From recommendation to reversal: an analysis of the reasons for changes in the National Commission for the Incorporation of Technology's position based on public consultations

Da recomendação à reversão: análise das razões de alteração do posicionamento da Comissão Nacional de Incorporação de Tecnologia a partir das consultas públicas

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Abstract

This study analyzes the reasons for changes to the initial recommendations of opinions issued by the National Committee for Health Technology Incorporation (Conitec) after public consultations. Through exploratory, documentary research, 45 public consultations conducted by the Committee in 2020 were analyzed. Of these 45 consultations, seven had their initial understanding changed based on the recommendations received during public consultations. Results show that the economic aspects of the analyzed technologies, along with safety and effectiveness criteria, were the main arguments considered to modify preliminary recommendations. Public consultation is a democratic mechanism with the potential to generate progress in the development of a more equitable Brazilian National Health System (SUS) that meets the real interests of society.

Keywords: Social Participation. Democracy. Public Consultation. Technology Assessment, Biomedical.

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Resumo

Este estudo teve como objetivo analisar as razões da mudança da recomendação inicial dos pareceres emitidos pela Comissão Nacional de Incorporação de Tecnologias no Sistema Único de Saúde (Conitec) durante o processo de consultas públicas (CPs). Tratou-se de pesquisa exploratória de base documental, que analisou 45 CPs da Comissão, realizadas em 2020, das quais sete tiveram entendimento inicial alterado a partir das recomendações recebidas. Os resultados revelam que os principais argumentos considerados para modificar a recomendação preliminar foram aspectos econômicos, bem como critérios de segurança e efetividade da tecnologia analisada. A CP é mecanismo democrático com potencial para avançar no desenvolvimento de um Sistema Único de Saúde (SUS) mais igualitário e que atenda aos reais interesses da sociedade.

Palavras-chave: Participação Social; Democracia; Consulta Pública; Avaliação de Tecnologias de Saúde.

Introduction

The concept of a comprehensive access to health includes the various technologies with in the health care system, including medical equipment, health products, medicines, vaccines, tests, diagnostics, orthoses and prostheses, materials, and technological systems (Francisco; Malik, 2019).

The continuous development of new health technologies results from several factors, such as the aging of the population, the emergence of new diseases, and the need for specialized treatments. In this context, the intersection between technological innovation and the health sector is essential, as it can help significantly expand the promotion of accessibility and equity in health systems (Francisco; Malik, 2019).

However, the decision on the incorporation of these technologies into the health care field requires a prior evaluation process, which must consider possible economic, social, ethical, and political impacts.

According to the Ministry of Health, health technology assessment (HTA) is "an evidence-based process that seeks to examine the consequences of using health care technology, considering aspects related to medical care, social assistance, and economic and ethical issues" (Brasil, 2016, p. 7). HTA also seeks to enable health systems or organizations to raise the quality of their services and patient care resources, to improve cost-effectiveness, and to adapt technologies to the real needs of society (Silva, 2020). The direct participation of society in these decisions is indispensable.

In Brazil, the organ responsible for carrying out technology assessments and incorporating them into the Brazilian National Health System (SUS) is the National Committee for Health Technology Incorporation (Conitec), an advisory body to the Ministry of Health in the processes of incorporation, exclusion or alteration of new medicines, products, and procedures, and in the constitution and/or alteration of clinical protocols and therapeutic guidelines. The final decision technology incorporation must be preceded by a public consultation (PC) assessing the preliminary opinion, as expressly provided for in Law No. 12,401/2011 (Brasil, 2011).

PC is a democratic instrument that is based on social participation and provides support for state decision-making. With PC, various sectors of society are consulted, which allows for the inclusion of multiple perspectives, the strengthening of the dialogue between State and society, and the expectation that public health policies will more deeply reflect the needs and interests of the population (Sacheto, 2008).

This practice reinforces the participatory and democratic character of the SUS, thus contributing to a more effective and inclusive management of the public health field, giving concrete form to the constitutional guideline of participation.

The PC procedure carried out by Conitec is divided into four phases: (1) provision of prior technology analysis reports and forms for participation; (2) organization and analysis of the contributions received by the Plenary; (3) issue of the final recommendation; and (4) referral to the Secretariat of Science, Technology, Innovation, and Strategic Inputs of the Ministry of Health (SCTIE/MS), which is responsible for deciding on the incorporation of technology into the SUS (Conitec, 2022).

The two reports made available by Conitec in the first phase of PC—a technical report and a report for society—present the Committee's initial recommendation and the reasons behind this choice, differing in the way they provide this information to the public. While the technical report, mainly intended for specialists in the subject and researchers, contains eminently technical language, the report for society is a summarized version of the former, but prepared in easy-to-understand language and equipped with representative images/illustrations. Conitec's main objective in presenting the documents in a different format is to make it easier for society as a whole to understand the topic that is being discussed, and to encourage greater social participation.

Similarly, two separate forms collecting contributions to PCs are also made available by Conitec: one is meant for technical-scientific contributions and the other gathers reports of experience or opinion.

In 2020, Conitec carried out 70 PCs focused on the analysis of new health care technologies and of the introduction of Clinical Protocols and Therapeutic Guidelines (CPTG). This article presents the analysis of the reasons for changing the Committee's initial recommendation, based on the contributions received in the PCs.

Methodology

This was a document-based exploratory study that analyzed Conitec's public consultations, which were held in 2020 and had their initial understanding changed based on the recommendations received during the PCs, both through the technical-scientific contribution forms and through the experience or opinion report forms. PCs that sought to introduce CPTG were not included in this study. The choice to exclude them was justified by the fact that issues related to the incorporation, exclusion, and expansion of medicines and products have a greater involvement of civil society.

Of the 70 PCs carried out by Conitec in 2020, 24 dealt with CPTG and one did not contain complete documentation. These 25 PCs were excluded from our study, and the remaining 45 were the object of this analysis.

The following documents were analyzed: (1) documents with Conitec's initial recommendations—technical reports and reports to society; (2) documents with contributions resulting from public consultations—reports with technical-scientific contributions and experience/opinion reports; and (3) reports with the final recommendation.

For the quantitative analysis of the contributions, only the information contained in question 6 of the available electronic forms (technical-scientific contribution forms and experience or opinion report forms) was considered. On both forms, this question assessed whether or not answerers agreed with Conitec's preliminary recommendation: "Question 6: Conitec's preliminary recommendation was (favorable or NOT favorable) to the proposal to incorporate the (technology to be incorporated). Do you agree with the recommendation?"

Since this study was based on essentially documentary research, which only collected publicly accessible data, it was not necessary to submit the work to the ethics committee, as recommended by Resolution No. 510, of April 7, 2016, of the National Health Council (CNS).

The results are organized into two parts: (1) profile of the participants in the PCs and (2) analysis of the content of the contributions, using Bardin's (2015) method, which makes it possible to explain and systematize the content of the investigations based on quantifiable indices, and to draw logical and justified inferences and deductions about the content of the messages.

Results

A total of 45 PCs were analyzed, with topics ranging from the inclusion of new drugs, pharmacological therapies, vaccines, and other formulations aimed at treating or preventing diseases, to new medical procedures and advanced tests for detecting diseases. Requests for the analysis of these technologies came from different sectors, including medical device manufacturers, pharmaceutical companies, government agencies, and medical societies.

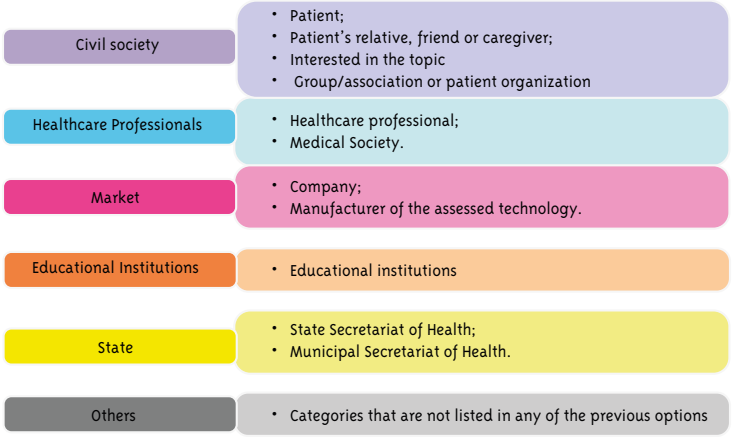
In the 45 PCs analyzed, a total of 59,028 contributions were obtained from both the technical-scientific forms (8,249 contributions) and the experience and opinion forms (50,779 contributions).

Profile of PC participants

Conitec's institutional website offers a prior classification of the authorship profile that the interested party must choose when submitting their contribution: 1) patient; (2) a patient's family member, friend, or caregiver; (3) health professional; (4) interested in the topic; (5) company; (6) company manufacturing the evaluated technology; (7) patient group/association/organization; (8) educational institution; (9) State Secretariat of Heath; (10) Municipal Secretariat of Health; (11) Medical Society; and (12) other.

Since this is an extensive classification, it was regrouped into six categories of analysis (Figure 1), which sought to bring together parties with similar interests. To this end, the qualification of the parties, their social and professional spheres of activity and the analysis of the economic or social activity they carried out were considered.

Figure 1 – Categories of participants of public consultations within the scope of the National Committee for Health Technology Incorporation



Source: Prepared by the authors based on the compilation of contributions from the selected public consultations

From this rearrangement of categories, the segments that participated most actively in the analyzed PCs were found to be Civil Society (69.59%) and Health Professionals (30.01%).

The new categories also showed that the other segments were poorly represented: Market (0.19%); Educational Institutions (0.054%); State (0.11%); and Others (0.05%).

Analysis of the content of the contributions

Results of the analysis of question 6 on the Conitec forms and of its preliminary recommendation showed that, in 21 PCs, there was a preliminary recommendation to incorporate a technology into the SUS.

In these cases, the participants of the PCs mostly agreed with the preliminary recommendation

(95.23%), demonstrating the interests of the various actors involved in the introduction of new technologies, thus ratifying Conitec's position.

On the other hand, in another 24 PCs Conitec decided not to recommend the incorporation of a new technology into the SUS. In these cases, most (95%) of the contributions from the various groups of parties registered disagreements with the Committee's preliminary recommendation.

However, only in seven public consultations was there a change in Conitec's initial position after receiving the contributions (Table 1).

Table 1 – PCs in which the initial understanding changed after contributions were submitted

PC N°	SUBJECT	PRELIMINARY DECISION BY CONITEC	DISAGREEMENT WITH THE INITIAL DECISION (%)	FINAL DECISION BY CONITEC
03/2020	Vestronidase alfa in the treatment of type VII mucopolysaccharidosis	Non-incorporation	93%	Incorporation
08/2020	Risankizumab in the treatment of moderate to severe plaque psoriasis	Non-incorporation	96%	Incorporation
23/2020	Meningococcal ACWY vaccine (meningococcal conjugate) for adolescents aged 11 and 12 years in the National Vaccination ScheduleW	Non-incorporation	89%	Incorporation
35/2020	Natalizumab for relapsing-remitting multiple sclerosis after first treatment failure	Non-incorporation	97%	Incorporation
38/2020	Ivacaftor for patients aged over 6 years who have one of the following gating mutations (class III): G55ID, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N or S549R	Non-incorporation	93%	Incorporation
56/2020	Burosumab in the Treatment of X-linked hypophosphatemia in adults and children	Non-incorporation	94%	(Partial) incorporation
63/2020	Nusinersen in the treatment of type II and III (late onset) 5q spinal muscular atrophy	Non-incorporation	95%	(Partial) incorporation

Source: Prepared by the authors based on the compilation of contributions from the selected public consultations.

PC Nº. 03: vestronidase alfa in the treatment of type VII mucopolysaccharidosis

The recommendation report was made for the analysis of the scientific evidence, requested by Ultragenyx Brasil Farmacêutica Ltda, on the efficacy, safety, cost-effectiveness, and budgetary impact of vestronidase alfa for individuals with a confirmed diagnosis of type VII mucopolysaccharidosis, in order to evaluate the possibility of incorporating the drug into the SUS.

In PC No. 3/2020, 83 contributions were received, 28 from health professionals and 55 from civil society. Conitec accepted the contributions of experts who pointed to a reduction in the budgetary impact of incorporation, based on the argument that the average weight and the number of patients in Brazil would be lower than the initially reported rates, *in verbis*:

> In addition, the arguments presented were considered plausible when stating that the average weight of the population living with type VII mucopolysaccharidosis and the number of individuals with this disease in Brazil would both be lower than what was indicated by the rates submitted in the first budget impact analysis, generating a decrease of more than 50% in the value of the originally projected impact (Conitec, 2022; our translation).

Thus, the Conitec plenary modified the initial unfavorable recommendation and issued a new one that favored the incorporation of vestronidase alfa into enzyme replacement therapy for individuals diagnosed with type VII mucopolysaccharidosis.

PC Nº. 08: risankizumab in the treatment of moderate to severe plaque psoriasis

PC No. 8/2020, requested by the company ABBVIE Farmacêutica Ltda, dealt with the incorporation (by the SUS) of risankizumab into the first line of biological treatment for patients with moderate to severe psoriasis.

Conitec's initial position for non-incorporation was justified, since the drug being evaluated was associated with incremental benefits in the effectiveness of the treatment for the analyzed clinical condition and since its efficiency was inferior to those of the treatments already available in the SUS, based on the price proposed by the manufacturer.

A total of 386 contributions were received, of which 214 came from the technical-scientific form and 172 resulted from the experience or opinion report form. In total, 96% of these contributions disagreed with the preliminary recommendation. Contributions were obtained from five groups: civil society, health professionals, the market, educational institutions, and the State. All participating groups predominantly disagreed with the recommendation, except for the State, from which two contributions were received—one agreeing with the recommendation and the other disagreeing with it.

The contributions emphasized that risankizumab is a new therapeutic option for the treatment of psoriasis and presents innovations that increase its efficacy. In addition, the introduction of this drug would ensure universal access to immunobiological treatment by the SUS. However, the Conitec plenary considered that the evidence to change the initial recommendation was insufficient, especially when considering the price proposed by the manufacturer.

The topic only returned to the plenary after the manufacturing laboratory presented a proposal to reduce the price of the drug. After this value update, Conitec decided to recommend the incorporation of risankizumab into the SUS, with the additional recommendation to renegotiate prices for the technologies already incorporated into the system for this indication. This fact evidences the relevance of economic issues in Conitec's decisions.

PC Nº. 23: meningococcal ACWY vaccine (meningococcal conjugate) for adolescents aged 11 and 12 years in the National Vaccination Schedule

The recommendation report was issued at the request of the Secretariat of Health Surveillance of the Ministry of Health to assess the efficacy and safety of the meningococcal ACWY vaccine (meningococcal conjugate) when compared to the meningococcal C vaccine (meningococcal C conjugate) in the prevention of invasive meningococcal disease, caused by *Neisseria meningitidis*, in patients aged 11 and 12 years.

It should be noted that, among the public consultations that led to a change in Conitec's understanding, this was the only one demanded by a member of the State category—the others were demanded by the market.

A total of 83 contributions were received, of which 13 came from the technical-scientific form and 70 resulted from the experience or opinion report form. Of this total, 93% of the contributions registered disagreements with Conitec's preliminary recommendation not to expand the use of the vaccine to adolescents aged 11 and 12 years. These contributions came from four different groups: civil society, health professionals, the market, and the State, all predominantly disagreeing with Conitec's initial recommendation.

The contributions highlighted the importance of expanding vaccination coverage to a specific age group due to the lethality of the disease, as can be seen in an excerpt from a contribution by a member of civil society:

> The meningococcal ACWY vaccine was something Brazilian people achieved via the National Immunization Program and expands IMD protection to adolescents, who act as carriers of the bacteria and consequently transmit it to other age groups in the community. Therefore, it is important that the vaccine remains on the national vaccination schedule—meningococcal disease are unpredictable, occur in previously healthy individuals, and have a high lethality (Conitec, 2022; our translation)

Other contributions emphasized and attached studies showing that the immunogenicity and effectiveness of the meningococcal ACWY vaccine (meningococcal conjugate) persists for over a year and that, despite the low incidence of the W serogroup of *N. meningitidis* in Brazil, it has stood out in some of the country's states; and its lethality has been shown to be the highest.

Based on this evidence, Conitec revised its preliminary understanding and recommended expanding the use of the meningococcal ACWY vaccine (meningococcal conjugate) to adolescents aged 11 and 12 years.

PC Nº. 35: natalizumab for relapsing-remitting multiple sclerosis after first treatment failure

The recommendation report was issued based on the initiative of Biogen Brasil Produtos Farmacêuticos Ltda, which recommended the incorporation of natalizumab into the treatment of relapsing-remitting multiple sclerosis (RRMS) after first treatment failure, as an alternative to fingolimod.

In its initial analysis, Conitec decided not to incorporate the use of natalizumab into the treatment of RRMS by the SUS, given that it would only be indicated for patients with high disease activity. It also considered the budgetary impact and the unproven safety of the drug, as well as the lack of provision for the treatment in the CPTG for multiple sclerosis.

A total of 706 contributions were received, of which 87 came from technical-scientific forms and 619 resulted from experience or opinion report forms. In all, 97% of the contributions disapproved of Conitec's preliminary recommendation. The contributions coming from the "State" group were only ones that did not present contributions.

> Some contributions discussed the lack of impact on the treatment budget, justifying that the two technologies have equivalent prices. As presented in this report, the annual cost of fingolimod is R$ 19,710.00 and that of natalizumab is R$ 22,344.00. However, this difference in the budgetary impact would occur due to the increase in the number of patients using natalizumab in the alternative scenario (Conitec, 2022; our translation).

While analyzing the new proposal to update the CPTG for multiple sclerosis, the plenary considered the presence of evidence of the superiority of natalizumab in the treatment of patients with high disease activity, as well as the absence of budgetary impact, and resolved that there was sufficient basis in the contributions of the public consultation to favorably recommend the incorporation of the technology.

PC Nº. 38: ivacaftor for patients aged over 6 years who have gating mutations

Vertex Farmacêutica do Brasil Ltda submitted a request for the SUS to incorporate ivacaftor into the

treatment of cystic fibrosis in patients aged 6 years and weighing 25 kg who have mutations in the gene.

Conitec's initial recommendation for non-incorporation was based on the fact that ivacaftor was a high-cost drug and would serve a specific population, that is, individuals with mutations in the G551D gene, and that benefits would be greater in patients over 12 years of age.

In the public consultation, 10,735 contributions were received—318 from the technical-scientific form and 10,417 from the experience or opinion report. In total, 93% of the contributions registered disagreements with Conitec's preliminary recommendation. The contributions came from five different groups—civil society, health professionals, the market, educational institutions, and the State—with civil society accounting for 7,648 (71.25%) of the contributions.

The contributions emphasized the need to consider that cystic fibrosis is a rare, severe, and progressive disease and that ivacaftor would prevent this progression by reducing the risk of hospitalization and death. The contributions also pointed out that ivacaftor represents hope for patients and their families, as no other drugs in Brazil have efficacy results that are as good in the reduction of chloride values in sweat.

Another argument in favor of the incorporation was the high cost of the medication is and the difficulty families have in acquiring it. An excerpt from a contribution submitted by a patient's relative states that: "This medicine is very expensive and many families cannot afford it" (Conitec, 2022; our translation).

In addition, Vertex Farmacêutica do Brasil Ltda, which manufactures the medicine, presented a proposal to reduce the cost of treatment compared to the initial price proposed for ivacaftor, considering a differentiated discount. The initial price for the incorporation of Kalydeco® 150mg was R$ 67,863.80. After five years, it was reduced to R$ 45,936.11—a reduction of R$ 90.8 million.

In view of the contributions and arguments, the initial recommendation on the subject was amended. Conitec considered that the evidence presented in the PC showed a benefit of the drug: it could efficiently reduce chloride values in sweat and improve lung function, factors that represent important outcomes in the disease. It also considered the severity and evolution of the disease and the fact that more studies are needed, stating that a re-evaluation should be carried out in three years.

PC Nº. 56: burosumab in the treatment of X-linked hypophosphatemia in adults and children

The request for SUS to incorporate burosumab into the treatment of X-linked hypophosphatemia was made at the initiative of the company Ultragenyx Brasil Farmacêutica Ltda. Conitec's initial unfavorable decision on the subject was based on the lack of robust evidence of the efficacy and safety of the use of the drug by the population presented, in addition to the high budgetary impact.

A total of 619 contributions were received, of which 103 came from technical-scientific forms and 516 resulted from experience or opinion report forms. In all, 94% of the contributions disapproved of Conitec's preliminary recommendation. The contributions were received from all the five groups mentioned earlier.

They focused on the benefits of the drug, such as treatment efficacy, symptom improvement, and better phosphate levels and quality of life. In addition, the manufacturing company presented a new price proposal with discounts.

> The company that manufactures the drug presented a new price proposal for its incorporation. According to the data submitted, the proposal would include a discount of 5% compared to the initial value and 6.3% considering the price adjustments made in June 2020 (increase of 3.23%) and the current CAP of 21.53% (Conitec, 2022; our translation).

In view of the contributions, Conitec decided to recommend the partial incorporation of this technology into the SUS.

This fact brought a peculiar issue to light: the fact that Conitec' preliminary understanding was only partially altered. Although Conitec recommended the incorporation of burosumab into the treatment of X-linked hypophosphatemia in children, it did not recommended the drug for the treatment of this disease in adults.

Since the clinical benefits of the treatment were more pronounced in children, the recommendation only covered this age group. Thus, the public consultation provided a new scenario for Conitec to modify its initial judgment.

PC Nº. 63: nusinersen in the treatment of type II and III 5q Spinal Muscular Atrophy

Biogen Brasil Produtos Farmacêuticos Ltda. requested an evaluation of the use of nusinersen in the treatment of patients with type II and III (late onset) 5q Spinal Muscular Atrophy (SMA), with the aim of incorporating the drug into the SUS.

Conitec's preliminary recommendation was negative, based on the high cost of the drug and the lack of studies presenting more robust data or demonstrating clearer benefits and more detailed information on the long-term safety of the drug.

In total, 5,950 contributions were received in the public consultation—271 from the technical-scientific form and 5,679 from the experience or opinion report. Of these, 5,647 (95%) disagreed with Conitec's initial recommendation. Only contributions from three groups—civil society, health professionals, and the market—were received.

The contributions focused on the benefit of nusinersen in terms of motor gains, quality of life and non-progression of the condition; and the fact that it was the only technology available for the treatment of patients with type II and III SMA.

Conitec initially considered that the PCs did not provide enough arguments to change the preliminary recommendation. However, on March 19, 2021, a virtual Public Hearing was held and broadcast to the population on Conitec's YouTube channel (Audiência..., 2021), with the aim of hearing society's opinion on the subject, in order to gather more elements for decision-making.

During this hearing, 17 participants presented their views: three from the market, five representatives of civil society, four representatives of health professionals, two representatives of the State (SUS Collaborating Centre and São Paulo State Department of Health), and three representatives of educational institutions (Federal University of Rio de Janeiro - UFRJ, University of São Paulo - USP, and State University of Campinas - Unicamp). The participants discussed personal experience, as well as the benefits of the technology, the increase in its judicialization and its impact on patients' quality of life.

During the public hearing, the plaintiff presented a new commercial proposal providing for a price reduction equivalent to 21% compared to the purchase price of nusinersen negotiated with the Ministry of Health for the year 2021.

In view of the contributions presented in the public hearing, the members of Conitec decided, by simple majority, to partially alter their final decision, recommending the incorporation of nusinersen into the treatment of type II 5q spinal muscular atrophy, diagnosed up to 18 months of age, but not recommending the incorporation of nusinersen into the treatment of type III 5q spinal muscular atrophy.

It should be noted that this modification was not a direct result of the CP, but of another participation instrument also provided for in Law 12.401/2011, which provides for the use of public hearings before decision-making, justified by the relevance of the topic (Brasil, 2011).

Discussion

The results show that civil society is interested in participating in Conitec's public consultations, even though they deal mainly with technical issues in the incorporation of medicines and/or technologies. This indicates that PCs can act as mechanisms that strengthen social participation (Escorel; Birth; Edler, 2005): they do not strictly approach technical, scientific, and economic aspects of medicine. PCs include the vision and experiences of other parties involved in the health area, especially patients and their families.

In this context, the use of reports with simplified language to disclose health care topics, combined with that of specific forms to collect experience and/or opinion reports from family members, allows for the greater participation of segments of society that act in a non-institutionalized way in the process of improving the quality of public health services (Dantas, 2006).

These actions, associated with the use of ICTs to carry out PCs virtually, also enhance the participation of segments that, alone, have little to no influence on technical decisions on health (Alves, 2021). In addition,

the sharing of ideas in this open environment allows for a decision-making process that is more in line with social desires (Gomes, 2005), and gives greater legitimacy and transparency to administrative decisions (Amorim, 2022).

It was also observed that the low percentage of contributions by some groups in the analyzed PCs does not necessarily mean that they have no influence on health decisions, since there are other means of influencing the proposal and drafting of public health policies (Souza; Souza, 2018).

This study found that contributions influenced the change processes, but the total number of these contributions was not necessarily decisive in reversing Conitec's initial understanding. It is evident that axes related to the budgetary impact were highlighted, but this does not disqualify social participation, which was able to influence decisions on the incorporation of health technologies through arguments linked to the efficacy and necessity of certain medicines.

In addition, it was possible to observe that the economic dimension frequently influenced the PCs: the outcomes of five public consultations (71.42%) mentioned in this study, all demanded by manufacturing companies, were directly tied to the revision or renegotiation of prices. Cost reduction was a factor that positively influenced the revision of Conitec's position, since it directly reduced budgetary impacts on the State's public accounts.

Reductions in the cost of medicines are relevant given that scarce of resources and budget constraints are obstacles to the SUS offering all the technological innovations demanded by society. Since its inception, the SUS has suffered from underfunding, which consists of the insufficient allocation of budgetary and financial resources. This difficulty is one of the biggest challenges for the consolidation of the right to health (Paim, 2018).

Thus, in order to incorporate a new technology into health care, it must be understood that decisions require detailed economic analysis due to the possibility that the SUS will be unable to offer all the technological innovations available in the market–the cost of medicines is an important barrier to universal supply. Public authorities must act to serve the public interest and not give in to purely market interests (Gomes, 2015).

On the other hand, although Conitec's reasoning for its final decision was based on financial issues, it was not limited to them–the decision process also considered the safety and efficacy of the technologies analyzed.

In this sense, aspects related to efficacy, transparency, safety, and cost-effectiveness are central to the incorporation process established in the SUS by Conitec. Social involvement is also fundamental to this process and represents both the exercise of citizenship and the population's right to contribute to the development of public policies in the health sector (Tanure; Menegaz; Melgaço, 2022).

It is also possible to observe that in the two PCs (28.58%) in which outcomes were not related to economic issues, other factors influenced the changes in Conitec's decision, especially those tied to the possible societal impacts of the medicines and to the presentation of studies that proved the drugs were safe, which reflects important advances in achieving the objectives of HTA (Tanure, Menegaz; Melgaço, 2022).

It can therefore be concluded that PCs are valuable allies for society in the process of participating in public health management. Their democratic potential is revealed in the fact that they allow various social actors from different segments, which have different interests, to influence the HTA process.

Final Considerations

Social participation is an integral part of the evaluation of new technologies and must be strengthened so that the wishes of society can be reflected in public health policies. This study showed that the PCs performed by Conitec are important mechanisms and allow social participation to influence the formulation of public health policies.

The contributions did influence the change processes, but the total number of these contributions was not necessarily decisive in reversing the Committee's initial understanding. It is evident that axes related to the budgetary impact were highlighted, but this does not disqualify social participation, which was able to influence decisions on the incorporation of health technologies with

arguments linked to the efficacy and necessity of certain medicines.

Thus, it can be concluded that the participation of social segments that defend collective interests based on their experiences, combined with the balance of financial aspects, positively influenced Conitec's recommendations. This scenario demonstrates that PC is a democratic mechanism with the potential to generate progress in the development of a more equitable SUS that meets the real interests of society.

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Authors' contributions

Martins contributed to the conception of the article, data analysis and interpretation, and writing. Alves contributed to the critical review of the article and approval of the final version.

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