

Incorporation of medicines in the Unified Health System (SUS): comparison between oncology and the specialized component of pharmaceutical care

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Abstract *Compliance with legal deadlines for the assessment and incorporation of technologies in Brazil's Unified Health System (SUS) is essential to ensure public access to essential medicines. The scope of this paper was to analyze the compliance with legal deadlines for incorporation and availability of medicines in the SUS, comparing Oncology and the Specialized Component of Pharmaceutical Assistance (SCPA). A comparison was made of the drugs incorporated that were submitted to Conitec in the period from January 1, 2017, to April 30, 2020. A total of 85 drugs were recommended for incorporation by Conitec, of which 15 (17.64%) were for Oncology and 70 (82.36%) were for SCPA. The time between analysis and recommendation by Conitec until the publication of the decision by the Ministry of Health was, on average, 86 days longer for oncological drugs and the availability timeframe of technologies incorporated in the oncology area was, on average, 389 days longer than for SCPA. The major progress achieved with the creation of Conitec in Brazil is acknowledged, but the results of this study point to a pressing need to improve the process of making available technologies incorporated into the SUS, especially in oncology.*

Key words *Access to Essential Medicines and Health Technologies, Biomedical Technology Assessment, Oncology, Pharmaceutical Assistance, Unified Health System*

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Introduction

A decade ago Law N^o 12,401/2011, which amended the Organic Law for the Unified Health System (Brazil's public health care system - *Sistema Único de Saúde* or SUS in Portuguese), introduced a regulatory framework for the adoption of health technologies by the SUS¹ and created the National Commission for the Adoption of Technologies by the SUS (CONITEC, acronym in Portuguese). The Commission advises the Ministry of Health on the adoption, exclusion or alteration of new medicines, products and procedures and the creation or modification of clinical protocols and therapeutic guidelines (CPTG)^{1,2}.

The so-called "SUS Comprehensiveness Law"¹ provides that the approval of new drugs should be based on scientific evidence and economic analysis and establishes timeframes for completing the assessment process that precedes the adoption, exclusion or alteration of technologies. These timeframes enable the monitoring of the implementation of decisions and recommendations³. In Brazil, the timeframe for approving the adoption of a technology is 180 days, extendable for another 90 days from the date on which the assessment application dossier is filed at CONITEC¹.

Approval must be published in the official government gazette; however, publication does not necessarily result in immediate availability as the relevant technical departments of the Ministry of Health have 180 days from publication to make the technology available on the SUS^{2,4}. A number of different departments may be involved in this process depending on the type of technology. Medicines are funded by either the pharmaceutical care components or Medium and High Complexity (MHC) Healthcare Component of the Ministry of Health's funding program, as is the case with cancer drugs⁵⁻⁷.

The Specialized Pharmaceutical Care Component (CEAF, acronym in Portuguese) is the component that receives the highest demand for new health technologies, with these technologies making up a larger part of the budget than in other components⁸. According to the Ministry of Health, the CEAF "is a strategy for promoting access to medicines through the SUS characterized by the pursuit of comprehensive drug therapy at outpatient level, whose lines of care are defined in CPTG issued by the Ministry of Health"⁹. The medicines funded by the CEAF must be on the National Essential Medicines List^{4,7}.

Unlike other medicines, cancer drugs are funded by the MHC component and provided by accredited cancer treatment centers after the technology has been included in the chemotherapy procedures recorded in the High Complexity Procedure Authorization (HCPA) subsystem of the Outpatient Information System. As a rule, centers provide the medicine and are subsequently reimbursed by the Ministry of Health through the HCPA. There are exceptions however where the Ministry of Health purchases anti-cancer drugs such as trastuzumab centrally through the CEAF¹⁰. Unlike other medicines funded by the CEAF, cancer drugs do not have to be on the National Essential Medicines List. In addition, while medicines funded by the CEAF must be included in CPTG, although the drugs used in cancer treatment are generally those recommended in diagnostic and therapeutic guidelines, service providers and prescribers are not obliged to strictly follow these recommendations.

Differences in drug funding and distribution processes can hinder compliance with the timeframes set out in the legislation. Although the time it takes for a new technology to be made available on the SUS is a widely debated issue in Brazil, the Ministry of Health does not disclose relevant data and research in this area is scarce. This study therefore seeks to address the gap in research into compliance with legal timeframes for adopting and making medicines available on the SUS by comparing the adoption and provision of cancer drugs and CEAF medicines during the period 2017 to 2020.

Methods

We conducted a quantitative retrospective study using document analysis to analyze applications for adoption of medicines by the SUS submitted to CONITEC between January 1st, 2017, and April 30th, 2020, considering all approvals of cancer drugs and CEAF medicines during the period.

The applications were analyzed according to applicant (within or outside the SUS). We assessed the time taken for each medicine to be adopted and made available by the SUS, comparing cancer drugs and CEAF medicines.

The time taken to adopt each medicine was calculated based on the number of days between the date the assessment application dossier was first filed at CONITEC and the publication of

the decision in the official government gazette. This information was taken from the technical reports recommending that the medicine should be adopted by the SUS from 2017, 2018, 2019 and 2020, available from the “CONITEC Recommendations” page of the Commission’s website.

The time between adoption and when each medicine was made available on the SUS was calculated based on the number of days between the publication of the decision in the official government gazette and: 1) the date on which the inclusion of the medicine in the SUS Procedures, Medicines and Orthoses/Prostheses and Special Materials (OPM) Schedule was published or, in the case of cancer drugs, the date the Ministry of Health decided to make a centralized purchase; or 2) in the case of CEAF medicines, the date that the CPTG including the technology were published, given that in some cases procedures including the medicine were incorporated into the SUS Procedures, Medicines and OPM Schedule and/or a code was published in the SIGTAP (SUS Procedures, Medicines and OPM Schedule Management System) before approval by CONITEC. It is important to highlight however that the publication of the SIGTAP code or incorporation of procedures into the SUS Procedures, Medicines and OPM Schedule do not necessarily mean that the cancer drug is made available immediately, because accredited treatment centers may decide not to acquire a medicine or purchase it at a later date. We therefore acknowledge the limitations of this method due to the lack of standardized procedures for making cancer drugs available on the SUS.

To assess compliance with timeframes, we used the following benchmarks based on the periods established by the legislation: 270 days for adoption (180 days extendable for another 90 days) and 180 days to make the medicine available on the SUS^{1,4}. Considering that the timeframe for making the medicine available on the SUS was 180 days and that the data was collected on November 30th, 2020, we included all medicines published in the official government gazette up to April 30th, 2020.

The analyses of the data and time taken to adopt and make the medicines available on the SUS were performed using descriptive statistics, the Shapiro-Wilk and Mann-Whitney tests, and survival analysis (Kaplan-Meier estimator), which estimates the time to an event of interest.

We tested the following hypothesis: the length of time between submission and adoption was longer for cancer drugs than for CEAF

medicines. Based on a 95% confidence level, the results of the Shapiro-Wilk test indicate that the sample of CEAF medicines comes from a normally distributed population, while the sample of cancer drugs comes from a population that is not normally distributed. We therefore performed the Mann-Whitney non-parametric test ($CI \geq 95\%$; $p < 0.05$).

The present study used publicly available data that does not identify participants, dispensing with the need to submit the study protocol to a research ethics committee.

Results

Eighty-three applications were approved by CONITEC between 2017 and 2020, 13 of which (15.66%) were for cancer drugs and 70 (84.34%) for CEAF medicines. Forty-eight (57.83%) of the applications came from organizations outside the SUS and 35 (42.17%) came from bodies within the health system, such as departments within the Ministry of Health. Ten of the applications for cancer drugs (76.92%) and 38 of the applications for CEAF medicines (54.28%) came from organizations outside the SUS.

Length of time between dossier submission and adoption

The average time taken to assess applications and publish the decision in the official government gazette was 15 days longer for cancer drugs (Table 1). The shortest and longest processing times (3 and 469 days, respectively) were for CEAF medicines.

Forty-six of the 70 applications (65.71%) for CEAF medicines and 10 of the 13 applications (76.92%) for cancer drugs were processed within the 270-day legal timeframe and mean and median processing times were within the specified period.

Average processing time only exceeded the 270-day legal timeframe in 2017, when it took an average of 282 days to process applications for cancer drugs (Figure 1).

Up to November 30th, 2020, only 2 of the 13 (15.38%) cancer drugs and 44 of the 70 (62.86%) CEAF medicines had been made available on the SUS. The cancer drugs that were made available were Trastuzumab and Pertuzumab, both of which were centrally purchased and distributed to care facilities.

Length of time between adoption and availability on the SUS

The average time taken to make the technologies available was 389 days longer for cancer drugs than for CEAF medicines. The shortest and longest processing times (29 and 1,314 days, respectively) were for CEAF medicines. The two adopted cancer drugs took an average of 2 years to be made available (Table 2).

It was initially intended to perform a statistical analysis to test the hypothesis; however, due to the small number of observations this was not possible even using non-parametric methods. We therefore performed a survival analysis using the Kaplan-Meier survival curve and log-rank test to compare the curves. The resulting survival curve suggests that, for all survival times, the probability of exceeding the legal timeframe for making medicines available on the SUS after adoption was greater for cancer drugs (Figure 2). This means that the chance of a medicine being made available in a timely fashion is greater for CEAF medicines at all points of the post-adoption process, as shown by the log-rank test results adopting a 5% significance level (χ^2 4.4; $p < 0.05$).

Of the adopted medicines that had yet to be made available by the end of the data collection period (November 30th, 2020), 13 cancer drugs and 36 CEAF medicines (30.7% and 65.1%, respectively) had exceeded the 180-day legal timeframe.

Table 1. Comparison of length of time in days between dossier submission and adoption of Cancer drugs and Specialized Pharmaceutical Care Component medicines by the SUS between January 1st, 2017, and April 30th, 2020.

Parameter (days)	Cancer drugs (n=13)	Specialized (n=70)
Minimum value	120	3
1st quartile	119.5	116.2
Median	233	221.5
Average	232.7	217.6
3rd quartile	284	293.8
Maximum value	429	464
Standard deviation	74.24	118.95

Source: Authors.

Discussion

The institutionalization of health technology assessment (HTA) in the SUS through the creation of CONITEC was a major step forward for Brazil. However, the findings of the present study show that the legal timeframes for adopting and making cancer drugs and CEAF medicines available on the SUS were not rigorously met between 2017 and 2020. Although average processing time between application submission and adoption of both cancer drugs and CEAF medicines was less than 270 days over the study period, average processing time was 15 days longer for cancer drugs and exceeded the legal timeframe by 12 days in 2017.

A comparative analysis of the HTA process in Brazil, the United Kingdom, Australia and Canada showed that there was a lack of systematic pre-selection and/or prioritization of topics for review and widescale dissemination, unlike in the other countries where these aspects provide greater transparency to the process³. The differences in the time taken to process the application and publish the approval of adoption between cancer drugs and CEAF medicines is therefore unjustified, given that differences are generally down to the prioritization of a specific area over other areas, which is not clearly defined in the approach currently adopted by CONITEC. Furthermore, although CONITEC assessed 285 adoption application dossiers during the study period, the legal timeframe for assessment is not dependent on the volume applications.

The authors of an article on the adoption of health technologies by the SUS⁵ highlight that HTA applied to cancer drugs has peculiarities that hinder the decision-making process and that the adoption of cancer drugs is different to that of CEAF medicines insofar as cancer treatment is not limited to availability of medicines. However, the legislation in Brazil does not establish different timeframes for the two areas, nor does it exempt the CEAF from establishing clinical protocols for diagnosis and treatment.

One of the ways of enhancing health technology assessment in Brazil suggested by Brazilian researchers is the promotion of cancer research to disseminate and strengthen the work of independent research centers specialized in HTA^{11,12}.

The findings of the present study support the suggestion⁵ that it is necessary to improve technology adoption and divestment policies and strategies to make processes more transparent. It is also important to apply the principle of equity,

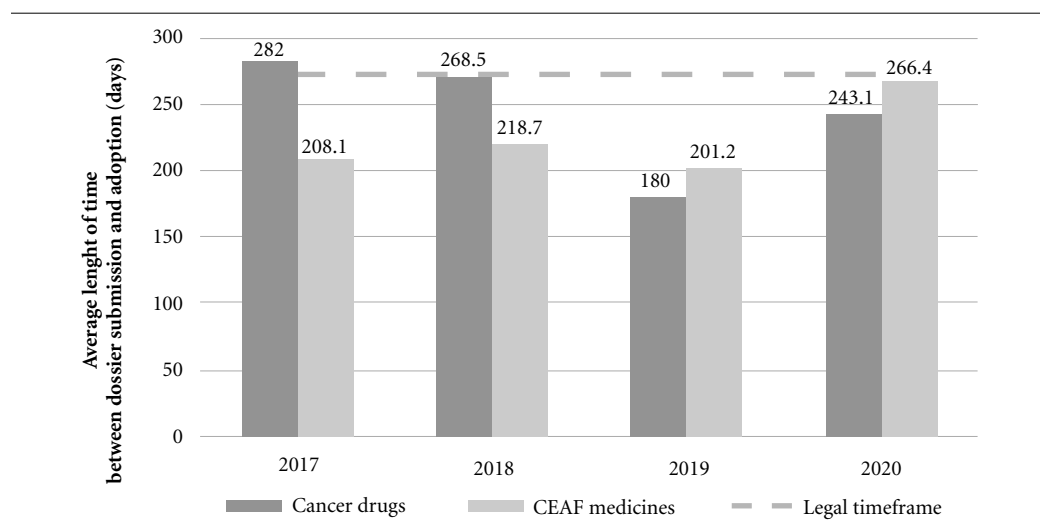


Figure 1. Comparison of average time in days between dossier submission and adoption of Cancer drugs and Specialized Pharmaceutical Care Component medicines between January 1st, 2017, and April 30th, 2020.

Source: Authors.

Source: Authors.

Table 2. Comparison of length of time in days between adoption of Cancer drugs and Specialized Pharmaceutical Care Component medicines and availability on the SUS during the period January 1st, 2017, and April 30th, 2020.

Parameter (days)	Cancer drugs (n=13)	Specialized (n=70)
Minimum value	581.0	29.0
1st quartile	671.5	180.8
Median	762.0	302.0
Average	762.0	372.9
3rd quartile	852.5	421.8
Maximum value	943.0	1314.0
Standard deviation	255.97	282.82

Source: Authors.

which requires policies that redress imbalances by prioritizing specific actions and reducing inequalities. As a report published by the Institute of Applied Economic Research¹³ highlights, “the adoption of medicines can be yet another factor that aggravates the already deep inequalities in health and access to health services in Brazil”.

The prioritization of assessment and provision of technologies according to the burden of the disease is one way of reducing inequalities.

Our findings show that CONITEC has reduced application processing times over the last two years, but continues to use the 90-day extension period. However, once adopted, technologies should be made available on the SUS within 180 days so that the accredited health services can ensure access to the new technology. In the United Kingdom, for example, this period is 90 days³. The results show important differences between the two types of drugs assessed by the study, with the average time taken to make technologies available being longer for cancer drugs and a higher proportion of CEAF medicines being made available than cancer drugs.

CONITEC has implemented initiatives to strengthen public participation in the decision-making process¹⁴, including the participation of patient representatives as witnesses at meetings and provision of meeting recordings on its website since 2020^{15,16}. The stages of the process involved in making the adopted technology available – such as the definition of the organization responsible for providing the medicine by the Tripartite Inter-management Commission (CIT)¹ – are not properly documented

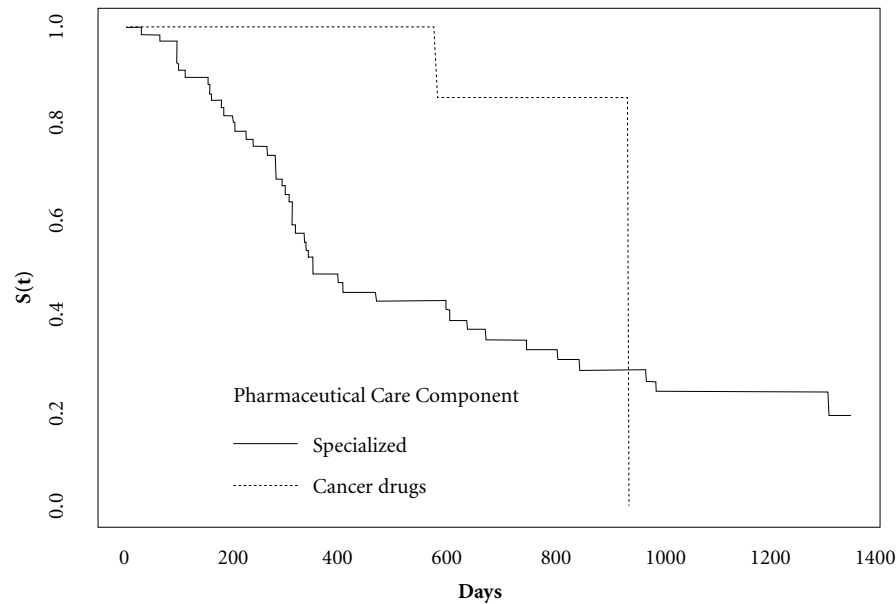


Figure 2. Comparison of time in days between the adoption of Cancer drugs and Specialized Pharmaceutical Care Component medicines and availability on the SUS using the Kaplan-Meier survival curve.

Source: Authors.

and disseminated in easily understandable terms to health professionals, the general population, and even health managers. This poses a barrier to effective public participation in health policy-making, one of the fundamental principles of Brazil's constitution^{16,17}.

The two cancer drugs made available during the study period were funded by the CEAf and purchased centrally¹⁸, which is unusual for this type of drug. This decision may have been taken to increase bargaining power and drive down prices, thus increasing the SUS's purchasing power. However, we are unable to confirm the reasons for choosing this procurement method as the Ministry of Health did not provide a justification.

In addition to the above, the adopted cancer drugs are not on the National Essential Medicines List, which, according to Decree No. 7,508/2011⁷, selects and standardizes the medicines indicated for use by the NHS. We were unable to find arguments in the literature and official documents for not including cancer drugs on the National Essential Medicines List.

Delays in making technologies available can result in loss of life, especially when it comes to cancer treatment, with studies finding a relation between delay in starting treatment and poorer outcomes¹⁹. It is known that delay in cancer diagnosis and treatment in Brazil is multifaceted²⁰ and occurs in other parts of the world²¹. However, it is up to the government to define and implement policies and organize SUS cancer care services to ensure the timely delivery of adequate treatment. Comprehensiveness is one of the guiding principles of the SUS and Brazil's National Policy for Cancer Prevention and Control in the Health Care Network for People with Chronic Diseases within the SUS²² recognizes the need to deliver comprehensive care to cancer patients and that cancer is a preventable disease, which is in accordance with the goal of reducing premature mortality from cancer in World Health Organization member countries²³. However, our findings show that, if this goal is to be met, technology adoption policies need to be improved in order to ensure that new medicines are made available within the specified timeframe.

This study has some limitations. First, the publication of the incorporation of procedures into the SUS Procedures, Medicines and OPM Schedule does not necessarily mean that the cancer drug is made available immediately. This is because accredited treatment centers may take months to acquire the product or decide against purchase, thus often extending the time it takes for a medicine to be made available and meaning that there are no guarantees that a technology will be made evenly available across the country's accredited services. This limitation was acknowledged when it was decided to assess only publicly available Ministry of Health documents rather than the range of products provided by each of the country's accredited services. This is because SUS facilities are not required to disclose their standard medicine lists, reinforcing the need for greater transparency in the process of making adopted technologies available on the SUS.

Second, it is important to highlight that only two of the 13 cancer drugs adopted during the study period were made available, meaning that a more in-depth analysis was not possible. Furthermore, specific knowledge is needed to identify the date that technologies were made available, considerably reducing the capacity to exercise

the right to public participation, given that the public do not possess such knowledge. Further research is needed to assess qualitative data from application for adoption assessment processes, the impacts of policies, and processing times for different types of technologies in different areas of health.

Final considerations

The creation of CONITEC was a major step forward for Brazil. However, the findings of this study show lack of compliance with legal timeframes for making adopted medicines available on the SUS. It is also notable that the average time taken to adopt and make technologies available was longer for cancer drugs than for CEAF medicines.

There is an urgent need to improve the process involved in making medicines available on the SUS, ensuring compliance with legal timeframes, implementing the principle of equity, and promoting greater transparency and legitimacy in order to ensure timely access to these technologies, which is one of the pillars of quality healthcare.

Collaborations

HC Capucho was responsible for study conception and design, data interpretation, and drafting this article. A Brito, A Maiolino, RA Kaliks and RP Pinto contributed to the critical revision of the article and approved the final version to be published.

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