

# INNOVATION IN BRAZILIAN REGULATORY AGENCIES: A STUDY OF SUCCESSFUL EXPERIENCES

## *INOVAÇÃO EM AGÊNCIAS REGULADORAS BRASILEIRAS: UM ESTUDO DE EXPERIÊNCIAS BEM-SUCEDIDAS*

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Monaliza Ferreira Rodrigues de Paula<sup>1</sup>  
Camila de Souza Filgueira<sup>1</sup>  
Napiê Galvê Araújo Silva<sup>1</sup>

*1 Universidade Federal Rural do Semi-Árido, Mossoró, Rio Grande do Norte, Brazil*

### ABSTRACT

**Objective:** the study aims to expose the relationship between innovation and regulatory activities through the experiences of Brazilian regulatory agencies.

**Methodology:** the study follows a bibliographical approach, adopting bibliographical and documentary research and collecting data from academic publications, reports and information published on the Federal Government's website.

**Findings:** through this essay it was possible to perceive how innovation is indispensable to regulatory activities, in view of the benefits provided to agencies and, especially, the positive impacts for society.

**Research limitations:** since this is a theoretical study, the relationship between innovation and regulatory activities was limited to the experiences shared in the researched sources. Given a certain deficit of approach to the subject in the prevailing literature, we believe that an *in loco* research would be a more robust source of information and, thus, other innovation actions, not shared in academic works and/or websites, would be identified.

**Originality/value:** the study's contributions permeate the universe of the link between innovation and regulatory agencies, demonstrating the relevance of innovative actions to ensure efficiency and effectiveness in public services, taking four Brazilian agencies as an example. The absence of research on innovation in regulatory agencies at the national level characterizes the originality of the work. It is suggested, therefore, that regulatory agencies systematize their information on innovation actions and make it available to the public, in the form of a report, presenting the results achieved and the benefits acquired.

**Keywords:** Innovation; Regulatory agencies; Regulation; Experiences.

## RESUMO

**Objetivo:** o estudo tem por finalidade expor a relação entre inovação e as atividades de regulação por meio de experiências de agências reguladoras brasileiras.

**Metodologia:** trata-se de uma abordagem qualitativa de um estudo de caso, adotando as pesquisas bibliográfica e documental, e procedendo a coleta de dados provenientes de relatórios, publicações acadêmicas, reportagens e informações divulgadas no sítio eletrônico do Governo Federal.

**Descobertas:** por meio desse ensaio pôde-se perceber o quanto a inovação é indispensável para as atividades de regulação, tendo em vista os benefícios providos às agências e, principalmente, os impactos positivos para a sociedade.

**Limitações da pesquisa:** por se tratar de um estudo teórico, a relação entre inovação e atividades de regulação limitou-se às experiências compartilhadas nas fontes pesquisadas. Tendo em vista o déficit de abordagem do assunto na literatura prevalente, acreditamos que uma pesquisa *in loco* seria uma fonte mais robusta de informações e, com isso, outras ações de inovação, não compartilhadas em trabalhos acadêmicos e/ou sites, seriam identificadas.

**Originalidade/valor:** as contribuições do estudo permeiam o universo da vinculação entre a inovação e as agências reguladoras, demonstrando a relevância de ações inovadoras para garantir eficiência e eficácia nos serviços públicos, tomando como exemplo 4 agências brasileiras. A ausência de pesquisas no âmbito da inovação em agências reguladoras a nível nacional caracteriza a originalidade do trabalho. Sugere-se, portanto, que as agências reguladoras sistematizem suas informações sobre ações de inovação e disponibilizem ao público, em forma de relatório, apresentando os resultados alcançados e benefícios adquiridos.

**Palavras-chave:** Inovação; Agências reguladoras; Regulação; Experiências.

## 1 INTRODUCTION

The present work emerged with the proposal to highlight the indispensable role of innovation in Brazilian Regulatory Agencies. To this end, we highlight successful experiences, through which innovation has brought irrefutable benefits for the development of regulatory activities.

According to Barizon (2016), Regulatory Agencies are administratively independent autarchies, that is, not subordinated to any government body, are financially anonymous, whose functions are to regulate and supervise activities of a certain economic sector of a country.

Inserted in this context, innovation emerges as a strategic tool with a strong impact on the progress of responsive and effective regulatory actions. But it is worth asking: what is innovation?

Kormann (2020) elucidates that innovation is characterized by the movement of creation and reorganization of things which allows to break with what is set and to propose new ways of performing old tasks.

In view of the above, the following question is instigated: How and by what means has innovation succeeded in Regulatory Agencies in Brazil? In order to answer this question, this study will deal with the exposure of some examples of Regulatory Agencies in Brazil, in which innovation has become an instrument of transformation so that they could achieve success in their activities.

It is undeniable that the benefits arising from innovation include the Public Administration. According to Fadul and Souza (2007), Regulatory Agencies are characterized as relevant institutional innovations in the Public Administration, since they are created with conjectures of structure and control that differ from the existing patterns in other organizations.

Renato Porto, Anvisa's Director of Health Regulation, highlighted at the 1st Latin American BIO-Pharmaceutical Innovation Week 2018 in Mexico City the importance of innovation for Brazilian Regulatory Agencies. Porto defined "Regulatory Agencies as one of the inducers of the technological development of a country," thus correlating regulatory activities with innovation.



That said, the relevance of this work is given to the visualization of possibilities for the implementation of innovative methodologies in Regulation Agencies in Brazil, and we do so by sharing examples of successful experiences.

Within this perspective, the central objective of this study is to map successful experiences of innovation in 4 regulatory agencies, at the national level. To this end, it was necessary to analyze the working methods of some Brazilian regulatory agencies, identify their innovative methodologies and verify the benefits derived from such innovation for the success of their regulatory activities.

To this end, a bibliographic survey was carried out regarding the use of innovative methods achieved by the following regulatory agencies: National Health Surveillance Agency (ANVISA), National Telecommunications Agency (ANATEL), National Electric Energy Agency (ANEEL), and National Supplementary Health Agency (ANS).

## 2 THEORETICAL FRAMEWORK

### 2.1 Regulatory agencies

With the reform of the Brazilian state in the 1990s, the private sector gained protagonism in the execution of relevant services within the public sphere (Humbert & Barbosa, 2019). According to Araújo (2018), with the major changes in the economic scenario in that decade, the state sought to adopt a more managerial model, characterized by state efficiency.

According to Miranda, Gonçalves and Siqueira (2021) these changes began, above all, with the advent of the 1988 Constitution, which prioritized the guarantee of quality of service and raised efficiency to constitutional principle.

Pacheco (2021) shows the privatization process in Brazil as a determinant in this new institutional design of the state that was constituted. The institutional reform, with privatizations in the early 1990s, was named the National Privatization Program (PND). PND was fiscally motivated and became an important instrument to address the country's budgetary difficulties. (Giambiamgi & Além, 2016)

In this new scenario, Araújo (2018) expresses the importance of regulation and its function of ordering the operation of economic activity, taking effect in Brazil through regulatory agencies. According to Miranda et al. (2021) regulatory agencies emerged with the purpose of regulating economic activities transferred to the private sector.

Cunha (2018) deprecates regulation as an action by which the state manages the functioning of important economic and social sectors. Also according to the author, regulatory agencies are organizations charged with the execution of such action, doing so in obedience to a specific economic-institutional logic.

Consolidating such a concept, Silva, Ramos, and Leal (2018) highlight the emergence of regulatory agencies as a new mechanism for acting in the economy, mainly due to the state's inability to fund the universalization of public service provision.

Regulatory agencies are special autarchies, created by laws, with their own budget, part of the indirect public administration and extended to the Ministries, but not directly subordinated to them (Paiva & Morais, 2020).

As already exposed, regulatory agencies are autarchies and according to the terms of article 37, "only by specific law may an autarchy be created;" (Constitution of Brazil, 1988 - our translation). Moreover, according to Pacheco (2021) they have their own legal personality that expresses rights and



obligations defined by law, as well as the ability to manage themselves and have their own employees and financial resources. It is a matter of their economic-financial autonomy.

Regarding the regulation of such institutions, Cunha and Goellner (2020) highlight the current existence of eleven regulatory agencies, pursuant to Law No. 13.848 of June 25, 2019. This norm advocates a kind of general law of regulatory agencies. Law 13.848 provides for the management, organization, decision-making process, and social control of regulatory agencies. (Law No. 13.848, 2019)

It is worth noting that the United States is the birthplace of Agencies. The Interstate Commerce Commission (ICC) was the first American agency founded in 1887 (Cunha; 2019). Although there is no reliable source of what political motivation induced the creation of the Interstate Commerce Commission, Oliveira, Werneck and Machado (2004) believe that the idea that guided the establishment of regulatory agencies over the next century in the United States was to remedy possible market failures and, especially, the abuse of power held by some economic agents.

For Gracindo (2019), some characteristics present in Brazilian regulatory agencies such as: administrative autonomy; no hierarchical subordination in relation to the Chief Executive; management carried out by a committee of leaders who have fixed mandates and stability; in addition to financial autonomy which can deduce a parity between such institutions and those belonging to the American model.

However, despite the similarities regarding the elements of autonomy of the entities, the historical motivation that preceded the implementations is distinct. According to Lorini (2018), in Brazil the creation took place as an attempt to escape the rigidity of the bureaucratic model enshrined by the constitutional text of 1988.

According to Cidade (2019), in Europe, the development of regulatory agencies began in France, serving as inspiration for Latin American countries such as Argentina and even Brazil, although the latter has a strong stimulus in the American model.

Considering the important role of regulatory agencies in the economic reforms undertaken in developed and developing countries, Oliveira et al. (2004) point out that the Organization for Economic Cooperation and Development (OECD) and the World Bank have produced evidence from international experiences, compiling lessons and ideal models that can be incorporated.

According to the author, analyses of the most successful practices of regulatory agencies indicate that their activity should be based on the following criteria: openness and objectivity, fairness, non-discrimination, promotion of free competition, and ensuring a fair balance between the interests of consumers, government, and economic agents in the regulated sector.

## **2.2 Successful experiences in implementing innovation in some brazilian regulatory agencies**

According to Cavalcante, Camões, Cunha, and Severo (2017), to innovate is to put the new into action, materializing changes, whether incremental or radical, as a result of human intentionality. The authors highlight innovation in the public sector, and for them, “nowadays, it is time for a public sector that acts for and by virtue of innovation”. Innovation presents itself as a public sector strategy to deal with situations in which government intervention would bring more problems than solutions (Cavalcante et al., 2017 - our translation).

Before sharing experiences in which Regulatory Agencies have succeeded through innovation, it is necessary to know that one of the premises for innovation adopted by the Federal Government, through an innovation network in the federal public sector, is Open Innovation.



Open Innovation was a term created by Henry Chesbrough and means the promotion of open ideas, thoughts, processes and research in order to improve the development of their products or services, increase efficiency and strengthen added value (Rodrigues, 2020).

Bansi, Andrade, and Galina (2021) contribute by explaining that innovation is a significant change, whether in a product or in a process, that is, anything that is different than what was made available to users before (in the case of a product) or used by the company (in the case of a process) is considered innovative.

Finally, innovate is not an easy term to define. Not least because its very meaning can be innovated over time, this means that innovation is not something neutral and its direction is given by society (Gadelha, 2021).

### **2.2.1 National health surveillance agency - ANVISA**

The National Health Surveillance Agency - Anvisa is a Regulatory Agency, created by Law 9.782, of January 26, 1999. It is defined as a special regime autarchy, whose objective is the sanitary control of products subject to sanitary surveillance, such as drugs, food, cosmetics, sanitizers, etc. (Amorim, 2020).

According to Marchetti et al. (2015), since Anvisa was created, the process of post-registration of drugs was extremely bureaucratic and time-consuming, but with the implementation of Resolution - RDC No. 48, of October 6, 2009, the situation was significantly improved.

The resolution, still in effect, brought several innovations to Anvisa, the most striking was the emergence of the History of Product Changes - HMP, which provides an annual update to Anvisa on the changes that occurred in the production of a drug, as well as the feasibility of implementing minor modifications, making improvements in processes more flexible and enabling the maintenance of quality medicines available to patients. The result of the innovative procedures implemented were the debureaucratization, speed and predictability of procedures related to post-registration modifications (Marchetti et al., 2015).

Another example of innovation at Anvisa was reported in the work of Aguiar, Duarte and Souza (2019), in which the authors address Telework in the National Health Surveillance Agency and the innovation in the approval of health products importation. In this case, the innovation occurred through the insertion of telework for the approvers of health products importing processes.

A very successful experience at Anvisa was the “Fábrica de ideias” (Idea Factory), where the maxim is to connect people to find solutions. The program was developed with an immersion approach, in which employees participate in cycles of lectures, debates, and technical visits to factories in the food, drugs, and medical equipment sectors. With this, they end up having closer contact with the reality of regulation outside their organizational environment. And at the end, they are challenged and stimulated to formulate proposals to improve regulation, through intervention projects (Cavalcante et al., 2017).

Finally, we can mention as an implementation of innovation at Anvisa the LAB-i VISA. This is a collaborative space for creating and sharing ideas and practices focused on people.

According to Anvisa (2021), LAB-i VISA is supported by 4 pillars: disseminate (share knowledge), foster (provoke innovative practices), connect (use collaboration networks in different areas) and accelerate (support the development of innovative initiatives). Within this context, Anvisa produced the Toolkit 2.0 of LAB-i VISA, a toolkit with the objective of giving more dynamism and practicality in the realization of innovation workshops. This kit is an important facilitating support, especially for beginners.



### 2.2.2 National telecommunications agency - ANATEL

The National Telecommunications Agency - ANATEL was the first Regulatory Agency to be installed in Brazil, created by Law 9.472, of July 16, 1997. It is a knowledge-intensive organization that has the mission to regulate, grant, manage, supervise, and promote the development of Brazilian telecommunication, in addition to fostering technological advances in the sector (Barizon, 2016).

Barizon (2016) explains about the Innovation, Knowledge and Value Management inserted in Anatel. The author found that Anatel uses strategic alignments, providing well-structured processes of innovation. It was found that innovation and value generation are bases for practices of its activities.

Another highlight of innovation at Anatel is brought to light in the work of Oliveira et al. (2009), in which the authors describe the interfaces between innovation and Regulatory Agencies, specifically Anatel. The authors found that the portability feature, governed by Resolution No. 460 of March 19, 2007, was an innovation by the Agency. This feature contributed to foster competition, strengthening the user's right to choose better service options, forcing providers to apply more quality in their services.

In 2021, Anatel was granted the Innovation Award in Dynamic Spectrum Access Policies. This award is at the international level and Anatel was given that for its innovation in radio frequency. This award recognizes initiatives for the implementation of dynamic spectrum access policies (Anatel, 2021).

According to Brandão (2021), the dynamic spectrum is a technology that allows equipment to identify the low use of a radio frequency channel and transfer communication to an available band, without the users' perception. Radio frequency, on the other hand, is not only a limited resource, but rather a public good. Each radio frequency band is specific and suitable for a particular application, so if it is used improperly, there is a high probability of interference that impairs transmissions.

### 2.2.3 National electric energy agency - ANEEL

The National Electric Energy Agency began its activities in 1997. It is an autarky under a special regime linked to the Ministry of Mines and Energy, and was created to regulate the Brazilian electricity sector, by means of Law No. 9.427/1996 and Decree No. 2.335/1997 (ANEEL, 2022).

This Regulatory Agency has a peculiar characteristic that is that of a differentiated and absolutely horizontal organizational model, having two hierarchical levels (Board of Directors and Superintendencies), promoting a process-based management model, thus efficiently performing its regulatory functions (Fadul & Sousa, 2017).

Padilha (2019) brings in his thesis Aneel as an example of companies that encourage innovation. According to the author, one of the biggest incentives is Law No. 9.991/2000, which obliges energy utilities to invest in innovation. And for this, partnership networks were created with technology-based companies and research centers of Scientific and Technological Institutions.

The distribution of resources, according to Schappo et al. (2021) happens as follows: 40% to the National Fund for Scientific and Technological Development (FNDCT), 40% to R&D projects, and 20% to the Ministry of Mines and Energy.

In addition, the Research and Development Program belonging to Aneel carries out the innovation incentives through resources coming from the tariffs of the power companies (Padilha, 2019).





Lima et al. (2018) also refer to Law No. 9.991/200. They state that, according to the law, utilities must apply their resources aiming at the creation of new equipment, stimulation of safe energy supply, mitigation of environmental impact, and reduction of Brazil's technological dependence.

Sanches (2019) states that, companies that have already integrated the R&D Program into their business strategies, have obtained positive impacts from R&D and innovation projects and plans and improved company performance in terms of operational productivity, service quality, and business performance.

Schappo et al. (2021) conclude that R&D investments have gained prominence in recent years, as energy efficiency incentives are intrinsically related to sustainable economic development.

In addition to the R&D Program, Aneel also has the Energy Efficiency Program (PEE), another prominent program, which according to ANEEL (2020), is "to promote the efficient use of electric energy in all sectors of the economy through projects that demonstrate the importance and economic viability of improving the energy efficiency of equipment, processes, and end uses of energy."

The Research and Development (R&D) and Energy Efficiency (PEE) programs regulated by Aneel completed 20 years in 2020. Since the publication of Law No. 9.991, of July 24, 2000, the programs have accumulated success stories and more than R\$ 13.5 billion in investments, resulting in about 325 patents and intellectual property registrations, 1.200 graduate degrees and more than 3.900 scientific articles and papers published (ANEEL, 2021).

#### **2.2.4 National supplementary health agency - ANS**

The National Agency for Supplementary Health is a Regulatory Agency linked to the Brazilian Ministry of Health and was created in accordance with Law No. 9.656, dated June 3, 1998, which regulates private health care plans and insurance (ANS, 2021).

One of the greatest innovation highlights within the ANS is the Innovation Laboratory on Primary Care Experiences in Brazilian Supplementary Health, an ANS initiative in cooperation with the Pan-American Health Organization/World Health Organization (PAHO/WHO).

This Innovation Lab aims not only to identify, but to recognize the effort, whether individual or collective, of health care operators in Brazil, in the implementation of Primary Health Care (PHC) and the monitoring of its impact on the results, as well as the sustainability of the sector (ANS, 2018).

A publication of the Pan American Health Organization for the year 2018 brought several PHC experiences selected under the Innovation Lab. Twelve companies were highlighted, among the 41 analyzed, considered as innovative in the organization of their services and that presented process and results indicators.

Another sign that the ANS values innovation is its support for the iLabthon, an initiative to promote an innovative culture in the public sector. The iLabthon is an online marathon that provides public servants with a connection to the national innovation ecosystem. There, mentors specialized in innovation in the public sector accompany the teams for the development of the so-called ilabs (Innovation Labs of Public Power).

Together with the support and participation of the ANS, the iLabthon was published in 2021 in the Innovation Case Bank of the Public Sector Innovation Observatory (OPSI) of the Organization for Economic Cooperation and Development (OCDE) (ANS, 2021).

In addition to the iLabthon, in the year 2021, the ANS also supported the Regulathon. This is an online event, a marathon of the world's regulatory activities for the dissemination of good regulatory practices.



### 3 METHODOLOGY

Scientific research comprises an organized process that is based on experience, whose reliability of the results obtained comes from the efficiency of the methodology employed. (Bruchêz et al., 2018)

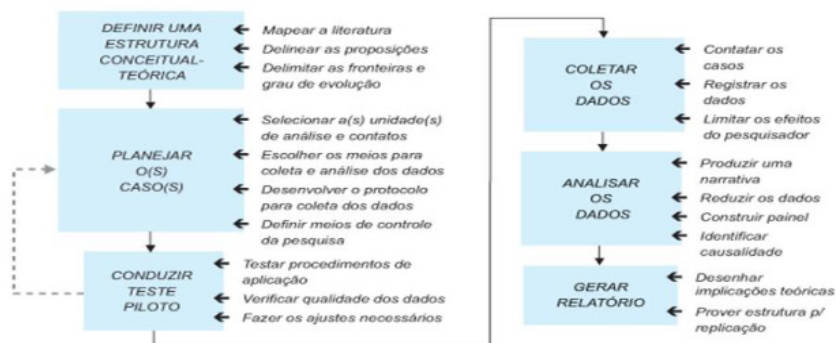
As for its objectives, the research is identified as exploratory, since it is a study that, among its objectives, aims at increasing knowledge on a specific topic (Appoliário, 2012).

The present work is a case study in which the methodology adopted was based on a qualitative approach, relying mainly on bibliographic research and supported by documentary research. Through the association of these two methods, it was possible to bring categories of analysis to support the discussion regarding the successful cases of innovation in Brazilian regulatory agencies.

According to Yazan (2016), case study is one of the widely employed methodologies within qualitative research. The author brings in his work the position of three competent authors on this matter: Yin, Merriam and Stake. However, Robert K. Yin's concept will be the basis of the present work.

Case study is an empirical inquiry that investigates a contemporary phenomenon in depth, relying on multiple sources of evidence. This type of technique allows researchers to focus on a case, retaining a holistic and real-world perspective (Yin, 2015). Figure 1 shows how the methodological path of our study was carried out, along the lines of Yin (2015).

Figure 1. Case study methodological approach



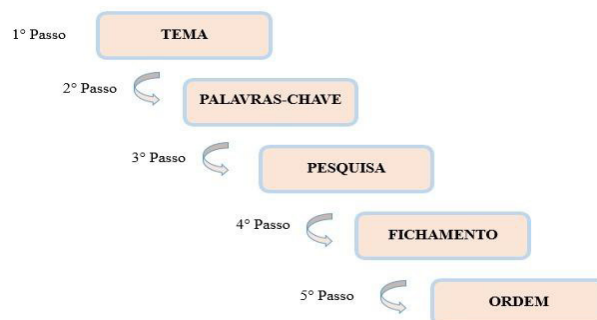
Source: Yin (2015)

Initially, the conceptual-theoretical framework of the study was defined, delimited between bibliographic and documentary research. The former provided the necessary theoretical basis so that we could identify aspects of innovation present in the regulatory activities of each agency, as well as the benefits acquired.

Martins and Theóphilo (2017) report that bibliographical research is the analysis developed through articles, reports and studies already completed and published. This research strategy is an important part in the preparation of any work, aiming at its theoretical construction, with the purpose of explaining and discussing the theme.



Figure 2. **Steps for a Bibliographical Research**



Source: adapted from Oliveira (2022)

The first step was the choice of the theme: innovation in Brazilian regulatory agencies. The second step was the choice of keywords, in order to facilitate the search for content, which were: innovation, regulatory agencies, regulation, experiences of regulatory agencies, innovative regulatory activities and Brazilian regulatory agencies.

In possession of such words, research sources were tracked, drawn exclusively from Word Wide Web and Websites: Portal of Periodicals from the Coordination for the Improvement of Higher Education Personnel (CAPES), Thesis and Dissertation Bank, Google Scholar, Scientific Electronic Library Online (SciELO), Institute for Applied Economic Research (IPEA), official Brazilian federal government websites, and official agency websites. The fourth step was summarization, in which, based on the keywords, literal excerpts were organized in the form of a summary, always citing the source. Finally, the last step was to put in order the concepts found and structure them according to the subject.

Following the bibliographical research, a conceptual bibliographical review was carried out, which, according to Oliveira (2022), consists of reading the researched materials and choosing, among them, the content of each author that supports the theme proposed in the study, laying the foundations for its theoretical referential.

The documentary research made use of the technique of qualitative data from reports and studies taken directly from the official websites of each agency. For Junior et al. (2021), documentary research is that in which the data obtained come from documents, with the purpose of obtaining information contained therein, in order to deduce a certain phenomenon.

In the case planning stage, the units of analysis were selected, which refer to the case that will be studied, in this context, it is the innovation in Brazilian regulatory agencies. And the means of collection were also chosen, as described previously in the steps of the bibliographical research. As for the sample, we first started the search for regulatory agencies that presented innovation as a preponderant factor of change and/or highlight in their regulatory activities.

The history and the end-activities of each of the 10 regulatory companies in Brazil were analyzed, investigating their possible innovative aspects, giving preference to studies published up to 5 years ago and articles published up to 2 years ago, thus characterizing this article as a current study.

Therefore, it was found that, among the Brazilian regulatory agencies, there were 4 that had the most material available in the sources researched and that stood out with innovation present in their activities. In chart 1 the regulatory agencies and their core activities are presented.

Chart 1. **Regulatory Agencies and their End Activities**

<b>Regulatory Agency</b>	<b>End-activity</b>
ANVISA - National Health Surveillance Agency	It promotes the sanitary control of the production and consumption of products, that is, its public includes everyone who deals directly or indirectly with products subject to sanitary surveillance (drugs, cosmetics, blood, etc.).
ANATEL - National Telecommunications Agency	Regulates and oversees the telecommunications sector, <i>i.e.</i> , affects everyone who owns a telephone or telephone company.
ANEEL - National Electric Energy Agency	Controls the services related to electric power, which means covering the entire population that uses electric power.
ANS - National Supplementary Health Agency	Regulates the private health insurance market, affecting those who have health insurance.

Once the sample was defined, a more in-depth research was started on each of the chosen agencies. Using concepts of innovation and regulatory agencies, when conducting the research, we sought to identify what innovator was employed in each agency and what the resulting positive impact was identified in its regulatory activities.

Since this is a survey of experiences and there was no in-loco research, the stages of data collection and analysis were based on the stages of bibliographic and documental research. The data were collected from the time the research was carried out since the evidence came from documents and archival records. And the data analysis, which consists of recombining evidence, was based on theoretical propositions that were given in the literature review phase.

The report of a case study is the exposure of the study to the public and can be in written or oral form (YIN, 2015). The present study took place in written form, using charts that will be presented in the results and discussions section.

## 4 RESULTS AND DISCUSSION

### 4.1 ANVISA

The post-registration process of medicines in Brazil was optimized and innovated directly from the implementation of - RDC No. 48. According to Marchetti (2015), such post-registration process followed a cast and slow model and was innovated with the introduction of a new system of post-registration of medicines, which comprised the classification under three axes: health risk, pharmacotechnical tests, and complexity of analysis, resulting in changes in procedures for conservation of medicines and worrying more effectively about the effects of inappropriate storage conditions.

Marchetti (2015) emphasizes in his studies, the damage that the lack of an innovative dynamic in post-registration procedures brought to the consumer, because it resulted in inefficiency in the regulation and supervision of post-registration of medicines. This was due to the large number of petitions to be evaluated, a consequence of the slowness of the system used.

The publication of RDC No. 48, which dealt with the post-registration of medicines, had as its most striking innovation the emergence of the History of Product Change (HMP), which allows an annual update to Anvisa on the changes that occurred in the production of a medicine as well as the feasibility of implementing minor changes, and immediate, making improvements more flexible and consequently offering quality medicines (Marchetti, 2015).

Another relevant point mentioned in the survey regarding innovation at Anvisa was telework and innovation in the approval of importation of health products. According to Aguiar et al. (2019), the first fruit resulting from telework was the feasibility of centralizing the information of the analysis flows, enabling the manager to establish decisions based on the indications of the import environment.

The restructuring of Information Technology was necessary in this new format, which culminated with the possibility of extracting data from previous years, which was not possible before. The author emphasizes that the average time for process analysis was shorter than in previous years, and quantifies the volume of processes and petitions filed from 2016 to 2018.

In the year 2018, in which telework was introduced, 79,122 expedients were analyzed, compared to 73,775 in 2017 and 68,369 in 2016. It also highlighted the possibility of foreseeing the analysis of the proceedings with the official arrangement of these indicators on Anvisa's website, a condition previously monitored inconsistently by importers. According to Anvisa (2021) with the adoption of telework, there was a 25% increase in the efficiency of medicines registration.

Furthermore, it is worth mentioning the Idea Factory as an innovative project in the Health Surveillance sector. Cavalcante et al. (2017) report that still in its initial phase a relevant result was appreciated through the diagnosis of the project's evaluation activities. A total of 72% of those who responded to the survey positively evaluated the effects of the project, and receptivity to innovation was also positively evaluated, as good or great, for 55% of respondents, reaching 67%, unlike a result measured in 2015, in the diagnosis performed before the project for the agency's strategic planning, when the result was evaluated as bad or terrible for 62.7%.

In terms of "leadership" regarding the importance of innovation for Anvisa, it was possible to observe a disparity in relation to the respondents' profiles. The leaders who had contact with the project were better evaluated. This indicated a positive gain for the image of the leaders who participated directly in the project.

According to Anvisa (2021) LAB-i Visa is an example of an initiative that emerged from the pilot of the Idea Factory in 2016, having an important role in the expansion of good ideas and providing appropriate methodology for improving services. Also according to Anvisa (2021) the methodology developed by LAB-I Visa is used in the improvement of the inspection of ports, airports and borders environments, and of the means of transport in these locations, which are also inspected by Anvisa, such as vessels and aircrafts.

## 4.2 ANATEL

One of the great innovative highlights within Anatel is the portability feature. Such innovation has been so well accepted over the years that by the year 2020, according to Braga (2020), Brazil reached the mark of 62 million portabilities performed.

And according to Julião (2021), mobile portability requests had a 49% increase in the second trimester of 2021, totaling more than 2.158 million mobile number portability requests. According to Amaral (2022), Brazil made 8.7 million portability requests in 2021.

The greatest impact of portability, according to the study by Nogueira, Mota, Almeida, Lima, and Moura (2012), conducted in a large Brazilian capital, was based on aspects of consumer perception and satisfaction, in other words, those people who use the mobile phone service.

In addition to the increased competitiveness among telephone companies, according to the study conducted with 1596 valid observations, the level of consumer satisfaction has increased. The fact that the customer has the option to choose the operator that offers the service they like best without losing the number is the biggest indication of acceptance of such innovation.



Santos (2019) describes in his study that the main indicators of customer satisfaction in relation to mobile phone service is the cost, the quality in signal coverage and the company's reputation. The author portrays, within the sample analyzed, that before portability, the main reason for the customer to remain loyal to the phone company is to change the phone number.

Another relevant point cited in the theoretical framework of the study was the innovation in radio frequency policy and spectrum access. With innovative methods in place, transmissions are much less susceptible to interference, which expands and improves the performance of services such as Wi-Fi.

### 4.3 ANEEL

The history of investment in innovation at Aneel was extremely important for the existence of the electricity matrix as it is today. With investments in studies and technology, the focus is currently on renewable energies, such as wind and solar.

It is possible to mention several companies that invest in R&D. According to Costa et al. (2010), the five companies in the electric sector that invested most in R&D projects in the period from 2001 to 2008 in Brazil were: Tractebel Engineering, Companhia Paranaense de Energia (Copel), Companhia Energética do Ceará (Coelce - now Enel Distribuição Ceará), Duke Energy, and Companhia Energética de Brasília (Ceb). The most notorious benefits that emerged from Research & Development projects were process improvement and operational cost reduction.

Bringing it to a more current context, Copel was also reported in Pará State News Agency. According to one of its articles, the company intends to invest R\$34.6 million in four R&D projects in the electric energy storage sector in the state by the year 2022. This investment will result in cleaner, more reliable energy, as well as a more modern Copel.

In chart 2 we can list some companies in the electric power sector whose R&D projects have already been completed and in chart 3 the companies whose projects are in progress, according to data extracted from a Research Group on Electricity Sector - *Grupo de Estudos do Setor Elétrico - GESEL* (2022).

Chart 2. Electricity Sector Companies with Concluded R&D Projects

Company	Project	Project Description
EDP BRASIL	Regulatory improvements for the introduction of an Energy Exchange and a <i>Clearing</i> .	The objective is to propose innovations and regulatory improvements to improve the Brazilian wholesale energy market, allowing the introduction of energy trading on an exchange environment, associated with a <i>clearing</i>
LIGHT ENERGIA S.A.	Regulatory aspects related to non-technical losses in Areas with Severe Operating Constraints	The objective is centered on four analytical vectors: 1) regulatory treatment for Areas with Severe Operating Constraints - ASOCs (commitments to loss reduction, quality of supply, universality, limitation of supply, etc. ), where the public power has little or no presence, especially when the concessionaire is a private company; 2) the role of differentiated tariff structures in the experiences of combating, mitigating and reducing losses in ASOCs; 3) distribution of risks and results associated with non-technical losses; 4) economic risk limits for losses and for the Distributor's quality indicators considering ASOCs.
ENERGISA	Impact of Distributed Energy Resources on the Distribution Sector	The project's general objective is to identify, systematize, and formulate proposals for more efficient regulatory adjustments and innovations to enable the large-scale diffusion of Distributed Energy Resources without causing negative financial impacts for Distributors and Consumers.



<b>ENEVA</b>	Economic Regulation of Thermoelectric Generation: forms of contracting and methodology for calculating the cost of operation	Its objective is to substantiate proposals for regulatory innovations with the central objective of giving more economic efficiency to long-term contracts for thermoelectric generation in Brazil, especially in the Regulated Market. The R&D Regulatory Innovation study intends to make a relevant and effective contribution to the formatting of thermal generation contracts.
<b>CPFL ENERGIA</b>	Energy in the City of the Future	The project aimed to establish the guidelines and technological, regulatory, and economic parameters that will guide the construction of the “City of the Future”. Having as analytical focus nine strategic vectors. The project was developed under the aegis of the R&D Program of ANEEL - the Brazilian Electric Sector Regulatory Agency.
<b>USINA HIDRELÉTRICA DE ITAIPU</b>	Comparative Analysis of Experiences in Binational Hydroelectric Developments	The objective of this research is to examine the characteristics and difficulties of the electrical integration of binational hydroelectric generation projects, mainly from the economic-financial point of view, in order to provide subsidies for the Brazilian government to position itself when the financing of Itaipu ends in 2023, as established in Appendix C of the International Treaty for the construction of the Binational Hydroelectric Power Plant
<b>ELETROBRAS</b>	Analysis of Economic-Financial Information of Electric Power Companies	It analyzed the evolution of the business strategy of companies in the Brazilian electricity sector since 1999, its corporate, marketing, operational aspects, investment plans, productivity and efficiency indicators, and mainly cash flow analysis.

Source: GESEL (2022)

Chart 3. Electricity Sector Companies With Ongoing R&D Projects

Company	Project	Project Description
<b>LIGHT ENERGIA S.A.</b>	Development of Solutions for Shared Electric Mobility: Infrastructure and Supply Systems for e-carsharing and Micromobility	The central objective of the research project is, based on a real experiment, to study alternative business models and technologies for shared electric mobility (EM) in e-carsharing systems and Light’s own fleet.
<b>NEOENERGIA</b>	Green Corridor and Urban Charging Stations for Performance Evaluation of Hybrid and Electric Vehicles	The project aims to create a green corridor in the Northeast (stretch between Salvador/BA and Natal/RN), containing 11 charging stations on highways (50 kW) and another 6 stations in urban malls (22 kW). The project also aims to evaluate a new business model for companies in the electric sector through the operation of charging stations for electric vehicles, and to bring a vision of scalability of the use of electric vehicles in Brazil.
<b>STATE GRID BRAZIL HOLDIN S. A.</b>	Reference Portal Project for Environmental Licensing of Transmission Systems	It aims to develop a reference portal to guide the process of environmental licensing of Transmission Systems (substations and lines), through the survey and systematization of processes, data and information, allowing the agility of the procedures, with reflections on the quality of socio-environmental gains and the mitigation of deadline and cost risks of the projects.
<b>ENERCAN – CAMPOS NOVOS ENERGIA S. A.</b>	Feasibility of Reversible Power Plants in the National Interconnected System	The central objective is to advance knowledge about Pumped Storage Hydropower Plant (PSH), contemplating the definition of regulatory, technical, operational and commercial arrangements to enable the implementation of this technology in the Brazilian Electric Sector, considering the potential impacts on the National Interconnected System. The research also seeks to map the potential sites for the implementation of large-scale PSH in the country, in order to select a project for further case study and detailing.

Source: GESEL (2022)

Another great result of innovation in the power sector was described by Padilha (2019), who says that the first auction contemplating photovoltaic energy in 2014 was a historical milestone, because from then on photovoltaic energy became a reality as a sustainable, clean and sustainable energy alternative in Brazil.

#### 4.4 ANS

As mentioned in the theoretical framework regarding the innovations performed in the ANS by means of Primary Health Care (PHC), we will explain here which companies have adopted innovative models, the purposes of each one, and the results achieved.

The companies considered as innovative were: Fundação São Francisco Xavier, Unimed Belo Horizonte - Medical Work Cooperative, Unimed de Guarulhos- Medical Work Cooperative, Unimed Grande Florianópolis - Medical Work Cooperative, Unimed Jaboticabal - Medical Work Cooperative, Unimed João Pessoa - Medical Work Cooperative, Unimed Santa Bárbara D'Oeste Americana - Medical Work Cooperative.

The chart 4 succinctly presents the main objectives of each model used, and the most significant results from the implemented innovation.

Chart 4. Companies that have obtained innovative experiences from APS

Company	Project	Objectives and results
FUNDAÇÃO SÃO FRANCISCO XAVIER	<i>Usifamília</i>	In 2014 a group was organized to visit CHA - Cambridge Helthcare Alliance, a health organization in Boston that had similarities with the Foundation. There, they found a management model based on the principles of Primary Health Care that promotes consistent changes. Based on this observation, the Foundation developed a mixed model of health care, based on primary care and the elderly health paradigm, which became known as Elderly Centered Integrated Health Management (EICHHC). The health care improvement was such that the strategy started to be marketed as a specific product, <i>Usifamília</i> , which expanded the link and the management of care to a younger and more active public.
UNIMED BELO HORIZONTE - COOPERATIVA DE TRABALHO MÉDICO	<i>Unimed Pleno</i>	The central objective of the project is to offer a care model with coordination of care by PHC. The proposal of this product is based on linking the beneficiary to a reference physician, who will perform the patient's continuous follow-up. The positive results of the product are directly linked to the exposure time of the portfolios. The rate of Hospitalizations for Conditions Sensitive to Primary Care (ICSAP) fell 27% among full customers and the cost of the full customer fell 12% among customers from the second year of the product





<p><b>UNIMED DE GUARULHOS- COOPERATIVA DE TRABALHO MÉDICO</b></p>	<p>Person-Centered Primary Care Service - change in the care model at <i>Unimed Guarulhos</i></p>	<p>The project has as objectives: redesign the current system to obtain better results in health, increasing economic efficiency, competitiveness, minimizing the effects of judicialization of medicine, high level of customer satisfaction, etc. The results were evaluated through satisfaction indicators, with a NPS of PHC recommendation score of 76; utilization indicators with a 63% reduction in consultations in the ER, and a reduction in the total per capita care cost of 34%; clinical care process indicators, with Perfect Care in SAH and DM reaching more than 60%; contra-referral of specialists in 46%, as well as monitoring of breast, colon and uterine cancer screenings.</p>
<p><b>UNIMED GRANDE FLORIANÓPOLIS - COOPERATIVA DE TRABALHO MÉDICO</b></p>	<p>New Care Model Based on Primary Health Care</p>	<p>The project seeks to provide care focused on the person, based on equity, efficiency and effectiveness, integrating health promotion actions and valuing principles such as access, integrality, longitudinality and care coordination. The significant increase in the mapping of diagnoses and risk conditions was the major positive result, as well as the decrease in waiting times for appointments.</p>
<p><b>UNIMED JABOTICABAL - COOPERATIVA DE TRABALHO MÉDICO</b></p>	<p>Primary Health Care</p>	<p>Since 2013, Unimed Jaboticabal has sought to redesign its care model. The project aims to improve the health of individuals, the experience with care and reduce care costs by eliminating waste. As a result, there was an increase in the percentage of beneficiaries, an increase in eligible men and women in PHC with rectal cancer screening.</p>
<p><b>UNIMED JOÃO PESSOA - COOPERATIVA DE TRABALHO MÉDICO</b></p>	<p><i>Plano Viver Mais: Pioneer Model of Integral Health Care at UNIMED João Pessoa - PB</i></p>	<p>This is a rational and sustainable health care model, which enables the expansion of the cooperative's product portfolio in accordance with current market requirements. It aims to gradually incorporate new ways of providing innovative payment services, through principles such as accessibility, integrality, longitudinality and coordination of care.</p>
<p><b>UNIMED SANTA BÁRBARA D'OESTE AMERICANA - COOPERATIVA DE TRABALHO MÉDICO</b></p>	<p><i>Viver Bem Viver Bem</i></p>	<p>In 2013, the service began with a grounded, holistic and safe care and has as its main objective the improvement in the health results of dependents, as well as employees. Through the model, there was a 40% increase in nursing care, a 16% decrease in emergency care, and even with inflation, the cost of care has remained stable.</p>

Source: adapted from Pan American Health Organization (2018)



## 5 FINAL CONSIDERATIONS

As presented in the analysis of the results, all four regulatory agencies studied were successful and obtained real benefits from the implementation of innovation in their regulatory activities.

Through the study of the experiences researched, it can be seen that innovation was an essential tool in several areas. At Anvisa, improvements were found in the process of drug registration, through the implementation of telework. Idea Factory is also a result of innovation within Anvisa, because it is considered an innovative project in the sanitary surveillance sector, and one of its fruits is LAB-i Visa.

Anatel, in turn, presented innovation in operations such as portability, leading to significant levels of satisfaction among telephony service users. Another innovation highlight was in radio frequency, improving WiFi services.

At Aneel, successful experiences were also observed. Law 9.991/2000, which obliges energy concessionaires to invest in innovation, is one of the biggest incentives. Several R&D projects, completed and in progress, adopted by various companies in the electric power sector were presented.

Finally, innovative projects and models through Primary Health Care adopted by several companies regulated by the ANS were shown, obtaining the most varied benefits according to their specific public niche.

It is legitimate to conclude that the verification of how innovation was employed in the Brazilian regulatory agencies studied and the analysis of the benefits brought, both for the agencies and for society, is in fact proof that innovative actions are essential in any kind of organization.

The study is an initial contribution to the construction of knowledge about the relationship between innovation and regulatory agencies, therefore, as an exclusively exploratory work, it is worth recognizing the limitation of the prevailing literature, and therefore, due to the small number of specific bibliographies found, it can be considered that the theme addressed is emerging in the literature.

Finally, future research is suggested to explore the relationship between innovation and regulation in the other Brazilian regulatory agencies that were not covered in the study, as well as to analyze the possible obstacles faced by agencies in implementing innovative actions.

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## AUTHORS

### 1. Monaliza Ferreira Rodrigues de Paula

Institution: Universidade Federal Rural do Semi-Árido

Mossoró, Rio Grande do Norte, Brazil. Master's student in Public Administration at Universidade Federal Rural do Semi-Árido

E-mail: monaliza.ferreira@ufersa.edu.br

ORCID: <https://orcid.org/0000-0001-7917-0413>

### 2. Camila de Souza Filgueira

Institution : Universidade Federal Rural do Semi-Árido

Mossoró, Rio Grande do Norte, Brazil. Master's student in Public Administration at Universidade Federal Rural do Semi-Árido

E-mail: camila.filgueira@ufersa.edu.br

ORCID: <https://orcid.org/0000-0003-4905-9057>

### 3. Napiê Galvê Araújo Silva

Institution: Universidade Federal Rural do Semi-Árido

Mossoró, Rio Grande do Norte, Brazil. Master in Economics (UFC); Master in Public Policy and Society (UECE)

E-mail: pie@ufersa.edu.br

ORCID: <https://orcid.org/0000-0002-7966-3311>





### Contribution of authors

Contribution	[Author 1]	[Author 2]	[Author 3]	[Author 4]
1. Definition of research problem	√		√	
2. Development of hypotheses or research questions (empirical studies)	√	√	√	
3. Development of theoretical propositions (theoretical work)				
4. Theoretical foundation / Literature review	√	√		
5. Definition of methodological procedures			√	
6. Data collection				
7. Statistical analysis	√	√		
8. Analysis and interpretation of data			√	
9. Critical revision of the manuscript				
10. Manuscript writing	√	√		
11. Other (please specify)				

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