older than 70 years Non-Contributory Pensions (PNC) holders, among other groups (ARGENTINA, MINISTERIO DE SALUD, 2015). Although it is organized from the national level and operates under the

aegis of the National Ministry of Health, the implementation is provincial (TOBAR et al., 2012).

## 1.2. SOCIAL INSURANCE SECTOR:

The social insurance is conformed for about 280 National *Obras Sociales* (regulated by laws 23.660 and 23.661), armed forces, security, university Obras sociales, and the National Institute of Social Services for Retirees and Pensioners/Integral Medical Care Plan (INSSJyP/PAMI). All of them are regulated by the National Ministry of Health and the Superintendence of healthcare services. On the other hand, the Provincial OS depend on and are regulated by the ministry of health of each Province (CAVAGNERO et al., 2006; PROGRAMA DE LAS NACIONES UNIDAS PARA EL DESARROLLO - PNUD; ORGANIZACIÓN PANAMERICANA DE LA SALUD - OPS; COMISIÓN ECONÓMICA PARA AMÉRICA LATINA Y EL CARIBE - CEPAL, 2011). Since the National OS creation in 1940s until 1993, they were associated with different industrial sectors that had a monopolistic right over the formal labour force of each sector. In 1993 the deregulation of OS (ARGENTINA, PRESIDENCIA, 1993) broke the monopoly allowing that the workers could choose the insurance fund according to their preference, including the option of the private insurance companies. The deregulation also allows the OS contract private insurance companies for the management of resources and healthcare services(ABRUTZKY; BRAMUGLIA; GODIO, 2009; LLOYD-SHERLOCK, 2006). National social health insurance, is funded by a compulsory payroll contribution from employees (3%) and employers (6%) (CAVAGNERO et al., 2006). In Argentina there are almost 300 OS, the number of beneficiaries per entity vary between 3000 and more than 1 million, almost 70% of the affiliates are concentrated in only 30 insurance funds, and the distribution of the population according to age and gender among the OS is heterogeneous (PROGRAMA DE LAS NACIONES UNIDAS PARA EL DESARROLLO - PNUD; ORGANIZACIÓN PANAMERICANA DE LA SALUD - OPS; COMISIÓN ECONÓMICA PARA AMÉRICA LATINA Y EL CARIBE - CEPAL, 2011).

PAMI is funded by a portion of the compulsory payroll of the employees, compulsory income-dependent contributions of retirees (3 to 6%) and national resources (Belló and Montekio-Becerril, 2011; PNUD, 2011). Provincial social health insurance is funded by civil servants

(3%-5%) compulsory payroll contributions and provincial governments' contributions as employers (4%-6%) (BELLÓ; BECERRIL-MONTEKIO, 2011; PROGRAMA DE LAS NACIONES UNIDAS PARA EL DESARROLLO - PNUD; ORGANIZACIÓN PANAMERICANA DE LA SALUD - OPS; COMISIÓN ECONÓMICA PARA AMÉRICA LATINA Y EL CARIBE - CEPAL, 2011).

### 1.3. PRIVATE SUBSECTOR:

The private subsector is constituted by private insurance companies of diverse nature (commercial societies, civil associations, for profit or not-for profit), called *Empresas de medicina prepaga*. These companies are concentrated in the bigger cities and focused on high-income population (PNUD, 2011). Private institutions provide the healthcare services in this sector. The affiliation to a private insurance company could be by two ways: (a) by the *deregulation* mechanisms, that means, the person is affiliated to an OS that has a covenant with a private insurance company or (b) voluntary private insurance that could be made for individual or companies. In the case of *deregulation*, the OS transfers part of the compulsory payroll contributions for the insurance company and the user must pay and additional premium and co-payments to get access to the healthcare services of the insurance company. In the case of voluntary private insurance, the person or company contract the service directly with the insurance company (BELLÓ; BECERRIL-MONTEKIO, 2011).

## 2. The Colombian Health system

Since 1993, two subsectors, the General System of Social Security in Health (SGSSS) and the private sector constitute the Colombian health system. The basic principles of the SGSSS are efficiency, universality, solidarity, integrity, unity and participation. The SGSSS has three regimes: contributory regime focused in formal workers and employees; subsidized regime focussed on low-income population; and special regimes focused in employees of specific sectors. People uncovered by the health system, denominated *linked* (*vinculados*), depend on the public sector for access to healthcare services (COLOMBIA, 1993b). In 2014, 48.01% of the population was coverage for subsidize regime; 43.56% for contributory regime, 3.9% for special regimes; and 4.55% of the population was *linked* (ASI

VAMOS EN SALUD, 2015). In addition, the affiliates to contributory regime can buy private insurance (*medicina prepagada*).

The health system is based on the structured pluralism model (or managed competition) including market logic in the system. The social security and healthcare services networks management was decentralized and entrusted to the insurance companies, denominated *Health Promoting Enterprises (Empresas Promotoras de Salud – EPS*) which could be public, non-profit or profit companies (Vargas et al, 2002). Following the market logic, the people could choose an EPS, according with his/her preference for accessing healthcare services, and the institutions that provide healthcare services (public and private) have to compete for being contracted by the EPS (COLOMBIA, 1993b).

## 2.1. CONTRIBUTORY AND SUBSIDIZED REGIMES:

The contributory regime is funded by general taxes, oil funds, the Compulsory insurance for traffic accidents (SOAT), and contributions a compulsory payroll contribution from employees (4%) and employers (8,5%) which are collected by the EPS (COLOMBIA, MINISTERIO DE SALUD, 2014c). In this regime, there are 15 EPS; but six companies concentrate 75% of the affiliates (COLOMBIA, SUPERINTENDENCIA DE SALUD, 2015a). The subsidized regime is funded with fiscal transfers from the national government to the departments and municipalities (*Sistema General de Participaciones-SGP*) and 1.5% of the mandatory payrolls of the contributory and special regimes affiliates. Currently there are 52 EPS in this regime, called EPS-S, 20 of them concentrate 90% of the affiliates (COLOMBIA, SUPERINTENDENCIA DE SALUD, 2015b). All these resources are joined in the Solidarity and Guarantee Fund (FOSYGA) and then redistributed among the EPS/EPS-S by means of the per-capita Unit (UPC) per each affiliate (HOMEDES; UGALDE, 2005). In order to avoid adverse selection by the insurers, the UPC is adjusted for variables such as gender, age and geographical location (VARGAS; VÁZQUEZ; JANÉ, 2002). However, the subsidized regime UPC value is 12% lower than the subsidized regime UPCs value (COLOMBIA, MINISTERIO DE SALUD Y PROTECCIÓN SOCIAL, 2014b). Each insurer organizes the healthcare service networks with their own clinical or hospitals (maximum 30% of the value of health spending) (COLOMBIA, 2007) or by contracting private (profit or non-profit) healthcare service institutions (COLOMBIA, 1993b). The EPS-S must

contract with public hospitals at least 60% of health spending (COLOMBIA, 2007). In both of the regimes, the users must pay prorated fees and co-payments for accessing the healthcare service and some medicines covered by the health system. These values depend on the affiliate's income and the maximum values are defined by the Ministry of Health (COLOMBIA, MINISTERIO DE SALUD Y PROTECCIÓN SOCIAL, 2014a).

## 2.2. SPECIAL REGIMES

The special regimes are the armed forces, the National oil company (Ecopetrol) and public school and universities professors. The healthcare network as in the aforementioned regimes, could be organizing by contracting their own institutions, public or private (profit and non-profit) institutions (GUERRERO et al., 2011).

## 2.3. POOR UNINSURED POPULATION

The healthcare for poor people do not affiliated to the SGSSS is funding with resources of the SGP, by means of supply subsidies (COLOMBIA, MINISTERIO DE SALUD Y PROTECCIÓN SOCIAL, 2015c). The Secretaries of health of each municipality, district or department are the responsible for organizing the healthcare network, which usually is constituted by public hospitals (ESE).

## 2.4. PRIVATE SECTOR:

The private sector could be divided in two parts, the private insurance (*Medicina prepagada – Prepaid medical service*) and the out of pocket expenditure. Prepaid medical service is a form within the additional health plans established by Law 100 of 1993, which contributory regime affiliates can acquire, in order to obtain optional benefits such as care for events not included in POS, or different or additional conditions of hospitality and technology (COLOMBIA, 1993a). According to the regulations, prepaid medicine companies manage and provide care and services covered by a health plan prescribed, receiving in return the payment of an agreed regular price (COLOMBIA, 1994). This price is adjusted considering the gender, age, and health status of the individual (pre-existences). Finally, out of pocket expenditure occurs when the people do not have coverage by the

health system or when the access to the healthcare services or medicines in the health system is not opportune (GUERRERO et al., 2011).

## 3. The Brazilian health system

The health system in Brazil consists of public and private sectors. The public sector involves the Unified Health System (SUS) created by the National Constitution of 1988 considering as principles the universal and equitable access to comprehensiveness healthcare (LEVINO; CARVALHO, 2011). The private sector, called supplementary health system, corresponds to the insurance companies and the private healthcare institutions. Although all the citizens can access the public services, in 2013, 72.1% of the population depends on the SUS for access to healthcare services and 27.9% had some health insurance plan (GADELHA et al., 2015).

### 3.1. PUBLIC SECTOR

Since the National Constitution established the health is everyone's right and duty of the state, all the citizens have right to access healthcare services and medicines in the SUS free of charges. The Unified Health System is funding by tax revenues and social contributions from the federal, state and municipal budgets (PAIM et al., 2011). The management model of the system is decentralized and upward (from local to federal level) (BRASIL, 1990b), as well as, participative by considering the voice of the deliberative bodies for social control, such as, national health conferences, health councils and intermanagerial committees bipartite (state and municipalities) and tripartite (Union, states and municipalities) (PAIM et al., 2011). In addition, the health sector organization allows the government hire private healthcare services in order to complement the coverage of public health services (ABRUTZKY; BRAMUGLIA; GODIO, 2009).

The municipalities are responsible by the organization of the primary health care network, constituted by basic healthcare units, and the implementation of the Family Health Program (PSF). PSF works through family healthcare teams (one doctor, one nurse, one auxiliary nurse and four to six community health workers), the teams are located at PSF clinics, and each team is responsible for a specific geographical area and a defined population of 600-1000 families. To provide secondary care services the SUS is highly dependent on contracts with

the private sector, especially for diagnostic and therapeutic support services. In the case of tertiary care, that include some high-cost procedures, the SUS contract these services also with private providers and public teaching hospitals. The payment of these services occurs by the modality fee for service, and the SUS define the price for each procedure (PAIM et al., 2011).

### 3.2. PRIVATE SECTOR

In the private sector three segments coexist: (*i*) the specific health insurance plans for public servants (civil and military) and their dependants, funded by public resources and the own beneficiaries resources; (*ii*) the health insurance plans, of elective link, funding by employers or families; and (*iii*) Autonomous private health providers, which can be reached directly by out-of-pocket expenditure (PIOLA et al., 2010). The three segments are funding in some way by public funds, being the most direct in the first segment. In the segments (*ii*) and (*iii*) the transference of public funds to the private sector occurs by means of tax exemptions or tax breaks that reach the households and enterprises spending with medical care and private health insurance (NORONHA; SANTOS; PEREIRA, 2010; PIOLA et al., 2010). The insurance companies organize the healthcare service network with their own providers and by hiding other private institutions. The out-of-pocket expenditure for consultations or diagnostic procedures usually occurs when the healthcare service are not opportune in the SUS or in the health insurance, and the patient need to meet the criteria of the PCDT to receive for first time or continue the treatment (ROVER et al., 2016).

## 4. The Chilean health system

The Chilean health system is constituted by three subsectors. The public sector corresponds to the National Health Fund (FONASA); the private sector corresponds to the Health Insurance Institutions (ISAPREs); and the third subsector is the Armed Forces' health system. In 2014, 77% of the population was covered by FONASA; 17% was affiliated to the ISAPRES; and the Armed Forces' health system covered 3% (CHILE, COMISIÓN ASESORA PRESIDENCIAL, 2014). However, most of the resources are concentrated in the private sector, since the high-income population is affiliated to ISAPREs (MONTOYA-AGUILAR, 2013).

## 4.1. PUBLIC SECTOR

The public sector is funded by general taxes, the payroll mandatory contributions of the employees (equivalent to 7% of the salary) and the co-payments, all of these resources are joined in the National Health Fund (FONASA) that constitutes a solidary system (Chile, 2014). The FONASA affiliates are classified in four groups according to their income *Group A* are people without means; *Group B* are people which income is less than one minimum wage; Group C and D are people which income is higher than a minimum wage. FONASA offers two possible modalities for accessing the healthcare services the Institutional Attention Modality (MAI) and the Free Choice Modality (MLE) (CHILE, SUPERINTENDENCIA DE SALUD, 2015b).

## 4.2. PRIVATE SECTOR

The private sector is constituted by the Health Insurance Institutions (ISAPRE). In 2015, there are 6 closed ISAPRES and 7 open ISAPREs. Closed ISAPREs belong to public enterprises (State Bank, the National Copper Corporation of Chile–COTELCO and the Chemical and Mining Society of Chile–SQM) and only affiliate their employees (CHILE, COMISIÓN ASESORA PRESIDENCIAL, 2014). Open ISAPREs allow registration to the entire population with ability to pay (BECERRIL-MONTEKIO; REYES; MANUEL, 2011; CHILE, SUPERINTENDENCIA DE SALUD, 2015e). These health plans are funding by the mandatory payroll of the employees (7% of the wage) and additional voluntary contributions to afford the total plan price. Since this insurance is individual (in contrast with FONASA that is solidary) the plan prices depend on factors such as, age, gender and health status, being cheaper for men, young and healthy people (MONTOYA-AGUILAR, 2013). In 2014, there were more than 12.000 health plans in the market (CHILE, COMISIÓN ASESORA PRESIDENCIAL, 2014).

## 4.3. ARMED FORCES

Since 1996 the Ministry of Defence established the Armed Forces Health System that covers the Armed Forces personal and their

dependents. This subsystem is funded by general taxes, and the resources are deposited in the Curative and Preventive Medicine Fund for the Armed Forces. The Armed Forces' healthcare institutions are considered public, but usually they supply healthcare services for their beneficiaries and also sell healthcare services for other institutions in the health market. Moreover, the beneficiaries of this health subsystem also can access to healthcare services in the public services network, or even private institutions according the covenants of the Ministry of Defence (BECERRIL-MONTEKIO; REYES; MANUEL, 2011) .

Similar to the Colombian health system, Chilean system also incorporate the market logic for the healthcare system. The individual can choose among FONASA and the ISAPREs (BECERRIL-MONTEKIO; REYES; MANUEL, 2011).

## 5. The Dutch Health system

Since the health system reform stated by the *Health insurance Act (Zvw)* in 2006, the Dutch health system is constituted by two sectors, the compulsory social health insurance and the voluntary health insurance (SCHÄFER et al., 2010). In 2013, less than 0.2% of the Dutch population were uninsured, and most of the population (85%) purchases a mixture of complementary and supplementary voluntary insurance (WAMMES,; JEURISSEN; WESTERT, 2015). The Armed Forces has an independent health system managed by the Ministry of Defence.

The changes introduced by the reform included the abolition of the distinction between mandatory sickness fund insurance that covered the employed population in a regionalized way, which salary was not superior to a threshold; and the voluntary private insurance that covered the rest of the population. In addition, the managed competition among the actors of the health system was introduced, thus the patients can choose the insurer according to their preference, and the insurers can negotiate the price of the health care services with the general practitioners (GP) and the hospitals (SCHÄFER et al., 2010).

### 5.1. COMPULSORY SOCIAL HEALTH INSURANCE

The compulsory social health insurance consists of two compartments, one for long-term care, regulated by the Exceptional Medical Expenses Act (AWBZ) and the other for "basic health

insurance" regulated by the Health Insurance Act (Zvw). The AWBZ is mainly financed by income-dependent contributions and it intends to provide care services for people with chronic conditions requiring continuous care that involves considerable financial consequences (e.g. disabled people with congenital physical or mental disorders). These services are provided both in institutions (residential care) and in communities (home care) (SCHÄFER et al., 2010). The basic health insurance is funded by means of different sources. Firstly by income-related contributions, which are defined by the Ministry of Health. The income-related contribution is set at 7.75 % of annual taxable income up to €51,414 (as of 2014). Employers must reimburse employees for this contribution (employers contributions), and employees pay tax on the reimbursement. For those without an employer who do not receive unemployment benefits, such as the self-employed, the income-related contribution is 5.4% (WAMMES,; JEURISSEN; WESTERT, 2015).

Tax Office collects these contributions and transfers the money to the Health Insurance Fund (Zvf) (SCHÄFER et al., 2010). The Zvf distributes the money among the insurers according to a risk adjusted capitation considering features such as age, gender, labour forced status, region and health risk (based on past medicines and hospital utilization). Other sources are the nominal premiums that an insured person must pay directly to the insurance company. The insurers are free for setting the nominal premium level, but this must be community-rated, that is, everyone with the same insurer pays the same premium, regardless of age or health status (WAMMES,; JEURISSEN; WESTERT, 2015). For children below 18, the government covers the premium through a contribution into the Zvf (SCHÄFER et al., 2010).

Every insured person over age 18 must pay an annual deductible of €360 (USD436) (as of 2014) for health care costs, including costs of hospital admission and prescription drugs but excluding some services, such as GP visits. Apart from the overall deductible, patients are required to share some of the costs of selected services, such as medical transportation, via co-payments, coinsurance, or direct payments for services that are subsidized to a certain limit (WAMMES,; JEURISSEN; WESTERT, 2015).

A reimbursement limit is set for drugs in equivalent drug groups. Costs above that limit are not reimbursed. Providers are not allowed to balance-bill patients—that is, they are not allowed to charge above the

fee schedule. Patients with an in-kind insurance policy may be required to share the costs of care from a provider that is not contracted by the insurance company. Out-of-pocket expenses represented 11.9 percent of health care spending in 2011 (WAMMES,; JEURISSEN; WESTERT, 2015). In order to compensate for undesired effects for lower-income groups a *health care allowance* was created. This allowance is funded from general tax, and is set by the Ministry of Health. The value is calculated as the estimated average of the premiums offered by health insurers plus the compulsory deductible (SCHÄFER et al., 2010).

The primary care services are supplied by general practitioners (GPs). The GPs work as gatekeepers, thus hospital care and specialists care are only accessible upon referral from a GP, except for emergency care. All citizens are registered with a GP of their choice, usually in their own neighbourhood. The payment for GP, by the insurance companies, is a combination of a fee per capita and a fee for services. GP consultation is free of co-payment and is excluded from the deductible. Specialist care is supplied by hospitals, independent treatment centres and top clinical centres (specialized in e.g. cancer or organ transplantation) (SCHÄFER et al., 2010; WAMMES,; JEURISSEN; WESTERT, 2015).

Hospitals' budgets are determined through negotiations between insurers and hospitals over price and volume. The great majority of payments take place through the case-based diagnosis treatment combination system, and the rates for approximately 70 percent of hospital services are freely negotiable; each hospital negotiates with each insurer to set the rates. The remaining 30 percent are set nationally. In 2012, the diagnosis treatment combination system was fundamentally reformed, and the number of diagnosis treatment combinations was reduced from 30,000 to 4,400. Diagnosis treatment combinations cover both outpatient and inpatient as well as specialist costs, thereby strengthening the integration of specialist care in the hospital organization (SCHÄFER et al., 2010; WAMMES,; JEURISSEN; WESTERT, 2015).

## 5.2. VOLUNTARY HEALTH INSURANCE

Health insurers offer voluntary health insurance in combination with basic health insurance, but are not allowed to deny people complementary insurance if they decide to take out basic health

insurance with another health insurer. Health insurances are allowed to screen applicants and refuse them based on medical risk. People with voluntary health insurance do not receive faster access to any type of care, nor do they have increased choice of specialist or hospital (SCHÄFER et al., 2010; WAMMES,; JEURISSEN; WESTERT, 2015).

# ANNEX B – SPEECHES FRAGMENTS IN ORIGINAL LANGUAGE CITED IN CHAPTER 4

Box 4-1. Examples of the categories at International level

**Right to health in the International Human Right treaties and essential medicines definition**

"Nosotros vemos desde la Federación, dos… dos *puertas* que se encuentran. Una que es la filosofía del mercado y la otra es la filosofía de los derechos humanos como tal… Lo que sucede con el tema del acceso a medicamentos es la expresión también de ese choque de esas dos filosofías" (Colombia, Patient).

"… esos tres pilares [acceso a medicamentos, sostenibilidad del sistema y garantía del derecho fundamental] que al final hacen que, entre más caro sea el medicamento me inclino más por la economía que por el acceso al derecho". Eso es básicamente lo que hemos visto como problema grave, que no es, consideramos nosotros, un problema exclusivamente colombiano, sino que es una tendencia globalizada, mundial a… a, digamos, tener un principio economicista de los derechos fundamentales, del acceso a los derechos fundamentales" (Colombia, Patient).

"…todos sabemos, que las farmacéuticas fueron las que más hicieron lobby tanto en la ONU, en la OMS, en todos lados para que el derecho a la salud fuera un derecho fundamental en todos los países, porque tenían claro que la sociedad de manera individual no iba a poder comprar y pagar los costos de sus productos y lo mejor era que los Estados los pagaran" (Colombia, Patient).

**The market and the Innovation model and intellectual property protection – TRIPS**

"A primeira [causa] é a questão do mercado, o interesse no mercado, nas vendas e no faturamento por parte da indústria farmacêutica. Esse é o primeiro grande motivo, na minha opinião" (Brazil, manager).

"Creo que eso [la judicialización] está muy relacionado con el modelo de investigación y desarrollo, con que para la industria farmacéutica el tema del precio se solucionó muy fácil encontrando lo que se denominaría modelos de tercer pagador, entonces para ellos ya no es un problema que el medicamento valga 600 millones de pesos o 700 millones de pesos paciente/año porque en últimas no es el paciente de su propio bolsillo quien tiene que acceder [pagar], sino que es el sistema [de salud]" (Colombia, professional).

"El gran conflicto que hay hoy en día, tiene que ver con los medicamentos de alto costo, obviamente, por los valores que hay, porque son medicamentos que se sabe que están en el mercado sin una evidencia científica de que logren mejoría. En algunos casos si hay otros medicamentos ya en el mercado, no aseguran que sean mejores que los que hay, que a lo mejor, no son de alto costo (Argentina, NGO).

Box 4-2. Examples of causes related to the category right to health in the Political Constitution

"Son muchas las causas [de la judicialización]. En primer lugar, fundamentalmente, las normas tenemos que son muy amplias. Normas constitucionales y tratados con rango constitucional… que son muy amplias, en cuanto a la cobertura, con lo cual, prácticamente, cualquier paciente que pida cualquier prestación, los derechos son tan amplios que, de alguna manera, [los derechos] lo respaldan [al paciente] para pedirla [beneficios]" (Argentina, Executive).

"... [a nova constituição] era uma constituição muito mais aberta do que as anteriores, ai do regime militar, do período de repressão e uma constituição pela primeira vez na história do Brasil trazia uma série de direitos, entre eles ai, o chamado artigo 196 da constituição, que é um artigo que, de uma maneira muito ampla, muito genérica, ele prevê a saúde como um direito do cidadão e obrigação do estado, sem delimitar isso claramente" (Brazil, manager).

"La Constitución del 91 hizo dos cosas fundamentales en el país, introdujo el mercado en la prestación de servicios sociales, de servicios públicos en el país y en contrapeso, garantizó los derechos... [la Constitución] dejó explícitos los derechos de los ciudadanos y creo el mecanismo de la tutela para reclamarlos en caso de... de que se considerara que se violaban esos derechos" (Colombia, NGO).

Box 4-3. Examples of consequences related to the category right to health in the Political Constitution

"Pero yo diría que uno de los aspectos más negativos [de la judicialización] es [...] lo que yo llamo [...] la farmaceuticalización del derecho a la salud, en donde pareciera que todo se resuelve con fármacos" (Colombia, University lecturer)

"La tutela es […] por el medicamento que puede ser que sea muy costoso frente a uno que está en el POS y le agrega muy poquito a la vida. O sea, la relación costo-efectividad es muy bajita pero es la persona, el derecho es individual y no colectivo. Entonces estamos presionando por cosas de altísimo costo, de bajo impacto en la salud colectiva, y la platica se nos está yendo allá. O sea, hay toda una discusión del derecho colectivo vs. el derecho individual" (Colombia, manager).

"Si no tiene plata para contratar a un abogado, salen a los diarios, a los medios de comunicación denunciar una situación, y la gente no acepta ser discriminada por ser pobre, por no tener recursos, porque el estado tiene que resolverles los problemas" (Chile, lawyer).

Box 4-4. Examples of causes related to the category health system hardware

... el problema… es más económico, porque los recursos son escasos. Entonces… la falta de protección… es un común denominador (Argentina, Executive)

[se debe diferenciar] Qué parte de ese problema [judicialización] es ineficiencia de la EPS, mala prestación y mala gestión de la EPS, y qué parte es un problema estructural de déficit de recurso humano, sobretodo en especialistas y subespecialistas (Colombia, manager).

Aquí [en Argentina], hay una Administración Nacional de la época de [presidente] Menen, que es el ANMAT, la Administración Nacional de Medicamentos, Alimentos y Tecnologías, que dice, cuando se cumplimenten determinadas normas, si un medicamento ...puede entrar al mercado o no. Pero no hay nadie, no hay ninguna organización nacional, que diga si eso lo va a cubrir o no la seguridad social o el Estado, está bien? No hay nada. O sea, que está al libre albedrío de cualquier médico, porque el médico puede recetar lo que quiera (Argentina, NGO).

Box 4-5. Examples of consequences related to the category health system hardware

"Mirá, a veces [los impactos] sobre la obra social, lo malo es que [los jueces] te obligan a dar una prestación, económicamente a la obra social, obviamente, no le conviene, porque por estar obligados a brindar una determinada parte de la prestación, termina dando el doble o el triple de lo que tenías que dar... a la empresa [las acciones judiciales] le perjudica porque gastas el doble de lo que tenías pensado gastar para cubrir esa enfermedad" (Argentina, Manager).

"[A judicialização] também prejudica obviamente o orçamento, o orçamento do ministério da saúde pode ser comprometido por... pelo fato de atender pontualmente uma determinada ação judicial, isso nos coloca numa situação de constrangimento frequente, porque eu tenho que automaticamente alocar recursos. Não existe um recurso para uma judicial... isso não está no nosso arcabouço de colocá-los no orçamento. Então nós temos que parar a nossa execução orçamentária para atender uma ação específica" (Brazil, Executive).

"Do ponto de vista do estado a judicialização, ela traz uma desorganização de serviço na prática. Nós temos muita dificuldade em lidar como o volume das ações judiciais aqui no estado... Nós temos hoje uma concentração de ações judiciais aqui; e isso do ponto de vista da Secretaria estadual e das Secretarias municipais de saúde representa um volume improcessável, a gente não consegue dar respostas ao volume de ações judiciais que nós temos aqui. A estrutura do estado não está dimensionada para isso" (Brazil, manager).

"Definitivamente hay un impacto negativo dentro de las finanzas del sistema, porque al ser desordenada la forma en que la gente accede a las prestaciones no contenidas en el plan de beneficios, el sistema se ve en la necesidad de gastar una gran cantidad de recursos... en unas tecnologías terapéuticas, incluidos medicamentos.... que son muy altos y que hacen que el sistema pues tenga que dedicar gran parte de recursos" (Colombia, professional).

"Entonces, todo el mundo [con las acciones judiciales] genera ese desorden y el único perjudicado es el paciente, porque finalmente no se sigue la ruta que estamos siguiendo ahora, de incluir tecnologías en le POS que sean seguras, que sean efectivas, sino que... esa tutela [judicialización] comienza a darle cosas a todo el mundo que finalmente pueda que en algún momento sí le sirvan como pueda que no (Colombia, Executive).

"Debe haber un organismo estatal que pueda surtir de estos medicamentos de alto costo, con un presupuesto dado en la parte de presupuesto fiscal porque... verás que para una entidad privada, sobretodo como nosotros que no perseguimos fines de lucro.... nosotros con una de estas sanciones [decisiones

judiciales] nos vamos para atrás porque de estas resoluciones judiciales para nosotros gastar 20 millones en un medicamento, en una persona es mucha plata dentro de nuestro presupuesto que siempre tiene que tender al equilibrio" (Chile, manager).

Box 4-6. Examples of causes related to the category health system software

"El segundo de ellos [causas] es un incentivo perverso que se genera en la creación de las EPS en Colombia. El incentivo perverso, que es el que las mata y mata la forma en que se diseñó el sistema en Colombia, es que... el ánimo de lucro de estas empresas supone que si gastan... que si dan menos servicios [...] o gastan menos dinero, pueden ganar más dinero... Entonces hay una opinión generalizada, consecuente de ese modelo de contrato, no es que las EPS siempre lo hagan por eso, pero cada vez que nieguen o no den un servicio la gente va a creer que es en función del lucro, que es para ganar más plata que le están negando el servicio" (Colombia NGO).

"Y después en otros casos de tratamiento donde no está muy clara como va a ser la cobertura. Por ejemplo últimamente, fertilización asistida está [...] dentro del programa médico obligatorio, pero como no se reglamentaron un montón de cuestiones, no se sabe si esos medicamentos, que son caros, van a ser cubiertos al 40%, al 70% o al 100% [...] Entonces generalmente, la mayoría hoy de los reclamos que hay en fertilización asistida tienen que ver con reclamos de medicamentos al 100%, porque claro la obra social intenta cubrirlos al 40% al no haber reglamentación" (Argentina NGO).

"A gente identificou que havia uma já na porta de entrada [do serviço de saúde] uma resistência, né? No sentido do servidor público não fazer o que ele tinha que fazer, e ai a defensoria pública [...] tinha aquela visão de que para ela se afirmar ela tinha que ajuizar, então ela estava entrando com a ação. Então... havia um movimento favorável [na defensoria], mas o servidor não queria fazer o trabalho dele, de certa forma o não fornecimento adequado... pelo município, pelo estado possibilita algum favorecimento para alguma farmácia que seja do parente do secretário de saúde ou do perfeito. (Brazil, Judiciary).

"[En el AUGE] hay patologías que estratifican en rangos de edad el acceso a medicamentos... En este caso hay algunas cosas que... ciertos casos... de tal edad a tal edad se les dan medicamentos y a los otros no [...] Entonces los accesos no son estándares para todo el mundo, entonces van a haber personas que por un año de edad o por una situación [clínica] van a quedar fuera del acceso que tiene este programa" (Chile, Patient).

Box 4-7. Examples of consequences related to the category health system software

[Como consecuencia de la judicialización] “La política pública está demasiado guiada por el litigio, y en el contexto macro del sistema de salud el litigio es marginal en términos de acceso [...] menos del 0,5% de las acciones en salud se acceden [...] por mecanismos judiciales” (Colombia, NGO).

“En el caso del No POS los mecanismos de contratación de servicios de salud es *fee for service*, [...], nadie dice nada, nadie cuestiona nada... Entonces pues desde el punto de vista de un prestador, de un proveedor [incluyendo a la industria farmacéutica] pues esa es la lógica más razonable desde el punto de vista económico, y pues está amparado por una cosa que se llama tutela en Colombia”. (Colombia, manager).

“En el caso de las prestaciones que están dentro del Programa Médico Obligatorio, ahí no cabe duda, están a cargo de las obras sociales, [...], si se llegara a judicializar algo, [...] está correcto [...]. Si el paciente no se encuentra conforme con lo que la obra social le brinda y está dentro del Programa Médico Obligatorio, está perfecto que vaya y que vía judicial solicite, porque de alguna manera hay un contrato que se quebró” (Argentina, manager).

“Então assim, um grande número de ações individuais causam uma desorganização no sistema deles [dos entes responsáveis pela organização do sistema de saúde], que eles começam se mexer. [...] Eles começam ficar tão incomodados, que aí eles efetivamente começam a fazer alguma coisa, a alterar a política pública, entendeu? Então esse é um aspecto positivo mesmo” (Brazil, Judiciary).

Box 4-8. Examples of the category Pharmaceutical marketing

**Causes**

“Há evidência das indústrias farmacêuticas e os médicos aí, que são de alguma maneira influenciados pela indústria, também [os médicos] acabaram entrando nessa coisa [a judicialização] na medida que perceberam que o judiciário tinha, digamos assim, bons olhos para esse tipo de coisa [judicialização]” (Brazil, manager).

“Pero también hay que ver que hay intereses creados detrás de ellos [organizaciones de pacientes], que provocaron una judicialización también, y todavía importante ¿no? O sea se mueven los laboratorios muchas veces detrás

de los pacientes y hacen que bueno, rápidamente un medicamento que salió nuevo, ya al otro día lo están pidiendo. Decís ¿pero cómo puede ser? ¿no? Claro, el laboratorio se quiere resarcir rápido de los gastos de la investigación, y ya lo quiere colocar [el medicamento] en el mercado (Argentina NGO).

Las transnacionales [farmacéuticas] [...] van a presionar por vender los medicamentos de alto costo siempre y usa todas las estrategias para ello, desde las asociaciones de pacientes hasta los mismos abogados pagados para las asociaciones de pacientes para que exijan los medicamentos. Entonces tienen las transnacionales empujando la tutela (Colombia, NGO).

**Consequences**

"Unos datos chéveres, que teníamos, mostraban cómo unas farmacéuticas se llevaban, concentraban todos unos rubros y recobros buenísimos, súper jugosos, o sea, claramente había unas empresas a las que sí les iba muy bien con los recobros" (Colombia NGO).

Box 4-9. Examples of the category National policies for science and technology development, intellectual property protection and medicines prices control

**Causes**

"Cuando [la innovación] está en manos privadas, no podemos saber cuánto es el valor de esa innovación [...] el interés por el lucro se interpone en medio del acceso, y de alguna manera [...] se sujeta a estos países [subdesarrollados] a la regla del mercado, es decir, proteger patentes [...] que nosotros entendemos que es un estímulo para [investigar sobre] ciertas enfermedades [como] en el caso de los medicamentos huérfanos o en el caso de los medicamentos para pocos pacientes, pues resulta un estímulo interesante para innovar, pero al mismo tiempo no se hacen otro tipo de políticas públicas en las que se destine mucho dinero del estado para esa misma innovación" (Colombia, Patient).

"Entonces eso sumado a los altos precios por un Estado, que en el caso colombiano, no intervino los precios, sino que al contrario desbordó absolutamente y permitió que se hiciera el abuso, pues esto sí originó un mayor gasto en un grupo de medicamentos, [...] una parte un poquito de biotecnológicos y algunos de estructura química conocida [...] Se llega a la judicialización por todas las variables que hemos tenido en cuenta y a eso se le suma que [el estado colombiano] ha sido [...] cómplice y ha vendido también su ética de ministros, de congresistas a la industria para permitir liberar los precios" (Colombia, Patient).

"Então, você pega o medicamento [oncológico] que saiu recentemente, que é monopólio, está sob patente, provavelmente esse procedimento que nós pagamos para o prestador não vai dar conta de financiar esse medicamento e acaba gerando ação judicial" (Brazil, Executive).

**Consequences**

"Uma outra questão importante, que nós temos interesse por esse conjunto de medicamentos [do Componente Especializado da Assistência Farmacêutica - CEAF] é uma ação altamente estratégica, que é o seguinte, é o fortalecimento do complexo industrial da saúde [...] Esse componente [CEAF] é um componente que contribui muito para a política brasileira no campo do complexo industrial em saúde. Nós já estamos numa fase em que nós não estamos indo no mercado apenas para comprar medicamentos, nós estamos estimulando a produção nacional por meio de transferência tecnológica para produtos deste componente" (Brazil, Executive).

Lo importante [...] es que la Sentencia T-760 y el instrumento de supervisión del cumplimiento de esa sentencia, sí han permitido, digamos, acompañar toda la problemática desde el poder judicial, [incluyendo] la obligación de las autoridades gubernamentales de dar informes periódicos a la Corte, [...] hacen, digamos, seguramente por otras razones, que recientemente haya un cambio de la política pública sobre el control de los precios de los medicamentos, y la necesidad de que las empresas farmacéuticas no fijen, digamos, lo valores a su criterio, sino que el Estado está interesado por controlar ese tema (Colombia, Judicial).

Box 4-10. Examples of causes related to the category Judiciary Power

"Entiendo que uno [el juez] a veces no cuenta con demasiados elementos, digamos, el juez entiende derecho, no entiende mucho, a veces, de medicina. Entonces, a veces, no tenemos los suficientes elementos, ya de por sí, como para resolver si corresponde o no el amparo, si es urgente o no. En mi experiencia lo que hago, es tratar de investigar por mi cuenta... me meto a internet y empiezo a averiguar, sobre si realmente es urgente la situación.... pero bueno, a veces, uno siempre opta por, ante la duda, de concederle a la persona este amparo" (Argentina, Judicial).

"Lo que piensa la justicia es [...] hay un médico que lo pide, esta persona lo necesita y hay alguien que se lo niega que es la empresa de medicina prepaga [o la obra social]. [...] Más allá de los argumentos que vos puedas tener como financiador, la justicia falla a favor de eso, del pedido y de la persona que lo necesita" (Argentina, manager).

"Eu quando judicializo, eu passo por cima de todas essas divisões [da organização do sistema de saúde]. Porque se elas não estão funcionando na prática, eu ignoro, entendeu? Porque na verdade, qual é nosso grande fundamento, que a Constituição Federal ela diz que a responsabilidade é da União do estado e do município, eles se organizarem internamente, eu acho ótimo, desde que esteja dando certo" (Brazil, Judicial).

"La Corte [Suprema] razona sobre la base que el derecho a la protección de la salud tiene que aportar los medios para protegerla [...] En Chile, yo diría que casi todos estos recursos de protección se ganan, yo he visto la situación en Uruguay y en Uruguay [...] prácticamente el 15% de los recursos de protección se ha ganado, el resto se pierden, el poder judicial está más alineado un poco con el estado o las aseguradores, en cambio acá [Chile] no, el poder judicial está muy alineado con los consumidores, con los usuarios, con los pacientes" (Chile, Lawyer).

[En Colombia]... "ha habido un tema que uno podría llamar de movilización jurídica, o sea, el reconocimiento del derecho [a la salud] en la Constitución [...] y los jueces [tienen] una idea de conceder el derecho [a la salud] con la idea de que los derechos sociales también son protegibles por vía judicial". (Colombia, NGO)

Box 4-11. Examples of consequences related to the category Judiciary Power

"Porque esto perjudica [...] en lo judicial también, porque judicial nosotros, ya de por sí, estamos desbordados con la cantidad de causas judiciales que tenemos de toda índole ¿no? tanto civil, como penal. Entonces todos estos casos que empiezan a llegar de esta manera por supuesto suman, a lo que ya el poder judicial tiene" (Argentina, professional).

"Yo creo que un juzgado que no debería estar recibiendo ese número [de acciones judiciales], es un trabajo adicional en horas/hombre sí? Y eso implica que debe tener más personas, porque [el juzgado] debe responder primero en 10 días, porque [la acción judicial] es [sobre] salud y segundo las [acciones judiciales] que colocan medida pre-cautelar [el plazo para responder] es en 24 horas, entonces obviamente eso implica un recargo más administrativo de la gente de la rama judicial, en lo cual creo que nadie lo proyectó... [Además] nadie tampoco previó que se le está perdiendo el respeto a la tutela [...] evolucionamos en que ya nadie cumple la tutela, y ya la Corte [Constitucional] se tiene que pronunciar frente a una tutela de desacato" (Colombia, patient).

"A via judicial, embora fosse muito utilizada, não era uma garantia de acesso [a medicamentos], por quê, porque o estado não conseguia dar conta" (Brazil, manager).

Box 4-12. Examples of the category Medicines as health needs

"Me parece que se há uma necessidade de judicialização de um pedido [de um medicamento] por parte de um paciente, parte do princípio [...] de que há uma negativa do estado para o fornecimento [do medicamento] e isso é o básico, é a negativa à necessidade" (Brazil, patient).

"Que lo que es hoy y, sabemos como todo, que el recurso es muy limitado [y] las necesidades son ilimitadas, pero nosotros no podemos hacer que el sistema de salud caiga por la borda" (Argentina, professional).

Box 4-13. Examples of causes related to the category Demand side level

"Con el avance evidentemente de la información que reciben los pacientes [...] los pacientes van cambiando [... de] Los que eran pacientes común denominador eran pacientes pasivos, podríamos decir: Doctor, ¿Qué será lo que tengo? ¿Qué es lo que me tengo que tomar o qué es lo que puedo tomar? A un paciente que dice tengo esto, tengo esta enfermedad, tengo que tomar este medicamentos, me hace la receta" (Argentina, Executive).

"La gente no se esmera en conocer a qué tiene derecho" (Colombia, Executive).

"Esa conciencia del derecho y [de] que el mecanismo de la tutela funciona rápido, eficaz, para obtener concretamente el medicamentos, entonces genera como esa idea de 'yo tengo ese derecho, entonces yo lo puedo reclamar, si [las EPS] me lo niegan [el medicamento] yo lo reclamo'..." (Colombia, NGO).

"Hay en la sociedad una creencia, de que el poder judicial tiene las soluciones cuando el resto de los poderes [Ejecutivo y Legislativo] fallan" (Argentina, Judiciary).

Box 4-14. Examples of consequences related to the category Demand side level

"Considero totalmente positivo lo que ha sido el mejorar el acceso a medicamentos [...] y defender evidentemente el derecho de los pacientes que sí lo necesitan" (Colombia Professional).

"Para el paciente es importante, que ya entendió que tiene un derecho [...], que ya la mayoría de la gente conoce que hay un derecho y que hay un mecanismo para exigirlo" (Colombia, Patient).

"Un tema [...] que generan las prestaciones a través de amparo es que no es del todo equitativo, no sólo por lo que afecta el presupuesto para los restantes pacientes, sino también porque el acceso al amparo es para determinado grupo de población, que de algún modo se entera, tiene cierta llegada a distintos grupos de abogados, a distintas organizaciones, etc." (Argentina, Executive).

"Pero también hay otro problema, que es que no todas las personas tienen acceso a un abogado para hacer un recurso de protección, entonces el tema es absolutamente perjudicial para los pacientes" (Chile, lawyer).

"Outra questão que pode colocar dificuldade é a falta de segurança do usuário. Então [o juiz] ao tomar a decisão de atender a uma determinada ação, por exemplo, de um medicamento que já foi incorporado no SUS [pero para indicações não consideradas no CEAF], isso pode colocar em xeque a própria segurança do usuário" (Brazil, Executive).