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Rational use of anticancer drugs and patient lawsuits in the state of São Paulo, Southeastern Brazil

ABSTRACT

OBJECTIVE: To assess the rationality of legal suits and administrative requests requiring anticancer drugs filed against and submitted to the São Paulo State Department of Health, in view of scientific evidence on efficacy and safety.

METHODS: A descriptive cross-sectional study was carried out based on information on lawsuits filed by cancer patients requiring anticancer drugs were furnished by the Department of Health. These drugs are among those having the greatest financial impact on the Brazilian Health System in 2006 and 2007. The drugs were assessed according to clinical evidence on efficacy and safety, based on Micromedex® categorization, on systematic reviews and meta-analyses. Indications present in the legal documentation were compared to the indications approved by regulatory agencies.

RESULTS: Bevacizumab, capecitabine, cetuximab, erlotinib, rituximab, imatinib, and temozolomide accounted for expenses over R$ 40 million to meet 1220 requests and lawsuits, at an average cost of R$ 33,500 per patient. Selected studies do not recommend all the indications for the prescribed drugs. Approximately 17% of requests and lawsuits did not provide evidence for the required indication, and these amounted to inappropriate expenses of, at least, R$ 6.8 million.

CONCLUSIONS: The results reinforce the need for technical expertise in dealing with legal suits and for capacity-building of health professionals in approaching the scientific literature, in order to appropriately select drugs and to ensure the best therapeutic decision for each clinical condition, and thus guarantee access to safe and effective health technologies and, therefore, to enhance the quality of the Brazilian pharmaceutical services model in oncology.

DESCRIPTORS: Antineoplastic Agents, supply & distribution. Judicial Decisions. Legislation, Drug. Health Expenditures. Pharmaceutical Services.

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INTRODUCTION

The Sistema Único de Saúde (SUS – Brazilian National Healthcare System) provides full and comprehensive healthcare to Brazilian citizens, including pharmaceutical services.[a] However, regardless of the fact that full and comprehensive mean high, mid, and low complexity medical assistance, many different interpretations of the term insist in understanding comprehensiveness as any and all kinds of known therapies, available or not under SUS. This results in distortions in terms of the strategies of access to technologies, among which access to medication.[13]

In Brazil, management problems concerning pharmaceutical services are common in the three branches of government. This combined with the constant pressure inflicted by the incorporation of new technologies under SUS, have resulted in an increase of court decisions ordering the supply of certain medicines. These lawsuits filed against the State have become an alternative means of having access to medication within SUS.[9]

On the other hand, the cost of complying with these court decisions is not budgeted for, thus consuming considerable resources from other areas of the budget and making it difficult to ensure the purchase of other medicines which are provided for under statute and agreed to by Inter-management Commissions.[b,c] On many occasions the medicines under the scope of these lawsuits are not considered essential according to the National Medicines Policy, nor have they had their safety and efficacy proven.[d]

Across the country, according to information from the Ministry of Health, the amounts spent with lawsuits in 2007 were over 500 million Brazilian *reais* in the federal, state and local administrations.[e] In the Ministry of Health alone the amount spent yearly went from R$ 188 thousand in 2003,[a] to R$ 52 million in 2008.[f] In the state of Paraná, southern region, between 2002 and 2007, the amount spent with lawsuits increased from R$ 200 thousand to R$ 14 million.[g]

These lawsuits have been on the media, above all in terms of the amount spent by the State and Local Health Departments and the Ministry of Health with the acquisition of medication. The unrestricted supply of medication through legal suits privileges segments of health service users with more financial resources to pay for attorney's fees, or that have more access to information, in detriment of the needy segment of the population.[4] In this context, the public health management has required consistent information on the benefits of new technologies and the financial repercussions on the public arena, with the goal of fostering new health policies and effective decision-making.[3]

The field of oncology has a large demand for this, due to its high cost and use of sophisticated technology.[h] In the city of São Paulo, Southeastern Brazil, in 2005, the number of lawsuits to obtain anticancer medicines accounted for 7.2% of the total number of items sought after through legal suits, resulting in expenses of R$ 661 thousand, representing 75% of the total expenses with medication obtained through court orders.[12]

Therefore, the objective of this study was to assess the rationality of lawsuits aimed at obtaining anticancer drugs, considering the scientific evidence based on efficacy and safety of these medicines. In addition, the cost of supplying these drugs in cases not grounded on the scientific literature was also estimated in order to contribute to a pharmaceutical services model for oncology in SUS.

METHODS

A cross-sectional study was carried out. The unit of analysis was the State of São Paulo, Southeastern Brazil, and the object lawsuits aimed at obtaining anticancer drugs. The period of investigation was from January 2006 to December 2007.

[a] Brasil. Lei nº 8.080, de 19 de setembro de 1990. Dispõe sobre as condições para a promoção, proteção e recuperação da saúde, a organização e o funcionamento dos serviços correspondentes e dá outras providências. In: Vieira JL, editor. Código sanitário do Estado de São Paulo. Normas técnicas e legislação complementar. Bauru: Edispro; 2000. (Série Legislação).

[b] Ministério da Saúde. Portaria nº 2.981, de 26 de novembro de 2009. Aprova o componente especializado da assistência farmacêutica. *Diario Oficial Uniao*. 30 nov 2009;Seção1:725.

[c] Ministério da Saúde. Portaria nº 2.982, de 26 de novembro de 2009. Aprova as normas de execução e de financiamento da assistência farmacêutica na atenção básica. *Diario Oficial Uniao*. 30 nov. 2009;Seção1:771.

[d] Nogueira RWL. Saúde, medicamentos, desenvolvimento social e princípios orçamentários. Jus Navigandi. 2005[cited 2009 Jan 20]9(542). Available from: http://jus2.uol.com.br/doutrina/imprimir.asp?id=6127

[e] Jungmann M. Ministério da Saúde classifi ca de "epidêmico" volume de ações judiciais contra o SUS. Brasília; 2007[cited 2009 Sep 10]. Available from: http://www.aids.gov.br/main.asp?View=%7BDA56F374-128A-40FB-B16F-D08A1F5DD07B%7D&Team=&params=itemID=%7B9016699E-670E-4209-B9DD-06C65CA88037%7D%3B&UIPartUID=%7BD90F22DB-05D4-4644-A8F2-FAD4803C8898%7D

[f] Conselho Regional de Farmácia do Estado do Rio de Janeiro. Ministério defende equilíbrio nas ações judiciais de saúde. Rio de Janeiro; 2009[cited 2009 Sep 10]. Available from: http://www.crf-rj.org.br/crf/noticia/2009/5/minist%C3%A9rio_defende_equil%C3%ADbrio_nas_a%C3%A7%C3%B5es_judiciais_de_sa%C3%BAde.htm

[g] Ministério da Saúde. Ações judiciais colocam em risco o Sistema Único de Saúde. Brasília; 2007[cited 2009 Jan 03]. Available from: http://portal.cnm.org.br/003/00301009.asp?ttCD_CHAVE=71155

[h] Vianna SM, Nunes A, Góes G, Silva, JR, Santos, RJM. Atenção de alta complexidade no SUS: desigualdades no acesso e no fi nanciamento. Brasília: Ministério da Saúde/Instituto de Pesquisa Econômica Aplicada; 2005. [cited 2009 Sep 10]. Available from: http://getinternet.ipea.gov.br/economiadasaude/adm/arquivos/destaque/alta_complexidade.pdf

The Secretaria Estadual de Saúde de São Paulo (SES-SP – State Health Department of the State of São Paulo) was asked to point out the seven anticancer drugs most sought after through legal suits with the highest financial impact on SUS. The sample of lawsuits was built based on the drugs on the SES-SP list. These drugs are indicated for the treatment of several types of cancer and are part of the anticancer therapy aimed at specific molecular targets, thus representing a new approach to the treatment of cancer.[5] In addition to the lawsuits, administrative requests – formal requests of medications patients were not able to obtain at SUS units to the government entity – containing the drugs scope of this study, according to the entries in the Sistema de Controle Jurídico (Court Control System) of the SES-SP. The study variables were: clinical indication, prescribing physician, attorney and origin of case.

To estimate the cost of acquiring these medications, the amount purchased during the period of study and the price paid were calculated based on the Banco das Atas de Registro de Preços (Price Registration Minutes Database) of the SES/SP.

Therapeutic indications expressed in the legal claims were compared to the evidence supplied by the medical literature in PubMed, LILACS, SciELO, and Cochrane BVS, in the form of systematic reviews and meta-analyses. Papers were selected if they assessed at least one of the seven drugs studied, for any therapeutic indication, in which the intervention was compared to another treatment or to placebo. Forty meta-analyses and 38 systematic reviews, published until July 2008, were selected. The findings of these studies coincide with the evidence described in Thomson Micromedex®.

The data on the approval of the drugs were obtained with regulatory agencies, such as the Agência Nacional de Vigilância Sanitária (Anvisa – National Sanitary Surveillance Agency), the Food and Drug Administration (FDA), and the European Medicines Agency (EMEA), thus enabling the clinical indication expressed on the legal claims to be compared to the ones approved by the regulatory agencies.

The data on the lawsuits were obtained from an SES-SP software called Court Control System. Data confidentiality was ensured concerning the identity of all the individuals identified during the study. This study was approved by the Ethics in Research Committee of the Universidade de Sorocaba on December 20, 2007 (Document 052/2007).

RESULTS

This study included 1,220 requests of the following anticancer drugs: bevacizumab, capecitabine, cetuximab, erlotinib, rituximab, imatinib, and temozolomide. Table 1 shows the number of lawsuits filed against the SES-SP between 2006 and 2007, the total cost and the average cost per lawsuit. The total amount spent by the Department with these seven drugs was 120% higher in 2007 than in 2006. This increase is explained by the one in the number of requests. In some cases, despite the increase in the number of requests, the average amount spent decreased (capecitabine, cetuximab, rituximab). On the other hand, the average amount spent per imatinib request almost increased five-fold.

Table 2 shows the characteristics of the administrative requests and legal suits. With some exceptions resulting from the incorporation of medications by the SES-SP, the requests are mostly made via the courts. A share of the lawsuits originated from prescriptions made by SUS professionals not complying with the protocols in force. The origin of the requests was concentrated in nine prescribing physician and seven lawyers. One single physician was responsible for almost 40% of erlotinib prescriptions and one single lawyer was responsible for 70% of the lawsuits requesting cetuximab.

Prescriptions written by five physicians cost R$ 7 million in two years. Five attorneys responsible for most of the lawsuits filed against the SES-SP cost almost R$ 16 million. Table 3 shows the itemized amounts per prescribing physician and attorneys.

Each of the drugs studied has been employed in several therapeutic indications, some of which have not been approved by the consulted regulatory agencies. Out of the 16 indications for bevacizumab, two met the criteria of evidence and degree of recommendation considered acceptable. About 30% of the requests were related to other kinds of cancer, for which there is no evidence that support its indication. capecitabine was used for treating colorectal cancer in 30% (in 2006) and 40% (in 2007) according to the lawsuits and the administrative requests filed against the SES/SP. Requests for capecitabine to treat breast cancer dropped from 46.2% (2006) to 28.1% (2007), whereas off-label indications (indications not approved by regulatory agencies) have been increasing (23.0% of the requests in 2006 and 31.2% in 2007 contained other indications, such as, pancreatic cancer, for which there is not a single registration in any of the consulted regulatory agencies).

More than 80% of the legal suits and administrative requests for cetuximab required the drug for colorectal cancer treatment. Despite metastatic colorectal cancer treatment benefiting from the EGFR-receptor inhibitors, and the indication having been approved by the FDA and by EMEA,[7] in Brazil the indication still has not been approved. Cetuximab indication for treating head and neck cancer, squamous cells, locally or regionally advanced cancer, in combination with radiotherapy is the only indication for the product in Brazil with evidence for use. However, less than 5% of

Table 1. Number of administrative requests and lawsuits filed by patients to obtain anticancer drugs and corresponding cost to the State Health Secretariat. State of São Paulo, Southeastern Brazil, 2006-2007.

Anticancer drug	Number of requests		Cost (R$)		Average cost per request	
	2006	2007	2006	2007	2006	2007
Bevacizumab	97	125	4,618,108.74	6,463,859.07	47,609.37	51,710.87
Capecitabine	14	33	136,796.79	292,231.23	9,771.20	8,855.49
Cetuximab	28	48	3,001,670.98	4,046,478.75	107,202.54	84,301.64
Erlotinib	73	160	1,852,682.80	4,352,155.20	25,379.22	27,200.97
Imatinib	126	164	1,402,226.16	8,543,003.08	11,128.78	52,091.48
Rituximab	49	170	460,168.58	1,301,591.20	9,391.20	7,656.42
Temozolomide	46	87	1,232,857.38	3,079,281.75	26,801.25	35,394.04
Total	433	787	12,704,511.43	28,078,600.28	29,340.67	35,678.02

Source: São Paulo State Health Department.

the administrative requests and lawsuits requesting the drug were related to types of head and/or neck cancer. On the other hand, the use of the drug in unapproved indications by the regulatory agencies consulted was around 14% in 2006 and 10% in 2007.

Erlotinib indication for pancreatic cancer, although not approved by Anvisa, has been approved by the FDA and the EMEA, in addition to there being defined benefit for locally advanced or metastatic pancreatic cancer, as first-line therapy, in combination with gencitabine.

About 12% in 2006 and 6% in 2007 of the administrative requests and legal suits were related to some kind of pancreatic cancer. The use of erlotinib in indications not yet approved by the consulted regulatory agencies was under 5% in 2006 and 2007.

Approximately 86% of the administrative requests and lawsuits seeking imatinib were related to chronic myeloid leukemia (CML). There is defined benefit for the use in Philadelphia chromosome-positive CML recently diagnosed or after failed therapy using alpha interferon, which is one of the indications approved by Anvisa, the FDA, and the EMEA.[7] Imatinib indications not supported by evidence of efficacy or safety increased from 10.4% (2006) to 14.4% (2007).

In 2006, rituximab was the aim of about 90%of the court and administrative requests and, in 2007, 75% corresponded to indications for non-Hodgkin's treatment. Although Rituximab has been approved by the three regulatory agencies for the treatment of rheumatoid arthritis (moderate to severe, in combination with methotrexate in patients responding inadequately to other therapies with TNF antagonists), the indication is not grounded on evidence in the literature in order for it to be incorporated to class IIb (recommended for some cases, but not for the majority of cases). There was an increase in the number of administrative requests and lawsuits aimed at obtaining this drug for this indication, from 1.1% in 2006 to 17.1% in 2007. And 4.7% and 8.1% of the requests in 2006 and 2007, respectively, were for indications with no clinical evidence of efficacy or safety.

Lawsuits and administrative requests for temozolomide (80% in 2006 and 86% in 2007) aimed at treating glioblastoma and astrocytoma. Temozolomide indication for metastatic melanoma has only been approved in Brazil, despite the lack of clinical evidence supporting its use for this indication. However, 1.6% of the lawsuits and administrative requests for temozolomide in 2007 were based on this indication. There are no records of lawsuits or administrative requests of this kind in 2006.

The findings show that part of the lawsuits and administrative requests lack scientific grounds supporting the effective and, above all, safe use of anticancer drugs on patients.

Table 4 shows the clinical indication of the seven anticancer drugs object of this study with levels of evidence (A and B) and degree of recommendation (classes I and IIa) and their respective approvals by the Anvisa, the FDA, and the EMEA. Some indications approved by other regulatory agencies have not been approved in Brazil and, nevertheless, there are lawsuits and administrative requests for such uses.

The assessment of the rates of lawsuits and administrative requests filed by patients to obtain anticancer drugs for indications that lack clinical evidence account for the inappropriate amount of R$ 6,870,926.83 in expenses to the SES-SP. Bevacizumab (59.5%) and rituximab (31%) were the drugs with use not based on clinical evidence with the highest request rate during the period of study (Table 5).

DISCUSSION

The seven drugs addressed in this study were selected by the SES-SP, according to the following criteria: cost

Table 2. Characterization of administrative requests and lawsuits according to type of claim, origin of request, main prescribing physicians and legal representatives. State of São Paulo, Southeastern Brazil, 2006-2007.

Variable	Bevacizumab		Erlotinib		Capecitabine		Rituximab		Imatinib		Cetuximab		Temozolomide	
	2006 (n = 97)	2007 (n = 125)	2006 (n = 73)	2007 (n = 160)	2006 (n = 14)	2007 (n = 33)	2006 (n = 49)	2007 (n = 170)	2006 (n = 126)	2007 (n = 164)	2006 (n = 28)	2007 (n = 48)	2006 (n = 46)	2007 (n = 87)
Lawsuits	99	96.8	100	97.5	100	90.9	100	80	59.3	61.6	100	100	93.3	88.5
Administrative requests	1	3.2	0	2.5	0	9.1	0	20	40.7	38.4	0	0	6.7	11.5
Origin of request: private sector	81.7	86. 1	52.1	52.2	64.2	75.8	18.8	22.7	44.9	45.9	92.6	75	60.9	62.1
Origin of request: public sector	18.3	13.9	47.9	47.8	35.8	24.2	81.2	77.3	55.1	54.1	7.4	25	39.1	37.9
Main prescribing physician	23.7 Phys. 1	9.6 Phys. 1	38.4 Phys. 2	31.3 Phys. 2	14.3 Phys. 3	12.1 Phys. 1	22.4 Phys. 4	16.3 Phys. 5	13.0 Phys. 6	11.0 Phys. 6	17.9 Phys. 7	10.6 Phys. 7	13.0 Phys. 8	11.5 Phys. 9
Lawyer representing patient	48. 4 Lawyer 1	33.3 Lawyer 1	39.7 Lawyer 2	31.4 Lawyer 2	33.3 Lawyer 1	35.7 Lawyer 1	60.4 Lawyer 3	31.3 Lawyer4	15. 7 Lawyer 5 Lawyer 6	12.6 Lawyer 6	70.4 Lawyer 1	43.8 Lawyer 1	16.7 Lawyer 7	9.5 Lawyer 1 Lawyer 7

Source: São Paulo State Health Department.

Table 3. Expenditure with prescribed medication in relation to t o prescribing physician and lawsuit. State of São Paulo, Southeastern Brazil, 2006-2007.

	Bevacizumab		Capecitabine		Cetuximab		Erlotinib		Imatinib		Rituximab		Temozolomide		Total
	2006	2007	2006	2007	2006	2007	2006	2007	2006	2007	2006	2007	2006	2007	
Prescribing physician															
1	1,094,491.77	620,530.47		35,359.97	213,118.63	343,950.69	227,879.98	326,411.64							2,861,743.18
2							711,430.19	1,362,224.57							2,073,654.77
6									182,289.40	939,730.33					1,122,019.74
8													160,271.45	212,470.44	372,741.90
9													80,135.72	354,117.40	434,253.13
Subtotal															6,864,412.72
Lawyer															
1	2,235,164.63	2,152,465.07	45,553.33	104,326.55	2,113,176.37	1,772,357.69	329,777.54	500,497.85						292,531.77	9,545,850.79
2							735,515.07	1,366,576.73							2,102,091.80
6	193,960.57	271,482.08					75,959.99	195,846.98	220,149.51	1,076,418.39			146,710.03	249,421.82	2,429,949.37
5									220,149.40	990,988.35					1,211,137.86
9	147,779.48	213,307.35				335,857.74									696,944.56
Subtotal															15,985,974.38

Table 4. Clinical indication (classified under levels of evidence A and B and degrees of recommendation I and IIa) and respective approval by regulatory agencies. State of São Paulo, Southeastern Brazil, 2006-2007.

Anticancer drug/Indication	Approved		
	Anvisa	FDA	Emea
Bevacizumab			
Metastatic colorectal cancer, in combination with 5-fluorouracil-based therapy for first or second line treatment	Yes	Yes	Yes
Lung cancer: non-small cell, non-resectable, locally advanced, recurrent or metastatic, non-squamous cell disease, first line treatment, in combination with paclitaxel and carboplatin	NA	Yes	Yes
Capecitabine			
In combination with docetaxel is indicated for treating patients with locally advanced or metastatic breast cancer	Yes	Yes	Yes
Metastatic breast cancer, as monotherapy, when resistant to regimes containing paclitaxel/ antracicline or resistant to paclitaxel and not to a candidate for later treatment with antracicline	Yes	Yes	Yes
Colon cancer, Adjuvant, Dukes C, when treatment with fluoropyrimidine alone is preferred	NA	Yes	Yes
Esophagogastric cancer, advanced or metastatic, in combination with chemotherapeutic agents	NA	NA	NA
Gastric cancer, first line treatment for advanced or metastatic disease, in combination with epirubicin and oxaliplatin or cisplatin	NA	NA	NA
Cetuximab			
Metastatic colorectal cancer, with EGFR, as monotherapy in patients who do not respond to treatment with irinotecan and oxaliplatin	NA	Yes	Yes
Metastatic colorectal cancer, with EGFR, in association with irinotecan, in patients refractory to isolated irinotecan	NA	Yes	Yes
Head and neck cancer: locally or regionally advanced squamous cells, in combination with radiotherapy	Yes	Yes	Yes
Erlotinib			
Lung cancer: non-small cells, locally advanced or metastatic (for patients who have failed prior chemotherapy)	Yes	Yes	Yes
Pancreatic carcinoma, locally advanced, non-resected, or metastatic, first line therapy in combination with gencitabine	NA	Yes	Yes
Imatinib			
Chronic myeloid leukemia, Philadelphia chromosome-positive, chronic stage, after failed Alpha-interferon therapy	Yes	Yes	Yes
Chronic myeloid leukemia, Philadelphia chromosome-positive, chronic stage, recently diagnosed	Yes	Yes	Yes
Acute lymphoblastic leukemia, Philadelphia chromosome-positive, recently diagnosed, as part of combined chemotherapy	NA	NA	Yes
Rituximab			
Non-Hodgkin lymphoma, diffuse large B-cell lymphoma, CD20-positive, in combination for first line therapy	Yes	Yes	Yes
Non-Hodgkin lymphoma, recurrent or refractory, low-grade or follicular, CD20-positive, B-cells	Yes	Yes	Yes
Chronic lymphoblastic leukemia, in combination with first line therapy	NA	NA	NA
Temozolomide			
Brain cancer: glioblastoma multiforme, recently diagnosed, simultaneously with radiotherapy and following as maintenance	Yes	Yes	Yes
Brain cancer: anaplastic astrocytoma, refractory (After progression of the disease after nitrosourea and procarbazine)	Yes	Yes	Yes

Anvisa: National Sanitary Surveillance Agency; FDA: Food and Drug Administration; EMEA: European Medicines Agency.
NA: Not available

Table 5. State expenditure with lawsuits and administrative requests without substantiated clinical evidence. State of São Paulo, Southeastern Brazil, 2006-2007.

Anticancer drug	State spending (R$)		% of non-evidence based requests and lawsuits		Cost of supplying drugs resulting from of non-evidence based requests and lawsuits (R$)	
	2006	2007	2006	2007	2006	2007
Bevacizumab	4,618,108.74	6,463,859.07	28.1	31.4	1,297,688.56	2,029,651.75
Capecitabine	136,796.79	292,231.23	17.4	19.2	23,802.64	56,108.40
Cetuximab	3,001,670.98	4,046,478.75	13.9	10.1	417,232.27	408,694.35
Erlotinib	1,852,682.80	4,352,155.20	2.8	4.4	51,875.12	191,494.83
Imatinib	1,402,226.16	8,543,003.08	10.4	14.2	145,831.52	1,213,106.44
Rituximab	460,168.58	1,301,591.20	5.8	25.2	26,689.78	328,000.98
Temozolomide	1,232,857.38	3,079,281.75	20.0	14.1	246,571.48	434,178.73
Total	12,704,511.43	28,078,600.28	-	-	2,209,691.36	4,661,235.47

Source: São Paulo State Health Department.

and demand in 2006 and 2007. In another biennium the requested drugs will probably be different, because the process is dynamic and needs change, thus constantly requiring new assessments.

The results do not enable an accurate assessment of the economic impact of the drugs on the SES-SP, because information was not provided on the amount spent with medication and with compliance to court orders in the State of São Paulo during 2006 and 2007.

The number of lawsuits and administrative requests increased twofold in the study period. In 2006, for each administrative request, about seven lawsuits were filed against the SES-SP. This proportion was the same in 2007. Administrative requests were mostly for treating CML and non-Hodgkin´s lymphoma, whereas the lawsuits were aimed at obtaining drugs for treating colorectal and lung cancer. Taking into account cancer prevalence in Brazil,[i] it is recommended that the SES-SP continue to carry out studies on clinical evidence on the treatment of these kinds of cancer, since they result in administrative and financial pressure on the State of São Paulo.

The seven drugs under the scope of this study reach almost R$ 30 million of the state healthcare 2007 budget. In the case of cancer treatment, therapy costs have increased by 450% since 1995, but have not improved the survival rates of patients or increased the cure rate for the disease.[j]

Findings show that patient lawsuits to obtain the anticancer drugs examined in this study are prescribed by a small number of physicians and filed by a small number of lawyers. This finding suffices to justify auditing the prescriptions, prescribing physicians and lawyers, so as to identify their direct and indirect relations with the pharmaceutical industry.

Several studies point out the influences prescribing physicians suffer in order to decide on possible therapeutic alternatives: concepts on the health-disease process; quality of education, sociocultural and economical conditions of the population they treat; availability of the drugs in the service for which they work; access to information, requirements by the pharmaceutical industry, among others[1,2,10]

In addition, a number of Brazilian organizations defending the rights of healthcare service users are funded by the pharmaceutical industry aiming at having the drugs they manufactured included under the SUS list. An entity representing lymphoma and leukemia patients headquartered in São Paulo, received R$ 1,5 million from eight multinational companies in 2007.[k]

The pharmaceutical industry is widely known for providing funding for scientific research across all areas of Medicine. This is a necessary and invaluable alliance. However, studies funded by pharmaceutical companies have a higher probability of reporting findings that favor their products when compared to independent studies. Friedberg et al[6] (1999) found unfavorable results in 5% of the studies funded by pharmaceutical companies manufacturing drugs for oncology; whereas, in independent studies this rate was 38%.

[i] Ministério da Saúde. Secretaria de Atenção à Saúde. Instituto Nacional de Câncer. Coordenação de Prevenção e Vigilância de Câncer. Estimativas 2008: Incidência de Câncer no Brasil. Rio de Janeiro; 2007. [cited 2009 Sep 10]. Available from: http://bvsms.saude.gov.br/bvs/publicacoes/estimativa_incidencia_cancer_2008.pdf

[j] Castilhos WO. Impacto do câncer no SUS. São Paulo: Agência FAPESP; 2007. [cited 2008 Jul 27]. Available from: http://www.agencia.fapesp.br/materia/8104/especiais/o-impacto-do-cancer-no-sus.htm

[k] Colucci C, Westin E. Indústria farmacêutica fi nancia ONGs. Folha de S Paulo, 2008 maio 15;Cotidiano[cited 2008 May 28]. Available from: www.folha.uol.com.br/fsp/cotidian/ff1805200801/htm

Critical assessment of the literature determines the quality, strength and boundaries of clinical evidence. In this way, public policies that actually contribute to the rationalization of the use of medical technologies could be drafted, based on good quality scientific data.

The incorporation of new technologies in healthcare should be based on correct assessment of their efficacy and safety, as well as of their effects on public spending in the health services. It should also be based on what is necessary, opportune, reasonable, convenient, and essential in ensuring individual and collective health and not on the mere market availability of these new technologies.[l]

More than 50% of the lawsuits and approximately 40% of the administrative requests came from the private sector. Therefore, it is recommended that SES-SP keep track of the claims and requests coming from the private sector. Furthermore, requests coming from public hospitals and/or hospitals accredited by the public health system should be systematically audited by the SES-SP, because the supply of medications must comply with SUS regulations.

The clinical use of a drug in different indications from those to which the literature has provided evidence of efficacy and safety is not recommended. Among the consequences is the possibility of employing a therapy of uncertain efficacy, with significant adverse effects, and the burdening of SUS. Moreover, to register a new indication with the regulatory agencies, the pharmaceutical company must provide evidence, through strict clinical trials, of efficacy and safety of the drug in regard to a certain condition. Supplying medication for non-formulary indication by means of court orders means placing an undue burden on SUS to fund studies that should be funded by the innovating manufacturer.

The finding that approximately 17% of the lawsuits and administrative requests were not based on evidence of the indications informed in the proceedings amounts to inappropriate spending of at least R$ 6.8 million during the study period. The limitations of this study in terms of the imprecise diagnosis provided in the prescription – instead of supplying the International Classification of Diseases – underestimates the rate of requested non-evidence based clinical indications, because the strength of the recommendation of use is specific to each condition. Therefore, the amount spent by the SES-SP in supplying medication for which there is no scientific evidence of efficacy and safety may be much higher than the amount estimated in this study.

Well-planned health policies result in effective actions to promote health and prevent health conditions, thus being translated as preventive medicine. In contrast, in curative medicine, medicines play an overly important role in healthcare.[8,11] Moreover, considering an equitable distribution of resources, which is one of the most complex dilemmas faced by SUS, there is an obvious need of technical expertise to deal with patient lawsuits. Therefore, this requires capacity building to enable appropriately selecting the drugs used in therapies and choosing the best therapeutic action for a certain clinical condition.[m]

Providing sound information on the use of medication and clinical data on the actual condition of the patient are essential to assessing the request and orders determining SUS to provide certain medicines to patients. Establishing clinical protocols for the use of immunobiologicals, that have limited indications and pose high risks, could rationalize the use of these drugs, thus contributing to improved pharmaceutical services for oncology in SUS.

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The authors declare that there are no conflicts of interest.