ISSN: 2358-1824

Cadernos Ibero-Americanos de Direito Sanitário
Cuadernos Iberoamericanos de Derecho Sanitario

Article

De-judicialization of health and inter-institutional dialogues in Minas Gerais: an analysis of the Technical Cooperation Agreement for the management of the drugs Ranibizumab and Aflibercept

Desjudicialização da saúde e diálogos interinstitucionais em Minas Gerais: a análise do Acordo de Cooperação Técnica para a gestão dos medicamentos Ranibizumabe e Aflibercept

Desjudicialización de lasalud y Acuerdo de Cooperación Técnica firmado entre el Departamento de Salud del Estado, laFiscalía General del Estado y laDefensoría Pública del Estado de Minas Gerais

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Submitted on: 03/19/24
Revision on: 08/16/24
Approved on: 09/01/24

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Abstract

Objective:to understand the judicialization of health in Brazil and analyze, from the perspective of health de-judicialization, the Technical Cooperation Agreement signed on December 2, 2021, between the State Health Departmentof Minas Gerais , the State Attorney General's Office of Minas Gerais, and the State Public Defender's Office of Minas Gerais for the management of the medications Ranibizumab and Aflibercept. **Method:** a narrative review of the literature on the judicialization of health and an exploratory study based on documentary analysis of the antecedents of the Technical Cooperation Agreement were carried out. **Results and discussions:** Self-composition and consensual resolution of conflicts by the Public Administration has broad legal support and, in the current legal and administrative scenario, is the most effective and efficient means of realizing the underlying public interest, notably the right to health, promoting its dejudicialization. This scenario points to the potential for new solutions, including the implementation of interinstitutional dialogues, such as the Technical Cooperation Agreement studied, which is expected to serve as the embryo for a permanent trend in the management of the judicialization of health within the scope of State Health Departmentof Minas Gerais. **Final considerations:** ahecooperation agreement studied has great potential for the dejudicialization of actions with requests for ophthalmological medicines, in addition to others whose incorporations are proposed within it. It also promotes synergistic and convergent action by actors involved in judicialization. The perspective is that, from this milestone, these legal actions will decrease and patients will begin to be served through the United Health System administrative supply route.
Keywords: Health Law; Justice System; Health Judicialization.

Resumo

Objetivo:compreender a judicialização da saúde no Brasil e analisar, na perspectiva da desjudicialização da saúde, o Acordo de Cooperação Técnica, firmado em 02 de dezembro de 2021, entre a Secretaria de Estado de Saúdede Minas Gerais, a Advocacia Geral do Estado de Minas Gerais e a Defensoria Pública Estadual de Minas Gerais para a gestão dos medicamentos Ranibizumabe e Aflibercept. **Método:**realizou-se revisão narrativa da literatura sobre a judicialização da saúde e um estudo exploratório baseado em análise documental dos antecedentes do Acordo de Cooperação Técnica. **Resultados e discussões:**a autocomposição e solução consensual de conflitos por parte da Administração Pública possui amplo respaldo legal e, no atual cenário jurídico e administrativo, é o meio mais eficaz e eficiente para concretizar o interesse público subjacente, notadamente o direito à saúde, promovendo sua desjudicialização. Esse cenário aponta para o potencial de novas soluções, entre elas a implementação de diálogos interinstitucionais, como é exemplo o Acordo de Cooperação Técnica estudado, o qual projeta-se poder servir de embrião para uma tendência permanente na gestão da judicialização da saúde no âmbito da Secretaria de Estado da Saúde de Minas Gerais. **Considerações finais:**oacordo de cooperação estudado tem grande potencial para a desjudicialização das ações com pedidos dos medicamentos oftalmológicos, além de outros cujas incorporações forem propostas em seu bojo. Ele também promove a atuação sinérgica e convergente dos atores que atuam na judicialização. A perspectiva é que, a partir desse marco, estas ações judiciais diminuam e os pacientes passem a ser atendidos pela via de fornecimento administrativo do Sistema Único de Saúde.
Palavras-chave: Direito Sanitário; Sistema de Justiça; Judicialização da Saúde.

Resumen

Objetivo:comprenderlajudicialización de lasaluden Brasil y analizar, desde la perspectiva de ladesjudicialización de lasalud, elAcuerdo de Cooperación Técnica firmado el 2 de diciembre de 2021 entre laSecretaría de Estado de Saludde Minas Gerais, laProcuraduría General del Estado de Minas Gerais (AGE-MG) y laDefensoría Pública Estatal de Minas Gerais para lagestión de losmedicamentos Ranibizumab y Aflibercept. **Método:** Se realizó una revisión narrativa de la literatura sobre

lajudicialización de lasalud y unestudioexploratoriobasadoenunanálisis documental de los antecedentes delAcuerdo de Cooperación Técnica. **Resultados y discusiones:** La autocomposición y resolución consensuada de conflictos por parte de la Administración Pública tieneun amplio respaldo legal y, enelactualescenario jurídico y administrativo, es elmedio más eficaz y eficiente para realizar elinterés público subyacente, en particular elderecho a lasalud. promoviendosudesjudicialización. Este escenarioapunta al potencial de nuevas soluciones, incluidalaimplementación de diálogos interinstitucionales, como elAcuerdo de Cooperación Técnica estudiado, que se espera sirva como embrión de una tendencia permanente enlagestión de lajudicialización de lasaludenelámbito de laSecretaría de Estado de Salud de Minas Gerais. **Consideracionesfinales:**elconvenio de cooperaciónestudiadotieneungran potencial para ladesjudicialización de accionescon solicitudes de medicamentos oftalmológicos, además de otrascuyasincorporaciones se proponen dentro delmismo. También promueveacciones sinérgicas y convergentes por parte de losactores involucrados enlajudicialización. La perspectiva es que, a partir de este hito, esasaccioneslegalesdisminuyan y los pacientes comiencen a ser atendidos a través de lavía administrativa de abastecimientodelSistema de Salud Unido.
Palabras clave: Ley de Salud; Sistema de justicia; Judicialización de la Salud.

Introduction

In Brazil, the relationship between the law and health has taken on its current shape since the 1988 Federal Constitution (FC/88), the result of wide-ranging debates between civil society and the state. This is due to the progressive constitutionalization of Brazilian social rights from the late 1980s onwards, which, coupled with the challenges of effective implementation by the state, meant that they were increasingly subjected to the scrutiny of legal institutions for their implementation[1].

Regarding the right to health, defined as a fundamental right of a social nature by the Federal Constitution of 1988, Aith[2] teaches that the three branches of government act to make it a reality, emphasizing that the Judiciary is responsible for analyzing individual and collective demands to ensure access to this right.

The judicialization of health began in the 1990s, with mass lawsuits requesting treatment for AIDS sufferers, and the judiciary granting them en masse, which had an impact on Brazil's world-class AIDS treatment policy[3]. Since the end of the 1990s, the judicialization of health began to present problems, as its growth became an epidemic, in addition to the isolated actions of the Judiciary, without dialogue with the Executive to understand the problems and with the imposition of mandatory measures on managers[4]. Judicialization can be a positive and virtuous phenomenon, guaranteeing health, affirming social rights and promoting policies and technological incorporation, but it can also have shortcomings and negative effects, such as interfering in public policies and burdening the system[5].

In order to better deal with judicialization, the "*Núcleos de Assessoria Técnica*" - Technical Advisory Nuclei (NATs) were set up to provide technical health support to magistrates, a strategy that presents the judicialization face of technical improvement of the process and judicial decisions[6].

In parallel with the implementation of NATs, various instruments have emerged in the country to effectively remove actions involving health law from judicial arbitration. An example of this are the initiatives of inter-institutional dialogues, the creation of committees and instances of self-composition, all focused on the issue of health and its de-judicialization, which demonstrates that extrajudicial resources are also legitimate for resolving health disputes.

It is from the perspective of the de-judicialization of health that this article aims to study the Technical Cooperation Agreement signed on December 2, 2021, between the "*Secretaria de Estado de Saúde*" - State Health Secretariat (SES-MG), the "*Advocacia Geral do Estado de Minas Gerais*" - Minas Gerais State Attorney General's Office (AGE-MG) and the "*Defensoria Pública Estadual de Minas Gerais*" - Minas Gerais State Public Defender's Office (DPE-MG), with a view to incorporating or drawing up provisional supply and administration protocols, via the Pharmacy and Therapeutics Commission (CFT), for the ophthalmic drugs Ranibizumab and Aflibercept, pharmacological items with high rates of judicialization in the state of Minas Gerais (MG); This instrument is seen as reinforcing inter-institutional dialog between entities such as SES, AGE and DPE-MG[7].

The choice of topic is justified by the fact that the inter-institutional dialogical instrument to be studied is potentially effective in reducing litigation over the supply of highly demanded medicines in the state of Minas Gerais.

Methodology

The methodological approach adopted comprised two complementary stages. Initially, a narrative review of the literature on the judicialization of health and extrajudicial solutions for de-judicialization was carried out. Based on this theoretical framework, an exploratory study was carried out based on a documentary analysis of the background to the Technical Cooperation Agreement signed on December 2, 2021, between SES-MG, AGE-MG and DPE-MG, with a view to incorporating or drawing up protocols for the provisional supply and administration, via CFT, of the ophthalmic drugs Ranibizumab and Aflibercept[7].

As a narrative review, this article aims to describe and discuss the development or "state of the art" of the judicialization of health in Brazil from a theoretical point of view, with a focus on the de-judicialization of health, based on mapping the most relevant scientific production on the subject, published in books, articles in printed or electronic journals[8].

Having delimited the theoretical framework of the judicialization of health in Brazil, with a focus on de-judicialization, this article turned to an exploratory study centered on the documentary analysis of the Technical Cooperation Agreement, focusing the investigation on this specific instrument and its contextualization in the real world[9]. We also analyzed various complementary documents that make up the background of the cooperation instrument under study, such as normative acts, technical opinions and minutes of public consultations.

The aim of this study was to understand the entire factual and legal context in which the aforementioned agreement was signed, so that it can serve as an important instrument for de-judicialization in the state of Minas Gerais.

Results

The judicialization of health in Brazil

As a fundamental and social right constitutionally provided for in art. 5, §1, FC/88 (1), the right to health in Brazil has immediate applicability and is characterized by requiring the State to take progressive and concrete actions for its promotion, protection and recovery. In addition, in Brazilian constitutionalism, the right to health also has the outlines of a subjective public right, as it gives individuals the power to sue the state to satisfy their individual interest when this coincides with the public interest[10].

The progressive constitutionalization of Brazilian social rights from the 1980s onwards, coupled with the challenges of effective implementation by the state, meant that they were increasingly subjected to the scrutiny of legal institutions in order to make them effective. In Brazil, the three branches of government act to make this right a reality: the Legislative Branch, by drafting the laws that regulate and protect it; the Executive Branch, by planning, executing and managing public health policies and actions; the Judiciary Branch, by analyzing the individual and collective demands submitted to it to ensure access to this right, with emphasis on the role of the Executive and Judiciary Branches in building the right to health. The judicialization of health began in Brazil in the 1990s, through mass demands for treatment for HIV/AIDS sufferers and mass grants by the Judiciary, which resulted in the incorporation of this treatment into a world reference health policy[3]. It is possible to say that this health policy was so successful that it is one of the few to have a specific law, Law Nº. 9.313/1996, guaranteeing free access to medicines to treat AIDS.

Until 1998, the judicialization of health was practically only for the supply of drugs to treat AIDS. Two years after the implementation of the policy of universal distribution of medicines, judicial demands for health began to diversify, with the inclusion of requests for treatment for other diseases[11] and dealing with the most diverse requests[12].

Among the various health lawsuits that have been filed en masse in the Judiciary, we highlight the countless lawsuits for the supply of the substance "phosphoethanolamine", most of which have been granted by the courts. This substance was presented in the press as a cure for cancer, based on reports of people who, having used it, said they had been cured or had seen significant improvements in their condition[13]: hence its nickname “the cancer pill”. This paradigmatic case occurred as a result of a study carried out by a researcher at the “*Universidade de São Paulo*” - University of São Paulo (USP) with the substance phosphoethanolamine, who began distributing it informally to volunteer cancer patients. With the end of the supply of the substance by a USP ordinance, patients began to file mass lawsuits to obtain it[14]. Thus, the pills, without a license from Anvisa, began to be distributed only through the courts. This is a case that represents access to the courts based on the universal right to health, but also based on requests for medicines that have not been registered with the competent bodies. According to Figueiredo et al.[4], the release by the judiciary of a substance such as phosphoethanolamine, without scientific evidence or clinical trials, demonstrates the legal and regulatory fragility in Brazil, with the potential to create a precedent that is harmful to people's health, as well as creating a jurisprudence in favor of releasing drugs that have not been approved in Brazil. According to Teodoro and Caetano[15], the interest of pharmaceutical companies that encourage patient associations, lawyers and medical societies to mobilize public opinion, driven by the goal of trying to incorporate their costly products into the market, reveals the negative side of the judicialization of health. There is a part of the judicialization of health that does not represent the interests of patients, but of the pharmaceutical industry and the market. The influence of the medical-industrial complex is driven by economic market interests stemming from the production of high-cost innovative inputs. New technologies and scientific discoveries in health are highly profitable because they are, in theory, linked to an asset of incalculable value, which is life[16].

In the midst of this discussion, it is important to mention “*Extraordinary Appeal*” – Recurso Extraordinário (RE) nº 566471/RN, which formed Theme 6 on the “duty of the state to provide high-cost medication to people with serious illnesses who cannot afford it”[17]. It has not yet become final, but it has brought greater complexities to the issue of the judicialization of health, involving whether

or not the judiciary respects the process of incorporating SUS technologies via CONITEC and the need to assess certain requirements in order to grant the request.

In this scenario, it can be seen that judges generally have little or no technical knowledge of health issues, resulting in judgments based on the literal right to health provided for in the first part of Article 196 of the 1988 Constitution. Based on the constitutional argument that "health is the right of all and the duty of the state", countless requests for health actions, goods and services are granted in court, without observing health policies. Thus, when art. 196 is not interpreted broadly, what occurs is a privileging of the demands of those who sue, which goes against the process of building the SUS as a social public policy for the realization of the right to health based on the principle of equity[18].

Schulze[19] points out that, when judging a health claim, the judge has to deal with issues relating to the essentiality of the drug or treatment, the stage of development and its effectiveness, whether a treatment is alternative and unproven, and whether there is an alternative therapy incorporated into the SUS. And Souza[20] adds that "the lack of technical knowledge about the health area on the part of magistrates generates a worrying level of decision-making insecurity".

With regard to the intervention of the Judiciary in the realization of this right, Schier and Schier[21] point to the commitment of a significant portion of the public budget caused by lawsuits, the disagreements over how to manage public policies and the health budget, the increase in costs, the reserve of the possible and the existential minimum.

In an attempt to remedy the negative effects of the judicialization of health, the "*Supremo Tribunal Federal*" – Supreme Court (STF) Public Hearing on Health No. 4, in 2009, resulted in recommendations for the creation of NATs, advisory bodies made up of various health professionals, implemented in various states of the federation to provide technical health support to magistrates and subsidize the knowledge needed to better judge judicial health requests[22].

The NAT strategy has proved to be an important tool for broadening the relationship between the Executive and the Judiciary in the search for ways to improve the balance of the system[4] and an alternative for the technical improvement of the process and judicial decisions. Despite being considered a successful initiative when comparing the before and after of its work, the NAT is a post-procedural strategy, as its work presupposes the existence of a lawsuit and does not prevent the emergence of new claims[4]. NATs, therefore, are a relevant strategy in the judicialization of health, but new strategies aimed at inter-institutional dialogue are needed[23].

In this context, Silva and Schulman[24] argue that going through the courts to pursue claims denied in other ways burdens the entire system, makes it complex and increases inequalities, which is why they believe it is necessary to create innovative non-judicial mechanisms for resolving conflicts that coherently scale access to health and the protection of the public, through instruments of de-judicialization. To this end, they raise the following measures: expanding non-judicial channels, facilitating access, reducing costs not earmarked for treatment and improving public health; adopting mediation chambers; strengthening inter-institutional dialog between entities such as the Public Defender's Office, the Public Prosecutor's Office, the Health Department and the NATs of the courts. At this point in the discussion, another facet of the judicialization of health comes into view, through which we intend to outline the instruments or mechanisms for the de-judicialization of the matter under discussion.

De-judicialization of health in Brazil

De-judicialization is based on the search for out-of-court solutions to conflicts and is supported by lessons dealing with the changes in contemporary Administrative Law, which is currently based on the guidelines of management, participation and consensus. Along these lines, Moreira Neto[25] argues that participation and consensus have become decisive for contemporary democracies.

From the perspective of contemporary Brazilian constitutionalism, Moraes[26] presents the principle of juridicity or legality in a broad sense, whereby the Public Administration no longer operates under the parameters of legicentrism or strict legality, since the administrator's attachment to the law has been replaced by subordination to the legal system as a whole, where the Constitution and its principles emerge[27]. Thus, it is inappropriate to talk about the inexorable supremacy of the public interest over the private interest, since it is a matter of weighing up public interests against private interests. Sarmento[27] points out that fundamental rights have emerged with absolute prominence and centrality. It is in the wake of the current constitutional paradigm of Public Administration that the possibility arises, in the abstract, of public managers participating in self-compositional procedures and entering into agreements.

Along these lines of consensuality in Administrative Law, Law nº 13.140, of 2015, introduces self-composition as a means of resolving conflicts in which the Public Administration participates as an interested party, concerning both conflicts between bodies or entities of the Administration itself, and between legal entities of public law and private individuals[28]. Likewise, Law 13.105 of 2015 (Code of Civil Procedure/Brazil) adopted a perspective of consensual conflict resolution and established mechanisms for this purpose, encouraging the search for alternative means of amicably resolving disputes in a reasonable time, in a cooperative manner and with a view to the common good[29].

In Minas Gerais, this guideline is provided for in State Law No. 23.172, of 2018, which encourages the prevention of judicialization of conflicts between private individuals and the state through the use of consensual means[30]; as well as in Complementary Law No. 151, of 2019, which provides for the organic structure of AGE-MG and contains provisions to promote, through conciliation, mediation and other self-composition techniques, the solution of conflicts, judicialized or not, of interest to the state Public Administration[30]. In fact, in the state of Minas Gerais, the strategy of out-of-court conflict resolution took shape with this law[27], which provides for a number of measures within the executive branch aimed at reducing the number of lawsuits involving the state, either by AGE-MG not filing them, not contesting them or not lodging an appeal, or by the self-composition of public disputes implemented by the "*Câmara de Prevenção e Resolução Administrativa de Conflitos*" - Chamber for the Prevention and Administrative Resolution of Conflicts (CPRAC).

Megna[32] believes that "(...) consensus does not pose any risks to the principles of legality, the unavailability of the public interest or the supremacy of the public interest". In the same vein, Justice Ellen Gracie ruled in Extraordinary Appeal Nº. 253.885/MG, establishing the validity of a transaction on the grounds that, although the public administrator does not have control over the interests of which he is the manager, there are cases in which the principle of the unavailability of the public interest must be attenuated, when it is borne in mind that the solution adopted by the Administration is the one that will best serve it[33].

According to Machado and Martini[34], the Brazilian socio-political context, guided by a guiding Constitution, has reshaped the role of the Judiciary with the consequent judicialization of politics; but this intervention must be exceptional and focus on the collective nature of the rights materialized in public policies, and the Judiciary cannot shy away from dialogue and unilaterally decide on them. The paradox lies in the fact that, looking at the national reality, it can be seen that the judicialization of health has failed to provide an effective response to society, as Machado and Martini[35] found in the growing number of lawsuits and the mismatch with the realization of the right in practice. It is therefore necessary to assess whether the opposite phenomenon - de-judicialization - is a viable alternative to the realization of the right to health, insofar as it proposes inter-institutional dialogues, administrative mediations and greater participation by society in decision-making.

Justice Luís Roberto Barroso's vote in Extraordinary Appeal Nº. 657.718/MG, in 2019[36], believes that it is necessary to de-judicialize the right to health in Brazil, given that the Judiciary is not the appropriate body to define public health policies, and can only intervene in extreme situations or to implement public policies already formulated in the SUS. This vote is also noteworthy for its assessment of the need for the Judiciary to engage in dialogue with entities or people with technical expertise in the area of health, such as technical support chambers and centers, SUS professionals and the "*Comissão Nacional de Incorporação de Tecnologias no SUS*" - National Commission for the Incorporation of Technologies into the SUS (CONITEC)[34].

In this sense, some strategies have been implemented by the country's various federal units in an effort to de-judicialize health demands, most of them centered on conflict mediation, which, according to the sole paragraph of article 1 of Law Nº. 13.140, of 2015, is "the technical activity exercised by an impartial third party without decision-making power, who, chosen or accepted by the parties, assists and encourages them to identify or develop consensual solutions to the controversy"[28].

Once the right of access to justice is recognized as the right to use all legitimate, legal and valid means to resolve conflicts, and given the provision in article 5, item XXXV, of the FC/88 that "the law shall not exclude any injury or threat to the right from the appreciation of the Judiciary"[1], it is worth questioning whether extrajudicial means are admissible or whether this orientation goes against constitutional norms. The question becomes more relevant in light of Resolution nº 127 of the "*Conselho Nacional de Justiça*" - National Council of Justice (CNJ), known as the National Judicial Policy, which, among other measures, provides for the movement towards conciliation. The answer to this question lies in the fact that FC/88 enshrines jurisdiction as a state monopoly, but does not prevent other forms of conflict resolution.

According to Delduque and Castro[36], the SUS has received valuable help from this form of conflict resolution, with initiatives by judges, members of the Public Prosecutor's Office, public defenders, federal lawyers and prosecutors, who have been setting up mediation groups based on individual demands, in order to resolve the conflict between the patient/plaintiff and the health manager and avoid legal action.

In the state of Minas Gerais, the Operational Support Center for Health Defense Prosecutors' Offices travels around the state holding conciliation meetings between users and managers, as well as dealing with specific issues such as prison health, technological incorporation and others. The CPRAC, coordinated by the AGE-MG, is an appropriate and effective forum, in addition to the consensual solution of general conflicts involving the Minas Gerais Executive Branch, to promote the de-judicialization of issues involving the right to public health. In 2023, the TJMG set up a specialized

unit to deal with health law matters within the scope of the Judicial "*Centro Judiciário de Solução de Conflitos e Cidadania*" - Center for Conflict Resolution and Citizenship (CEJUSC). This is the CEJUSC Saúde, based in the District of Belo Horizonte, with statewide competence for pre- and post-procedural conciliation and mediation for the treatment of individual and collective health law issues by the courts[37].

Background to the Technical Cooperation Agreement

Until the mid-1990s, there was still no evidence-based therapy available on the market to effectively "*degeneração macular relacionada à idade*" - tackle age-related macular degeneration (DRMI). To this day, understanding of the disease is still at a mature stage, despite the significant scientific advances of recent decades, due to the apparent multifactorial nature of the pathogenesis. In addition to the genetic coefficient, numerous risk factors seem to contribute to the development of DRMI, such as smoking, advanced age, pre-existing systemic arterial hypertension and others[38]. As for the scope of the disease, it is known that it affects around 15 to 30% of individuals aged 55 to 80 and is responsible for 8.7% of all blindness nationwide[39].

It is a chronic degenerative disease that affects the central area of the retina, called the macula, which is responsible for the resolution and sharpness of human vision. It is now known that the pathogenesis develops in two basic forms: a) the dry form, which is more common and causes slower and more progressive wear and tear of the macula through cell loss, is milder and affects around 90% of patients; b) the wet, neovascular or exudative form, which is characterized by the development of new blood vessels in the layer between the retina and the sclera and can cause blindness in a short time[40].

The first and most rudimentary therapeutic approaches used against DRMI were based on a destructive logic, mechanically attacking the excessive cell membrane by means of laser photocoagulation, which projects a laser onto the retina, coagulating the abnormal tissues and promoting the destruction of the neovascular complex[39]. Used as the only therapeutic alternative for a long time in the SUS, the technology has only proved effective for some types of DRMI and has the disadvantage of causing permanent scarring in the photoreceptor layer of the eye.

Similarly, photodynamic therapy consists of the intravenous injection of a photosensitive drug (verteporfin) combined with low-intensity laser irradiation[41]. As far as this alternative is concerned, a low number of patients show a significant improvement in vision, and almost all of them develop irreversible structural sequelae[39].

The great revolution in the fight against DRMI was the advance of anti-VEGF technologies, starting with Pegaptanib sodium (Macugen®, EyeTech/Pfizer), the first anti-VEGF approved by the Food and Drug Administration (FDA). Subsequently, other vascular endothelial growth factor (VEGF) inhibiting agents were developed: Ranibizumab (Lucentis®, Genentech), Bevacizumab (Avastin®, Genentech), Aflibercept (Eylea®, Bayer) and Brolucizumab-dbll (Beovu®, Novartis)[38].

The intravitreal application of these drugs is now the best and least aggressive therapeutic resource available, as it works by inhibiting the angiogenic protein, regulating the growth factor of the vascular endothelium[42].With regard to efficacy and safety, the studies that supported CONITEC's recommendation for incorporation indicate that Ranibizumab is similar to Aflibercept for the treatment of neovascular DRMI[39].

To understand the factual context of the Technical Cooperation Agreement signed between SES-MG, AGE-MG and DPE-MG, we need to go back to Official Letter 177/2020/DPMG, sent to AGE by DPMG on June 28, 2020. This document listed the 12 medicines most demanded by patients assisted by the DPMG. Based on the survey, the State of Minas Gerais is asked to take measures to reduce the intense judicialization of drugs, promoting their administrative dispensation to the final recipient.

Among the drugs listed in the document are Aflibercept (Eylia®) and Ranibizumab (Luscentis ®), whose incorporation into the SUS was the subject of intense demand by civil society at the time. According to information from SES-MG, between 2018 and 2020, 717 lawsuits were filed against the state of Minas Gerais for Ranibizumab, and R$7,980,553.40 was spent on acquiring the drug. In relation to Aflibercept, 510 lawsuits were filed against the state and R$6,319,897.00 was spent.

Around 10% of DRMI patients develop the neovascular type of DRMI, which can cause blindness or severe vision loss[35]. For these cases, the current "*Protocolo Clínico e Diretrizes Terapêuticas*" - Clinical Protocol and Therapeutic Guidelines (PCDT) provided for the prescription of laser photocoagulation therapy, as well as the use of the anti-VEG agent Bevacizumab, an *off-label* technology that interferes with the formation of subretinal neovascularization[39].

At that time, there was a significant gap in care for the treatment of DRMI[39]. Bevacizumab, whose use within the SUS was authorized on an exceptional and provisional basis, according to RDC Nº. 111, of September 6, 2016, had its license discontinued by ANVISA. After the initial three years of the instrument, it was no longer extended due to a lack of information on the safety and efficacy of fractional doses of the drug[42]. One of the great advantages of Bevacizumab was its substantially lower cost than other anti-VEG drugs available on the market[34]. From then on, Aflibercept (Eylia®) and Ranibizumab (Lucentis ®) became the only drug technologies licensed by ANVISA for neovascular DRMI.

It should be noted that Aflibercept (Eylia®) was then dispensed by SUS exclusively for the treatment of patients with diabetic macular edema, in accordance with Ordinance Nº. 50 of November 5, 2019[43].

At the moment, therefore, the approach to neovascular DRMI in the SUS only includes a non-drug therapeutic approach (laser photocoagulation), which is recognized as less effective and tends to develop sequelae in the neurosensory tissue[44].

In light of the procedure launched by Bayer S.A. and the "*Secretaria de Ciência, Tecnologia e Inovação e Insumos Estratégicos em Saúde do Ministério da Saúde*" - Ministry of Health's Secretariat for Science, Technology and Innovation and Strategic Health Supplies (SCTIE/MS), CONITEC was asked to give its opinion on the possible care gap resulting from this and on the feasibility of incorporating the two anti-VEG agents. In order to gather information, it was proposed that Public Consultation Nº. 06 be held between February 18, 2021 and March 9, 2021. A total of 931 contributions were received by CONITEC, including 244 of a technical-scientific nature and 687 relating to personal reports from patients, family members, caregivers and others. After analyzing this material, CONITEC expressed its opinion through Record of Decision no. 603/2021, recommending the use of both technologies, given the total lack of anti-VEGF technologies in the SUS. This resulted in the formalization of the incorporation, subject, however, to the development of its own PCDT by the Ministry of Health, according to SCTIE/MS Ordinance nº. 18, of May 7, 2021:

Em face de procedimento deflagrado pela empresa Bayer S. A. e pela Secretaria de Ciência, Tecnologia e Inovação e Insumos Estratégicos em Saúde do Ministério da Saúde (SCTIE/MS), a

CONITEC foi instada a se manifestar sobre o possível vazio assistencial decorrente e sobre a viabilidade de incorporação dos dois agentes anti-VEG. Para colheita de informações, foi proposta a realização da Consulta Pública n. 06, entre 18 de fevereiro de 2021 e 09 de março de 2021. Ao todo, foram recebidas pela CONITEC 931 contribuições, entre elas 244 de caráter técnico-científico e 687 relativas a relatos pessoais de pacientes, familiares, cuidadores e outros. Após análise desse material, a CONITEC se manifestou por meio do Registro de Deliberação n. 603/2021, recomendando a utilização de ambas as tecnologias, diante da total ausência de tecnologias anti-VEGF no SUS. Disso resultou a formalização da incorporação, condicionada, entretanto, ao desenvolvimento de PCDT próprio pelo Ministério da Saúde, conforme Portaria SCTIE/MS n. 18, de 7 de maio de 2021:

> Art. 1 Incorporate aflibercept and ranibizumab for the treatment of neovascular Age-Related Macular Degeneration (DRMI) in patients over 60 years of age within the scope of the Unified Health System (SUS), according to the Protocol of the Ministry of Health and Ophthalmic Care in the SUS.[45] (translated by the translator).

Currently, even after the approval of the PCDT, the administrative availability of drugs for patients with neovascular DRMI remains unfeasible, since it is pending an agreement on its financing by the Tripartite Interagency Commission - CIT, as can be seen in Information Note nº. 15/2022-DAET/CGAE/DAET/SAES/MS[46].

This is the factual and legal situation that led to the increase in the judicialization of drugs and the consequent demand by the DPE-MG for incorporation at the state level. It should be noted that, of the 12 drugs listed in Official Letter 177/2020/DPMG, eight were already provided by some SUS public policy and two had been technically evaluated by CONITEC, which decided not to incorporate them, due to the lack of sufficient scientific evidence[47]. Therefore, only the two drugs, Aflibercept (Eylia®) and Ranibizumab (Lucentis ®), proved to be eligible for the drafting of their own clinical protocol by the CFT of the State of Minas Gerais.

It is important to note that the increase in the judicialization of these medicines, motivated by the advent of a care gap, as well as the active participation of the DPMG, led to a series of internal moves within the SES-MG in search of de-judicialization.

Firstly, after discussion and approval at the 278th Ordinary Meeting of the CIB-SUS/MG, on September 22, 2021, Deliberation CIB/SUS/MG nº 3.546 was published, establishing an Ophthalmology Working Group, with the aim of organizing the Ophthalmology Care Network in the State of Minas Gerais.

Subsequently, as a direct result of the facts described, on December 2, 2021, a Technical Cooperation Agreement was signed between SES-MG, AGE-MG and DPE-MG, for the incorporation or drafting of provisional supply and administration protocols, via the CFT, for Ranibizumab and Aflibercept, until the final decision on their financing by the CIT. In addition to the drugs in question, the instrument provided for the CFT to analyze the incorporation of other drugs with a high rate of judicialization, according to the list periodically indicated by the DPMG[47].

Discussion

It is clear that the technique of consensual conflict resolution and the signing of agreements by the Public Administration has ample legal backing and is proving to be the cheapest and most appropriate means of realizing the underlying public right or interest. In fact, there are various

instruments for the consensual and out-of-court resolution of conflicts in health matters, which have proven to be the appropriate and effective strategy for this purpose, since, in resolving issues involving state or government policy, it is essential to give the interested parties the opportunity to deal with the conflict through mediation and dialogue[48].

Given the collective and distributive nature of the right to health, it must be affirmed by public policies and not by judicial decisions, since mastery of the community's social needs, the best technique for distributing scarce resources and budgetary possibilities is essential for defining public policies aimed at realizing the right to health[49].

As we have seen so far, there is no denying the inadequacy of the current judicial model. However, the usual censure of judicial interference in public policies is not resolved by making it impossible to access the judicial sphere, but by offering real and concrete alternatives[24]. Access to the courts should be supported by public pharmaceutical policy, in accordance with Article 196 of the Federal Constitution[1], combined with Articles 19-M to 19-U of Law 8080 of 1990[50], but this is not the case in most cases, as in the example of RE 56471/RN[51]. It would be important for the STF to give clear guidelines on the need for the plaintiff to minimally prove that the incorporation process is deficient in order for the judiciary to intervene.

The scenario that has been shaping up regarding the de-judicialization of health shows the potential for new solutions, the possibilities of using more appropriate conflict resolution strategies, the need for a joint effort to adopt effective instruments to make the right to health a reality and the implementation of inter-institutional dialogues, such as the Technical Cooperation Agreement. The growing phenomenon of judicialization has led to the development of new formulas for settling health claims, whether through pre-judicial conflict resolution mechanisms, or through instruments for reviewing and improving current public health policies, especially at their weakest points or care gaps[36].

Valuing the out-of-court settlement of health conflicts does not contradict the constitutional right to legal action, because what is sought, as an alternative to the intense and massive judicialization of this right, are mechanisms that facilitate the assessment of the particularities of the specific case, and its swift and less costly solution. And even if a lawsuit is subsequently filed over the same controversy, it can be instructed by the probative content captured in the administrative procedure[24].

According to a survey by the CNJ, the congestion rate, which measures the efficiency of the Judiciary, considering the total number of new cases, the number of dropped cases and the backlog of cases from the base period and the previous year, reached 72.9% in 2022. In other words, only around 27% of all the cases dealt with in the period were duly resolved, which indicates the remarkable slowness of the judicial machine. It should also be noted that the electronic cases that were resolved in 2022 had an average processing time of 2 years, and the physical cases had an average processing time of 7 years and 9 months[52]. This scenario is even more sensitive when it comes to health matters, which are marked by the need for urgent satisfaction of rights.

In order to mitigate the effects of the growing culture of judicialization of conflicts, the state of Minas Gerais has encouraged the use of alternative and consensual means of composition. In this case, the increase in the judicialization of two medicines led to the signing of a Technical Cooperation Agreement, opening up an important channel for dialogue between the bodies and making it possible to periodically propose the incorporation of medicines with high rates of judicialization. On the other

hand, it can be seen that the Public Defender's Office has continued to judicialize requests for medicines for a long time, even though the parties have not asked for the technology to be incorporated.

The diagnosis of the increase in actions precipitated a broad movement to structure the ophthalmology network in this state, which is currently underway.

The advantages of acquiring and dispensing drugs through administrative channels are numerous, starting with better compliance with SUS principles, such as equity, since the ordinary supply follows strictly technical criteria, following an objective order of prioritization. It can be seen that oblique access to health services through the courts often favors patients with more access to information and greater purchasing power, which tends not to occur in the administrative provision of the SUS[52].

In terms of efficiency, administrative purchases are also advantageous, as they are massive and allow for greater gains in scale. Judicial purchases, on the other hand, are fragmented and have low predictability, which hampers procurement management[52].

It has not yet been possible to see a reduction in the judicialization rates for both drugs, Ranibizumab and Aflibercept. According to information from SES-MG, between 2021 and 2023, the state of Minas Gerais was the defendant in 947 lawsuits for Ranibizumab, and R$9,236,360.94 was spent on acquiring the drug. In relation to Aflibercept, the state of Minas Gerais was the defendant in 609 lawsuits for Ranibizumab, and R$9,249,791.80 was spent on acquiring the drug. It should be noted that it will be necessary to carry out a study to understand the impact of this de-judicialization initiative once the initiatives proposed under the Technical Cooperation Agreement have been completed.

It is also hoped that the instrument can serve as the embryo for a permanent trend in the management of health judicialization within the SES-MG: the preference for organic solutions to pacify demands, with judicialization data serving as a true thermometer of public policy.

Final considerations

In the wake of a broad movement promoted by the state of Minas Gerais to encourage alternative ways of complying with judicial demands, it can be seen that the increase in the judicialization of two drugs has led to the structuring of the ophthalmological network in the state, as well as the opening of a channel for dialogue between the SES and the DPE-MG, with the periodic proposal for the incorporation of judicialized drugs.

The organic action of the specialized judicialization sector and the other areas of the SES responsible for public health policies, together with inter-institutional collaboration between actors such as the Public Defender's Office, the Public Prosecutor's Office and the Judiciary itself, if encouraged and developed, tend to mitigate or even reverse the culture of health judicialization that has spread across the country in recent decades.

Based on the literature analyzed, it can be concluded that the cooperation agreement uses instruments with great potential for de-judicializing lawsuits with requests for the two ophthalmic drugs and others whose incorporation is proposed under the agreement. In addition, the agreement promotes synergistic and convergent action by independent actors working in the field of judicialization, such as the SES-MG, AGE-MG and DPE-MG, who feed each other important information to efficiently meet citizens' demands and comply with the public interest. The prospect is that, based on this framework, these lawsuits will decrease and patients will start to be served through the SUS administrative supply route.

Conflict of interest
The authors declare that there is no conflict of interest.

Authors' contribution
Castro MCA and Silva Netto FT contributed to the conception/design of the article, writing, critical revision of its content and approval of the final version. Dos Santos FP and De Castro MSM contributed to the critical review of the content and approval of the final version of the article. Figueiredo IVO contributed to the conception/design of the article, critical revision of its content and approval of the final version.

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How to cite
Castro MCA, Silva Netto FT, Dos Santos FP, De Castro MSM, Figueiredo IVO. De-judicialization of health and inter-institutional dialogues in Minas Gerais: an analysis of the Technical Cooperation Agreement for the management of the drugs Ranibizumab and Aflibercept. Cadernos Ibero-Americanos de Direito Sanitário. 2024jul./set.;13(3):83-103
https://doi.org/10.17566/ciads.v13i3.1253