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 pharmaceutical 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.


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.¹

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

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.

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To identify judicial requests for medications that are covered by SUS programs, we consulted Ministerial Directive (Portaria) 2,577 of December 24, 2007, which defined the reference list of the basic component of pharmaceutical services; Ministerial Directive 2,577, of October 27, 2006, which approved the component of exceptionally dispensed medications (CEDM); and Ministerial Directive 106 of January 22, 2009, 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 and 2,982, 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) 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.

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.

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.

<table>
<thead>
<tr>
<th>Medical condition listed in the proceedings</th>
<th>Indicated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atenolol Coronary disease</td>
<td>Yes</td>
</tr>
<tr>
<td>Amlodipine besylate Hypertension</td>
<td>Yes</td>
</tr>
<tr>
<td>Captopril Diabetes mellitus</td>
<td>No</td>
</tr>
<tr>
<td>Metformin Cardiovascular Disease</td>
<td>Yes</td>
</tr>
<tr>
<td>Hydrochloride Myocardial infarction</td>
<td>No</td>
</tr>
<tr>
<td>Spironolactone Diabetes mellitus</td>
<td>Yes</td>
</tr>
<tr>
<td>Phenobarbital Diabetes mellitus</td>
<td>No</td>
</tr>
<tr>
<td>Furosemide Cerebral Palsy</td>
<td>No</td>
</tr>
<tr>
<td>Hydrochlorothiazide Cardiovascular Disease</td>
<td>Yes</td>
</tr>
<tr>
<td>Human insulin Myocardial infarction</td>
<td>No</td>
</tr>
<tr>
<td>Enalapril maleate Diabetes mellitus</td>
<td>Yes</td>
</tr>
<tr>
<td>Maleato de enalapril Hypertension</td>
<td>Yes</td>
</tr>
</tbody>
</table>

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

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1 Ministro da Saúde. Portaria nº 2.577, de 27 de outubro de 2006. Aprova o componente de medicamentos de dispensação excepcional. Diário Oficial Uniao. 13 nov 2006;Seção1:44.
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.

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.\(^1\)\(^,\)\(^2\)\(^,\)\(^3\)\(^,\)\(^4\)\(^,\)\(^5\)\(^,\)\(^6\)\(^,\)\(^7\)\(^,\)\(^8\)\(^,\)\(^9\) The highest percentage (69.2%) of requests for medications covered by the SUS...
was observed by Messeder et al. (2005), followed by Borges (2007) (52%) and Sant’Ana (2009) (50%), all in the State of Rio de Janeiro (Southeastern Brazil). Vieira & Zucchi (2007) found a percentage of 62% in the São Paulo municipality, whereas Chieffi & Barata (2009) found 23% in the same city. Romero (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 (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 (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. In this study, requests for CEDM medications accounted for 19.5% of the tested sample, a percentage larger than that identified by Chieffi & Barata (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.

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 (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. Pereira (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 there are contraindications for the prescribed pharmaceuticals.

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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\textsuperscript{a} (2006) identified medications without SUS funding in 59% of the judicial cases evaluated. Chieffi & Barata\textsuperscript{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\textsuperscript{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.\textsuperscript{3}

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\textsuperscript{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\textsuperscript{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.\textsuperscript{4}


\textsuperscript{4} Lopes et al. (2010)
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.

REFERENCES


Article based on the Master’s dissertation Macedo EI, presented to the Universidade de Sorocaba in 2010.
The authors declare no conflicts of interests.