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Social participation in Anvisa's regulations: hybrid, colloquial, and scientific evidence for democratic decision-making

Telma Rodrigues Caldeira (https://orcid.org/0000-0003-1385-7233) [1,2]
Ana Valéria M. Mendonça (https://orcid.org/0000-0002-1879-5433) [1]

Abstract *Anvisa's public consultation (PC) is the most widely used social participation mechanism in current health regulations, which was based on antagonistic movements: the democratization of decision-making and State counter-reformation. Starting from the concept of social participation, defined as various actions from society related to public decision-making, which values diversity and the exercise of citizenship, the present article discusses the possibility of PCs configuring a democratic regulation process by considering popular beliefs and colloquial evidence, and promoting the creation of hybrid evidence in an evidence-moderated model. Despite the different interests, the PCs open the door to opportunities for democratic deliberation by society in the search of understanding, where it is expected that the State will make the best decision and justify it. In this sense, the role of evidence in clarifying complex issues is defined as a space where dissent, believed to democratize society, is important in revealing the limits of scientific evidence in an environment of information asymmetry. Finally, this article aims to refute technocracy as an instrument of power in health regulations, thereby achieving the greatest democratic potential of Anvisa's regulations.*

Key words *Social participation, Public health surveillance, Government agencies, Government regulation, Democracy*

[1] Pós-Graduação em Saúde Coletiva, Faculdade de Ciências da Saúde, Universidade de Brasília. Campus Universitário Darcy Ribeiro, Asa Norte. 70910-900 Brasília DF Brasil. telma.caldeira@gmail.com
[2] Agência Nacional de Vigilância Sanitária (Anvisa). Brasília DF Brasil.

Introduction

The constitutional principle of popular participation in public management has paved the way for the interaction between State and society in the formulation of policies, thus transforming Brazil into a democratic country with a wide range of participatory practices[1]. However, Koga et al.[2] observed that 45% of all federal public managers have never had any direct contact with beneficiaries. According to regulatory experts, by prioritizing scientific evidence, the technical rationality of the proposed standards is recommended[3]. On the one hand, instrumental rationality has limitations. Moreover, it is possible that scientific evidence may well biased in such a way as to displace the discussion of the health issue into economic aspects[4].

By contrast, social problems in the health sector, which motivate the development of regulations, can always be reformulated in moral terms, with potential harm to legitimacy and the objectives of preventing, reducing, and eliminating risks to the population[5]. In Brazil, for example, the influence of popular movements has led the judiciary and legislative powers to support the use of phosphoethanolamine in 2016 in order to guarantee access to a medicine with no proven efficacy, safety, or quality[6]. Other examples of social articulation via the judicial and legislative powers, whether due to economic interests or groups of patients, are found in the decisions of the National Health Surveillance Agency (*Agência Nacional de Vigilância Sanitária* – Anvisa) regarding the prohibition of the use of flavoring substances in cigarettes in 2012 and anorectic medicines in 2011[6]. Therefore, although social participation has legitimized the agency's decision-making process[7], such examples[4-6] demonstrate the health risks that society can pose, based on undue information or interests contrary to the health of the community. In this context, scientific evidence is an important counterpoint.

In addition to information, there are issues related to communication, as mediators (professionals and technicians) who work with popular participation encounter certain limitations in interpreting the content and value of popular speech. The educational background of the interlocutors likely prevents popular culture from being understood as accumulated and systematized knowledge of reality[8], and, consequently, they disregard the population as a strategic subject of public health action.

With the expansion of democratic spaces, driven by the Federal Constitution of 1988[9], and with the institution of community participation as a guideline of the Unified Health System (SUS), the question arises as to how popular speech, with its knowledge and the entire set of knowledge can be systematically considered, in conjunction with scientific evidence, when deciding on public affairs. In an attempt to raise possibilities, this article presents some of the challenges for democratizing health regulations through Anvisa's Public Consultations (PCs). Furthermore, clues are sought to integrate types of knowledge into the health regulation process, discussing PCs as a potential locus of influence on public decision-making, where a democratic discursive process is necessary so that other rationalities can also be considered evidence for the final decision.

To support this reasoning, in addition to the introduction and final considerations, this theoretical debate is divided into three parts. The first part will characterize what is meant by social participation. In the second part, CPs will be presented as Anvisa's most frequent social participation mechanism, exemplifying some cases studied by the academy. Finally, the third part will discuss how an evidence-moderated model can be a way to integrate different forms of knowledge, encompassing scientific, hybrid (constructed during the fruitful interrelationship between different social actors in the participation process)[10] and colloquial (empirical, opinions and views of experts, the population, as well as other data and reports)[11].

Polysemy and contextualization of social participation

Social participation is a polysemic term, contextualized in history and in different areas of knowledge. In the social sciences, the term participation is used in two senses: the first relates to the degree of integration of an individual into a group; and the second is linked to the value by which organizations of a social, economic, and political nature, related to democratization, are evaluated[12-14].

The term *participation*, in the 1950s to the 1970s, was associated with the inclusion of "marginalized" people in a capitalist consumer society, given the situation of poverty, ignorance, and passivity, a conception of blaming the individual for their condition, which disregards social structural inequalities. "Participation" was also linked to joint efforts for social actions to build houses, schools, and other structures precariously provided by the State. Derived from this vision of social action, associations, or communitaria-

nism, are also understood as forms of participation, in which the population plans its decisions with little funding from the State, without increasing societal participation in the division of the wealth produced[8,15,16].

The term participate is also associated with the idea of making people actors in their own history and their own interests. In this aspect, it is used as a resource to guide distributive demands and access to services and rights by popular strata, participating in the construction of a society without exploitation[17].

In the 1970s, the meaning of popular participation in civil society began to be theorized in the field of social sciences, in contrast to Latin American political-military regimes[18]. This vision differs from the previous ones, as it refers to popular and social classes and carries with it a broader conception than the unions movement or party politics. Therefore, popular participation is not about political action by entities representing civil society in the state structure 8,16, but is rather about collective actions of a socio-political and cultural nature, organized to express and vindicate demands for different pressure strategies[15]. In Brazil in the economic recession of the 1980s and the bubbling social movements and political redemocratization, actors engaged in popular participation began to rework their discourse, incorporating the definition of citizen[17,19].

In the field of Public Health, the Health Reform links the term participation to the exercise of citizenship, as a form of democratic achievement beyond the traditional representative model. Thus, Brazilian society, in its diversity of expressions, is called upon to participate in decision-making as a mobilizer of the redemocratization of the State[17,19]. However, for the practice of citizenship, the creation of accessible and non-exclusive language in participatory spaces is essential, in addition to the development of democratic means of communication[18].

According to Paim, Health Reform configures social participation as a set of interventions from different social forces to influence the formulation, execution, and evaluation of health policies. This includes a reform consisting of three elements: the democratization of health (raising awareness about health and recognition as a right); the democratization of the State (ensuring the decentralization of the decision-making process, social control, and transparency); and the democratization of society (reaching the spaces of socioeconomic organization and culture, around a set of policies and practices)[20].

Cavalcanti et al.[21], when reviewing studies on participation in the field of Public Health, identified three dimensions of the meaning of engagement: 1) a strategy to expand citizenship and recognize the right to health; 2) a strategy to democratize the State and strengthen the health system, involving society in political, managerial, and supervisory decisions; and 3) community participation, in which individuals and families share health responsibility with the State. In particular, studies with a bias towards the democratization of the State characterized participation as an element of "good" governance, a means to legitimize public decisions in the face of traditional forms of the representation of interests in liberal democracies.

Although social participation has been linked to a democratizing political project, it is also aligned with the neoliberal project that seeks to guarantee the Minimum State[19]. Administrative reform in the 1990s in Brazil (or the counter-reform of the State), based on the idea of inefficiency of public power to solve social problems, based its project on the trinomial of neoliberal ideas: privatization, targeting, and decentralization, which made it possible to transfer state actions to civil society[22,23]. Faced with problems related to low efficiency, productivity, and quality of public services, managerialist proposals began to be applied in the public sector. By contrast, the reform brought such values as accountability, transparency, participation, and equity into public affairs[24].

In this aspect, social participation is presented as an innovation in public administration, aimed at legitimizing the actions of Regulatory Agencies and overcoming the democratic deficit inherent in the exercise of the normative function by the Executive Branch. Consequently, PCs are structured as a mechanism for social participation in the regulatory process[7], with the discourse of the need to guarantee the effectiveness of results due to the democratization of the process and to meet capitalist interests[25].

When exercising power sharing, experiences with social participation can be conflicting. In this dispute, one of the obstacles to effective social participation is the requirement for technical and political qualifications, which a lay citizen often does not have[26]. Therefore, despite democratic advances in public health, due to the technical capacity of mediators, value is a certain "profile", comprised of a set of skills for a deliberative exercise, such as argumentative capacity and specialized knowledge about health policy[27].

Thus, technocracy is characterized as an instrument of power in relations with the State.

Given the different conceptions and the need for the democratization of the State, social participation is defined as various actions of society that occur so as to influence the formulation, execution, inspection, and evaluation of public policies, with the objective of the community acting in the decision-making process including the right to reflect on health conditions; to propose alternatives to solve their problems, with the appreciation of technical-scientific and popular knowledge; and, ultimately, to exercise citizenship and democracy.

Anvisa public consultations: evolution and paths toward the democratization of the health regulation process

The term health surveillance is specific to Brazil, but its activities are global. It is constitutionally defined as one of the main aspects of SUS, consisting of a set of actions capable of eliminating, reducing, or preventing health risks arising from the environment, the production and circulation of goods, and the provision of services of interest to health[9]. To this end, health surveillance activities are summarized into three groups: 1) regulatory action taken on products and therapeutic inputs of interest to health; 2) normative and supervisory action on the services provided; and 3) permanent assessment and prevention of health risks[28].

The objects of health regulation are numerous and include medicines, foods, cosmetics, sanitizers, tobacco derivatives, medical products and equipment, diagnostic reagents, pesticides, blood and its derivatives, human organs, and tissues for transplantation, including environments, inputs, processes, and technologies related to these products. It also exercises control over health services, public health laboratories, ports, airports, and borders[29]. Anvisa is a special agency whose institutional purpose is to promote the protection of the population's health, through the sanitary control of the production and commercialization of products and services subject to health surveillance, including environments, processes, inputs, and technologies related to them, as well as the control of ports, airports, and borders. Due to its nature of action, the Brazilian Institute of Geography and Statistics (IBGE) estimated that 22.7% of the gross domestic product (GDP) of the Brazilian economy in 2014 was made up of activities regulated by Anvisa[30], thus demonstrating its economic relevance and how much the agency is inserted in a space for the dispute of economic interests.

Silva et al.[6] reported the various controversies in reaction to Anvisa's exercise of its regulatory function, presented both by business sectors and by citizens with strong pressure on the executive and judiciary powers, who diverged from the decisions of the health authority[6], demonstrating how the public sphere represents the pressure space to influence the State's decisions as a whole. The majority of such dispute actions are related to Anvisa regulations.

The lack of the standardization of regulatory procedures had already been discussed at Anvisa since its inception. However, driven by the federal government's Institutional Capacity Strengthening Program for Management in Regulation (PRO-REG), Anvisa carried out a diagnosis in 2007 to identify problems related to standardization. This assessment highlighted a series of needs, including: standardizing the regulatory process, promoting transparency, and improving the mechanisms for society's participation in the regulatory process[31,32].

Another assessment, carried out by the Consumer Protection Institute (*Instituto de Defesa do Consumidor* – IDEC), detected the need to grant more space for the institutionalized participation of consumers and society in general. IDEC understood that the lack of diversity allows institutions to act inwardly, disregard important aspects for society and become more subject to information asymmetry in favor of regulated entities[31,32].

As a result of the aforementioned evaluation processes, an action plan was formulated to address the identified problems, unfolded in the Anvisa Regulatory Process Improvement Program (*Programa de Melhoria do Processo de Regulamentação da Anvisa* – PMR) in 2008. This program defined the guideline of the fortifying of transparency and social control in the regulatory process. Furthermore, it standardized regulatory processes, including the implementation of PCs, by publishing the Guide to Good Regulatory Practices[31,32]. After years of experience, in 2018 and 2021, Anvisa updated the PMR by replacing it with guidelines and procedures to improve regulatory quality. Among the main objectives were the strengthening of the Regulatory Impact Analysis, and developing standards and recommendations based on evidence and in a more participatory manner from the onset of discussions[33,34].

From 2008 onwards, the diversification of Anvisa's forms of social participation intensified,

and to make them clearer to citizens, employees and managers of the Agency, in January 2019, the "Social Participation Menu", a document that briefly describes the different mechanisms that can be used in interaction with society during the regulatory process, was launched (Figure 1)[35, 36].

Among the different participation mechanisms set out in the aforementioned menu, based on documentary research on the Anvisa website (carried out on August 9, 2022), it was found that PCs, when compared to the others, are applied more frequently in the regulatory process. According to the Agency, the PC is a non-binding decision-making support mechanism, in which society is consulted in advance concerning proposed standards, to improve the quality of the analysis that will guide the final decision[36,37]; however, this was the not always the reality of health regulations.

The regulatory action on health surveillance that existed at the federal level before Anvisa was carried out by secretariats linked to the Ministry of Health. However, there are no public records of PCs carried out by such secretariats (according to a survey conducted on October 08, 2022, at Base Saúde Legis – available at: http://saudelegis.saude.gov.br/saudelegis/secure/norma/listPublic.xhtml - with the keywords: (COP) Public Consultations, SNVS, and SVS, for the period January 1, 1989 to December 1998). Therefore, the institution of the PCs, the expansion of their publicity and transparency, in addition to enabling the democratization of the State and legitimizing decisions, opened a field of study to analyze the social dynamics locked in this arena of power dispute, which allowed the scientific community to evaluate of some of the cases.

In an analysis of the Agency's PC process on the regulation of medicine advertising (PC nº 84/2005), two studies[38,39] reported a lack of transparency, justification, and clarity in the analysis of contributions in response to society to expose the reasons for the exclusion of contributions from consumer protection and public health associations. In the case of food advertising regulations, the study on industry lobbying demon-

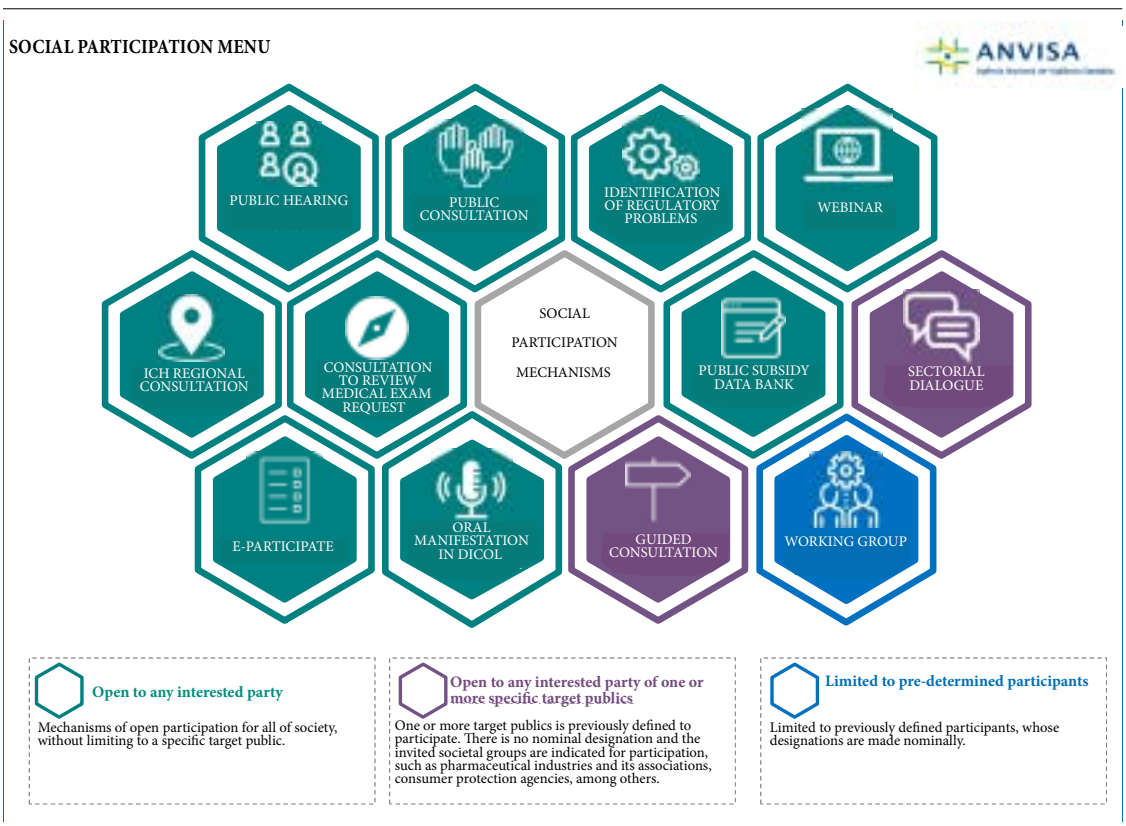

Figure 1. Menu of Social Participation in Anvisa health regulation[36].

Source: Anvisa, 2021.

strated the difference that exists when there are organizational and financial powers of regulated entities. During PC no. 71/2006, a number of business groups presented a series of opinions, along with counter-arguments during the preparation of the draft regulation, including the questioning of the constitutionality of the proposed rule, which was successful in the judiciary by suspending the effects of the standard published at that time. The subject aroused the interest of a varied group, as of the total participants in CP no. 71//2006, around 32% were from the regulated sector, 29% were individuals (citizens), and 25% were representatives of organized society, as well as governmental and teaching institutions, proving to be a relevant participation device for different groups[40].

In the selection of PCs carried out between 2000 and 2006 in the area of health services, Alves[7] demonstrated that different segments of civil society participated to a greater or lesser extent, and that, in addition to those sectors organized around economic ideals, there was also involvement of citizens and NGOs in defense of collective interests. Furthermore, the author highlights the complete absence of consumer protection NGOs, confirming the assessment of IDEC[30]. Regarding influence, the author[7] observed that consulting companies are more successful at incorporating suggestions into the standard proposal, followed by individuals and private companies subject to health regulations. During that period, the author highlighted some obstacles to participation, including restricted disclosure to official media or the internet; a lack of disclosure of the reasons that supported the decision; delay in concluding consultations on standards; and a lack of transparency regarding the results of the consultation.

The studies on the PC cases mentioned above referred to cases prior to the PMR. This program initiated the standardization of PC procedures, implying some obligations, including publicity for the analysis of contributions.

Another study points out how PCs can be used as an instrument of influence in decision-making based on the strategic use of scientific evidence. Lencucha and Pontes[4] analyzed the document presented by Fundação Getúlio Vargas (FGV) in defense of the use of additives in cigarettes, a report addressed to Anvisa during the PCs held in 2010. The authors concluded that scientific information was used as a rhetorical and strategic tool to create uncertainty and doubt. This tactic is classified as data reframing and involves manipulating information to divert the topic from health to some other concern, such as the economy or employment.

The evaluation of the FGV report carried out by the Pan American Health Organization (PAHO) concluded that the report was based on unreliable studies generated with funding from the tobacco industry. Furthermore, FGV used misleading statements from reputable sources, and its conclusions are based on hypotheses without presenting the methods and materials used[41]. This reasoning corroborated the Agency's decision to prohibit the use of flavor additives, herbs, fruits, and other substances used to mask unpleasant taste and aroma[4].

Another study[42] focused on PCs no. 42/2015 (Good Manufacturing Practices for food packaging), no. 255/2016 (mandatory declaration of the presence of lactose on food labels), and no. 256/2016 (technical regulation relating to foods for lactose-restricted diets). This research, based on Douglasian Cultural Theory, analyzed the extent to which PC encourages the participation of people with different points of view. According to this theoretical framework, culture becomes the central aspect in explaining social life, as people share values and beliefs – their "cultural orientations" – which determine both their way of life and their social interactions. From this structure, discourse can be evaluated in a matrix with two axes: behavior (whether the individual is limited by rules or can negotiate their own behavior) and identity (whether the individual belongs to a unit or can form its own social identity). The intersection of these dimensions leads to four types of voices that allow us to analyze how some may try to persuade others with arguments. They concluded that social participation is unequal, as some points of view are dominant in the final decision, and this indicates the need to promote more inclusive and pluralistic public engagement.

Therefore, speech in the PC process matters for regulation, and such speech is based on different sources of legitimacy, in which science and cultural orientation can influence the final decision. Sufficiently broad participation will, in theory, enable different types of understandings, coming from different public spheres, to be put into debate. It is therefore up to the Agency, in addition to using critical evidence analysis techniques, to develop strategies and actions to obtain different perspectives (voices) on the problem in question and consider them in the final decision.

One of the paths towards a democratic regulation process is the provision of participatory

mechanisms as spaces for debates based on Habermasian communicative rationality, that is, places to undertake discussions to choose the best argument in a free and egalitarian discursive process. Places of social engagement for the exercise of communicative action, where participants interact with the aim of understanding the problem and the proposals to overcome it through debates, a locus where speeches (with their variety of contributions) meet conditions of comprehensibility, truth, veracity, and fairness (legitimacy)[43,44,45]; where misinformation or the reframing of scientific evidence for interests contrary to health (characterized as strategic action) has no place in the final decision.

In these spaces of social engagement, to guarantee democratic participation, attention must be paid to the protagonism of experts, as in this case, it is unlikely that ordinary citizens will have a voice in their different expressions. Therefore, democracy is defended in opposition to technocracy, a system to which only those few who have specific knowledge are summoned to decide[46,47]. It is understood that technocracy in health regulation violates the principles and guidelines of SUS, especially equity and community participation.

Despite the difficulties presented, it is understood that the PCs open up opportunities for participation in arguments by any interested party, as a means of social interaction in the search for a better understanding, through (written) speech, where the State is expected to make the best decision and justify its choice in a clear, transparent, and accessible manner. Therefore, for the PCs, as part of an evidence-based decision-making process, to configure the democratic character of regulation, the Agency must look for ways to treat the wide range of manifestations (including beliefs, values, and knowledge) in an equitable manner, observing them as evidence in a broad sense.

Democratization of the regulatory process: diversity of discourse and evidence-moderated model

According to Bobbio[47], democracy is characterized by dissent, but also by majority consensus, which, in a system in which dissent is free to express itself, consensus is real. The author concluded, therefore, that the freedom to disagree is necessary in a pluralistic society with a greater distribution of power, opening the doors to the democratization of civil society.

However, if dissent is the path to the democratization of society, social participation in health regulation needs to be diverse; the multiple voices need to be properly treated as different sources of evidence to reach the final decision. This idea breaks with the hegemonic model of using evidence, constituting a moderate model.

The evidence-moderated model is discussed by Pinheiro[48], who criticizes approaches restricted to instrumental rationality and defends the use of evidence after analyzing the given context of the case. This moderate model understands social reality and public decision-making conditions as multifaceted situations; therefore, it must be able to accommodate and reconcile the diversity of evidence in different areas. The moderate character of the model opens up plurality, diversity, attentive to the limits of knowledge and realities of action, which requires the use of specific methods to produce evidence for public policy decisions aligned with its objects.

According to the researcher[48], for beliefs, values and knowledge to support public decisions, some previously developed groundwork (conceptual, methodological, and theoretical) is necessary, demonstrating the correlation between those other types of evidence and theoretical conclusions. This allows for more "subjective" aspects to be subjected to critical-rational scrutiny, and inserted into a coherent background and centralized by a conceptual, methodological, and theoretical framework[48]. The risks of harmful effects of the use of malicious information are thereby reduced.

Technocracy sometimes comes at the expense of the use of information collected from various social actors – mainly citizens and other strategic policy subjects – contributions considered to be of inferior quality. Such prejudgment generates negative impacts on the legitimacy of public policies in a democratic regime. In a moderate model, the role of evidence is meant to shed light on complex problems, clarify issues, and inform a broader public debate, in addition to decoupling the idea of a neutral instrument of information for decision-making[48]. Understanding scientific evidence as complete is tricky, since, despite its relevance, it has limitations, including problems of external validity, which impact the results achieved in health, for example.

Thus, when recognizing the limitations of scientific evidence for public decision-making, colloquial evidence emerges as a possibility of complementing (increasing the evidence scenario) or challenging scientific evidence. It is the-

refore an umbrella term that joins different types of data, including informal expert opinions; doctors' and/or patients' opinions, their views, and narratives; electronic data; policy documents and other reports, among others. Namely, in the United Kingdom, the process of incorporating health technologies considers inputs from the deliberative processes of advisory councils, made up of health professionals and patients[11].

The perspective of colloquial evidence dialogues with the concept of "hybrid evidence"[10], which in the field of public policies, considers aspects such as language, argumentation, representations, ideas, and meanings to understand the processes of the production of public policies and their effects, constructed through the interaction of social actors in mechanisms and institutions of social participation. "Hybrid evidence" is defined by Fonseca et al.[10] as knowledge that arises from fruitful relationships between different actors in spaces of social participation; its forms go beyond technical, scientific, or bureaucratic knowledge. Such evidence can generate solutions based on difference and not on the attempt to standardize languages towards consensus. To this end, technicians must be open to the "knowledge of ordinary citizens".

In this light, for social participation mechanisms to be democratic and with space for equal treatment of the different discourses, it is understood that the application of the evidence-moderated model in the regulatory process will promote favorable participation spaces to generate hybrid evidence, open to the use of colloquial evidence, combined with scientific evidence, as a set of inputs for better decision-making.

Outlooks and final considerations

Anvisa's PCs are configured as an important mechanism of social participation in which society, in its diversity of expression, can influence health regulations, a form of participation that gained strength through the process of the democratization of the State and the counter-reformation of the State.

Throughout Anvisa's existence, PCs have consolidated themselves as the most frequent mechanism for participation in health regulations, undergoing processes of standardization and improved transparency of decisions. Despite social structural inequalities, it is understood that carrying out deliberation processes between distinct and discordant elements in the public sphere is the best strategy to promote greater social justice in health surveillance. Therefore, PCs are defended as a space for exercising the right to citizenship and democracy,; however, both popular and other forms of knowledge need to be systematically considered in the decision-making process, developed under the evidence-moderated model. Furthermore, it is essential to see and develop PCs as a space for generating alternative solutions, based on the concept of hybrid evidence.

Finally, the use of dissent as a form of discursive expression is also relevant for other voices to demonstrate the potential limits of scientific evidence, as the Agency also finds itself in an environment of information asymmetry. It is understood that this could prevent the use of technocracy (with its false impartiality) as an instrument of power in health regulation, placing scientific evidence on an equal footing with other types of evidence, thus increasing the democratic potential that Anvisa's regulation can also achieve.

This text is the responsibility of the authors and does not reflect the opinion of Anvisa.

Collaborations

TC Caldeira worked on the theoretical conception, formatting of the work, bibliographic research, and analysis and review of the collected material; AVM Mendonça worked on the theoretical conception, the guidance of the work, and the review of the article as a whole.

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