Failures in Pharmaceutical Services management for Judicialized Medicines, in 16 municipalities of the Brazilian Southeast

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ABSTRACT Since the 1990s, judicial demands for medicines have intensified. Several studies have outlined these demands. We describe the organization of the management of Municipal Pharmaceutical Services (PS) for the provision of medicines demanded through litigation. The sample included 16 municipalities, four for each state in the Brazilian Southeast. To describe the management profile of PS, a matrix of indicators was developed including dimensions of human and financial resources, and PS activities. In nine municipalities, management of medicines acquired through litigation was the responsibility of the local manager of PS. Indicators on expenditures with litigated medicines were the ones with the worst performance. Only six managers informed using technical analysis of prescriptions and regular contact with the judiciary. In seven municipalities, managers were unable to specify the modality of acquisition of medicines. Municipal management plays a major role in the management of PS and must be reviewed, with the need for a thorough questioning regarding its role and possible changes it needs to implement.


RESUMO Desde a década de 1990, as solicitações de medicamentos por via judicial vêm se intensificando. Vários estudos têm traçado o panorama destas demandas. Buscou-se descrever a existência de organização própria da gestão da Assistência Farmacêutica (AF) Municipal para o atendimento de medicamentos demandados judicialmente. Um conjunto de 16 municípios incluiu 4 de cada estado da região Sudeste brasileira. Para a descrição do perfil da gestão da AF, foi estruturada uma matriz de indicadores que contemplou suas dimensões de recursos humanos, financeiros e suas atividades. Em nove municípios, a gestão dos medicamentos solicitados por via judicial coube ao gestor local da AF. Os indicadores com os piores desempenhos em todas as respostas foram aqueles que versaram sobre as despesas com Medicamentos Judicializados. Somente seis gestores informaram que realizavam análise técnica das prescrições e contato regular com o judiciário. Em sete municípios, os gestores não souberam especificar a modalidade de aquisição dos medicamentos demandados. A gestão municipal tem papel preponderante sobre a gestão da AF e precisa ser revista, havendo a necessidade de amplo questionamento a respeito do seu papel e de eventuais mudanças pelas quais possa passar.

Introduction

Starting in the 1990s, demands for medicines, resources and health services through litigation were intensified in specific areas, such as Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome (HIV/AIDS), becoming more acute and wider-reaching in the 2000s. Studies on health litigation (which in Brazil is known as judicialization) have focused on different subjects, but some stand out: the profile of plaintiffs; provision failures; high costs of demands; patents and monopolies of demanded products; most-demanded pharmaceutical products and associated clinical situations; safety and efficacy of Litigated Medicines (LitMed); interference from civil society and the pharmaceutical industry; and, the effects of judicialization on the Unified Health System (SUS, in Portuguese).

Since the responsibility for medicines provision is shared between the federal, state and municipal levels and has wide-reaching repercussions, judicialization seems to interfere directly with this aspect of the management of Pharmaceutical Services (PS), especially at the municipal level, which has proportionally the smallest purchasing power and greatest dependence on federal and state entities. Regardless, the quality of PS, whether at the state or municipal level, also matters; it is a ‘fertile’ ground for the establishment and rise of judicialization. Santos-Pinto, while investigating certain municipalities, argued that an incipient PS management would feedback into the occurrence of litigation for access to medicines. Given resource scarcity and the need to mobilize management to meet these demands, it is important to know how a municipality manages LitMed. Some studies have already discussed judicialization at the municipal (and state) level, but we still lack information from a standpoint of regionalization, which has not been sufficiently addressed by the literature.

From this premise, we initially proposed an approach according to geographical regions, observing common contexts. The Brazilian Southeast region is important in the national context, whether because of its socioeconomic development or because it concentrates medical-health care facilities and services. Due to the increase of volume and financial impact of judicial demands in the country, especially in this region, over the last decade, it was considered a privileged locus for studying these demands, verifying different municipal managements.

Thus, this study sought to describe the profile of PS management in medium- and large-sized municipalities in the Brazilian Southeast region in terms of their organization for addressing medicines demands made through lawsuits or administrative procedures, offering a diagnosis of the problems that affect these municipalities, favoring the persistence and magnitude of judicialization.

Methods

Four municipalities from each state in the Brazilian Southeast region were selected for analysis, totalling 16 municipalities, scaled, by state, according to the following aspects: those which, in the past five years, were most affected by litigation (in absolute terms); and those which suffered from disasters and health emergencies. Both aspects simultaneously put pressure on municipal budgets. Small municipalities were excluded so as not to include cases of municipalities with lower management capacity and low availability of PS resources, something reported by many authors with regard to very small municipalities.

This is a descriptive multiple-case study. We sought to describe whether or not a specific organization of Municipal PS for addressing medicines demands made through lawsuits or administrative procedures exists. In order to describe the profile of, we structured an indicator matrix.
1) based on the work by Santos-Pinto and Osorio-de-Castro. We included the following dimensions: human resources, financial resources and PS activities considered to be essential in the study of demands (specific procedures for managing demands, processes for purchasing LitMed and dispensation of LitMed).

### Chart 1. Matrix of indicators for PS management of Litigated Medicines in municipalities in the Brazilian Southeast region

<table>
<thead>
<tr>
<th>Analytical dimension</th>
<th>Item</th>
<th>Measure</th>
<th>Reasoning for measure</th>
<th>Judgment criteria</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Human Resources</strong></td>
<td>Management of LitMed made via lawsuits and administrative procedures.</td>
<td>Existence of a team responsible for managing LitMed made via lawsuits or administrative procedures, with participation of a pharmacist.</td>
<td>To verify whether a pharmacist participates in managing LitMed made via lawsuits or administrative procedures.</td>
<td>The Municipal PS management is responsible or shares the responsibility for responding to medicines demands made via lawsuits or administrative procedures.</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>A different sector of the Municipal Health Secretariat is responsible for responding to medicines demands made via lawsuits or administrative procedures.</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Did not know who is responsible for responding to medicines demands made via lawsuits or administrative procedures.</td>
<td>-1</td>
</tr>
<tr>
<td><strong>Financial Resources</strong></td>
<td>Own financial resources 1.</td>
<td>Volume of expenditures with emergency medicines purchases in relation to expenditures with forecasted medicines purchases.</td>
<td>To verify the sums spent on emergency medicines purchases.</td>
<td>Municipality does not purchase medicines on an emergency basis.</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Municipality spends less on emergency purchases than on forecasted medicines purchases.</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Municipality spends more on emergency purchases than on forecasted medicines purchases.</td>
<td>-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Manager did not know the sum spent on emergency purchases.</td>
<td>-2</td>
</tr>
<tr>
<td></td>
<td>Own financial resources 2.</td>
<td>Volume of expenditures with LitMed purchases.</td>
<td>To verify the sums spent on LitMed purchases.</td>
<td>Municipality spends less on LitMed purchases than on forecasted medicines purchases.</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Municipality spends more on LitMed purchases than on forecasted medicines purchases.</td>
<td>-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Municipal PS does not know LitMed values.</td>
<td>-2</td>
</tr>
<tr>
<td><strong>Activities</strong></td>
<td>Specific procedures for handling lawsuits and administrative procedures.</td>
<td>Existence of specific procedures for carrying out legal or administrative demands.</td>
<td>To verify whether the PS management has specific established procedures for handling legal demands or administrative procedures.</td>
<td>Municipality carries out a technical analysis of plaintiffs’ prescriptions, regular contact with the Judiciary and monitoring of demands.</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Municipality does not have specific procedures or manager did not know.</td>
<td>-1</td>
</tr>
</tbody>
</table>
During data collection, in 2013, each municipality was visited once. In these visits, we conducted semi-structured interviews with the local PS manager and with the professional responsible for judicial demands. Additional information regarding the municipalities' budgets in the data collection period were retrieved from the Public Health Budgets Information System (Siops, in Portuguese) of the Ministry of Health. All information from the interviews was registered in an Excel® spreadsheet in order to create a database. Each municipality received a code: the letter M followed by a number (1 to 16).

Indicators were analyzed using a decision matrix, with scores scaled according to the level of activity complexity and to a pattern of expected responses, based on the existing legislation and literature, which form a corpus of information and concepts on which the study is based. We structured a system of positive and negative scores (chart 2). We applied a cut-off point to the sum of each indicator, which limited the status of the management profile to four different levels, reflecting effectiveness (actual achievement of that which the PS sets out to achieve): Satisfactory, Regular, Deficient and Inadequate (chart 3).
Chart 2. Criteria for scoring answers to the survey of profiles of PS management of Litigated Medicines, in municipalities of the Brazilian Southeast

<table>
<thead>
<tr>
<th>Answer score</th>
<th>Assigned criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>Answer encompasses the best possible situation for the indicator.</td>
</tr>
<tr>
<td>5</td>
<td>Answer offers 50% of the best expected scenario.</td>
</tr>
<tr>
<td>0</td>
<td>Answer does not meet the indicator, but does not demand a direct action from the PS manager.</td>
</tr>
<tr>
<td>-1</td>
<td>Situations in which the answer indicates direct harms to PS management or when the manager does not have information regarding the situation</td>
</tr>
<tr>
<td>-2</td>
<td>As with -1 (minus one), corresponds to answers that indicate harms to PS management or to cases in which the manager does not have information regarding the situation, but for activities considered to be central or essential to Municipal PS</td>
</tr>
</tbody>
</table>

Source: Own elaboration.

Chart 3. Scores for classifying profiles of PS management of Litigated Medicines, in municipalities in the Brazilian Southeast

<table>
<thead>
<tr>
<th>Maximum score</th>
<th>Cutoff points for categorization</th>
<th>Percentages</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>60</td>
<td>60-42</td>
<td>100%-70%</td>
<td>Satisfactory</td>
</tr>
<tr>
<td></td>
<td>41-30</td>
<td>69%-50%</td>
<td>Regular</td>
</tr>
<tr>
<td></td>
<td>29-18</td>
<td>49%-30%</td>
<td>Deficient</td>
</tr>
<tr>
<td></td>
<td>≤17</td>
<td>≤29%</td>
<td>Inadequate</td>
</tr>
</tbody>
</table>

Source: Own elaboration, adapted from Santos-Pinto, 2013.

The study was approved by the Ethics Review Board of the National School of Public Health, under n. 237/11, Certificate of Presentation for Ethical Appreciation (CAAE) number 0301.0.031.000-11. All the managers we invited to participate agreed and signed an Informed Consent Form.

Results

The scores for all municipalities, according to all indicators, are presented in chart 4. The sums of these scores enabled us to determine each municipality’s profile in terms of the effectiveness of their management of medicines demands made through lawsuits or administrative procedures, as well the main positive and negative aspects (chart 5). The percentage of compliance according to dimension indicates challenges for PS management for issues that are considered to be consolidated by the literature or by legal regulations.
CHART 4. Scores for effectiveness of Litigated Medicine management in selected municipalities of the Brazilian Southeast region, 2013

<table>
<thead>
<tr>
<th>Municipalities</th>
<th>Item</th>
<th>M1</th>
<th>M2</th>
<th>M3</th>
<th>M4</th>
<th>M5</th>
<th>M6</th>
<th>M7</th>
<th>M8</th>
<th>M9</th>
<th>M10</th>
<th>M11</th>
<th>M12</th>
<th>M13</th>
<th>M14</th>
<th>M15</th>
<th>M16</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human Resources</td>
<td>Management of demands made via lawsuits and administrative procedures.</td>
<td>10</td>
<td>10</td>
<td>10</td>
<td>(-1)</td>
<td>0</td>
<td>0</td>
<td>10</td>
<td>10</td>
<td>10</td>
<td>(-1)</td>
<td>0</td>
<td>(-1)</td>
<td>10</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Financial Resources</td>
<td>Own financial resources 1.</td>
<td>(-2)</td>
<td>(-2)</td>
<td>(-2)</td>
<td>5</td>
<td>(-2)</td>
<td>(-1)</td>
<td>(-2)</td>
<td>(-2)</td>
<td>(-2)</td>
<td>(-2)</td>
<td>(-2)</td>
<td>(-2)</td>
<td>(-2)</td>
<td>10</td>
<td>(-2)</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>Own financial resources 2.</td>
<td>(-2)</td>
<td>(-2)</td>
<td>(-1)</td>
<td>(-2)</td>
<td>(-2)</td>
<td>(-2)</td>
<td>(-2)</td>
<td>(-2)</td>
<td>(-2)</td>
<td>(-2)</td>
<td>(-2)</td>
<td>(-2)</td>
<td>(-2)</td>
<td>(-2)</td>
<td>(-2)</td>
<td>(-2)</td>
</tr>
<tr>
<td>Activities</td>
<td>Specific procedures for handling LitMed.</td>
<td>10</td>
<td>(-1)</td>
<td>10</td>
<td>(-1)</td>
<td>(-1)</td>
<td>(-1)</td>
<td>(-1)</td>
<td>10</td>
<td>10</td>
<td>(-1)</td>
<td>(-1)</td>
<td>10</td>
<td>(-1)</td>
<td>(-1)</td>
<td>10</td>
<td>(-1)</td>
</tr>
<tr>
<td></td>
<td>LitMed purchasing processes.</td>
<td>(-1)</td>
<td>(-1)</td>
<td>10</td>
<td>(-1)</td>
<td>(-1)</td>
<td>(-1)</td>
<td>(-1)</td>
<td>(-1)</td>
<td>(-1)</td>
<td>(-1)</td>
<td>(-1)</td>
<td>(-1)</td>
<td>(-1)</td>
<td>(-1)</td>
<td>(-1)</td>
<td>(-1)</td>
</tr>
<tr>
<td></td>
<td>LitMed dispensing.</td>
<td>10</td>
<td>10</td>
<td>10</td>
<td>10</td>
<td>10</td>
<td>5</td>
<td>(-1)</td>
<td>10</td>
<td>10</td>
<td>10</td>
<td>10</td>
<td>10</td>
<td>10</td>
<td>(-1)</td>
<td>(-1)</td>
<td>10</td>
</tr>
<tr>
<td>General effectiveness score</td>
<td>25</td>
<td>14</td>
<td>37</td>
<td>32</td>
<td>3</td>
<td>1</td>
<td>(-7)</td>
<td>26</td>
<td>25</td>
<td>14</td>
<td>14</td>
<td>26</td>
<td>(-7)</td>
<td>4</td>
<td>26</td>
<td>17</td>
<td></td>
</tr>
<tr>
<td>Municipality’s percentage</td>
<td>42%</td>
<td>23%</td>
<td>62%</td>
<td>53%</td>
<td>5%</td>
<td>2%</td>
<td>(-12%)</td>
<td>43%</td>
<td>42%</td>
<td>23%</td>
<td>23%</td>
<td>43%</td>
<td>(-12%)</td>
<td>7%</td>
<td>43%</td>
<td>28%</td>
<td></td>
</tr>
</tbody>
</table>

Source: Own elaboration.

LitMed = Litigated Medicines.

CHART 5. Main results of Pharmaceutical Service Management of Litigated Medicines in 16 municipalities in the Brazilian Southeast, 2013

<table>
<thead>
<tr>
<th>Municipality</th>
<th>Main positive aspects</th>
<th>Main negative aspects</th>
<th>Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>M1</td>
<td>• CoordMPS was responsible for responding to LitMed demands or administrative demands and was in regular contact with the Judiciary. • LitMed were purchased through in-person reverse auctions, according to a public notice.</td>
<td>• Did not require technical reports in order to acquire LitMed. • PS management could not inform the financial sums required to meet legal demands and administrative demands regarding LitMed.</td>
<td>Deficient</td>
</tr>
<tr>
<td>M2</td>
<td>• CoordMPS was responsible for responding to LitMed demands or administrative demands.</td>
<td>• There was no technical analysis of plaintiffs’ prescriptions. • PS management could not inform the financial sums required to meet legal demands and administrative demands regarding LitMed. • The purchase modality for LitMed was price quotes.</td>
<td>Inadequate</td>
</tr>
<tr>
<td>M3</td>
<td>• CoordMPS was responsible for responding to LitMed demands or administrative demands and was in regular contact with the Judiciary. • All plaintiffs’ prescriptions underwent technical analysis. • LitMed were purchased via bidding or direct purchase, and technical reports were required.</td>
<td>• The sums needed to meet legal demands and administrative demands in 2013 were higher than those spent on forecasted medicines.</td>
<td>Regular</td>
</tr>
</tbody>
</table>
| M4 | CoordMPS was responsible for responding to LitMed demands or administrative demands. | • There was no technical analysis of plaintiffs’ prescriptions.  
• PS management could not inform the financial sums required to meet legal demands and administrative demands regarding LitMed. | Regular |
| M5 | • No relevant aspects were identified. | • The manager did not know who was responsible for responding to LitMed demands or administrative demands; how many lawsuits were received; the purchasing modality; or if there were specific procedures for this activity.  
• Manager did not how LitMed were dispensed. | Inadequate |
| M6 | • No relevant aspects were identified. | • The responsibility for LitMed or administrative demands fell to the Health Secretary.  
• No technical reports were required.  
• The financial sums disbursed with legal demands and administrative demands were greater than those spent on selected and forecasted medicines.  
• Manager did not know which bidding modalities were used for purchasing LitMed.  
• Manager did not how LitMed were dispensed. | Inadequate |
| M7 | • No relevant aspects were identified. | • The responsibility for LitMed or administrative demands fell to the Health Secretary.  
• No technical reports were required.  
• The financial sums disbursed with legal demands and administrative demands were greater than those spent on selected and forecasted medicines.  
• Manager did not know how LitMed were dispensed. | Inadequate |
| M8 | • CoordMPS was responsible for responding to LitMed demands or administrative demands and was in regular contact with the Judiciary. | • The manager did not know when medicines demands began or how many they received over the previous year.  
• The financial sums disbursed with legal demands and administrative demands were greater than those spent on selected and forecasted medicines.  
• The sums were mobilized from the Municipal Municipal Middle and High Complexity Outpatient and Hospital funds.  
• Manager did know which purchasing modality was used for LitMed. | Deficient |
| M9 | • CoordMPS was responsible for responding to LitMed demands or administrative demands.  
• Required technical reports in order to acquire LitMed. | • The manager did not know how many lawsuits they received; or what was the source of the financial sums disbursed to comply with the lawsuits and administrative demands. | Deficient |
| M10 | • CoordMPS was responsible for responding to LitMed demands or administrative demands. | • PS management could not inform the financial sums required to meet legal demands and administrative demands regarding LitMed or how many lawsuits were complied with.  
• No technical reports were required for purchasingLitMed. | Inadequate |
| M11 | • CoordMPS was responsible for responding to LitMed demands or administrative demands.  
• Medicines were purchased via reverse auction and required technical reports.  
• Medicines was dispensed exclusively by the PS manager. | • The manager could not inform the sums used to meet these demands; how many lawsuits they received; or what was the source of the financial sums disbursed to comply with the lawsuits and administrative demands. | Inadequate |
| M12 | Technical reports were required for purchasing procedures via reverse auction. | • The manager did know who was responsible for meeting LitMed demands or administrative demands; the financial sums needed to meet these demands; or how many lawsuits they received. | Deficient |
The dimension ‘Human Resources’ sought to identify the team responsible for addressing judicial demands in the municipality, and whether or not a pharmacist was involved in this process. In nine (56%) of the municipalities, the management of litigated medicines and materials fell under the purview of the local PS manager. Four (25%) managers reported that this management fell to another sector in the Municipal Health Secretariat and three (18.75%) managers did not even know which sector was responsible.

In the dimension ‘Financial Resources’, the indicators that performed the worst in all answers were related to LitMed purchase expenditures. Most managers (75%) were unable to inform the sums they had disbursed. Of those who were able to provide that information, four (25%) stated that the sums disbursed with LitMed were higher than those mobilized for purchasing previously selected and scheduled medicines.

Ten of the 16 managers (62.5%) were unable to inform the amount of financial resources mobilized for ‘emergency’ purchases. Among these ten managers, two stated that the municipality spent more on emergency purchases than on regular ones. All managers stated that financial resources for acquiring medicines in compliance with lawsuits and administrative procedures were mobilized from the Municipal Treasury or the Municipal Health Fund.

Using Siops data, we investigated financial independence according to municipalities’

| M13  | • No relevant aspects were identified. | • The responsibility for LitMed or administrative demands fell to the Health Secretary. |
|      |                                     | • The manager did not know the financial sums needed to meet these demands; how many lawsuits they received; what was the source of the financial sums disbursed to comply with the lawsuits and administrative demands; the purchasing modality used; and whether there were specific procedures for this activity. |
|      |                                     | • Manager did not how LitMed were dispensed. |
| M14  | • No relevant aspects were identified. | • Manager did not know who was responsible for responding to medicines demands made via lawsuits or administrative demands in the municipality. |
|      |                                     | • Did not know when medicines demands began; how many they received in the previous year; the financial sum required to meet these demands; where these resources came from; the purchase modality; or how the medicines were dispensed. |
| M15  | • CoordMPS was responsible for responding to LitMed demands or administrative demands and was in regular contact with the Judiciary and required technical reports. | • The manager did not know when medicines demands began; how many they received over the previous year; the financial sums needed to meet these demands; or the purchasing modality. |
| M16  | • Required technical reports in order to acquire LitMed. | • The responsibility for LitMed or administrative demands fell to the Mayor’s assistants. |
|      |                                     | • The financial sums disbursed with legal demands and administrative demands were greater than those spent on selected and forecasted medicines. |

Source: Own elaboration.

LitMed= Litigated Medicines; CoordMPS= Municipal PS Coordination.
tax revenues, and medicines expenditures in terms of total health resources. All municipalities had low tax revenues, defined in terms of the share of taxes in the municipality’s total net revenue. Net expenditures with ‘Prophylactic and Therapeutic Support’ (which includes medicines expenses) varied between 0% and 2.37% of total health expenditures. All municipalities had a significant ‘dependence percentage’, varying between 60% and 90%, with regard to the contribution of government transfers as sources of funds.

Seven (43%) of the managers were unable to specify the type of bidding process, or even if a bidding process was used for purchasing litigated medicines; three (18.75%) stated they used the reverse auction modality; three (18.75%) others stated they used price registers; and the remaining 3 (18.75%) stated they used direct purchases.

As for dispensing LitMed, 12 (75%) managers stated they followed the norms of Best Dispensing Practices (BDP), 3 (18.75%) were unable to inform whether or not they followed BDP and 1 (6.25%) manager stated he only carried out a control of dispensed items.

The sum of scores for the effectiveness of PS management with regard to LitMed classified nine (56.25%) municipalities as having Inadequate management, five (31.25%) as having Deficient management and only two (12.5%) – M3 and M4, respectively, medium and large-sized – as having Regular management. Among the municipalities classified as having Inadequate management, two (M7 and M13) had negative scores on all indicators, revealing a lack of capacity for managing LitMed. No municipality had sufficient scores for the Satisfactory management profile.

Discussion

The matrix we used to analyze the 16 municipalities enabled us to describe the processes related to LitMed that involve Municipal PS, its actors, limitations, challenges and possibilities. Our findings regarding PS organization in terms of litigated medicines, for all municipalities, is cause for concern.

Santos-Pinto and Osorio-de-Castro proposed that, rather than judicial demands bringing inefficiency to PS management, pre-existing inefficient management would lead to the occurrence of judicial demands in the municipality, though this is not the only determining factor. This study’s findings seem to corroborate the problem signaled by the authors. Managers had little knowledge of demands, whether related to resources or to the management of the medicines.

As for medicines expenditures, in the summary budget execution report in Siops, the reported sum was so low that one may imagine there was a data entry error, which also points to deficiencies in PS management, or in other municipal management loci. The low amounts reported were incongruous, considering that medicines accounted for an expressive share (22%) of health expenditures.

Most interviewed managers were unable to inform the sums disbursed with demands. An extensive national research carried out by the National Justice Council showed that municipalities are important ‘defendants’ in lawsuits, in many Brazilian states, at both the first and second levels of courts of law. We may assume that municipal budgets are overloaded with these expenditures, which cause difficulty for the other municipal health actions and services. The realization that the disbursed sums came from the Municipal Treasury showed that financial losses to health care services may not be the only consequences – other aspects that make up health (in a broader sense) may be equally affected, such as housing and education.
Many studies have shown an exponential increase of public expenditures with LitMed, alerting to the scarcity of financial resources. It is therefore unacceptable that the Municipal Treasury sums used to comply with lawsuits (such as emergency medicines purchases) not be known, especially without the appreciation of a technical report, both of the demand and of the purchase. Wang et al. 38-40 identified that expenditures with LitMed purchases, in 2011, in the wealthiest Brazilian municipality, corresponded to 10% of the total expenditures with medicines and hospital, outpatient and dentistry material. In 2016, Mello et al. found a per capita cost for LitMed that was 200 times greater that the per capita sums disbursed with funding the Basic Component of Pharmaceutical Services (for primary health care medicines).

This study found that all municipalities included in the analysis had low tax revenues and high degree of dependence on government transfers. This points to the vicissitudes of municipalities as independent federated entities, since they are basically supported by transfers and do not take on the responsibility of providing accountability mechanisms. Judicialization, an omnipresent phenomenon in Brazil, propitiates this analysis 41, especially because the literature shows that the demanded medicines, for the most part, should be available through SUS and, therefore, are directly related to problems in the organization of PS management 37,42-45.

As for assessing and monitoring demands, Pepe et al. 48 have proposed a list of indicators (digitally and publicly available) which express the characteristics of the phenomenon in different dimensions, applicable to any public sphere, and which enable a perspective that can indicate strategic paths for confronting these growing and constant challenges. This tool could, and should, be used by all municipal managers. The commitment from management, PS and the municipal Executive branch should lead to monitoring, follow-up and formulation of strategies that can minimize the financial, social and therapeutic impacts of demand, which are indispensable for the adoption of new forms of public management 49-52.

When analyzing the criteria taken into consideration by the managers who claimed to follow BDP, we found the arguments ‘three-month patient control’ and ‘delivery receipt’, without considering the clinical, pharmacotherapeutic or dosage regimen aspects, or the treatment period, as criteria of BDP. Pharmacists can train and supervise technicians or assistants in this activity, but the technical accuracy for identifying possible problems related to medicines is the attribution of pharmacists themselves 53. Furthermore, the medicines that are usually demanded may have their treatment duration modified at any moment, considering those not selected or even registered in the country 54-56.

A management with failures and deficiencies does not favor the public provision of medicines or the guarantee of quality pharmaceutical services, which compromises users’ health situation. According to Jaramillo and Cordeiro 29,57, a new PS model must be based on meeting the population’s health needs, considering that activities, especially those related to logistics, must be carried out efficiently and without creating barriers for management.

Nonetheless, the findings show an adverse scenario that runs counter to this postulate. Finding primitive failures in...
LitMed management is concerning because, inevitably, demand intensify and, if this form of responding to them continues, the system becomes unable to meet the population’s needs\textsuperscript{58-60}.

Although the Judiciary’s understanding is that of indistinctly providing medicines, whether or not they are included in official lists, and regardless of federative arrangements, PS management should carry out the activities in its purview, always seeking the rationalization of finite public resources, patient safety when using different, at time simultaneous, medicine therapies, the assurance that stocks will be adequately maintained, and, especially, seeking closer ties with the local judiciary\textsuperscript{61-53}.

This study was limited by scope and time. We were only able to collect data in 16 municipalities of the Brazilian Southeast region. We sought to overcome the limitation in terms of numbers through the care in characterizing the municipalities’ profiles. On the other hand, an important limitation was a result of information failures, both those originating in Siops and those found in answers related to litigated medicines management (38% of answers). However, the lack of information, made evident by ‘did not know’, if connected with information failure (left blank) was, in fact, a very interesting answer, which corroborates the perception of management problems. The five years between data collection and analysis prompted a return to Siops, through which we observed that the information failure profile persisted among these municipalities. This reality points to doubts: (a) regarding municipalities’ responsibility for presenting reliable data; (b) regarding the responsibility of superior management spheres when monitoring indicators for financial transfers.

Beyond the financial scope, the inconsistencies found by this study, in activities considered to be central to PS, reveal the inability of local management to ensure the guiding principles defined by the Brazilian Medicines Policy (PNM) and the Brazilian Pharmaceutical Services Policy (PNAF), for Municipal PS\textsuperscript{64,65}.

**Conclusions**

Although PS management was identified as being responsible for the provision of LitMed in most municipalities included in the analysis, the profile we found points to inadequacies in this process. Negative aspects, such as lack of knowledge regarding sums disbursed for purchases, and regarding purchasing modalities, the lack of technical reports, irregular contacts with the Judiciary and contradictions regarding best dispensing practices indicate the need for broadly calling into question the role that municipal management pharmacists play and the possibilities for changing this situation.

Problems in municipal PS management have been presented and discussed for years, but the fact remains that its resolution has not been sufficiently sought. The persistent scenario must be called into question given the almost 20 years that PNM has been in force, as well as Ordinance n. 176/1999 – which decentralized PS to the municipalities –, and the 14 years of PNAF – which guided the practices of quality-based services. We still lack a more careful look at the municipal management’s responsibility and the effectiveness of its services.

The practice of municipal management as a whole, which influences PS management, must be revised. Results point to the need for broadly calling into question the role that municipal management has played in Brazil and the possibilities for changing this scenario with possible keys for improving services and management.

**Collaborators**

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Failures in Pharmaceutical Services management for Judicialized Medicines, in 16 municipalities of the Brazilian Southeast

Osorio-de-Castro CGS (0000-0003-4875-7216)*: substantial contributions to study conception and design; preliminary article drafting; approval of the final version for publishing; agreement with being responsible for all aspects of the work. Magarinos-Torres R (0000-0003-4559-3770)* and Santos-Pinto CDB (0000-0002-5478-4977)*: support to writing and technical review.

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