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ARTICLE

Open Exceptions: Why Does the Brazilian Health Regulatory Agency (ANVISA) Exempts RIA and *Ex Post* Reviews?

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Abstract
In this article, we examine the evolving landscape of Regulatory Impact Assessment (RIA) decisions made by the National Health Regulatory Agency (Agência Nacional de Vigilância Sanitária [Anvisa]), a prominent federal agency leading RIA implementation in Brazil. We quantify Anvisa's RIA usage rates, exploring the influence of emergency and other justifications for RIA exemptions both pre and post the enactment of detailed procedural requirements in a recent Presidential Order No. 10,411/2020. Our quantitative analysis shows a sharp decline in RIA usage after Presidential Order No. 10,411/2020 came into force in April 2021, as well as a diversification of the justifications given in decisions not to use RIA (exception decisions). This effect is present even if we take into consideration a large proportion of exception decisions tied to Anvisa's regulatory stock review and to urgent measures prompted by the COVID-19 pandemic. Additionally, we conduct a qualitative analysis of exception decisions due to emergency, post-Presidential Order. We find that Anvisa failed to provide compelling justifications for exempting RIA in emergency regulations in several cases and avoids *ex post* reviews when RIAs are waived due to emergencies. We conclude the article with recommendations to enhance the scrutiny and transparency of Anvisa's exception decisions to conduct RIA.

1. Introduction

In 2021, the Organization for Economic Cooperation and Development (OECD) released an updated edition of its Regulatory Policy Outlook (OECD, 2021), shedding light on the growing trend among its member countries in employing exceptions for conducting Regulatory Impact Assessments (RIAs) when introducing regulations in response to emergencies.

The trend underscored in the cited OECD report was amplified by the impact of the COVID-19 pandemic. The number of OECD member countries not mandating RIAs when implementing emergency-related regulations rose from 13 in 2017 (OECD, 2018) to 18 in 2020 (OECD, 2021a,b). While consolidated information on emergency regulation in a post-COVID-19 scenario is lacking, deviations from normal regulatory practices persist (Staronova et al., 2023).

The OECD deems this practice highly problematic due to the increased risks and potential impacts of regulations during crises, turning Regulatory Impact Analysis (RIA) even more crucial in such situations (OECD, 2021b). This creates a dilemma for the regulator when urgent new regulations are needed, since her decision to exempt RIA can mitigate the costs of delay, but this may come at the expense of the rule's effectiveness in serving the public interest. Additionally, since exception decisions are rarely scrutinized or published, regulators may strategically use non-genuine emergencies as a justification for exempting RIA (OECD, 2021). Furthermore, beyond fostering more rational, evidence-based decisions, RIA also plays a crucial role in the political and social oversight of the bureaucracy (Radaelli & De Francesco, 2007), as it enhances administrative accountability. This function is impaired by exemption decisions, which may ultimately conceal agencies' preferences and value judgments.

A solution embraced by a limited number of OECD countries—specifically 8 in 2020—to address public interest and accountability concerns is to complement rulemaking with post-implementation reviews (OECD, 2021). In doing so, countries would be required to retrospectively assess the effects of their regulatory decisions in the context of emergencies (OECD, 2021). The use of exemptions may serve the public interest when the cost of delaying a rule outweighs the cost of adopting an inferior rule compared to one that would be adopted if RIA was used. However, agencies and their overseers can only determine whether the exemption was justified by requiring an impact evaluation. In this approach, regulators avoid the costs of delaying the passage of a regulation while committing to consider amending the rule adopted without RIA in response to the results that the *ex post* review generates.

A problem overshadowed by this solution is that an accurate *ex post* evaluation relies on a prior *ex ante* review. For the evaluator to assess the outcomes of a regulation, understanding the problems, objectives and the selecting criteria that led to the adoption of a specific regulatory solution is crucial (Coglianese, 2012). However, in cases of regulatory decisions made without RIAs, this information may not be readily available or appropriately documented.

Therefore, OECD has acknowledged that countries need flexibility in the use of RIA, advocating for fast-track or streamlined procedures in the case of genuine emergencies (OECD, 2021a,b). This approach would require countries, at the very least, to follow the basic RIA steps and explicitly provide substantiated reasons—even if grounded on qualitative data when quantitative information is not readily available—for adopting a rule without RIA.[1]

Although exceptions to conduct RIA in cases of emergency have increased during the COVID-19 crisis, they appear to have persisted in a post-crisis scenario and "have become institutionalized as new norms of swift law-making" (Staronova et al., 2023).

In Brazil, exception decisions related to RIA in response to emergencies have consistently been high, with their causes unrelated to the COVID-19 pandemic (Salinas & Gomes, 2021). The Agência Nacional de Vigilância Sanitária ("Anvisa"), a prominent national health regulatory agency recognized for its leadership in RIA implementation in Brazil, has mandated RIA as a procedural requirement for major regulations since 2011.

However, our previous study revealed that 48.9% of all regulations adopted by Anvisa between 2012 and 2020 exempted the use of RIAs due to emergencies (Salinas & Gomes,

[1] OECD (2021a,b) cites the example of Canada, which allowed a greater emphasis on qualitative rather than quantitative impacts of COVID-related laws.

2021). These decisions were not supplemented by post-implementation reviews, as, during the period covered in that study, such reviews were not a statutory requirement.

In April 2021, new legislation on RIA implementation took effect, and Anvisa began to comply with the new RIA implementation rules mandated by national legislation. These rules encompass new causes for exempting RIA and a requirement for post-implementation evaluations following exception decisions made in cases of emergency. Given these recent statutory changes, we have chosen to expand our study to include a more recent timeframe—specifically, the years 2021-2022.

The primary objective of this article was to discern the reasons behind Anvisa's exemptions for RIA and *ex post* reviews. In this article, our aim is to understand the role that emergency plays in Anvisa's decisions to exempt the use of RIA for major regulations. Furthermore, we seek to determine whether Anvisa has recently been conducting *ex post* reviews to comply with the new national legislation that imposed a post-implementation requirement in the specific case of RIA being exempted because of an emergency.

Our analysis begins in 2012, when RIA became a mandatory procedural requirement for Anvisa, extends until the year 2021, when a new presidential order implementing RIA was issued, and concludes on December 31, 2022, representing the date of our last data collection. The article is structured into five sections. In the second section, following this introduction, we will detail how RIA has been implemented in Brazil—initially as an initiative of individual agencies, a period during which Anvisa independently determined its RIA procedures, and subsequently, as part of a nationwide regulatory policy. The third section will outline the methodology employed in our study, encompassing descriptive statistics and qualitative analysis of the reasons provided for Anvisa in exception decisions justified as cases of emergency.

In the fourth section, we present our results, including (i) a quantification of percentage rates of emergency and other types of justifications used in Anvisa's exception decisions over time, as well as (ii) a qualitative analysis of the agency's primary justifications for exempting RIAs due to emergency under the recently approved national legislation, spanning from April 2021 to December 2022. In the fifth and concluding section, we will recapitulate our main findings and conclude with our final remarks.

2. RIA Implementation by the Brazilian Health Regulatory Agency (Anvisa)

Anvisa, the Brazilian Regulatory Health Agency, has played a proactive role in shaping RIA practices in the country. The agency possesses extensive regulatory authority, covering sanitary control of the production, marketing and use of products and services that may pose a risk to health. Collectively, Anvisa's regulatory targets, which include food products, drugs, cosmetics, vaccines, and a wide range of products and services used in health treatments, account for 20% of the Brazilian Gross Domestic Product (GDP).[2] As the agency responsible for regulating the tenth-largest pharmaceutical market in the world and the main market in Latin America (Sindusfarma, 2023), Anvisa's regulations exert a significant impact on the Brazilian economy.

[2] See Anvisa completa 24 anos. 2023. Available at https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2023/anvisa-completa-24-anos-de-defesa-da-saude-publica (accessed December 1, 2023).

In this article, we categorize the implementation of RIA by Anvisa in Brazilian regulatory policymaking into three stages. The initial stage is marked by the gradual and experimental adoption of RIA by a selected group of independent agencies. These agencies began utilizing the tool with the support of the federal Program for Strengthening the Institutional Capacity for Management in Regulation—PRO-REG in 2007.[3]

During this time, there were no mandatory requirements for the use of RIA; it was entirely optional. The integration of RIA into Anvisa's rulemaking processes began gradually. Anvisa introduced its own better regulation program, named the "Program for the Improvement of Anvisa's Regulatory Process", through Ordinance No. 422/2008. Under this program, Anvisa also established an index (I-Reg) for monitoring the implementation of better regulation tools, including RIA (Trindade, 2009; Alves *et al.,* 2011). In that same year, Anvisa published its first guidelines on *Good Regulatory Practices*, dedicated to explaining concepts and procedures related to RIA and stakeholder engagement in the rulemaking process.[4] However, at that point, there were no specific legal provisions determining the systematic and widespread implementation of the tool. Simultaneously, Anvisa was selected for a pilot project by the federal government to conduct the first systematic effort to measure the economic impacts of a federal agency's regulatory activities.

These events led to the second stage of RIA implementation by Anvisa and other agencies, which integrated RIA as a mandatory tool into their rulemaking processes. Starting in 2011, Anvisa independently formalized its RIA procedures through a series of internal rules and administrative decisions, establishing standards and procedures for RIA and ultimately turning it into a mandatory tool. This approach was subsequently adopted by other independent agencies in the following years.[5]

As of 2011, Anvisa started to regularly disclose whether the rules published on its legislation website were preceded by RIA, also publishing justifications when they did not. From 2012, when the tool became mandatory for the agency, until 2018, when Anvisa issued a new Ordinance governing RIA, exception decisions were made in an *ad hoc* manner, without any overarching legal provision governing the process. A resolution by Anvisa's board of directors, dated June 26, 2012[6], mandated the inclusion of RIA as a procedural requirement in the agency's rulemaking process. In our view, as articulated elsewhere (Salinas & Gomes, 2021), this represented a fragile mechanism for formalizing the use of RIAs in Anvisa. Nevertheless, this resolution established that the Board of Directors would have the discretion to determine simplified processes for the issuance of urgent and low-impact rules. For these rules, RIA would be exempted, and not even a rudimentary impact analysis would take place. During this time, as the standard to be used in most cases, Anvisa conducted a simple method based exclusively on qualitative analysis (level-1 RIA). However, urgent cases were not even subjected to level-1 RIA.

[3] For a history of the program, see Histórico do PRO-REG. 2013. Available at https://www.gov.br/casacivil/pt-br/assuntos/governanca/regulacao/sistema-regulatorio-brasileiro/historico-do-pro-reg. (accessed December 1, 2023).

[4] Interestingly, these guidelines recommended a fast-track impact analysis for urgent matters but did not refer to exemption decisions in such cases.

[5] Before the passage of national legislation in 2019 that made RIA mandatory for the entire federal administration, nine out of the eleven existing federal independent agencies had already approved internal rules requiring RIA for their regulations. See Trigo (2022).

[6] Ordinary Board's Deliberation No. 19 dated June 26, 2012 (Reunião Ordinária da Diretoria Colegiada No. 19, de 26 de junho de 2012).

In 2018, Anvisa issued Ordinance No. 1,741 to align its practices with RIA guidelines issued by the Civil House of the Presidency (Casa Civil da Presidência da República). Beyond stipulating more rigorous quantitative methodologies for evaluating alternatives and implementing a novel workflow to incorporate public participation with RIA, Ordinance No. 1,741/2018 explicitly set forth provisions for scenarios in which RIA is deemed inapplicable and, notably, for instances in which it could be exempted.

Section 12 outlined the following scenarios for warranting exemption of RIA: (i) instances of urgency; (ii) cases of administrative simplification, provided the core regulatory substance remained unchanged; (iii) low-impact rules. Section 11 of Ordinance No. 1,741/2018 specified three cases where the use of RIA was deemed inappropriate (cases of inapplicability): (i) correction of grammar and numerical errors in regulatory texts; (ii) modification or annulment of outdated rules, given that the regulatory content remained unchanged; (iii) consolidation of rules, given that the fundamental regulatory content remained unaltered.

Section 12 of Ordinance No. 1,741/2018 granted legal status to exemption decisions made by de agency since 2011. As we will demonstrate later, emergency was the exclusive justification used by the agency in the first years of the mandatory use of RIA (specifically between 2012 and 2014), while other reasons—namely, low impact, administrative simplification and rule updating—began to emerge from 2015 onwards. However, urgency remained the primary reason provided by the agency to exempt the use of RIA in most of the subsequent years, as we will illustrate later.

The third and current stage is characterized by the mandatory application of RIA to all rules enacted by federal administrative agencies, particularly those that significantly impact regulated entities and consumers. In 2019, RIA became compulsory for the eleven Brazilian independent agencies following the enactment of Law No. 13,848/2019 (The Regulatory Agencies General Act). Shortly thereafter, Law No. 13,874/2019 (Economic Freedom Act) expanded its use to all bodies of the federal government with regulatory authority, and Presidential Order (*Decreto*) No. 10,411/2020 established specific rules of implementation and methodological guidelines for RIAs.

Although, as described, RIA was already a mandatory tool for Anvisa well before the enactment of these statutes and issuance of this Presidential Order, the agency had to adapt some of its internal rules to comply with this national legislation. Presidential Order No. 10,411/2020 expressly outlined new situations, not anticipated in Anvisa's previous rules, in which RIA may be exempted, at the discretion of regulatory agencies. For example, the formulation and updating of rules to align to international standards would be exempted from RIA. We have criticized elsewhere these facilitating standards for the international standardization of Brazilian rules (Salinas & Gomes, 2020; Salinas, 2022). It should be noted that Presidential Order No. 10,411/2020 also added causes for exemption that are just remotely related to Anvisa's work, such as the exemption of RIA for rulemaking with the aim of ensuring the solvency of securities, financing, and insurance markets.

Furthermore, Presidential Order No. 10,411/2020 introduced additional cases where RIA must not be applied—instances of inapplicability—beyond the previously mentioned cases of grammar and numerical corrections, normative consolidation, and periodic rule updating outlined in Anvisa's Ordinance No. 1,741/2018.[7]

[7] Section 3 of Presidential Order No. 10,411/2020 stipulates that internal administrative rules, administrative decisions with concrete effects, as well as rules governing the national budget, exchange and monetary policy, and national security are not subject to RIA.

But the significant development, for the purposes of our analysis, is that Section 12 of Presidential Order No. 10,411/2020 mandated an *ex post* evaluation for cases in which RIA was exempted due to an emergency. Section 12 of Presidential Order No. 10,411/2020 specifies that 'Regulations for which the RIA has been waived due to an emergency shall be subject to Regulatory *ex post* evaluation within a period of 3 years, starting from the date of their entry into force.' Before national legislation came into effect, Anvisa did not explicitly state the obligation to conduct an *ex post* review in case of adopting emergency regulation without RIA, despite this being already recommended in the guidelines issued by the Civil House of the Presidency.[8] Presidential Order No. 10,411/2020 was enacted on June 30, 2020; however, its implementation was scheduled to begin only on April 15, 2021. During this period, Anvisa and other independent agencies had the opportunity to make essential preparations for compliance with the new requirements.

Anvisa issued Ordinance No. 162/2021, replacing Ordinance No. 1,741/2018 to establish new "better regulation" guidelines and procedures aligned with the requirements of Presidential Order No. 10,411/2020. Ordinance No. 162/21 stipulated that exemptions from RIA in response to urgent matters must be supplemented by an *ex post* review within a 3-year timeframe. However, on November 25, 2021, a new Ordinance (No. 624/2021) amended Section 57 of Ordinance No. 162/2021 to introduce two exceptions to the obligation of conducting *ex-post* review when RIAs are not conducted due to emergencies. The provisions added in Section 57 empowered the board of directors with the discretion to exempt emergency rules from the requirement of *ex post* reviews, particularly in cases where these rules were intended for temporary duration (Section 57, § 2°, I) or in exceptional circumstances where conducting such a review might appear 'disproportionate to the potential impacts expected with the normative act' (Section 57, § 2°, I). As we will demonstrate in Section 4, these exceptions led to the inapplicability of the *ex post* review requirement for the vast majority of rules issued during the pandemic. In the following sections, we will analyze how this federal legislation has influenced Anvisa's practices concerning the utilization and exemption of RIAs.

3. Methodology

3.1 First stage of data collection

In this study, we scrutinized the evolution of Anvisa's RIA instruments using data obtained from the agency's official website. This data collection occurred in two stages. In the first stage, the collection process was facilitated by an automated web scraping tool, primarily sourcing from Anvisa's website legislation section.

The gathered data included details about the application or non-application of RIA, along with the *rationale* for any exemptions granted. Subsequently, we cross-referenced the collected data with Anvisa's own classification of rules, focusing on the theme and scope of these rules.

This first stage of the data collection process, including the extraction of data through web scraping and its subsequent correlation with Anvisa's spreadsheet, spanned from February 17, 2021, to March 3, 2021.

[8] The guidelines already recommended conducting an *ex post* implementation review within a 2-year timeframe from the issuance of the exemption decision. See Casa Civil da Presidência da República (2018).

3.1.1. Selection criteria

In the first stage, the collected data formed a database comprising 2,185 normative rules, of which 2,077 were issued by Anvisa and 112 by other entities like the Department of Health, the Department of Agriculture, and the President's Office. Regulations from other departments are accessible on Anvisa's website due to their substantial association with Anvisa's own rules, despite not being issued by Anvisa.

In the realm of Anvisa's regulations, Directors' Collegiate Resolutions (RDCs) were predominant, constituting 1,656 instances, followed by Normative Instructions (INs/INCs) with 181 cases. Collectively, RDCs, INs, and INCs comprise approximately 88% of Anvisa's rules in the database. However, when examining all rules published by Anvisa in the Federal Official Gazette, these types are not the most frequent. Other rule types, such as Ordinances and Special Resolutions, are more commonly observed.

Anvisa's preference for publishing these particular types of rules on its website stems from the fact that they typically contain regulatory rules of broad applicability to private regulated agents. As outlined in Anvisa's Internal Rules of Procedure (RDC No. 255/2019), ordinances are typically designated for issues related to the agency's internal interests, such as administrative management. On the other hand, Special Resolutions are often specific rules with limited implications, such as permissions and authorizations directed at particular products or companies. Anvisa's database also includes non-binding measures, such as guidelines. Although these do not have legal force, they are relevant to private regulated agents and, therefore, have been published in the legislation section of the website.

Therefore, among the diverse types of rules in the database, Directors' Collegiate Resolutions and Normative Instructions most accurately reflect Anvisa's regulatory activities. Consequently, our analysis was limited to RDCs, INs, and INCs issued by Anvisa. This initial criterion narrowed the focus of the analysis to 1,837 rules.

Additionally, while Anvisa took its first steps to incorporate RIA after the establishment of the Program for the Improvement of the Regulatory Process through Ordinance

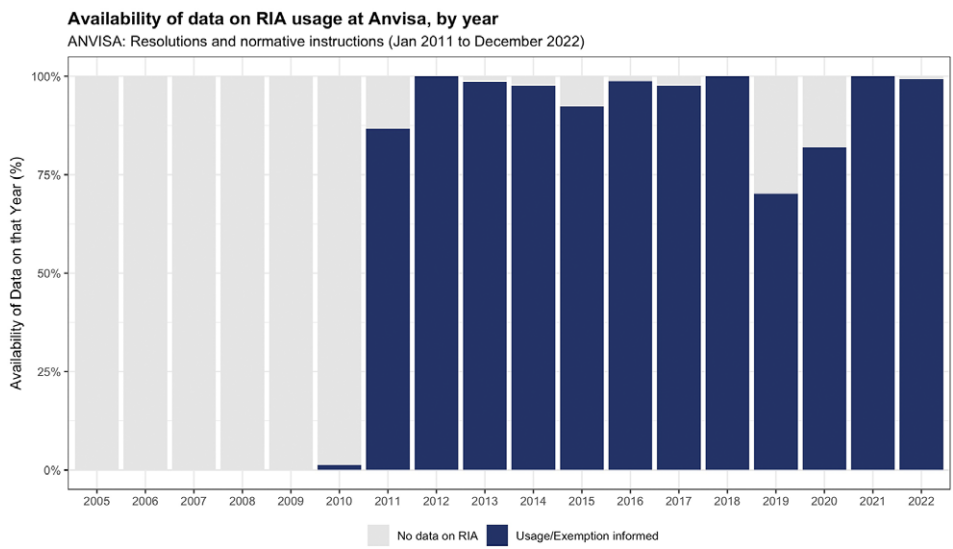

Figure 1. *Availability of data on RIA by year.*

No. 422/2008, the agency only began disclosing data on RIA usage or exemptions after 2011. This coincided with the creation of the Center for Regulation and Good Practices on Regulation by Ordinance No. 1,381, which marked the inclusion of RIA in Anvisa's Internal Rules of Procedure. Figure 1 illustrates the percentage of normative acts (RDCs, INs, and INCs) with available information on RIA on Anvisa's website, by year.

Given our specific focus on the implementation of RIAs by Anvisa, a second selection criterion became imperative. As previously mentioned, before 2008, RIA practices were non-existent within Anvisa. Between 2008 and 2011, the agency engaged primarily in preliminary discussions on RIA implementation, and data from this period are scarce, with minimal examples of actual RIA application. Given this scenario, a second criterion was adopted to select only those RDCs, INs, and INCs issued after 2011. Thus, the first stage of data collection gathered information on rules published between 2011 and 2020. Employing these criteria, based on the origin, type of rule, and the relevant period, we identified a total of 843 rules (comprising 719 RDCs, 114 INs, and 10 INCs). These rules formed the basis for our previous exploratory analysis (Salinas & Gomes, 2021) of the data collected in this first stage.

3.2. Second stage of data collection

In 2022, the previously collected database began receiving updates. However, with our current focus on investigating the reasons that led Anvisa to exempt the use of RIA, we opted to manually collect information from the new RDCs, INs, and INCs issued from 2021 onwards. This approach enabled the collection of more detailed information on the normative acts, including non-structured data that had not been gathered previously. It should be noted that this approach was only feasible because the selection criteria had already been established in the previous stage, thus eliminating the need to collect all acts published on the website.

Opting for manual collection enabled us to gather additional information about the use or exemptions of RIA in each case. In particular, for all cases where RIA was not used, we sought a document in which the agency analyzed the provided justification. Typically, in cases of exemption, the agency generates a technical note on the normative proposal that incorporates an assessment of the reasons for not conducting the RIA.

Another significant development in the study of RIA exemption by Anvisa was the agency's decision to reformulate what was disclosed on its website as a justification for not conducting RIA. As we will explore later, the agency previously used only a more restricted set of justifications, with the main one being exemption due to urgency. However, starting from 2021, the agency began to reproduce the justifications provided in the RIA Regulation (Presidential Order No. 10,411/2020). As discussed in the previous section, this order encompasses not only a more extensive list of exemption cases but also cases where RIA is deemed 'inapplicable.'

In light of this, in the second phase, we opted to carry out a new process of manual collection of information from rules (RDCs, INs, and INCs) published by Anvisa in 2021 and 2022. This collection was conducted by undergraduate Law students,[9] under our guidance. Regular meetings were held to monitor the collection process. This phase resulted

[9] We thank the students João Pedro Paravidino and Luiza Denobi for conducting this data collection.

in two spreadsheets: one with information about the rules and any possible exemption or inapplicability justifications used, another about the documents published by the agency in which the justifications were presented and substantiated. Thus, 431 new RDCs, INs, and INCs published in 2021 and 2022 were identified and categorized, and a total of 221 justification documents related to these normative acts were collected.

Finally, for a comprehensive analysis of the use of emergency as a reason for exempting RIA, we thoroughly reviewed all supporting documents used to justify exemptions due to emergency granted after April 15, 2021, when Presidential Order No 10,411/2020 came into force for Anvisa. We categorized these documents as either related or unrelated to the COVID-19 pandemic, assessed whether they provided clear justifications and used quantitative parameters in the exemption decisions, and determined whether exemptions were complemented by the *ex post* review required by federal legislation.

4. Findings

4.1. Use, exemption and inapplicability of RIA at Anvisa: A quantitative analysis

The data collected in the second stage of the research show a substantial increase in the total number of rules (RDCs, INs, and INCs) issued by Anvisa in recent years. Between 2011 and 2018, the agency's annual publication of rules fluctuated between 65 and 85. However, starting in 2019, there was a noticeable increase, reaching a total of 265 rules in 2022 (see Figure 2).

This substantial increase in rulemaking can be explained by a combination of factors. In recent years, Anvisa underwent a process of reviewing its regulatory stock, which possibly led to a high volume of rules consolidating existing regulations, with punctual revocations of obsolete provisions, systematization of the normative texts, updates to figures and values, as well as the elimination of some regulatory requirements for the purpose of simplifying the administrative procedures of the agency, thus reducing regulatory costs for the regulated industries. Concurrently, the advent of the COVID-19 pandemic in 2020 also favored the issuance of many regulatory responses in a short period of time, since Anvisa is the agency in charge of sanitary and health regulation in Brazil. Even after the pandemic crisis waned, these provisions continued to demand regulations from the agency, not only to revoke provisions that were no longer necessary, but also to consolidate and systematize the legacy of the period, keeping some measures and changes tested during the pandemic in force.

It is possible that this increase in rulemaking is also associated with the significant reduction in the percentage of rules that are actually subjected to an RIA prior to their issuance. The earlier mentioned statutory reforms that made RIA mandatory and outlined its implementation seem to have had the opposite effect to what was intended by the legislators, at least for Anvisa. Before the entry into force of Presidential Order No. 10,411/2020, which regulated these changes, about one in every three rules (RDCs, INs, and INCs) published on the Anvisa website indicated that an RIA had been conducted. After the reform, this proportion dropped substantially, and only about one in every 10 rules were preceded by RIA (see Figure 3).

Additionally, the data shows that the hypotheses foreseen in federal legislation resulted in more cases being classified as "non applicable" at Anvisa. Before the order, all cases were presented as exemptions from RIA—and, as we will see later, only a very limited set of *rationales* were ever used to justify the exemptions. After Presidential Order No. 10,411/2020, cases of inapplicability became frequent, and in these cases the agency does not have the statutory obligation to justify why it did not use RIA.

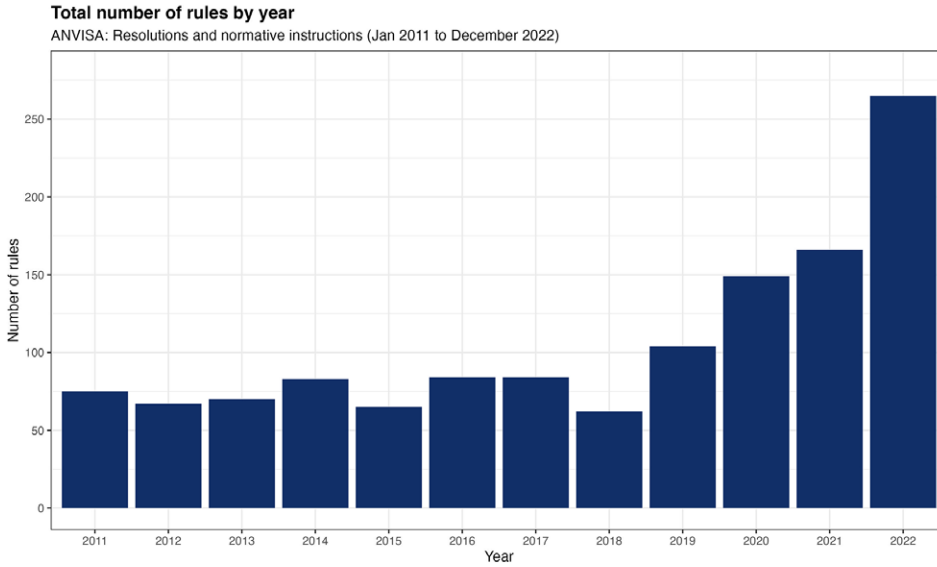

Figure 2. *Total number of rules by year.*

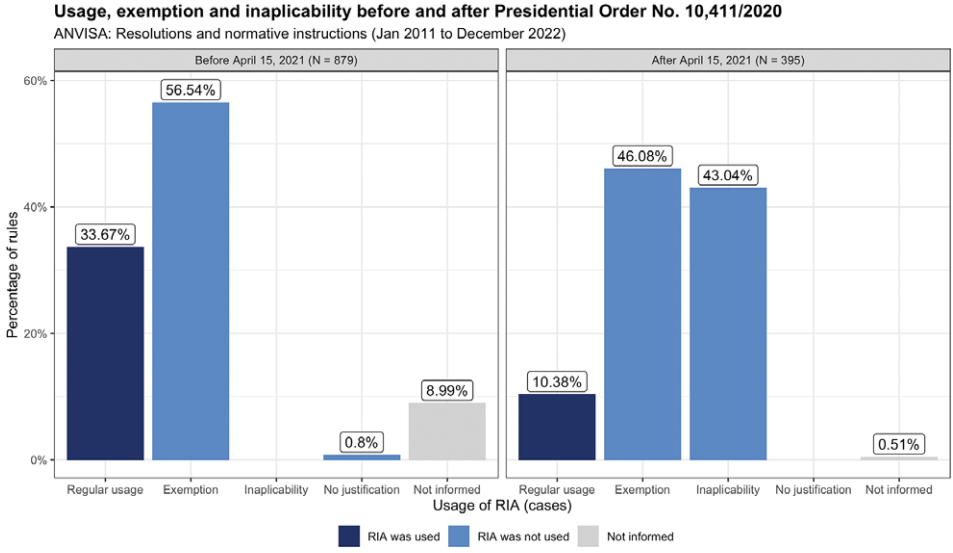

Figure 3. *Use, exemption, and inapplicability before and after Presidential Order No. 10,411/2020.*

Anvisa, a particularly transparent agency in its practices when compared to other Brazilian agencies, indicates in concise form in its website, when RIA was not used due to inapplicability, the main reason for considering RIA non applicable in that instance. Nevertheless, in those cases usually there is no formal document available substantiating this decision or discussing the justification given in any depth.

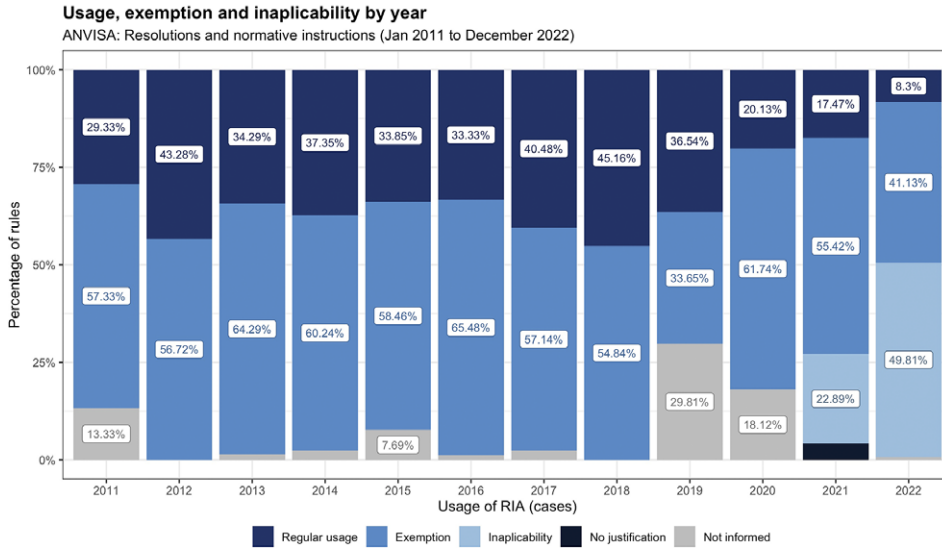

Figure 4. *Use, exemption, and inapplicability by year.*

The trend towards a reduction in use of RIA and an increase in cases of inapplicability becomes even more evident when we look at the historical series, comparing percentages year by year (see Figure 4). Over the first 9 years of the series (2011 to 2019), the percentage of cases in which RIA was used fluctuated around 30% to 40%. In 2020, 2021, and 2022, this proportion showed successive drops, reaching 20.13%, 17.47%, and 8.3%, respectively. Cases of inapplicability did not appear before 2021.[10] In contrast, 22.89% of the rules issued in 2021 were considered inapplicable, a proportion that rose to 49.81% in 2022.

The marked decrease in the use of RIA in 2022 is likely partly attributable to the surge in rulemaking, especially the significant number of rules focused on consolidating the regulatory stock. In fact, for most instances of inapplicability, the agency's website cited "rule consolidation" as the primary reason. This needs to be considered in the analysis, as the 8.3% usage rate of RIA might be influenced by the large number of rules that are essentially consolidating the agency's regulatory texts without substantially changing any regulatory provisions (thereby negating the need for RIA in these situations). Nevertheless, even after accounting for this factor and excluding all instances of inapplicability, there is still a noticeable decline in the use of RIA in recent years. The rate of RIA usage in 2022, even under these considerations, would stand at 16.54%, which is substantially lower than the historical series rates observed in the years preceding the statutory reform.

The decrease in the utilization of RIA, coinciding with an uptick in cases deemed inapplicable where justification does not need to be substantiated, has been accompanied by a diversification in the *rationales* given for exemptions. This shift can likely be attributed to Presidential Order No. 10,411/2020, which introduced a broader spectrum of exemption cases, when compared to the previous internal rules of Anvisa. This evolving trend is evident

[10] It is possible that a portion of the cases where there is no available information on the website about the conduct of RIA might be those that would be classified as inapplicability, according to the internal rules of the agency. However, even these cases are infrequent in the historical series.

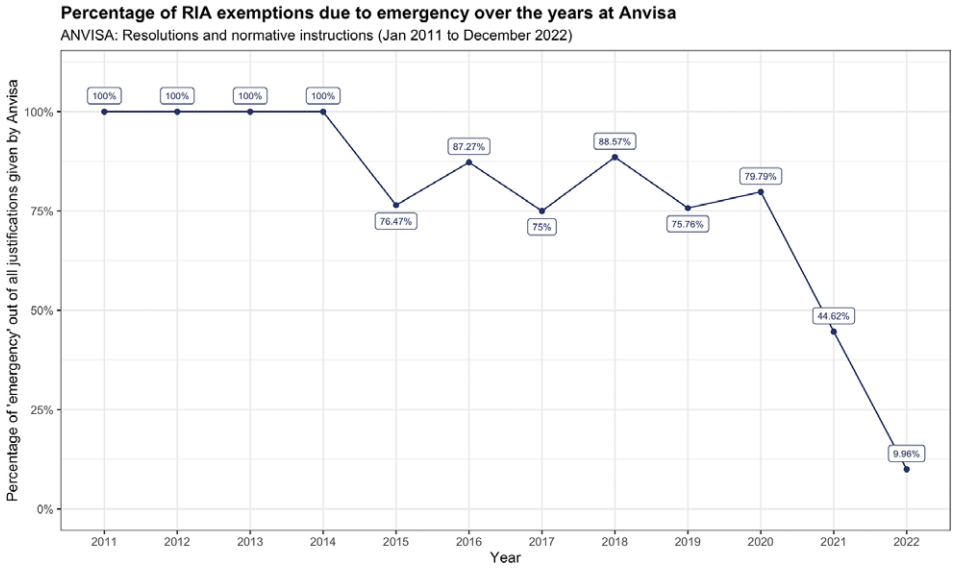

Figure 5. *Percentage of RIA exemptions due to emergency over the years at Anvisa.*

when we examine the agency's increasing reliance on citing the emergency nature of a rule as a basis for exemption. Prior to the order, emergency-based exemptions dominated in instances where RIA was not employed. In the initial four years of the historical series (2011 to 2014), emergencies accounted for 100% of all the cases where the agency provided some form of justification for not using RIA (see to Figure 5). Between 2015 and 2020, this figure varied between 75% and 88%. However, following the order's enactment, there was a notable decline in this trend, with emergency justifications dropping to 44.62% in 2021 and plummeting further to 9.96% in 2022.

Table 1 provides a more detailed breakdown of justifications given in all instances where RIA was not used and some justification was available, both before and after the Presidential Order came into effect. This data highlights a marked increase in the diversity of reasons cited to support the agency's decisions in cases of both exemption and inapplicability. Additionally, it's worth noting that most cases of RIA inapplicability for the issuance of RDCs, INs, and INCs relate to the consolidation of the regulatory stock. The proportional decrease in emergency justifications is also impacted by the significant number of normative consolidation acts issued in 2022.

However, focusing solely on instances where RIA exemptions were granted (excluding inapplicability cases), it becomes clear that emergency-based justifications still predominate among other justifications for exemption, accounting for 36,29% of exemption cases for normative acts approved after Presidential Order No. 10,411/2020 (see Figure 6). Thus, over one third of exemption cases were still justified as "emergency" regulations.

Thus, despite Anvisa's evident shift towards a wider array of justifications, the agency's logic for designating certain situations as emergencies remains a critical factor in understanding its approach to RIA exemptions. Accordingly, the next section will delve into a qualitative examination of the exemption documentation that accompanied emergency cases, post-presidential order implementation.

Table 1. *Justifications for not using RIA before and after Presidential Order No. 10,411/2020*

		Before April 15, 2021		After April 15, 2021		Total	
	Justification	*N*	%	*N*	%	*N*	%
Exemption	Emergency	433	87.65	66	18.75	499	58.98
	Low impact	23	4.66	50	14.20	73	8.63
	Norm of higher hierarchy	0	0.00	54	15.34	54	6.38
	Update/revoke obsolete norm	36	7.29	1	0.28	37	4.37
	Following int. standards	0	0.00	8	2.27	8	0.95
	Reducing regulatory costs	0	0.00	3	0.85	3	0.35
	Administrative simplification	2	0.40	0	0.00	2	0.24
Inapplicability	Text consolidation	0	0.00	165	46.8	165	19.50
	Administrative nature	0	0.00	5	1.42	5	0.59
	Total	494	100	352	100	846	100

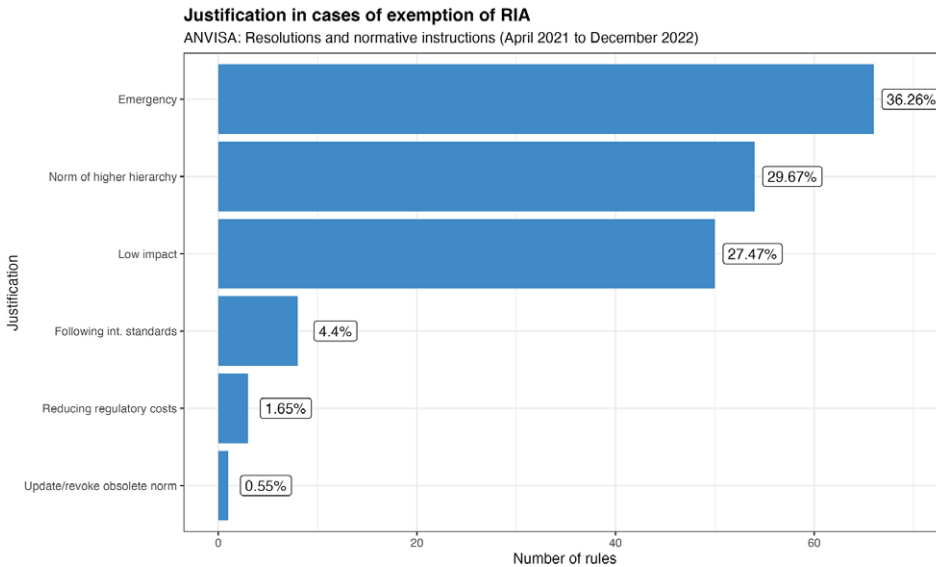

Figure 6. *Justifications in cases of exemption of RIA after Presidential Order No. 10,411/2020.*

4.2 Emergency as a justification for RIA exemption: A qualitative analysis

As mentioned, during the timeframe of our qualitative analysis (April 15, 2021 to December 31, 2022), Anvisa used "emergency" as a reason for exempting RIA 66 times. We identified two distinct patterns of justification depending on whether the rule was related or not to the COVID-19 pandemic.

In the years 2021-2022, approximately one-third (23 out of 66) of the emergency rules issued by Anvisa were not related to the COVID-19 pandemic. Anvisa exempted the creation of these rules from both RIA and notice-and-comment procedures,[11] on the grounds that issuing those rules immediately would best serve the public interest.

In the case of this specific subset of emergency rules unrelated to the COVID-19 pandemic, we observed that, for most cases, Anvisa did not offer sufficient and compelling reasons to justify the urgency in avoiding the adoption of RIA. In more than half of these rules—namely, 12 out of 23—the agency failed to disclose documents containing justifications[12] for exempting RIA. As stipulated by Section 19 of Anvisa's Ordinance No. 162/21, an exemption from RIA necessitates a substantiated opinion that precisely delineates the problems and objectives of the intended rule. Additionally, this opinion must present evidence of imminent health risks that warrant urgent regulatory intervention. But the webpages that contain information about these rules did not contain any documents providing these required justifications.

The only information provided in these webpages is that the corresponding rules were adopted without RIA in response to an emergency. Moreover, these webpages also informed that the adoption of those rules were already outlined in the agency's regulatory plan. Anvisa and other independent agencies are obligated by law (under Statute No. 13,848/19, Section 21) to release a regulatory plan every 2 years. This plan delineates the most significant regulations they expect to issue in the upcoming two fiscal years. We found it noteworthy that 17 out of the 23 emergency rules issued by Anvisa without RIA were already part of the agency's regulatory plan. While it is acknowledged that some form of emergency may arise when an agency includes the anticipation of issuing a rule in its regulatory plan for the upcoming fiscal year, what remains unclear is the definition of emergency that qualifies as an acceptable cause for exempting RIA.

Presidential Order No. 10,411/2020 lacks specific definitions or standards to interpret the emergency requirement, and Anvisa's Ordinance No. 162/2021 maintains the use of broad and vague language. Section 19 stipulates that agencies can forego RIA in response to (i) "situations that impose risk to health" or (ii) force majeure and unforeseen circumstances. The inclusion of these rules in Anvisa's regulatory plan rules out the unforeseen circumstances' option. Additionally, it is impractical and particularly inaccurate to presume that any situation posing a risk to health necessarily requires urgent intervention, especially considering that Anvisa's regulatory authority is fundamentally centered on addressing health risks.

No *ex post* reviews required by Presidential Order 10,411/2020, as a condition for RIA exemption of emergency rules, have been disclosed by Anvisa thus far. This is not a concern because these rules were issued in the years 2021-2022, and the deadlines for concluding *ex post* reviews had not expired at the time of our data analysis. However, we found that in eight out of the 10 rules whose webpages contained documents with reasons for exempting RIA, *ex post* reviews were also waived. As detailed in Section 2, Anvisa made amendments to Section 57 of Ordinance No. 162/2021 to introduce two exceptions to the requirement of conducting *ex post* review when RIAs are not carried out in response to emergencies. One of

[11] Virtually all of Anvisa's decisions in cases of emergency exempt RIA and notice-and-comment procedures simultaneously. However, addressing exemptions of notice-and-comment and analyzing their implications is beyond the scope of this article.

[12] We have not inquired with the agency to confirm whether these documents were produced, despite not being disclosed. Therefore, we can only assert that these documents were not accessible to the public on Anvisa's website.

these exceptions, particularly employed in cases of RIA exemption for rules unrelated to the COVID-19 pandemic, is the 'exceptional circumstance cause". This provision allows for the waiver of a post-implementation if it may appear 'disproportionate to the potential impacts expected with the rule' (Section 57, § 2°, I of Ordinance No. 162/2021).

We could not discern a clear meaning for the 'exceptional circumstance cause' through our analysis of the agency's exemption decisions.[13] A literal interpretation of the aforementioned provision suggests that this exception was established for situations in which the costs of implementing *ex post* reviews are disproportionate compared to the implementation costs of the corresponding rule. In simpler terms, monitoring and reviewing the implementation of a specific rule may incur higher costs than the actual implementation of the rule itself. An illustrative example is Normative Instruction No. 152/2021, which altered the maximum limit for contaminants in "nuts, including walnuts, pistachios, hazelnuts, macadamias, and almonds". The exemption of this rule from RIA was justified by the emergency cause, whereas low impact would have been the more fitting reason in this case.

In cases where the impacts of a particular rule are low, an RIA should not be required in the first place. The confusion stems in part from the fact that Presidential Order No. 10,411/2020 is notably vague in establishing parameters for identifying low-impact rules.[14] Furthermore, the order does not provide proportionality standards and threshold tests, which OECD recommends (OECD, 2020) for adjusting the depth of impact assessments based on the potential impact of the forthcoming regulation.

According to the OCDE (2022), which recently reviewed Brazil's regulatory policies, these legal loopholes may exempt regulations from RIA that would otherwise merit them. This is precisely what occurred in some emergency cases unrelated to COVID-19 pandemic. One notable instance is the rulemaking process of RDC No. 743/22, which outlined deadlines for the agency to respond to various licenses and registration applications. In addition to setting deadlines with duration proportionate to the risks involved in each kind of economic activity, this rule also specified the activities subject to tacit approval and those that are not. Tacit approval takes place when the lack of response by Anvisa by the deadline is considered a formal approval. Anvisa exempted the issuance of this rule from both RIA and notice-and-comment on emergency grounds. Moreover, it exempted the rule from *ex post* review citing the 'exceptional circumstance cause'. As mentioned earlier, Section 57, § 2°, I of Ordinance No. 162/2021 is typically invoked when *ex post* reviews would incur disproportional costs, a scenario not applicable to license and registration procedures, which impose significant regulatory costs on most industries.

The great majority, however, of emergency rules adopted without RIA during the years 2021-2022 were related to the COVID-19 pandemic. Being the agency at the forefront of confronting the pandemic, Anvisa had to regulate a wide range of subjects, including standards for manufacturing and distributing medicines to treat the disease; manufacturing, importing and commercialization controls for medical devices needed for treating patients hospitalized with coronavirus; sanitary control in ports, airports and land borders;

[13] There are compelling reasons to argue that the agency's broadening interpretation of the emergency provision to exempt RIA is contrary to legislative intent, but we will not delve into this issue in this article.

[14] Presidential Order No. 10, 411/2020 defines a low-impact rule as meeting any one of the following three criteria: (i) a minimal increase in costs for economic agents or users of the services provided; (ii) a negligible rise in budgetary or financial expenses; (iii) a limited impact on public health, safety, environmental, economic, and social policies. Anvisa's Ordinance 162/21 reaffirmed these identical provisions in its text in Section 2.

manufacturing standards for disinfecting products; technical criteria for conducting coronavirus tests in blood, cells, tissues and organs; guidelines for conducting clinic essays and experiments for treating the disease; vaccination measures against influenza during the pandemic; measures against contamination with SARS-CoV-2 in elderly care institutions, etc.[15]

Anvisa waived the requirement for RIA for most of these regulations but committed to conducting the *ex post* review mandated by Section 12 of Presidential Order No. 10,411/2020 within 3 years.[16] Nevertheless, after amending its RIA procedural rules, Anvisa began to waive *ex post* reviews of COVID-19-related rules on the ground they were temporary. As mentioned earlier in Section 2, beyond the 'exceptional circumstance cause' the additional provisions in Section 57 of Anvisa's Ordinance No. 162/2021 granted the agency flexibility to exempt emergency rules from the requirement of *ex post* reviews when these rules were intended for temporary duration (Section 57, § 2°, I). After Anvisa created these *ex post* review exceptions, virtually all emergency rules were simultaneously exempted from RIA and *ex post* review.[17]

The *rationale* behind the "temporary duration" cause for exempting *ex post* reviews, from Anvisa's standpoint, is that it is unwarranted to conduct such a study for a rule that will only be in effect during the period of time in which an emergency or crisis situation persists. Although, to our knowledge, the agencies' exceptions to conduct *ex post* review of emergency rules have not yet been challenged in courts, they appear to embrace the misguided assumption that assessing temporary rules is unimportant. Firstly, because the effects of a temporary rule may have a long duration, much longer than the duration of the interim rule. Second, because health and sanitary crises have become ever more recurrent, and the measures undertaken by the agency to confront COVID-19 might be useful in various other contexts.

An illustrative example is the recently issued RDC No. 760/2022, through which Anvisa temporarily authorized the use of ethyl alcohol 70% as a preventing measure against Monkepox disease. Anvisa has prohibited the use of ethyl alcohol in liquid format since 2002,[18] responding to the high rate of household accidents with the product. However, this prohibition has been temporarily relaxed for short periods since the onset of the COVID-19 pandemic, as a complement to other sanitizing products (see e.g, RDC No. 347/2020). In none of those instances, however, has Anvisa conducted any sort of study to ensure the actual costs and risks involved in authorizing or banning the production and commercialization of the substance, which would be advisable to keep or relax the restrictions for the product either during crises or normal times. These studies appear to be essential either to maintain or relax restrictions for the product, both during crises and normal times.[19]

[15] For a more detailed description of Anvisa's main measures in confronting the pandemic, see (Guerra *et al.*, 2020).

[16] Typically, the documents containing reasons for exempting RIA also included a commitment from the agency to conduct the necessary *ex post* review.

[17] The only two exceptions out of 21 rules issued after the amendment of Ordinance 162/2021 were RDC No. 754/2022 and RDC No. 759/2022, both establishing urgent shipboard sanitary rules. While the Board of Directors contemplated waiving the *ex post* review for these rules, they ultimately decided not to do so.

[18] RDC No. 322/2002 restricted the use of alcohol 70% due to an increase in accidents with this substance.

[19] Anvisa recently determined that ethyl alcohol 70% can be manufactured and commercialized in the country until December 31st, 2023. A company filed a suit to extend Anvisa's licence to sell ethyl alcohol 70% products until

5. Conclusion

Anvisa has been a leading agency in implementing RIA in Brazil for the past 15 years. However, our analysis reveals a decreasing trend in Anvisa's utilization of RIA over time, with a significant drop observed in the years 2021-2022.

Although, at first sight, one might draw the conclusion that the COVID-19 pandemic might have contributed to this scenario, our findings suggest that procedural requirements recently approved by national legislation may have also contributed to the decrease in RIAs and the corresponding rise of exception decisions.

One possible effect of the introduction of more detailed procedural requirements may be an increasing tendency to use causes for not adopting RIA as a convenient procedural short-cut (Smith, 2003; Trigo, 2022).

In this article, we demonstrated that after the implementation of the new RIA regulation, Anvisa started diversifying its reasons for not conducting RIA, with a particular emphasis on cases where the agency deems RIA inapplicable, such as it happens with rules consolidating the agecy's regulatory stock. In these cases, Anvisa does not provide any formal document substantiating which rules are being consolidated and, more importantly, demonstrating that the new consolidating rule does not imply the creation of new regulatory burdens on regulated entities or consumers. As these cases have become predominant in recent times, they should also become more transparent.

Regarding exemption cases, where agencies have the discretion not to proceed with RIA when they consider it necessary, we have shown that emergency still remains the main justification, even after the recent passage of federal RIA regulation. We observed that Anvisa has incorrectly classified some of its exemption cases as "emergency cases" when they should be categorized as "low impact" cases. This issue will only be resolved when the agency establishes better standards for recognizing low-impact cases and determines transparent, fast-track procedures to address them.

An unanticipated effect of this misclassification is the trivialization of the use of emergencies for exempting RIA. By classifying everything as "urgent," it becomes challenging to differentiate genuine emergencies from non-genuine ones. This trivialization leads to a second unanticipated effect, essentially avoiding *ex post* reviews of regulations when they should otherwise occur.

We contend that Anvisa's approach to handling a large number of exemption cases for emergency regulations is misguided. If a regulation is truly worthy of an RIA but urgency demands its exemption, an *ex post* review, even for a temporary rule, is essential to enhance the agency's capacity to deal with emergencies, to allow regulators to learn from occasional mistakes, and, more importantly, to ensure that the agency is held accountable to the public.

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