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THE REGULATION OF THE USE OF ELECTRONIC CIGARETTES IN BRAZIL: AN ANALYSIS BASED ON ANVISA'S RDC 855[1]

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ABSTRACT

The popularization of electronic cigarettes in Brazil has generated intense legal and health debates, especially due to the growing adherence of young people to these devices. Even though they are prohibited by ANVISA through RDC No. 855/2024, the so-called "vapes" and "pods" continue to be widely used, challenging the current regulatory effectiveness. The absence of specific regulation on their trade and use reveals a critical gap in state control of this new form of consumption of nicotine and other psychoactive substances. The present research is based on the following problem: what are the guidelines brought by ANVISA's RDC 855 regarding the regulation of the use of electronic cigarettes in Brazil? In addition, the legislation applicable to traditional cigarettes, the grounds for the prohibition by ANVISA and the possible fiscal effects of a possible release are investigated. The general objective of the research is to analyze the regulation of the use of electronic cigarettes based on ANVISA's RDC No. 855. The methodology adopted was based on the analysis of scientific articles, specific laws, norms and resolutions of agencies such as the Ministry of Health and ANVISA itself. The approach was quantitative-qualitative, supported by the legal dialectical method, with systematic bibliographic and documentary review. Data collection was carried out through databases such as SciELO, PubMed, Web of Science, and UNA-SUS, using descriptors such as "electronic cigarette", "right to health", and "impact". The results demonstrate that electronic cigarettes are inserted in a fragile regulatory scenario, in contrast to traditional cigarettes, which are already widely regulated. ANVISA's performance is based on the precautionary principle, while legislative projects diverge between criminalization and regulation. It is concluded that facing the issue requires integrated public policies, based on scientific evidence, aimed at protecting public health, especially among Brazilian youth.

Keywords: Electronic cigarette. ANVISA. Sanitary regulation. Right to health. Selective taxation.

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INTRODUCTION

The popularization of electronic cigarettes in Brazil has generated intense legal and health debates, especially due to the growing adherence of young people to these devices. Even though they are prohibited by ANVISA through RDC No. 855/2024, the so-called "vapes" and "pods" continue to be widely used, challenging the current regulatory effectiveness. The absence of specific regulation on their trade and use reveals a critical gap in state control of this new form of consumption of nicotine and other psychoactive substances.

The choice of the topic is justified by the alarming growth in the use of electronic cigarettes, which increased by 600% between 2018 and 2023. Such progress reveals a phenomenon that goes beyond the boundaries of health law, also becoming a public health problem. In addition, the presence of substances such as nicotine and THC increases the risk of addiction, raising concerns about the medium and long-term effects of these products on the population, especially among adolescents and young adults.

The present research is based on the following problem: what are the guidelines brought by ANVISA's RDC 855 regarding the regulation of the use of electronic cigarettes in Brazil? In addition, the following question is asked: which laws are applicable to traditional cigarettes? What are ANVISA's main arguments for banning electronic cigarettes? Would it be possible to release these provisions through legislation? If so, what are the tax impacts of the release? Such questions guide the legal, normative and fiscal analysis of this investigation.

The general objective of the research is to analyze the regulation of the use of electronic cigarettes based on ANVISA's RDC No. 855. As specific objectives, it is proposed: to compare the legislation applicable to traditional cigarettes with that of electronic cigarettes; present ANVISA's main arguments for the prohibition of these devices; discuss the possibility of its release through legislation; and analyze the tax impacts that could result from this eventual release.

The methodology adopted is based on the analysis of scientific articles, specific laws, norms and resolutions of agencies such as the Ministry of Health and ANVISA itself. The approach is quantitative-qualitative, guided by the legal dialectical method. Data collection was carried out in databases such as SciELO, PubMed, Web of Science and UNA-SUS, using descriptors such as "electronic cigarette", "nicotine", "tobacco", "right to health" and "impact". The systematization allowed an integrated understanding of the legal, health and fiscal implications of the theme.

TRADITIONAL CIGARETTE AND ELECTRONIC CIGARETTE

INITIAL CONSIDERATIONS

The consumption of tobacco products has undergone significant transformations in recent decades. Traditional cigarettes, long known for their harmful effects on health, have started to share space with new forms of consumption, such as electronic cigarettes. These devices emerge as technological alternatives to conventional smoking, changing not only consumer behavior, but also the regulatory challenges imposed on the State (Rotta et al., 2024).

Traditional cigarettes are made up of processed tobacco leaves, wrapped in paper and usually accompanied by a filter. When lit, the tobacco combusts, releasing a mixture of toxic substances, including nicotine, tar, and carbon monoxide. The smoke generated is highly harmful to both active and passive smokers, being one of the main preventable causes of death according to the World Health Organization (Cavalcanti et al., 2023).

Electronic cigarettes, also called electronic smoking devices (DEFs), work by vaporizing liquids. These liquids, called e-liquids or juices, contain propylene glycol, vegetable glycerin, nicotine in different concentrations and flavorings. The goal is to simulate the act of smoking, without involving the direct combustion of tobacco, which would supposedly reduce health risks (ROTTA et al., 2024).

Despite this promise of less harm, e-cigarettes continue to generate controversy. The absence of burning does not mean the absence of toxicity, and the long-term effects of inhaling vapor with nicotine are not yet fully known. In addition, research points to an increase in the use of these devices among adolescents and young adults, raising concerns about a possible "gateway" to smoking (BARUFALDI et al., 2021).

A point of convergence between the two products is the presence of nicotine. This psychoactive substance acts on the central nervous system, generating dependence and changes in behavior. Whether in traditional or electronic cigarettes, nicotine is the main agent responsible for the continuity of the smoking habit, which keeps the topic at the center of public health debates (INSTITUTO NACIONAL DE CÂNCER, 2024).

As a result, the regulatory challenge intensifies. Traditional cigarettes are already subject to a well-established legal structure in Brazil, with express prohibitions on advertising, requirements for health warnings and restrictions on use in closed environments. However, electronic devices still face a legislative vacuum, being mostly regulated by administrative rules, such as those of the National Health Surveillance Agency (ANVISA) (NATIONAL CANCER INSTITUTE, 2024).

In this context, it is urgent to analyze comparatively the legal regimes applicable to these two products. The tension between technological innovation and the protection of public health imposes on the Law the need to balance constitutional principles, such as freedom of initiative and the right to health, with effective regulatory strategies. The normative comparison allows us to understand how the Brazilian legal system responds to the challenge of protecting public health in the face of new and traditional forms of exposure to nicotine.

LEGISLATION APPLICABLE TO TRADITIONAL CIGARETTES

Traditional cigarettes are regulated in Brazil by a robust set of rules that aim to restrict their consumption and mitigate damage to public health. The starting point of this regulation is in the Federal Constitution of 1988 itself, which establishes, in article 196, that health is a right of all and a duty of the State, and must be guaranteed through public policies aimed at reducing the risk of diseases and other problems.

Based on this constitutional guideline, several infra-constitutional laws were enacted with the objective of regulating the production, commercialization and consumption of cigarettes. Among the most relevant, Law No. 9,294/1996 stands out, which provides for restrictions on the use and advertising of tobacco products, alcoholic beverages, medicines and therapies. This rule prohibits smoking in closed collective environments, public or private, in addition to establishing strict limits for commercial advertising of cigarettes (BRASIL, 1996).

Complementing this legal framework, Law No. 10,167/2000 amended provisions of Law No. 9,294/1996, tightening the prohibition of cigarette advertising in the mass media. Any form of commercial advertising of smoking products is now prohibited, except in places of sale, and even then with restrictions on form and content. This legislation was a milestone in the fight against smoking induction by the industry. (BRAZIL, 2000).

In the administrative field, the performance of the National Health Surveillance Agency (ANVISA) stands out, through the Resolution of the Collegiate Board of Directors (RDC) No. 46/2009. This resolution provides for the packaging of tobacco products, requiring the inclusion of health warnings with impactful images and informative texts about the harm of smoking. It also prohibits the use of terms such as "light", "mild" or any other expression that suggests less harm (ANVISA, 2009).

Another measure with a strong impact was RDC No. 14/2012, or rather Resolution of the Collegiate Board of the Ministry of Health, which prohibited the addition of substances that can confer flavor or aroma to cigarettes, such as menthol and cloves. The

objective was to prevent such additives from making the product more attractive, especially for young people and beginners. This measure follows the international trend of making cigarettes less palatable and, therefore, less consumed (BRASIL, 2012).

Brazil is also a signatory to the Framework Convention on Tobacco Control, an international treaty of the World Health Organization ratified by the country through Decree No. 5,658/2006. This instrument commits signatory countries to adopt public policies to restrict tobacco, including pricing actions, control of advertising, warnings on packaging and smoking cessation programs (BRASIL, 2006).

Still from a tax perspective, cigarettes are heavily taxed in Brazil. High taxes on tobacco products are part of a public health strategy, as price increases are one of the most effective factors in reducing consumption. This is achieved through high rates of IPI, ICMS and contributions on the sector, with direct effects on the final price to the consumer.

From the consumer's point of view, the Consumer Protection Code (Law No. 8,078/1990) also applies to cigarettes. Even if it is a legally marketed product, there are duties of clear information about the risks of consumption, civil liability of the industry in certain situations and protection of consumer health, as provided for in article 6, item I, of the CDC (BRASIL, 1990).

Therefore, traditional cigarettes are the object of a broad legislation, articulated between constitutional norms, ordinary laws, decrees, administrative resolutions and international treaties. The focus of this regulation is to reduce the impact of smoking on the community, without, however, promoting an absolute prohibition, which demonstrates a state option for restrictive regulation instead of illegalization.

LEGISLATION APPLICABLE TO ELECTRONIC CIGARETTES

Unlike traditional cigarettes, electronic cigarettes or electronic smoking devices (EDDs) face a fragmented and constantly disputed regulatory landscape. In Brazil, these provisions are not expressly regulated by ordinary law, but by administrative rules, especially those of the National Health Surveillance Agency (ANVISA). The initial milestone of this regulation is the Resolution of the Collegiate Board of Directors (RDC) No. 46/2009, which prohibited the commercialization, importation and advertising of any electronic smoking devices, including those with or without nicotine (BRASIL, 2009).

This rule was later reinforced by RDC No. 528/2021, which maintained the current prohibition and recommended the continuation of the restriction until there is robust scientific evidence regarding the safety and efficacy of DEFs. ANVISA's central justification is the precautionary principle, enshrined in health law, which authorizes restrictive

measures in the face of potential risks to public health that are not yet fully known (BRASIL, 2021).

Based on this understanding, the sale of electronic cigarettes in Brazil is, so far, considered illegal, even if widely disseminated in practice. Digital platforms, informal trade and direct importation by individuals challenge the effectiveness of the rule, revealing a mismatch between formal regulation and market reality. This situation reinforces the urgency of a specific and updated legal framework on the subject.

At the international level, some countries adopted different approaches, which influenced the debates in Brazil. The United Kingdom, Canada, and the United States have chosen to regulate e-cigarettes as smoking cessation devices as long as they meet stringent technical requirements. Countries such as Australia and India, on the other hand, have adopted restrictive measures similar to those in Brazil, also based on the precautionary principle (AGENCIA BRASIL, 2025).

From a constitutional point of view, ANVISA's understanding is anchored in health protection (article 196 of the Federal Constitution) and in the agency's competence to regulate and restrict products that pose a health risk, as provided for in Law No. 9,782/1999. This law gives ANVISA the authority to act in the regulation of products that affect individual and collective health, and its action is linked to the public interest and the defense of the Unified Health System (SUS) (BRASIL, 1999).

ANVISA AND THE BAN ON ELECTRONIC CIGARETTES

The National Health Surveillance Agency (ANVISA) has maintained its position against the release of electronic smoking devices (DEFs) through an eminently technical-scientific approach, aligned with the protection of public health. This position was consolidated in RDC No. 855/2024, which updates and replaces the former RDC No. 46/2009, reaffirming the prohibition of the manufacture, commercialization, distribution, transportation, and advertising of these products in the national territory. The new regulation not only reiterates the historical foundations of the prohibition, but also updates concepts and expands the hypotheses of prohibition, based on recent health and consumption data.

The text of RDC No. 855/2024 is emphatic in establishing that the prohibition extends to all types of electronic smoking devices, including electronic cigarettes, vapes, pod systems, heated tobacco devices (HTPs), and any associated accessories, refills, parts, or components. In addition, the rule innovates by expressly prohibiting the entry of these products into the country even by means of accompanied luggage, preventing their circulation under any form of private importation. The scope of the rule demonstrates

ANVISA's attempt to contain the growth of an informal market that, although illegal, has been consolidating especially among young people.

The agency's central motivation is based on the absence of solid scientific evidence about the safety of DEFs. According to the technical reports of the General Management of Registration and Inspection of Smoking Products (GGTAB), no electronic smoking device has been approved in Brazil as safe for human use or as an auxiliary therapy in smoking cessation. The studies analyzed by the agency show that most of these products contain nicotine at high levels, as well as solvents and flavorings that, when heated, can generate toxic and potentially carcinogenic compounds, such as formaldehyde and acrolein.

Another central element in ANVISA's reasoning is the finding that DEFs do not promote harm reduction, as is often alleged by the industry. The Regulatory Impact Analysis (RIA) conducted in 2022, available on the agency's official website, makes it clear that reducing the emission of toxic substances does not necessarily translate into a reduction in health risk. The lack of standardization of liquids, the different device models and the variability of consumption make it impossible to establish a homogeneous risk profile, making any regulation based on consolidated scientific evidence difficult.

The GGTAB also shows that DEFs are being strongly promoted to vulnerable groups, especially adolescents and young adults. The marketing of these products, often linked to digital aesthetics and pop culture, associates e-cigarettes with concepts of modernity, freedom, and healthy lifestyle — elements that mask the real dangers of the product. Reports presented by the agency point out that first-time users of DEFs are two to three times more likely to migrate to conventional tobacco, contrary to the argument that the devices would act as transition tools for smoking cessation.

In addition to toxicological and behavioral risks, ANVISA highlights the emergence of new dangers associated with the poor quality of electronic devices. The lack of inspection and technical control in the units sold clandestinely has resulted in cases of burns, leaks of concentrated liquids, electrical failures and even explosions. In view of this situation, RDC No. 855/2024 also prohibits indirect advertising of these devices, including through the internet or visual elements that may refer to their formats, colors, or modes of use.

Another robust argument of ANVISA is the potential negative economic impact on the Unified Health System (SUS). The agency projects that, if released, DEFs would contribute to the increase in respiratory, cardiovascular and neurological diseases related to the use of nicotine and other volatile compounds. Although long-term data are not yet fully consolidated, the prevalence of new clinical conditions associated with the use of these

products in countries that have released them, such as the United States, has already shown significant pressure on public health systems.

Public Consultation No. 1,222/2023, which preceded the publication of RDC No. 855/2024, aimed to expand the democratic debate and capture technical, legal, and social contributions on the subject. The process registered more than 7,600 manifestations from civil society, medical, scientific and business entities. Most of the contributions, according to ANVISA, supported the maintenance of the ban, especially based on data presented during the 19th Ordinary Public Meeting of the Collegiate Board, held on December 1, 2023. This process guaranteed democratic legitimacy to the decision, even in the face of pressure from the tobacco industry.

It is important to note that RDC No. 855/2024 keeps open the possibility of future revision of the ban, provided that new robust scientific evidence is presented. To this end, article 5 of the rule determines that ANVISA carries out systematic reviews of the literature, as long as they are free of conflict of interest, and allows the protocol of independent scientific studies. This provision demonstrates that the agency's position is not ideological or dogmatic, but rather based on objective and technical criteria, based on public health and science.

Another point often emphasized is that the release of electronic cigarettes would put Brazil in disagreement with its public policy for tobacco control, internationally recognized as one of the most effective in the world. The country is a signatory to the WHO Framework Convention on Tobacco Control, whose guidelines guide the development of legislative and administrative measures aimed at preventing smoking initiation and promoting smoking cessation. For ANVISA, allowing DEFs to enter the Brazilian market would represent a regulatory and sanitary setback.

The data on the prevalence of use presented by the GGTAB also reinforce the effectiveness of the current prohibition. According to national studies, such as Vigitel (2019-2023) and PeNSE (2019), Brazil has one of the lowest rates of electronic cigarette use in the world. This is in stark contrast to countries that have adopted liberalization policies, such as the United Kingdom, Canada, and New Zealand, where consumption among young people exceeds 20%. The agency warns that, even with the growth of the illegal market, the ban in Brazil is still effective in containing large-scale use.

TAX ASPECTS OF THE RELEASE OF ELECTRONIC CIGARETTES

The taxation of electronic cigarettes in Brazil is one of the great regulatory challenges of today, involving fiscal, health, environmental and child and youth protection

aspects. The recent entry into force of Complementary Law No. 214, of January 16, 2025, which institutes the Selective Tax (IS), in addition to the IBS and CBS, inaugurates a new phase for the taxation of products harmful to health, including electronic smoking devices (DEFs), such as electronic cigarettes and heated tobacco products (BRASIL, 2025).

The Selective Tax was created with the objective of levying on goods and services that are harmful to health and the environment. Its purpose, clearly extra-fiscal in nature, is precisely to discourage the consumption of these products through high rates. In this sense, electronic cigarettes are now part of a list of goods subject to differentiated taxation, given their proven health impact, as attested in several INCA technical notes and reports by the National Commission for the Implementation of the Framework Convention on Tobacco Control (CONICQ) (INCA, 2023; CONICQ, 2023).

The normative consolidation conferred by LCP No. 214/2025 eliminates the legal uncertainty that marked the previous debates. With the creation of the IS, the tax system now has a permanent tool to selectively levy on products such as electronic cigarettes. This measure is in line with Article 6 of the WHO Framework Convention, which guides signatory countries to adopt tax policies as a central instrument in tobacco control and public health protection (CONICQ, 2023).

In the Brazilian case, the fiscal and health scenario imposes a rigorous approach. The annual financial impact of smoking — including electronic devices — has already reached the mark of R$ 125 billion, of which R$ 50 billion is directly related to the cost of medical treatments in the Unified Health System (SUS). On the other hand, the most optimistic projections of revenue from the regularization of electronic cigarettes indicate gains of only R$ 2 to R$ 3 billion, revealing a profound disproportionality between cost and fiscal benefit (PINTO, 2024).

Given this equation, the high taxation of DEFs via Excise Tax is not only a technical choice, but an ethical imposition from the point of view of public policies. It is about preventing the collection from occurring at the expense of a collective illness that overloads the health system and aggravates social inequalities, especially among the youngest — the public most vulnerable to the marketing appeals of these products (INCA, 2023; PINTO, 2024).

Complementary Law No. 214/2025 regulates in detail the calculation basis, the taxable event and the rates applicable to IS. The calculation basis will be the value of the operation, including the full amount charged, including charges and applicable taxes. The IS rates, as provided, must be set by a specific law with a regulatory function, allowing their adaptation to the severity of the risk that the product represents. This reinforces the

possibility of applying increased rates to DEFs, analogous to those already applied to conventional cigarettes (BRASIL, 2025).

From a technical point of view, electronic smoking devices cannot be considered less harmful or tax-exempt alternatives. The INCA Technical Note (2023) points to robust evidence that such devices cause severe lung injury (such as EVALI), cardiovascular damage, severe nicotine dependence, and increase the risk of smoking initiation among young people. In addition, they generate toxic waste — such as lithium batteries and heavy metals — with significant polluting potential, which aggravates the reasons for their taxation via SI (INCA, 2023).

Another relevant aspect is that, unlike what occurs with medicines or essential inputs, the consumption of DEFs is not productive or necessary. Its increased taxation does not distort beneficial economic decisions, nor does it compromise strategic productive sectors. On the contrary, it contributes to reallocating public resources currently spent on hospitalizations and treatments, and discourages practices that are harmful to public health (CONICQ, 2023).

Historically, Brazil has achieved important victories in tobacco control, especially after the traditional cigarette tax reform in 2011, which raised prices, reduced accessibility, and increased revenue, even in the face of the growth of illicit trade. However, after 2014, there was a freeze in pricing policies, making room for the advance of cheap brands and the introduction of electronic cigarettes, often marketed clandestinely and without any effective taxation (UIC, 2020).

Complementary Law No. 214/2025 corrects part of this gap by structuring a more efficient and harmonious system of taxation on goods and services, with emphasis on IS. In addition, the law provides for the adoption of the split payment mechanism, which allows the automatic collection of taxes at the time of the financial transaction, significantly reducing tax evasion — a recurring problem in the tobacco sector (BRASIL, 2025).

The role of digital platforms as joint and several tax liables in transactions with tobacco goods — including electronic cigarettes — also represents a relevant innovation. This measure attacks one of the main irregular sales channels of DEFs, which use applications, social networks and marketplaces to reach young consumers. Tax control is thus strengthened as an instrument of health policy and consumer protection (BRASIL, 2025).

Finally, the consolidation of the IS as a tax with a regulatory function reinforces the responsibility of the Brazilian State to protect public health, especially that of future generations. International experience, such as that of the United Kingdom, which recently

banned the sale of electronic cigarettes to children under 15 years of age, signals that Brazil must maintain the vanguard line in tobacco control, now extended to electronic devices. Taxation is, in this sense, a fundamental pillar of national health sovereignty (PINTO, 2024; INCA, 2023).

POSSIBILITIES FOR THE RELEASE OF ELECTRONIC CIGARETTES IN BRAZIL

The possibilities of releasing electronic cigarettes in Brazil reveal an intense clash between different regulatory views. In progress in the National Congress, two antagonistic bills highlight this dispute: Senator Soraya Thronicke's bill, which proposes a broad and detailed regulation to authorize the use of these devices; and the bill by Deputy Flávia Morais, which intends to completely criminalize the production, commercialization and advertising of electronic smoking devices (DEFs).

The Senate bill, filed in 2023, proposes to release DEFs, provided that strict requirements are met. The proposal provides for the mandatory registration of products with Anvisa, the requirement of toxicological reports, quality control by Inmetro and technological regulation by Anatel. Clear limits are set for nicotine content, prohibition of open systems and dangerous substances, such as vitamin E, caffeine and essential oils, in order to ensure consumer safety.

The senator argues that the current prohibition, provided for in Anvisa's Resolution RDC No. 46/2009, has proven to be ineffective. Data show that the number of electronic cigarette users rose from 500 thousand in 2018 to 2.2 million in 2022. Despite the legal prohibition, the growth in use demonstrates inspection failures and growing informality, which would justify, according to the author of the bill, a regulatory approach instead of a simple prohibition.

The project's justification cites international experiences as a basis for change. Countries such as the United Kingdom, Canada, and the United States have chosen to regulate e-cigarettes. The United Kingdom even uses them as a tool for smoking cessation, according to a study by King's College London. The US FDA has also approved devices considered less harmful to health, reinforcing the viability of rigorous and scientific regulatory models.

In this context, Soraya Thronicke's proposal emphasizes the need to align Brazil with modern regulatory practices. It is argued that the regulation will not only allow greater sanitary control, but will also enable tax collection and effective protection of consumers. The absence of rules would favor the informal market, where there is no control of composition, labeling or marketing, which increases the risks to public health.

In total opposition, Bill No. 2,158/2024, presented by Flávia Morais, intends to criminalize all steps related to DEFs. The proposal inserts in the Penal Code the typification of a crime with a penalty of imprisonment of one to three years, in addition to a fine, for those who manufacture, sell or advertise these products. The use of the devices in closed places, public or private, is also prohibited, reinforcing the restrictive stance of the proposal.

The deputy bases her proposal on the protection of collective health, especially of children and adolescents. It highlights WHO studies that indicate the risk of electronic cigarettes in early smoking initiation and lung and cardiovascular damage. Anvisa's Resolution RDC No. 855/2024, which reinforced the prohibition of DEFs in the country, is mentioned as institutional support for criminalization, reiterating Brazil's position of health precaution.

The bill also proposes changes to the School Health Program (PSE), established by Decree No. 6,286/2007, to include actions to prevent the use of DEFs. The proposal bets on educational campaigns, more intense inspection and criminalization to contain the advance of use, especially among young people. According to data from the Ministry of Health, adolescents who use electronic cigarettes are more likely to consume conventional cigarettes in the future.

Proponents of the ban allege that the e-cigarette industry uses covert marketing strategies, especially on social media, luring teenagers with sweet flavors, colorful packaging and apparent modernity. For these critics, allowing commercialization, even if regulated, opens space for normalization of consumption and reinforces a culture of use among non-smokers, especially in younger age groups.

On the other hand, the defenders of the regulation argue that the Brazilian model is ineffective. The ban did not reduce consumption, nor did it prevent clandestine marketing. For these parliamentarians, following the regulatory models adopted by OECD countries would bring tax benefits, greater quality control and greater protection for consumers, including health warnings and sales restrictions.

The two bills reflect diametrically opposed views on the role of the state. While the senator's bill defends a regulatory state that allows controlled access to devices, the deputy's proposes a prohibitionist state, based on the precautionary principle. Both recognize the risks of using electronic cigarettes, but differ on the most effective legal path to address them.

From a legislative point of view, the debate will require complex balances between economic freedom, the right to health and state responsibility. The release may facilitate the collection of taxes and give legal support to inspection, but it also imposes challenges

regarding the control of access by minors and veiled advertising. The ban, on the other hand, aims to prevent the spread of use, but can push consumption to illegal and unsupervised markets.

The Brazilian reality shows a market for DEFs already in full expansion, despite the ban. There is circulation of uninspected products, without quality control and with commercial strategies aimed at children and adolescents. This situation weakens the principle of consumer protection and requires a clear legislative position on the normative treatment of electronic cigarettes in the country.

If Brazil opts for regulation, as proposed by the Senate bill, it will be necessary to institute a robust regulatory framework. This framework should provide for strict sanctions, sanitary control and limitations on advertising, as occurs with medicines and alcoholic beverages. The priority will be to protect vulnerable groups without ignoring the existence and risks of consumption already present in society. As the National Cancer Institute (INCA) points out, effective regulation of these devices is essential to reduce harm and prevent early access among young people (INCA, 2023).

On the other hand, if the criminalization proposed by the Chamber's bill prevails, it will be essential to strengthen inspection mechanisms, curb irregular trade and invest in preventive education. The fight against the indiscriminate use of DEFs, in this case, will depend on the effectiveness of public health and safety policies, as well as on society's adherence to the paradigm of total abstinence. As pointed out in a report by the World Health Organization, the prevention of the use of electronic devices is more effective when combined with firm prohibitions and educational strategies aimed at young people (WHO, 2021).

In short, the legislative fate of electronic cigarettes in Brazil is open, divided between two distinct paths. On the one hand, regulation as a form of control and protection. On the other hand, prohibition as an instrument of absolute prevention. In both cases, the debate must be guided by scientific evidence, respect for fundamental rights, and commitment to the public health of future generations. According to Pinto (2024), the tax and health regulation of DEFs, which still does not exist, represents a fiscal and public health risk that needs to be seriously addressed.

The regulation or prohibition of electronic cigarettes is not limited to an individual health issue, but directly involves the formulation of effective, transparent public policies supported by scientific data. Recent studies indicate that the absence of specific legislation favors informality, smuggling, and the exposure of young people to potentially harmful products (CONICQ, 2023). Thus, any legislative decision needs to consider not only the

immediate impacts, but the intergenerational and structural effects on the health system and the national economy.

FINAL CONSIDERATIONS

Based on the analysis developed throughout this study, it is concluded that electronic cigarettes represent one of the most complex regulatory challenges in Brazil today. The growing adherence to these provisions, even in the face of the current prohibition imposed by ANVISA's RDC No. 855/2024, reveals a normative gap that compromises the effectiveness of health control policies. The persistence of consumption, especially among adolescents, requires more consistent responses from the State, which unite regulation, inspection and preventive education.

The comparison between traditional cigarettes and electronic cigarettes shows significant normative inequalities. While conventional cigarettes are part of a robust legal framework, with well-consolidated constitutional, infra-constitutional and administrative provisions, electronic devices still depend mostly on administrative resolutions. This difference contributes to the expansion of the informal market and weakens the control over products with relevant toxicological risks.

In the tax field, the importance of Complementary Law No. 214/2025, which instituted the Selective Tax as a tool to discourage the consumption of products harmful to health, stands out. Although the regulation of electronic cigarettes may generate some revenue, the estimated costs for the Unified Health System (SUS) far outweigh the possible fiscal gains. Thus, taxation must fulfill an extra-fiscal function, discouraging consumption and reinforcing the protection of collective health.

The legislative dispute between the bills in progress in the National Congress reveals two distinct paths: strict regulation, as advocated by the Senate bill, and total criminalization, as proposed by the Chamber of Deputies. Both recognize the risks of DEFs, but differ on the most appropriate strategy. The decision between regulating or prohibiting will require considerations about economic freedom, the state's duty to protect and the effectiveness of the rules in the face of the reality of consumption already installed.

Thus, any normative measure regarding electronic cigarettes must be based on robust scientific evidence, in line with the constitutional principles of human dignity and the right to health. Tackling this phenomenon requires articulated public policies that consider the intergenerational impacts of consumption and prioritize the protection of vulnerable groups. Only an integrated approach will be able to efficiently respond to the challenges brought about by electronic smoking devices.

REFERENCES

1. Agência Nacional de Vigilância Sanitária. (2009a). Resolução RDC nº 46, de 28 de agosto de 2009. Dispõe sobre as embalagens de produtos fumígenos derivados do tabaco. Diário Oficial da União.

2. Agência Nacional de Vigilância Sanitária. (2009b). Resolução RDC nº 46, de 28 de agosto de 2009. Dispõe sobre a proibição da comercialização, importação e propaganda de quaisquer dispositivos eletrônicos para fumar. Diário Oficial da União. https://www.in.gov.br

3. Agência Nacional de Vigilância Sanitária. (2024). Resolução RDC nº 855, de 27 de março de 2024. Dispõe sobre a proibição de dispositivos eletrônicos para fumar no território nacional. Diário Oficial da União. https://www.in.gov.br

4. Barufaldi, L. A., & et al. (2021). Risco de iniciação ao tabagismo com o uso de cigarros eletrônicos: Revisão sistemática e meta-análise. Ciência & Saúde Coletiva, 26(12), 6089–6103. https://doi.org/10.1590/1413-812320212612.35032020

5. Brasil. (1988). Constituição da República Federativa do Brasil. Diário Oficial da União.

6. Brasil. (1990). Lei nº 8.078, de 11 de setembro de 1990. Dispõe sobre a proteção do consumidor e dá outras providências. Diário Oficial da União.

7. Brasil. (1996). Lei nº 9.294, de 15 de julho de 1996. Dispõe sobre as restrições ao uso e à propaganda de produtos fumígenos, bebidas alcoólicas, medicamentos e terapias, nos termos do § 4º do art. 220 da Constituição Federal. Diário Oficial da União.

8. Brasil. (2000). Lei nº 10.167, de 27 de dezembro de 2000. Altera dispositivos da Lei nº 9.294, de 15 de julho de 1996. Diário Oficial da União.

9. Brasil. (2006). Decreto nº 5.658, de 2 de janeiro de 2006. Promulga a Convenção-Quadro para o Controle do Tabaco da Organização Mundial da Saúde. Diário Oficial da União.

10. Brasil. (2007). Decreto nº 6.286, de 5 de dezembro de 2007. Institui o Programa Saúde na Escola - PSE, e dá outras providências. Diário Oficial da União. https://www.planalto.gov.br/ccivil_03/_ato2007-2010/2007/decreto/d6286.htm

11. Brasil. (2011). Lei nº 12.546, de 14 de dezembro de 2011. Altera dispositivos da legislação tributária federal relativos à incidência do IPI sobre cigarros. Diário Oficial da União.

12. Brasil. (2012). Resolução RDC nº 14, de 15 de março de 2012. Dispõe sobre os aditivos nos produtos fumígenos derivados do tabaco. Diário Oficial da União.

13. Brasil. (2024). Projeto de Lei nº 2.158, de 2024. Altera o Decreto-Lei nº 2.848, de 7 de dezembro de 1940 (Código Penal), para tipificar os crimes relacionados à produção, comercialização, distribuição e uso de dispositivos eletrônicos para fumar. Câmara dos Deputados. https://www.camara.leg.br/proposicoesWeb/fichadetramitacao?idProposicao=2367575

14. Brasil. (2025). Lei Complementar nº 214, de 16 de janeiro de 2025. Institui o Imposto sobre Bens e Serviços (IBS), a Contribuição Social sobre Bens e Serviços (CBS) e o Imposto Seletivo (IS). Diário Oficial da União. https://www.planalto.gov.br

15. Brasil. Senado Federal. (2023). Projeto de Lei do Senado, de 2023. Dispõe sobre a regulamentação da produção, comercialização e uso de dispositivos eletrônicos para fumar. https://www25.senado.leg.br/web/atividade/materias/-/materia/160870

16. Cavalcanti, J. V. C., & et al. (2023). Análise comparativa dos efeitos do uso de cigarro eletrônico e cigarro convencional nos sistemas cardiovascular e respiratório. Research, Society and Development, 12(7), Article e13312742655. https://doi.org/10.33448/rsd-v12i7.42655

17. Comissão Nacional para Implementação da Convenção-Quadro para o Controle do Tabaco. (2023). Cigarros eletrônicos e reforma tributária: Contribuições para a regulação fiscal de produtos de tabaco no Brasil. Instituto Nacional de Câncer. https://www.inca.gov.br

18. Food and Drug Administration. (2022). Premarket tobacco product applications. https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/premarket-tobacco-product-applications

19. Instituto Nacional de Câncer. (2023). Nota técnica 2023 – Dispositivos eletrônicos para fumar. https://www.inca.gov.br/publicacoes/nota-tecnica-dispositivos-eletronicos-para-fumar

20. Instituto Nacional de Câncer. (2024). Dispositivos eletrônicos para fumar: Conheça os danos que eles causam. https://www.inca.gov.br

21. King's College London. (2022). Nicotine vaping in England: 2022 evidence update. Office for Health Improvement and Disparities. https://www.kcl.ac.uk/news

22. Pinto, É. G. (2024). Risco fiscal da liberação do cigarro eletrônico alcança R$ 125 bi/ano. Comissão de Assuntos Econômicos do Senado. https://legis.senado.leg.br

23. Rotta, A. E. S., & et al. (2024). Os efeitos do uso do cigarro eletrônico na saúde dos usuários: Uma revisão integrativa. Research, Society and Development, 13(3), Article e9913345359. https://doi.org/10.33448/rsd-v13i3.45359

24. University of Illinois at Chicago. (2020). Política tributária do cigarro no Brasil: Tendências recentes, desafios atuais e caminhos a seguir. Tobacconomics.

25. World Health Organization. (2021). Electronic nicotine delivery systems: A policy brief. https://www.who.int/publications/i/item/9789240039903