Time until Oncologic Treatment Approval in Brazil Compared to Europe and the United States

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Abstract

Introduction Oncology therapy development has accelerated worldwide, with approvals based on safety and efficacy. This study compares approval timelines in Brazil, the United States, and Europe from 2010 to 2021, highlighting regulatory differences and their impact on patient access. In Brazil, after Brazilian Health Regulatory Agency (Agência Nacional de Vigilância Sanitária, ANVISA, in Portuguese) approval, oral drugs require National Supplementary Health Agency (ANS, Agência Nacional de Saúde Suplementar, in Portuguese) review for private coverage, and all drugs need National Committee for Health Technology Incorporation (Comissão Nacional de Incorporação de Tecnologias no Sistema Único de Saúde, CONITEC, in Portuguese) evaluation for public incorporation, further delaying access.

Objective To compare approval times for novel oncology therapies in Brazil, the US, and Europe over the past decade, and to evaluate secondary approval processes in Brazil (ANS and CONITEC).

Materials and Methods Regulatory databases were reviewed to identify oncology therapies approved between 2010 and 2021. Kaplan-Meier curves estimated median approval times (95%CI), and Cox regression assessed differences. The National Supplementary Health Agency and CONITEC timelines were analyzed to estimate access in Brazil.

Results In total, 61 drugs were included (2010–2021). The Food and Drug Administration (FDA) had the shortest median approval time: 184 days (95%CI: 168–236), followed by ANVISA: 331 days (95%CI: 327–382), and the EMA: 426 days (95%CI: 391–453). In Brazil, 35 therapies were oral; by 2021, 27 had ANS coverage while 8 (23%) had not been incorporated. Only three therapies were approved by CONITEC. The median ANS approval time was 940 days (95%CI: 786–1444), and the median CONITEC time was 2,816 days (95%CI: 1,652–not estimable).

Keywords
- regulatory agencies
- Brazil
- European Union
- FDA
- antineoplastic agents
- drug approval

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Conclusion Although ANVISA was faster than the EMA, additional Brazilian reviews by ANS and CONITEC substantially delayed patient access. Streamlining these processes and adopting reliance mechanisms are critical to ensuring more timely and equitable availability of innovative cancer therapies.

Introduction

Several novel cancer treatments have received global approval in recent years. However, there are many barriers to rapid access to new drugs, which can occur at various stages of the approval process: during research, at regulatory agencies, in cost-effectiveness and pricing analysis, or during implementation into local practice.[1,2] It is the role of regulatory agencies to ensure timely access to new medicines based on safety and efficacy assessments.[3–5] Despite the expectation for quick access to medications that have proven clinical benefits, it often takes longer than expected for patients to receive prescriptions, especially in low- and middle-income countries.[1,6,7]

Cancer is a medical condition that is often associated with relatively short survival durations and significantly high mortality rates. In an effort to enable faster access to treatments that may offer meaningful clinical benefits, a variety of intermediate outcomes—such as disease-free survival, event-free survival, progression-free survival, and objective response rates—are being increasingly utilized in both clinical and regulatory decision-making processes. Nevertheless, while these surrogate endpoints can provide useful early indications of treatment efficacy, they can also become subjects of debate, particularly when used in cost-effectiveness evaluations and reimbursement-making decisions.[1]

According to the Global Cancer Observatory (GLOBOCAN), the global cancer burden is expected to rise to 29.9 million cases by 2040, a 49% increase from 2022, with a more significant increase in transitioning countries compared to those already transitioned.[8] Efforts to build a sustainable infrastructure for disseminating cancer prevention and treatment strategies in transitioning countries are critical to global cancer control.[8] This includes providing access to new cancer treatments that may improve survival and quality of life.

There are national differences in the regulatory processes for new approvals. The United States, through the Food and Drug Administration (FDA), and Europe, via the European Medicines Agency (EMA), are the most important global regulatory bodies.[3,4] Both agencies have developed strategies to create accelerated approval pathways, such as the FDA's accelerated approval and the EMA's Priority Medicine (PRIME) scheme.[1,3,4] Recent data show that new cancer therapies have been approved more quickly in the United States than in Europe.[3,4] However, concerns have been raised about these accelerated procedures' general safety and efficacy, as some drugs have been approved before the formal publication of their pivotal trials.[3–5]

Across Latin America (LATAM), the processes for granting marketing authorization for new pharmaceutical products differ significantly from one country to another. In certain nations, these processes are characterized by regulatory restrictions and a limited degree of flexibility, which can result in substantial delays or, in some cases, prevent innovative medicines from reaching the market altogether.[6,9] In response to these regulatory hurdles, various strategies and initiatives are being adopted to improve the efficiency and timeliness of drug approvals. One such strategy is the implementation of reliance procedures, which allow local regulatory authorities to expedite the evaluation and authorization process by recognizing or partially depending on the prior approval of a drug by well-established international regulatory bodies, such as the FDA or the EMA.[6,9] These reliance mechanisms are being increasingly employed as a practical solution to accelerate access to essential new therapies throughout the region.

In Brazil, the Brazilian Health Regulatory Agency (Agência Nacional de Vigilância Sanitária, ANVISA, in Portuguese) defines the criteria and steps for releasing a new drug to the population.[7,10] Additional procedures must be completed after ANVISA approval, which differs between the private and public systems.[7,10] The National Supplementary Health Agency (Agência Nacional de Saúde Suplementar, ANS, in Portuguese) regulates, controls, and monitors health plans in Brazil, establishing a list of oral medications and procedures that health plans must cover; non-oral medications are immediately incorporated after ANVISA's approval.[11,12] In the Unified Health System (Sistema Único de Saúde, SUS, in Portuguese), secondary analysis and approval by the National Commission for the Incorporation of Technologies (Comissão Nacional de Incorporação de Tecnologias no Sistema Único de Saúde, CONITEC, in Portuguese) is required for all drugs, regardless of the administration route[13–15] These additional stages further delay the entry of medications onto the market. Disparities between the public and private systems are significant and directly impact the care provided to cancer patients in Brazil.[7,10] More than 70% of the Brazilian population relies exclusively on the public health system. Providing timely access to safe and efficacious treatments in the public health system should be a priority.[7]

Given the multitude of regulatory hurdles, administrative complexities, and structural delays inherent in both the public and private healthcare systems in Brazil, the present study advances the hypothesis that Brazilian patients face significantly longer waiting periods to access newly approved oncologic drugs when compared to patients in countries such as the United States and various European nations. Moreover, it is posited that these extended delays in treatment availability may adversely affect the clinical outcomes and overall prognosis of cancer patients in Brazil, potentially

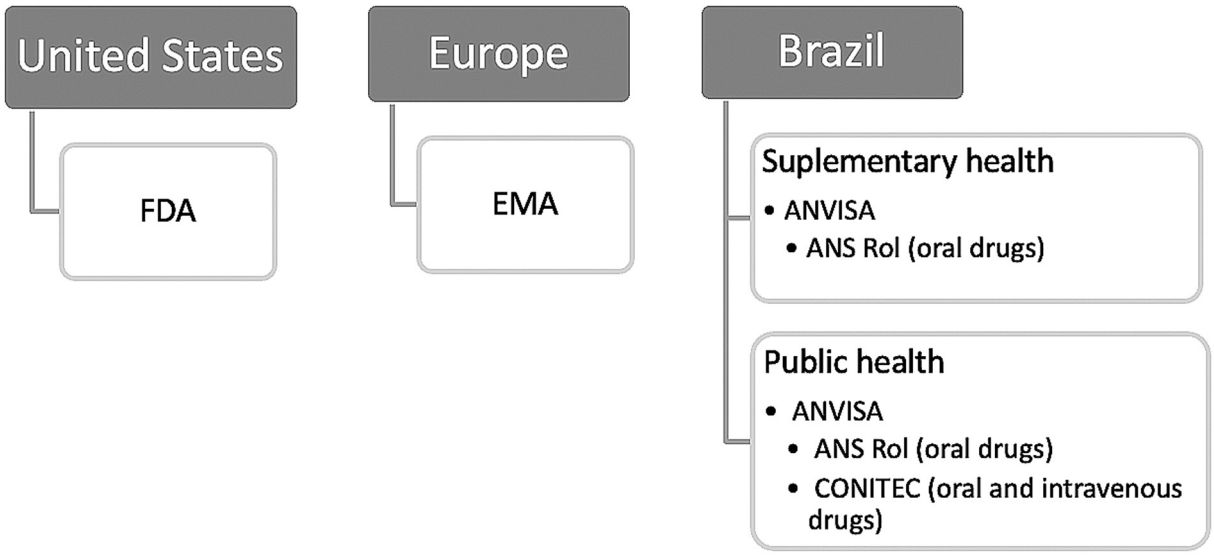

Fig. 1 Approval flow in the United States, Europe, and Brazil.

widening the gap in survival rates and quality of care between Brazil and higher-income regions.

The primary objective of the current study is to highlight and analyze the disparities in submission and authorization timelines for novel oncological therapies between 2010 and 2021, focusing on Brazil, the United States, and Europe. The study compares the approval timelines of the key regulatory bodies in each region: ANVISA, the FDA, and the EMA. Additionally, the study examines the duration of the review and analysis processes carried out by these agencies, providing insight into the efficiency of their regulatory frameworks and the factors that may influence the speed of approval.

In Brazil, after ANVISA approval, oral drugs require additional review by the ANS for private coverage, and all drugs undergo CONITEC assessment for public incorporation. Considering these steps, a secondary objective of this study was to evaluate oral drug approval timelines in Brazil, including ANS and CONITEC processes. (►**Fig. 1**).

Materials and Methods

The present study reviewed the regulatory databases of the FDA, EMA, and ANVISA to identify new oncology therapies approved in the United States, Europe, and Brazil from 2010 to 2021, analyzing the timing of regulatory activities. Additionally, it evaluated the time required for incorporation by ANS and CONITEC in Brazil. The submission histories for the FDA and EMA were obtained from public data and verified through their official websites (https://www.fda.gov/) and (https://ema.europa.eu/en/homepage). For Brazil, the data on process and registration dates were sourced from ANVISA's national government systems (https://consultas.anvisa.gov.br/), allowing the extraction of relevant national process information.

This article's structure is based on the study "Cancer Therapy Approval Timings, Review Speed, and Publication of Pivotal Registration Trials in the United States and Europe, 2010-2019,"[3] which conducted a comparative analysis of the FDA and EMA across 89 drugs.

The approval times (in days) for oncological therapies were assessed using the Kaplan–Meier (KM) method, presenting results as medians and 95% CIs. The Log-Rank test was used to compare KM curves across regulatory agencies, while Cox regression was applied to estimate hazard ratios (HRs), with a 95%CI. The analyses were performed using R software (R Foundation for Statistical Computing) version 4.4.0, with a significance level set at $p < 0.05$.

The current study did not require approval from an Ethics Committee, as it does not involve human subjects.

Results

The present study focuses solely on medications submitted for analysis in Brazil between 2010 and 2021, totaling 61 therapies. The analyzed drugs and their indicated diseases are shown in ►**Table 1**. Approval times differed across agencies: the FDA demonstrated a median of 184 days (95%CI: 168–236), followed by ANVISA at 331 days (95%CI: 327–382) and the EMA at 426 days (95%CI: 391–453) (►**Fig. 2**).

Of the 61 ANVISA-approved therapies, 35 were oral (►**Table 3**) and, therefore, required additional ANS appraisal for mandatory private coverage. By December 31, 2021, 27 had ANS coverage, while 8 (23%) remained unincorporated; the median ANS approval time was 940 days (95%CI: 786–1,444) (►**Fig. 3**). Within SUS, only three oncologic drugs were approved by CONITEC (abiraterone, ado-trastuzumab emtansine, and pertuzumab). The median CONITEC time was 2,816 days (95CI: 1,652–not estimable).

Discussion

With approximately 10 million cancer-related deaths in 2020, the disease remains one of the leading global causes

Table 1 Drug and initial disease indication

Drug	Initial disease indication
Abemaciclib	Breast cancer
Abiraterone	Prostate cancer
Acalabrutinib	Differing indications
Ado-trastuzumab emtansine	Breast cancer
Afatinib	NSCLC
Alectinib	NSCLC
Alpelisib	Breast cancer
Apalutamide	Prostate cancer
Atezolizumab	Urothelial cancer
Avelumab	Merkel cell carcinoma
Axitinib	Renal cell carcinoma
Brentuximab vedotin	Hodgkin & anaplastic large cell lymphoma
Brigatinib	NSCLC
Cabazitaxel	Prostate cancer
Cabozantinib	Medullary thyroid cancer
Carfilzomib	Multiple myeloma
Cemiplimab	Squamous cell carcinoma
Cobimetinib	Melanoma
Crizotinib	NSCLC
Dabrafenib	Melanoma
Daratumumab	Multiple myeloma
Darolutamide	Prostate cancer
Decitabine	Myelodysplastic syndrome
Dinutuximab	Neuroblastoma
Durvalumab	Differing indications
Elotuzumab	Multiple myeloma
Encorafenib	Melanoma
Enzalutamide	Prostate cancer
Eribulin	Breast cancer
Gilteritinib	Acute Myeloid leukemia
Ibrutinib	Mantle cell lymphoma
Inotuzumab ozogamicin	Acute lymphocytic leukemia
Ipilimumab	Melanoma
Ixazomib	Multiple myeloma
Larotrectinib	*NTRK* gene fusion
Lenvatinib	Papillary thyroid cancer
Lorlatinib	NSCLC
Midostarium	Acute Myeloid leukemia
Moxetumomab pasudotox	Hairy cell leukemia
Neratinib	Breast cancer
Niraparib	Ovarian cancer
Nivolumab	Melanoma
Obinutuzumab	Chronic lymphocytic leukemia
Ofatumumab	Chronic lymphocytic leukemia
Olaparib	Ovarian cancer
Osimertinib	NSCLC
Palbociclib	Breast cancer
Pazopanib	Renal cell carcinoma
Pembrolizumab	Melanoma
Pertuzumab	Breast cancer
Radium 223	Prostate cancer
Ramucirumab	Gastric cancer
Regorafenib	Colorectal cancer
Ribociclin	Breast cancer
Ruxolitinib	Myelofibrosis
Siltuximab	Castleman's disease
Trabectedin	Differing indications
Trametinib	Melanoma
Vemurafenib	Melanoma
Venetoclax	Chronic lymphocytic leukemia
Ziv-aflibercept	Colorectal cancer

Abbreviation: NSCLC, non-small-cell lung cancer; *NTKR*, neurotrophic tyrosine receptor kinase.

Table 2 Time to approve oncological drugs according to regulatory agencies

Agencies	Median time in days (95%CI)*	HR (95%CI)	*P*-value (HR)
ANVISA	331 (327, 382)	–	–
EMA	426 (391, 453)	0.90 (0.62; 1.30)	0.600
FDA	184 (168, 236)	5.38 (3.44; 8.40)	< **0.001**

Abbreviations: ANVISA, Agência Nacional de Vigilância Sanitária (Brazilian Health Regulatory Agency, in English); EMA, European Medicines Agency; FDA, Food and Drug Administration; HR, hazard ratio (estimated by the Cox model).
Notes: *Median time evaluated by Kaplan-Meier method, $p < 0.001$ in the Log-Rank test for curve comparison.

of mortality.[16] Although significant progress has been made in the development of innovative therapies, equitable and timely access continues to be a challenge, particularly in low- and middle-income countries. Regulatory authorities play a crucial role in this scenario by ensuring that new drugs are evaluated based on safety and efficacy before becoming available to patients.[5,10]

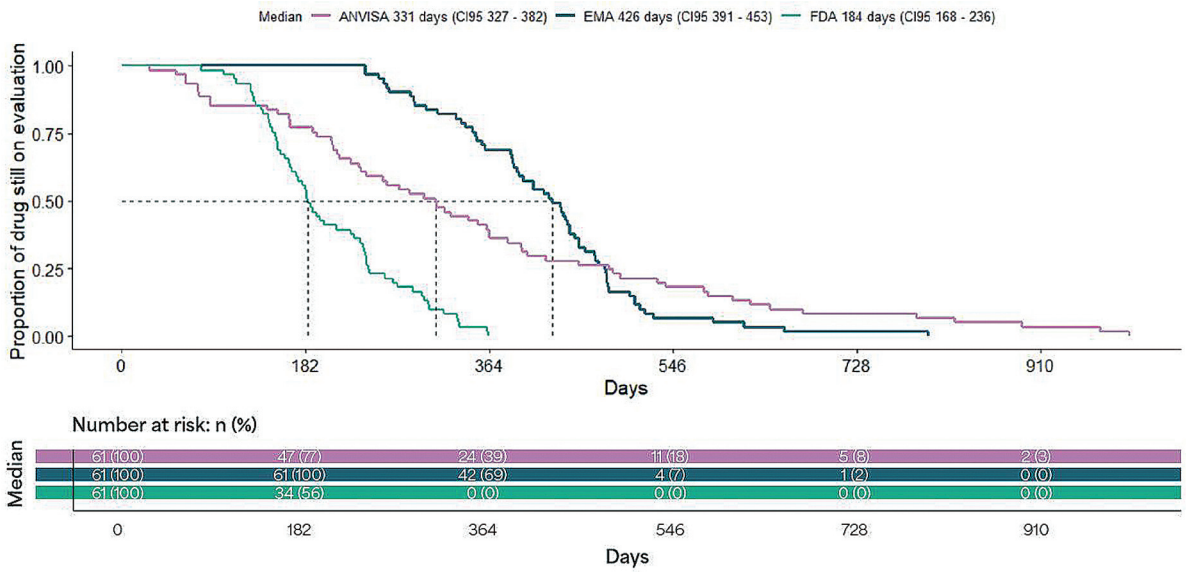

Fig. 2 Kaplan-Meier curves comparing the time until approval from the Brazilian Health Regulatory Agency (Agência Nacional de Vigilância Sanitária, ANVISA, in Portuguese), the European Medicines Agency (EMA), and the Food and Drug Administration (FDA).

Table 3 Oral drugs and approval in the ANS list

Drug	Initial disease indication
Abemaciclib	Breast cancer
Abiraterone	Prostate cancer
Acalabrutinib	Differing indications
Afatinib	NSCLC
Alectinib	NSCLC
Alpelisib	Breast cancer
Apalutamide	Prostate cancer
Axitinib	Renal cell carcinoma
Brigatinib	NSCLC
Cabozantinib	Medullary thyroid cancer
Cobimetinib	Melanoma
Crizotinib	NSCLC
Dabrafenib	Melanoma
Darolutamide	Prostate cancer
Encorafenib	Melanoma
Enzalutamide	Prostate cancer
Gilteritinib	Acute myeloid leukemia
Ibrutinib	Mantle cell lymphoma
Ixazomib	Multiple myeloma
Larotrectinib	*NTRK* gene fusion
Lenvatinib	Papillary thyroid cancer
Lorlatinib	NSCLC
Midostarium	Acute myeloid leukemia
Neratinib	Breast cancer
Niraparib	Ovarian cancer
Olaparib	Ovarian cancer
Osimertinib	NSCLC
Palbociclib	Breast cancer
Pazopanib	Renal cell carcinoma
Regorafenib	Colorectal cancer
Ribociclin	Breast cancer
Ruxolitinib	Myelofibrosis
Trametinib	Melanoma
Vemurafenib	Melanoma
Venetoclax	Chronic lymphocytic leukemia

Abbreviations: ANS, Agência Nacional de Saúde (National Supplementary Health Agency, in English); NSCLC, non-small-cell lung cancer; *NTKR*, neurotrophic tyrosine receptor kinase.

In the present study, the FDA demonstrated the fastest approval times, being more than 5 times quicker than ANVISA (HR: 5.38; 95%CI: 3.44–8.40). While ANVISA proved faster than the EMA in granting marketing authorization, Brazilian patients face additional delays due to post-ANVISA reviews by ANS and CONITEC. For example, nearly ¼ of oral therapies had not been incorporated into ANS by 2021, and only 3 drugs were approved by CONITEC, reflecting substantial barriers to access within the public system. These findings underscore that, although regulatory performance in Brazil has improved, real-world access remains significantly delayed.

Delays in oncology drug availability have direct consequences on survival and quality of life. Previous studies have shown that longer times to market access are associated with

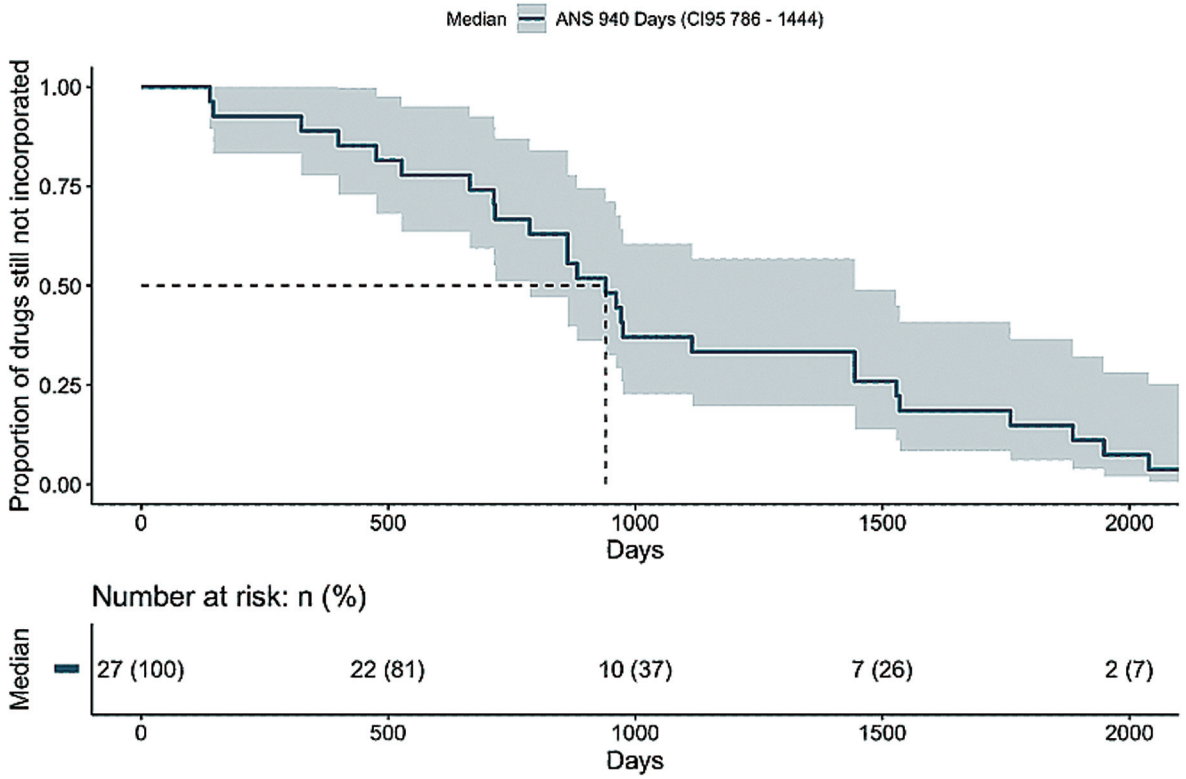

Fig. 3 Kaplan–Meier curves of the time until approval from the ANS.

worse clinical outcomes and increased inequities across health systems.[17] In Brazil, where over 70% of the population depends exclusively on the public health system, such delays exacerbate disparities between patients treated in public and private sectors.[7,10]

The present study has several limitations. First, the regulatory databases available in FDA, EMA, and ANVISA do not always provide precise and comprehensive submission or approval dates, which may affect accuracy. Second, the study period (2010–2021) encompasses the coronavirus disease 2019 (COVID-19) pandemic, when expedited pathways and emergency authorizations may have artificially shortened approval times for some drugs. Third, all oncologic therapies were aggregated into a single category, despite the heterogeneity between immunotherapies, hormone therapies, tyrosine kinase inhibitors, and antibody-drug conjugates, which likely face different regulatory dynamics. A subgroup analysis by drug class could provide additional insights. Fourth, heterogeneity in submission strategies and requirements across FDA, EMA, and ANVISA (such as dossier completeness, reliance mechanisms, or submission timing) may confound direct comparisons of approval timelines.[6,9]

Despite these limitations, our findings highlight meaningful disparities in drug approval and access among Brazil, the United States, and Europe. Streamlining post-ANVISA evaluations, especially through ANS and CONITEC, is critical to reducing delays. Efforts to adopt more efficient reliance mechanisms, improve regulatory transparency, and harmonize requirements could help ensure that Brazilian patients gain faster access to life-saving oncologic therapies.

Conclusion

There are notable disparities in the time required for patients to gain access to newly approved oncologic therapies across Brazil, the United States, and Europe. While ANVISA demonstrated faster approval timelines than the EMA, actual patient access in Brazil remains substantially delayed due to additional evaluations by ANS and CONITEC. During the study period, 23% of oral drugs approved by ANVISA were not incorporated by the ANS, and only 3 therapies were approved by CONITEC, underscoring persistent barriers to timely access. Streamlining these post-ANVISA processes and adopting reliance mechanisms, as increasingly applied in other Latin American settings, will be essential to ensure more equitable and timely availability of life-saving cancer treatments in Brazil.

Ethics Approval

Not applicable.

Authors' Contributions

All authors have approved the submitted version.

DJP: project administration, writing – original draft, and writing – review & editing; ANR: conceptualization, supervision, and writing – review & editing; CMV, FCMJO,

TMP, AVC, FRP, PRS, and MCS: data curation, writing – original draft, and writing – review & editing.

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Conflict of Interests
The authors have no conflict of interests to declare.

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