DOI: 10.1590/1413-81232017226.33922016

Why do people appeal to the courts for access to medication? The case of insulin analogues in Bahia (Brazil)

Erick Soares Lisboa [1]
Luis Eugenio Portela Fernandes de Souza [1]

Abstract *Insulin analogues have been the object of controversy concerning their therapeutic superiority to human insulin. Perhaps, in part, because of this, insulin analogues are frequently the subject of lawsuits. The judicialization of health has been well studied, but little is known about the reasons that lead people to go to the courts to obtain access to medicines on SUS (the Brazilian National Health System). Therefore, this study aims to analyze the reasons that led people to appeal to the courts to obtain access to insulins analogues in the state of Bahia. This is a case study based on documentary sources. Between 2010 and 2013, 149 lawsuits requiring insulin analogues from the state health authority were filed in the courts. The main reasons for the appeal to the courts, cited in the cases, can be grouped into four categories: the users' lack of finances, an essential need for insulin analogue, the duty and obligation of the state to provide them and bureaucratic difficulties. People turned to the courts, mostly, because doctors who accompany their patients have shifted from the official policy, believing that insulin analogues are better than human insulins. They also recognize that the public health system does not distribute them nor does it give doctors the wherewithal to purchase them with their own resources.*

Key words *Court decisions, diabetes mellitus, insulin, right to health*

[1] Programa de Economia, Tecnologia e Inovação em Saúde, Instituto de Saúde Coletiva, Universidade Federal da Bahia. R. Barão de Jeremoabo, Ondina. 40170-115 Salvador BA Brasil.
es.lisboa18@gmail.com

Introduction

Insulin analogues have been the subject of controversy relative to their therapeutic superiority and in relation to regular insulin and NPH. The Brazilian National List of Essential Medications (Rename) includes human insulin NPH (with intermediate action) and regular human insulin (with fast action) but it does not include the insulin analogues, be they for extended action (Glargine and Detemir) or ultra-fast action (Aspart, Lispro and Glulisine). However, the insulin analogues are available on the Brazilian market and they have been the subject of frequent judicial actions in Brazil[1-6].

In the ambit of the executive arm of government, the 'Comissão Nacional de Incorporação de Tecnologias' (Conitec) in SUS is responsible for making recommendations on the incorporation, exclusion or alteration of technologies in health through the Brazilian National Health System (SUS) and in 2014 it conducted a public consultation with reference to the incorporation of insulin analogues. After the consultation and the carrying out of meta-analysis of the published studies, Conitec published its reports nº 103 and nº114 with its recommendation of not incorporating insulin analogues in SUS owning to its high costs and the lack of scientific evidence that demonstrates its therapeutic superiority in relation to NPH and regular insulin[7,8].

Also, the Cochrane Collaboration reviews did not provide results that indicate that insulin analogues present relevant advantages in comparison with human insulin. They showed that the scientific debate on the use of insulin analogues in relation to human insulin, is still controversial[9,10].

Even with the lack of evidence on the therapeutic advantages of the insulin analogues in relation to human insulin and despite the fact they are not included in Rename, doctors continue prescribing them to their patients and they have been appealing to the courts so that the state provides these medications. In addition to this, even without the recommendation from the Ministry of Health, the state of Bahia has incorporated insulin analogues into its state list of medications, making its use official in 2013. This was done due to the need to guarantee its rational use and to reduce the budgetary impact of judicial actions[11].

The phenomenon of the judicialization of access to medications has been studied a lot in Brazil. In general, some empirical studies have highlighted that in Rio de Janeiro[5] the insulin Aspart was the most asked for medication via judicial actions between 2009 and 2010. The insulin Glargine appears amongst the three medications that were most requested via judicial actions in the states of São Paulo[2], Minas Gerais[4], Santa Catarina[3] and Pernambuco[12].

Particularly in Bahia, judicial actions concerning insulin analogues have been growing over the last few years. Between 2002 and 2008 the insulins Glargine and Aspart were amongst the four medications most required and given by the courts in the state[13] and between 2010 and 2013 they corresponded to 91% of requests for medications for the treatment of diabetes[14].

Some studies have noted a tendency for the initiation of judicial action for medication that is expensive and has not been placed on the public lists. Amongst these medications which have been highlighted, are those developed through advanced technology and can sometimes be found in clinical trial phases. Medication that is already available on the market but its not available through SUS which is the case for insulin analogues, is also covered[4,5,15-17].

What has been noted is that there is no evidence that justifies the incorporation of insulin analogues and that even though this is the case, this medication is on the state list. Can this be the reason why people are appealing to the courts in Bahia to have access to the insulin analogues?

Therefore, the purpose of this paper is to identify, based on preliminary judicial action or verdicts that have been given, the reasons that propel people to appeal to the courts with the view to forcing the state of Bahia to provide insulin analogues. This will contribute towards shedding some light on the reason for the use of judicial actions.

Methods

This is a study supported by documentary evidence on judicial actions against the Health Secretary for the state of Bahia (Sesab) for the provision of insulin analogues in the treatment of diabetes. The unit of analysis was the judicial actions against Sesab in the period from 2010 to 2013. The use of this period was justified by the fact that from 2010 the judicial actions involving the Secretary were digitized, making it easy to access the data.

The collection of data was conducted in November 2014 by the Pharmaceutical Assistant Board of Sesab which held the files for the regis-

Ciência & Saúde Coletiva, 22(6):1857-1864, 2017

tration of judicial actions involving medication. It was organized by the type of medication. The analysis of judicial actions included insulin analogues which referred to the treatment of diabetes and which also had the state of Bahia as the defendant. What was excluded from the lawsuits studied were those that referred to diabetes but which did not have the medication as the overall objective and those where the medication in question was not insulin analogues. Also, judicial actions which did not have all of the legal paperwork available or were illegible owing to the quality of the digitization, were excluded.

In total 325 judicial cases were identified that had at their heart the obtaining of medication for diabetes. Of these, five were excluded that did not cover some type of insulin analogue. 58 were outside of the period from 2010 to 2013 and two had defendants who were not from Sesab. As a result, 265 processes were selected. Subsequently 111 processes were excluded as they were either incomplete or when digitized the content could not be read. As a result, 149 cases were analyzed.

In order to analyze the reasons that led people to appeal to the courts in Bahia for the provision of insulin analogues, some delimiting changes were made in the period from 2010 to 2013. On the one hand the delimitation covered processes referring to the years from 2010 to 2012 before the incorporation of the insulin analogues by the state of Bahia and on the other hand it referred to 2013 after the incorporation and commencement of the distribution of the insulin analogues by the Centro de Diabetes and Endocrinologia of Bahia (Cedeba) of Sesab. Also, defense arguments from the state of Bahia through Sesab were included in our analysis which were used while it was the defendant in the actions covering insulin analogues.

The following classifications were used in the analysis of the reasons from the protagonist: (a) an indication of the need to use the insulin analogue, (b) the lack of financial resources on the part of the plaintiff, (c) the obligation of the state in providing insulin analogues and (d) access difficulties due to administrative issues or bureaucracy. This was only present in cases referring to the year 2013 post-incorporation.

Based on these classifications, it was possible to analyze the people´s reasons and to discuss the reasons for judicialization of access to insulin analogues in the treatment of diabetes in Bahia in the period between 2010 to 2013.

Lastly, it should be noted that this study adhered to the ethical criteria that is required for conducting studies of this nature which involves humans. We followed the recommendations of the Resolution nº 466/2012 from the Conselho Nacional de Saúde. It should also be noted that the collection of data was carried out after formal authorization was given by Sesab and the study was approved by the ethics committee at the Instituto de Saúde Coletiva of the Universidade Federal in Bahia.

Results

Of the 149 actions selected for analysis, 24 (16.1%) were started in 2010, 37 (24.8%) in 2011, 55 (36.9%) in 2012 and 33 (22.2%) in 2013. The most common reason was a lack of financial resources of the plaintiff which was the case in 117 cases. What followed was: the indication of the need to use insulin analogues (71 cases), the obligation of the state to provide the insulin analogues (54 cases) and the access difficulties to insulin analogues caused by administrative issues or bureaucracy (26 cases) (Chart 1).

In the 149 cases that were analyzed, the state of Bahia argued that in actions covering the period from 2010 to 2012, it was not legally obliged to make insulin analogues available as: (a) neither the Official Notice MS nº 2583/07 that provides guidance to SUS with reference to the treatment of diabetes, nor Rename and the state list of medications covered insulin analogues and (b) the scientific journals have not provided any proof of the therapeutic superiority of insulin analogues to regular insulin and NPH. In the actions referring to the year 2013, post-incorporation, the argument existed that the Cedeba dispensed insulin analogues in accordance with the defined clinical protocols and therefore the user should go there for the complete treatment which was not restricted to a pharmacological approach.

Discussion

The demand for insulin analogues through judicial means grew in the period between 2010 to 2012, following the tendency of growth demonstrated in the previous years[13]. However in 2013 the number of actions fell in relation to the previous year. This can be explained due to the incorporation of the insulin analogues by Sesab in that year.

Insulin analogues are expensive medications that require the person that needs them to be

Chart 1. Peoples' reasons for appealing to the courts in Bahia on the issue of insulin analogues.

Reasons	Arguments
A lack of financial resources on the part of the plaintiff.	The plaintiffs argued that they did not have money to foot the bill for the medical fees as the insulin analogue medications were expensive or paying for such medications could put at risk the covering of their domestic expenses.
	They also mentioned having to take leave from their work due to complications presented by the disease and the lack of the medication which reduced even further, their financial ability to purchase it.
Indication of the need to use insulin analogues.	Based on the prescriptions or the medical reports, they stated that the insulin distributed by SUS was not effective causing serious glycemic oscillations, severe hypoglycemia and hyperglycemia crises and it put their health at risk.
	They also affirmed that no medication for diabetes that had been made available by SUS resulted in a satisfactory therapeutic response. They highlighted that the medical report should take precedent over clinical and scientific studies.
	They added that the application of the insulin analogue in the form of a pen was less invasive which was not to do with mere convenience but was important for the health of the diabetic person.
The obligation of the state in the provision of insulin analogues.	They argued that health care is the right of everyone, as documented in the Federal Constitution.
	The fact that insulin analogues are not a part of the SUS medication does not take way the state's duty and obligation in providing it as the right to life and dignity surpasses administrative standards.
	The Public Authority has the duty and obligation of providing medication that is essential to the health of a person in need. They must be those that are the most adequate and efficient for the preservation of the life of the diabetic person.
	The provision of health resources by the state can be viewed as the right of a consumer.
	In the actions in 2013 some plaintiffs alleged that the fact that Sesab had brought into force the Official Notice nº 1603 of 2012 that set out the criteria for the distribution of insulin analogue was to recognized the obligation to make the medication available. And the fact that the Centro de Diabetes and Endocrinologia in Bahia (Cedeba) exists, attests to the fact that Sesab is responsible for the dissemination of the treatment that is recommended by doctors.
	And the non-provision of medication is a form of negligence on the part of the state towards health care and a lack of or poor service provision which demands the intervention of the courts.
Access difficulties due to administrative or bureaucratic issues.	They justified appeals to the courts as a means to speed up the receipt of the medication as waiting on the Cedeba register could last for long periods of time.
	The residents on the outskirts of the city that took actions did not have the wherewithal to travel to the city of Salvador every month to receive their insulin.
	In twelve cases, it was noted that the administrative route was taken to obtain the medication from Sesab, but there was no success.

in a good financial position to purchase them. The 'Instituto de Pesquisa Econômica Aplicada' (IPEA) demonstrated that medication expenses for Brazilian families is the main component for health spending by Brazilian families which is higher amongst families with lesser incomes[18]. Therefore, high prices, the low incomes of families and the lack of availability on SUS of the insulin analogues especially in Bahia by 2012, were the main reasons that led people to take judicial action in this area. A lack of financial resources was the most common reason.

Ciência & Saúde Coletiva, 22(6):1857-1864, 2017

Some studies[19-21] suggest that judicialization provides benefits for citizens who are financially better off and as a result makes the problems of access to health worse. This study, to the contrary, converges with the study by Ventura et al.[22] that identified that the majority of people on a low income were amongst those who were the plaintiffs in judicial actions.

Even in the face of a lack of scientific evidence concerning the superiority of the insulin analogues over human insulin[9,10], the doctors prescribed them including for patients who were not in a good financial position to purchase them outright. In the prescriptions or doctors' reports that would reinforce the lawsuits, they alleged the necessity of the patient in using the insulin analogues even though there was no proof to justify their choice. What drew our attention here was the use of the argument that the doctors' report should prevail over the findings from clinical and scientific studies (Chart 1).

This position is worrying in so far that these lawsuits are successful without these arguments ever being questioned. With effect, several studies have shown that medical prescriptions are accepted as sufficient proof by the courts (incontestable and legitimate) of the need for use in relation to innumerable medications[12,22-24].

Certainly, the prescription and the medical reports are and should be fundamental elements for allowing the courts to take their decisions. However, it is common to find inadequate prescriptions sometimes involving, as a negative consequence, the involvement of the pharmaceutical industry acting with doctors through its representatives, which provides publicity for its medication and it finances congresses amongst other benefits offered[25].

The 'Conselho Nacional de Justiça' (CNJ) has already expressed its concern in this area. In one of its statements approved in its I Congress on Law and Health that took place in 2014 (which was the 15th congress) it stated that for medical prescriptions to be adequate, any necessary treatment or medication must be given containing its Brazilian Common Denomination (DCB) or International Common Denomination (DCI) as its principal asset, followed by (when relevant) the reference name, dosage, mode of administration and the treatment time[26].

Curiously, Sesab defense argument did not question the sufficiency of the medical prescription as proof of the need for insulin analogue or its obligation to provide it. They restricted themselves to affirming that insulin analogues do not have therapeutic superiority in relation to NPH or regular insulin available on SUS and they are just an equivalent therapeutic alterative. They sought to persuade the courts that there was no negligence in the treatment of diabetes in the way that they recommended.

In the period from 2010 to 2012 in 54 lawsuits, the plaintiffs justified their demands stating that the duty and obligation of the state was to provide insulin analogues. Pepe et al.[27] reminds us that the state does not just have the obligation to guarantee access to medication, but also and more importantly, it must guarantee the protection of the population's health.

In this way when the courts accept the argument that the state has the obligation to provide medication just based on a medical prescription independent of what exists in the public health system (Chart 1), it may be putting the patients' health at risk. Therefore, the need for greater understanding by the courts of health policies that are in force, is clearly needed which includes policies on medications.

Throughout the total period that was analyzed, there were different positions from Sesab. Initially the Secretary defended itself arguing that there was therapeutic equivalence between human insulin and the insulin analogues and that it did not have the responsibility for distributing them, as this had not been set out by SUS. Subsequently in 2013, it incorporated the insulin analogues[11] on its list with the justification that it sought to widen access to it and to guarantee the rational use of the medication.

It is worth adding that the incorporation of the insulin analogues by Sesab has been accompanied by the adoption of the technical protocol for its distribution[11]. On bringing this protocol into force for the treatment of diabetes, in addition to providing standards for access, the Secretary had as its objective, the reduction of the budgetary impact of lawsuits. This is because procurement based on specific volume, made it possible to obtain better prices when compared to isolated purchases in each case. However, contrary to that which had been expected, this did not stem the tide of lawsuits in the first year of it being in force, even though it did manage to reduce the amount of cases.

In practice, what could be seen in the lawsuits in 2013 was that the criteria established by the protocol was not met due to: incomplete documentation or the clinical state of the patient. As a consequence, Cedeba did not make insulin analogues available. The patients then appealed

to the courts using the arguments of the need to use insulin and the access difficulties caused by administrative issues or bureaucracy. Also, the plaintiffs' resident on the outskirts of the city argued that the centralized distribution done in the city capital, hindered their access when taking into consideration travel costs for every month to the city of Salvador.

In this aspect, it should be remembered that the decentralization of pharmaceutical assistant actions including the distribution of medication, is an integral part of the health policies. However, Sesab could facilitate access for the patients living on the outskirts of the city, decentralizing the assistance for diabetics. This initiative would most definitely reduce the number of lawsuits related to this medication.

Macedo et al.[16] concluded, as is the case in this study, that the bureaucratization of the pharmaceutical services and the centralization of the distribution, made access to the medication difficult principally for the underprivileged in society, which forced users to take legal action. In a similar vein, Sant'Ana et al.[24] affirmed that the judicial actions are seen as a faster route that is less bureaucratic and more beneficial in terms of gaining access to medication.

It is worth emphasizing however, that the administrative procedures do not necessarily represent bureaucratic obstacles. In this way Sant'Ana[28] expresses regret, for example, that the judicial decisions accept the theory that the clinical protocols and therapeutic guidelines are mere bureaucratic formalities.

The analysis of the reasons that lead people to take legal action in Bahia to obtain insulin analogues, shows that the phenomenon of judicialization in health is both complex and multi-determinate. One of the conditioning factors most definitively refers to constitutional legitimation of the principle of health care as a right for all and the obligation of the state. With this in mind, legal formalization of the principle will create a favorable environment for social mobilization which has as a resource the courts, which can be one of its strategies.

Also, the incorporation of insulin analogues by the State of Bahia goes against their own defense arguments from Sesab given some years prior to 2013. This has generated ambiguity in public policies in as much as the sphere of government (the state in the case of Bahia) has incorporated on its list, a class of medications whose incorporation is not recommended[7,8] by the sphere responsible for the national coordination of policies (the Union).

Thus, the incorporation of insulin analogues into SUS has become even more controversial. Firstly, the position of the doctors goes against what the clinical studies[9,10] have shown which indicates that insulin analogues do not present any relevant advantages over human insulin. Secondly, the SUS managers have differing positions. While the Ministry of Health understands that this is not the case of incorporating insulin analogues into the public health system, the managers in Bahia have decided to incorporate them.

As prescriptions or medical reports make up the basis for the arguments of those that appeal to the courts, the aforementioned are accepted by the courts as sufficient proof of the need for medication. Favorable verdicts are given to the plaintiffs and in this way SUS is required to make insulin analogues available. In this way, the conviction of the doctors concerning the therapeutic superiority of insulin analogues vis-à-vis regular and NPH insulin is the principal reason for appeals to the courts seeking access to this medication.

Final Considerations

The reason for appeals to the courts for obtaining the provision by SUS of insulin analogues that was most commonly found in the lawsuits against Sesab, was the lack of financial resources on the part of the plaintiffs. This was the case for the whole period that was analyzed between 2010 to 2013.

Management failures, especially those related to the centralization of the distribution of medication, made access to the insulin analogues difficult after its the official incorporation by Sesab. This constituted an important reason for appeals being made to the courts in lawsuits in 2013.

However, it is clear that the strong belief of the prescribing doctors concerning the therapeutic superiority of the insulin analogues which is not backed up by scientific proof, is the motivating and principle reason for judicialization involving this medication in Bahia.

In this way, tackling this judicialization phenomenon for insulin analogues essentially requires a construction of a consensus between the medication prescribers and the health care managers on the existence or not of therapeutic superiority of these insulin analogues in relation to regular insulin and NPH. If it is agreed that insulin analogues are better, SUS should use them. If the contrary is the case, the prescribers must adhere to the current protocols and guidelines that

Ciência & Saúde Coletiva, 22(6):1857-1864, 2017

do not set out the use of the insulin analogues.

It is worth remembering that the formation of a consensus requires there to be a resolution in the divergence between the SUS managers and the different spheres of government in relation to incorporation or not of the insulin analogues.

With reference to management failures, a solution does not appear to be easy to obtain. We are dealing with the decentralization of insulin analogues and the maintenance of flexibility and updated protocols. These are things that the Secretaries in health know about and can tackle.

Lastly, it is necessary that in the decision-making process on the provision of medication, the courts should give decisions that are, at the very least, based on prescriptions that have been adequately made in accordance with their own 'Conselho Nacional de Justiça', taking into consideration the available alternatives on SUS and the clinical protocols that are in force.

To make headway in the construction of this consensus, those that must be involved include the prescribers, the health care managers, the law officials and the Ministry of Health that covers Conitec. Having all of the aforementioned involved will allow for advances to be made in this debate being a large scale initiative. It would certainly be a worthwhile initiative in the sense of ensuring the most safe and effective treatment for those who are diabetic.

Collaborations

ES Lisboa contributed to setting the scope of this paper as well as: analyzing and interpreting the data, redrafting this paper and approving the final draft. LEPF de Souza contributed to setting the scope of this paper as well as: providing a critical review and approving the final draft that was published.

References

1. Sociedade Brasileira de Diabetes (SBD). *Diretrizes da Sociedade Brasileira de Diabetes 2009*. São Paulo: SBD; 2009.
2. Chieffi AL, Barata RCB. Ações judiciais: estratégia da indústria farmacêutica para introdução de novos medicamentos. *Rev Saude Publica* 2010; 44(3):421-429.
3. Pereira JR, Santos RI, Nascimento Júnior JM, Schenkel EP. Análise das demandas judiciais para o fornecimento de medicamentos pela Secretaria de Estado da Saúde de Santa Catarina nos anos de 2003 e 2004. *Cien Saude Colet* 2010; 15(Supl. 3):3551-3560.
4. Campos Neto OH, Acurcio FA, Machado MAA, Ferré F, Barbosa FLV, Cherchiglia ML, Andrade ELG. Médicos, advogados e indústria farmacêutica na judicialização da saúde em Minas gerais, Brasil. *Rev Saude Publica* 2012; 46(5):784-790.
5. Lima GS. *Demanda judicial de medicamentos e uso de indicadores de avaliação e monitoramento no estado do Rio de janeiro* [dissertação]. Rio de Janeiro: Fundação Oswaldo Cruz; 2012.
6. Canadian Diabetes Association (CDA). *A utilização da insulina*. 2009. [acessado 2014 fev 10]. Disponível em: http://www.health.gov.on.ca/en/public/programs/diabetes/docs/ diabetes_factsheets/Portuguese/10_port_Insulin.pdf
7. Brasil. *Insulinas análogas de longa ação: diabetes mellitus tipo II*. Brasília: Ministério da Saúde; 2014. (Relatório de Recomendação da Comissão Nacional de Incorporação de Tecnologias no SUS – CONITEC – nº 103).
8. Brasil. *Insulinas análogas para diabetes mellitus tipo I*. Brasília; Ministério da Saúde: 2014. (Relatório de Recomendação da Comissão Nacional de Incorporação de Tecnologias no SUS – CONITEC – nº 114).
9. Siebenhofer A, Plank J, Berghold A, Jeitler K, Horvath K, Narath M, Gfrerer R, Pieber TR. Short acting insulin analogues versus regular human insulin in patients with diabetes mellitus. *Cochrane Database Syst Rev* 2006; (2):CD003287.
10. Fullerton B, Siebenhofer A, Jeitler K, Horvath K, Semlitsch T, Berghold A, Plank J, Pieber TR, Gerlach FM. Short-acting insulin analogues versus regular human insulin for adults with type 1 diabetes mellitus. *Cochrane Database Syst Rev* 2016; (6):CD012161.
11. Bahia. Portaria nº 1.603, de 14 de novembro de 2012. Institui o protocolo técnico para a dispensação de análogos de insulina de ação basal e ultra-rápida para pacientes com diagnóstico de Diabetes Mellitus. *Diário Oficial* 2012; 16 nov.
12. Marçal KKS. *A judicialização da assistência farmacêutica: o caso de Pernambuco em 2009 e 2010* [dissertação]. Recife: Fundação Oswaldo Cruz; 2012.
13. Torres IDC. *Análise das ações judiciais de medicamentos na Secretaria de Saúde do Estado da Bahia – 2002 a 2008* [monografia]. Salvador: Universidade Federal da Bahia; 2010.
14. Lisboa ES. *Acesso ao tratamento da diabetes na Bahia: por que se recorre ao judiciário?* [dissertação]. Salvador: Universidade Federal da Bahia; 2015.
15. Machado LR, Resende ALR, Saturnino LTM. Medicamentos especializados na judicialização da saúde: uma análise das demandas judiciais no estado de Minas Gerais. In: Aith F, Saturnino LTM, Diniz MGA, Monteiro TC, organizadores. *Direito sanitário: saúde e direito, um diálogo possível*. Belo Horizonte: ESP-MG; 2010. p. 323-338.
16. Macedo EI, Lopes LC, Barberato-Filho S. Análise técnica para a tomada de decisão do fornecimento de medicamentos pela via judicial. *Rev Saude Publica* 2011; 45(4):706-713.
17. Ventura M. *O processo decisório judicial e a assessoria técnica: a argumentação jurídica e médico-sanitária na garantia do direito à assistência terapêutica* [tese]. Rio de Janeiro: Escola Nacional de Saúde Pública Sérgio Arouca; 2012.
18. Instituto de Pesquisa Econômica Aplicada (IPEA). *Dimensões do acesso a medicamentos no Brasil: perfil e desigualdades dos gastos das famílias, segundo as pesquisas de orçamentos familiares 2002-2003 e 2008-2009*. Brasília: IPEA; 2013.
19. Marques SB, Dallari SG. Garantia do direito social à assistência farmacêutica no Estado de São Paulo. *Rev Saude Publica* 2007; 41(1):101-107.
20. Chieffi AL, Barata RCB. Judicialização da politica pública de assistência farmacêutica e equidade. *Cad Saude Publica* 2009; 25(8):1839-1849.
21. Machado MAA, Acurcio FA, Brandão CM, Faleiros DR, Guerra Júnior AA, Cherchiglia ML, Andrade ELG. Judicialização do acesso a medicamentos no Estado de Minas Gerais. *Rev Saude Publica* 2011; 45(3):590-598.
22. Ventura M, Simas L, Pepe VLE, Schramm FR. Judicialização da saúde, acesso à justiça e a efetividade do direito a saúde. *Physis* 2010; 20(1):77-100.
23. Figueredo TA, Pepe VLE, Osorio-de-Castro CGS. Um enfoque sanitário sobre a demanda judicial de medicamentos. *Physis* 2010; 20(1):101-118.
24. Sant'ana JMB, Pepe VLE, Figueredo TA, Osorio-de-Castro CGS, Ventura M. Racionalidade terapêutica: elementos médico-sanitários nas demandas judiciais de medicamentos. *Rev Saude Publica* 2011; 45(4):714-721.
25. Pepe VLE, Ventura M, Sant'ana JMB, Figueredo TA, Souza VR, Simas L, Osorio-de-Castro CGS. Caracterização de demandas judiciais de fornecimento de medicamentos "essenciais" no Estado do Rio de Janeiro, Brasil. *Cad Saude Publica* 2010; 26(3):461-471.
26. Conselho Nacional de Justiça (CNJ). *Enunciados aprovados no I Jornada de Direito da Saúde do CNJ em 15 de maio de 2014*. São Paulo; CNJ: 2014.
27. Pepe VLE, Figueredo TA, Simas L, Osorio-de-Castro CGS, Ventura M. A judicialização da saúde e os novos desafios da gestão da assistência farmacêutica. *Cien Saude Colet* 2010; 15(5):2405-2414.
28. Sant'ana JMB. *Essencialidade e assistência farmacêutica: um estudo exploratório das demandas judiciais individuais para acesso a medicamentos no estado do Rio de Janeiro* [dissertação]. Rio de Janeiro: Fundação Oswaldo Cruz; 2009.

Article submitted 11/12/2016
Approved 16/03/2017
Final version submitted 18/03/2017