Analysis of medicine procurement lawsuits in the state of Paraíba, Brazil

Análise das demandas judiciais para aquisição de medicamentos no estado da Paraíba

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Abstract

This study aimed to describe the medical, scientific, and sanitary aspects of lawsuits for drug supply filed with the Court of Paraíba (TJ-PB) against public officials in the state of Paraíba, Brazil. It was a descriptive and cross-sectional study, which had as source the Information System of the Paraíba Court. Drug processes judged at the second instance between the years 2009 and 2010 with a final decision already made at the time of consultation were analyzed. About the scientific evidences of efficacy and safety, drugs were evaluated through systematic reviews in the Brazilian Cochrane Centre database. The groups of drugs most frequently requested were the antineoplastic agents, followed by insulin and angiotensin II antagonists. The antineoplastic agents' costs accounted for 76% of the total spent on litigation, representing an approximate cost of R$ 343,000 per month, of which an item had no record in Brazilian sanitary organ. The results pointed to a high number of lawsuits with prevalence of requests for drugs standardized by the Brazilian Unified Health System (SUS), of which the antineoplastic agents are noteworthy and reinforce the need for revision of the National Pharmaceutical Assistance Policy, both regarding deployment strategies as the urgency to expand the list of drugs available through SUS.

Keywords: Pharmaceutical Assistance; Lawsuits; Public Health.

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Resumo

O objetivo deste estudo foi descrever os aspectos médico-científicos e sanitários dos mandados judiciais para fornecimento de medicamentos impetrados ao Tribunal de Justiça da Paraíba (TJ-PB) contra agentes públicos no estado da Paraíba. Teve caráter descritivo, transversal, e foi realizado no Tribunal de Justiça da Paraíba. Foram analisados processos de medicamentos julgados na segunda instância entre os anos de 2009 e 2010 com decisão definitiva. Quanto às evidências científicas da eficácia e segurança, os medicamentos foram avaliados por meio de revisões sistemáticas na base de dados do Centro Cochrane do Brasil. Os grupos de medicamentos solicitados com maior frequência foram os agentes neoplásicos, seguidos de insulinas e antagonistas da angiotensina II. Os custos com medicamentos antineoplásicos representaram 76% do gasto total com demandas judiciais, representando um custo aproximado de R$ 343 mil por mês. Desses, um item não tinha registro em orgão sanitário brasileiro. Os resultados apontam para um elevado número de demandas judiciais com prevalência de solicitações de medicamentos padronizados pelo Sistema Único de Saúde (SUS), dos quais os antineoplásicos obtêm destaque e reforçam a necessidade de revisão da Política Nacional de Assistência Farmacêutica tanto das estratégias de implantação como da premência em ampliar a relação de medicamentos disponibilizados pelo SUS.

Palavras-chave: Assistência Farmacêutica; Decisões Judiciais; Saúde Pública.

Introduction

Logistics of pharmaceuticals for a long time have been restricted to purchase and distribution, and until late 1990s, in Brazil, the Central Drug Agency (CEME) coordinated these activities. Pereira (2006) mentions that only after the implementation of the Brazilian Unified Health System (SUS) and its regulations there have been significant changes in pharmaceutical assistance approach, from a merely administrative process to a process inserted in the production of health care, stimulating practices of rational use of medicines.

The implementation of the National Medicines Policy (PNM) (BRASIL, 2001) in 1998 and, in 2004, of the National Pharmaceutical Assistance Policy (PNAF) (BRASIL, 2004) are important pharmaceutical assistance milestones in Brazil. PNM adopted as its policy listing essential medicines; sanitary regulation on medicines and the promotion of their rational use; reorientation of pharmaceutical assistance; scientific and technological development; promoting pharmaceutical production; safety assurance; effectiveness and quality of medicines; human resources development and training; and it has established competencies of each federative entity. In turn, PNAF defined pharmaceutical assistance as a guiding public policy for sectoral policies, among which the pharmaceuticals, science and technology, industrial development, and human resources training policies, ensuring the intersectional approach inherent to the country's public system, whose implementation involved public and private health care sectors (Bermudez; Bonfim, 1999).

However, Pereira (2006) demonstrated in a study conducted in the Southern region of Brazil that joint actions that made possible the full implementation of these policies in the country's health system were insufficient to make PNAF effective. Even after the development of a concept of pharmaceutical assistance more suited to SUS principles and the incorporation of this understanding to proper legislation, distribution of medicines did not meet the demand, generating much dissatisfaction in the community and distortions in the flow of services.

In this context, the judicialization of health emerged as main alternative to overcome bureaucracy and limitations within standardized lists, serving as a shortcut for acquiring prescribed drugs (Leite et al., 2009).

This research had as its main objective to describe medical-scientific and sanitary aspects of lawsuits for the supply of medicines filed in the Court of Justice of Paraíba (TJ-PB) against public agents in the state of Paraíba. The authors will assess thus the extent of barriers in the implementation of Pharmaceutical Assistance in SUS and the possible impacts on health care promotion.

Methods

We conducted a cross-sectional study with quantitative analysis of lawsuits against public agents in the state of Paraíba. TJ-PB website was used as data source, accessing the "jurisprudence" link. The universe of analysis was composed of: cases involving pharmaceuticals heard by the court of appeals from 2009 to 2010, available for consultation; cases whose summaries presented the term "medicine"; and lawsuits with definitive decisions already made when they were consulted.

Due to TJ-PB website settings, we could not specify the search by type of lawsuit heard by the court of appeals, therefore the first selection took into account only the first three criteria for inclusion, resulting in a total of 277 cases. Later, we read all previously selected cases, excluding those not involving the purchase of medicines by public entities; court files with incomplete data; and court of appeals decisions that did not end the case. Finally, we obtained a total of 58 cases.

Variables researched were: municipality of residence, number of authors of the case, type of case, legal representation, free legal advice, judiciary district, injunction, sentence date and passing into matter adjudged, defendant, main diagnosis, medications and other inputs required, prescribed medication, dosage, therapeutic indication, Common Brazilian Designation (DCI/DCB) and Anatomical Therapeutic Chemical Code (ATC), prescription by generic name, registration on the National Health Surveillance Agency (Anvisa), presence in standardized lists of medicines, treatment approximate cost.

Information about the records of medicines in Brazil were obtained from the database of Medication and Blood Products of Anvisa[1] .

We verified the existence of scientific evidence on safety and effectiveness of medicines in systematic reviews from Brazilian Cochrane Center database. Classification was carried out according to World Health Organization recommendations, through ATC.

Data analysis proceeded from simple frequency calculation of all variables, stored in Microsoft Office Excel 2003 spreadsheet and Statistical Package for the Social Sciences (SPSS) 17.

The study was approved by the Ethics and Research Committee of State University of Paraíba, on December 19, 2011, CAAE No. 0767.0.133.000-11.

Results

We identified 58 active lawsuits against the Secretariat of Health of the state of Paraíba and/or municipalities, demanding procurement of medicines. In 46 (79.3%) cases was the State the defendant and in 12 (20.7%) cases the municipal Secretariats of Health of João Pessoa and Campina Grande.

As for the responsible by processes filed, 32 (55.17%) cases had private legal representation (law firms) and 26 (44.83%) state legal representation (Public Defender's Office or Prosecutor's Office). In both situations there were applications for gratuity and they obtained judicial recognition of economic insufficiency of the applicant in 29 (50.0%) cases. Regarding the content of decisions made, sentences were considered totally valid in 45 (77.6%) cases; 2 (3.4%) applications were considered partially valid, and 11 (19%) cases not valid.

In the analysis of time taken to obtain the medicine by legal means (Table 1), there was an average of 206 days between entry date and judgment; and an average of 453 days between entry and definitive decision after appeal.

1 Available for consultation: <http://www.anvisa.gov.br/medicamentos>

Table 1 – Summary of time (in days) elapsed between originating cases and sentences in trial and appeals Court of Paraíba, Campina Grande, Brazil, 2011

Elapsed time between:	Minimum	Maximum	Average
Initiation of legal proceedings and trials court decision	21	951	206
Initiation of legal proceedings and appeals court decision	94	2,065	453

Regarding medical-scientific and sanitary aspects, we identified 97 items requested, representing a variety of 75 different drug presentations. Ordering them according to the third level of the ATC classification, we observe that the most frequent subgroup is "Other antineoplastic agents" (L01X - Platinum compounds, methylhydrazines, monoclonal antibodies, sensitizers used in photodynamic/radiation therapy, protein kinase inhibitors, and other antineoplastic agents) with 15 (15.31%) cases, followed by insulin (A10A) with 8 (8.25%), and angiotensin II antagonists (C09C) with 5 (5.15%) cases (Table 2). The higher demand among antineoplastics was for treatment of non-Hodgkin lymphoma (rituximab), 21.75% (Table 3). Antineoplastics requested generated approximately R$343,000 in expenses per month, equivalent to 76% of total money spent with medicines in consequence of lawsuits. One of these drugs is not registered in Brazil: Alemtuzumab®.

Table 2 – Drugs requested according to the third level of the ATC* classification, Campina Grande, Brazil, 2011

ATC*	Pharmacologic class	n	%
L01X	Other antineoplastic agents	15.0	15.46
A10A	Insulins	8.0	8.25
C09C	Angiotensin II antagonists	5.0	5.15
L02B	Hormone antagonists and related agents	4.0	4.12
N03A	Antiepileptics	4.0	4.12
B01A	Antithrombotic agents	3.0	3.09
J05A	Direct acting antiviral drugs	3.0	3.09
L03A	Immunostimulants	3.0	3.09
N05A	Antipsychotics	3.0	3.09
A10B	Blood glucose lowering drugs, excluding insulins	2.0	2.06
C07A	Beta blocking agents	2.0	2.06
C08C	Selective calcium channel blockers with mainly vascular effects	2.0	2.06
C09A	Angiotensin-converting-enzyme inhibitors, plain	2.0	2.06
C10A	Lipid modifying agents	2.0	2.06
H05A	Parathyroid hormones and analogues	2.0	2.06
L01A	Alkylating agents	2.0	2.06
L04A	Immunosuppressive agents	2.0	2.06
R03B	Other drugs for obstructive airway diseases, inhalants	2.0	2.06
	Others	31.0	2.06
	Total	97.0	100.0

*ATC = Anatomical Therapeutical Chemical Code.

Table 3 – List of requested antineoplastics, Campina Grande, Brazil, 2011

ATC	DCB	Clinical Indication	Clinical Evidence*	n	%
L01XC02	rituximab	Non-Hodgkin lymphoma	Limited	5.0	21.75
L01AX03	temozolomide	Anaplastic astrocytoma	Limited	2.0	8.69
L01XC07	bevacizumab	Diabetic Retinopathy	There is none	2.0	8.69
L01XE01	imatinib	Chronic Myelogenous Leukemia	Limited	2.0	8.69
L01XE05	sorafenib	Renal Cell Carcinoma	There is none	2.0	8.69
L02BG04	letrozole	malignant breast neoplasm	Second choice in breast cancer treatment for postmenopausal women	2.0	8.69
L01XC04	alemtuzumab	Chronic Lymphocytic Leukemia	Limited	1.0	4.35
L01XE04	sunitinib malate	Renal Cell Carcinoma	Limited	1.0	4.35
L01XE06	dasatinib	Chronic myelogenous leukemia	Limited	1.0	4.35
L01XE07	lapatinib	Carcinoma	There is none	1.0	4.35
L02AE02	leuprorelin	Prostate cancer	There is none	1.0	4.35
L02AE04	goserelin	Prostate cancer	There is none	1.0	4.35
L02BG03	anastrozole	Malignant breast neoplasm	There is none	1.0	4.35
L02BG06	exemestane	Malignant breast neoplasm	There is none	1.0	4.35
-	-	-	Total	23.0	100.0

Identified morbidities have been classified according to the 10th Revision of the International Classification of Diseases (ICD-10). Most frequent diagnosis according to ICD-10 were neoplasms (C00 - D48), 19 cases (32.76%); musculoskeletal and connective tissue disorders (M00-M99), 5 cases (8.62%); and hypertensive heart diseases (I10 - I15), 4 cases (6.89%) (Table 4).The research revealed 28 (28.86%) drugs prescribed by generic name and 23 (23.71%) were at the Rename 2008, drug list valid at the time the cases were filed (Table 5).

Table 4 – Classification of identified morbidities in court cases analyzed, Campina Grande, Brazil, 2011

ICD-10	Pathology	n	%
C00 – D48	Neoplasms [tumors]	19.0	32.76
M00 – M99	Diseases of the musculoskeletal system and connective tissue	5.0	8.62
I10 – I15	Hypertensive diseases	4.0	6.89
B15 – B19	Viral hepatitis	3.0	5.17
E10 – E14	Diabetes mellitus	2.0	3.45
N17 – N19	Renal failure	2.0	3.45
F00 – F99	Mental and behavioural disorders	2.0	3.45
H30 – H36	Disorders of choroid and retina	2.0	3.45
-	Other morbidities	15.0	25.86
-	Without information	4.0	6.90
	Total	58.0	100.0

Table 5 – Profile of medicines requested judicially in Court of Justice of Paraíba, Campina Grande, Brazil, 2011

	n	%
Prescribed by generic name?		
Yes	28.00	28.86
No	69.00	71.14
Does it have registration at Anvisa[1]?		
Yes	93.00	95.87
No	4.00	4.13
Is it listed at Rename[2]?		
Yes	23.00	23.71
No	74.00	76.29
Is it on other PAF[3] lists?		
Remume[4]	11.00	11.34
Resme[5]	11.00	11.34
Others	2.0	2.06
Do not apply	73.00	75.26

[1]National Health Surveillance Agency; [2]National List of Essential Medicines; [3]Pharmaceutical Assistance Programs; [4]Municipal List of Essential Medicines; [5]State List of Essential Medicines.

Discussion

Because of the clinical condition of some patients, applications often have an urgent character (injunction or request for interim relief) for the pharmaceutical claimed to be provided immediately. The medical prescription is the only document taken into account when determining the applicant's need. There was not an evaluation by health care professional on the possibility of the drug inclusion on SUS programs, resulting in the immediate approval of the request by the judge. This fact has had an effect on the accessibility of services, amplifying works carried out in South and Southeast regions of Brazil. Distortions, with delay in the start of treatment (Lopes et al., 2010).

Medicines supply by the public system is linked to integral patient care through services organization. According to Pepe et al. (2010), mere dispensation breaks the system comprehensiveness logic and results in using resources to purchase medicines available in another government sphere, forcing the incorporation of technologies whose effectiveness is not always verified. Opposed to such assertion, 23 (23.71%) of requested medicines were within SUS standards, a fact that underscores the state substantial responsibility in the increased number of lawsuits alleging non-compliance with PNAF policies.

Frailty of the defense of Executive Powers, defendants in lawsuits, as well as of the judiciary when dealing with this issue have raised questions about possible harms to patients. The study also restates Pepe et al. (2010) findings, which proved to be 413 days the average time between entry of the judgment and definitive decision from the court of appeals. It is thus a long period for the patient to start treatment; however, it is not time enough to review cases to potentially prevent prescription errors and therapeutic safety failures.

Despite the lack of access to prescriptions, during analysis we could identify on case records the lack of compromise of most clinicians in registering in the prescription the medicine's generic name, not complying with Law No. 9.787/1999, which establishes the compulsory adoption of the generic name in dental and medical prescriptions (Brasil, 1999).

The study draws attention to cancer patients' problems, since most common items were antineoplastics and the most requested were bevacizumab, imatinib, rituximab, temozolomide, sorafenib tosy-

late, and letrozole (Table 5). Requests focused on treatment of malignant neoplasms of lymphoid, hemopoietic, and related tissues, identified in Lopes et al. (2010), study carried out in the state of São Paulo.

Studies point out that despite high expenditures with antineoplastics there is no evidence of improvement in patient survival rates or cure rates. They demonstrate also that medicine procurement cases involve few clinicians and few lawyers (Lopes et al., 2010). One the one hand these facts are sufficient to conduct prescription audits, on the other hand many Brazilian entities for consumer protection are financed by pharmaceutical companies and also some are off-label prescription drugs (non-approved by regulatory agency) that do not present proof of efficacy and effectiveness, e.g., Alemtuzumab, an antineoplastic indicated for treatment of lymphocytic leukemia and not approved by Anvisa for distribution in Brazil[2].

When making a prescription, physicians decide the type of treatment based on their conceptions of the health-disease process; technical training quality; social, cultural, and economic conditions of the population attended; medicines available in the health care service; access to information; harassment by pharmaceutical companies, among others (Vieira; Zucchi, 2007).

If every agent involved continue to perform their activities without seeing the big picture, the dispute between judicialization of health and organization of the public health system remains unresolved. The judiciary will continue to have difficulty in judging the relevance of the request, since health care is a fundamental right; public management will be limited to regulate access that sometimes restrains real health care demands; clinicians will disregard public policies; pharmaceutical companies will continue to influence medicines purchase, regardless of proven efficacy of the product; and the population will not receive proper attention.

Final remarks

An important contribution of this study is the diagnosis of judicialization of health in the state of Paraíba, a new research approach for the Northeast region of Brazil. Results obtained restates findings from research carried out in the state of Santa Catarina, in which there was predominance of cases conducted by private legal representation with high frequency of requests for medicines standardized by SUS (Pereira, 2006). Moreover, there are demands for medicines that are not part of SUS standardization and the prescription of these drugs are due to the influence of pharmaceutical companies over health care professionals, revealing the necessity of ethical discussions on the subject.

Besides, prevalence of antineoplastic agents reinforce the importance of discussing public policies that meet the community's demands, based on changes caused by demographic transition and increased number of chronic and degenerative diseases.

Finally, we suggest the re-structuration of medicines policy in order to meet more specific demands. An alternative would be to expand medicine programs, currently carried out by municipalities and states, allowing non-standard medicines to be purchased, after evaluation of a technical commission. We also propose reformulation of PNAF, reviewing implantation strategies in order to expand its reach. A great advance is the creation of the National Committee for Health Technology Incorporation (Conitec) in the SUS through federal law No. 12.401/2011 (Brasil, 2011). This committee incorporates evidence-based analysis and takes into account aspects such as efficiency and cost-benefit evaluation in relation to existing technologies. Conitec has the objective of supporting the Ministry of Health in the field of health technologies used in the SUS, as well as elaborating clinical protocols and therapeutic policies.

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Authors' contribution

Leitão worked on project's concept and design, writing and final approval of the paper's version to be published. Silva worked on data interpretation and writing the paper. Simões, Barbosa, and Pinto worked on data analysis and writing the paper. Mônica Simões participated in the conception and design, critical review of intellectual content, and final approval of the paper's version to be published.

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