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BRAZILIAN JOURNAL OF PUBLIC ADMINISTRATION

Article

Policy diffusion in practice: the case of Brazilian medicinal products regulation

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The present study seeks to contribute to a better understanding of policy diffusion processes, more specifically, of the diffusion process from a transnational arena that influenced the regulation of Good Manufacturing Practices (GMP) for medicinal products in Brazil in a context surrounded by international authorities. By conducting qualitative research, we analyzed the process of adhesion of the Brazilian Health Regulatory Agency (Anvisa) to the Pharmaceutical Inspection Co-operation Scheme (PIC/S), initiated in 2010 and achieved in 2021. A process influenced by two constellations of diffusion was identified, motivated by the national agency's interests in maintaining its relevance and by actors that make up the National Sanitary Surveillance System, in which the PIC/S model of regulatory equivalence and convergence proved to be fundamental for the adaptation of the international reference to the national level, keeping the national system functioning. Such a policy diffusion process became even more relevant in the past years due to the expansion of regulatory convergence and potentially making the various health authorities' GMP assessment of medicinal products more efficient.
Keywords: policy diffusion; Anvisa; good manufacturing practices for medicinal products; regulation.

Difusión de políticas en la práctica: el caso de la regulación brasileña de medicamentos

El presente estudio pretende contribuir a una mejor comprensión de los procesos de difusión de políticas, más concretamente, del proceso de difusión que influyó en la regulación de las Buenas Prácticas de Fabricación (BPF) de medicamentos en Brasil, a partir de arenas transnacionales. A través de una investigación cualitativa, analizamos el proceso de adhesión de la Agencia Nacional de Vigilancia Sanitaria (Anvisa) al Esquema de Cooperación de Inspección Farmacéutica (PIC/S), iniciado en 2010 y alcanzado en 2021. Se identificó un proceso influenciado por dos constelaciones de difusión, motivado por el interés de la agencia nacional en mantener su relevancia y por los actores que componen el Sistema Nacional de Vigilancia Sanitaria, en el que el modelo de equivalencia y convergencia normativa del PIC/S resultó fundamental para la adaptación de la referencia internacional al ámbito nacional, manteniendo el sistema nacional en funcionamiento. Este proceso de difusión de políticas adquirió aún más relevancia en años recientes al ampliar la convergencia normativa y hacer potencialmente más eficiente la evaluación de las BPF de los medicamentos por parte de las distintas autoridades sanitarias.
Palabras clave: difusión de la política; Anvisa; buenas prácticas de fabricación de medicamentos; regulación.

DOI: https://doi.org/10.1590/0034-761220220125x
ISSN: 1982-3134
Article received on April 17, 2022 and accepted on April 25, 2023.
[Translated version] Note: All quotes in English translated by this article's translator.
Editor-in-chief:
Alketa Peci (Fundação Getulio Vargas, Rio de Janeiro / RJ – Brazil)
Associate editor:
Gabriela Spanghero Lotta (Fundação Getulio Vargas, São Paulo / SP – Brazil)
Reviewers:
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Two reviewers did not authorize the disclosure of their identities.
Peer review report: the peer review report is available at this URL.

Difusão de política na prática: o caso da regulação brasileira de medicamentos

O presente estudo busca contribuir para a melhor compreensão de processos de difusão de política com base em arenas transnacionais – mais especificamente, do processo de difusão que influenciou a regulação das Boas Práticas de Fabricação (BPF) de medicamentos no Brasil num contexto envolto por atores internacionais. Por meio de pesquisa qualitativa, analisamos o processo de adesão da Agência Nacional de Vigilância Sanitária (Anvisa) ao arranjo de cooperação Pharmaceutical Inspection Co-operation Scheme (PIC/S), iniciado em 2010 e alcançado em 2021. Foi identificado um processo influenciado por 2 constelações de difusão, motivado por interesses da agência nacional em manter sua relevância e por atores que integram o Sistema Nacional de Vigilância Sanitária, no qual o modelo de equivalência e convergência regulatória do PIC/S se mostrou fundamental para a adaptação da referência internacional em nível nacional, mantendo o sistema em funcionamento. Tal processo de difusão de política ficou mais relevante nos últimos anos por ampliar a convergência regulatória e, potencialmente, tornar mais eficiente a avaliação das BPF de medicamentos pelas diversas autoridades sanitárias.
Palavras-chave: difusão de política; Anvisa; boas práticas de fabricação de medicamentos; regulação.

ACKNOWLEDGMENTS

We would like to thank FGV EBAPE ProPesquisa for the partial funding for this research.

1. INTRODUCTION

When facing transnational issues, the practices regarding the adoption and implementation of public policies often conform to international diffusion patterns (Engler et al., 2021; Gilardi, 2010; Simmons, Lloyd, & Stewart, 2018). Policymakers worldwide, spanning various domains, draw upon the experiences and lessons learned in different countries to consider local policies (Eta & Mngo, 2020; Krenjova & Raudla, 2018; Montero, 2017).

Entering global value chains requires adapting rules to achieve broader international acceptance. In particular, health crises that transcend national boundaries, such as the COVID-19 pandemic, highlight the relevance of government responses to disseminate medicinal product regulation strategies internationally (Weible et al., 2020). In addition, these emergencies underscore the need to reassess the existing regulatory framework and medicinal product regulatory policies (Sebhatu, Wennberg, Arora-Jonsson, & Lindberg, 2020).

Therefore, the theme of policy diffusion, which encompasses various processes such as transfer, diffusion, and policy circulation (Newmark, 2002; Porto de Oliveira & Faria, 2017; Porto de Oliveira & Pal, 2018), has gained prominence and relevance, particularly regarding the regulation and production of medicinal products at the local level (Pepe, Novaes, & Osorio-de-Castro, 2021). Internationally, institutions have increasingly moved towards the harmonization of technical requirements in order to address the challenges posed by limited financial and human resources allocated to regulate the medicinal product market (Costa, 2004; Gouveia, Rijo, Gonçalo, & Reis, 2015; S.K. Jain & R.K. Jain, 2017; Rago & Santoso, 2008; Vilarins, Shimizu, & Gutierrez, 2012).

The good manufacturing practices (GMP) for medicinal products intended for human use represent a collection of guides and guidelines that establish the necessary standards for manufacturing health products, ensuring their quality, safety, and efficacy (Gouveia et al., 2015). The Brazilian Health Regulatory Agency (Anvisa) has been responsible for medicinal product regulation since

its establishment in 1999. In 2010, Anvisa initiated efforts to join the Pharmaceutical Inspection Co-operation Scheme (PIC/S), an informal cooperation arrangement among regulatory authorities.

The PIC/S was established in 1995, comprises over 50 member countries and aims to standardize and harmonize GMP inspection procedures. Following the evaluation process, Anvisa officially became a member in January 2021.

Thus, aiming to contribute to the existing literature on policy diffusion (Hassenteufel, Benamouzig, Minonzio, & Robelet, 2017; Porto de Oliveira & Pal, 2018; Stone, Porto de Oliveira, & Pal, 2020) and the ongoing debate surrounding the regulation of GMP for medicinal products (A. P. J. Silva & Tagliari, 2016; Vilarins et al., 2012), this study addresses the following question: How has policy diffusion influenced the regulation of GMP for medicinal products in Brazil? The objective of this research is to comprehend the mechanisms that explain policy diffusion from transnational arenas and its specificities and consequences for the Brazilian regulation of GMP for medicinal products.

The results highlight the significant influence of transnational arenas on the policy diffusion process within Brazilian regulation, emphasizing the interdependency between national regulations and international actors. This interdependency shapes the scope of diffusion, the degree of adaptation, and the drivers behind the alignment of national rules. Despite partial adaptation, the policy implemented at the national level aligns with parameters that correspond to those employed by other health authorities within the well-established transnational arena. This study characterizes the transnational arena as a closed system with self-attributed sealing power.

The article is organized into seven sections, starting with the introduction. The subsequent section presents the theoretical framework, focusing on policy diffusion. The third section outlines the methodology, including details of data collection and content analysis processes. Following that, the fourth section provides an overview of the context of GMP for medicinal products in Brazil and explores the alignment of these practices with international standards. The study's findings are presented in the fifth section, while the sixth section discusses these findings in the context of the theoretical framework. Finally, the last section offers the concluding remarks, emphasizing the study's contributions and suggesting directions for future research.

2. POLICY DIFFUSION

In an era of growing globalization, local public policies are increasingly influenced by international institutions and organizations (Farazmand, 2001; Faria, 2018). Issues that transcend a country's individual capacity for resolution, such as terrorism, pandemics, and biosecurity, have driven this discussion. Unlike unilateral governance models, more inclusive models require collaborative efforts between governmental and non-governmental actors, strengthening connections between individuals and states (Karns & Mingst, 2004; Weiss, 2009).

The existing literature has discussed policy transfer or diffusion through horizontal transmission – from one state to another – or vertical transmission – from international organizations to states (Kuhlmann, Reufels, Schlichte, & Nullmeier, 2020). Three approaches are commonly employed to analyze these processes: policy transfer, policy diffusion, and policy circulation (Porto de Oliveira & Faria, 2017).

The first approach, policy transfer, generally refers to a specific process of moving policies from one jurisdiction to another and is often perceived as a more limited process involving a small number

of political units and interactions. However, Stone (2004) suggests that policy transfer can be more complex and involve multiple actors. The notion of "lesson drawing" is incorporated within this approach, which acknowledges various methods of acquiring knowledge and influencing public policy based on successful cases implemented in other jurisdictions. These methods include copying, emulation, hybridization, synthesis, and inspiration (Rose, 1991).

The second approach is more suitable for understanding the collective adoption of policies (Porto de Oliveira & Faria, 2017) based on structural factors (Newmark, 2002). It examines the identification of good practices and their dissemination, often analyzed through the lens of the diffusion chain (Rogers, 2003). This perspective assumes that change occurs "by osmosis; something that is contagious rather than chosen" (Stone, 2012, p. 484). Policy diffusion places significant emphasis on the role of transnational collective action in policy diffusion, correlated with the cognitive shortcuts policymakers employ to decide to implement local policies (Porto de Oliveira & Faria, 2017). It also considers the pursuit of compliance with international standards (Stone, 2012).

The third approach, policy circulation, is characterized as a more extensive and multidirectional process that unfolds over a long period of time and covers a wide geographic scope. It may involve back-and-forth movements of policies. This approach closely examines the actors involved in the process and their interactions. The transnational flow of ideas, instruments, terminology, and policies also assumes a significant role in policy circulation (Hassenteufel et al., 2017; Porto de Oliveira & Faria, 2017).

Despite their differences, the three approaches aim to analyze the processes through which knowledge about policies, administrative arrangements, institutions, ideas, and philosophies are adopted and transferred from one political context to another, including the potential transformations associated with this process (Dolowitz, 2017; Dolowitz & Marsh, 2000; Gilardi, Shipan, & Wüest, 2021; Hassenteufel et al., 2017). Several authors, such as Porto de Oliveira and Faria (2017), Newmark (2002), and Eta and Mngo (2020), acknowledge that these approaches are complementary and that their combination can yield valuable insights. In this research, the term "policy diffusion" was used as a broad concept that encompasses various types of policy change based on policies established in different contexts or instances, thus serving as the process that connects domestic policies to international ones (Newmark, 2002; Porto de Oliveira & Faria, 2017; Porto de Oliveira & Pal, 2018).

In this study, to understand how policy diffusion influenced the regulation of GMP for medicinal products in Brazil, we deemed it essential to employ several analytical categories from the existing literature. One category is the identification of the actors involved in the diffusion process and their characteristics. Works such as Evans and Davies (1999), Stone (2004), and Stone et al. (2020) emphasize the significance of transnational arenas as networks for policy transfer. These arenas consist of diverse groups of actors who collaborate in formulating, promoting, and implementing policies across various domains.

In their study on the policy diffusion process, Kuhlmann et al. (2020) introduced an innovative concept in their analytical framework called "constellations of diffusion." They propose that diffusion can occur in various ways: from one country to another, from an international organization to a country, from one country to another, or from a dominant regime. In addition to policy diffusion through international organizations or between countries, it is crucial to acknowledge the role of

non-state actors, such as social movements, non-governmental organizations, think tanks, multinational consulting firms, and global public policy networks (GPPNs).

Global public policy networks play a significant role in the field of health, and the literature provides examples such as the Global Alliance on Vaccination and Immunization (Gavi), the Global Fund to Fight AIDS, Tuberculosis and Malaria, and the Global Alliance for Improved Nutrition (Gain) (Stone, 2004; Stone et al., 2020). While these networks may not exclusively operate at a global level, as they also engage in regional activities, they can be conceptualized as "communities of practice," as described by Gautier, Allegri, and Ridde (2021).

In the field of health, there is a growing trend toward establishing international forums and cooperation mechanisms involving regulatory authorities (Nolte & Groenewegen, 2021; A. P. J. Silva & Tagliari, 2016). The nature of integration within these transnational forums determines the content that is disseminated – whether it be ideas, paradigms, lessons, or interpretations (referred to as soft elements) or instruments, legislation, and regulations (considered hard elements) (Stone, 2004) – and the degree of adaptation of these objects (Stone, 2017).

The study on the regulation of international health practices conducted by A. P. J. Silva and Tagliari (2016) identified that various tools of international dialogue are employed in addressing regulatory or commercial barriers in the health sector. These tools include harmonization, equivalence, and regulatory convergence of health measures and technical regulations. Harmonization is used to form consensus and standardization, although its implementation may face challenges due to the countries' unique circumstances and characteristics.

The tools of equivalence and convergence provide options for adapting international references in a flexible manner. Equivalence involves adopting similar but not identical measures as long as they meet the level of protection deemed appropriate by the country that originally established the measure. Convergence entails a technical alignment process to enable the application of local regulatory requirements that adhere to internationally recognized principles and standards (A. P. J. Silva & Tagliari, 2016).

The drivers behind policy diffusion are considered a significant category of analysis. According to Stone (2004), the diffusion process can occur voluntarily, under coercion, or somewhere between these extremes. Evans and Davies (1999) discuss the agency power of those who choose to adopt a particular public policy, as well as the influence of economic, technological, ideological, and institutional structures that guide or even compel the adoption of certain policies, even without direct coercion. For instance, competition between countries can be one of the factors that drive the adoption of specific policies (Stone, 2017).

Dolowitz (2006) highlights that policy diffusion can be associated with a better understanding a specific topic. However, it can also be related to the fear and the risks of being under scrutiny at the global level or submitted to pressure for a symbolic action. In terms of drivers for diffusion processes, Kuhlmann et al. (2020) criticize the neglect of micro-level actors in the literature, emphasizing the importance of recognizing their role and the complexity involved in understanding how diffusions occur.

The authors propose to fill this gap by examining the individuals actively participating in the diffusion process and the financial incentives and resources available. Additionally, they emphasize

the role of rules and procedures, which are often influenced by specific, dominant ideologies. Furthermore, when connecting the actors involved with the elements motivating them, it is crucial to recognize the significance of discursive aspects, as "policy discourses cannot be separated from the actors that shape and use argumentative strategies in order to legitimate and strengthen policy proposal by convincing other actors" (Hassenteufel et al., 2017, p. 81).

The last relevant analytical category for this study refers to the diffusion implementation process, which involves examining the mechanisms utilized and the barriers or facilitators encountered during the actual implementation phase. Evans and Davies (1999) have identified 12 steps for voluntary policy transfer processes, including stages such as dissatisfaction, search, contact, emergence of information networks, cognition and reception, emergence of transfer networks, elite and cognitive mobilization, interaction, evaluation, decision-making in the policy flow, process, and objective. They also identified ten steps for coercive transfer processes, where a country or international organization compels another government to adopt a specific program or policy.

According to Kuhlmann et al. (2020), the diffusion process can be divided into three stages: perception and translation, cooperation and conflict, and collective decision-making. Additionally, Stone et al. (2020) emphasize the role of public servants – working as statisticians, lawyers, or parliamentary researchers – in everyday life as key actors in learning from international experiences and initiating the diffusions.

From these analytical categories – actors involved and transnational scale, the object of diffusion and degree of adaptation, the drivers, and the diffusion implementation – this study seeks to understand policy diffusion regarding the regulation of GMP for medicinal products in Brazil. The subsequent section presents the methodology adopted in this research, followed by the context of good manufacturing practices for medicinal products in Brazil and their adherence to international standards

3. METHODOLOGY

This qualitative study gathered data from documentary research and semi-structured interviews. The documentary study involved the analysis of public documents and materials provided by relevant personnel at the Brazilian Health Regulatory Agency (Anvisa). This included inspection procedures and manuals, legislation, management reports, presentations, documents from the international relations department concerning the PIC/S membership process, and information available on the websites of institutions involved in the process, as detailed in the Appendix.

Fourteen semi-structured interviews were conducted with knowledgeable respondents, as indicated in Box 1. The interviewees consisted of representatives from both the productive and public sectors – members of the National Health Surveillance System (SNVS) – who were directly involved in the process of updating the regulation of GMP for medicinal products based on the PIC/S. The aim was to gather a comprehensive range of perspectives from the various actors involved since the process's inception. The interviews took place in February and March 2020 and were fully transcribed for analysis.

BOX 1 INTERVIEWS

Number of interviews	Interviewees' institution and position	Identification
9	Anvisa, occupying technical and management positions, including director	I1 to I9
4	Representatives of other institutions members of the SNVS, occupying technical and management positions, including director	I10 to I13
1	Representative of a leading employer association gathering businesses in the pharmaceutical industry	I14

Source: Elaborated by the authors.

The data collected in this study were analyzed using the content analysis method developed by Bardin (2016). The analysis aimed to draw inferences and deductions based on the information gathered during data collection. In alignment with the theoretical framework, specific categories were selected for the content examination in order to delve into the process of policy diffusion. These categories included aspects such as the source of the policy, the degree of adaptation, the decision-making process, the actors involved, the contextual factors, and the facilitators or barriers to diffusion. The collected data were organized into categories and subcategories to facilitate a comprehensive analysis, which allowed for the detailed description of the results presented in section 5.

4. CONTEXT: GOOD MANUFACTURING PRACTICES FOR MEDICINAL PRODUCTS IN BRAZIL AND THEIR ADHERENCE TO INTERNATIONAL STANDARDS

Low-quality medicinal products pose a significant global problem, particularly in developing countries, jeopardizing people's health and squandering valuable resources (Jain & Jain, 2017; Wirtz et al., 2017). The regulation of medicinal products plays a crucial role in promoting access, ensuring quality, safety, and efficacy (Rago & Santoso, 2008). The World Health Organization (WHO) emphasizes that the only way to guarantee the medicinal products safety and quality is through robust regulation and an effective control system, necessitating government intervention (Gouveia et al., 2015; Wirtz et al., 2017). Among the key activities in this domain is the regulation of good manufacturing practices (GMP), which sets forth the minimum technical requirements for production, ensuring adherence to predefined quality standards.

In Brazil, the regulation of GMP for medicinal products dates back to 1946. However, it was in 1995 that the regulation became more detailed, requiring compliance of pharmaceutical industry with the Guide for Good Manufacturing Practices. Despite these efforts, the late 1990s witnessed several scandals involving counterfeit medicinal products and quality deviations, which caused a significant health surveillance crisis (Costa, 2004; J. A. A. Silva, Costa, & Lucchese, 2018). One notable case is the "flour pill" scandal, where the pharmaceutical company Schering do Brasil was found to have manufactured and distributed contraceptive pills containing starch instead of the active ingredient (Santini, 2007).

In 1999, through Law No. 9,782 (Lei nº 9.782, de 26 de janeiro de 1999), the Brazilian Health Regulatory Agency (Anvisa) was created and the National Health Surveillance System (SNVS) was defined. The SNVS comprises federal, state, and municipal surveillance institutions with shared responsibilities.

Under the responsibility of Anvisa, the regulations of GMP for medicinal products were published in 2001, 2003, and 2010. They were based on WHO guidelines and incorporated inspection processes influenced by health authorities from several countries, including Germany, Canada, Denmark, the United States, Mexico, and the United Kingdom. Additionally, international references such as the European Medicines Agency (EMA), WHO, and the Medical Devices Single Audit Program (MDSAP) were taken into consideration. In 2019, the regulatory framework underwent an update and was aligned with the guidelines published by the PIC/S.

The PIC/S is an international arrangement established by regulatory authorities, specifically focusing on the field of GMP for human and veterinary medicinal products. It originated as an extension of the Pharmaceutical Inspection Convention (PIC), which was established in 1970 among regulatory authorities in European countries. The main purpose of the convention is to facilitate mutual recognition of inspections in pharmaceutical product manufacturers.

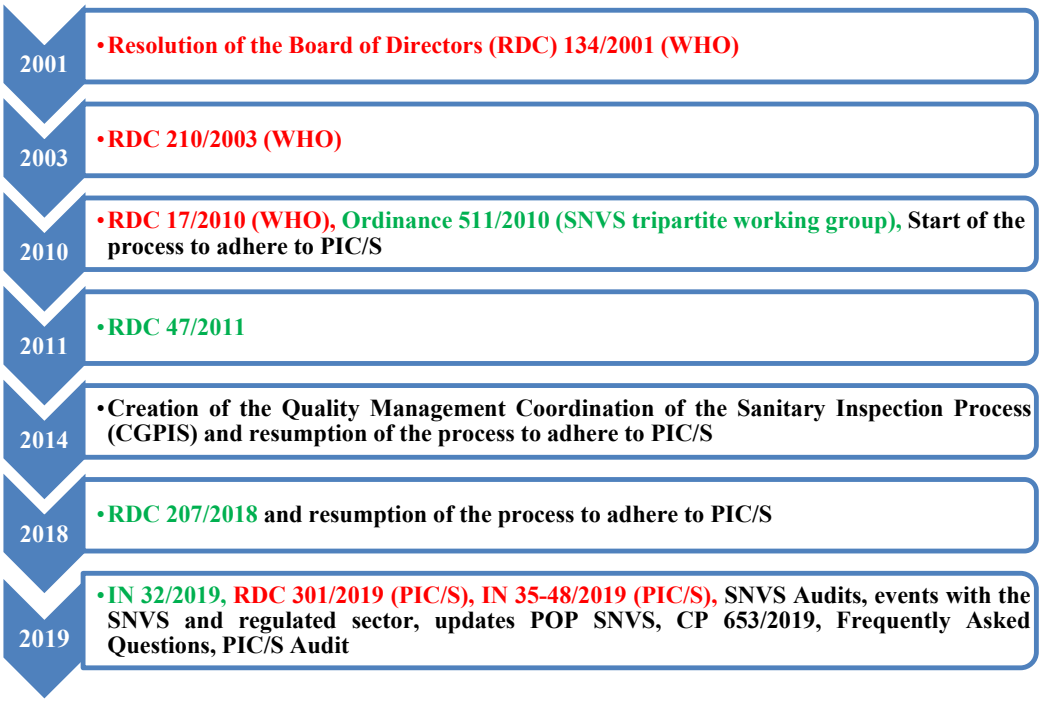
Due to restrictions on admitting non-European members, the PIC Scheme (PIC/S) was established in 1995 as an informal and non-binding international cooperation arrangement open to regulatory authorities that have a GMP system for medicinal products equivalent to the PIC/S members. Presently, 54 member authorities are participating in the PIC/S. The primary goal of this cooperation is to harmonize and converge GMP inspection procedures on a global scale. This is achieved through the development of technical guides and the provision of training for inspectors.

The main harmonization document within the PIC/S is the PIC/S Guide to Good Manufacturing Practice derived initially from the WHO GMP Guidelines and subsequently amended to include new areas and scientific and industrial advances. Since 1989, it has closely resembled the GMP guidelines utilized by the European Union. Among the Latin American countries, the PIC/S includes regulatory authorities such as the Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (Anmat) of Argentina (joined in 2008), the Comisión Federal para la Protección contra Riesgos Sanitarios (Cofepris) of Mexico (joined in 2018), and Anvisa of Brazil (joined in 2021).

The PIC/S is involved in various key activities, including training inspectors, organizing annual seminars that also contribute to the production of GMP documents, conducting joint visits and supervised inspections, and facilitating the exchange of information and the development of guidelines through specialist input. To adhere to the PIC/S, a regulatory authority must undergo a thorough analysis to assess the comparability of its inspection system, which encompasses inspection procedures, licensing processes, quality systems, inspector training, and legislation, with those of existing member authorities. Following technical visits, the responsible committee provides recommendations and conducts follow-up visits to verify the implementation of corrective actions. Since 2014, the PIC/S has implemented a "pre-review" to assist regulatory authorities willing to join the system.

In 2010, Anvisa initiated the process of joining the PIC/S by submitting a questionnaire containing information about the Brazilian inspection system to the PIC/S secretariat. However, the approval and formal adherence were only achieved in January 2021, following an inspection conducted in 2019. This inspection involved auditors from the PIC/S and health agencies of other countries who assessed the regulatory practices of Anvisa, as well as the state health surveillance agency in Minas Gerais, the municipal health surveillance agency in São Paulo, and public and private pharmaceutical laboratories. Figure 1 presents the key milestones and events in this process in a timeline that spans from the initial GMP regulation implemented by Anvisa to its ultimate approval as a member of the PIC/S.

FIGURE 1 **KEY MILESTONES AND EVENTS IN THE DEVELOPMENT OF THE REGULATION OF GMP FOR MEDICINAL PRODUCTS SINCE ANVISA'S CREATION**



Key: Norms of GMP for medicinal products published are presented in red; regulations and ordinances associated with decentralization and harmonization in the SNVS are presented in green; other actions carried out by Anvisa in order to adhere to PIC/S are in black.
Source: Elaborated by the authors.

5. RESULTS

The data obtained from interviews and evaluated documents offer a panorama of the development of the Brazilian regulation of GMP for medicinal products influenced by the policy diffusion process. This section presents this process considering the following categories: diffusion objects, sources, and degree of adaptation; drivers; facilitators and barriers to implementation.

5.1 Object, sources, and degree of adaptation

For Anvisa's adherence to the PIC/S, both regulatory framework of the GMP for medicinal products and the quality management model of the inspection area (which includes the processes of (i) sanitary inspection in medicinal product manufacturers, (ii) qualification and training of inspectors and (iii) management of inspections carried out by SNVS entities) were modified. The primary sources of inspiration for these modifications were the PIC/S Guide to Good Manufacturing Practices and procedures and practices from various health authorities already affiliated with the PIC/S, including the United States, Mexico, Denmark, and other international references like MDSAP. The study found that the policy diffusion object of regulations of GMP for medicinal products did not demonstrate complete harmonization of legislation and processes with the international sources, which is explained by the adaptations made to suit the Brazilian context.

In the adherence process, the PIC/S assesses whether the mechanism for regulating the GMP for medicinal products is equivalent to those of other health authorities already in the system, seeking regulatory convergence. While acknowledging the need for adaptations to account for market-specific peculiarities, a negotiation process involving multiple stakeholders, including Anvisa and the regulated sector represented by councils, associations, unions, and individual companies, led to the approval of a regulatory framework that closely aligns with the PIC/S guidelines. As part of this agreement, the productive sector was granted staggered deadlines to comply with certain requirements.

> The regulatory framework for the PIC/S currently adopted by Anvisa, has very few divergences from the PIC/S, almost nothing. The difference is a section at the end of the regulation [...] that provides deadlines to start enforcing compliance with each requirement – which could not be implemented immediately – offering predictability for the productive sector (I3).

In general, the adaptation of the regulatory framework for the GMP for medicinal products based on the PIC/S was minimal. Alongside the changes, Anvisa developed a document containing frequently asked questions to enhance transparency, inclusivity, effectiveness, and efficiency in the regulatory process. This initiative was widely recognized as beneficial by members of the National Health Surveillance System (SNVS):

> It [company] understood that it needs to go through a rational [path]; it is not surprising. It is clear what the position of the regulatory agency is. I think the main point I would mention is the transparency in the process. […] Today, the [regulation] 301 may have some unclear items. But, if we go to the frequently asked questions, we find the answer (I11).

In contrast, varying degrees of adaptation were observed in the quality management model. Specifically, in the area of sanitary inspection in medicinal product manufacturers, a high degree of adaptation was observed with updates in inspection processes. The approach of classifying companies based on inspections was inspired by the model used in the United States, where the issuance of a certificate of compliance with GMP for medicinal products does not exist. In this case, the model was adapted to the Brazilian context (E14).

In this new model, obtaining the certificate is not the focus of the inspection. Instead, the focus is the risk assessment and evaluation of the need to apply market restrictive measures such as suspension of the production or importation and recalls, which can be applied by the health authority when it identifies non-compliance with the GMP for medicinal products.

Another innovation introduced was the establishment of standardized sanitary actions, which defined specific responses for different types of irregularities: "We have advanced a little further compared to the FDA (Food and Drugs Administration) model. It doesn't have what we have in terms of standardized sanitary action, what kind of non-compliance generates an action or not. This was our creation" (I5).

One crucial requirement to joining the PIC/S is the qualification and training program for inspectors, which is also integrated into the quality management model for the inspection area. In order to align the program with PIC/S standards, the processes employed by the health authorities

of Mexico and Denmark served as benchmarks. A significant level of adaptation was observed in this aspect, as the qualification and training program for inspectors implemented in Brazil differs considerably from those in the benchmarked countries:

> We intensified the meetings of the tripartite working group on documents and carried out a major revision. Two main points are the qualification process and inspector training, which have been greatly improved compared to what they were before and had already been criticized in the audit conducted by the European Community. [...] Aware of this criticism, we networked with the authorities in Mexico and Denmark. We held a conference call for them to explain the inspector qualification and training process. Denmark and Mexico are PIC/S authorities […] We will try to reach a compromise (I6).

In terms of managing inspections conducted by SNVS entities, there was a limited level of adaptation with regard to the source used. With the implementation of the 2018 and 2019 regulations, a new process was established for delegating the inspections of GMP for medicinal products, which became dependent on the results of audits conducted within the SNVS entities. This process was inspired by the models used by PIC/S and MDSAP. The audit tool utilized was developed based on the assessment model employed by PIC/S for admitting and monitoring its members (PIC/S, 2022d). The rationale behind this approach was that by utilizing the same tool, the SNVS could conduct a self-assessment before the PIC/S assessment and address any deviations, thus ensuring continued membership in PIC/S. While the same tool was adopted, it was necessary to adapt the interpretation of each criterion to align with the Brazilian context:

> [...] the audit criteria were internalized to give delegation to the states, and they [the criteria] were incorporated into the internal audits in the general management of inspection and sanitary monitoring. These are the same criteria that the PIC/S adopts. What we did was give an interpretation of those criteria, considering the national scenario. [...] So, all those criteria in which the PIC/S audited us, we incorporated them to audit the states, informing how we were going to evaluate (E1).

The interviewees recognized the restructuring of the delegation process for inspections at the state and municipal levels as a significant and challenging change, particularly due to the complexities involved in the activities of the GMP for medicinal products and concerns regarding the autonomy of SNVS entities: "The great challenge was negotiating with 27 different health authorities, each with its autonomy and independence protected by the Federal Constitution" (I2). Additionally, adaptations were made to suit the Brazilian context, such as adjusting the periodicity for reassessing the fulfillment of evaluation criteria: "It occurs in cycles, but they have slightly different deadlines. [...] Ours is shorter" (I1). In the PIC/S, reevaluations occur every five years, whereas in the SNVS, they occur every three years. These initiatives aimed to enhance the coordination, control, and standardization of SNVS actions.

5.2 Drivers

The analysis of documents and interviews identified four drivers motivating Anvisa to adapt national legislation and join the PIC/S. One of them stemmed from the recognition of deficiencies in the existing national normative, which were considered outdated because it was based on previous international parameters: "I think that we win, a priori, with harmonization, [...] not making it [the regulation] obsolete, as happened with the last regulation we had, the 17 [Resolution RDC 17, of April 16, 2010 (Resolução RDC nº 17, de 16 de abril de 2010)], which referred to [regulations of] the WHO from 2003" (I7). "We had a very outdated framework; we followed our regulations, which were still based on the [regulations of the] WHO from 2003" (I14). Consequently, Anvisa aimed to enhance the national system by aligning it with more current international parameters.

Another driver highlighted by the interviewees was Anvisa's interest in strengthening its international presence and reputation: "[...] occupying relevant international spaces was one of the agency's strategies to strengthen its image" (I3). By actively participating in forums and engaging with established health authorities, Anvisa aimed to improve its qualifications and outline mechanisms to the convergence of requirements and regulatory processes.

The interviewees highlighted several benefits that come with being a member of the PIC/S. They emphasized that joining the PIC/S grants recognition to regulatory authorities, signifying their equivalent regulatory capacity. This recognition facilitates international agreements and enhances the exchange of information with other health authorities. It also promotes resource optimization, streamlines the process of exporting medicinal products, and strengthens the national pharmaceutical industry: "The product from Brazil becomes more competitive to enter new markets, [...] and we have to look for strengthening our industry, so it can operate both in our market and the external market" (I7).

For Anvisa, joining the PIC/S brings a sense of legitimacy within the national context. It addresses the concerns raised by regulated companies regarding the performance of health surveillance: "Often, we go to an inspection, especially with multinationals, and they understand that the legislation is weak, fragile. Now, harmonized with the PIC/S, there is less questioning" (I12).

The productive sector expressed support for the change in the regulatory framework based on the PIC/S, recognizing the potential benefits it would bring, particularly in facilitating the export of Brazilian products: "[...] the first thing I can see is that it will make it easier for Brazilian companies to export. [...] This pairing in relation to PIC/S makes Brazil a very important player in the international market" (I13).

The harmonization of Brazilian regulations with international parameters was deemed necessary to mitigate risks and address potential barriers to the trade of pharmaceutical products: "[...] it is very bad for the economy of the pharmaceutical industry if we are not at the same level with international regulation. [...] We keep using different criteria, and this closes the market" (I8). Furthermore, other consequences of the lack of harmonization are the weakening of the SNVS and the productive sector operating in Brazil and the lack of standardization in the actions carried out by SNVS entities.

5.3 Facilitators and barriers to implementation

The main difficulty and challenge highlighted by the interviewees in the policy diffusion process was related to the involvement and maintenance of the decentralized system of the SNVS: "There is no doubt

that discussing decentralization was the main challenge because our model is different from most of the world" (I9). Given the decentralized nature of the system, the adaptation of the policy diffusion objects had the participation and collaboration from Anvisa, state and municipal health surveillance agencies, as well as representatives of the productive sector such as unions and employer associations.

The interviewees considered that the development of the SNVS posed significant challenges in terms of monitoring and harmonizing actions, which required changes in the criteria for delegating inspection activities. The discussion surrounding the criteria for decentralization and delegation was acknowledged as difficult and time-consuming, but it was considered crucial in the overall process (I14).

According to the interviewees, another factor that complicated the process of joining the international context was the discontinuity in prioritizing the project to join the PIC/S over the years. This discontinuity was attributed to the high demands faced by the technical area, challenges related to urgent national needs, and frequent changes in Anvisa's management and organizational structure. As time passed, the regulatory requirements of the PIC/S became increasingly stringent, presenting an additional barrier to Anvisa's accession. However, in late 2018, adherence to the PIC/S was once again given priority. Considering the maximum 10-year period stipulated by the PIC/S for completing the process, there was a limited timeframe for its completion, which was set to take effect after an audit conducted by the PIC/S at SNVS, scheduled for October 2019.

The limited time available was recognized as a significant barrier, as it required the simultaneous execution of numerous activities and decision-making on complex issues within a strict timeline. For the interviewees, "many activities took place simultaneously in order to comply with the schedule agreed with the PIC/S executives" (I2). "I think it [the main barrier] was the short time; [...] the inspection was scheduled to occur in October [...], the inspectors were scheduled to come and conduct the inspections here in Brazil. It was quite rushed" (I13). However, the time constraints were also seen as a catalyst for implementing necessary changes in the regulation of the GMP: "The sense of urgency […] ended up being a driver to get everything done, to get everything implemented so quickly" (I8).

Among the factors identified during the interviews as facilitators of the changes in the diffusion objects stand out the strong political and executive support from Anvisa's top management and the engagement and dedication of the technical staff and managers: "The great facilitator was that the team was engaged in the process. [...] It was important for the public servants who worked on this topic. I would say that this was the main facilitator. Another facilitator was the commitment of top management at that time" (I7).

Throughout 2018 and 2019, an extensive dialogue process was carried out with the regulated sector to foster and engage in a debate on the impacts of the new regulation:

> We invited each association to an individual meeting [...]. This was discussed with all the major associations, with some unions. We sought engagement from them from the beginning. [...] After that, we had a sectoral dialogue in the auditorium to present the initiative again, to discuss it, and to make a general presentation of the basis of the regulatory framework and part I of the PIC/S guidelines. Afterward, working groups were created so that each group discussed an annex on a specific topic and raised those issues that could be a problem or to clear up doubts. [...] After that, we held a round of discussions in São Paulo, Rio de Janeiro, Belo Horizonte, and Porto Alegre. [...] At the end of it all, there was a last meeting in São Paulo, with 300 people in the auditorium and 1900 or so connected to the internet, watching the discussion about each item (I3).

In addition to Anvisa's work, there was intense interaction among the various SNVS entities, facilitating the process: "For the PIC/S, we felt included in the process from the beginning" (I10, member of one of the SNVS entities).

6. DISCUSSION

Based on the results, it is evident that transnational arenas have had a significant influence on the regulation of GMP for medicinal products in Brazil, as highlighted by studies such as Evans and Davies (1999), Stone (2004), and Stone et al. (2020). Among these arenas, the PIC/S has played a crucial role in shaping the new policy. Two constellations of diffusion – as proposed by Kuhlmann et al. (2020) – were instrumental in establishing this new policy. The first constellation was "from the international organization to the country," which involved Anvisa's efforts to join the PIC/S and the subsequent harmonization of Brazilian policy to align with the international convention's criteria. The second constellation was the "from country to country" interaction, wherein the Brazilian agency proactively engaged with countries already members of the PIC/S. This proactive approach sought to adapt the policy to the national context and secure approval in the PIC/S audit.

Anvisa carried out the process of adapting the national policy with the objective of joining the transnational arena, which serves as an international cooperation forum consisting of regulatory authorities in the specific field (Nolte & Groenewegen, 2021; A. P. J. Silva & Tagliari, 2016). This diffusion process encompassed soft aspects, such as ideas, concepts, and attitudes, as well as hard elements, including programs, tools, structures, and practices (Evans & Davies, 1999; Stone, 2004).

While achieving full harmonization of regulatory instruments was not feasible in certain aspects due to local circumstances (A. P. J. Silva & Tagliari, 2016), the regulatory equivalence and convergence model proved to be a valuable approach for adapting the international reference to the national level. In the case of joining the PIC/S, although complete harmonization is not required, significant divergences or deviations are not accepted, as a thorough evaluation is conducted to determine if the authority is capable of implementing a comparable inspection system to that of existing PIC/S authorities (PIC/S, 2022e, p. 4). Therefore, in line with the existing literature, the integration of authorities in this international arena guided the adoption of the new policy, the diffusion object (Stone, 2004).

The influence exerted on Anvisa by external agents was not a one-way process, driven solely by their power asymmetry over the national agency. This case highlights the importance of critically examining the categories that distinguish between voluntary and coercive diffusion. It emphasizes the presence of complex dynamics involving the interplay between the power of individual agency and the strength of economic, technological, ideological, and institutional structures (Evans & Davies, 1999).

The results reveal the existence of market pressure, the risk of being under scrutiny internationally, and competition between countries – which leads to the adoption of certain policies that place a country in a more competitive position in the pharmaceutical industry (Dolowitz, 2006; Evans & Davies, 1999; Stone, 2004). Simultaneously, there is evidence of an internal arrangement within the field itself to regulate medicinal product production based on knowledge acquired from other locations.

The identification of two key moments suggests a voluntary diffusion process. The first was in 2010 when the Brazilian agency initiated the process to apply to join PIC/S. The other was in 2018, when the regulatory framework was prioritized for adaptation – given the proximity of the time limit

to complete the application process – and the bureaucrats' recognition that the national regulations were obsolete (Evans & Davies, 1999). The agency noticed this situation when questioned by regulated companies, who preferred to follow more up-to-date or internationally validated regulations.

At the same time, there is some level of coercion since the PIC/S demands a process of mimicking policies in the face of what is identified as good practice by international arenas. The PIC/S does not only represent a transnational arena but also a closed transnational arena, with sealing power imbued by the very arrangement that differentiates health authorities with GMP considered up-to-date from those with obsolete practices. Thus, it is possible to perceive the stage of diffusion called perception and translation (Kuhlmann et al., 2020), in which national actors recognize international interdependence and begin to acquire new knowledge about the policies of other countries and the model established by the international body to adapt them to the national scenario.

Using the framework developed by Kuhlmann et al. (2020), it is important to highlight that among the elements fostering policy diffusion is the financial perspective, which proved to be a relevant source of motivation for the interviewees. On the one hand, becoming obsolete, it is possible that the legitimacy of the national agency itself was questioned by the regulated actors and was affected by a scarcity of resources. On the other hand, the productive sector also saw adherence to the PIC/S as a competitive advantage: "This pairing in relation to the PIC/S makes Brazil a very important player in the international market" (I14).

As for the last category of analysis, i.e., the implementation of the diffusion process, it was possible to observe the perception and translation stage (Kuhlmann et al., 2020). It involves the recognition of interdependence with the international scenario. The interviewees acknowledged the obsolescence of Brazilian standards, which signifies the dissatisfaction and the search for improvement, characteristic of the initial stage of voluntary diffusion as proposed by Evans and Davies (1999). This obsolescence was primarily identified from the perspective of the transnational arena that national actors sought to integrate, including the productive sector.

Thus, we can examine this perception through the lens of coercive diffusion, which involves the imposition of a policy based on a specific regime. In this context, the notion of obsolescence does not emerge solely from an analysis of national demands but rather from the necessity for national rules to align with the regulations of the transnational arena.

Interestingly, the PIC/S follows a structured policy diffusion process, where countries must demonstrate interest and adapt their national policies within a specified timeframe. In the case under study, there is a stage of research and exploration, which is part of the voluntary diffusion process (Evans & Davies, 1999). However, this stage is limited to authorities that have already obtained approval to participate in the arena. Building on Stone's (2004) perspective, the members of the PIC/S seek to learn from countries that share cultural similarities, such as Mexico. At the same time, they also analyze and learn from regulations in different countries, like Denmark, in order to enhance national regulations based on what actors perceive as ideal regulatory scenarios.

Considering that the Brazilian health surveillance policy operates within the framework of the SNVS, there was a lengthy and intensive negotiation stage among the actors involved in the system to bring about policy change, and they also played a pivotal role in the diffusion process (Kuhlmann et al., 2020). This modification aimed to translate the regulations into the national context and adapt them to better serve the motivations mentioned above. As noted by Farazmand (2001) and Porto de

Oliveira and Pal (2018), the formation of strategic alliances and coalitions with the private sector, represented in this case by the pharmaceutical industry, as well as government representatives from various SNVS entities, proved to be important factors for successful adaptation and implementation. One of the main challenges encountered in the process of joining the PIC/S was the decentralized nature of the SNVS and the autonomy of its entities, which aligns with the findings of J. A. A. Silva et al. (2018).

However, given the existence and continuity of the SNVS within the new policy, there was a reliance on the trajectory associated with the national institutional framework through which international policies were submitted to diffusion and translation. This aligns with the findings of Hassenteufel et al. (2017), who identified that the translation processes are influenced by institutions inherited from previous policies. None of the interviewees mentioned seeking to dismantle the SNVS and establish a centralized system. It can be inferred that such a disruption would introduce risks or conflicts within the system, making it challenging to join the PIC/S and potentially undermining the entire Brazilian surveillance system.

What occurred was a reorganization of the responsibilities among the entities within the system, potentially strengthening both the system itself and the GMP for medicinal products. This involved a continuous process of discussion and research: "With this issue of international harmonization, our discussions became more technical. 'Let's understand why things are like this. If you cannot or if you can, what are the risks of the process?' So, we raise the level of surveillance, raise the level of regulation" (I12).

The diffusion process is not limited to adapting the regulations of GMP for medicinal products. With Anvisa becoming a member of the PIC/S, the expectation is that this international arena will have a growing influence on policy formulation and diffusion in the future, significantly shaping Brazilian politics and enhancing the country's integration into the global network. This closer engagement with the international environment holds particular significance amidst the challenges posed by the COVID-19 pandemic, as highlighted by Pepe et al. (2021). It can potentially have a positive impact on Anvisa's decision-making processes by leveraging information and insights from other PIC/S authorities.

7. FINAL CONSIDERATIONS

Taking into account the globalization of the medicinal product production and distribution chain, the regulation of GMP for these products is inherently connected to the international context. It is an issue that requires collaboration among various stakeholders and has implications for multiple countries. Policy diffusion serves as a mechanism to bridge the gap between different national instances or between supranational bodies and local management. It allows for the possibility of having multiple constellations of public policy diffusion within the same process (Kuhlmann et al., 2020).

This study sought to contribute to the literature on policy diffusion for regulations of GMP for medicinal products. The analytical dimensions used – identified in Dolowitz (1996); Evans and Davies (1999); Stone (2004); Stone et al. (2018); Kuhlmann et al. (2020) – were relevant to identify and understanding the concepts and complexities in the phenomenon of policy diffusion in transnational arenas. The analytical propositions of Hassenteufel et al. (2017) and Kuhlmann et al. (2020) were

essential, enabling an increased understanding of the constellations of diffusion, stages, promoters of the process, and the dimensions of translation.

The research findings highlight the significant influence of the transnational arena on local regulation in the case under study. The translation and adaptation of the policy, along with the active engagement of the actors involved, played a crucial role in facilitating the adaptation of the policy to the national context. The closed transnational arena, represented by the PIC/S, exhibited a sealing power that guided and facilitated policy diffusion worldwide (Porto de Oliveira & Pal, 2018). However, it is important to note that the diffusion process would not have occurred without the interest of national actors in joining these forums, driven by the potential benefits associated with membership. In this regard, Anvisa strategically positioned itself within the transnational arena, actively participating in discussions and creating new regulations to enhance its international and national legitimacy.

In the specific context of the COVID-19 pandemic, the advantages of being part of the transnational arena became even more evident. An example is the publication of Resolution RDC 346 on March 12, 2020 (Resolução RDC nº 346, de 12 de março de 2020), which permitted GMP certification based on information provided by foreign regulatory authorities who are members of PIC/S (for medicinal products) and MDSAP (for medical devices). This measure aimed to ensure the uninterrupted supply of essential medicinal products and health products during a time when conducting on-site inspections of international facilities was challenging or not feasible.

Future research should examine the extent to which the changes made at the national level have been implemented and their impact. It is also important to analyze the role and influence of national health agencies, such as Anvisa, in shaping and contributing to the development of new regulations within the transnational arena.

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APPENDIX

BOX A LEGISLATION AND OFFICIAL DOCUMENTS

Type	Identification
Procedures of the National Health Surveillance System (SNVS)	POP-0-SNVS-001 (Anvisa, 2022a); POP-0-SNVS-002 (Anvisa, 2022b); POP-0-SNVS-014 (Anvisa, 2022c); POP-0-SNVS-015 (Anvisa, 2022d); POP-Q-SNVS-021 (Anvisa, 2022e); POP-0-SNVS-022 (Anvisa, 2022f); POP-0-SNVS-023 (Anvisa, 2022g); PROG-SNVS-001 (Anvisa, 2022h).
Brazilian legislation (in Portuguese)	Decreto n° 20.397, de 14 de janeiro de 1946; Lei n° 6.360, de 23 de setembro de 1976; Decreto n° 79.094, de 05 de janeiro de 1977; Lei n° 8.080, de 19 de setembro de 1990; Lei n° 9.782, de 26 de janeiro de 1999; Resolução RDC n° 207, de 3 de janeiro de 2018; Instrução Normativa - IN n° 32, de 12 de abril de 2019; Portaria n° 16, de 6 março de 1995; Resolução RDC n° 134, de 13 de julho de 2001; Resolução RDC n° 210, de 04 de agosto de 2003; Resolução RDC n° 17, de 16 de abril de 2010; Resolução RDC n° 301, de 21 de agosto de 2019; Instrução Normativa - IN n° 35, de 21 de agosto de 2019; Instrução Normativa - IN n° 36, de 21 de agosto de 2019; Instrução Normativa - IN n° 37, de 21 de agosto de 2019; Instrução Normativa - IN n° 38, de 21 de agosto de 2019; Instrução Normativa - IN n° 39, de 21 de agosto de 2019; Instrução Normativa - IN n° 40, de 21 de agosto de 2019; Instrução Normativa - IN n° 41, de 21 de agosto de 2019; Instrução Normativa - IN n° 42, de 21 de agosto de 2019; Instrução Normativa - IN n° 43, de 21 de agosto de 2019; Instrução Normativa - IN n° 44, de 21 de agosto de 2019; Instrução Normativa - IN n° 45, de 21 de agosto de 2019; Instrução Normativa - IN n° 46, de 21 de agosto de 2019; Instrução Normativa - IN n° 47, de 21 de agosto de 2019; Instrução Normativa - IN n° 48, de 21 de agosto de 2019; Resolução - RDC n° 34, de 8 de julho de 2013; Resolução RDC nº 47 de 19 de setembro de 2011; Resolução RDC n° 346, de 12 de março de 2020.
Documents PIC/S	Guide to good manufacturing practice for medicinal products: part I (PIC/S, 2022a); Guide to good manufacturing practice for medicinal products: part II (PIC/S, 2022b); Guide to good manufacturing practice for medicinal products: annexes (PIC/S, 2022c); PIC/S Audit Checklist (PIC/S, 2022d).
Miscellaneous	Manual of Quality of the General Management of Inspection and Health Surveillance (provided by a responsible employee at Anvisa); Documents from the international relations department (provided by a responsible employee at Anvisa); Questions & Answers from Public Consultation 653, May 24, 2019; Management Report of the Quality Management Coordination of the Health Inspection Process 2019 (provided by a responsible employee at Anvisa); Presentations given at the Sectoral Dialogue event on Good Manufacturing Practices for medicinal products and adoption of PIC/S guidelines, held on March 26, 2019; Presentation given at the Ordinary Public Hearing – Consumer Defense Committee, 56th Legislature - 1st Ordinary Legislative Session, Topic: "Quality of generic drugs."
FDA and PIC/S websites	https://www.fda.gov/ and https://picscheme.org/

Source: Elaborated by the authors.