Legal actions and incorporation of medicines into SUS: the performance of Conitec

Ações judiciais e incorporação de medicamentos ao SUS: a atuação da Conitec

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ABSTRACT This study was aimed at analyzing the influence of lawsuits on the process of evaluating requests for the incorporation of biological medicines into the Unified Health System (SUS), by the National Committee for Health Technology Incorporation in SUS (Conitec), from 2010 to 2015. The research investigated the performance of Conitec focusing on the analysis of the recommendation of incorporation or not of biological medicines to SUS. The following were used as data collection strategies: document analysis, interviews with members of the Committee, and non-participant observation of the plenary meetings. The data analysis has shown that, although the lawsuits were often part of the plenary discussions, the existence of legal actions is not a decisive factor for the Committee's decision-making. No evidence of a direct relationship between health lawsuits and the incorporation of biological medicines into SUS was found, as members strictly follow the technology incorporation flow as established by the Law No. 12.401/2011 and by Decree No. 7.646/201. However, the existence of an indirect influence of the phenomenon of health judicialization on the process of incorporation of technologies in SUS became evident when the motivations for the formulation of the law and the rules that regulate the operation of Conitec were analyzed.

KEY WORDS Biological products. Health's judicialization. Unified Health System.

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RESUMO *Este estudo teve como objetivo analisar a influência das ações judiciais sobre o processo de avaliação de solicitações de incorporação de medicamentos biológicos ao Sistema Único de Saúde (SUS) pela Comissão Nacional de Incorporação de Tecnologias no SUS (Conitec), no período de 2010 a 2015. A pesquisa investigou a atuação da Conitec, tendo como foco a recomendação de incorporação ou não de medicamentos biológicos ao SUS. Foram utilizadas como estratégias de produção de dados: análise documental, entrevistas com membros da Comissão e observação não participante das reuniões do plenário. A análise dos dados revelou que, apesar de ser, muitas vezes, objeto de discussão no plenário, a existência de ações judiciais não constitui um fator decisivo para a tomada de decisão da Comissão. Não foi encontrado qualquer indício de relação direta entre as ações judiciais em saúde e a incorporação de medicamentos biológicos ao SUS, visto que os membros seguem, rigorosamente, o fluxo de incorporação de tecnologias regulamentado pela Lei nº 12.401/2011 e pelo Decreto nº 7.646/2011. No entanto, revelou-se a existência de uma influência indireta do fenômeno da judicialização da saúde sobre o processo de incorporação de tecnologias no SUS, quando se analisou a motivação para a formulação da lei e das normas que regulamentam o funcionamento da Conitec.*

PALAVRAS-CHAVE *Medicamentos biológicos. Judicialização da saúde. Sistema Único de Saúde.*

Introduction

The technologies used to provide health assistance have been changing quickly in the last years. If on the one hand they bring undeniable benefits, related to the increase in longevity, prevention, disease healing, protection, and health rehab, on the other hand, they bring challenges related to the risks and the costs of their use[1].

As far as the industry is concerned, there are several production areas involved to meet the health needs. Gadelha and colleagues[2] classify the Economic-Industrial Health Complex (Complexo Econômico Industrial da Saúde, Ceis) in three segments: the one with chemical and biotechnology basis; the one with mechanic, electronic and material basis and the segment consisting of health services.

The high investments of the biochemical and biotechnological industry show that the biotechnologies are a great long-term bet, leading several countries to implement industrial policies that are active in the search for innovation in this area[3]. The 20th century witnessed an extraordinary development of science and technology, and the convergence of both produced results in several productive sectors, such as that of health, with processes of medicine developments, vaccines, reactants for diagnosis and implants, representing an important advance in the treatment of several diseases[4,5].

The biological medicines are defined as complex molecules of high molecular weight obtained from biological fluids, animal tissues or biotechnological procedures, through the manipulation or insertion of another genetic material or gene mutation due to irradiation, chemical products or forced selection[6]. Today, the registration of the biological medicines includes seven product categories, such as allergens, monoclonal antibodies, biomedicines, hemoderivatives, probiotics, hyperimmune serum and vaccines[7].

In Brazil, the perspective of the increase in the demand for health services – together with the challenge of increasing the access of the population to technologies – suggests the existence of a great potential for increasing the use of biotechnology for health[2]. Therefore, it is important to establish a stable regulatory environment. The regulation of the development and the incorporation of new technologies into health and, especially of biological medicines, is essential to assure that the production meets the health needs at bearable costs to society.

The decision process related to the incorporation of technologies in the health systems is permeated by the influence of several groups of interests, such as: physicians, institutions that provide health services, financing institutions, policy and service managers, technology producers, patient associations, among others that can play decisive roles in decision-making[8].

A study conducted in Europe[9], focusing on England, France, Germany and Sweden, pointed out that the Health Technology Assessment (HTA) has played an increasing role in the health systems in the last years, with the establishment of agencies or programs to assess and incorporate health technologies. Although the countries studied share some purposes, there are differences in the way the HTA agencies and programs are organized, operate and influence decision-making. Despite these differences, all systems face opportunities and challenges related to the involvement and acceptance of the stakeholders[10].

To regulate the incorporation of technologies in the Unified Health System (SUS), in 2011, by means of the Law No. 12.401[11], the National Committee for Health Technology Incorporation in the Unified Health System (Comissão Nacional de Incorporação de Tecnologias no Sistema Único de Saúde, Conitec) was established. The Decree No. 7.646[12], of the same year, regulates the law, which mentions the permanent nature of the committee aimed at helping the Ministry of Health (MH) in the attributions related to the incorporation, exclusion or change of health technologies by SUS, as well as in the constitution or change of clinical protocols and therapeutic guidelines[11,12].

The increase in public expenses with medicines is partially due to the incorporation of new technologies into SUS. And the latter, on the other hand, may be associated with the phenomena of the judicialization of health. In the last seven years, the MH has spent R$ 4.5 billion to purchase medicines, equipment, dietary supplements and coverage for surgeries and hospital stays from court orders. Most of this amount was used to purchase biological medicines. In 2016, the MH spent R$ 654.9 million in the purchase of only 10 medicines for the treatment of 1,213 people[13].

According to the data of the Secretariat of Science, Technology and Strategic Inputs (Secretaria de Ciência, Tecnologia e Insumos Estratégicos, SCTIE) of the MH, the real increase of the expenses with legal actions regarding medicines was of 547% between 2010 and 2016, from R$ 199.6 million to R$ 1.3 billion in 2016. The total expense was R$ 4.8 billion[14]. It is worth mentioning that, in 2015, half of the twenty most expensive technologies requested to SUS through Court was not registered in the Brazilian Health Regulatory Agency (Anvisa), with emphasis to the requests for biological medicines[15].

In addition to lawsuits involving especially new and more expensive products, the technological incorporation may be a significant factor for the increase of the public expenses with medicines. A study has reported that, in the period between January 2012 and June 2016, of the 485 submissions to Conitec, 267 (55%) were related to requests for the incorporation of pharmaceutical products. Of 171 requests, 93 medicines (54%) were incorporated[15].

A research reported that, regarding the greatest public expenses with medicines, in 2016, the following were identified: a biological medicine that was bought due to lawsuits (eculizumab – R$ 376.6 million), two products incorporated to SUS (sofosbuvir16 – R$ 510.5 million; and vaccine against human papilloma virus 17 – R$ 288.4 million), three other biological medicines used mainly to treat arthritis rheumatoid (adalimumab – R$ 621.9 million; etanercept – R$ 322 million, and infliximab – R$ 298.5 million), and hemiderivative (factor VIII18 – R$ 471.5 million)[10,15].

Several studies have been performed to evaluate the effects of judicialization on health policies[16-23]. Researches point out a tendency to divert from the debate about the incorporation of technologies to the world of legal prosecution. In fact, in many countries, the decisions regarding the opportunity of incorporating a technology have increasingly been taken in the discourse and doctrinaire field of Law[24].

In addition, the high number of lawsuits in health has led to the incorporation of some technologies, often high-cost ones, especially by state and municipal health secretariats in several regions in the country. It is worth mentioning that these cases do not deal with the incorporation into SUS as a whole, based on Conitec's technical recommendation and on the decision of the MH[21,23,24].

This article is aimed at analyzing the influence of lawsuits on the recommendation of the incorporation of biological medicines into SUS by Conitec.

Methodology

The influence of the legal decisions on the decision process related to the incorporation of the biological medicines into SUS in the 2011-2015 period was analyzed using the study case as a method. Conitec was taken as the case and the focus of analysis was the recommendation of the incorporation or not of the biological medicines into SUS.

For data production, official documents, semi-structured interviews with Conitec's members and non-participant observation of the ordinary meetings of the Committee were used as sources of evidence. The documents selected for analysis were: the Law No. 12.401/2011, the Decree No. 7.508/2011, the Decree No. 7.646/2011, the Decree No. 8.065/2013, the Regulation GM/MS No. 152/2006, and official documents produced

by Conitec – 44 meeting minutes of the committee, 54 technical reports of incorporation of biological medicines about the technology evaluated showing data on technology, the analysis of scientific evidence, the economic evaluation, the budget impact of the incorporation, Conitec's decision, public consultation and the final deliberation. In addition, the set of norms regarding the Registration of the Biological Products was checked, and it shows the resolutions regarding biological products published by Anvisa.

Thirteen interviews with 13 members of Conitec were carried out after the interviewees have read and signed the Informed Consent Form. It is worth mentioning that the plenary of the Committee is a forum responsible for issuing the recommendation about incorporation, exclusion or change of technologies in the context of SUS, about the constitution or change of the clinical protocols and the therapeutic guidelines and the Brazilian National Relation of Essential Medicines (Relação Nacional de Medicamentos Essenciais, Rename)[25]. The issues were related to the routines, activities and work organization, and the relationship between the judicialization of biomedicines and Conitec's decisions.

The non-participant observation of Conitec's ordinary meetings took place between October 2015 and April 2016. More specifically, the 40th, 42nd and 44th meetings were attended, resulting in a total of 39 hours of observation. To process the empirical material from documents, interviews and observation, the technique of theme-based content analysis was used[26,27].

Regarding the ethical aspects, it is worth noting that the study was previously submitted and approved by the Research Ethics Committee of the Federal University of Bahia, under the protocol No. 022/2015, in compliance with the Resolution No. 466/2012[28].

Results

In the period analyzed (2012-2015), 168 medicines were evaluated by Conitec, of which 56 (33%) were biological medicines and 112 (67%) were other types of medicines. Of the 56 biological medicines, 22 (39%) were recommended for incorporation, 26 (47%) were not recommended to be incorporated and 8 (14%) were recommended to be excluded from the official distribution lists of SUS.

Conitec's members that were interviewed were asked about their perceptions regarding health judicilization and the possibility that the legal demands on Conitec's final decision have influence on the recommendation of the incorporation or non-incorporation of medicines into SUS, including biological medicines.

The recognition of the health judicialization was verified as a legitimate strategy to safeguard the social rights that may be guaranteed by the Federal Government, among them, the right to healthcare:

> *The judicialization has a normative reason. We have a legal framework that grants people considerable freedom, and they have the freedom to access the Court to search for their rights.* (Int. 3).

> *The legal demands, from the constitutional point of view, are legal and reflect a social necessity.* (Int. 6).

According to interviewee 8, health judicialization is twofold. On one hand, there is the 'good judicialization', represented by the legal demands of goods, actions or health services, which have to be formally offered by SUS, but, for some reason, are not being offered. According to this interviewee,

> *This type of judicialization is welcome, as it requires from the public bodies that measures be taken so that these technologies or health services be offered to the population, correcting failures of access to SUS.*

On the other hand, there is the 'damaging judicialization', when the legal actions require technologies and/or services that are not predicted in the system and that occasionally are not registered at Anvisa. This is damaging, as

it involves expenses that are not predicted by the Federal, State and Municipal governments.

According to interviewee 3, the judicialization is usually used to promote an unregulated access or, at least, an easier access to new drugs, a strategy adopted by the pharmaceutical industry to promote the sale of its products. According to interviewee 1, it is common that companies that produce medicines that are judicialized do not demand Conitec's evaluation, because they know the evidence is not good, the benefits are small and the price is too high. Therefore, it is better for the company to not have Conitec's evaluation instead of a contrary recommendation, because the judge can eventually consult Conitec and see in the report the reasons why the technology was not incorporated into SUS.

Holding a similar opinion, interviewee 8 states that

> *The representatives of the industry state that they will not submit a certain medicine to Conitec's evaluation, because this takes time. It will be necessary to conduct several studies and come up with a negative recommendation. And in a certain way, they say that they are incorporating it through court.*

In addition, interviewee 3 says:

> *Sometimes, it is not interesting to submit a new treatment to Conitec's evaluation, because the industry understands that it does not offer great advantages in comparison to what already exists. Therefore, it will have a negative deliberation. Many industries choose not to try access to SUS via Conitec, but they use judicialization.*

These statements point to a possible effect of lawsuits in health in Brazil: the creation of a new way to incorporate technologies into the public health system. Indeed, health judicialization has enabled the demandants to have access to health goods and services, which are offered or not by the system.

In a scenario where there are several elements acting as pressure mechanisms on Conitec, all interviewees answered that the legal decisions in health do not influence the decision process of the committee. As interviewees 2, 4 and 10 state respectively:

> *The fact that a technology is frequent object of judicialization may not be a reason for its incorporation.*

> *It is clear to me that the occurrence of judicialization does not interfere in the decision of incorporation. Conitec is based on scientific data, and judicialization not always occur based on evidence.*

> *Undoubtedly, Conitec is not based on judicialization!*

Some interviewees admit that sometimes the topic 'health judicialization' is discussed in the plenary, especially in the evaluation of some technologies that have a high number of legal demands. Others think that Conitec could evaluate the technologies that are objects of lawsuits, until evidence can be provided on them, as stated by interviewee 5:

> *When some technology is under judicialization, it means that it should be analyzed. Conitec's role is to analyze exactly the priority of the use, the extension of this use, so that you can have a rational use.*

The case of the analog insulins, for example, observed in the meeting minutes, indicates that there is no influence of health judicialization on Conitec's work. Despite the deep discussions regarding the judicialization of these insulins and the knowledge of the costs of its provision to the states and municipalities, "the use of the analog insulin is much more a question of the convenience of the use than the patient's need"[29(8)].

Facing the lack of evidence in the studies shown, one of the members of Conitec suggested that the reports that show that the analogs are not superior be sent to the Brazilian

National Council of Justice (Conselho Nacional de Justiça, CNJ) to clarify the judges[30]. In the 20th meeting, the proposal was sent for public consultation with an unfavorable technical report regarding the incorporation of the analog insulin for Diabetes Mellitus into SUS. In addition, in the 24th meeting, the members of the plenary deliberated on the subject and they were unanimous in not recommending its incorporation[31,32].

Another strong indication that there is no influence of the legal actions, regarding the incorporation of the biological medicines, was the consideration of the proposal of the incorporation of the Infliximab medicine, as mentioned in the following fragment of the meeting minute:

> during the consideration of the proposal of the incorporation of Infliximab for severe corticoid-refractory ulcerative colitis, the contributions of the public consultation with Conitec's technical report that was unfavorable to the incorporation were shown. One of the contributions received, from a municipal health secretariat, reported the importance of the incorporation of the medicine due to a great demand via lawsuits, suggesting the medicine dispensation via specific protocols. The members of the plenary deliberated, we unanimous in not recommending the incorporation of Infliximab[33(11)].

The third indication of the non-direct influence of judicialization on Conitec's decision is related to the case of Trastuzumab. According to interviewee 1, in the case of the monoclonal antibody, there was a public civil action to incorporate the medicine throughout Brazil, for all the population diagnosed with breast cancer. Therefore, a consent decree was signed with the Court so that Conitec could evaluate this technology before the judge's final decision. In this case, Conitec's decision in recommending the incorporation was based on scientific evidence and economic evaluations, as shown in the report on the recommendation of Conitec's incorporation. For this reason, it was possible to map which groups of the population with breast cancer would have access to the medicine and what would be the requirements to the manufacturer so that the biological medicine could be incorporated into SUS.

According to some interviewees, the fact that Conitec is quite heterogeneous in its composition – the Plenary consists of representatives of seven secretariats of the MH, the Brazilian Federal Medicine Council, the Brazilian National Health Council, the National Council of the Health Secretaries, the National Council of Municipal Secretariats, the Supplementary Health National Agency and Anvisa – which makes the decision-making process more balanced.

> *In theory, everybody has signed and has to declare their conflict of interests, but the plenary, due to its plurality, [...] will have interests of each stakeholder involved, but there is the main, central interest, which is the citizen/user. Therefore, these interests, this correlation of forces, the plenary plurality itself, help to balance these influences.* (Int. 8).

> *In all human relations, you'll have Always some ideological or personal issues that will have influence on certain situations. The important thing is to have all visions inside the same place. If you have this, you overcome the conflicts of interest, which is the case here.* (Int. 10).

> *Conitec's design has incorporated a little bit of this social representation. The presence of these people brings another dimension, and this does not refer to the vote itself, but to the content of the discussion that is promoted in Conitec's plenary.* (Int. 2).

> *Here we have a kind of balance between the stakeholders and the people prepared to identify eventual biases or search for additional information that support their opinions and decisions. There is a certain balance that is really important here.* (Int. 11).

The diversity of individuals that are members of the Committee seems to facilitate the decision-making process at Conitec. According to the interviewees, it is exactly the diversity that provides balance and safety to the members of the Plenary, as several issues can be considered and clarified based on the opinion and knowledge of the stakeholders involved in the decision, which was also observed in the meetings.

Another element that can minimize the conflicts of interest of the potential stakeholders and, therefore, legitimate Conitec's work is the transparency with which the actions are performed (required by the Law No. 12.401/2011 and the Decree No. 7.646/2011)[11,12]. Thus, the entire process of technology incorporation is of public access and sent to public consultation before the final decision.

> *I believe that, because it is a transparent process, its legitimacy is really guaranteed. I think that we have to develop so that everyone recognizes Conitec as a legitimate entity, with all these characteristics of transparency, safety, aiming at benefiting the users of the Unified Health System.* (Int. 9).

Discussion

The analysis of the interviews, meeting minutes and reports, in addition to what was observed in Conitec's meetings, revealed that, although the existence of legal actions regarding the incorporation of technologies is usually part of the discussions of the plenary, this is not a decisive factor for the Committee's decision making. On the contrary, this study showed that Conitec's members follow strictly the flow of technology incorporation regulated by the Law No. 12.401/2011, Decree No 7.646/2011 and by the Committee's internal regulation.

However, although no evidence of direct influence of lawsuits on Conitec's decision regarding the incorporation of biological medicines into SUS was found, it became clear that the health judicialization topic is much present in the Committee's discussions.

Some studies point out the existence of a relationship between the number of lawsuits that require medicines and their incorporation into SUS and conclude that health judicialization, as it has a great interference in the health policies, has been transformed into pressure on the public sector to incorporate drugs[18,21,23].

The findings of this study, which show that there is no direct influence of lawsuits on the decisions of recommendation of incorporation or non-incorporation of biological medicines, can be seen as an evidence that the robust legislation regarding the incorporation of health technologies and its strict observance by the members of Conitec, in the period analyzed, are due to initiatives and behaviors adopted, in a certain manner, as strategies of protection against illegitimate influences that sometimes turn into legal actions.

Thus, Conitec is able to concentrate its attention and base its decisions on the results of the studies on the evaluation of health technology, the analysis of cost-effectiveness and the budget impact, recommending only the incorporation of safe and effective technology into SUS, and with the best cost-effectiveness relationship.

In this sense, it is possible to identify the existence of an indirect influence of the health judicialization on the process of technology incorporation into SUS when the motivations for the law formulation and the rules that regulate how Conitec works are considered and when the concern of Conitec's decision makers to truly respect the legal norms and avoid the illegitimate influences are identified.

The Health Open Court, called in 2009 by the Federal Supreme Court, has definitely stimulated the approval of the Law No. 12.401/2011, as the necessity of the formalization of the process of technology incorporation into SUS was extensively discussed, which made things more transparent, with the possibility of a greater participation of the SUS users in the decisions[34,35]. This open court was

especially aimed at promoting the social participation through the testimony of the authorities and stakeholders, thereby contributing to the development of technical, scientific, management, political and economic issues involved in the legal decisions about health[35].

Another evidence of influence of the phenomena of health judicialization about the definition of the process of technology incorporation into SUS is related to two initiatives established in 2010 by the Institution.

The first initiative is related to the Recommendation No. 31/2010[36], which guides the courts from all over the country to adopt a series of measures to support judges and other law operators in order to assure a greater efficiency in the solution of the legal demands regarding health law.

The other initiative of the CNJ was the creation of the National Court Forum to 'monitor and meet the health assistance demands' and to create concrete measures aimed at the optimization of the procedural routines, as well as the structuring and organization of the specialized court units through the Resolution No. 107[37].

In general, the recommendations of the CNJ guide de approximation between the fields of law and health.

In fact, at least partially, because of the recommendations, Conitec has been closer to Court. Therefore, among other strategies, it has promoted actions aimed at providing information for the decision making of the judges. One of these actions is the partnership established between Conitec and the CNJ, which resulted in the creation of a direct channel (conitec@saude.gov.br) to answer the questions of the judges about medicine, product or procedure incorporation into SUS.

Conitec's 2012-2014[38] Balance Sheet informs that the responses to the questions from the Federal Prosecution Office and bodies from the Court, regarding the incorporation of technologies into SUS, is a daily job performed by the Executive Secretariat. From January 2012 to August 2014, 701 questions were answered.

Another strategy to get closer to Court is to make the technical reports about health technologies available at Conitec's site, with the purpose of helping the decisions of the judges. Nowadays, 77 technical reports of several health technologies are available at Conitec's site (www.conitev.gov.br), 23 of which are about biological medicine. These technical reports have information about medicines and products for health, regarding the availability or not of the technology by SUS, the recommendation or not of its incorporation, the treatment cost, the existence of alternatives in the health public system and the availability or not of the Clinical Protocols and Therapeutic Guidelines for the related clinical situation.

A third initiative undertaken by Conitec to get closer to Court has been the participation of its members in events promoted by the Health Executive Committees, created after CNJ's recommendation. In addition, Conitec has participated regularly, together with the Legal Consultancy of the MH in several courts in the Federal Prosecution Office and Court to deal with topics about the incorporation of technologies in health.

Because of the complexity of the object of investigation of this study, it was not possible to explore all the possibilities related to the influence of lawsuits regarding biological medicines in the recommendation of their incorporation into SUS by Conitec. Therefore, the conduction of new studies is necessary to try to fill in the following gaps: to follow the incorporation and availability of the biological medicines to SUS users, to evaluate the changes in the Clinical Protocols and in the Therapeutic Guidelines, to update the Rename and to evaluate the deadlines to make the medicine available at SUS. Another possibility of the study is related to the comparison of the number of legal actions in health to require biological medicines to SUS before and after their incorporation into the system.

Conclusions

In the face of the phenomenon of judicialization and its several political, economic, ethical, technical and sanitary aspects, and due to the lack of consensus on the effects of legal actions on the health public system and on the ways of facing the phenomenon among managers, law operators, doctors and the researchers of the topic, as well as due to the market interests behind the legal actions that require health goods and services, we can see that Conitec's operation is regulated by laws and decrees aimed at protecting the process of incorporation of technologies of illegitimate influences for the incorporation of technologies into SUS, including when they become legal demands. In addition, it is noticeable that Conitec's members are concerned about following the laws.

Thus, it is possible to conclude that the phenomenon of health judicialization does not influence directly Conitec's decision-making process aimed at incorporating technologies into SUS, including the biological medicines. However, such phenomenon has indirectly influenced the process of health technology incorporation in the context of SUS, through the elaboration of a solid legal framework by the managers, consisting of laws, decrees and rules, as a way of protecting against the pressure that can be exerted by several interests, including by means of lawsuits.

Collaborators

Souza KAO has substantially contributed to the conception, analysis, planning, and data interpretation, participating in the draft production and in the approval of the final version of the article. Souza LEPF has contributed to the conception and planning of the article, critical review and approval of the final version of the article. Lisboa ES has contributed to the critical review of the topic and approval of the final version of the article. ■

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