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Judicialization of access to medicines in Minas Gerais state, Southeastern Brazil

ABSTRACT

OBJECTIVE: To analyze the profile of claimants and medicines demanded in lawsuits.

METHODS: Descriptive study that examined 827 lawsuits with 1,777 demands of access to medicines in the period between July 2005 and June 2006 in the state of Minas Gerais, Southeastern Brazil. There were examined the type of health care provided to claimants and their attorneyship. The medicines were described based on the following: drug registration at the National Health Surveillance Agency (Anvisa); wheter they were essential medicines; supply in the Brazilian Health System programs; and evidence of drug efficacy.

RESULTS: More than 70% of the claimants were provided care in the private health system and 60.3% hired private lawyers. The most common diagnosis of claimants was rheumatoid arthritis (23.1%) and the immunosuppressant agents were the most frequent demand medicines (mainly adalimumab and etanercept). Approximately 5% of the medicines demanded were not registered at Anvisa, 19.6% were included in the Brazilian List of Essential Medicine, 24.3% were included in the High-Cost Drug Program and 53.9% showed consistent evidence of efficacy. Among the medicines that were not available in Brazilian Health System, 79.0% had therapeutic alternatives in drug programs.

CONCLUSIONS: The phenomenon of judicialization of health in Brazil can point out failures in the public health system as some medicines demanded are included in its lists. However, it is a barrier for rational drug use and application of the National Drug Policy guidelines, especially when there are demanded medicines with no evidence of efficacy and that are not included in Brazilian Health System standards.

DESCRIPTORS: Pharmaceutical Services. National Drug Policy. Right to Health. Judicial Decisions.

INTRODUCTION

The judicialization of health care is a phenomenon that may hinder the implementation of health policies within the Sistema Único de Saúde (SUS – Brazilian Unified Health System) as the enforcement of court orders regarding supply of medicines, inputs and provision of health services entails non-budgeted high costs. In 2005, the Brazilian Government spent 2.5 million reais to provide medicines demanded through lawsuits and was named as a defendant in 387 lawsuits. In 2007, it spent 15 million reais in about 3,000 lawsuits and in 2008, it totaled 52 million reais.[a,b] The southeastern state of Minas Gerais spent 8.5 million, 22.8

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[a] Ministério da Saúde. Ações judiciais comprometem política de saúde. Brasília; 2008[cited 2008 Oct 06]. Available from: http://portal.saude.gov.br/portal/aplicacoes/noticias/default.cfm?pg=dspDetalheNoticia&id_area=1450&CO_NOTICIA=9633

[b] Ministério da Saúde. Ministério defende equilíbrio nas ações judiciais de saúde. Brasília; 2009[cited 2010 Feb 02]. Available from: http://portal.saude.gov.br/portal/aplicacoes/noticias/default.cfm?pg=dspDetalheNoticia&id_area=124&CO_NOTICIA=10167

million and 42.5 million reais in 2005, 2007 and 2008, respectively to enforce health-related court orders.[c]

The Brazilian National Council of Secretaries of Health reported that in 2004 lawsuits for the supply of high-cost medicines were frequent in 18 Brazilian states and the main reasons for filing them included drug shortages, non-compliance with criteria of clinical protocols and demand of non-standard medicines.[d] Medicines available at the primary care level and other drugs either not registered at the Agência Nacional de Vigilância Sanitária (ANVISA – National Health Surveillance Agency) or without evidence of efficacy were also demanded through lawsuits.[10,14]

One of SUS functions is to provide comprehensive health care. The Brazilian National Drug Policy[e] was developed to ensure people's access to safe, effective quality drugs and to promote their rational use. However, patients have been resorting to the court actions and the use of this means for ensuring access to medicines may have a negative impact on health equity.[14] This policy establishes the responsibilities of each government sphere regarding pharmaceutical services but this is overlooked in the process of judicialization of health. The local level is often required to provide medicines included in the High-Cost Drug Program,[f] which is managed by the state administration, and in turn the states are required to provide primary care drugs.[10,14]

Few studies have evaluated the judicialization of public health. This is a new phenomenon that needs further understanding to be appropriately addressed. Among the actions filed against the Brazilian Ministry of Health between January 2003 and August 2005, the greatest number of claims for drugs was seen in the state of Minas Gerais.[g] Thus, the present study aimed to examine the profile of claimants and medicines demanded in lawsuits.

METHODS

A descriptive study of lawsuits for access to medicines was conducted in the state of Minas Gerais in July 2005 to June 2006. Data was collected by trained staff using a pre-tested structured questionnaire. Data were obtained at the Attorney General Office of the State of Minas Gerais in the city of Belo Horizonte and at regional offices in Juiz de Fora, Uberlândia, Divinópolis and Passos from November 2006 to May 2007.

The variables studied included: number of lawsuits; counselor,[h] sex, age, occupation, city of residence and attorneyship; prescriber's name; type of health care provided (public/private); city where health care was provided; the claimant's diagnosis; name, presentation and concentration of the drug(s) demanded. Attorneyship was categorized as follows: attorney office, public defender, prosecutor, legal advice services and special court at the federal level.

The drugs were classified according to the Anatomical Therapeutic Chemical Classification System (ATC code),[i] drug registration at Anvisa; whether they were essential medicines; and supply in SUS programs.

Information on drug registration in Brazil was obtained from Anvisa database for drugs and blood products.[j] It was checked whether the drugs were listed in the Brazilian List of Essential Medicines (2006) and the World Health Organization (WHO) Model List of Essential Medicines (2007).[k,l]

The drugs were classified according to whether they were included in standard lists of medicines of the Health Department of the State of Minas Gerais (HD/MG)[m] as follows: (1) High-Cost Drug Program (HCDP);[n] (2) drugs included in the basic pharmaceutical services component; (3) strategic programs; (4) not included in any HD/MG program (not included in any previous classification).

For drugs in category 4, it was checked whether there were alternative therapies available in HD/MG pharmaceutical services programs (categories 1 to 3). Drugs with the same third-level ATC code (pharmacological subgroup) were considered therapeutic alternatives to each other.

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[c] Data provided by the Technical Advisory Board of the Health Department of the State of Minas Gerais.
[d] Conselho Nacional de Secretários da Saúde. Assistência Farmacêuitca: mediamentos de dispensação de caráter excepcional. Conselho Brasil. Brasília; 2004. (CONASS documenta, 5).
[e] Brasil. Portaria GM/MS No. 3916 de 30 de outubro de 1998. Define a Política Nacional de Medicamentos. *Diario Oficial Uniao*. 10 Nov 1998.Seção1:18-22.
[f] The Decree No. 2981/2009 of the Brazilian Ministry of Health changed the name of the High-Cost Drug Program to Specialized Pharmaceutical Services Component.
[g] Faleiros DR, Guerra Jr AA, Szuster DAC. A questão das demandas judiciais por medicamentos no SUS. Brasília; 2007.
[h] Counsellor means attorney/public defender/prosecutor responsible for the lawsuit.
[i] World Health Organization. Collaborating Center for Drug and Statistics Methodology. Anatomical Therapeutic Chemical Classification. Geneva; 2008[cited 2008 May 22]. Available from: http://www.whocc.no/atcddd/
[j] Agência Nacional de Vigilância Saniotária. Banco de dados de medicamentos. Brasília; 2002[cited 2008 Sep 11]. Available from: http://www.anvisa.gov.br/medicamentos/banco_med.htm
[k] Ministério da Saúde. Secretaria de Ciência, Tecnologia e Insumos Estratégicos. Departamento de Assistência Farmacêutica Insumos Estratégicos. Relação nacional de medicamentos essenciais. 5 ed. Brasília; 2007.
[l] World Health Organization. WHO Model List of Essential Medicines. 15 ed. Geneva;2007[cited 2007 Apr 18]. Available from: http://www.who.int/medicines/publications/essentialmedicines/en/
[m] Minas Gerais. Secretaria de Estado de Saúde. Superintendência de Assistência Farmacêutica. Relação estadual de medicamentos de Minas Gerais. Belo Horizonte; 2009.
[n] In Minas Gerais, the Specialized Pharmaceutical Services Component program is called High-Cost Drug Program.

Scientific evidence of drug efficacy was assessed through systematic reviews in the Brazilian Cochrane Center[o] database and the literature,[2] and the drugs were checked against the claimants' diagnoses.

The study data was summarized. Frequency distributions were presented for categorical variables and measures of central tendency for continuous variables. Microsoft Excel® 2003 was used to build the database and EpiInfo v. 3.4.3 was used for statistical analyses.

The study was approved by the Research Ethics Committee at Universidade Federal de Minas Gerais (protocol nº ETIC 292/08).

RESULTS

Of 873 lawsuits with demands of access to medicines during the study period, 820 (93.9%) were examined. Among those not examined, ten (1.1%) were not available (they were with prosecutors), eight (0.9%) were not found at the Attorney General Office in Belo Horizonte, 29 (3.3%) were in offices in other cities, and not information was found for six (0.7%). A lawsuit with eight claimants was divided in parts for examinations. Thus, 827 lawsuits were examined with 1,777 demands of access to medicines, accounting for 381 different items. The lawsuits had on average 2.1 demands (standard deviation – SD: 2.2, range: 1 to 16), 66.3% included only one drug and 16.0% four or more demands.

Among the lawsuits with information available (Table 1) 60.2% of claimants were female, 35.4% were 60 years old or more, and the mean age was 48.2 years old (SD: 22.3, range: 1 to 94). Approximately 63% of them lived in the interior of the state of Minas Gerais, 37.4% were retirees or pensioners, and 20.8% were homemakers. The most common diagnosis was rheumatoid arthritis (23.1%), followed by diabetes mellitus type 1 (6.5%) and hypertension (5.5%).

The city where medical care was provided was identified in 545 lawsuits, and 49.9% were in the interior of the state and 47.9% in the state capital city. The type of health care provided was identified in 535 lawsuits: 70.5% received private care and 25.8% were seen in the SUS (Table 1). In the private care system, ten medical doctors provided care to 106 claimants (28.1% of 377 patients), and one provider provided care to 84 claimants (22.3%, n = 377). The remaining 217 medical doctors saw 271 patients (71.9%, n = 377).

More than half of the claimants hired private lawyers and 23.1% were represented by a public defender (n = 785) (Table 1). Among law firms, 10 filed 304 lawsuits (64.3%, n = 473), two filed 155 lawsuits, and one 77, while 140 lawyers filed 169 lawsuits (35.7%, n = 473).

Based on the ATC classification, 21.4% of the drugs (n = 1,777) were classified as nervous system drugs, 18.3% cardiovascular system, 16.4% antineoplastic and immunomodulating agents, 15.6% alimentary tract and metabolism, 5.7% blood and blood forming organs, 4.7% respiratory system, 4.7% musculoskeletal system, 3.9% systemic hormonal preparations, excluding sex hormones and insulins, 2,1% antiinfectives for systemic use, 1.5% sensory organs, 1.4% genitourinary system and sex hormones, 0.5% antiparasitic products, 0.3% Group V, and 0.2% dermatologicals. A total of 3.3% were not classified due to missing information or ATC code.

The pharmacological subgroup of immunosuppressants was the most demanded one (13.6%), mostly including adalimumab (155 demands) and etanercept (50 demands), required primarily for the treatment of rheumatoid arthritis and ankylosing spondylitis (Table 2).

Approximately 5% of the medicines were not registered at ANVISA, 19.6% were included in the Brazilian List of Essential Medicines and 11.1% were considered essential medicines according to the WHO list. Nearly 25% were in the HCDP, 10.9% were included in the basic pharmaceutical services component, 3.5% were included in strategic programs and 56.7% were not included in any HD/MG program (Table 3).

Of the 1,008 drugs not included in HD/MG programs, there were alternative therapies for 79.0% and no alternative therapies for 16.9%. The analysis was not performed for 4.1% of the drugs with no ATC code.

Scientific evidence of efficacy was assessed for 1,675 drugs where the diagnosis had been reported in the lawsuit. Consistent evidence of efficacy was found for 53.9% of the drugs examined, limited evidence for 7.3% and no evidence for 3.7%. No information on efficacy was found for 33.4% of the drugs examined. Vitamins either alone or in combination (20.7%, n = 58) most often did not show evidence of effectiveness. Of 559 drugs without information on evidence, 5.4% were combinations of two or more drugs.

DISCUSSION

Most patients filing lawsuits demanding access to medicines to the state administrator of the SUS in Minas Gerais were provided care in the private health system and hired private lawyer services. In the southern state of Santa Catarina, between 2003 and 2004, 56% of care was provided in the private health sector and 59% of lawsuits were filed by law firms.[12] In the city of São Paulo, Southeastern Brazil, most claimants hired private lawyers: 54% in 2005 and 74% in 2006.[4,14]

These results suggest that patients who resort to lawsuits are socioeconomically better-off as they can

[o] Cochrane Library. [cited 2008 Oct 02] Available from: http://cochrane.bireme.br.

Table 1. Profile of claimants of lawsuits filed against the State. Minas Gerais, Southeastern Brazil, 2005-2006.

Variable	N[a]	%
Sex (n = 825)		
Female	497	60.2
Male	328	39.8
Age (years, n = 441)		
0 to 18	54	12.2
19 to 39	97	22.0
40 to 59	134	30.4
60 and more	156	35.4
City of residence (n = 762)		
Belo Horizonte	281	36.9
Interior of Minas Gerais	481	63.1
Occupation (n = 597)		
Retired or pensioner	223	37.4
Homemaker	124	20.8
Student	50	8.4
Unemployed	33	5.5
Teacher	20	3.4
Self-employed (college degree)	19	3.2
Public servant	15	2.5
Rural worker	10	1.7
Housemaid	9	1.5
Trader	7	1.2
Self-employed (technical degree)	6	1.0
Other	81	13.6
Diagnosis (n = 806)		
Rheumatoid arthritis	186	23.1
Diabetes mellitus type 1	52	6.5
Systemic arterial hypertension	44	5.5
Schizophrenia	32	4.0
Alzheimer's disease	29	3.6
Osteoporosis	29	3.6
Chronic obstructive pulmonary disease	21	2.6
Ankylosing spondylitis	17	2.1
Epilepsy	15	1.9
Pulmonary artery hypertension	13	1.6
Other	368	45.7
City where medical care was provided (n = 545)		
Belo Horizonte	261	47.9
Interior of Minas Gerais	272	49.9
Other states	12	2.2
Type of medical care (n = 535)		
Public	138	25.8
Private	377	70.5
Mixed (public and private)	20	3.7
Legal representation (n = 785)		
Law firm	473	60.3
Public defender	181	23.1
Prosecutor	33	4.2
Legal advice service	24	3.1
Special court at the federal level	74	9.4

[a] n = number of claimants of lawsuits.

afford legal costs and are more aware of their rights. This hypothesis corroborates studies that found a higher proportion of lawsuits originating from patients with lower social exclusion.[4,14] The judicialization of health may increase health inequalities within a system already characterized by socioeconomic inequalities.[5]

A small number of private lawyers and doctors were involved in many lawsuits, mainly demanding etanercept and adalimumab, both of which registered in Brazil in 2003. Etanercept is regarded as an innovative therapy, the first of its class, although it may not add much to the therapy depending on the indication. On the other hand, adalimumab is a supplementary drug in its therapeutic class and it is believed that it also does not add any significant benefits.[p] Both drugs accounted for 205 demands (24.8% of 827 lawsuits) and they have been included in the HCDP (rheumatoid arthritis protocol) since October 2006, i.e., after they have been demanded. This involvement of doctors and lawyers may suggest interests other than patient protection, their health recovery and exercise of their right to treatment. These lawsuits may represent the interests of those who market new drugs that are not affordable to the general population.[3,8] SUS –whose function is to guarantee health care as a right to all– has become a large consumer market for new drugs that do not always meet the population's health needs.[13]

Approximately 56% of the drugs examined were not included in the SUS programs and most were not essential medicines. Studies focusing on judicialization of health have showed greater number of essential drugs and/or available in SUS,[10,14] but studies conducted in São Paulo[4] and Santa Catarina[12] have indicated a preponderance of drugs not available in the public system.

In the present study, we found that a significant number of the drugs demanded were included in the HCDP (about one fourth of all), and a similar trend has been described in other studies.[4,10,12] The main motivation for patients to file a demand may be drug costs. Also, to have access to these drugs through the HCDP the

[p] Bonfim JRA. O registro de produtos farmacêuticos novos: critérios para a promoção do uso racional de fármacos no Sistema Único de Saúde [Master's dissertation]. Coordenadoria de Controle de Doenças da Secretaria de Estado da Saúde de São Paulo; 2006.

Table 2. Medicines demanded and their third-level ATC classification in lawsuits filed against the State. Minas Gerais, Southeastern Brazil, 2005-2006.

Drug	Third level of ATC code	n[a]	%
Adalimumab	Immunosuppressants	155	8.7
Etanercept	Immunosuppressants	50	2.8
Insulin glargine	Insulins and analogues	39	2.2
Omeprazole	Drugs for peptic ulcer and gastro-esophageal reflux disease	33	1.9
Aripiprazole	Antipsychotics	33	1.9
Simvastatin	Lipid modifying agents	30	1.7
Clopidogrel	Antithrombotic agents	29	1.6
Acetyl salicylic acid	Antithrombotic agents	23	1.3
Teriparatide	Parathyroid hormones and analogues	23	1.3
Insulin aspart	Insulins and analogues	21	1.2
Carvedilol	Beta blocking agents	20	1.1
Tiotropium	Other drugs for obstructive airway diseases, inhalants	20	1.1
Insulin lispro	Insulins and analogues	19	1.1
Budesonide and formoterol	Adrenergic inhalants	19	1.1
Other		1,263	71.1
Total		1,777	100.0

ATC: Anatomical Therapeutic Chemical; n: number of demands for medicines.

Table 3. Profile of medicines requested in lawsuits filed against the State. Minas Gerais, Southeastern Brazil, 2005-2006. (N = 1,777).

Variable	n[a]	%
Registration at the National Health Surveillance Agency		
Yes	1,672	94.1
No	85	4.8
Missing information[a]	20	1.1
Included in the Brazilian List of Essential Medicines 2006		
Yes	349	19.6
No	1,342	75.5
Missing information[a]	86	4.8
Included in the WHO Model List of Essential Medicines 2007		
Yes	197	11.1
No	1,517	85.4
Missing information[a]	63	3.5
Included in the HD/MG programs		
High-Cost Drug Program	431	24.3
Primary care drug program	193	10.9
Strategic programs	62	3.5
Not included in these programs	1,008	56.7
Missing information[a]	83	4.7

[a] Medicines with missing information on concentration and/or presentation.
WHO: World Health Organization; HD/MG: Health Department of the State of Minas Gerais; n: number of demands for medicines.

patients have to meet the inclusion criteria of clinical protocols and therapeutic guidelines of the Brazilian Ministry of Health and follow the procedures of the State Departments of Health. If these criteria are not met, the drugs are not supplied. It may be a lengthy process and some patients may choose to get them more promptly through the court. It should be noted that some drugs were demanded for diseases other than those covered in the program, which *a priori* is an impediment for drug supply. Pereira et al[12] have reported that some patients go through administrative channels to get medicines in the HCDP but because of incomplete documentation or failure to meet the criteria their requests are denied and then they resort to the courts.

Other reasons for demands of medicines in the SUS programs may include drug shortages in pharmacies due to failed management of pharmaceutical services and the lack of knowledge of official lists of medicines available in the public system by prescribers and claimants.[4,14]

The demand of several medicines in a single lawsuit may reflect the demand of all drugs that have been prescribed to the patient when at least one of them was not supplied by the SUS, regardless of the availability of the others.[11] This may explain why medicines included in the SUS programs were demanded in these lawsuits,[4] particularly primary care drugs that are more easily supplied as there is no need to meet the criteria of specific protocols.

Among the medicines not available in HD/MG programs, approximately 80% had a therapeutic alternative in the public care system, which is close to that found in a study in São Paulo where 73% had alternatives in the local list of essential medicines and in the SUS programs.[14] However, it cannot be assumed that all patients would benefit from the alternatives available in the SUS. Each case would have to be evaluated based on the patient medical history and drug experience (treatment failure, allergies and adverse reactions). However, the fact that alternative therapies are available shows that access to drugs has not been neglected by SUS managers and that SUS has implemented comprehensive public policies to cover several areas of health.

The study showed that a small proportion of the medicines demanded were not registered at Anvisa, which is consistent with other studies.[12,14] Gefitinib, for example, was demanded twice for lung cancer

treatment but it was not registered and showed limited evidence of efficacy. According to Machado,[7] a court order requiring the government to purchase medicines that are not regulated in Brazil "makes the judiciary into a champion of privileged minorities rather than a partner of 'disenfranchised groups'."

The study also showed there was evidence of efficacy for 53.9% of the medicines examined. Thus, excess judicialization can be a barrier to the full implementation of the Brazilian National Drug Policy intended to ensure safe, effective quality medicines to the population through the promotion of rational drug use. The use of drugs having uncertain efficacy was also reported by Vieira & Zucchi[14] when they examined antineoplastic agents demanded in São Paulo. In the present study, vitamins were the most commonly demanded drugs without evidence of efficacy in diseases for which they were prescribed. Although the literature describes the efficacy of several vitamins here examined, their use is often unnecessary and irrational, as seen in this study, because they are associated to a healthy lifestyle and recovery of vitality to perform daily activities. Laporte & Capella[6] warned in the 1980s that drugs with no evidence of efficacy cannot be simply regarded as placebos and their use can be harmful to patients.

The low rate of essential medicines demanded suggests that judicialization counters public health priorities in Brazil. Essential medicines are selected based on criteria of efficacy, safety and relevance to meet major health needs of the population.[15] The Brazilian List of Essential Medicines should guide drug prescription and supply of medicines in the SUS. Carvalho[3] pointed out that the lack of criteria for the selection of medicines can cause serious harm instead of benefits to users.

The profile of the medicines demanded does not seem to agree with the collective needs covered by public health policies, i.e., the demands are basically a result of individual needs. Public policies are developed with the aim of ensuring the right to universal comprehensive health care as determined in the Brazilian Constitution and to reduce inequities as well. The State selects services and actions that will be prioritized based on the available resources and the best evidence of efficacy, safety and cost-effectiveness. Ferraz & Vieira[5] affirmed that "individual needs are clearly an inadequate allocative criterion."

As judicialization can markedly interfere with health policies, it has become a means to exert pressure on the public sector for drug supply. Messeder et al[10] have identified a relationship between the increase in lawsuits demanding access to medicines and their inclusion in the SUS lists of medicines. This is particularly true for AIDS drugs[q] and possibly true for insulin glargine that was included in the HD/MG programs in October 2005, adalimumab and etanercept included in the HCDP in October 2006, and bosentan and sildenafil included in the HD/MG programs in October 2009. This pressure can be beneficial as it promotes an updating of programs and protocols as new knowledge about therapeutic practices is gained. Moreover, public managers may find it more appropriate and feasible to plan the purchase and supply of certain drugs than to obey court injunctions. However, when certain medicines are included under pressure into routine pharmaceutical services, efficacy and safety criteria and health priorities of the population can be potentially overlooked.

Missing information in some lawsuits hindered data analysis. We had access only to copies of original documents, and specific information about the claimants, prescription, medical records, among others, was missing in many lawsuits. Nevertheless, the data available for analysis was considered sufficient to meet the study objectives.

Lawsuits demanding access to a particular medicines are legitimized by the claim that health care is an inviolable right, irrespective of political and budgetary issues.[8] Health is then reduced to access to medicines, tests, consultations and absence of disease without recognizing that ensuring health involves social, economic and environmental factors and comprehensive actions and services that promote, protect and restore health. The judicialization of health reverses this logic by disregarding public policies and, consequently, the SUS principles of universality, comprehensiveness, and equity.[3]

Filing lawsuits is a resort citizens have to guarantee their rights. Lawsuits demanding medicines contemplated in public policies established by the legislature and occasionally not available in the SUS are legitimate as they aim to ensure a fundamental right. And to consider them as "judicialization" is to discredit the law, assuming that the judiciary is unduly interfering with another power.[9] But what we see is excess judicialization with the proliferation of judicial orders that sentence the Government to fund irrational treatment and delegate to managers the responsibility for resource allocation that quite often counters the principle of equity in health and access to quality health care.[1]

Although the judicialization of health can point to failures within the health system that should be addressed, it tends to be largely an encouragement to medicalization and a barrier to the rational use of medicines. This practice undermines the full implementation of the Brazilian National Drug Policy principles leading to disconcerted pharmaceutical actions and services.

[q] Ministério da Saúde. Secretaria de Vigilância Sanitária. Programa Nacional de DST e AIDS. O Remédio via Justiça: um estudo sobre o acesso a novos medicamentos e exames em HIV/AIDS no Brasil por meio de ações judiciais. Brasília; 2005.

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