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A technical analysis of medicines request-related decision making in Brazilian courts

ABSTRACT

OBJECTIVE: To analyze judicial requests for medications that are covered by the pharmaceutical assistance components of the Sistema Único de Saúde (SUS – Brazilian Unified Health System).

METHODS: We analyzed 81 judicial requests for medications in the State of São Paulo between 2005 and 2009. The details of these cases were obtained electronically from the Court of Justice of the State of São Paulo. Directives that regulate pharmaceutical assistance were consulted to identify judicially requested medications that are covered by the SUS. To assess the level of evidence supporting the use of these medications to treat the clinical indications described, we consulted the Thomson Micromedex® database.

RESULTS: The number of individual medications requested in each case ranged from 1 to 7; in total, 77 different pharmaceuticals agents were identified. Of the medications requested, 14.3% should have been available through SUS primary care, 19.5% were classified under the exceptionally dispensed medications component of the SUS, and 66.2% were not on any official list. Medications of the exceptionally dispensed medications component showed better clinical evidence when indicated for the treatment of medical conditions covered by the Clinical Protocols and Therapeutic Guidelines of Brazil's Ministry of Health.

CONCLUSIONS: The judicial process has been used to ensure access to medications that are covered by the SUS and to request access to those that are not covered. Our assessment of the level of available evidence reinforces the need for technical analysis in the decision-making process in cases of judicially requested medications.

DESCRIPTORS: Judicial Decisions. Pharmaceutical services. Brazilian Unified Health System. National Drug Policy. Equity in Access. Right to health. Rational use of medicines.

INTRODUCTION

The right to health means that the State guarantees dignified living conditions and universal and equal access to programs and services for the promotion, protection, and restoration of health at all levels. In Brazil, this guarantee applies to all of the inhabitants and enables the full development of human beings as individuals.[a]

In contemporary societies, the recognition of the right to health has been the subject of controversies involving politicians, lawyers, social scientists,

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[a] Comissão Nacional da Reforma Sanitária. 8º Conferência Nacional de Saúde: 17 a 21 de março de 1986. Relatório Oficial. Brasília; 1986 [cited 2010 Aug 10]. Available from: http://portal.saude.gov.br/portal/arquivos/pdf/8_CNS_Relatorio%20Final.pdf

economists, and health professionals. In particular, the effectiveness of legal arguments regarding social rights and externalities that cannot be internalized in the evaluation of health as an economic good are frequently discussed.[b]

In Brazil, Articles 6 and 196 to 200 of the Federal Constitution state that the right to health is a social right to be guaranteed by policies that promote and ensure universal and equal access to programs and services for the promotion, protection, and restoration of the health of citizens. The recognition of health as a right has two important practical implications: 1) the ethical and legal responsibilities of the government to formulate and implement policies that ensure people's access to health care services and 2) the ability of citizens to individually or collectively make legal requests for the fulfillment of this obligation by the state.[8]

The government has the responsibility to offer the population medications that are the safest (i.e., known to cause no harm), most efficacious (i.e., effective in promoting the desired result), most practical (i.e., effective when used by people in non-clinical settings), and most cost-effective (i.e., having the desired effect and the lowest cost among the available alternatives) options.[11]

One of the largest challenges facing health managers is legal actions that are aimed at obtaining products, treatments and/or health procedures; frequently, such legal actions request goods that are not provided by the *Sistema Único de Saúde* (SUS – Brazilian Unified Health System).[2] According to Vieira[10] (2009), the percentage of total spending by the Ministry of Health dedicated to medical expenditures rose from 5.4% in 2002 to 10.7% in 2007. The State of São Paulo spent R$ 1.2 billion on medications in 2006.[2] Nonetheless, according to the Ministry of Health, more than R$ 500 million was spent in 2007 at the federal, state, and municipal levels to meet judicial demands.[c]

When a medication is provided due to a court order, there is no assessment of whether it is the best treatment in terms of the cost/benefit ratio, whether the patient truly needs the medication requested, whether it can be replaced by another treatment provided by the SUS pharmaceutical programs, or even whether provision of this medication breaks a fundamental law or principle of the health care system. The court order is simply followed.[1]

The judiciary needs to evolve by incorporating the political factors that constitute the right to health, as public administrators have to progress in the formulation and implementation of health policies in Brazil. The health administration must also improve the provision of services because citizens are often deprived of proper medical and pharmaceutical care due to the health administration not providing clear information on the formal path that must be taken to obtain medications or treatments from the SUS.[6] According to the Federal Supreme Court there is need to rescale judicialization so that judicial intervention does not occur only because of the omission of public policies aimed at protecting the right to health but also due to a failure to observe the current policies.[d] Although judicial orders for the supply of medications create difficulties for the SUS, judicial power can serve to expand activities and health services and to revise existing policies.[5]

Thus, the objective of this study was to analyze judicial requests for medications covered by the pharmaceutical services components of the SUS.

METHODS

This was a descriptive epidemiological study using qualitative data that were obtained from 2005 to 2009. All information regarding legal actions involving medications was obtained from the database of the Court of Justice of the State of São Paulo (CJ-SP), in Southeastern Brazil; online access to this information is public and freely accessible. The database search was performed from March to April 2009.

The units of analysis in this study were legal actions filed against state entities (either state or municipal) requesting a supply of medications. The sample consisted of the first five cases identified in the municipal headquarters of each of the 17 Regional Health Departments (administrative divisions of the Health Secretariat of the State of São Paulo). The cases used in this study met the following inclusion criteria: a) the medications requested and the applicant's medical condition were identified; b) the case had been ruled on trial court, with the decision in favor of the applicant; and c) the records provided access to the complete proceedings. When the proceedings of the municipal headquarters were not available in the CJ-SP database, the search was extended to other municipalities in the same catchment area.

[b] Dallari SG. Direito sanitário. In: Brasil. Ministério da Saúde. Secretaria de Gestão do Trabalho e da Educação na Saúde. Departamento de Gestão da Educação na Saúde. Direito sanitário e saúde pública. Brasília: Ministério da Saúde, 2003. p.39-61.

[c] Jungmann M. Ministério da Saúde classifica de "epidêmico" volume de ações judiciais contra o SUS. Brasília; 2007[cited 2009 Sep 10]. Available from: http://www.aids.gov.br/es/node/6713

[d] Conselho Nacional de Secretários de Saúde. Nota Técnica no. 8 de 28 de abril de 2010. Decisão do STF sobre os recursos interpostos pelo Poder Público nas ações: Suspensões de Tutela (STA) 175, 211 e 278; Suspensões de Segurança 3724, 2944, 2361, 3345 e 3355; Suspensão de Liminar (SL) 47. Brasília; 2010[cited 2010 Aug 10]. Available from: http://www.conass.org.br/arquivos/file/nt_08_decisao%20do%20stf%20sobre%20os%20recursos%20interpostos%20pelo%20poder%20publico.pdf

[e] Ministério da Saúde. Portaria nº 3.237, de 24 de dezembro de 2007. Aprova as normas de execução e de financiamento da assistência farmacêutica na atenção básica em saúde. *Diario Oficial Uniao*. 26 dez 2007;Seção1:16.

To identify judicial requests for medications that are covered by SUS programs, we consulted Ministerial Directive *(Portaria)* 3,237 of December 24, 2007,[e] which defined the reference list of the basic component of pharmaceutical services; Ministerial Directive 2,577, of October 27, 2006,[f] which approved the component of exceptionally dispensed medications (CEDM); and Ministerial Directive 106 of January 22, 2009,[g] which amended Annex II of Ministerial Directive 2,577 of October 27, 2006. The website of the Ministry of Health was used to identify the medicines specified in the strategic component. Directives *(Portarias)* 2,981[h] and 2,982[i], both issued on November 26, 2009, were not considered in this analysis because the data collected are based on a period when the legal provisions mentioned above were still in place. In this report, we use the term "component of exceptionally dispensed medications" (CEDM), which was amended by Directive 2,981 to "specialized component of pharmaceutical services".

The *Relação Nacional de Medicamentos Essenciais* (RENAME – National List of Essential Medicines)[j] and the website of the Health Secretariat of the State of São Paulo (Secretaria Estadual de Saúde de São Paulo – SES-SP) were consulted to verify that the medical conditions listed in the proceedings coincided with the indications provided by the SUS.[k]

The medications specified in the CEDM were evaluated with regard to the degree to which they were recommended for the medical conditions listed in the legal proceedings, according to information available in the Thomson Micromedex® database. The same database was used to determine whether drugs that were not covered by the SUS were sufficiently validated by clinical evidence to justify their indication for the treatment of the medical conditions listed in the legal proceedings.[3]

RESULTS

In total, we analyzed 81 legal actions. In the area covered by the Regional Department of Health Registry, one proceeding met the inclusion criteria. The cases examined requested 128 medications with 77 different active components. The most frequently requested pharmaceuticals were the following: teriparatide (9.9%), clopidogrel (8.6%) insulin glargine (8.6%), rituximab (8.6%), infliximab (7.4%), bevacizumab (3.7%) insulin aspart (3.7%), and sunitinib (3.7%).

Of the medications requested through the courts, 33.8% were included in national policies for supply by the SUS, 14.3% were provided by the primary care component (Table 1), and 19.5% were included in the CEDM (Table 2).

In the case of medications included in the basic component of pharmaceutical care, most of the medical conditions listed in the case proceedings corresponded to NLEM indications. Moreover, of the 16 medical conditions listed in cases requesting medications included in the CEDM, 81.3% were not included among the indications of the medications requested, according to the Clinical Protocols and Therapeutic Guidelines (CPTG) of the Ministry of Health.

Table 3 presents an analysis of the degrees of recommendation of CEDM medication requests separated

Table 1. Medicines included in the basic component of pharmaceutical services that were requested in lawsuits, the respective medical conditions listed in the proceedings, and the indications provided by the 2008 National List of Essential Medicines. State of São Paulo, Southeastern Brazil, 2005-2009.

Acetylsalicylic Acid	Medical condition listed in the proceedings	Indicated
Atenolol	Coronary disease	Yes
Amlodipine besylate	Hypertension	Yes
Captopril	Diabetes mellitus	No
Metformin hydrochloride	Cardiovascular Disease	Yes
	Myocardial infarction	No
Spironolactone	Diabetes mellitus	Yes
Phenobarbital	Hypertension	Yes
	Diabetes mellitus	No
Furosemide	Cerebral Palsy	No
	Epilepsy	Yes
Hydrochlorothiazide	Cardiovascular Disease	Yes
	Myocardial infarction	No
Human insulin	Hypertension	Yes
Enalapril maleate	Diabetes mellitus	Yes
Maleato de enalapril	Hypertension	Yes

Source: The Court of Justice of the State of São Paulo

[f] Ministério da Saúde. Portaria nº 2.577, de 27 de outubro de 2006. Aprova o componente de medicamentos de dispensação excepcional. *Diario Oficial Uniao*. 13 nov 2006;Seção1:44.
[g] Ministério da Saúde. Portaria nº 106, de 22 de janeiro de 2009. Altera o Anexo II da Portaria nº 2.577 de 27 de outubro de 2006, que aprova o componente de medicamentos de dispensação excepcional. *Diario Oficial Uniao*. 23 jan 2009;Seção1:40.
[h] Ministério da Saúde. Portaria nº 2.981, de 26 de novembro de 2009. Aprova o componente especializado da assistência farmacêutica. *Diario Oficial Uniao*. 30 nov 2009;Seção1:725.
[i] Ministério da Saúde. Portaria nº 2.982, de 26 de novembro de 2009. Aprova as normas de execução e de financiamento da assistência farmacêutica na atenção básica. *Diario Oficial Uniao*. 30 nov 2009;Seção1:771.
[j] Ministério da Saúde. Secretaria de Ciência, Tecnologia e Insumos Estratégicos. Departamento de Assistência farmacêutica e Insumos Estratégicos. Relação nacional de medicamentos essenciais. 6. ed. Brasília; 2009.
[k] Secretaria de Estado da Saúde. Assistência farmacêutica. São Paulo; 2010[cited 2010 Aug 10]. Available from: http://www.saude.sp.gov.br/content/assistencia_farmaceutica.mmp

Table 2. Exceptionally dispensed medications requested in lawsuits, medical conditions listed in the legal proceedings and the indications considered. State of São Paulo, Southeastern Brazil, 2005-2009.

Medication	Medical condition listed in the proceedings	Indicated by the CEDM
Cyproterone acetate	Prostate cancer	No
Glatiramer acetate	Multiple Sclerosis	Yes
Peginterferon alfa-2a	Hepatitis C	Yes
Atorvastatin	Hypertension	No
Azathioprine	Inflammatory polyneuropathy	No
Budesonide	Chronic obstructive pulmonary disease	No
Cyclosporine	Atopic dermatitis	No
Etanercept	Ankylosing spondylitis	No
	Rheumatoid arthritis	Yes
Formoterol	Chronic obstructive pulmonary disease	Yes
Human immunoglobulin	Multifocal motor neuropathy	No
Infliximab	Psoriasis	No
Mesalazine	Diffuse nonspecific proctitis	No
Olanzapine	Bipolar disorder	No
Ribavirin	Hepatitis C	Yes
	Cardiovascular Disease	No
	Myocardial infarction	No
Simvastatin	Angioplasty	No

CEDM: Component of exceptionally dispensed medicines
Source: The Court of Justice of the State of São Paulo

into two groups: indications included and not included in the CPTG. It also shows the degrees of recommendation of medications not provided by the SUS for the medical conditions listed in the proceedings. Medications for which there was insufficient information regarding the degree of recommendation for the medical conditions listed in the proceedings were not included in the analysis.

The recommendations for five CEDM medications prescribed to treat five different medical conditions covered in their respective protocols were supported by the literature. An analysis of the degree of recommendation of the seven CEDM medications requested to treat medical conditions not covered in the protocols showed that three of the medications were not recommended for the medical conditions referred to in court proceedings, and three were recommended in some cases.

Table 3. The degree of recommendation of exceptionally dispensed medications and medications not covered by the health system, according to the medical conditions listed in the legal proceedings. State of São Paulo, Southeastern Brazil, 2005-2009.

Degree of recommendation	n	%
CEDM-approved medications (n = 12)		
Degree of recommendation on the indication provided in the CEDM		
Recommended	2	16.7
Recommended in most cases	3	25.0
Recommended only in some cases	0	0.0
Not recommended	0	0.0
Degree of recommendation without indication under the CEDM		
Recommended	0	0.0
Recommended in most cases	1	8.3
Recommended only in some cases	3	25.0
Not recommended	3	25.0
Medications not covered by the SUS (n = 37)		
Degree of recommendation of the medical condition mentioned in the legal proceedings		
Recommended	2	5.4
Recommended in most cases	26	70.3
Recommended only in some cases	8	21.6
Not recommended	1	2.7

Source: The Court of Justice of the State of São Paulo; Klasco[3] (2009)
CEDM: Component of exceptionally dispensed medicines
SUS: *Sistema Único de Saúde* (Brazilian Unified Health System)

Nearly two thirds of the drugs requested by the courts were not included in the official lists for free supply by the SUS.

DISCUSSION

Approximately one third of the medications that were judicially requested were included in the SUS list for free supply. Other studies have found similarly high proportions of such cases.[1,7,9,l,m,n,o] The highest percentage (69.2%) of requests for medications covered by the SUS

[l] Borges DCL. Uma análise das ações judiciais para o fornecimento de medicamentos no âmbito do SUS: o caso do estado do Rio de Janeiro no ano de 2005 [master's dissertation]. Rio de Janeiro: Escola Nacional de Saúde Pública Sérgio Arouca da Fiocruz; 2007.
[m] Pereira JR. Análise das demandas judiciais solicitando medicamentos encaminhados a diretoria de assistência farmacêutica da Secretaria de Estado da Saúde de Santa Catarina nos anos de 2003 e 2004 [master's dissertation]. Florianópolis: Universidade Federal de Santa Catarina; 2006.
[n] Romero LC. Judicialização das políticas de assistência farmacêutica: o caso do Distrito Federal. Brasília: Consultoria Legislativa do Senado Federal; 2008[cited 2009 Oct 12]. Available from: http://www.senado.gov.br/Agencia/todasNoticias.aspx
[o] Sant´Ana JMB. Essencialidade e assistência farmacêutica: um estudo exploratório das demandas judiciais individuais para o acesso a medicamentos no Estado do Rio de Janeiro [master's dissertation]. Rio de Janeiro: Escola Nacional de Saúde Pública Sergio Arouca da Fiocruz; 2009.

was observed by Messeder et al[7] (2005), followed by Borges[k] (2007) (52%) and Sant'Ana[n] (2009) (50%), all in the State of Rio de Janeiro (Southeastern Brazil). Vieira & Zucchi[9] (2007) found a percentage of 62% in the São Paulo municipality, whereas Chieffi & Barata[1] (2009) found 23% in the same city. Romero[m] (2008) stated that 47.2% of the medications requested in the Federal District were part of the 2002 NLEM. In Santa Catarina (Southern Brazil), this rate was 37.8%, according to Pereira[l] (2006). These percentages, though disparate, reveal that appeals to the courts are not restricted to medications that are not provided by the SUS.

The present study identified requests for 11 medications covered by the primary care component of the SUS. When they are available in health units, the dispensation of these medications requires only a prescription. According to Vieira & Zucchi[9] (2007), the solicitation to the courts for drugs covered by SUS programs suggests either flaws in ensuring the availability of these medications or ignorance, of both the prescriber and the applicant, regarding the availability of these medications. Thus, these findings support the hypothesis of deficiencies in the management of pharmaceutical policies.

The lack of medications in health facilities, due to problems with selecting, planning, purchasing, inventory control, storage, distribution, or the dispensation of medications by unqualified workers, legitimizes the judicial process as a mechanism for access to rights provided by the Constitution, particularly when access to these medications is guaranteed by specific public policies, such as the pharmaceutical care policy.

Researchers have found a demand for CEDM medications in previous studies.[1,7,9,o] In this study, requests for CEDM medications accounted for 19.5% of the tested sample, a percentage larger than that identified by Chieffi & Barata[1] (2009) in the São Paulo municipality (13%). The bureaucratization of pharmaceutical services and centralized dispensation hinders access to exceptionally dispensed medications, particularly for populations living in more socially vulnerable municipalities. Requests for medications unsubstantiated by diagnosis and the therapeutic indications detailed by the CPTG, non-standardized concentrations or pharmaceutical formulations, medications supplied in limited quantities, outdated clinical protocols, therapeutic approaches supported by sufficient scientific evidence but not yet incorporated into SUS programs, and even difficulty in interpreting these clinical protocols due to their academic characteristics, all have contributed to increasing the number of judicial requests.[p]

CEDM medications were requested for the treatment of 16 different medical conditions. Five drugs were requested for the treatment of medical conditions specified in the CPTG. The degree of recommendation described in the literature supported the use of these medications for these indications. These facts suggest that even when medications are covered by the SUS and prescribed according to clinical protocols, other factors influence the legal demands for access.

Seven drugs with the same active component were requested for the treatment of medical conditions that were not supported by clinical protocols. In three cases, there was no evidence of benefit to justify the prescribing and use of the drugs. According to the precepts of rational pharmaceutical use, the dismissal of such appeals would be more beneficial for the patients than granting them access to the requested medications. In three other cases, the medications requested were not recommended for most patients. In such rulings, there was insufficient information available to analyze the needs of the patients, though the judges could request medical examinations before making their decisions. One of the medications (etanercept, which is used to treat ankylosing spondylitis), which was requested for an indication not included in the applicable protocol, could be used by most patients, according to the degree of recommendation described in the literature. In cases like this, it is the clinical protocol itself that should be reviewed. We were unable to identify the degree of recommendation for four of the requested drugs (atorvastatin, azathioprine, intravenous immunoglobulin, and simvastatin); however, the use of these medications may have been related to associated medical conditions that were not mentioned in the proceedings.

Chieffi & Barata[1] (2009) found that in legal actions, standard medications for use in certain medical conditions were often prescribed for situations not covered in the protocols. A systematic review that assessed the effectiveness of medications marketed for the treatment of osteoporosis has alerted public health authorities to the need for new clinical protocols for the appropriate treatment of osteoporosis.[q] Pereira[m] (2006) noted the importance of evaluating and incorporating into the official lists non-covered medications that represent important treatment options, but are accessible only by judicial means. He also stressed the need to simplify access to medications that are covered by the SUS and to periodically review those that are provided.

The lists of medications covered by SUS are limited to the first line of care and typically do not include alternative options for cases in which in there are contraindications for the prescribed pharmaceuticals,

[p] Lamb L. Os desafios do enfrentamento das ações judiciais de medicamentos. Rio de Janeiro: Fiocruz; 2008[cited 2009 Oct 10]. Available from: http://chagas2.redefiocruz.fiocruz.br/drupalsesdec/?q=node/92

[q] Brandão CMR. Avaliação econômica dos medicamentos destinados ao tratamento da osteoporose no programa de medicamentos excepcionais do Ministério da Saúde [master's dissertation]. Belo Horizonte: Universidade Federal de Minas Gerais; 2008.

such as cases of drug interactions in elderly patients taking multiple medications. This type of demand can be significantly reduced through improved training in pharmaceutical care services, enabling them to assess the individual needs of each patient, and by providing formal mechanisms in health management for accommodating claims based on the rational use of medications not covered by the SUS.

Of the medications requested through the courts, 66.2% were not part of the official lists for free prescription through the SUS. Pereira[m] (2006) identified medications without SUS funding in 59% of the judicial cases evaluated. Chieffi & Barata[1] (2009) showed that 77% of medications requested through the courts were not covered by SUS pharmaceutical assistance programs.

The high frequency of judicial requests for non-covered drugs may be related to the lack of therapeutic alternatives offered by the SUS because the lists are restrictive and frequently do not offer choices. The pressure placed on prescribers by the pharmaceutical industry, aimed at generating demand for particular drugs, may represent another problem, as highlighted by Chieffi & Barata[2] (2010). The concept of essential medicines, which guides the inclusion of medications in the SUS, also contributes to the use of the judicial process as a mechanism for access to non-covered medications. This concept was created in response to the need for improved access, quality, equity, and efficiency of health systems; it is not a static concept and should be adapted to our growing knowledge of medications and treatments.[r]

Contrary to the expectation that the growing number of legal actions would make medications of dubious effectiveness available to users, this study revealed that only 2.7% of the drugs requested were not recommended for the indication listed in the proceedings. Moreover, 5.4% of the drugs requested were characterized by a high degree of recommendation for the medical conditions listed, leaving no doubt of their therapeutic value. For most requests, the careful assessment of the specific therapeutic needs of each patient was explicit, with the findings that 70.3% of drugs are recommended for most (but not all) patients, and 21.6% are recommended for some (but not most) patients with the medical condition listed.

These findings further justify the importance of incorporating technical analysis in the decision-making process regarding medication requests through the courts. The grounds for each request must be identified. This analysis must be supported by knowledge of the following items: public health policies, the list of drugs covered by the SUS, restrictions on the use of such drugs in specific patient populations and in patients with specialized needs, the evidence-based clinical indications of medications, and any alternative treatments available through the SUS. Furthermore, whenever appropriate, recommendations should be made to the judiciary to request reviews by experts who are free from conflicts of interest.

Judicialization should not represent a path of access to medications. However, demands made through the courts are understandable when the expected supply required by public policy is not guaranteed, or when treatment coverage for a certain medical condition is not attended by the pharmaceutical policies of the SUS.

According to Vieira & Zucchi[11] (2009), legal actions can be grouped into two categories: justified and unjustified. Despite controversies surrounding the distinction between these two categories, requests for medications included in the SUS lists for public supply can be considered justified when access is blocked due to management problems in the pharmaceutical services or restrictive and outdated protocols and even when the request is for medications not covered by the SUS, but that possess good evidence of benefit and represent an important alternative indication in case the approved drugs cannot be used.

Some requests are inaccurately classified as justified; these including the following: requests for medications that lack proper documentation with the National Health Surveillance Agency, requests for drugs not covered by the SUS to treat medical conditions for which alternative treatments are covered that are at least as effective as the requested drug and without contraindications for the patient, and requests for medications prescribed for medical conditions that are not recommended in the scientific literature. Lopes et al[4] (2010) found that between 2006 and 2007, at least R$6.8 million was spent by the Health Secretariat of the State of São Paulo to meet court orders for the supply of antineoplastic drugs for indications that were not supported by medical evidence.

As a result of a public hearing held by the Federal Supreme Court in 2009, the National Council of Justice recommended to the courts that magistrates be provided with technical support (both medical and pharmaceutical). This support would help the magistrates make value judgments regarding the assessment of clinical issues for decision-making on requests for health services through the courts.[s]

[r] Santos MRC. Rename: o processo de revisão e atualização. In: Ministério da Saúde. Relação nacional de medicamentos essenciais. 4. ed. Brasília; 2007.

[s] Conselho Nacional de Justiça. Recomendação nº 31, de 30 de março de 2010. Recomenda aos Tribunais a adoção de medidas visando a melhor subsidiar os magistrados e demais operadores do direito, para assegurar maior eficiência na solução das demandas judiciais envolvendo a assistência à saúde. Diario Justiça. 07 abr 2010[cited 2010 Apr 07]:4-6. Available from: http://www.cnj.jus.br/images/stories/docs_cnj/recomendacoes/reccnj_31.pdf

The reorganization of pharmaceutical services to ensure the availability and supply of medications included in government policies is a responsibility of the managers of the SUS. This problem must be handled in a timely manner, and with intersectoral focus, by a team of professionals who are qualified to evaluate the clinical indications of the requested medications. Such evaluations must be made based on the best available evidence, according to the unique needs of each patient and identifying any safe and effective alternatives covered by the SUS, which would avoid justified demands that result in legal actions.

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