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Distortions to national drug policy caused by lawsuits in Brazil

ABSTRACT

OBJECTIVE: To describe how lawsuits, which demand the supply of drugs, impact on elements of the national drug policy.

METHODS: This is a desk-based study using qualitative and quantitative methods. All legal proceedings brought by citizens against the Municipal Secretary of State of Sao Paulo, relating to the supply of drugs in 2005 were analyzed. A standardized form was used to collect data, with a view to carrying out an exploratory analysis.

RESULTS: A total of 170 cases relating to the supply of drugs were brought against the Municipal Secretary of State. The National Health System (SUS) was the source for 59% of the prescriptions: 26% from the municipal level, 33% from other levels. Cancer and diabetes were the diseases most commonly involved (59%). About 62% of drugs requested are on the lists of SUS services. Total expenditure was R\$876,000 (Brazilian Reais), covering only non-selected items (i.e. those which are not included in the Municipal Register of Essential Medicines), 73% of which could be substituted. Of the total expenditure, 75% was spent on purchasing anticancer drugs, for which further clinical trials are required to prove their effectiveness. Two of these medicines were not registered in Brazil.

CONCLUSIONS: The majority of demands for drugs that have led to legal proceedings could be avoided if two SUS directives were followed, namely the organization of oncology services and the observance of reporting on essential medicines. Failure to do so causes a breakdown in the National Drug Policy, in equality of access and in the rational use of drugs within the National Health System.

KEYWORDS: National Drug Policy. National Policy on Pharmaceutical Care. Unified Health System. Legal Decisions.

INTRODUCTION

International trade in medicines increased rapidly between 1980 and 1999, rising from US\$5 billion to US\$120 billion during that period. Within this market, a smaller number of multinational companies dominate the global production and sale of medicines. Ten of these companies are responsible for almost half of all sales and this concentration has grown considerably since 1987. Changes between 1985 and 1999 show that the value of drug production has increased four times more quickly than world income, although this has not translated into greater access to medicines amongst the population. In 1999, the 15% of the world's population who live in high-income countries were responsible for buying and consuming medicines equivalent to 90% of total world expenditure on drugs. The USA alone, in 2000, made up 52% of this market, while low-income countries' share of global consumption of drugs dropped from 3.9% in 1985 to 2.9% in 1999.¹³

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In Brazil, it was estimated that in 2000, the number of people who did not have access to drugs was 70 million, representing approximately 41% of the population in that year. This is one of the main challenges to the public health system.

The Brazilian Health System, SUS (from the Portuguese acronym), was set up under the Federal Constitution of 1988 and established in law in 1990. Under the SUS, universal equality of access is guaranteed, and health services and systems are integrated. The right to pharmaceutical services, including therapy, was also anticipated but was not regulated and only in 1998 was the National Medicines Policy (PNM) published. This document included policy proposals for guaranteeing safety, effectiveness and quality of drugs, the promotion of rational use, and universal access to medicines considered essential. The directives established under the PNM included the drawing up of essential drug lists, regulation of drug hygiene, and the promotion of their rational use, the reorganization of pharmaceutical services, scientific and technological development, the promotion of drug production, safety guarantees, the effectiveness and quality of drugs, and the development and training to human resources.*

Due to the size of Brazil and regional differences in morbidity and mortality indicators, the management of SUS is divided between the three spheres of government. For this reason, guidelines set out how state- and municipal-level governments should select medicines for their regional lists, based on a national report.**

Health services can be operated by the private sector and, as occurs in the municipality of São Paulo, private service providers often write prescriptions that are then supplied by SUS pharmacies. This practice goes against the policy of integration of actions and services of the unified system, since the supply of drugs should only be guaranteed through prescriptions originating from SUS.***

In spite of the advances made by SUS since its creation, the State is still falling short in guaranteeing access to essential drugs for the Brazilian population. At present, one particular issue trend is giving rise to a breakdown in Brazilian medicines policy and as such is diminishing the amount of resources available for drug purchasing. It has become common for citizens to

make legal claims, through the judicial system, for the acquisition of drugs which do not appear on the lists of essential medicines.⁶

Thus, bearing in mind the distortions that this practice can cause, the present study aimed at describing the effects that legal proceedings relating to demands for the supply of drugs, have on elements of the National Medicines Policy.

METHODS

This is a desk-based study using qualitative and quantitative methods. The unit of analysis of the study is the lawsuit, brought by the citizen against the Municipal Secretary of Health of São Paulo (SMS-SP, in the Portuguese), and in particular those that are within the judicial system to demand the supply of drugs required by patients. Only those legal proceedings that were brought between January and December 2005 and related to demands for drugs were evaluated. In addition, the researchers used information relating to on-going proceedings sourced from the Juridical Advisory and the Support Division of SMS-SP.

The study used a standardized form for collecting data relating to cases that were successfully brought, so as to allow for a subsequent exploratory analysis. The variables under consideration were: declared illnesses, types of therapeutic groups of medicines demanded, the existence of alternatives in the São Paulo Municipal Register of Essential Medicines (REMUME, in the Portuguese),**** the register of medicines at *Agência Nacional de Vigilância Sanitária* (ANVISA – the Brazilian Health Surveillance Agency) and at the USA's Food and Drug Administration (FDA), and the existence of scientific evidence upon which recommendations for use of the drugs were founded.

Verification of the scientific evidence of the effectiveness and safety of drugs was carried out by means of a systematic review of studies in the database of the Cochrane Centre of Brazil***** and the existing monographs in the Micromedex database.***** This same database was used to collect data regarding the approval of medicines by the FDA for the cases referred to in the lawsuits. Information about the register of medicines in Brazil were obtained from the Anvisa

* Câmara dos Deputados. Relatório da Comissão Parlamentar de Inquérito destinada a investigar os reajustes de preço e a falsificação de medicamentos, materiais hospitalares e insumos de laboratórios. Brasília (DF); 2000.

** Ministério da Saúde. Política nacional de medicamentos. Brasília (DF); 1999.

***Santos L. Saúde: conceito e atribuições do Sistema Único de Saúde. Available from: <http://jus2.uol.com.br/doutrina/texto.asp?id=7378> [Accessed on 17 Jan 2006].

**** The municipality of São Paulo adopted the directives of the PNM and of the World Health Organization (WHO) with regards to decisions on the access and rational use of drugs. According to the WHO, essential medicines are those that meet the priority health needs of the population; they are chosen on the basis of their relevance to public health, proof of their safety and effectiveness and their cost-effectiveness.

***** Cochrane Library. Available from: <http://cochrane.bireme.br> [Accessed on 5 Jan 2006]

***** These databases provide evidence-based information, used particularly for the basis of a recommendation or rejection of a drug for a specific illness. There is no free access via the Internet. In Brazil, access is available in São Paulo at the Regional Medical Library, BIREME of the Pan-American Health Organization.

database of Drugs and Blood Products,* between 10 and 16 January 2006.

The prescriptions were classified according to origin as follows: 1) SUS services (prescriptions originating from the SUS network): SMS-SP or other; 2) Private services: Contracted by SUS (service provision to SUS) or Not contracted (other).

The prescribed drugs were distributed across five categories, as follows: 1) High cost – drugs dispensed by SUS through the Program for Exceptional Dispensation of Medicines, run by the state- and federal-level governments; 2) REMUME – drugs dispensed by SUS under the responsibility of SMS-SP; 3) Anti-cancer drugs – medicines financed by SUS for patients treated under the network of private contractors; 4) REMUME active ingredients – drugs whose active ingredients appear on the list, but which do not appear on the list in their pharmaceutical form or in the required dosage for treatment; 5) Non-selected – drugs which do not make up the REMUME or other SUS programs.

The counting of the medicines requested and their classification were carried out for all legal cases. Some data were repeated, since certain drugs were requested in more than one case.

The drugs that are not listed on REMUME and other SUS lists were drawn up and classified under the Anatomical Therapeutic Chemical System up to level 3 (therapeutic subgroup).** Those defined as alternative therapies were taken to include those drugs requested through legal proceedings which belong to the same therapeutic subgroup as others that appear on the SUS lists.

The measurement of total expenditure on medicines demanded through legal means was carried out only for non-selected items. The REMUME items are usually dispensed through municipal health units and for this reason, the cases were forwarded to the coordinating bodies so that they could manage the supply of these drugs.

Amounts spent on non-selected drugs were taken from the administrative document of the registry of budgetary expenditure (note of allocation), appearing in the legal proceedings. In addition, the documents issued by the Juridical Advisory of SMS-SP were used, with permission for their use granted by the Support Division.

The residential addresses of those individuals bringing

legal cases for the acquisition of medicines were superimposed upon a map of social exclusion and inclusion in the municipality of São Paulo.***

The research project was submitted to and approved by the Committees for Ethics in Research of the Universidade Federal de São Paulo and for the Municipal Secretariat of Health of São Paulo.

RESULTS

In 2005, 170 cases were brought against the municipal government to demand the supply of drugs. In 78% of these cases (N=133), the data collection form had been completed in full. For the remaining cases, the entire proceeding was not available for consultation and it was only possible to obtain information about the drugs demanded, the illness of the plaintiff and the amounts spent in acquiring the drugs.

Total expenditure on drugs from these cases was R\$876,000 Brazilian Reais (or \$374,000 US Dollars). Of this, only the additional expense incurred by the SMS-SP in buying the drugs demanded through the lawsuits was considered. The amount relating to medicines that were requested through lawsuits but that are regularly dispensed at the municipal health services was not calculated.

Of the 133 completed forms, 66% of cases include information about the age of the plaintiffs and 79% their occupation. In addition, 90% provided a copy of the medical prescription and 54% of plaintiffs were represented by legal professionals not working for the State. The profile of the claimants and the origin of the prescription that gave rise to the case are detailed in Table 1.

The majority of legal proceedings for the acquisition of drugs from the SMS-SP was brought by women (63.5%). With regard to age range, more than half of the cases were brought by claimants aged between 0 and 19 (30.7%) and 70 and 79 (23.9%). A total of 74.2% of claimants declared their occupation to be retired, pensioner, unemployed, student or home maker. Prescriptions originated from SUS services made up 59% and 13% from SUS contractors.

Figure 1 shows the illnesses most commonly mentioned to justify the legal case for the acquisition of drugs. The figure shows that the illness most commonly involved in such legal proceedings was diabetes (37%), followed

* Agência Nacional de Vigilância Sanitária. Banco de dados de Medicamentos. Available from: http://www.anvisa.gov.br/medicamentos/banco_med.htm [Accessed on 10 Jan 2006]

** WHO Collaborating Centre for Drug and Statistics Methodology. Anatomical Therapeutic Chemical classification. Available at <http://www.whooc.no/atcddd/> [Accessed on 7 Jan 2006]

*** The composition of the index for social exclusion and inclusion (lex) is attained through summing indicators from various categories such as, the indicator for autonomy, quality of life, human development, and equality and varies from 1 to -1. The closer the index to -1, the greater the degree of social exclusion of the population who live in the region or micro-region. More information can be found at: Centro de Estudos de Desigualdades Sócio-Territoriais [Internet site]. Mapping social exclusion/inclusion in developing countries: social dynamics of São Paulo in the 1990s. Available from: http://www.dpi.inpe.br/geopro/papers/saopaulo_csiss.pdf [Accessed on 14 Jan 2006]

Table 1. Profile of plaintiffs and origin of prescriptions from legal proceedings against the São Paulo Municipal Secretariat of Health, 2005.

Variable	N	%
Sex	170	100
Female	108	63,5
Male	62	36,5
Age group (years)	88	100
0 - 9	13	14,8
10 - 19	14	15,9
20 - 29	11	12,5
30 - 39	2	2,3
40 - 49	5	5,7
50 - 59	10	11,4
60 - 69	8	9,1
70 - 79	21	23,9
80 and over	4	4,5
Occupation	105	100
Retired and pensioner	40	38,1
Unemployed	9	8,6
Student	12	11,4
Home maker	17	16,1
Other	27	25,7
Origin of prescription	120	100
SUS services	71	59,2
Municipal	31	25,8
Other	40	33,3
Private services	49	40,8
Contracted to SUS	16	13,3
Non-contracted	33	27,5
Legal Representation	124	100
Private	67	54,0
Independent lawyer	63	50,8
Lawyer within association	4	3,2
State	57	46,0
Government Ministry	11	8,9
Attorney General of the State	46	37,1

SUS – Brazilian Health System (in the Portuguese)

by cancer (22%), combined diabetes and hypertension (9%), osteoporosis (8%) and hepatitis (5%). Taking into account reporting on both isolated diabetes (37%) and diabetes linked to hypertension (9%), the results show that 46% of all legal cases related to patients afflicted with diabetes.

With regard to the number of drugs per case, 43.5% (N=74) related to just one drug and 20% (N=34) request more than four drugs, generally prescribed by two or three health professionals.

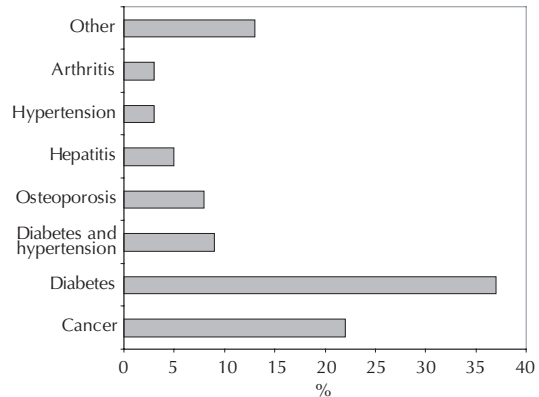


Figure 1. Illnesses connected to legal proceedings against the São Paulo Municipal Secretariat of Health for procurement of drugs. São Paulo, 2005.

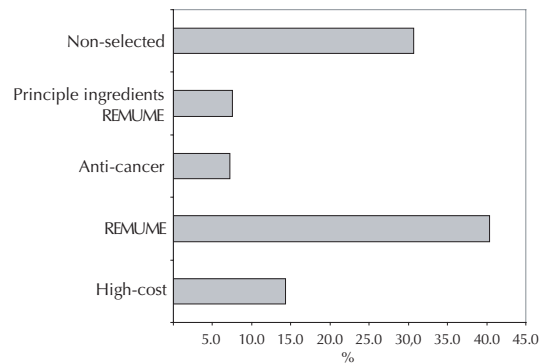


Figure 2. Classification of medicines demanded in legal proceedings for the procurement of drugs from the São Paulo Municipal Secretariat of Health, according to supply from the Brazilian Health System (SUS). São Paulo, 2005. REMUME: São Paulo Municipal Register of Essential Medicines

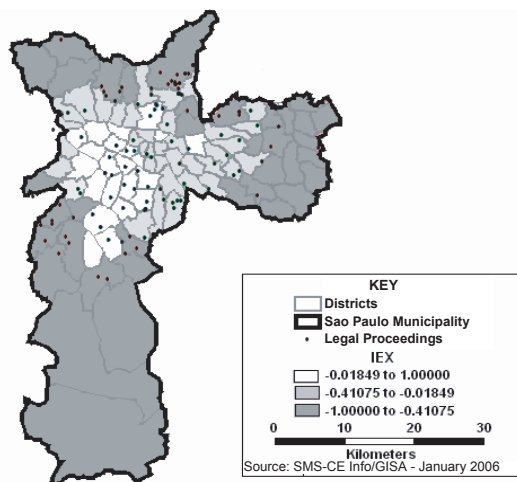


Figure 3. Legal proceedings for the procurement of drugs from the São Paulo Municipal Secretariat of Health, by index of social exclusion/ inclusion (IEX). São Paulo, 2005.

Table 2. Evaluation of the existence of evidences that support the use of anti-cancer drugs demanded in legal proceedings against the São Paulo Municipal Secretary of Health, 2005.

Drug	Principal therapeutic use	Cochrane Library (systematic review)	Micromedex	Register	
		Efficiency/effectiveness		FDA	Anvisa
Anastrozol	Breast cancer with hormonal receptor in post-menopausal women	Second choice of treatment for post-menopausal women ¹¹	Recommended in most cases	Yes	Yes
Capecitabin	Breast cancer	Limited evidence ⁴	Recommended in most cases	Yes	Yes
Erlotinib	Pancreatic cancer, cancer of the colon, cancer of the head and chest, renal cell cancer and ovarian cancer	None	Not recommended	No	No
	Non-small cell lung cancer	None	Recommended in some cases	Yes	No
Etoposide	Non-small cell lung cancer	Limited evidence ⁷	Recommended in some cases	No	Yes
Gefitinib	Non-small cell lung cancer	None	Recommended in some cases	Yes	No
Imatinib	Chronic myelogenous leukemia	Limited evidence ³	Recommended in most cases	Yes	Yes
Letrozol	Breast cancer with hormonal receptor in post-menopausal women	Second choice of treatment for post-menopausal women ⁵	Recommended in most cases	Yes	Yes
Mercaptopurin	Acute lymphoid leukemia	None	Recommended in some cases	Yes	Yes
Rituximab	Non-Hodgkin lymphoma	Limited evidence ⁹	Recommended in some cases	Yes	Yes
Temozolomide	Cerebral anaplastic astrocytoma	Limited evidence ¹	Recommended in most cases	Yes	Yes

FDA: Food and Drug Administration

Anvisa: Brazilian Health Surveillance Agency

The drugs from each case were classified according to their availability through SUS, or in other words if they were publicly provided or not, as per Figure 2. The diagram shows that 62% (N=282) of the items requested are listed as drugs from SUS programs, and as such appear on the REMUME – São Paulo or on the list of the Program for Exceptional Dispensation of Medicines (High Cost).

Medicines classified as anti-cancer drugs, which represent 7.2% of the total items requested generate expenditure of R\$661,000 Brazilian Reais (approximately \$281,000 US Dollars), equivalent to 75% of total expenditure on the acquisition of medicines involved in legal proceedings. Among these medicines, two are not registered in Brazil: gefitinibe and erlotinibe. Qualitative evaluation of these items resulted in the list of medicines included in Table 2, for which research was carried out to test for evidence of their therapeutic effectiveness.

Among those not selected, which after a qualitative evaluation amounted to 59 specific pharmaceuticals, 27% (N=16) do not have an alternative therapy avail-

able through REMUME and other SUS programs. The majority (73%) did, in principle, have a substitute for treatment. All were registered in Brazil.

Of the 133 cases for which the research form had been completed, 92% (N=122) include the residential address of the plaintiff. Of these, 116 were distributed across the index of social exclusion/ inclusion in the Municipality of São Paulo (Iex). The remainder were not classified because the addresses given in the court cases were found in other municipalities. Figure 3 shows the result of the superimposition of the cases over the Iex map of the municipality. Of the plaintiffs whose addresses were given, 63% (N=73) reside in areas with an Iex of between -0.4 and 1, corresponding to the areas of São Paulo Municipality with lower levels of social exclusion.

DISCUSSION

One of the limitations of this present study stems from the inability to collect complete data from all the cases

(22% lacking), since not all information was available at the SMS-SP Cabinet when the data were gathered. Some had been archived since the plaintiffs were already being attended by the State Health Secretariat or because they had died; others because the case has been sent to the Health Coordinator for the management of drugs which form part of REMUME and are available at the health units.

The greater chance that cases with a larger number of medicines from the REMUME list had originated from SUS services, and SMS-SP in particular, is related to the knowledge that these services have of the REMUME. The printed version of REMUME is available at all SMS-SP services. Thus, doctors responsible for prescribing such services know exactly which medicines are available at the municipal SUS health units. This is not the case for doctors prescribing at private clinics, principally those which are not contracted under SUS. In the present study, 59% of prescriptions originated from SUS and 62% of medicines requested are on the list of SUS programs.

These incomplete cases which were not analyzed could have influenced the result of some variables such as residency of the plaintiff relative to the Iex and origin of prescription, since they make up 22% of the total number of court cases.

With regard to the variable for the origin of the prescription, there is a greater probability that those cases with a greater number of medicines on the REMUME or other SUS lists had originated at services within the SUS system, and particularly SMS-SP. This is the case because the lists of medicines that can be found at these services are available at the health units for consultation by medical staff responsible for prescribing drugs. Since these incomplete cases that were not included in the analysis mostly originated from the Health Coordinating Bodies, this implies that the drugs involved are listed on the REMUME and as such, there is a greater probability that the prescriptions originated in SUS. Thus, it is possible that the percentage of cases whose prescriptions came from SUS services is greater.

The inability to determine the social conditions of all plaintiffs also prevents a more in-depth analysis of vertical equality. In spite of this, the present study furthers discussion about the effect of these cases on the PNM and the structure of the system.

In relation to the profile of the plaintiffs, one possible explanation for the larger number of court cases brought by women is their greater concern about health, which in itself would be an incentive for them to be more interested in searching for other means to guarantee

the supply of drugs that were prescribed to them. This could also be related to the fact that 74% of plaintiffs declared themselves to be retired, pensioners, unemployed, students or home makers.

The greater number of cases brought by young people under the age of 19 could be associated with their increased consumption of medicines to treat serious deficiencies and by older people because of the need to treat chronic illnesses.

It is not possible to say whether the services performed by providers contracted to SUS were carried out specifically for SUS, since these same providers offer services covered by various forms of health insurance provider. The fact that municipal services were responsible for 26% of demand may indicate a failure in the Municipal Policy on Medicines, be it either on account of not guaranteeing access to essential medicines, or because health professionals in the municipal network did not abide by the REMUME.*

If on the one hand SUS services generate more income than they do law suits, on the other hand one would expect the main source of judicial support to be public (free legal support), which is not the case. A total of 54% of the lawyers contracted by plaintiffs were private. This subtle difference suggests that these people probably have sufficient financial leverage to pay legal charges. However, it is noteworthy that SUS services are being used to transfer prescriptions that had initially been written by private services, so as to bring a law suit against SMS-SP.

Cancer and diabetes were the illnesses most involved in the legal proceedings. The fact that they are both chronic diseases of relatively high cost may be cause for bringing about law suits. This would also justify peoples' willingness to pay for a lawyer, since if the medicine is subsequently received, the long-term financial gain outweighs the initial legal costs.

The research showed that 62% of those medical items claimed appear on the medical lists of the SUS program. This percentage leads one to believe that at some stage a failure to guarantee access to drugs on the part of SMS-SP (REMUME) and of the state-level government (high-cost) could have occurred. Or, more probably, the health staff who prescribed or requested the drugs may not have had sufficient knowledge about the availability of the medicines, bearing in mind that the majority of prescriptions came from SUS services that do not fall under SMS-SP (33%) or from private providers (41%). The supply of REMUME drugs (40% of items claimed) was made without committing any additional resources. This implies that SMS-SP expenditure on

* São Paulo Municipal Secretariat of Health. Municipal list of essential medicines. São Paulo; 2004. Available from: http://ww2.prefeitura.sp.gov.br/arquivos/secretarias/saude/ass_farmaceutica/0002/remune2004.pdf [Accessed on 17 Jan 2006]

drug acquisition from legal cases applied to those classified as High Cost, anti-cancer drugs, medicines whose dosage or pharmaceutical make-up differs from those listed in the REMUME (principle ingredients) and non-selected items.

The obligation of SMS-SP to procure anti-cancer drugs, which are supplied by SUS through centres for highly complex cancers, known as CACON, and the high cost that are involved in purchasing medicines show the considerable distortion that legal cases are causing to SUS. The normal supply of anti-cancer drugs through the system is linked to the integrated care provided to the patient in specialized centres, by means of the commitment of specific financial resources. The basic failure to supply goes against the logic of integrated care, and diverts resources from the purchasing of medicines used in primary care and medium-complexity care and forcing the incorporation of new technologies, the effectiveness of which may be doubtful.

Among the anti-cancer drugs awarded through legal proceedings, two have not even been registered in Brazil, while most have not yet undergone sufficient controlled randomized clinical testing to prove their effectiveness. In summary, US\$281,000 was spent in the acquisition of these medicines, not counting the cost of the participation of SUS, which anticipated meeting this demand in a different way. In addition to this, this money was spent on medicines that, for the most part, do not demonstrate significant benefits to patients.

Another important point is that of the non-selected items, an alternative therapy was unavailable on REMUME in only 27% of cases. Even in these instances, this does not mean that the illness would go totally untreated, since drugs made from other substances could be prescribed. For example, REMUME does not list alternatives to the angiotensin II receptor, but hypertension can be treated with enzyme inhibitor converters of angiotensin, among other treatments. This shows that these legal proceedings could have been avoided if the health professionals who had prescribed the drugs had referred to REMUME and/or if the judicial system had consulted the SMS-SP or independent specialists, before ordering the procurement of the drugs.

The observation that 63% of the plaintiffs involved in the court cases reside in municipal regions with a low degree of social exclusion is supported by the finding that most of these patients hired private legal representation. It also suggests that those who are bringing legal cases against the municipal government tend to be those least in need of social protection, and thus suggests that the legal proceedings do not support SUS's aim of equality.

In this way, it is possible to point to factors, inherent in the legal claims for drugs, which go counter to the directives of both SUS and the PNM:

- Failure to recognize the tripartite responsibility within the system's organization, such that SMS-SP acts as follows: it acquires drugs that are listed as being under state-level responsibility; it resolves judicial decisions for citizens from other municipalities; it purchases anti-cancer medication, which is supplied by means of integrated care to the patient through the private system;
- Procurement of drugs that are not listed on the National Register of Essential Medicines (RENAME) or REMUME:
- Procurement of drugs prescribed by health professionals working in private clinics, while ignoring the principle of comprehensiveness in SUS care.
- Procurement of drugs not registered under Anvisa.
- Break down in attempts to ensure the rational use of drugs, which suggests that the choice of drugs is not given enough importance; supply of medicines that are different, but duplicated in terms of therapeutic effect, since the plaintiffs put forward several prescriptions from different doctors and, on account of their demand for an immediate resolution, SMS-SP does not manage to question this before supplying the drugs; failure to comply with therapeutic directives; procurement of drugs for which proof of their effectiveness and safety is unsubstantiated, and which are costly, even with the availability of substitutes that are effective, safe and have clearly defined cost-benefit ratios;
- Less rationality in the use of public funds;
- Equality under threat.

The failure to consider these issues completely goes against the directive of rationality in the use of medicines in Brazil, that was established by the PNM and by SUS directives.

With all the difficulties involved in dealing with the waste of resources in the face of the growing demand for a universal health system, SUS is not failing to treat patients with cancer or diabetes (the diseases most commonly involved in the legal proceedings). A structured network already exists to treat these diseases and to provide the appropriate drugs. At issue is the demand for treatment for cancer or diabetes by means of medicine A or B, for which there is often very little clear proof of its safety and effectiveness, which highlights preferences and implies that there is considerable influence of market mechanisms. The imposition of legal proceedings has meant that SUS is procuring drugs that are not registered in Brazil.

To conclude, it is worth underscoring the strain that

these legal demands place on the management of SUS. The right of the citizen to demand, through the legal system, that access to drugs be guaranteed is fundamental to avoid any negligence by the State. However, to take as a starting point the assumption that any claim for medication should be met, since the right to health is guaranteed, reveals, in a pharmaceutical market of more than 15,000 specialized products, a lack of understanding of public health policies and the accompanying pharmaceutical management.¹² The legal proceedings

referred to here show that the PNM and its directives were not taken into consideration, in obvious contradiction to the international trend for rationalizing the use of technologies in the area of health.^{2,8,10} The judicial system and the executive need to find a joint solution so that the right of the Brazilian citizen to integrated care is guaranteed with safe and effective drugs that are cost effective, in line with the best and strongest scientific evidence available, without causing the distortions that are currently occurring.

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