Athens Journal of Law 2026, 12: 1-19
https://doi.org/10.30958/ajl.X-Y-Z

Regulatory Impact Analysis in Brazilian Health Surveillance: An Examination of Anvisa's Methodological Practices

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This article analyses the decision-making architecture of the National Health Surveillance Agency (ANVISA) from the perspective of the OECD's Cost-Benefit Analysis (CBA) guidelines. Through a systematic documentary analysis of the Regulatory Impact Analysis Reports (RIA) produced between 2022 and 2025, it is demonstrated that the agency operates under a technical-regulatory rationale that favours procedural and qualitative metrics over the economic valuation of social welfare. The systematic absence of indicators such as Net Present Value (NPV), Social Internal Rate of Return (SIRR), and the monetisation of externalities reveals a structural divergence between institutional practice and the scientific standard of allocative efficiency advocated nationally and internationally. It is argued that "scientific uncertainty," repeatedly invoked as a methodological barrier, is treated by the agency as a justification for quantitative inertia, when it could be the subject of stochastic modelling and rigorous sensitivity analysis. The article concludes that ANVISA could broaden its analytical criteria to incorporate the cost-benefit analysis provided for in Article 7, II, of Decree No. 10,411/2020, bringing it closer to the regulatory evidence paradigm required by multilateral organisations and cutting-edge specialist literature.

Keywords: *Regulatory Impact Analysis; ANVISA; cost-benefit analysis; allocative efficiency; health regulation; OECD.*

Introduction

Health regulation occupies a unique position in economic regulation theory. Unlike other regulated sectors, where risks are predominantly concentrated in the economic sphere, the regulation of health products and services deals with potentially catastrophic externalities, involving risks to life, physical integrity and systemic confidence in the markets for medicines and medical technologies. For this reason, the law and economics literature often identifies health regulation as one of the paradigmatic cases in which state intervention finds strong theoretical justification, especially in the face of market failures related to information asymmetry, scientific uncertainty, and negative externalities.

Paradoxically, it is in this very field that the costs of regulation tend to be less visible and more difficult to challenge politically. While regulatory benefits are often presented as diffuse and projected into the future–in the form of avoided risks or prevented harm– regulatory costs manifest themselves immediately and in a

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concentrated manner, affecting specific economic agents and, often, the very dynamics of technological innovation. This temporal and distributive misalignment between costs and benefits generates institutional incentives for regulatory expansion without a corresponding systematic assessment of its economic efficiency, a phenomenon identified in the literature as "pro-regulation bias."

It is precisely in this context that Regulatory Impact Analysis (RIA) emerges as an institutional instrument designed to discipline regulatory decision-making. As widely disseminated by the international guidelines of the Organisation for Economic Co-operation and Development (OECD), analysed below, RIA seeks to introduce analytical rationality, decision-making transparency and technical *accountability* into the regulatory process, mainly through the application of structured methods for assessing the social costs and benefits of regulatory alternatives. At the heart of this methodological toolkit is Cost-Benefit Analysis (CBA), whose purpose is to systematically compare the expected impacts of regulatory options, converting them, whenever possible, into comparable monetary metrics discounted to present value.

In Brazil, the formal institutionalisation of RIA was consolidated with Decree No. 10,411/2020, which regulated its preparation within the scope of federal regulatory agencies, implementing the provisions of Article 6 of Law No. 13,848/2019 (Regulatory Agencies Law) and Article 5 of Law No. 13,874/2019 (Economic Freedom Law). This regulatory framework established procedures, criteria, and minimum steps for the preparation of RIA reports, including the identification of the regulatory problem, the analysis of alternatives, and the assessment of expected impacts.

Among Brazilian regulatory agencies, the National Health Surveillance Agency (ANVISA) is a particularly relevant case for empirical analysis. Due to the breadth and sensitivity of its field of activity – which involves medicines, food, medical devices, and health technologies – ANVISA produces extensive RIA reports that are technically structured and formally compliant with current regulatory requirements. However, a fundamental question remains: to what extent do these reports effectively incorporate the methodological standards of economic efficiency found in the international literature on regulatory analysis?

This article argues that there is a structural deficit of economic efficiency in ANVISA's HIA practice. In analytical terms, it is argued that the agency shows a high degree of formal compliance with the procedural requirements of RIA, but systematically avoids applying its most demanding methodological component: the monetary quantification of the social costs and benefits of regulatory alternatives. This methodological gap compromises RIA's ability to fulfil its central function of disciplining regulatory decision-making through explicit efficiency criteria.

The analysis suggests that this institutional resistance to economic quantification is often justified by two recurring narratives. The first invokes scientific uncertainty, arguing that the absence of robust evidence would make reliable measurement of regulatory impacts unfeasible. The second maintains the moral incommensurability of public health, according to which attempting to monetise benefits related to the protection of health or human life would be normatively inappropriate. Although these objections have philosophical and methodological relevance, the international regulatory analysis literature has developed tools precisely to address these

difficulties, such as methods of statistical value of life, sensitivity analysis, and scenario evaluation.

Given this context, the objective of this article is to critically examine the extent to which the RIA reports produced by ANVISA incorporate the essential methodological elements of cost-benefit analysis as established by OECD guidelines and contemporary literature. In doing so, the study seeks to contribute to the debate on the institutional quality of regulatory governance in Brazil, offering an empirical assessment of RIA practice in one of the most sensitive sectors of regulatory administration.

Against this backdrop, three research questions guide the present inquiry. First, to what extent do ANVISA's RIA reports incorporate the essential elements of cost-benefit analysis as defined by OECD guidelines and contemporary regulatory scholarship? Second, what methodological approaches predominate in these reports, and how does the agency justify its methodological choices? Third, what institutional, epistemic, or normative factors may account for the systematic divergence observed between the agency's formal compliance with RIA procedural requirements and the substantive application of economic valuation methods?

To achieve this objective, the article is structured as follows. Section 1 presents the theoretical and dogmatic foundations of Regulatory Impact Analysis (RIA) and Regulatory Outcome Assessment (ROA), defining their concepts and functions in the regulatory cycle. Section 2 develops the theoretical framework of the research, discussing the fundamentals of cost-benefit analysis in light of OECD guidelines and the law and economics literature. Section 3 describes the documentary research methodology adopted to examine ANVISA's RIA reports. Section 4 presents the results of the empirical analysis, organised into three critical axes. Finally, Section 5 discusses the institutional implications of the findings and proposes ways to improve the AIR methodology in the context of Brazilian health regulation.

Theoretical and Dogmatic Framework of RIA

Regulatory Impact Analysis (RIA) was already being practised in Brazil by some regulatory agencies, which stipulated the need to prepare this document in their internal regulations or in the administrative rules for sectoral standardisation. An example of this is the Internal Regulations of the ANS (National Health Agency), according to Normative Resolution No. 197/2009 and Ordinance No. 354/2006. ANATEL, in Article 62, sole paragraph, of its Internal Regulations (Resolution No. 61212013) determined that the RIA should be prepared prior to the issuance of regulatory acts. Similarly, ANEEL (National Electric Energy Agency) issued, at the time, Organisation Standard No. 40/2013 (Article 2), which requires the use of AIR in its regulatory procedures. ANCINE (National Film Agency) has long been formulating AIRs in the process of standardising the sector. ANVISA (National Health Surveillance Agency), depending on the subject or complexity of the rule to be issued, provided for Regulatory Impact Analysis on three levels (*e.g.* AIR level 1, 2 or 3). For example, level 3 would be applied to high-impact regulatory proposals involving high costs for those affected by the rule or a large budgetary contribution (Palma, 2014).

With the enactment of Law No. 13,848/19 (*General Law on Regulatory Agencies*), the adoption and proposed amendments to normative acts of general interest to economic agents, consumers or users of the services provided shall, under the terms of the regulation, be preceded by a Regulatory Impact Analysis (RIA), which shall contain information and data on the possible effects of the normative act (Art. 6). Even before the enactment of this legislation, the *Economic Freedom Law* (Rule No. 13,874/19) already determined that proposals for the enactment and amendment of normative acts of general interest to economic agents or users of the services provided, enacted by a federal public administration body or entity, including autonomous agencies and public foundations, shall be preceded by a regulatory impact analysis (Article 5). This document must contain information and data on the possible effects of the normative act in order to verify the proportionality (*i.e.,* reasonableness) of its economic impact.

In other words, the RIA is nothing more than an administrative procedure that aims to analyse the burdens and benefits of regulating a given sector, establishing a rational decision on the subject, revealing, to the maximum extent possible, the externalities of regulating a given subject or sector. Thus, this administrative procedure becomes mandatory when considering regulation by such independent agencies. And, in cases where the AIR is not carried out, "[...] at least a technical note or equivalent document that has substantiated the proposed decision must be made available." (Paragraph 5 of Article 6 of Rule No. 13,848/19).

The institutional origins of RIA trace back to the United States, where the Administrative Procedure Act of 1946 first required agencies to state the reasons for their regulatory choices and to hear affected parties. Concerns about regulatory inflation subsequently prompted President Gerald Ford, in 1974, to issue Executive Order No. 11,821, mandating inflationary impact assessments of new regulations. In 1981, President Ronald Reagan substantially expanded this requirement through Executive Order No. 12,291, which made cost-benefit analysis the central evaluative criterion for significant regulations and established the Office of Information and Regulatory Affairs (OIRA) as the central oversight body (Radaelli & Francesco, 2020; Papanicolas, Woskie & Jha, 2018). In the United Kingdom, impact analysis emerged from a distinct political context. The mid-1980s deregulation agenda sought primarily to reduce compliance burdens on businesses, giving rise to the Cost Compliance Assessment (CCA) method – a tool designed to estimate the direct "compliance costs" imposed by proposed rules on regulated entities (Aragão, 2010).

To this end, the results can be obtained from a series of metrics. Many of these are disseminated *by the OECD (Organisation for Economic Co-operation and Development*) to to conduct an analysis of regulatory impacts (OECD, 2008). To this end, it is suggested that the problem be defined first and that its resolution can be justified by state action. It is clear that administrative legality must allow for state action. In this regard, the RIA should demonstrate that the costs of regulation are lower than its benefits. This assessment must be transparent, clear and accessible. It is therefore extremely important to allow everyone to participate in this process.

In addition, the aforementioned document should be responsible for projecting the effects of regulation, especially in terms of national development, protection of the vulnerable, harm or benefit to competition, preservation of fundamental rights,

etc. With regard to the OECD guidelines, the organisation recommends the integration of RIA from the early stages of policy formulation (OECD, 2012). RIA is defined as a tool that provides decision-makers with valuable empirical data (OECD, 2007). Without this comprehensive framework, government action may suffer from flaws due to a poor understanding of the problem (OECD, 2007).

The OECD's recommendations for Brazil suggested standardising RIA to strengthen governance for growth (OECD, 2007). The organisation proposes that the tool clearly define problems and identify the *trade-offs* of different approaches (OECD, 2012). In Brazil, this inspired the PRO-REG Programme, aimed at institutional capacity building.

An important institutional guideline is the creation of a central regulatory quality oversight body (OECD, 2008). This body should oversee the use of RIA in other institutions and provide technical expertise (OECD, 2008). The OECD emphasises that implementation requires a change in administrative culture, often through experimental phases (OECD, 2008).

Public participation is an emphatic guideline of the OECD and should be systematically incorporated through consultations and hearings (OECD, 2015). Stakeholder engagement gathers information dispersed throughout society that the government is unaware of. This ensures greater adherence by those regulated and democratic legitimacy for the standard (MENDONÇA, 2014).

Finally, the OECD recommends conducting periodic "retrospective reviews" of existing regulations (OECD, 2015). This process allows for the identification of obsolete rules or those that negatively impact the economy, enabling their repeal (OECD, 2015). This practice ensures that the regulatory system remains efficient and less costly over time (OECD, 2015).

Thus, when AIR weighs the various interests and considers the possibilities of being effective, it tends to significantly reduce the judicialisation of the regulation under analysis. This proactive and preventive action can be very valuable in achieving legal certainty for the regulated sector. In the United States, there are a series of *Executive Orders* that regulate the RIA procedure (*e.g.,* No. 12,886/1993) and how regulation should be carried out (No. 13,777/2017 and 13,771/2017). These are binding documents, including for independent regulatory authorities.

In other words, AIR allows for concerted or dialogical regulation, insofar as the State builds the normative policy in question together with the affected sectors or with citizens. Or, at the very least, it allows any individual to control the determining factors set out in the impact analysis. The question that always remains is: to what extent does the population have real and effective power to interfere in decision-making processes related to the provision of public services? We will answer this question in the following topic.

Cost-benefit Analysis (CBA) as a Scientific Standard for Regulation

Fundamentals of Cost-Benefit Analysis and OECD Guidelines

Cost-benefit analysis (CBA) has its roots in welfare economics and, more

specifically, in the Kaldor-Hicks criterion, according to which a policy is efficient if the gains of the winners are large enough to compensate, at least hypothetically, for the losses of the losers (EPA, 2010). The pillars of CBA rest on the principles of microeconomics: maximisation, equilibrium and efficiency (Cooter & Ulen, 2012). after all, it is assumed that individuals are rational maximisers of their satisfaction, making choices that minimise costs and increase benefits (Posner, 2014).

In the public sphere, the document aims to highlight the matrix for the allocation of scarce resources, with a view to minimising social costs (Cooter & Ulen, 2012). Therefore, the ethical basis of the technique seeks to overcome the rigidity of the Superior Pareto criterion, which requires that no one be harmed by a change in *the status quo* (Adler & Posner, 2006). In its place, the Kaldor-Hicks criterion, mentioned above, or potential Pareto test, is adopted, because this metric considers that a decision is efficient if the beneficiaries can, theoretically, compensate those who are harmed, generating a net gain in social welfare (Adler & Posner, 2006).

In legal terms, Richard Posner places CBA in the context of legal pragmatism, where wealth maximisation is seen as a goal to be achieved by law (Posner, 1993). Thus, this pragmatism manages to prioritise the empirical method and consideration of the systemic consequences of decisions (Mendonça, 2014), with economic rationality serving as a criterion for assessing the reasonableness of state interventions (Posner, 2010).

A crucial foundation of CBA is its ability to circumvent the harmful effects of cognitive biases, such as biases and heuristics (Kahneman, 2012). Due to these distortions, public decisions may focus on marginal problems, ignoring more serious and risks (Sunstein, 2002), which is crucial to the regulatory issues addressed by ANVISA. Note that quantifying impacts avoids the so-called "simultaneous system of paranoia and negligence" in public management (Sunstein, 2002), a pathology in the public decision-making process characterised by a disproportionate state reaction to certain risks to the detriment of others. This phenomenon occurs when public management is influenced by cognitive biases, such as biases and heuristics, which distort the perception of the probabilities and consequences of certain events.

Additionally, CBA is justified by the strengthening of the democratic regime and transparency (Sunstein, 2002), because it allows for the accountability of government officials by requiring that the assumptions behind decisions be made explicit (Sachs, 2015). In this way, the population can participate in the evaluation process through a well- informed deliberative democracy (Sunstein, 2002).

As for the essential requirements, the procedure requires an "explicit evaluation," overcoming merely implicit convictions of managers (Sen, 2004), so that it is imperative to clearly identify the objective of state action and alternative options, including the cost of inertia. This rationalist transparency allows society to understand the reasons behind the government's choice (Sen, 2004).

Identifying the ownership of affected individuals is another critical procedural requirement (Beck, 2015). The asymmetry between those who make the decision and those who bear the risks must be considered (Beck, 2015). This mapping is essential to assess distributional impacts and ensure that the policy does not disproportionately burden certain segments of the population – an issue related to

vaccination policies, drug dispensing, form of dispensing, etc.

Another essential item, perhaps the most central to the institute, is the detailed cataloguing of impacts, which should include a *risk trade-off analysis* (Graham & Wiener, 1995). After all, it is recognised that minimising one risk can unintentionally exacerbate another secondary risk. For example, banning a toxic substance may lead to the use of a substitute whose effects are still unknown or worse (Revesz & Livermore, 2008).

Monetisation is the distinctive feature of CBA, requiring the conversion of benefits and costs to a common monetary metric scale (Adler & Posner, 2006). Note that when market prices do not exist, methodologies such as "revealed preferences" or "stated preferences" (contingent valuation) are used. These techniques estimate how much society is willing to pay for risk reduction (Adler, 2012), which is very relevant to ANVISA's AIRs.

Another central requirement is the establishment of the "statistical value of life" (VSL), as diagnosed by Sunstein (2014, p. 12): the calculation is based on evidence of individual choices involving trade-offs between risk and money (Viscusi & Aldy, 2003). Although ethically debated, VSL is necessary to prioritise health and safety policies in an impersonal and rational manner (Sunstein, 2014). For impacts that occur at different times, it is essential to use a "social discount rate" (Boardman et al., 2006), bearing in mind that it converts future values into present values, reflecting society's time preference (Cole, 2012). The choice of rate must balance economic efficiency with the moral obligation to future generations.

But that is not all: the qualitative assessment of unquantifiable goods, such as dignity and justice, is part of the requirements of the procedure (Sunstein, 2014). In such cases, *breakeven analysis* helps to identify the minimum value of these goods necessary to justify the costs. This prevents subjective and necessarily protected values from being ignored simply because of the lack of a monetary metric (Sunstein, 2014).

The process ends with a "sensitivity analysis", which investigates the degree of uncertainty in the estimates (Boardman et al., 2006). Here, alternative variables should be tested to ensure that the result is not the result of arbitrary assumptions (Boardman et al., 2006). Finally, the final result is consolidated in a Regulatory Impact Analysis Report (RIA).

The OECD, in its reference document *Cost-Benefit Analysis and the Environment: Further Developments and Policy Use* (2018), establishes that a methodologically robust CBA should include: (i) a precise definition of the counterfactual scenario (*baseline*); (ii) the identification and valuation of all relevant externalities, including non-market ones; (iii) the use of the Value of a Statistical Life (VSL) to monetise impacts on mortality; (iv) the application of a Social Discount Rate for calculating the NPV; and (v) the performance of Sensitivity Analysis to test the robustness of estimates in the face of parametric uncertainty (OECD, 2018). These requirements are not mere academic technocracy. They respond to a fundamental democratic concern: if citizens cannot compare, in common terms, how much a regulation costs them versus how much it benefits them, political deliberation on regulatory choices loses its intersubjective rationality. Monetisation is not a mercantile reduction of human values – it is, on the contrary, a requirement for transparency about the *trade-*

offs that any regulation inevitably imposes.

When RIA obscures this analysis, there is a choice not to account for the benefits of protective regulations, which paradoxically weakens the very justification for regulatory intervention. The literature on *behavioural regulation* also shows that regulations that avoid monetisation tend to create a *pro-status quo* or pro-regulation bias, depending on how the alternatives are framed (Thaler & Sunstein, 2008). In the context of ANVISA, this bias manifests itself in the asymmetry between the meticulous measurement of internal administrative costs – via the Standard Cost Model – and the complete absence of valuation of the corresponding social benefits.

It is important to acknowledge, however, that cost-benefit analysis is not without its critics. Scholars in legal theory and ethics have raised legitimate concerns about the use of the statistical value of life, noting that monetary proxies for human wellbeing inevitably rest on normative assumptions that are themselves contestable (Adler & Posner, 2006, p. 78). Distributional effects pose a further challenge: standard CBA aggregates gains and losses across individuals without regard to who bears the costs and who receives the benefits, potentially obscuring regressive impacts (Revesz & Livermore, 2008). These limitations do not undermine the case for CBA, because they do, however, counsel in favour of complementing monetary analysis with distributional impact assessments and explicit sensitivity testing of key normative assumptions.

It is equally necessary to situate ANVISA's methodological choices within their institutional context. The agency operates under a legal framework that explicitly assigns priority to the Precautionary Principle, and its technical staff may face genuine constraints regarding access to reliable epidemiological data, econometric training, and dedicated resources for economic modelling. The gap documented in this study may therefore reflect, at least in part, structural limitations of capacity rather than deliberate resistance to quantitative analysis. Addressing this gap will require not only methodological guidance but also institutional investments in data infrastructure and human capital.

Precaution and Efficiency: False Antinomy

Although ANVISA has consolidated Regulatory Impact Analysis (RIA) as a pillar of its governance, there is a methodological gap in relation to OECD guidelines. The agency often adopts a qualitative or multi-criteria analysis approach which, although legally robust, could be further improved by translating health risks into comparable economic variables.

Note that this is the logic of the OECD: regulation must be justified by a Cost-Benefit Analysis (CBA) that minimises "precautionary paralysis". At ANVISA, the Precautionary Principle is often interpreted in a "strong" way, in the sense of Sunstein (2005), where scientific uncertainty justifies prohibition or severe restriction without proper quantification of opportunity costs or trade-offs.

In other words, the proposed integration – that uncertainty is not the opposite of efficiency, but its object – challenges the bureaucratic culture of Brazilian health regulation. For ANVISA to achieve the standard of economic efficiency expected in global markets, the transition from qualitative to stochastic is imperative. If

ANVISA adopted CBA in accordance with OECD standards, the discipline of comparison would further reduce the uncertainties of the effects of regulation, because the use of mathematical models allows the regulator to decide not only "whether" to regulate, but also "how much" the adopted safety margin costs.

The operationalisation of this transition relies on statistical simulation techniques. Rather than yielding a single deterministic figure, stochastic modelling allows the Net Present Value (NPV) of a health regulation to be expressed as a probability distribution, converting scientific uncertainty into confidence intervals. Uncertainty in key parameters (such as the magnitude of morbidity reductions on the benefit side, or the cost of regulatory compliance) is thus rendered analytically tractable, rather than treated as a justification for abandoning quantification altogether.

The adoption of this technical rigour by ANVISA would make it possible to overcome the false dichotomy between public health and economics, considering that, by using the OECD standard, the agency would not be "monetising life", but rather ensuring that society's scarce resources are allocated where they generate the greatest net social gain, i.e., save more lives. But that is not all: with balance, it is possible to prevent fear of the unknown from generating regulations that, in attempting to protect, end up stifling innovation and access to new health technologies.

Data Analysis Methodology

Nature of the Research

This research adopts a qualitative approach of an interpretative nature, anchored in the method of critical documentary analysis (Cellard, 1997; Sá-Silva, Almeida & Guindani, 2009). Between 2022 and 2025, ANVISA produced twenty-five AIR reports, which is the total production made available by the agency's portal during that period (BraziL, 2026). No progress was made in previous years because the context of the pandemic caused by the Covid-19 virus naturally altered the Agency's mode of operation, and in many cases, a CBA could not even be required.

The analytical procedure was structured around a seven-item methodological checklist applied uniformly to each report: (i) explicit definition of the regulatory problem; (ii) identification and comparative assessment of regulatory alternatives; (iii) application of cost-benefit analysis or explicit monetisation of impacts; (iv) use of quantitative efficiency indicators such as Net Present Value (NPV) or Social Internal Rate of Return (SIRR); (v) use of the statistical value of life (VSL) or equivalent willingness-to-pay estimates; (vi) performance of sensitivity or scenario analysis; and (vii) use of outcome indicators (e.g., variations in morbidity, mortality, or market prices) rather than purely process-based outputs. For each item, presence or absence was coded as a binary variable, and the overall methodological profile of each report was mapped accordingly.

The replicability of this analysis is assured by the public availability of all twenty-five RIA reports on ANVISA's official portal (Brazil, 2026). Consistent application of the checklist across reports of varying thematic scope required

interpretive judgements in borderline cases, which are acknowledged as a limitation of single-coder documentary research. Where ambiguity arose regarding the classification of a given methodological element, the more conservative interpretation (recording absence rather than partial presence) was adopted, so as not to overstate the degree of CBA incorporation.

The sample of 25 reports is distributed as follows, considering their completion or official publication dates:

2022 (4 reports)

1. Donation of Food with Health Safety (April 2022).
2. Food and Packaging Regularisation (May 2022).
3. Electronic Smoking Devices (ESDs) (June 2022).
4. Modernisation of the Framework for Novel Foods and Ingredients (2022).

2023 (6 reports)

1. Control of Degradation Products in Medicines (March 2023).
2. Administrative Resources (General Resource Management - GGREC) (July 2023).
3. Cosmetovigilance (July 2023).
4. Risk Classification for Economic Activities (August 2023).
5. Health Control of Travellers (September 2023).
6. Cannabis Products for Medicinal Purposes (November 2023).

2024 (10 reports)

1. Health Control of Aircraft and Airports (2024).
2. Clinical Research with Medicines and Biological Products (March 2024).
3. Organisation of the SNVS and Decentralisation (RDC 560/2021) (April 2024).
4. Prosecution and Judgement of Health Violations (PAS) (May 2024).
5. Imported Goods and Products (RDC 81/2008) (May 2024).
6. Designation and Selection of Reference Medicines (2024).
7. Regularisation of Companies in Ports, Airports and Borders (AFE/BPA) (2024).
8. Health Control of Ports and Vessels (2024).
9. Prioritisation and Special Procedure for Medicinal Product Analysis (November 2024).
10. Health Requirements for Dental Care (November 2024).

2025 (5 reports)

1. Prices of New Products (CMED) (March 2025).
2. Handcrafted Cosmetics (August 2025).
3. Good Manufacturing Practices (GMP) for Food (2025).
4. Infection Prevention and Control (IRAS) (November 2025).
5. Fractionation of Hygiene and Cosmetic Products (December 2025).

Table 1. *Methodological Characteristics of ANVISA's RIA Reports (2022–2025)*

RIA Report (Year)	CBA/Mon.	Quant. Ind.	Sens. Analysis
Food Donation / Safety (2022)	No	No	No
Food & Packaging (2022)	No	No	No
Electronic Smoking Devices (2022)	No	No	Partial
Novel Foods & Ingredients (2022)	No	No	No
Degradation Products / Medicines (2023)	No	No	No
Administrative Resources GGREC (2023)	No	No	No
Cosmetovigilance (2023)	No	No	No
Risk Classification / Econ. Activities (2023)	No	No	No
Health Control of Travellers (2023)	No	No	No
Cannabis / Medicinal Purposes (2023)	No	No	No
Health Control of Aircraft (2024)	No	No	No
Clinical Research / Medicines (2024)	No	No	No
SNVS Organisation / Decentralisation (2024)	No	No	No
Health Violations / PAS (2024)	No	No	Partial
Imported Goods / RDC 81 (2024)	No	No	No
Reference Medicines (2024)	No	No	No
Companies in Ports / Airports (2024)	No	No	No
Health Control of Ports & Vessels (2024)	No	No	No
Priority Procedure / Medicines (2024)	No	No	No

Dental Care Requirements (2024)	No	No	No
Prices of New Products / CMED (2025)	No	No	No
Handcrafted Cosmetics (2025)	No	No	No
GMP for Food (2025)	No	No	No
Infection Prevention / IRAS (2025)	No	No	No
Fractionation / Hygiene Products (2025)	No	No	No

Note: CBA/Mon. = cost-benefit analysis or explicit monetisation; Quant. Ind. = quantitative efficiency indicators (NPV, SIRR); Sens. = sensitivity or scenario analysis. "Partial" indicates limited qualitative scenario discussion without full stochastic modelling.

Through the analysis of twenty-five Regulatory Impact Analysis (RIA) Reports completed between 2022 and 2025, the study identifies a methodological hegemony of Multicriteria Analysis (MCA) and the systematic neglect of economic valuation. It is argued that the agency uses the "complexity of the issue" and the "unavailability of data" as rhetorical shields to avoid the monetisation of externalities, distancing itself from the OECD guidelines and Decree No. 10,411/2020.

Results obtained from the Analysis of the AIRs surveyed during the Period

Contemporary regulatory governance requires that state intervention be justified not only by technical imperatives, but also by a full demonstration of its allocative efficiency. In Brazil, Decree No. 10,411/2020 established the AIR as the gold standard for this accountability (ANVISA, 2024). However, systematic analysis of ANVISA's documentary *corpus* reveals a different reality. The pattern identified is the almost universal replacement of Cost- Benefit Analysis (CBA) by Multi-Criteria Analysis (MCA), generally operationalised by the *Analytic Hierarchy Process* (AHP) method (ANVISA, 2025). Although AHP is a valid tool for dealing with subjective criteria, the agency uses it as an absolute substitute for economic valuation, rather than as a complement to it (ANVISA, 2025). In the AIR Report on *Cannabis* products, the agency justifies this choice by stating that quantitative methodologies would bring a "reductionist view of a complex issue," focusing on economic aspects that "would not adequately reflect reality" (ANVISA, 2024). This ideological resistance to monetisation ignores the fact that CBA is, by definition, the instrument that allows the marginal social utility of different public policies to be compared.

The absence of indicators such as Net Present Value (NPV) and Social Internal Rate of Return (SIRR) is not an accidental technical flaw, but a recurring methodological choice. In the report on infection control (IRAS), it is noted that the

criterion of "health safety" received an overwhelming weight of 65.99%, while "costs to the regulated sector" were weighted at only 4.39% (ANVISA, 2025). This disproportion demonstrates that economic impact is treated as a mere procedural accessory, rather than an essential component of social welfare. The agency admits that the monetisation of health benefits is "highly complex," opting for descriptive qualitative comparison (ANVISA, 2024). The incorporation of the method would reveal whether the billion-dollar investment required for infection control is higher or lower than the social cost of antimicrobial resistance, estimated at 100 billion dollars globally (ANVISA, 2025). Without CBA, the agency decides in the "monetary dark," without knowing whether the marginal weight assigned to safety justifies the increased cost of health services.

In the AIR Report on *Cannabis* products, ANVISA opted for a qualitative approach, arguing that monetisation would bring a "[...] reductionist view (...)" (ANVISA, 2024). However, it is understood that the method could reveal the cost of judicialisation to the SUS compared to the cost of more permissive regulation. By monetising patient waiting times and legal costs, CBA would demonstrate that the agency's qualitative "prudence" has a real and high price for the treasury and families.

The argument of "unavailability of data" is systematically invoked to avoid stochastic modelling. In the report on the review of prices for new products, the agency claims that "[...] no data were available that would allow the application of quantitative methodologies (...)" (ANVISA, 2025). Even in areas of post-market monitoring, such as Cosmetovigilance, the agency explicitly states that "[...] it is not appropriate to quantify and/or monetise the benefits (...)" due to uncertainty about future prices and behavioural responses (ANVISA, 2023). This position is corroborated in the report on clinical research, which states that monetisation would make the analysis "[...] even more complex (...)" (ANVISA, 2024). The concrete benefit of migrating to CBA would be transparency regarding the social *trade-off*: society would have clarity on whether the gain in health security justifies, for example, the loss of competitiveness or the increased cost of access to new technologies.

In summary, ANVISA operates under a technical-regulatory rationale that favours process over allocative efficiency. To align itself with Article 7, II, of Decree No. 10,411/2020 and the OECD evidence paradigm, the agency must transcend the purely qualitative use of AMC. The inclusion of CBA would allow scientific uncertainty to be addressed through statistical modelling rather than analytical inertia. As Sunstein (2014) aptly summarises, regulation that avoids quantification is not more prudent, it is merely less transparent. Health regulation cannot be an end in itself; it must demonstrate, with verifiable evidence, that the value it generates for society outweighs the burden it imposes on the economy and innovation.

Table 2. *Synthetic Comparison of the Three Critical Analytical Axes identified in ANVISA's RIA Corpus (2022–2025)*

Critical Axis	Pattern Observed	Illustrative Reports
Scientific uncertainty as barrier	Data unavailability or epistemic complexity invoked to justify non-monetisation; stochastic alternatives not considered.	CMED Price Review (2025); Cosmetovigilance (2023); Clinical Research (2024)
MCA as substitute for CBA	AHP-based multi-criteria scoring replaces economic valuation; weights assigned without monetary comparability.	Cannabis Products (2023); IRAS Infection Control (2025); Dental Care (2024)
Asymmetric cost–benefit treatment	Internal administrative costs quantified via Standard Cost Model; social benefits remain exclusively qualitative.	Traveller Control (2023); Aircraft & Airports (2024); PAS (2024)

Note: Illustrative reports are cited for each pattern; the pattern itself was observed across the full corpus. Page references appear in the individual report citations in the text above.

Implications and Reform Agenda

The Hidden Cost of Quantitative Inertia

We have seen that ANVISA has standardised the use of Multi-Criteria Analysis, especially the *Analytic Hierarchy Process* (AHP) method (ANVISA, 2024; ANVISA, 2025). In the report on Good Practices for the Prevention and Control of IRAS, it is noted that the criterion of "Health Safety" dominates the overall score, while the costs for the regulated sector are minimised (ANVISA, 2025). The benefit of migrating to CBA would be the requirement for a sensitivity analysis and stochastic modelling that would test the robustness of these choices in the face of uncertainty, rather than treating it as a justification for not doing so.

The inclusion of CBA, as recommended by the OECD, would transform AIR reports from mere procedural documents into instruments of social transparency. The concrete benefit would lie in the valuation of externalities: In the analysis of "cosmetovigilance" , it would be possible to quantify the social gain in reducing adverse events against the compliance cost of micro-enterprises (ANVISA, 2023). In the report on "traveller control", it would be relevant to demonstrate how to balance the operational cost of enforcement with the economic impact of potential outbreaks at airports and ports (ANVISA, 2023).

Systematic resistance to full CBA has specific distributional and political consequences. When ANVISA decides not to monetise the benefits of a regulation, it removes from public debate the information needed to compare that regulation with alternatives, structurally favouring the maintenance of *the* regulatory *status*

quo. Furthermore, the absence of rigorous CBA weakens the agency's position in the face of legal challenges. The "cost consideration" test (*Michigan v. EPA*, 135 S.Ct. 2699, 2015) requires agencies in the US to demonstrate that they have weighed the economic impacts of their choices – a precedent whose normative weight grows as Brazil advances in its process of joining the OECD. The 2023 *Regulatory Policy Outlook* points out that the quality of RIA is a central criterion for evaluating national regulatory systems, and the absence of systematic monetisation of benefits is explicitly identified as a methodological deficiency (OECD, 2023).

Suggested Methodological Reforms

Based on the analysis undertaken, and in line with OECD guidelines and the best literature on regulatory quality, four priority methodological reforms are proposed:

(a) Incorporation of VVE into AIRs on mortality impact: ANVISA could adopt a reference VVE, estimated by revealed preference studies in the Brazilian labour market or transferred from international studies adjusted for GDP per capita – *benefit transfer* methodology (Rosenberger & Loomis, 2017)[1].
(b) Introduction of stochastic models for uncertainty analysis: Monte Carlo simulations or scenario analyses with probability distributions allow confidence intervals to be derived for the regulatory NPV, making uncertainty manageable without eliminating the discipline of comparison.
(c) Expansion of the scope of AIRs to *outcome* indicators: these documents should evolve from monitoring *outputs* to *outcome* indicators (variation in morbidity and mortality, effective patient access, price variation in the regulated sector), systematically integrating the capabilities of DATASUS, VIGITEL, and INCA into the agency's assessments.
(d) Institutionalisation of methodological review by external peers? Following the model of the US *Office of Information and Regulatory Affairs* (OIRA) or the British *Regulatory Policy Committee*, Brazil should create an independent review mechanism for AIRs and ARRs, with the technical capacity to assess the robustness of methodological choices and recommend corrections before the publication of standards.

Conclusions

ANVISA's regulatory output, examined through the content of twenty-five AIR reports, reveals an agency that has mastered the formal process of impact analysis, producing technically structured qualitative analyses. However, the documents analysed could be strengthened by essential methodological cores, notably Cost-Benefit Analysis (CBA), whose incorporation could substantially raise the quality

[1]The *benefit transfer* methodology, as described by Rosenberger and Loomis (2017), is an economic technique for estimating the value of environmental goods or ecosystem services in unstudied locations by transferring results from pre-existing primary studies.

and legitimacy of regulatory decisions. It was found that governance based on Multi-Criteria Analysis (MCA) and the internal Standard Cost Model formally meets national regulatory requirements, but is insufficient to provide the allocative transparency required by international best practices and Brazil's accession process to the OECD.

Three patterns emerged from the analysis. First, the systematic invocation of scientific uncertainty as a barrier to quantification, when stochastic models and sensitivity analyses are precisely designed tools to make it manageable. Second, there was a lack of analytical differentiation between internal operational efficiency (understood as the reduction of the agency's own administrative costs) and social allocative efficiency, which presupposes the maximisation of net collective welfare. Third, treating public health as an intrinsically immeasurable value produces a particularly serious analytical paradox: an agency unable to calculate the value of the benefits it produces also cannot demonstrate, in a transparent and verifiable manner, that these benefits outweigh the costs it imposes on society.

Overcoming this *deficit* does not require abandoning the principles of precaution or public health protection, nor does it imply the indiscriminate monetisation of values. On the contrary, it is argued that these principles should be supported by the best available evidence: an agency that quantifies the benefits of its regulations is not reducing human life to a market value, but rather building the most solid and transparent argument possible for the legitimacy of its interventions. At the current stage of Brazil's accession to the OECD, the adoption of full CBA is not a technocratic concession, but rather an imperative of democratic *accountability*. Without it, there is a risk of making health protection invisible in its foundations, incalculable in its effects and, therefore, immune to rational challenge by both its beneficiaries and its critics.

Several limitations of this study merit explicit acknowledgement. The analysis relies exclusively on publicly available RIA reports and does not draw on internal agency documents, staff interviews, or budgetary data that might illuminate the institutional factors underlying the patterns observed. As previously mentioned, the analysis relies exclusively on publicly available Regulatory Impact Assessment (RIA) reports and does not utilize internal agency documents, employee interviews, or budgetary data. Therefore, the coding of methodological elements was carried out using a binary and relatively objective approach for most checklist items, introducing the possibility of interpretive bias, which does not detract from, but rather enhances, the merit of the results. The final, publicly available outcome of a broader regulatory process can be explored in future research, which could be achieved through multi-coder designs.

For Brazilian health regulation to reach the standard of evidence required by international literature and OECD membership criteria, it is imperative that "scientific uncertainty" cease to be the end of the analysis and become its object. Imperfect quantification, transparent in its limits and methodologically explicit in its premises, is infinitely more valuable to regulatory democracy than the calculated silence of strategic imprecision. In this sense, this research contributes to the debate on the institutional quality and scientific nature of regulatory governance by empirically demonstrating that ANVISA has the technical capacity for formal impact analysis

and could mobilise the economic valuation instruments that would give the decision-making process the analytical robustness required by the contemporary scientific paradigm. Future research could investigate the institutional, budgetary, and technical training factors that explain this gap, as well as assess whether specific reforms in the agency's organisational structure – such as the creation of a unit specialising in economic modelling – would be sufficient to bring ANVISA's practice closer to the OECD standard, or whether broader legislative reforms in the regulatory framework of AIR in Brazil would be necessary.

References

Adler, M. D., & Posner, E. A. (2006). *New foundations of cost-benefit analysis*. Harvard University Press.

Agência Nacional de Vigilância Sanitária (ANVISA). (2025). *Relatório de AIR sobre boas práticas de prevenção e controle das IRAS em serviços de saúde*. Anvisa.

Agência Nacional de Vigilância Sanitária (ANVISA). (2025). *Relatório de AIR sobre a revisão dos critérios para definição de preços de produtos novos (CMED)*. Anvisa.

Agência Nacional de Vigilância Sanitária (ANVISA). (2024). *Relatório de AIR: produtos de cannabis para fins medicinais*. Anvisa.

Agência Nacional de Vigilância Sanitária (ANVISA). (2023). *Relatório de AIR sobre cosmetovigilância*. Anvisa.

Agência Nacional de Vigilância Sanitária (ANVISA). (2023). *Relatório de AIR sobre as diretrizes para classificação de risco para as atividades econômicas*. Anvisa.

Agência Nacional de Vigilância Sanitária (ANVISA). (2024). *Relatório de AIR sobre controle sanitário de aeronaves e aeroportos*. Anvisa.

Agência Nacional de Vigilância Sanitária (ANVISA). (2023). *Relatório de AIR sobre o controle sanitário de viajantes*. Anvisa.

Agência Nacional de Vigilância Sanitária (ANVISA). (2022). *Relatório de AIR sobre procedimentos para regularização de alimentos e embalagens*. Anvisa.

Agência Nacional de Vigilância Sanitária (ANVISA). (2023). *Relatório de AIR sobre controle de produtos de degradação em medicamentos*. Anvisa.

Agência Nacional de Vigilância Sanitária (ANVISA). (2023). *Relatório de AIR sobre análise e deliberação dos recursos administrativos (GGREC)*. Anvisa.

Agência Nacional de Vigilância Sanitária (ANVISA). (2024). *Relatório de AIR sobre priorização e procedimento especial de análise de medicamentos*. Anvisa.

Agência Nacional de Vigilância Sanitária (ANVISA). (2024). *Relatório de AIR sobre indicação e eleição de medicamentos de referência*. Anvisa.

Agência Nacional de Vigilância Sanitária (ANVISA). (2024). *Relatório de AIR sobre regularização de empresas em PAF (AFE e BPA)*. Anvisa.

Agência Nacional de Vigilância Sanitária (ANVISA). (2024). *Relatório de AIR sobre requisitos sanitários para serviços de assistência odontológica*. Anvisa.

Agência Nacional de Vigilância Sanitária (ANVISA). (2024). *Relatório de AIR sobre controle sanitário de portos e embarcações*. Anvisa.

Agência Nacional de Vigilância Sanitária (ANVISA). (2025). *Relatório de AIR sobre fracionamento de produtos de higiene e cosméticos*. Anvisa.

Agência Nacional de Vigilância Sanitária (ANVISA). (2024). *Relatório de AIR sobre procedimentos para autuação e julgamento de infrações sanitárias (PAS)*. Anvisa.

Agência Nacional de Vigilância Sanitária (ANVISA). (2022). *Relatório de AIR sobre doação de alimentos com segurança sanitária*. Anvisa.

Agência Nacional de Vigilância Sanitária (ANVISA). (2024). *Relatório de AIR sobre revisão do regulamento de bens e produtos importados (RDC 81/2008)*. Anvisa.
Agência Nacional de Vigilância Sanitária (ANVISA). (2025). *Relatório de AIR sobre cosméticos produzidos de maneira artesanal*. Anvisa.
Agência Nacional de Vigilância Sanitária (ANVISA). (2022). *Relatório de AIR sobre novos alimentos e novos ingredientes*. Anvisa.
Agência Nacional de Vigilância Sanitária (ANVISA). (2024). *Relatório de AIR sobre pesquisa clínica com medicamentos e produtos biológicos*. Anvisa.
Agência Nacional de Vigilância Sanitária (ANVISA). (2022). *Relatório final de AIR sobre dispositivos eletrônicos para fumar*. Anvisa.
Agência Nacional de Vigilância Sanitária (ANVISA). (2024). *Relatório final de AIR sobre organização do SNVS e descentralização (RDC 560/2021)*. Anvisa.
Agência Nacional de Vigilância Sanitária (ANVISA). (2025). *Relatório parcial de AIR obre BPF para industrializadores de alimentos*. Anvisa.
Aragão, A. S. de. (2010). Análise de impacto regulatório. *Revista de Direito Público da Economia*, (32), 9–15.
Beck, U. (2015). *Pioneer in cosmopolitan sociology and risk society*. Springer.
Boardman, A. E., et al. (2006). *Cost-benefit analysis: Concepts and practice* (4th ed.). Prentice Hall.
Brasil. Agência Nacional de Vigilância Sanitária. (2026). *Análises de impacto regulatório*. https://www.gov.br/anvisa/pt-br/assuntos/regulamentacao/air/analises-de-impacto-regulatorio
Brasil. (2020). Decreto nº 10.411, de 30 de junho de 2020. *Diário Oficial da União*.
Cellard, A. (1997). A análise documental. In J. Poupart et al., *A pesquisa qualitativa* (pp. 295–316). Vozes.
Cole, D. H. (2012). Law, politics, and cost-benefit analysis. *Alabama Law Review*, 64, 55–89.
Cooter, R., & Ulen, T. (2012). *Law and economics* (6th ed.). Pearson.
EPA. (2010). *Guidelines and specifications for preparing economic analyses*. U.S. Environmental Protection Agency.
Gico Júnior, I. (2014). Introdução ao direito e economia. In L. B. Tim (Ed.), *Direito e economia no Brasil* (2nd ed., pp. 1–33). Atlas.
Goldman, D. P., et al. (2018). The value of medical innovation in the United States: 1983–2012. *RAND Health Quarterly*, 8(1).
Graham, J. D., & Wiener, J. B. (1995). *Risk versus risk*. Harvard University Press.
Kahneman, D. (2012). *Rápido e devagar: Duas formas de pensar*. Objetiva.
Mendonça, J. V. (2014). *Direito constitucional econômico*. Fórum.
OECD. (2008). *Building an institutional framework for regulatory impact analysis*. http://www.oecd.org/regreform/regulatory-policy/40984990.pdf
OECD. (2018). *Cost-benefit analysis and the environment*. OECD Publishing.
OECD. (2023). *OECD regulatory policy outlook 2023*. OECD Publishing.
OECD. (2009). *Regulatory impact analysis*. OECD Publishing.
OECD. (2012). *Recommendation of the council on regulatory policy and governance*.
OECD. (2015). *Regulatory policy outlook*.
OECD. (2007). *Relatório sobre a reforma regulatória – Brasil*.
Palma, J. B. de. (2014). Processo administrativo normativo na regulação. *Revista de Direito Administrativo Contemporâneo*, 12.
Papanicolas, I., Woskie, L. R., & Jha, A. K. (2018). Health care spending. *JAMA*, 319(10), 1024–1039.
Posner, R. A. (2010). *Direito, pragmatismo e democracia*. Forense.
Posner, R. A. (2014). *Economic analysis of law* (9th ed.). Wolters Kluwer.
Posner, R. A. (1993). *The problems of jurisprudence*. Harvard University Press.

Radaelli, C. M., & De Francesco, F. (2007). *Regulatory impact assessment*. http://regulation.upf.edu/ecpr-07-papers/cradaelli.pdf
Revesz, R. L., & Livermore, M. A. (2008). *Retaking rationality*. Oxford University Press.
Rosenberger, R. S., & Loomis, J. B. (2017). Benefit transfer. In P. A. Champ et al. (Eds.), *A primer on nonmarket valuation* (pp. 431–462). Springer.
Sachs, J. D. (2015). *The age of sustainable development*. Columbia University Press.
Sá-Silva, J. R., Almeida, C. D., & Guindani, J. F. (2009). Pesquisa documental. *Revista Brasileira de História & Ciências Sociais*, 1(1), 1–15.
Sen, A. (2004). *Rationality and freedom*. Harvard University Press.
Sunstein, C. R. (2005). *Laws of fear*. Cambridge University Press.
Sunstein, C. R. (2014). *The cost-benefit revolution*. MIT Press.
Sunstein, C. R. (2002). *The cost-benefit state*. ABA Publishing.
Sunstein, C. R. (2014). *Valuing life*. University of Chicago Press.
Sunstein, C. R. (2007). *Worst-case scenarios*. Harvard University Press.
Thaler, R. H., & Sunstein, C. R. (2008). *Nudge*. Yale University Press.
Viscusi, W. K., & Aldy, J. E. (2003). The value of a statistical life. *Journal of Risk and Uncertainty*, 27(1), 5–76.