

## Reversal of the recommendations issued by the National Commission for the Incorporation of Technologies in SUS after Public Consultations

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**Abstract** *The work analyzed the effect of Public Consultations (PC) and their contributions to the recommendations of the National Commission for the Incorporation of Technologies (CONITEC). This is a descriptive and retrospective study with a qualitative-quantitative approach using a secondary data source of public access, between 2012 and 2017. A database was developed to characterize the PC of medications and their contributions, which allowed the identification of cases of reversals between the preliminary and final recommendation of CONITEC. We analyzed the contributions in cases of reversal for characterization of argumentative axes and type of basis. Of the 307 demands for incorporation of medications, 205 went through PC, with 23,894 contributions. The reversal of the recommendations occurred in 9% of the open PC (15 medications), all in the sense of non-incorporation for incorporation. Main argumentative axes dealt with clinical benefits and minor adverse events, with prevalence of the submission of clinical experiences and opinions. Advances in the processes of incorporation of technologies in the SUS by performing PC were found and the challenge that decision makers face in institutional spaces for the improvement of social participation to strengthen the public benefit was clear.*

**Key words** *Medications, Health Technology Assessment, Decision Making, Community Participation, Unified Health System*

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## Introduction

The Unified Health System (SUS) is responsible for guaranteeing universal, equitable and integral access to health, including health technologies (HT) that can be used in its scope<sup>1</sup>. This promoted adjustments over time on the decision-making process regarding the incorporation of HT, often permeated by the tension between their absorption and the limitation of economic resources that challenge the integrality and sustainability of the SUS<sup>1,2</sup>.

The Health Technology Assessment (HTA) studies public policies from the perspective of their clinical, social, ethical and economic implications, related to the development, diffusion and use of HT from aspects such as efficacy, effectiveness, safety, costs, cost-effectiveness, among others<sup>3</sup>.

Without underestimating the clinical and technocratic aspects, there has been an effort to value the ethical, legal and social impacts, especially after the discussion held in 2016 at the Health Technology Assessment International Global Policy Forum<sup>4</sup>.

The evolutionary process of HTA in the country has undergone changes that involve, among others, the creation of the Department of Science and Technology (DECIT) in 2000, through the Commission for the Incorporation of Technologies, all linked to the Ministry of Health (MH)<sup>5</sup>. In 2011, Federal Law 12,401 established the National Commission for the Incorporation of Health Technologies (CONITEC), consisting of a Plenary and Executive Secretariat. This Committee advises the Ministry of Health in decisions related to the incorporation, exclusion or alteration of new medications, medical products and procedures in the SUS<sup>5,6</sup>.

As part of the assessment process, CONITEC, during the analysis of the demands submitted to it, provides spaces for social participation, such as public consultations (PC), which occur after publication of its preliminary recommendation and precedes the final recommendation opinion of the Commission's Plenary<sup>7</sup>. This allows society to submit contributions and suggestions, both of a technical-scientific nature and of the experience of patients, caregivers and family members<sup>8</sup>.

The aforementioned Law also predicts for the possibility of assessment by simplified processes, which are those exempt from mandatory PC in their assessment flow. According to CONITEC, assessments through simplified processes involve proposals of relevant public interest, medications

with traditional use or new presentation. In addition, they deal with low cost and budget impact technologies for SUS related to the elaboration or revision of Clinical Protocols and Therapeutic Guidelines<sup>9</sup>.

Medications were the main technology demanded (62% of the total) in CONITEC in the period between 2012 and July/2016<sup>5</sup>. Recent data showed a similar outcome, since between 2012-2019 there were 804 demands for assessments, of which 69%, 18% and 13% corresponded, respectively, to medications, procedures and health products<sup>10</sup>. In the same period, 420 PC were published by CONITEC, with 190 thousand contributions received<sup>10</sup>. Still, the medication is the HT that most mobilizes the participation of society<sup>11</sup>.

Public Consultations have been identified as the main and most frequent strategy for social participation in HTA, which has been growing in recent years<sup>11,12</sup>. They are considered an instrument of publicity and transparency used by the public administration to obtain information, opinions and criticisms from society regarding a given theme, constituting a relevant mechanism in the formulation and definition of public policies, including the HTA process in the SUS<sup>3</sup>.

The expansion of the discussion and the possibility of participation of a greater diversity of actors would aim to contemplate these various perspectives in the debate. As this participation and its possible impacts are still recent and little studied, understanding this form of "listening", how social involvement has occurred and how it can interfere in the decision-making process of CONITEC are points to be explored, which may allow a better understanding of the potential and limitations of this strategy<sup>3,13</sup>.

We did not find other articles that, in addition to accounting for public consultations regarding the incorporation of medications<sup>3,11,14</sup>, also analyzed in a more qualitative way the contributions made focusing on the reversals of the position of the CONITEC Plenary.

Thus, the understanding of the influence of PC and their contributions on the directionality of the recommendations issued by the CONITEC Plenary raises important questions about the role of social participation in the process of incorporating medications into the SUS, which was the focus of the study. For this reason, the objective of this article was to analyze the changes in the position of recommendation of the CONITEC Plenary after the public consultations on the incorporation of medications.

## Methods

This was an exploratory and retrospective descriptive study of the demands related to medications analyzed by CONITEC between 01/01/2012 and 31/12/2017, considered the year of opening of the PC, provided that the final deliberation had also been concluded through publication in this period, which involved from the year of commencement of CONITEC's activities until the closing of the study. In situations with simplified procedures, the year of final recommendation was taken as a reference due to the availability of information.

### Context of the study

In the flow foreseen for the assessment process in force at the time of the research, the PC occurred between the opinion present in the preliminary report and the final recommendation (recommendation report), the result of the analysis by the members of the CONITEC plenary. In the end, this final recommendation was approved by the secretary of the Secretariat of Science, Technology and Strategic Health Inputs (SCTIE), formalized in a ministerial ordinance.

The preliminary report contained evidence data, economic assessments (including budgetary impact), being published before the PC, allowing to understand the previous position of CONITEC's plenary (incorporation/non-incorporation; exclusion/non-exclusion and expansion or not of the use of the technology). The final recommendation report, in addition to the information contained in the initial opinion, discussed elements of the PC process (quantity of contributions and some qualitative assessment), bringing as an outcome the final deliberation, with two exclusionary possibilities: (1) Maintenance of the previous positioning; and (2) Change/Reversal of the initial recommendation.

As already pointed out, demands for incorporation through simplified processes do not require the realization of PC, consequently they do not allow to identify the occurrence of position reversal in the opinions of the recommendations issued by the CONITEC Plenary.

The materialization of PC occurred through the online completion of forms for technical-scientific contribution (FTS) and/or experience or opinion (FEO) in the established time (maximum of 20 days), thus allowing the expression of the opinion of various actors in society (defined here as types of contributors) regarding the deci-

sion-making process. Each PC was linked to the evaluative follow-up of at least one technology demanded from CONITEC, and the same PC may present more than one assessment as the case of PC 25/2016.

Both forms available for submitting PC contributions were also initiated by a participant characterization section. The FEO had three fields of questions in order to know the participant's opinion on: (1) the initial recommendation of CONITEC, (2) previous experience with the medication under analysis and (3) previous experience with other medication indicated for the clinical condition in question. The FTS was structured into five blocks of questions: (1) clinical evidence, (2) economic assessment, (3) budgetary impact, (4) CONITEC's initial recommendation, and (5) additional aspects.

### Source of data and information of interest

The work was structured in three main stages (1) Extraction and updating of data related to medications from the source research project<sup>15</sup>; (2) Identification and description of the situations in which there was a change in the recommendation after performing the PC; and (3) Specific analysis of the cases of reversal of the previous recommendation.

Data were extracted regarding the main claimants, whether there was an opening of PC, the justifications available in the pre- and post-PC recommendation reports, the quantification of PC, the types of contributors, the type of basis for the contribution sent, and the main argumentative axes with relevance to HTA.

As for the reversals, the amount and type of basis of the contributions (if scientific evidence, clinical experience or opinion) were re-categorized as Scientific/Administrative Evidence; Clinical Experience; and Opinion, identification of the types of contributors (Government; Industry; Health institution; Teaching and research institution; Medical Societies; Patient and other NGOs; Health Professionals; Patient/Family; and Others). The content of the contributions was classified according to the common argumentative axes of the HTA process (Clinical benefits, New scientific evidence, Less adverse effects, Evidence of economic assessment, Budget impact and Equity and ethics). The type of foundation and the argumentative axes are summarized in Chart 1.

Finally, the final reports were analyzed in order to identify the central justification that

supported the opinion of the CONITEC recommendation on major themes: (1) economic (treatment cost, price negotiation, taxation); (2) clinical (survival, clinical effectiveness, etc.); (3) both and (4) not clear. Only contributions from the FTS were analyzed, due to the fact that they are close to the proposed argumentative axes.

### Analysis

The total number of medication assessed in the period was quantified both in the simplified processes and those that had the opening of PC. The PC was distributed according to the types of contributors per year and the type of basis of the contributions sent.

The medications involved in PC with decision reversal were classified according to the Anatomical Therapeutic Chemical (ATC) System<sup>16</sup>. The argumentative axes presented, the type of basis of the contributions and the central theme of CONITEC's final opinion were categorized by consensus of the authors based on the content of the final recommendation reports. The frequency of the argumentative axes and the type of basis presented were expressed in quartiles in such a

way: very little present 0-25%, little present >25-50%, moderately present >50-75%, very present >75-100%.

Data supporting the results of the manuscript are available in the SciELO Data repository (<https://doi.org/10.48331/scielodata.4SP3XA>).

### Results

CONITEC assessed 307 medications in the analyzed period, with demands related to the incorporation, exclusion or alteration of use. A total of 205 PC were identified, and 23,894 contributions were recorded between 2012 and 2017, with 38 to 72 medications assessed in the same year. There was variation in the proportion of simplified processes (without opening PC), which tended to decrease over time, with prevalence of the analysis by PC, which reached 78.9% in 2017.

In these cases, it was not possible to observe the performance of PC and the possibility of changes in position, with a view to issuing only one assessment report, with final opinion of the plenary of CONITEC. In the period, 66.8% of the medications had the opening of PC in their

**Chart 1.** Classification axes of the arguments present in the contributions to public consultations in cases of change of position of initial recommendation of the plenary of CONITEC and type of basis of the contribution. Brazil, 2012-2017.

Variable Type	Description
Argumentative Axes	
Clinical Benefits	Benefit related to the achievement of therapeutic results, shorter time of action, dosage convenience, better adherence to treatment
New Scientific Evidence	Literature research and recovery of evidence related to the technology assessed not mentioned by the plaintiff in the initial process filed with CONITEC
Less Adverse Effects	Less serious adverse effects, or with lower incidence in relation to alternative technologies for the same indication and even target audience
Evidence of Economic Assessment	It will involve any category of comparison between costs and consequences between technologies with the same indication and target audience, be it cost-effectiveness, cost-utility, cost-minimization and cost-benefit
Budgetary Impact	It considers the balance between the information on the costs involved with the offer of technology in the SUS, in view of the line of care and the magnitude and epidemiological characteristics of potential users, from the perspective of management
Equity and Ethics	Minimization of social injustices to vulnerable groups and compatibility with priorities established in health policy
Type of Contribution Basis	
Scientific/ Administrative Evidence	Submission of studies published in scientific or grey literature journals
Clinical Experience	Experience related to conduction to the clinic of the target disease of the discussion
Opinion	Personal judgment

Source: Authors.

assessment process (Table 1). No temporal trend was identified in any of the analyzed aspects.

The profile of contributors (Table 2) has changed over time, although we recognize the limitation that self-reference imposes. In the first three years analyzed, the most involved in the demonstrations were government structures, industry, health and research institutions, as well as patient associations, that is, institutional segments. In the last three years, contributions with individual characteristics, such as health professionals, patients or family members, prevailed. In a more discreet way, but still present were the patient associations and medical societies.

Sixty-one (61) PC opened in the period were excluded from the analysis, but did not have a final recommendation of the Plenary published by the end of 2017. Of the 144 PC related to medications only 13, involving a total of 15 medications, presented reversal of the recommendation, all of them from non-incorporation to incorporation. Two of them included more than one medication, PC 25/2016 with assessment of three medications (rapid-acting insulin analogues for type 1 diabetes mellitus) and 31/2016 with 33 otological solutions for the treatment of acute otitis external (AOE).

There were 6,455 contributions, with the participation of several types of contributors. PC 25/2016 and 21/2017 (dimethyl fumarate for multiple sclerosis) presented the highest number of contributions, corresponding together to 2845 contributions, about 44% of that verified in the studied period.

Although with fluctuations, the sending of contributions tended to increase. There were also cases with a low number of contributions: PC

22/2014 (abatacept) and 31/2016 (different topical medications for AOE), in which only 10 and 7 contributions were counted, respectively.

Most of the medications in which cases of reversal were identified were from the antineoplastic and immunomodulatory group (Table 3).

The main argumentative categories arising from the contributions were mainly related to clinical benefits and lower adverse effects; on the other hand, the content related to the budgetary impact was, in general, less present. The type of contribution sent was mostly based on clinical experience or opinions. Scientific/administrative evidence was present in only four PC, corresponding to the incorporation of the medications Erlotinib, Dimethyl Fumarate, Gefitinib and inhaled Tobramycin (Chart 2).

Regarding the justifications or central themes present in the recommendation reports of the CONITEC Plenary, there was a massive participation related to economic issues (70%), such as price negotiations (Chart 2).

## Discussion

Medication is the sanitary technology most requested by CONITEC with frequent recommendation of incorporation, both those that refer to totally new products and for new indication of use<sup>13,15</sup>.

Of the 307 demands for assessment of medications related to incorporation, exclusion or alteration of use, 205 resulted in PC, of which in 13 there was a reversal of the recommendation of the preliminary decision, all in the sense of non-incorporation for incorporation.

**Table 1.** Type of assessment (public consultation or simplified processes) of medications carried out by CONITEC and number of contributions. Brazil, 2012-2017.

Selected characteristics of medication assessment demands	N and % according to year of public consultation						Total
	2012	2013	2014	2015	2016	2017	
Total medications assessed	72	54	38	49	56	38	307
	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Total simplified procedures	27	31	10	12	14	8	102
	37.5%	57.4%	26.3%	24.5%	25.0%	21.1%	33.2%
Total assessments with PC opening	45	23	28	37	42	30	205
	62.5%	42.6%	73.7%	75.5%	75.0%	78.9%	66.8%
Total contributions	2,119	969	1,234	8,592	2,592	8,388	23,894

PC=Public consultation. Simplified Processes: Evaluative processes in which there is no opening of public consultation. Technologies procedures and equipment were excluded from the analysis.

**Table 2.** Percentage distribution according to type of contributors identified in public consultations on medications. Brazil, 2012-2017.

Types of Contributors	%					
	2012	2013	2014	2015	2016	2017
Governmental	13.6	4.9	17.9	1.0	0.2	0.0
Industry	13.2	11.0	5.8	0.5	0.9	0.3
Healthcare Institution	21.7	41.7	7.1	1.3	0.4	0.1
Teaching or research institution	16.5	8.3	5.6	0.9	0.1	0.0
Medical societies	4.4	3.1	4.9	2.5	0.4	0.2
Patient Association and other NGOs	11.2	10.5	14.4	2.5	1.1	0.9
Health professionals.	0.3	0.1	17.3	16.2	41.1	26.1
Patient/Family	0.8	0.1	16.3	60.0	44.7	54.1
Others	18.3	20.3	10.7	15.1	11.1	18.3
Total contributors identified	1,807 (100.0%)	969 (100.0%)	1,234 (100.0%)	8,592 (100.0%)	2,592 (100.0%)	8,387 (100.0%)

Note: (1) the Judiciary Branch was suppressed for presenting only two contributions over the period, one in 2015 and the other in 2016; (2) the others category refers to the identification completed by the contributor, in this analysis it is considered as a category, and not absence of it.

Source: Authors.

There was a reduction in simplified processes (those in which there is no opening of PC) between 2012 and 2017. However, this format remained significant, ranging from 57.4% in 2013, when it reached the highest proportion, to 21.1% in 2017. All simplified processes originated internally from the Ministry of Health, converging with what has been demonstrated in other studies<sup>11,17</sup>. Although this mechanism is provided in the legislation<sup>18</sup>, it is not clear the criterion of when it should be applied, in addition to making it impossible to carry out PC, involving social participation and, consequently, preventing studies on changes in CONITEC's position between the preliminary and final recommendation opinions.

Polanczyk<sup>19</sup> mentions that the public consultation mechanism is adopted by agencies of HT incorporation in different countries, such as England, Canada, Germany and Australia. In addition, in countries where HTA processes are more structured, such as those mentioned, it is understood as necessary to separate those who assess (agencies or equivalent) and the decision maker (governments), aiming at mitigating possible conflicts of interest to contaminate these two processes<sup>13,15</sup>. In the case of Brazil, CONITEC is formed by a Plenary in which more than half of the members (7 out of 13) are from the structures of MH.

Although no international study was identified that dealt with the volume of reversals of HTA agencies, a national study that described social participation during the process of incorporation of HT by CONITEC, verified a quantity of six medications with changes in position between the preliminary and final recommendation, all also in the sense of not incorporation for incorporation, diverging from our finding of 15 changes in position in the same period, but converging when it comes to directionality<sup>3</sup>.

Despite important fluctuations, the number of contributions to PC increased almost four times in the analyzed period. Some PC had a high amount of contributions (PC 21/2017) and others little (PC 31/2016). It is interesting to note that even PC with few contributions, such as 22/2014 (abatacept) and 31/2016 (topical medications for AOE), resulted in reversal of the initial recommendation. According to the respective reports, in 22/2014, economic issues were of fundamental importance. The same medication had already been submitted to analysis in 2012 and not incorporated at that time. In the PC 31/2016 there was no clarity in the conduct of the study or in the decision making<sup>20,21</sup>.

There was a great increase in the participation of patients and family members in PC on medications during the six years of analysis, which may be the result of the use of some strategies used

**Table 3.** Number of Public Consultations on medications with reversal of recommendation by CONITEC plenary and total contributions, according to indication of use and first and second level of the anatomical classification of chemical therapy (ATC), Brazil, 2012-2017.

PC Number	Number of Contributions	Medication	Indication	First Level	Second level ATC
16/2013	116	Erlotinib	Lung cancer	L - Antineoplastics and immunomodulators	L01 – antineoplastics
17/2013	64	Gefitinib	Lung cancer	L - Antineoplastics and immunomodulators	L01 – antineoplastics
22/2014	10	Abatacept	Rheumatoid arthritis	L - Antineoplastics and immunomodulators	L04 – Immunosuppressants
22/2015	277	Dolutegravir	Human immunodeficiency virus infection	J - Anti-infectives for systemic use	J05 – antivirals for systemic use
03/2016	242	Tobramycin	Cystic fibrosis infection	J - Anti-infectives for systemic use	J01 – Antibacterials for systemic use
15/2016	284	Rivastigmine	Alzheimer Disease	N Nervous system	N06 – psychoanaleptics
25/2016	1,032	Insulin aspart	Diabetes mellitus	A- Alimentary tract and metabolism	A10 – medications used in diabetes
		Insulin lispro	Diabetes mellitus	A Alimentary tract and metabolism	A10 – medications used in diabetes
		Insulin glulisine	Diabetes mellitus	A Alimentary tract and metabolism	A10 – medications used in diabetes
26/2016	770	Fingolimod	Multiple sclerosis	L - Antineoplastics and immunomodulators	L04 – Immunosuppressants
31/2016	7	Topical medications (antibiotics, antifungal, anti-inflammatory and anesthetics or the combination of these substances)	Acute otitis external	S - Sensor organs	S02 – otological
33/2016	342	Tofacitinib	Rheumatoid arthritis	L - Antineoplastics and immunomodulators	L04 – Immunosuppressants
01/2017	863	Teriflunomide	Multiple sclerosis	L - Antineoplastics and immunomodulators	L04 – Immunosuppressants
13/2017	635	Pertuzumab	Breast cancer	L - Antineoplastics and immunomodulators	L01 – antineoplastics
21/2017	1,813	Dimethyl Fumarate	Multiple sclerosis	L - Antineoplastics and immunomodulators	L04 – Immunosuppressants

Source: Authors.

by CONITEC, aiming precisely at the expansion and involvement of these types of contributors. Examples are Reports to Society, digital social media, email lists, etc. Although it has increased, there are still challenges so that the assessment processes are also oriented by social and ethical dimensions<sup>3</sup>.

Another point is whether these individual contributions can be instructed or influenced by organizations such as the pharmaceutical industry, which has a prominent role in the volume of demands for incorporation, with market inter-

ests different from SUS priorities<sup>1</sup>. In this sense, it is possible that, as occurs in other countries, before or early the opening of the PC, the company that manufactures the technology monitors and activates social spaces, such as groups of contributors of interest (health professionals, medical societies, patient associations and other NGOs) that synergistically can exert pressure for incorporation<sup>22</sup>.

The PC is not a full guarantee of the participation of society, as an expression of citizenship, which needs to rely on increasingly qualified

**Chart 2.** General characterization of the argumentative axis in the contributions to public consultations of medications with position reversal status and main synthesis of justification basis used by CONITEC for the change of position and type of basis of the contributions sent. Brazil, 2012-2017.

Medication	Presentation	Argumentative axis in contributions to Public Consultations - predominance in the text						Type of basis of contributions sent			Central theme of the CONITEC
		Clinical Benefits	New scientific evidence	Less Adverse effects	Evidence of EA	Budgetary Impact	Equity and ethics	Evidence Scientific/Administrative	Clinical experience	Opinion	
Abatacept	Subcutaneous solution for injection (125 mg and 250 mg being 125 mg/ml inj. CT 1 or 4 SER)	XXXX	X	XX	XX	XXX	XX	**	***	*	Economical
Dolutegravir	Oral tablet (50 mg/30 tablets)	XXX	XX	X	X	X	XX	**	*	***	Economical
Erlotinib	Oral tablet (25, 100 or 150 mg/30 tablets)	XXX	XX	XX	X	XX	XX	**	*	**	Clinical
Fingolimod	Oral capsule (Capsule containing 0.56 mg fingolimod hydrochloride, equivalent to 0.5 mg fingolimod)	XXXX	XX	XX	X	X	XX	**	***	*	Both
Topical medications <sup>1</sup>	Otological solutions or ointments (various presentations as reported in the Report 253 CONITEC)	XXXX	XXXX	XXX	XXX	XX	XX	***	*	*	Not clear
Dimethyl Fumarate	Oral capsule (120 and 240 mg/capsule)	XXXX	XX	XXX	XX	XX	X	**	*	**	Both
Gefitinib	Oral tablet (250 mg/30 tablets)	XXX	XXX	X	X	X	X	***	*	*	Clinical
Insulin aspart	Subcutaneous solution for injection 100 000 IU/ml	XXX	X	XX	XX	X	XX	*	**	***	Economical
insulin glulisine	Subcutaneous solution for injection 100 000 IU/ml	XXX	X	XX	XX	X	XX	*	**	***	Economical
Insulin lispro	Subcutaneous solution for injection 100 000 IU/ml	XXX	X	XX	XX	X	XX	*	**	***	Economical
Pertuzumab	Intravenous solution (14 mL solution (420 mg/14 mL))	XXXX	XX	XX	X	X	X	**	**	**	Economical

it continues

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		Clinical Benefits	New scientific evidence	Less Adverse effects	Evidence of EA	Budgetary Impact	Equity and ethics	Evidence Scientific/Administrative	Clinical experience	Opinion	
Rivastigmine	Transdermal patch (patch 5 and 10)	XXXX	X	XXXX	XXX	XX	XX	*	***	**	Economical
Teriflunomide	Oral Tablet (14 mg/30 tablets)	XXXX	XXXX	XXX	X	X	X	***	*	*	Economical
Tobramycin	Inhalation solution (300mg)	XXXX	XXX	XXX	XXX	XX	X	***	*	**	Clinical
Tofacitinib	Oral Tablet (5 mg/60 tablets)	XXXX	X	XX	XXXX	X	X	*	****	*	Economical

Note: <sup>1</sup>Topical medications (antibiotics, antifungal, anti-inflammatory and anesthetic or the combination of these substances); EA=Economic assessment, X=very little mentioned; XX=little mentioned; XXX=moderately mentioned, XXXX=very mentioned; \*Very little present; \*\*Little present; \*\*\*Moderately present, \*\*\*\*Very present.

Source: Authors.

performance<sup>3,11</sup>. The possibility of existence of mechanisms of e-democracy (participation or virtual democracy) per se does not legitimize or guarantee the fullness of the involvement, which requires the existence of instances, formats, information and effective communication to strengthen the HTA process, in addition to the recognition of its capacity to choose in health decisions<sup>13</sup>.

The self-reported identification filled in on CONITEC's electronic PC form can lead to inconsistencies in both the type of contributor and its content. Adjustments could be designed to better characterize these contributors and the quality of the information submitted.

Distortions were observed in the completion of identifications related to social segments. For example, in PC 16/2013, self-reported forms as industry presented manifestation content compatible with the user/patient's speech<sup>23</sup>. There were also distortions in the use of the forms, in which patients used the FTS, contrary to the recommendation to use the FEO. Some issues could be fixed with system adjustments. For example, after the users identify their qualification for the contribution, the system could offer them the most appropriate form. Additionally, there could be control and blocking of repeated messages.

Regarding the medications that underwent reversal of the initial decision (non-incorporation for incorporation), this may indicate that the changes in the CONITEC recommendations, after analyzing the contributions sent when the PC was performed, have acted in order to provide a second chance for the incorporation of the technology.

More than half of the reversed PC were related to the class of antineoplastic and immunomodulatory medications, indicated for the treatment of cancer, rheumatoid arthritis and multiple sclerosis. The position change was concentrated on products indicated for non-communicable diseases, compatible with the general standard of incorporation that has been carried out by CONITEC<sup>24</sup>.

Several decisions (tofacitinib, rivastigmine and dimethyl fumarate) established the incorporation conditioned to the need to update or elaborate clinical protocols and therapeutic guidelines in SUS, a fact also observed in another study<sup>15</sup>.

In the assessment of fingolimod, analogous insulins, dimethyl fumarate and transdermal rivastigmine, the phenomenon of recurrence of submissions was identified, that is, successive demands of the same technology, until the favorable recommendation of incorporation. This

situation, already pointed out by Caetano *et al.*<sup>15</sup>, shows that the previously contrary positions of CONITEC were related to the proposals initiated for broader uses of medications that, later, ended up being restricted in terms of indications for use, to be, finally, incorporated.

Another aspect identified in the reversals was the action of the pharmaceutical industry as a plaintiff. Its argumentation was based on points highlighted in the preliminary reports indicated as limiting factors for the incorporation. Its performance during the process was strategically based on themes related to price adjustments and other possibilities, such as the realization of technology transfer, via the productive development partnership (PDP), exemplified by the transdermal patch rivastigmine and pertuzumab. The PDP is an instrument designed to strengthen the health industrial economic complex, which emphasizes innovation and the reduction of Brazil's dependence on the production of medications<sup>25</sup>. Thus, the use of this agenda is perceived to favor the incorporation of technologies in the SUS.

It was possible to infer that PC is used as an influence strategy regarding the decision to allocate resources, since much of the argumentation of reversal situations had an axis in the economic issue.

The economic dimensions were often mentioned as a central justification of CONITEC, as an outcome related to the revision and/or negotiation of prices (price reduction in public purchases) or indication of adherence to a tax exemption agreement, especially the Tax on Circulation of Goods and Provision of Services (ICMS). In fact, medication prices are crucial for the development of health systems and constitute an important barrier for both families and governments to access them, and they have a prominent role especially in universal public systems, in which the right to health and to access medications are present<sup>26</sup>.

Another issue is that the HTA process is permeated by often conflicting interests. During the achievement of PC, there may be tension mainly from manufacturers, patient associations, physicians, health professionals due to the pressure for public funding of technologies that often have insufficient scientific evidence for incorporation and its rational use. So much so that the National Institute for Health and Clinical Excellence (NICE), which carries out the role similar to that of CONITEC for the English health system, relies on evidence and support from the perspective of health professionals and patients, aiming

to reduce pressures exerted, such as from the pharmaceutical industry, patient associations, political groups, and professional societies<sup>22</sup>. It noteworthy that new technologies are not always better therapeutic options than existing ones, as they may not be a safe option<sup>27</sup>.

The classic attributes of HTA, such as evidence of efficacy, effectiveness, safety and cost-effectiveness are central to the process of incorporation established in the SUS, and were present in the contributions submitted. Elements related to clinical benefits and safety were more cited. Both are related to health safety and minimization of risks, essential for the protection of public health and foundations of the trinomial of health regulation: quality, safety and efficacy<sup>28</sup>.

Although there are national guidelines to consider the social, ethical and legal impacts in the assessment process, such attributes still appeared in a secondary way. Even so, the basic elements of HTA have been used as a tool to support decision-making in the incorporation of new technologies, even though they present limitations in their application, such as the imbalance of economic issues vis-à-vis equity and ethics<sup>13,29</sup>.

The scenario brings numerous challenges for the PC to fulfill its role of expressing social participation in times when the expansion of spaces for democratic discussions is so important. Thus, the degree of quality of information is essential for the effectiveness of this strategy. Elements conditioned to the asymmetry of information by different types of contributors, observed in this work by the complexity of technical elements on the process of incorporation of technologies, may have influences and constitute, at the same time, barriers to adequate social participation<sup>11,30</sup>.

Investing in the dissemination of the HTA field, informing and publicizing the topics of interest for discussion of the Plenary, having an information system both via social networks and in the common media can be interesting strategies, in addition to those already initiated through the Report for Society and others, which aim to contain information asymmetries<sup>3</sup>.

The scenario of dependence on investments in mechanisms of involvement of the various contributors in social participation in HTA remains latent. There is also a need to change the plenary paradigm, focusing on aspects other than economic arguments.

Public policies for the involvement of users in health decisions, although initiated, still need to make efforts to meet the expectations of users, who seek guarantees of access to health and HT.

These users include both those with diseases of great epidemiological expression and those with rare diseases<sup>31</sup>.

Some limitations need to be pointed out. The study used records obtained from documents from the reports and PC forms, which are not always completely reliable. For example, the identification information of the participants presented flaws, such as identification and completion of the virtual forms. This can lead to inconsistencies in both the origin of the type of contributor and its content. Another limitation refers to the heterogeneity in the content provided by the reports, which resulted in greater arbitrariness in the categorizations used in the study. Finally, the analysis of the contributions with changes in the positioning of CONITEC was based on FTS, which may have reduced the uptake of manifestations of social segments, such as patients and family members.

The study found that the contributions influenced the reversal processes, but not necessarily the quantity was the fundamental factor. Although higher frequencies of argumentative axes related to clinical benefits and lower adverse effects were identified, it seemed that the arguments related to the budgetary impact were more accurate.

In addition to the valorization of the PC mechanism, it is important to advance in the sense that the HTA considers aspects that go beyond budgetary and clinical evidence, seeking the sustainability of the system, but without detriment to ethical and social aspects.

In this sense, public agents need to improve institutional spaces so that HTA and the incorporation process are better understood and transparent.

## Collaborations

SGP Lopes, VL Luiza and RM Silva conceived and planned the study, drafted the text, and approved the final version of the article. SGP Lopes collected, analyzed, and interpreted the data. All authors read and approved the final manuscript for submission. Finally, the authors declare that there are no potential conflicts of interest.

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